

Consortium Steering Committee

CTSA ABSTRACTS

Face-to-Face Meeting

October 8-9, 2013

Rockville, MD

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Albert Einstein

Abstract 1: Einstein-Montefiore Biomarker and Analytic Research Core (BARC) and Biorepository (BioR)

Daniel T. Stein MD and Harry Shamoon MD

In the first CTSA project, an analytical laboratory was created that supported multiple analyses, novel mass spectrometry (MS) methods, and sample handling. As investigator demands for biospecimen services became a priority, an additional major component was added to facilitate biobanking. Over the past 5 years, these functions have grown dramatically, requiring significant investments to: 1) add the capability for measuring biochemical analytes in animals for T1 researchers; 2) develop novel MS methods, one of which (vitamin D in human serum) is now CLIA-approved, 3) develop specialized services for pediatric investigators for isolation of PBMCs; 4) implement a high-throughput robotics and liquid handling system; and 5) initiate a multi-pronged approach that engaged surgeons, T1 investigators, bioethicists, legal affairs, and patients to facilitate a universal consent for patient samples with EMR data integration. The ***new analytic assay robotics*** automates a diverse menu of tests provided to researchers. As part of capital investments, BARC has successfully created high throughput semi-automated methods for sample preparation and analysis by RIA, ELISA and MS. BARC offers investigators the ability to measure multiple analytes from an individual patient specimen simultaneously, minimizing the need for redundant aliquot vials and freeze/thaw cycling of biospecimens. BARC has thus minimized analytical variation inherent in manual protocols for immunoassay and MS methods, and increased throughput to more rapidly provide results for large-scale epidemiology sample sets. A second initiative was to establish a Biorepository (BioR) to enhance translational, clinical and population research by providing investigators with a ***centralized, coordinated, quality controlled and quality assured facility for acquisition, processing, storage, and distribution of human specimens*** with annotations from the EMR. As the institutional Biorepository, the CTSA's oversight and management role is broad and consistent with its bridging and integrative functions. The BioR eliminates multiple un-linked biobanks, and will continue to prospectively acquire biospecimens through an institutionally-sponsored universal informed consent process for the donation of biospecimens to bank for future research. The BioR also provides biospecimen storage for individual investigators and regional consortia for investigator-initiated and sponsored clinical and epidemiologic research protocols. The coordination of these two translational technology cores allows for greater efficiencies and improved services.

Albert Einstein

Abstract 2: **Einstein-Montefiore CTSA; Integrating Resources and Building Research Teams**

Marla Keller MD and Harry Shamoon MD

A significant challenge encountered at the Einstein-Montefiore CTSA was the need to efficiently coordinate resources to streamline and enhance project coordination and implementation. Supporting translational research is an inherently complex enterprise, since any one project involves multiple team members, scientific expertise, and resources. Among the lessons learned since initial funding in 2008, it is clear that multiple cores are often engaged to support a given project, and that many different areas of expertise are needed to develop a team or design a project. We therefore established a Project Acceleration Resource (PAR) to integrate clinical investigation services, resource navigation, study implementation, and administrative support. The PAR has 4 specific goals: support investigators throughout the life cycle of a study; accelerate translational research by identifying potential collaborators and sources of support; streamline access to core facilities by coordinating resource delivery; assist team building, project planning, and project management. We also seek to advance partnerships with out NIH-designated disease-specific centers (cancer, diabetes, liver and GI diseases, aging, AIDS, developmental disabilities). The PAR also coordinates issues related to informatics, core laboratories, the biorepository, institutional and funding resources, and financial expertise. The CTSA PI and CISC director lead the PAR as they are often called upon to support complex research protocols. The PAR provides a “one-stop-shop” with a centralized campus location, and a single website portal, telephone number and email address, and is staffed by administrative and project managers who use the platform Rocket to integrate project management and they also meet F2F bi-monthly. For complex projects, the PAR designates a project team comprised of staff with various skill sets that are responsible for anticipating the needs of investigators and streamlining the behind-the-scenes work that investigators typically have to undertake themselves. The PAR has succeeded in launching new multidisciplinary projects and networks as a result of integrative program acceleration (eg, NeuroNEXT, GRADE, and others), as well as to design and customize key components of research infrastructure for the Cancer Center, the Center for AIDS Research, the Liver Research Center, and the Intellectual and Developmental Disabilities Research Center.

Albert Einstein

Abstract 3: **Einstein-Montefiore Institute for Clinical and Translational Research (ICTR): Building Bridges from T1 to T4**

Harry Shamoon, Paul Marantz, Brian Currie, Marla Keller

Our CTSA developed two new partnerships—a) **Therapeutics Sciences Bridge (TSB)** with our Center for Experimental Therapeutics (CET) to accelerate drug discovery and b) **Outcomes Research Collaborative (ORC)** with our Care Management Organization (CMO) for patient- and population-centered research (PPCOR). These partnerships demonstrate the robust and diverse research environment that our CTSA can leverage for our research community and the Consortium. Implementation of new scientific advances requires the translation of new findings into biomarkers, targets for therapeutic intervention, and safe and effective drugs. **TSB:** TSB is a uniquely designed resource whose focus is to assist translational investigators. We aligned the CTSA with Einstein's ongoing investments totaling ~\$60 million in drug design, chemical biology, genomics, imaging, and stem cell technologies, and strategically integrated T1 programs with the CTSA's clinical services and resources. The CET, whose objective is to facilitate essential pre-clinical steps in drug discovery, will provide the pharmacological probes for early proof-of-concept animal studies and the CTSA will support human Phase 1 studies. An outcome of this new partnership is the joint funding of translational pilot awards for new projects for small-molecule probe development, drug design, and chemical synthesis. Target-related chemical synthetic efforts across the spectrum of research disciplines and designs include compound library design, specific synthesis, structure-activity studies and rational drug design. **ORC:** The ORC builds on work in trials infrastructure, education, community engagement, methods development, and informatics. Our faculty developed a plan to enhance CER, now published as a novel multi-disciplinary model. This approach focuses on health services, health system and health policy research related to Montefiore's pioneer ACO and CMO, and the public health infrastructure for urban underserved patients. Our investigators can benefit from an array of assets and methodologies for PPCOR, including health services and community engagement programs connected through the CTSA. Two outcomes of the ORC are the establishment of a new institutionally-funded Center for CER Training partnered with our CTSA (AHRQ R25 pending) and a multi-institutional New York City CTSA research network with the Columbia, Cornell, Rockefeller, NYU, Mount Sinai and Einstein-Montefiore CTSA's (PCORI CDRN grant pending).

Arkansas

Abstract 1: **The experience of small states; the Western States Collaborative Group**

Curtis L. Lowery, M.D.
Translational Research Institute
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Engaging with other CTSA's is an activity that is encouraged by NCATS leaderships and will likely be mandated in future years. For CTSA's in small states, often the only CTSA in a large geographic region, this has been a particular challenge.

We were invited to join a group that included New Mexico, Kansas, Utah, and Arkansas; The Western States Collaborative Group (WSCG). These four CTSA's share many similarities; a) the only CTSA in their respective states b) small largely rural states and c) geographically isolated from other CTSA institutions.

We scheduled monthly meetings via interactive video that included the PIs' and others. During the formative stages we identified challenges and opportunities at our respective institutions and agreed on areas of focus in the short- and long-term. After identifying areas of research strengths, we invited speakers from those research areas to discuss their work with the hope of mutual interest sparking collaboration. Though in a common but broad subject area, this did not prove to be fruitful. We learned that though putting people together in a room can be good, in this case, it wasn't enough.

The group then made the decision to release a joint pilot funding announcement that required collaboration across at least one other institution in the WSCG. A RFA was developed and agreed upon and then released at each institution. Collectively we received approximately ten applications. Of those, five were funded.

We considered this to be successful however we did learn that we lacked some coordination regarding release of the announcement, timing of releasing award announcements, and institution specific policies. For instance, one institution requires IRB approval before investigators can submit and other do not, and one institution has only one pilot cycle per year.

Future plans include

- Bringing the awardees together to help us gain greater insight into needed improvements to the process
- Releasing the exact same RFA with each institutions specific requirements in a call-out box for greater transparency
- Meeting of the pilot leadership from each institution prior to funding announcement for greater coordination and assessing project merits
- Harmonization of scoring criteria to more closely match those of NIH
- Review of progress reports to assess outcomes that will inform future initiatives

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Arkansas

Abstract 2: **Research Friendly Communities**

Curtis L. Lowery, M.D.

Translational Research Institute (TRI)

University of Arkansas for Medical Sciences

Recognized as a top priority among CTSA's is the issue of engaging the communities we serve. In Arkansas, a state that is approximately 16% African-American (AA), a large Hispanic community that is expected to surpass AA's numbers within 5 years, and the largest number of Marshallese in the United States; we face particular challenges related to these diverse groups. Each group has a unique set of health challenges and often divergent societal norms related to trust.

In research language, a "community-linked infrastructure for racial health disparities research" is being developed in Jefferson County Arkansas, a county with a large minority population. We call it "A Research-Friendly Community," translating its title into a description that researchers and community developers alike understand as readiness for increased participation in research by institutions, individuals, and the community. A Research Friendly Community is built by synergizing collaboration among UAMS researchers and local institutions, awareness of the value of research across the community, community connectors who are bridging the society-created gaps between institutions and citizens most affected by disparities, a ready pool of individuals experiencing disparities to volunteer for research participation, and commitments to improving community and individual health by governmental, educational, business, and nonprofit leaders.

There are two major weaknesses that could impede sustainability as well as use of the infrastructure: lack of research projects recruiting participants and the limited scope (one county) of the "Research Friendly Community." This infrastructure was first developed by an NIHMN grant and TRI is supporting this project to increase the number of research projects, greater participation in the projects, increased enrollment in Research Match, and planning for expanding the boundaries of "The Research Friendly Community" from one county to the entire South Central AHEC Region and long-term across the state. Sustainability will become possible through community and research support within five years.

This project has been a success of terms of individuals expressing an interest in participating in research with approximately 1000 minority individuals enrolling in ResearchMatch since the beginning of this project a little over a year ago. Over the next year, we plan to expand this research friendly concept to Northwest Arkansas, the location of the large Hispanic and Marshallese communities. We will also develop a strategy for educating researchers about reaching out to these communities for participation in research design and implementation.

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Boston

Abstract 1: Inefficient and Duplicated Pilot Award Programs

G. O'Connor, D. Seldin, D. Felson, B. Corkey and D. Center (PI)

Problem. Duplication of Reviews and overlapping funding for “Pilot” award programs from BU CTSI Partner Institutions. The BU CTSI is comprised of the Medical Campus, Boston Medical Center Hospital and Boston University Charles River Campus. Amongst the three there are 8 different pilot award programs providing funding from earliest stage to support for biotechnology start-ups; including engineering, biological, computational and T3-T4 research. Each has a separate review panel and there are frequent duplicate applications to multiple pilot programs. There was no communication between the entities prior to the BU CTSI formation.

Rationale/Approach. We hypothesized that central grant review with representation from all stakeholders would expedite review time, improve review consistency and eliminate duplicate applications and funding.

Methods. We engaged Pilot Program Directors in the hypothesis and potential benefits. We solicited senior scientists from all three partners to serve on separate T1-T2 and T2-T4 standing study sections and created a representative parent committee to normalize scores. We centralized (web based) application processes and instituted post review a co-funding mechanism in which we offered matching funds from the CTSI for support offered by the individual scientists’ departments over and above the Pilot grant support. Results were graded by survey.

Outcome. Three of eight pilot programs participated. Time for review shortened by 50% and reviewers were able to redirect applications to more appropriate pilot programs. We were able to increase the numbers and levels of funding for each program and provide consistent feedback to applicants on how to make their applications competitive internally and for NIH funding. The outcomes received excellent ratings in post review surveys. Participating Pilot Program directors have been enthusiastic with the efficiency, consistency and quality of reviews.

Lessons. We improved the review processes of our internal pilot programs by centralized review panels. Matching/co-funding subsidies were a powerful incentive in increasing applications and applicant satisfaction. Full participation remains a significant obstacle as some Institutional Pilot Programs consider their support proprietary (despite the potential for matching funds). Solutions to lack of participation are being sought.

Boston

Abstract 2: **Overcoming Obstacles for Access to Clinical Data Bases at BU**

John Meyers, David Seldin and David Center (PI)

Problem. Inefficient clinical data sharing among The BU CTSI partner institutions. The University and Boston Medical Center Hospital have separate IT systems to protect human subjects research data. Once data is removed from our hospital EMR data warehouse for research by University investigators it is no longer subject to access control and auditing and therefore BMC required that every request for use of EMR be considered individually to assure HIPAA compliance. This resulted in long delays in data sharing despite numerous attempts by stakeholders to find common solutions.

Rationale/Approach. We approached the obstacle with root cause analysis after negotiated generalizable data sharing agreements failed. We found that the major objection to EMR data sharing was concern over possible local breaches of security (e.g. hacked or lost computer). Our approach was to construct a secure virtual desktop private cloud where data can be stored and manipulated without allowable transfer to untrusted endpoints in an acceptable format for the BMC data warehouse.

Methods. The BU-CTSI leveraged the DOM Technology group design for a virtual desktop cluster on an isolated network, only accessible via VDI protocols through a connection broker and now hosts this system. Access requires two-factor authentication and data is encrypted in transit and at rest. No access to external networks is available from the VPNs. We made analytic packages available in the VPN for data management. A secure portal allows selected users to transfer data into and out of the isolated space in an audited manner.

Outcome. The system is now NIST 800-53 approved. It permits data owners to allow selected users to interact with highly sensitive data while preventing intentional or unintentional transfer to unsecure devices or unauthorized persons.

Lessons. We approached a major roadblock in investigator access to data by identifying the fundamental cause for the delay (data protection) and then created a system acceptable to our data warehouse owners that assured them that data could not be lost or stolen. The system is available to the CTSA network.

Case Cleveland Clinic

Abstract 1: **The Ohio Clinical Trials Collaborative**

Pamela B. Davis, MD, PhD – Case Western Reserve University

There are three CTSA in Ohio, based at Case Western Reserve University, The Ohio State University, and the University of Cincinnati/Children's Hospital of Cincinnati Medical Center. To extend the reach of the CTSA in enhancing the conduct of clinical trials and in response to the desire of the Ohio Governor Kasich to leverage the resources to enhance the health of the citizen and clinical trials attraction within Ohio, these three academic institutions, their local partners (Cleveland Clinic Foundation, MetroHealth Hospital, Nationwide Children's Hospital) came together to form the Ohio Clinical Trials Collaborative. The idea was to capitalize on the existing CTSA resources, including a robust AHRQ-funded practice-based research network, the presence of 3 of the top 20 children's hospitals to facilitate pediatric research, informatics platforms that allow search of the electronic health record to establish the number of patients eligible for trials, and an IRB sharing plan that includes both facilitated and reliance review capabilities among OCTC. We have established the collaborative, arranged working groups for pediatrics and PBRNs, as well as IRB and the health informatics platforms, and are now establishing the administrative structure and an external advisory board. Regular review allows for redistribution of funds if required. Early challenges included the terms of the grant from the State that require matching dollars, and an inability to easily achieve consensus on setting cross-institutional priorities for initial program focus where competing programs and alliances were already in place. In addition, although we have a reliant IRB agreement among the hospitals, there is no comparable agreement on contracting. It remains to be seen the extent to which this is a limiting factor. Lessons learned are 1) forming a statewide collaborative between public and private institutions is more complex than it first appears, both in the details and in the legal issues to be solved. 2) In order to build a collaborative spirit, it is critical to involve the stakeholders at multiple levels in the planning and early negotiation phases and 3) external advice is essential.

Case Cleveland Clinic

Abstract 2: Training Community Members - the PEER program

Pamela B. Davis, MD, PhD – Case Western Reserve University

In an effort to further the CTSC's mission of bringing research from bench to bedside, with the CTSC Community Engagement Core has collaborated with the Prevention Research Center at CWRU, and various community organizations to create the Partners in Education, Evaluation and Research (PEER) Training Program.

The PEER Training Program is a comprehensive, 18-month program that combines instruction and mentorship to build ties between academic and community researchers and enhance the research capabilities of community organizations.

The program is designed with a bi-monthly didactic instructional phase taught within a framework of culturally competent research. Topics include: partnership dynamics, research methods, study design, basic statistics, question/topic development, literature review, researching best practices, IRB protocol, grant writing, data interpretation and dissemination of results and information to diverse audiences, and are taught by CWRU research scientists from across the campus.

Fellows are sought from health-related organizations that have an emphasis on the dissemination of health-related information to the community and must have the ability to further the research capacity of their organization. Each fellow is paired with a mentor from their organization and a CWRU research scientist. During the instruction phase of the program, PEER fellows explore a number of topics to enhance their research abilities, such as research practices, study designs, and grant writing. Research projects, chosen by the respective organizations, are developed throughout the program, and lay the foundation for continuing community/academic partnerships once the fellow has graduated from the program.

The program's first cohort of five scholars began their fellowship on June 6, 2012 recruited from a broad representation of organizations including the AIDS Taskforce of Greater Cleveland, Komen of Northeast Ohio, Environmental Health Watch, Ohio State University Extension, and the Cuyahoga County Board of Health. The fellows and their faculty partners are currently in the active phase of carrying out their collaborative research project culminating in a poster session in November. However, most have expectation to publish and/or present their research; one group has already received external funding for their project. The PEER program plans to train two additional cohorts of 5-7 fellows each over the course of the next five years.

Chicago

Abstract 1: **Community Grand Rounds: A Community-University Partnership Addressing Health Concerns on Chicago's South Side**

Julian Solway, CTSA PI, University of Chicago

Donald Lloyd-Jones, CTSA PI, Northwestern University

Background: Community participation in population health improvement can assist university researchers in targeting intervention resources more effectively and efficiently, leading to more effective implementation of interventions, because of joint ownership of both process and product.

Objective: Two CTSA programs (University of Chicago's Institute for Translational Medicine [ITM] and Northwestern University's Center for Advancing Translational Science [NUCATS]) partnered with community based organizations to develop a bidirectional educational seminar series called 'Community Grand Rounds' (CGR) that identified health concerns of Chicago's South Side residents and provided information regarding university and community resources that addressed community health concerns.

Methods: Representatives of community based organizations worked as Community Consultants (CC) to determine topics, delivery vehicle, audience development and venues on a variety of health related topics. CGR implemented delivery vehicles that reflected the day to day realities of community members such as plays, music and poetry. Each topic presented included faculty from ITM and NUCATS as well as community members identified by the CC's, doing work in the same area. All events were held in community based venues (schools, churches, theatres).

Results: Nineteen CGR's have been held in 2010-2013. Attendance at the events ranged from 50 to over 200 participants (median: 120). Audience evaluations were collected after each event. In addition, focus groups were held with the CC's semi-annually to monitor program development and partnership strength. Audience members reported knowledge gains about the topics presented and were very satisfied with the venues and speakers. Audience members also supported continuation of the series. CC's felt that the community university partnership engendered trust with the project director and project staff, but were concerned about continued support for the project by university leadership. CC's also desired additional programming focused on decreasing health disparities in the target communities.

Conclusions: Community Grand Rounds is an effective mechanism for providing needed community health information in an easily accessible format. Additional work is needed to determine whether this format represents a sustainable community university partnership.

Chicago

Abstract 2: **D4Lab – Teaching Entrepreneurship using Design Principles**

Julian Solway, CTSA PI, University of Chicago

One goal of our CTSA program is to encourage entrepreneurship among Institute of Translational Medicine (ITM) faculty and trainees. To provide experiential and formal training in identifying and solving worthy problems, processes at the core of entrepreneurship, we have developed the D4Lab. D4Lab is a collaboration among the Polsky Center for Entrepreneurship at the Booth School of Business of the University of Chicago, the Institute of Design at the Illinois Institute of Technology (and ITM affiliate), and the ITM. It is a new workshop series and project-based training program that combines entrepreneurship education with human-centered design for solutions to problems, with focus on biomedicine and healthcare. The four Ds represent the D4Lab principles: to discover, design, develop, and do. Participants learn to identify problem areas, perform user research studies and derive insights from observations, build prototypes to test ideas, and generate new concepts that could become viable new ventures. Last year, a series of 2 hr seminars (attended by 100-200) provided overviews of these design approaches; in addition, 24 trainees (medical and graduate students, residents, faculty, MBA students, staff) worked weekly in 4 groups at UC and ITM affiliate NorthShore University HealthSystem to design solutions to two vexing problems: how to speed transfer of admitted patients from the ER to the floor, and how to accomplish morning discharge of patients ready for discharge; these solutions were presented to top hospital leadership at the conclusion of the experience. An expanded program this year is being offered for graduate credit (“D4 Foundations”); two tracks will focus on education and on healthcare delivery, but the two cohorts will meet and interact in the same classroom to help foster the cross-pollination of the D4 Foundations methods and ideas. See D4Lab.com.

Children's National

Abstract 1: **FACTS** (*Focus on Clinical and Translational Science*) **Learning Management System**

PI Name: Lisa M. Guay-Woodford, MD

Institution: The Clinical and Translational Science Institute at Children's National (CTSI-CN)

Challenge: While multiple on-line educational resources are available for clinical and translational researchers, a needs assessment by the CTSI-CN determined that our investigators would benefit from a "one-stop" web-based platform that collated and organized these educational assets.

Rationale: With the June 2013 release of the Institute of Medicine (IOM) report, *The CTSA Program at NIH*, the FACTS Learning Management System (LMS) was initiated to address Recommendation 5, "Advance Innovation in Education and Training Programs". FACTS provides a compendium of educational resources to guide knowledge acquisition by clinical and translational researchers through a self-paced, interactive platform.

Method: In early 2013, the Children's National recruited an instructional designer to develop a LMS for diverse constituents (e.g., medical students, residents, and fellows) that would compile on-line training modules and related information. In response to the IOM Report, the CTSI-CN forged a partnership between the Research Education, Training, and Career Development component and the instructional designer to create the FACTS LMS.

The CTSA Core Competencies in Clinical and Translational Research are the foundational elements of the FACTS LMS. Core thematic areas were populated with existing content from the NIH, the CTSA National Consortium, CNMC, GW, and other on-line resources. The FACTS portal provides a distance-learning repository of these resources and allows participants to monitor their personal progress. The CTSI-CN can track who is accessing each resource and how often and thus, determine the impact of FACTS for our research community.

Progress/Outcome: The FACTS LMS has been completed. The Phase I goal is to beta-test FACTS with current CTSI-CN KL2 scholars and other institutional K-awardees. This group will provide end-user feedback. The Phase II goal is to incorporate an on-line Individualized Academic Career Development Plan into FACTS, allowing users to conduct self-assessments and provide links to resources within FACTS that would allow users to increase their competency in identified areas.

Lessons Learned: Although educational materials exist in a variety of on-line domains, we have established the CTSI-CN as the organizational hub for these resources. This effort was made possible through collaboration with an existing resource at CNMC. Creating FACTS has required a significant commitment by the CTSI-CN, involving staff training in the LMS, identification and collation of existing educational resources, and creation of new content.

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Children's National

Abstract 2: **Assembling a New Tracking and Evaluation Team at the CTSI-CN: A Necessary Mid-Course Correction**

PI Name: Lisa M. Guay-Woodford, MD

Institution: The Clinical and Translational Science Institute at Children's National (CTSI-CN)

Problem: Initial efforts to establish a robust Tracking and Evaluation (T&E) component within the CTSI-CN were unsuccessful.

Rationale: The initial CTSI-CN T&E support was provided through a contractual agreement with an outside consulting firm. An interval assessment after two years revealed that insufficient processes and procedures had been implemented to track the deployment and evaluate the impact of CTSI-CN resources within our research community.

Methods: The initial contractual agreement was dissolved and in late 2012, a completely revamped T&E team was assembled, which included intramural faculty with T&E expertise, administrative support from a senior CTSI-CN staff member, and consultative assistance from the RAND Corporation. This new team, with expertise in clinical and translational research, program and network evaluation, data collection/analysis and result dissemination, has developed a multi-step approach to evaluate four key areas in accordance with the CTSA common metrics project: Collaborations, Publications, Education and Resources/Support. REDCap was used as the main data collection tool. Quarterly evaluations are now performed. In addition, a semi-annual network analysis is planned using PARTNER – an on-line survey and analysis tool to identify which collaborations/interactions produce better outcomes.

Results: As of September 2013, the new T&E team has completed two quarterly evaluations of all our component programs, as well as the CTSI-CN as a whole. Data collected during quarterly reports have been summarized and submitted to each component director and the CTSI-CN leadership. Key measures of component productivity and effective collaborations have been identified. In addition, several areas for improvement at the component level, as well as for the overall CTSI-CN program, have been defined. Corrective actions are in progress.

Outcome: We were able to create in mid-course an optimal T&E team with both in-house and outside expertise. Our team has identified metrics of success and is tracking them over time.

Lesson Learned: A successful T&E team needs to include internal and external expertise, as well as administrative support from senior staff. It also needs to iteratively re-evaluate the types of data requested from each component to ensure that quality information is identified with a minimal burden for data collection.

Children's National

Abstract 3: *The Translational Research in Pediatrics Program (TRIPP): A Collaborative Initiative between CTSI-CN and the NIH Clinical Research Center*

PI Name: Lisa M. Guay-Woodford, MD

Institution: The Clinical and Translational Science Institute at Children's National (CTSI-CN)

Challenge: To leverage existing resources and create synergistic collaborations between two geographically proximate institutions with complementary strengths in child health research.

Rationale: The TRIPP program was initiated in 2012 to foster collaborations between Children's National Medical Center (CNMC) and the NIH Clinical Research Center (CRC). The goals were: 1) to provide support for NIH investigators with protocols that involve children less than 2 years of age and/or that weigh less than 20 pounds, and 2) to facilitate collaborative partnerships between CNMC investigators and colleagues in the NIH intramural program.

Methods: Under the auspices of the TRIPP program, the CTSI-CN facilitates partnerships between CNMC investigators and those from the NIH intramural program. NIH protocols that focus on the target pediatric population are implemented in the Clinical Studies Resource of the CTSI-CN. In addition, the CTSI-CN assists investigators at CNMC in identifying potential collaborators from the NIH intramural program to further research projects that require specialized capabilities, technologies, and expertise available at NIH.

Results: A total of 6 collaborative, disease-focused studies are currently in development within the TRIPP program. These include studies on methylmalonic academia, McCune-Albright syndrome, rheumatic heart disease, congenital heart disease, Legg-Calve-Perthe disease, and Aicardi-Goutieres syndrome. The majority of the studies focus on defining natural history, identifying markers of disease progression, and using the natural history data to assess new therapeutics.

Outcome: The TRIPP program is a successful model of leveraging complementary resources/expertise to establish inter-institutional collaborations for child health research that facilitate studies neither institution could accomplish on its own. In addition, this program facilitates mentoring relationships between relatively junior CNMC faculty and senior NIH investigators.

Lesson Learned: Outlining clear goals, timelines, roles/responsibilities and supplemental sources of funding, as well as establishing a reliance agreement between the two institutions for regulatory oversight early in the planning process is paramount for success.

Cincinnati

Abstract 1: **Reliance Agreement among IRBs in Greater Cincinnati Metropolitan Area**

James E. Heubi, Joel Tsevat, Jeremy Corsmo, Jane Strasser, Michael Linke
Center for Clinical and Translational Science and Training, University of Cincinnati,
Cincinnati Children's Hospital Medical Center, Cincinnati Veterans Affairs Medical
Center

Problem/Challenge: Human subjects research conducted at multiple sites in the Greater Cincinnati area requires independent IRB review at each site.

Rationale/Approach: Multiple IRB review is burdensome to the research team, is resource intensive, and leads to delays in initiating research and increased costs without clear benefit. A reliance agreement among local IRBs could alleviate such problems.

Methods/Outcome: In 2010, the Center for Clinical and Translational Science and Training (CCTST) formed a committee with representatives from 8 local IRBs to explore the possibility of establishing a community-wide IRB and determined that it was neither practical nor efficient.

As an alternative, in 2011, we formed the Consortium of Greater Cincinnati IRBs (CGCI). In 2013, the CCTST supported the development of a collaborative IRB review agreement among the 7 CGCI members engaged in multisite research. This agreement allows any of the CGCI IRBs to act as the IRB of record for studies conducted at multiple sites, decreasing investigators' administrative burdens and IRB workloads without incurring the costs of establishing a standalone community-wide IRB. The CGCI collaboratively drafted an agreement incorporating each institution's concerns. A final reliance agreement has been accepted by 6 of the 7 IRBs to date; one institution's IRB has declined so far, citing the lack of AAHRPP accreditation by some of the other IRBs. The CGCI plans to implement uniform informed consent documents so that each site does not have to create its own version for a given study, and plans to first try out the reliance agreement on minimal-risk protocols.

Obstacles/Lessons Learned: Because each IRB had to navigate unique institutional pathways to approving the agreement, it was important to provide individual assistance to each IRB during the approval process. The use of a consultant who was independent of the University of Cincinnati and Cincinnati Children's Hospital Medical Center, dedicated to shepherding the agreement through the approval process at each institution was critical to the success of the project. In conclusion, the development of a local collaborative review agreement is a potentially low-cost, practical alternative to a community-wide IRB.

Cincinnati

Abstract 2: **Facilitating Access to REDCap for VA Investigators**

Joel Tsevat, MD, MPH¹; James E. Heubi, MD¹; Catherine McGraw¹; Paul Harris, PhD²; Denise Hynes³

¹University of Cincinnati Center for Clinical and Translational Science and Training; ²Vanderbilt Institute for Clinical and Translational Research; ³University of Illinois at Chicago Center for Clinical and Translational Science

Problem/Challenge: VA data security regulations pose an impediment for VA researchers to use their university affiliate's CTSA's instance of REDCap.

Rationale/Approach: Over the last several years, a few CTSA's have been able to provide REDCap access to their VA researchers in either of 2 ways: 1) by creating a separate instance of REDCap residing behind the VA firewall (e.g., Nashville VA), or 2) by capturing only de-identified data in the university's instance of REDCap and keeping all linked protected health information in a separate database behind the VA firewall (e.g., Cincinnati VA). Still, many CTSA's have not been able to provide REDCap access to VA researchers. As such, the VA Research Collaboration Thematic Special Interest Group has prioritized this issue.

Methods: To facilitate REDCap access to all VA researchers, we are creating a centralized installation of REDCap on the VA Informatics and Computing Infrastructure platform, a secure central workspace for VA investigators located in Salt Lake City.

Outcome: The centralized REDCap instance is currently undergoing early testing with over 40 VA investigators. Future work will include education and dissemination more broadly throughout VA.

Lesson learned: Although data security concerns and other regulatory issues have often presented impediments to research collaboration between universities and their VA affiliates, access to REDCap in VA has proven to be surmountable. The centralized collaborative approach described may be extended to facilitate use of REDCap for FISMA or 21 CFR Part 11 compliant installations available to CTSA researchers with maximized security, efficiency and economy.

Columbia

Abstract 1: **Changing the culture of research at an institution: Is top down or bottom up the way to go?**

Institution: Columbia University

PI: Henry N. Ginsberg, MD

The Irving Institute for Clinical and Translational Research, home for our CTSA, had, as one of its central goals, to change the culture of research at Columbia and enhance multi-disciplinary research. We used both “bottom up” and “top down” approaches to this key issue. For the bottom up approach, we identified several outstanding junior/mid-level faculty members across a wide range of departments and schools and supported them with salary and research funds as Irving Institute Fellows. We asked them to work together to develop new approaches to increase collaborative research. This experiment, which involved two successive classes of Fellows over a period of 5 years, led to collaborations amongst some of the Fellows and initiation of projects that if successful, would have achieved our goal. However, it became clear that our modest level of funding for these young faculty members was not adequate enough to support the sustained effort needed to develop and launch broad based generic programs, such as a website for investigators interested in disease prevention, and all but a few, very focused projects, failed to reach maturity. In contrast, top down approaches focused on providing incentives for collaborative and multidisciplinary work has been very successful. Thus, pilot award programs requiring collaborators from different disciplines, different departments and schools, and having the prerequisite of new collaborations, have been extremely successful. Not only have the winners of these awards continued their efforts and obtained NIH or foundation funds, but even some of the groups that were not funded by the Irving Institute have continued to be active and have obtained outside funding. Other top down, incentive-based approaches include development of seminar series that offer investigators the opportunity to both learn how to develop collaborative research as well as hear from investigators who are not in their usual research sphere. For example, we have had several seminar series given by faculty from the Department of Biomedical Engineering in the School of Engineering at the main Columbia campus. These have launched some exciting and innovative collaborations with faculty in the School of Medicine. In addition, we give priority for space and training support to individuals conducting collaborative, multidisciplinary research. In summary, although bottom up approaches using young faculty to launch broad-based programs to support collaborations could have a large impact campus-wide impact, we have concluded that targeted funding of specific multidisciplinary projects is the best way to change the culture of research at our institution, one project with one group of investigators at a time (at least within the constraints of limited/existing resources).

Columbia

Abstract 2: From GCRC to CTSA: Expansion of Clinical Research Support in the Face of Less Direct Support within the Overall CTSA Budget.

Institution: Columbia University
PI: Henry N. Ginsberg, MD

When the GCRC era ended, CTSAs were faced with significant barriers and opportunities related to their inpatient and outpatient research facilities. The major barrier was financial: although CTSA budgets were larger than the GCRC budgets, the marked increase in programs made maintenance of the existing GCRC extremely difficult. A major opportunity resulting from the conversion of GCRCs to CTSAs derived from the elimination of the many restrictions placed on who we could serve. At Columbia, we have been able to take significant advantage of this opportunity. Specifically, with outstanding support from NewYork-Presbyterian Hospital and the Dean of the School of Medicine, we have been able to use our inpatient space for “long outpatient” studies, utilizing the same nursing staff for both inpatient and outpatient protocols requiring infusions, repeated sampling, and/or frequent observation. This has been our largest growth area. We have also worked with hospital administration to accommodate research that involves children less than 18 years of age on our adult facility. We have been successful in expanding our efforts to develop young clinical investigators. The second major advance we made was to provide support for research coordinators who are deployed in the ICUs and EDs. We have been able to do this because of cost-sharing with each of the Departments involved. This has been very successful in units that had a tradition and infrastructure in place to do research e.g. the NICU, PICU, the Neuro-ICU, and the Emergency Departments. In units that have fewer clinical investigators or those that primarily perform industry studies e.g. CCU, SICU, it has been less successful. We have learned that there has to be a designated physician to whom these coordinators report and who assigns them to projects. Overall, however, our expansion across the breadth of hospital facilities has been very well received and rewarding. In conclusion, we have taken maximal advantage of the ability to expand services beyond those allowed for GCRCs and now provide hospital-wide support for patient oriented research.

Cornell

Abstract 1: **Fostering Innovation: Creative Thinking “A Crash Course on Creativity**

Excellent Course –Wrong Audience

PI: Julianne Imperato-McGinley, MD
Weill Cornell Clinical and Translational Science Center

Problem

It is difficult if not impossible to win federal funding without creative and innovative ideas.

Rationale

In order to explore and stimulate creativity in individuals, teams, and organizations, the CTSC hosted a massive, open online class in the fall of 2012 called “A Crash Course on Creativity,” offered by the Stanford Technology Ventures Program. This course was an addition to our series of seminars - Skills Acquisition Workshops- open to all partners.

Methods

The free online course was broadcasted worldwide over the span of 8 weeks. Streaming from the CTSC Administrative office, it drew 25 participants from WCMC and from CTSC partner institutions. Participants were offered unlimited access to CTSC resources.

Outcomes

Implementation proved challenging. Participants who were part of our short seminar series- Skills Acquisition Workshops- were extremely engaged at the beginning, but due to their structured schedules had difficulty working in a team environment on a regular basis and in videotaping their weekly assignments.

To help ease the workload, the CTSC hosted weekly meet-ups and provided administrative and technical resources to team members. In the end, three teams completed the course and found it extremely useful in enhancing creativity. For the remainder of the group, the challenges of working overtime were barriers to their success. Our shorter workshops succeeded because these participants planned ahead and allocated sufficient time and effort in their hectic schedules for a defined period of time.

Lesson Learned

Although many participants signed up initially, gauging their ultimate commitment and intention to complete the program was not anticipated. This excellent course will be hosted again, if offered, as part of a Certificate and/or Master’s Program where the participants take semester long courses and for others who have a declared time effort.

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Cornell

Abstract 2: **A Retrospective Case Study of Successful Translational Research**

PI: Julianne Imperato-McGinley, MD

Weill Cornell Clinical and Translational Science Center, New York, NY

Problem: It takes a long time (estimated at a median of 17 years) to translate from an initial idea in basic research to a result that affects the public's health. CTSA's would need to wait as much as another decade before we could expect to see a significant number of successful results that address this key purposes of the CTSA initiative.

Rationale/Approach: Retrospective case studies of recent successfully translated interventions can enhance our ability to understand the key drivers and barriers of translational research.

Methods: In this pilot study, we conducted a detailed historical empirical analysis of one successful translational case (Gleevec) developed at a partner institution (MSKCC). The methodology included: a comprehensive literature review; creation of a timeline and a database of key markers (publication and patent dates, FDA approval) and events (collaborative onset between key researchers; pressure from patient community/advocates); an intensive semi-structured interview with the key informant/researcher; a sophisticated bibliometric analysis of the key papers associated with this case study; and linking of the project database with national age-adjusted U.S. mortality data on leukemia.

Outcomes: The time to translation is dependent on the selection of the "origin" study. If the origin is the key discovery of the Philadelphia chromosome, the translation took 41 years (1960 – 2001) to FDA approval. If it is the first clinical trial, the process took only three years (1998-2001). Results showed a coincidental decline in age adjusted mortality rates from over .80 to about .35 within a ten-year period following the first clinical trial.

Lessons Learned: The translational process appeared in this case to be a "punctuated" one with fairly long latency periods between major breakthroughs until clinical trials began. At that point, the process moved rather rapidly. It was clear from interviews and published accounts that the community of patients and families with chronic leukemia played a key role in moving the process along by convincing the pharmaceutical company to produce Gleevec for the critical Phase II trials after the extremely promising Phase I results. Retrospective case studies were demonstrated to have significant potential for advancing our understanding of research translation.

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Cornell

Abstract 3: **Development of a Centralized Translational Research Support Team Program at Weill Cornell Medical College CTSC / “Be Prepared for Success”**

PI: Julianne Imperato-McGinley, MD

Weill Cornell Clinical and Translational Science Center, New York, NY

Problem

As the transition of the Weill Cornell GCRC to the CTSC made services available to partner institutions, the need arose for increased centralization to help facilitate access to resources.

Rationale

The creation of the Translational Research Support Team (TREST) transformed clinical and translational research within the center. TREST acts as a gatekeeper to the CTSC and a “concierge” to services by supporting investigators in the planning and execution of protocols, with a particular focus on multi-disciplinary, trans-institutional team research. TREST members include: 1) a Research Manager; 2) Research Study Coordinators; and 3) a Subject Recruitment Specialist.

Methods

Recognizing the importance of TREST, the CTSC recruited and trained the majority of TREST staff within six months of initial CTSC funding. In year 4, the Subject Recruitment Specialist was added to provide investigators with targeted assistance recruiting and retaining research subjects. TREST facilitates collaboration among the various disciplines and partnering institutions by advancing the translation of basic science projects into clinical research—in essence, acting as the “critical link” uniting these traditionally disparate fields and newly created research teams. TREST continues to develop innovative methods to meet the needs of investigators in the CTSC community, including the promotion of a “CTSC without walls” that assists investigators at off-site facilities and within the community.

Outcomes

TREST has achieved remarkable progress in breaking new ground with the Weill Cornell research community and its partners. However, the long-term sustainability of this program remains in question. The overwhelming demand for TREST support and our inability to hire additional staff due to recent budget cuts have begun to tax organizational capacity. To control overutilization, establishing a system for prioritizing and awarding different levels of support may help maintain the range and quality of services offered. The creation of a charge back mechanism, whereby investigators with funding support help keep CTSC services financially solvent and affordable by sharing in costs, may help alleviate financial pressures.

Lesson Learned

Creating a flexible, service-oriented mechanism at the nexus of the diverse research constituents that the CTSC serves has proved successful for our institution. Meeting investigators’ need for support in the current fiscal climate is a significant challenge.

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Denver

Abstract 1: “The PACT Council: a solution to community engagement challenges in Colorado”

Montelle Tamez, Larry Green, and Ronald J. Sokol, Colorado Clinical and Translational Sciences Institute

The Challenge: There is wide-spread agreement that health is a community affair requiring Communities of Solution of sufficient reach and competence to be able to address health care and health challenges. Investigators have their societies and infrastructures, communities have their leaders and organizations, but there is an unfortunate deficiency of a suitable infrastructure and system to bring investigators and communities together for common cause. This situation impedes translational research.

The CCTSI Solution: The Colorado Clinical and Translational Sciences Institute (CCTSI) Community Engagement and Research Core created a Partnership for Academicians and Communities for Translation (PACT) in 2008 and operationalized it through systematic development of statewide relationships and strategies that are imagined, implemented, tested, and deployed through the leadership and governance of the PACT Council. This Council is a balanced governance structure comprised of equal numbers of community and academic experts who have equal influence over decisions. The Council oversees statewide initiatives for translational research functioning very much as a non-profit board of directors guided and constrained by carefully crafted rules of operation equivalent in scope and content to by-laws. The Director of Community Engagement and Research has dual reporting relationships to the Principal Investigator and Director of the CCTSI, who retains authority over all aspects of the CCTSI.

Results: The PACT creates and sustains relationships and an enduring infrastructure that enables the people who can solve a health or health care problem to work together. The PACT operates a spectrum of programs and services that provide educational and research infrastructure for collaborative translational research. The Immersion Program for investigators into community life and for community members into academic life is oversubscribed and has changed the participants in career-changing ways, as well as stimulated new ways of working together. The Community Engagement Pilot Grants program, which supports both the development of new community-academic research partnerships and implementation of individual projects, has so far tested innovative serving locally relevant ideas in pertinent environments, and has demonstrated a 10 to 1 return on investment in acquisition of subsequent external grant support. These Pilot Grants require both a community and an academic co-Principal Investigator forming a partnership. In fact, PCORI has modeled some of our infrastructure and procedures into their new community grants program. Eleven Community Research Liaisons work daily across the state of Colorado in defined communities known to the Liaisons, to assist investigators in engaging community members and groups and to ensure that community members have input, engagement and involvement in the research developed within their communities. A novel mechanism has been developed by which funds can be transferred to community organizations and members rapidly and without significant barriers by a local foundation devoted to improving the health of Colorado (Colorado Foundation for Public Health and Environment). These combined efforts have generated opportunities for communities and academic researchers to leverage their respective assets to move discovery into practice.

Conclusions: The PACT and its governance and operating structures are poised to stimulate and enable translational research. Building trust and balancing power takes consistency over time, and does not just leap into existence. The PACT is an exemplar of an emerging research structure and approach called out decades ago, with an opportunity to gain traction across all CTSAs. The use of the Colorado Foundation for Public Health and Environment as a business partner to manage funding out into the community is a successful strategy that avoids the often cumbersome research bureaucracies of universities and federal agencies. The CCTSI and PACT have undergone major transformative growth in their first five years. The PACT serves as a foundational platform for a dynamic assortment of research efforts aimed at eliminating health disparities in Colorado. By forming the supportive scaffolding and infrastructure to develop and sustain Communities of Solution, the CCTSI and PACT are well down the road towards addressing and eliminating health disparities. This infrastructure may be an emerging technology necessary to truly eliminate health disparities in the United States.

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Denver

Abstract 2: The Colorado Leadership for Innovative Team Science (LITeS) Program: Creating Effective Teams

Judith Albino, PhD; Marc Moss, MD; and Ronald J. Sokol, MD.

The Challenge: Higher education has been slow to adopt training to enhance leadership skills and build highly effective teams. As a result, clinical and translational research faculty rarely bring strong management and teamwork skills to their leadership and administrative responsibilities. Interdisciplinary and collaborative research creates additional challenges that require even more sophisticated skills. Clearly, clinical and translational research efforts stand to benefit substantially from the exploration of individual strengths and development needs, the understanding and practice of critical team building skills, and the creation of support networks to sustain intentional and effective leadership.

The CCTSI Solution: The *Leadership for Innovative Team Science* (LITeS) program of the Colorado Clinical and Translational Sciences Institute (CCTSI) accepted its first cohort in 2008. The aim of the LITeS Program is to enhance effective leadership for team science by: 1) providing training in exemplary leadership skills for senior and emerging leaders; 2) providing focused opportunities to practice and reflect on those skills most critical for team science; and 3) creating communities of clinical translational researchers who will foster innovation and mutually support effective leadership. Program directors of externally funded training programs (T32 and K12 directors, and K24 recipients), and the mentors for the KL2 scholars were invited to participate, along with graduate program chairs, department chairs, and deans, and directors of collaborative research centers, and major laboratories, and clinical services with major research activity. LITeS content includes work focused on leadership and team building skills in three domains: 1) Self-Awareness aimed at identifying individual strengths and areas for development, 2) Interpersonal Skills for working with others, and 3) Task or Management skills, focused on process issues for getting work accomplished. These skills are addressed through six types of training experiences: (1) didactic training in a workshop format with small group exercises; (2) quantitative, validated assessments and feedback on critical skills; (3) self-reflection through journaling related to key learning; (4) individual coaching focused on the creation of Personal Leadership Development Plans; (5) homework exercises for trying new skills from prior trainings and peer coaching sessions; and (6) team projects for interdisciplinary groups of 7-9 participants. The focus on team projects has been enhanced by participation of University leadership at the highest levels, both in the suggestion of critical issues for team efforts, and final review of projects.

Results: Four cohorts and more than 100 individuals have completed the program. LITeS participants have included roughly equal numbers by gender and by training degree - PhDs (53%) and MDs (47%); half were translational and half clinical researchers. Most were full professors (75%). About 42% are from the School of Medicine and 20% from Public Health, with approximately 17% each from Pharmacy and Nursing, and 5% from Dentistry. All deans on the Medical Campus participated, and two new deans will do so in 2013-14. Table 1 shows participant self-reports of

Table 1: Team Science Knowledge	Before		After		Change *
	Mean	Std. Dev.	Mean	Std. Dev.	Mean
Effective Feedback	2.75	1.18	4.13	0.50	1.38
Emotional Intelligence	2.46	1.14	3.71	0.81	1.25
Building Respective Workplaces	2.90	0.77	4.05	0.67	1.14
Effective Meeting Strategies	3.07	0.78	4.00	0.73	0.93
High performing Teams	2.81	0.91	3.68	0.90	0.88
Conflict Management	2.77	0.86	3.46	0.76	0.69

* All differences in mean significant at the $p < 0.01$ level

knowledge gains for session topics that addressed team science concepts. Quantitative ratings of programs were high, using a 5-point scale. Participants reported implementing new skills immediately and an eagerness to share concrete strategies to improve teamwork and meeting efficiency. Participants reported plans to use leadership and teamwork skills in their academic environment, and 83% reported using their new skills in leading their research teams. All participants said that LITeS increased their sense of connection to the University, and all valued their interactions with investigators from other schools and disciplines. Over the one-year course, a remarkable 30% develop new collaborations through LITeS.

Conclusions: The LITeS program has successfully trained clinical and translational researchers in leadership and team science. Future directions for the LITeS program include: expansion to accept emerging faculty leaders of outstanding potential, programs for intact research groups, and assistance to campus groups interested in specialized spin-off leadership programs.

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Denver

Abstract 3: “Natural Animal Models Core”: Advancing T0.5 translational research

Susan VandeWoude, Douglas H. Thamm, Wayne Jensen and Ronald J. Sokol
Colorado Clinical and Translational Sciences Institute

The Challenge: The temporal gap between preclinical research and phased human clinical trials is a significant impediment to rapid and efficient drug discovery and medical advancements. Better utilization of well-characterized, relevant, adaptable animal models could greatly enhance this process. Concerns regarding the applicability of many rodent models to human patients include lack of heterogeneity of an outbred population with concurrent diseases, and differences in drug distribution, metabolism, physiology, immune status and “achievable” drug concentrations in rodents vs. humans. These dichotomies contribute to the poor correlation between results of many rodent studies and subsequent early clinical trials. More predictive animal models are thus warranted and highly desirable to more rapidly advance translation of basic discoveries into human clinical trials and application.

The CCTSI Solution: The Colorado CTSA, based at University of Colorado Denver in Aurora, Colorado, will launch a new ‘Natural Animal Models Core (T0.5 translation) that will take advantage of the significant expertise of veterinary clinical and basic scientists at Colorado State University (CSU) in Fort Collins, Colorado in applying pre-clinical drug solutions to naturally occurring diseases in veterinary patients. CSU’s College of Veterinary Medicine and Biomedical Sciences (CVMB) is rated as one of the top 3 veterinary colleges in the US, and currently manages a robust veterinary clinical trials program with many natural similarities to the human clinical trials counterpart. *Clinical trials in companion/domestic animals with spontaneous diseases are to date underutilized translational models.* Advantages of using such models as compared to rodents are many, and include: larger body size, relative outbreeding, immunocompetence, and comparability with many of the biological, physiological, and pathological processes of humans. Logistical advantages of conducting clinical trials as a stepwise process in animals with naturally occurring clinical disease as an ‘advanced preclinical trial’ include: 1. Significantly reduced regulatory burden, 2. Potential for excellent owner compliance from enrollment to completion, 3. “Patient” enrollment, procedural conduct and compensation issues are less complex in veterinary vs. human applications, 4. Greater capacity to collect serial samples during the conduct of the trial as well as after euthanasia, 5. Significant knowledge base relative to appropriate disease predictors, diagnostics, biomarkers, and monitoring capacity. Thus, conduct of a veterinary clinical trial for a drug that has completed pre-clinical assessments can inform. The Faculty in CVMB has expertise in small animal, equine, livestock, and zoologic medicine in more than 30 specialty areas with equivalent counterparts in human medicine. The CSU Veterinary Teaching Hospital (VTH) receives over 40,000 cases per year; the Veterinary Diagnostic Laboratory (VDL) performs over 500,000 tests on >120,000 cases annually. Examples of expertise in diseases with direct relevance to human diseases and amenable to veterinary clinical trial implementation include a variety of cancers, arthritis, degenerative disc disease, diabetes, obesity, atopy, renal, hepatic, and heart failure, mitral valve disease, idiopathic epilepsy, immune mediated anemia, glaucoma, pain management and others. CSU VTH and VDL have diagnostic capabilities in pathology, clinical pathology, advanced imaging, and many of the ‘-omics’. Yr 01 of this Core will be used to plan a well-considered implementation process that will begin in Yr 02. Collaborations between human biomedical researchers at UC Denver and its affiliate hospitals with CVMB faculty will be facilitated through targeted retreats and combined seminars. Communication with and development of collaborations with other Veterinary Colleges at other CTSA sites to enhance patient populations will be a component of this process. We anticipate this core will both validate natural animal models, and initiate veterinary clinical trials in concert with Phase 1 human clinical trials to significantly enhance therapeutic feasibility and efficacy during the evaluative period.

Results: The initiation of this core will provide extraordinary opportunities for collaborations between biomedical scientists, and human and animal clinical researchers in protocols that will provide capacity to streamline proof of concept ‘T0.5’ translational science. We intend to launch a world-class resource that will have significant impact to this CTSA.

Conclusions: This innovative, solution-oriented, and highly collaborative Core will provide a unique and potentially transformative approach to proof of concept pre-clinical studies and will embed T0.5 translational research into the therapeutics development pipeline in relevant disciplines.

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Duke

Abstract 1: **Strengthening Clinical and Translational Research Relevant to Child Health**

PI: Robert M. Califf, Duke University

Problem/challenge: Many barriers exist to conducting clinical and translational research in child health, including the relative rarity of many conditions, disease heterogeneity, limited research infrastructure, and ethical issues in pediatric research.

Rationale/approach: Duke Translational Medicine Institute (DTMI) Child Health has fostered therapeutic discovery in child health through the Pediatric Trials Network sponsored by the Best Pharmaceuticals for Children Act Program and the NICHD (PI: Benjamin DK; HHSN275201000003I). The Network facilitates collaborative trials to accelerate the FDA approval of key drugs and devices for use in children.

Methods: DTMI provides regulatory expertise, ethical consultation, and statistical support to the Pediatric Trials Network and has established master service agreements with each of the 100 Network sites, thereby reducing time to contract execution. A total of 24 CTSA institutions participate in the Network and the Pediatric Trials Network collaborates with other NIH networks, such as the Neonatal Research Network, for enrollment, study design, and drug development.

Outcome: Awarded October, 2010, the Pediatric Trials Network enrolled its first patient into an IRB-approved protocol on January 3rd, 2011. Data from this protocol, conducted under an IND, have been published and submitted to FDA. To date, 1647 children have been enrolled in 24 protocols evaluating > 35 drugs (including antibiotics, sedatives and narcotics, proton pump inhibitors, diuretics, and cardiac drugs) and 1 device. Four studies have been completed with study reports sent to the FDA.

The Pediatric Trials Network has two protocols that employ an innovative design. The first actively enrolling under FDA guidance and is the Pediatric Off Label PK Study (POPS). The POPS protocol is able to enroll any child who is receiving a molecule for which dosing has not been described. The second trial was recently approved by FDA and is a 4-arm trial in neonates to simultaneously secure a new indication for 4 molecules.

Lessons learned: NIH-funded networks working in concert with the CTSA sites can form a mutually beneficial environment fostering collaborative child health research that can accelerate patient enrollment and efficiently complete clinical trials that will improve child health.

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Duke

Abstract 2: The use of the Epic Electronic Medical Record system for the comprehensive management of clinical research at an academic medical center.

PI: Robert M. Califf, Duke University

Challenge: The efficient and cost-effective management of site based clinical trials is a key objective of the CTSA collaborative (NCATS RFA). At many complex academic medical centers much of the process of clinical trials management remains spreadsheet and paper- based (ref here). A few centers have implemented Clinical Trials Management Systems (CTMS), but very few CTMS have been integrated into the Electronic Medical Records (EMR) used for clinical care. This gap is significant as research efficiency requires harnessing the clinical infrastructure in terms of scheduling study appointments, placing research related orders, documenting evaluations, drawing labs and viewing results. These processes are interwoven with routine clinical care and the clinical and research revenue cycles, making it challenging for academic medical centers to address with a comprehensive information system.

Approach: Duke has embraced the Epic EMR, going live successfully across our outpatient and inpatient areas with over 6000 simultaneous users in June 2013. Our research implementation involves the comprehensive management of clinical studies, subjects, enrollment, research appointments, order sets for research, study calendars, and documentation of research visits and management of the research and clinical revenue cycles (split billing).

Methods: "Model" Epic 2012 functionality for research was used for all studies with "billing risk", maintaining the master study registry, subject registry and subject enrollment status in Epic. Our implementation deviated from model in the requirement to build an order set for each clinical study, enabling a close linkage between orders and the cycles of a study calendar with underlying billing codes and the charge master. Planning for go-live included the building of study administrative records, order sets and study calendars for over 600 actively enrolling clinical trials at Duke in a process that engaged study teams, central research administration and the patient revenue management organization in multiple cycles of validation. Over 1100 clinical trials coordinators received 4 hours of classroom training in the month prior to go-live, with an active communications strategy of town halls, websites, FAQ's, tip sheets, newsletters and "Research Wednesday" events involving the entire research community.

Results: Epic has become Duke's Research Patient Management System with much of the functionality of a traditional CTMS woven into our EMR. This initiative has already forced efficiencies into clinical trials management, from the analysis and agreement on a universal workflow, to the prioritization of studies based on productivity and enrollment, to a rationalization of costs and redundancies inherited in our legacy trial "grids" as they were exposed to the rigor demanded of the new approach.

Lessons learned: Building order sets and study calendars in volume is complex and expensive, but we believe is key to the success of this approach. Integration of traditional CTMS functionality into EMRs is inevitable for complex academic medical centers, but we believe efficiencies in research management can be achieved by embracing the evolving functionality in comprehensive EMR systems.

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Duke

Abstract 3: Formalize and Standardize Evaluation Processes for Individual CTSA and the CTSA Program

PI: Robert M. Califf, Duke University

Challenge: To improve research efficiency and productivity, CTSA must use iterative methods to assess productivity (P), cost (C), quality (Q), and human capital (HC) and then set goals for improvement.

Approach: A balanced scorecard is used to assess P, C, Q and HC and is implemented across 15 disease-oriented site based research units (SBRUs). All researchers work in an SBRU subject to common SBRU oversight utilizing consistent practices with common research management tools. With our eResearch Management System and Research Data Mart, we track and evaluate specific research metrics across SBRUs.

Methods: The following metrics are evaluated quarterly: Number and quality/diversity of: NIH studies, investigators, invention disclosure forms, patents, INDs/IDEs, technologies moved to the next phase, patients enrolled, trials completed, communities participating, publications; cost; time to IRB/contract decisions.

Results: We have assessed our current status and developed SMARTER (specific, measurable, attainable, relevant, time sensitive, evaluate and reevaluate) goals:

SMARTER Goal	Current Status	Delivery Date	Scorecard Domain
Increase the # of investigators using CTSA resources by 20%	425	Annually	HC
Increase IDFs, patent applications, patents issued, and licensing agreements by 15%	IDFs= 242 Applications= 111 Issued= 52 Agreements= 102	Annually	P
Increase # of Investigational New Drug applications (INDs) or Investigational Device Exemptions (IDEs) issued by 10%	63	Annually	P
IRB and contract decisions made within 30 days in 90% of research protocols	Median time, 57 days	Yr 3+	C
>= 1 publication for 100% of completed clinical research protocols (or a sound reason for non-publication)	90%	Yr 3+	P
100% of completed trials will have timely results reporting in ClinicalTrials.gov	100% registered; result reporting not yet tracked	Yr 3+	P
Increase enrollment for NIH funded trials by 20% annually	2560/yr	Yr 3+	P
Increase the # of high impact publications from clinical/translational NIH studies by 20% annually	200/yr	Yr 2+	Q
Increase the satisfaction scores for research subjects by 30% and then yearly by 20%	Survey under development	Annually	Q

Lessons learned: A governance structure and balanced scorecard allows us to make informed decisions to change course and initiate alternatives. We will benefit from the experience of other CTSA and NCATS in refining these metrics and goals.

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Emory

Abstract 1: **Capstone Design Project**

Atlanta Clinical & Translational Science Institute (ACTSI)

PI: David S. Stephens, MD, Emory University

Abstract Topic Area: Advance Innovation in Education and Training Programs

The ACTSI engages Emory and two other academic partners in metropolitan Atlanta – Morehouse School of Medicine (MSM) and Georgia Institute of Technology (Georgia Tech) – to form a strategic multi-institution alliance, supporting clinical and translational research.

Problem/Challenge – One of the ACTSI’s unique challenges is developing collaborations across campuses that highlight the strengths of each institution.

Rationale/Approach – The existing Capstone Design programs for undergraduate students at Georgia Tech provide an avenue for collaboration with the partners of the ACTSI. Undergraduate students work in teams to design, build, and test prototypes with real world applications.

Methods - The ACTSI Georgia Tech Biomedical Engineering Senior Research Design Partnership is the result of engaging ACTSI investigators and undergraduate Biomedical Engineering (BME) students in the Senior Design Project I and II (BMED 4600 & 4601) courses. The course focuses on product development, FDA regulations, ISO standards and business and management processes. Working with ACTSI clinical and translational investigators and Georgia Tech faculty, students in teams of four construct a problem statement and during the course of an academic year create a solution to the problem. Investigators gain access to dedicated teams of individuals who strive to help solve problems using engineering and develop enhanced collaborations with Georgia Tech and BME in general. ACTSI also supports the Senior Design program through communications and other promotions, administrative support, and funding for educational symposia.

Outcome – Since the beginning of the program in 2008, 47 students have been supported by the ACTSI with direct funding and 6-12 months of mentoring and team meetings. In the 2011 InVenture Competition at Georgia Tech, 4 of the finalist teams worked with ACTSI investigators: Device that Powers Hospital Equipment in Third World Countries, Device that Improves Cataract Surgery, Device that Improves Hospital Intubation Procedures, and Device that Discreetly Screens for Medical Implants. One BME-ME/ACTSI team took top prize in the Mechanical Engineering Design Expo symposium.

Lessons Learned – The Senior Research Design partnership would not have happened without the ACTSI and is an example of how the ACTSI is enhancing collaborative opportunities and awareness of new technologies within the ACTSI partnership through new channels of communication and educational initiatives.

Emory

Abstract 2: **Education and Training for Nurses Engaged in Clinical and Translational Research**

Atlanta Clinical & Translational Science Institute (ACTSI)

PI: David S. Stephens, MD, Emory University

Abstract Topic Area: Advance Innovation in Education and Training Programs

The ACTSI is a partnership of three academic partners in metropolitan Atlanta, Emory University, Morehouse School of Medicine, and Georgia Institute of Technology. Nursing is involved in all areas of the ACTSI, from leading scientific investigations, serving as research coordinators and research nurses, and advancing the culture of knowledge discovery among all nurses in the ACTSI network. We established the ACTSI Nursing Advisory Committee to support nursing and to recommend educational and training programs to advance nursing's role throughout the ACTSI.

Problem/Challenge – Promoting the important role of nursing in the ACTSI and beyond.

Rationale/Approach – Our approach has been threefold: 1) assure that nursing scientists and trainees are engaged in all components of the ACTSI, 2) provide education and professional support to clinical research nurses and coordinators, and 3) assure that all nurses caring for patients in our healthcare system have a culture of clinical research and knowledge discovery.

Methods – The *Clinical Research Nursing Alliance* consists of clinical research nurses and coordinators engaged in ACTSI clinical trials and focuses on workforce/professional development issues and standards for clinical practice including innovation, recruitment, and training. Approximately 125 research nurses across the affiliated units under the ACTSI meet regularly to focus on these issues. To facilitate the integration of clinical and translational research throughout the ACTSI network, we also completed an assessment of current research training needs for all nurses employed in the system. The ACTSI Nursing Advisory Committee then assumed a lead role in the development of an expanded research training module to assist all nurses in understanding the importance of clinical trials and nursing's critical role throughout the academic health center.

Outcome – The Nursing Advisory Committee has demonstrated a consistent and comprehensive voice for all nursing issues throughout the ACTSI. This focus on the multiple roles nurses play throughout the system has resulted in more representation of the discipline in ACTSI leadership, support for clinical research nurses throughout all institutions represented in the ACTSI, and a heightened recognition of the importance of nursing in advancing clinical and translational science.

Lessons Learned – This is an ongoing initiative which we plan to make more visible in the Atlanta community and throughout the CTSA's.

Florida

Abstract 1: **Bridging resources for research, patients and care**

University of Florida CTSA:

David R. Nelson, M.D., Principal Investigator

To improve the efficiency and quality of translational research at the University of Florida and strengthen its capacity to function as a “learning health system,” the UF Clinical and Translational Science Institute created and integrated three major resources that serve as pillars for linking researchers to data, biospecimens and patients of interest:

- The CAP-accredited **CTSI Biorepository** links researchers to high-quality biospecimens and biospecimen collection and storage services. As of Sept. 2013, it hosts 149,283 samples.
- **Consent2Share** links UF Health patients to researchers through a system-wide initiative underway to offer patients treated at UF Health an opportunity to allow UF researchers to contact them about future research studies for which they might be eligible, and/or to allow the CTSI Biorepository to store blood or tissue leftover from their health care visits for future use in research. Patient consent is recorded in the Epic electronic medical record system. During the six-month pilot, 8,200 valid consent forms were received from patients, with 78% consenting for re-contact and 84% for tissue storage.
- The **UF Health Integrated Data Repository** links researchers to data securely aggregated from UF Health’s clinical, administrative and research systems. From their desktops, researchers can use the IDR’s i2b2 tool to query a HIPAA-compliant Limited Data Set for cohort discovery and study planning. The IDR includes data from Epic, Consent2Share, the CTSI Biorepository and the CTSI Personalized Medicine Program. IDR data is refreshed monthly. As of August 2013, it includes more than 48 million observational facts pertaining to more than 380,000 patients.

We will evaluate whether these new resources ultimately improve study design, recruitment and results. Major new NIH and industry funding already has been awarded for national and statewide research collaborations that leverage this infrastructure. The CTSI is next focusing on how to align these resources with its HealthStreet and Study Registry initiatives to streamline and improve recruitment and retention. Over time, the IDR will incorporate genomics and metabolomics data from CTSI cores. Future integration of clinical data will broaden in scope from patients to populations as the CTSI advances implementation science at UF Health and across the state. Many lessons learned are informing how we move forward: Close collaboration with and buy-in from the IRB, health system and university leadership are critical. Champions, pilots, quality assurance, flexibility and operational support are key enablers. Use and adoption by the research community requires continuous outreach and support. Integration of resources is essential for true transformation.

Florida

Abstract 2: **Building on Strengths—Personalized Medicine as a Model for Implementation Science**

University of Florida CTSA:

David R. Nelson, M.D., Principal Investigator

Studies have estimated it takes an average of 17 years for scientific discoveries to reach medical practice. The national CTSA consortium was created to help shorten that timeframe and accelerate discoveries toward better health. In 2011, with an administrative CTSA supplement of \$499,920, the UF Clinical and Translational Science Institute created its Personalized Medicine Program to help tackle this challenge in pharmacogenomics, starting with clopidogrel for interventional cardiology patients.

Over the course of one year, the CTSI Personalized Medicine Program created the clinical, laboratory and informatics infrastructure required to generate electronic medical record alerts that allow UF Health clinicians to take a patient's genetic information into account when prescribing certain medications. Since the program's clinical launch in June 2012, more than 1,000 patients at the UF Health cardiac catheterization lab have received this routine genetic testing, approximately 28% of whom have genetic variations contra-indicated for clopidogrel. With a \$3.7 million implementation grant awarded in June 2013 by the National Human Genome Research Institute, the program is now expanding in three ways. First, it is expanding within UF Health to include additional medications for which there is strong evidence linking genetic variations to drug response. Second, through statewide research networks established through the UF CTSI, the program is transferring its model to other health-care providers in Florida to introduce similar genetic testing in private and community-based physician practices. Third, the program is developing innovative training models to prepare health care professionals, health sciences students and patients for a future in which genomic medicine is commonplace.

In implementing this program, the UF CTSI identified institutional strengths and a model that could be applied more broadly to strengthen UF Health's capacity as a learning health system and advance implementation science across the state: alignment and support of institutional leadership, a commitment at UF Health to more fully integrate research and clinical care, the CTSI's system-wide infrastructure for implementing evidence into practice, and the CTSI's research collaborations and networks through which implementation models developed at UF Health can be tested and adapted for use in other types of health-care settings. The UF CTSI is now building on these strengths through its new Implementation Science Program and through collaborative initiatives that seek to expand statewide capacity for translational research.

Georgetown Howard

Abstract 1: Leveraging Diversity to Focus On Underserved Populations

Georgetown Howard Universities Center for Clinical and Translational Science (GHUCCTS):
Thomas A. Mellman and Joseph G. Verbalis, PIs

GHUCCTS' location in the Nation's capital with its diverse and predominately African-American population, inclusion of a historically black university in the leadership, and a VAMC and rehabilitation institute as participating institutions influenced us to formulate a key aim of our CTSC as addressing underserved populations, defined as including minorities, the elderly, and the disabled. As our programs became established, an opportunity for branding led to designation of the theme "Discovery through Diversity" to highlight GHUCCTS' diversity of institutions, populations, and disciplines. The challenge we faced was to effectively utilize our diversity to implement our aim to focus on increasing research in underserved populations.

Strategies to facilitate this aim have concentrated on building an infrastructure that capitalizes upon our diversity. First, the leadership across the GHUCCTS institutions was fully integrated to ensure inter-institutional collaboration. To this end, the CTSA award has 2 PI's, one representing Georgetown and the other Howard, and each of the components is led by a director and co-director typically from one of the two lead institutions, though sometimes including representation from the additional participating institutions that are also represented on the GHUCCTS Executive Committee. Second, the GHUCCTS pilot and collaborative studies program (PCSP) was designed to require inter-institutional representation for its higher level funding mechanism and includes inter-institutional and inter-disciplinary involvement, as well as relevance to public health including disparities, among its review criteria. Third, we have established a highly-engaged community advisory board that represents diverse community groups and interests across the greater Washington DC area.

Multiple outcomes have supported the success of these efforts. Of the projects utilizing GHUCCTS Clinical Research Unit (CRU) resources, it was recently estimated that 54% focused on an "underserved population". African American men and women represent a majority of the recruitment population for all protocols, particularly among men. Nine of 15 (60%) of the applications awarded through our PCSP that involve clinical data bases or human subjects also focus on underserved populations. Two of 8 of our KL2 scholars, 10 of 66 PCSP investigators, and many of those attending grant workshops and other seminars are from under-represented minority groups. Although there has been some effort for the leadership to develop projects with health disparities relevant foci, the portfolio of supported projects has largely developed organically and selection of trainees has been merit based.

While institutional administrative and cultural obstacles, and determining an optimal level of activism in shaping the research and training portfolio, continue to be ongoing challenges, we conclude that the planned infrastructure of GHUCCTS has succeeded in increasing the representation of underserved populations in translational research. The lesson we have learned is that the diversity of multi-institutional CTSA's can be leveraged to increase participation of underserved populations in research through establishment of an effective governance and programmatic infrastructure.

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Georgetown Howard

Abstract 2: Partnering CTSA's with non-NIH Governmental Institutions - the Food and Drug Administration

Georgetown-Howard Universities Center for Clinical and Translational Science (GHUCCTS):
Joseph G. Verbalis and Thomas A. Mellman, PIs

GHUCCTS is a relatively smaller CTSA based on the summed sizes of our member institutions. One of the challenges we have faced has been to increase the scope of the programs and opportunities available to our faculty, investigators and trainees beyond the combined resources of our universities. Our approaches have prominently included partnering with non-NIH governmental agencies to expand our programmatic offerings. We had already accumulated considerable experience with this approach by the inclusion of Oak Ridge National Laboratory and the Washington DC Veterans Administration Medical Center as member institutions of GHUCCTS. To further expand this network, GHUCCTS partnered with the recently established Georgetown Program for Regulatory Science & Medicine (PRSM) to apply for a Food and Drug Administration (FDA) grant as a Collaborating Center of Excellence in Regulatory Science and Innovation (CERSI). The CTSA was intimately involved in the grant application, with one of the GHUCCTS PI's serving as a co-Investigator and Director of Research of the CERSI, and the GHUCCTS Biomedical Informatics component serving as a major focus of collaborative research activities between our CERSI and the FDA. The GU CERSI (U01 FD004319) was one of two such centers funded in October, 2011. Since then, our CERSI has been involved with multiple collaborations between the faculty of CERSI, GHUCCTS and the FDA. These have included: 1) developing analytical tools to guide use of pharmacogenomic data in drug development and to enhance safety signal detection for the occurrence of autoimmune diseases associated with vaccines; 2) analysis of issues, attitudes and beliefs surrounding data sharing in industry and academia; 3) pilot research studies focused on health and science literacy in underserved and minority populations; and 4) establishment of a new curriculum in Regulatory Science as a fourth track in the GHUCCTS Masters of Science in Clinical and Translational Research, which is co-taught by faculty from CERSI, GHUCCTS, the FDA and industry. The close relationship between our CTSA and CERSI has therefore resulted in increased collaborations, pilot grants and educational opportunities for our faculty and trainees. In addition, CERSI and GHUCCTS actively participate in the RK and RETCD KFCs to share our curriculum with other CTSA's interested in integrating regulatory science into their educational programs. The lessons we have learned from this process is that the strength, personnel and resources of the CTSA's can be effectively engaged with other governmental agencies, as well as public-private partnerships, to establish new research and educational initiatives that can broaden the capabilities of individual CTSA's. However, from our multiple partnerships it is clear that each governmental agency has special roles, approaches and challenges that need to be customized to achieve effective collaboration. An unwelcome added lesson is that this FDA-funded CERSI grant will not count toward our institutional base for future CTSA funding.

Harvard

Abstract 1: **Boston Marathon Bombings Collaborative Lesson**

Lee Nadler
Harvard Catalyst

The day following the Boston Marathon bombings, a second serious medical problem was rapidly emerging. Many who only had limited bodily injuries were appearing in emergency rooms in all of our hospitals with the chief complaint that could not hear. No one had a clue what to do.

Michael Hoffer, the director of the Spatial Orientation Center at the Naval Medical Center in San Diego and a Navy Representative to the Department of Defense's Hearing Center of Excellence, directs a lab that focuses on damage to the inner ear from noise, and from blunt and blast trauma. Working with Carey Balaban, vice provost for faculty affairs and professor of otolaryngology at the University of Pittsburgh School of Medicine, they have conducted studies of blast injury in military combat. They published data that demonstrate the efficacy of treating hearing-related symptoms following a blast injury with N-acetylcysteine. On April 15, Hoffer saw a significant uptick in downloads of his study published in PLoS One in 2010, "Blast Exposure: Vestibular Consequences and Associated Characteristics"

A team of young clinical investigators at the Mass Eye and Ear Infirmary consulted Hoffer. They decided to launch a study that would involve several Boston hospitals. The study proposed to include several lines of inquiry: whether eardrum perforations will heal independently or ultimately require surgery, and also whether the characteristics of an eardrum perforation are different when caused by a blast or another cause; looking at the use of steroids as treatment for patients suffering from sensorineural hearing loss immediately after a blast; and examining the correlation between distance from the blast and the severity of hearing loss and eardrum perforation. Collecting distributed good-quality data was going to be a time-consuming affair so RedCap was implemented. The research protocol was submitted to the IRB 10 days after the attacks.

Traditionally, launching such a study would be a time-consuming, cumbersome process lasting weeks, even months. However, since 2008 Catalyst has facilitated a framework for HMS-affiliated institutions to speed the review of human studies. Just one week after submitting the protocol to the Mass. Eye and Ear IRB, the team got to work using the Harvard Catalyst cede review form for the first time, requesting a single IRB review to seven area hospitals that included Brigham & Women's, Beth Israel Deaconess, Mass General, Boston Children's Hospital, Boston University Medical Center, Tufts Medical Center and Harvard Vanguard Medical Associates. Responses from the other IRBs came within a day or two, and they all accepted to cede review.

Several hundred patients across all these sites were accrued within weeks to the protocol. Currently, the physicians at each of the participating hospitals are monitoring patients' progress and have already begun collecting outcomes.

Mechanism like the Cede Review Process will be essential to implement across multiple sites or even the entire consortium if we plan to be able to respond to opportunities such as described here and to respond to the NIH institutes and industry in a timely and collaborative fashion.

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Abstract 2: **The Eagle Opened Its Eyes but Struggles to Find Its Nest**

Lee Nadler
Harvard Catalyst

Sharing research resources should generate two transformative outcomes. First, it should speed translation thereby impacting health. Second, if widely implemented, it should save significant dollars opening opportunities for reallocation to support other novel initiatives. Addressing this challenge would not be simple. There was no mechanism to identify research resources since they were in the hands of investigators, divisions, and/or departments at our institutions. If research resources could be identified and catalogued how to optimally display them? What would be necessary to incentivize sharing and to simplify transactions?

Harvard Catalyst responded to a 15 million dollar ARRA research resource challenge by partnering with OHSU, Morehouse, Jackson State, Puerto Rico, Alaska, Hawaii, Montana, and Dartmouth to apply for an opportunity to build a federated network that could display resource resources as open linked data. 58 days after convening in the Chicago airport, our proposal was submitted and to our great surprise, we were selected launching eagle-i.

Three teams would be necessary to deliver the product in 24 months. The informatic build team was at Harvard and their responsibility was to establish the data warehouse, data entry tool, and search function. At OHSU, the curation team created the ontologies essential to support each of the multiple required research resources. Each of the sites had on the ground resource navigators who would find the required resources and then use the data the entry tool to create site-specific repositories' of research resources. An absolutely extraordinary multi-institutional collaborative team delivered the desired product (approximately 40,000 curated research resources) as open source displayed as open linked data to the world on time and under budget.

Although we had the tools in hand to identify and display research resources, demonstrating value and sustainability would become the prevailing challenges. If we could solve the problem of funding, how might we demonstrate added value? One immediate success was led by our investigators at four sites (Morehouse, Jackson State, Puerto Rico, and Hawaii) that were part of the Research Centers in Minority Institutions (RCMI). Sharing would be natural for RCMI where resources were scarce. With the help of RTRN at Jackson State, all 20 RCMI institutions were able to implement eagle-i and this achievement helped them refund their collaborative grant. Selfless sharing occurs across RCMI.

The challenge was to implement eagle-i to a broader audience and to demonstrate sharing across the CTSA. Harvard and OSHU joined U Penn and Vanderbilt and successfully competed for funding. We were driven to make the invisible visible thus we named the CTSA effort open-i. Using the eagle-i operating model, we collected thousands of resources including all cores, bioalgorithms, models of disease, and integrated an external repository. Again, we exceeded the required resources numbers and again completed the project this week on time and on budget.

Now we can discover and display research resources. That is no longer the issue. However, the critical questions have not answered and they must be addressed by NCATS and by each individual CTSi. What are we willing to share? What resources will have real impact on clinical and translational research? How can we incentivize and reward displaying and sharing research resources? What is success and how do we measure it? This is the challenge for NCATS and for all of us. Answering this question will ensure the success of the consortium.

Indiana

Abstract 1: Partnering with Business School to Create Business Development Program for Technology Cores

Problem addressed: Most academic medical centers have dozens of technology cores that provide services to investigators. Some of these are large and are supported by standard business infrastructure (e.g., imaging centers). Most are small cores that are run by investigators within departments and lack a rigorous business development (BD) plan for providing services in a sustainable manner. Thus, the costs of services are not rigorously researched, customer service is poor, and most such cores run in deficits.

Rationale/approach: Most CTSA institutions have affiliated business schools where faculty routinely work on training students to develop work-flow and financial plans for small businesses as part of their training. Partnering with such a business school and providing a small support for the student/faculty teams to help technology cores develop a sustainable business plan would be a potential solution to address the above problem.

Methods: The Indiana CTSA partnered with the Indiana University Kelley School of Business to create a joint training/service program. A team of 3-5 MBA students are paired with a CTSA core facility to tackle a management problem identified by the core director. The students are supervised by a business school faculty on this project and the MBA students receive independent study credit towards their degree for participation. An RFA is issued each year to all the cores for this competitive resource. The application process is brief. The project applications are reviewed jointly by the CTSA technology program and the business school representatives. The winners for this award are chosen on scientific impact and business development opportunity.

Outcome: The program has been ongoing for the last 3 years and has been highly successful. In this year's grant cycle, we are expanding the program to include an implementation phase, where an MBA Intern Implementation team will help implement a business plan developed by a prior team. From 2013 on, the business development program will assist about 8 cores per year and the implementation program will assist 3 cores per year.

Lesson learned: CTSA's have unique resources within their institutions that can be leveraged with creative partnerships to develop best business practices to improve access and sustainability of core resources to investigators.

Indiana

Abstract 2: **Creating a Successful EMR based, Clinic-embedded, City-wide Subject Recruitment Program**

Problem addressed: One of the major barriers plaguing many clinical trials is effective and timely recruitment of participants. The CTSA's are charged to assist recruitment of subjects in a 'disease agnostic' manner. Building unique subject registries for every possible major disease group is not an efficient approach and new models are required. Therefore, there is a great need to develop models where broad recruitment can be done in clinical settings, perhaps using electronic medical records (EMR).

Rationale/approach: Most CTSA institutions have affiliated health care systems that provide care for large patient populations. Partnering with them and creating subject recruitment 'cores' could develop a sustainable model to recruit a wide range of patient populations. However, there are many barriers to setting up a system embedded into clinical service flow that can actually recruit patients. This report describes a successful implementation of one such model.

Methods: Indiana CTSI created an enhanced subject recruitment program called Subject Enrollment and Research Volunteer Engagement (SERVE) which provides EMR-based recruitment resource to investigators. The SERVE program utilizes the Central Indiana Network (Ci-NET) within its informatics core that has accesses to all partner hospital medical records and scheduling systems. The EMR data is utilized to identify potential patients, so that specially trained and authorized recruiters can get approval from the patients' treating physicians, and approach the patients during a clinic visit. SERVE utilizes several practice based research networks (PBRNs) associated with the Indiana CTSI

Outcome: Since its roll out in 2010, SERVE has conducted 239 feasibility assessments, and recruited over 6,000 research participants. In 2011, SERVE also created a patient friendly, self-managed research volunteer virtual home (www.INresearch.org) currently used by nearly 1,500 Indiana residents. At this site, an individual creates his or her own health profile that allows him/her to provide health information including medication usage, their availability and preferred times and contact methods etc. They are also automatically directed to register to the National consortium's *ResearchMatch.org* site.

Lesson learned: CTSA's can roll out a wide range of tools with their health care provider partners to create critically helpful resources for subject recruitment, as well as research volunteer empowerment, to assist clinical trials.

Iowa

Abstract 1: **An Integrated Educational and Mentoring Program for Research Coordinators**

CTSA Institution: University of Iowa

Presenter: Gary E. Rosenthal, MD

Problem / Challenge: Research coordinators play central roles in the safe and effective conduct of clinical studies. However, institutional infrastructures for training, career development, continuing education, and mentoring of research professionals are often limited. Consequently, many coordinators are trained experientially without the benefit of an organized knowledge base or optimal skill set and may further experience professional isolation with limited opportunities for peer mentoring.

Rationale / Approach: In 2010, the University of Iowa Institute for Clinical and Translational Science (ICTS) implemented an integrated program to support the developmental needs of research coordinators. The program sought to bring together research coordinators across departments and colleges and provide a range of educational programming and opportunities for peer mentoring and networking.

Methods: An advisory committee was chartered to develop the program. The committee first sought to identify personnel across the university who might benefit from program by reviewing job classifications and descriptions. The committee then developed a list of unmet educational needs that centered around a number of core issues, including subject recruitment, IRB approval, FDA regulations, clinical research ethics, informed consent, principles of good clinical practice, study drug management and source document management. Committee members also reviewed educational programs offered by other CTSA programs.

Outcome / Results: The program encompasses three core elements: (1) a semester-long formal certificate program that covers core topics and that, to date, has been completed by 84 coordinators from 18 different departments across the university; (2) a monthly seminar series that reviews issues of emerging importance and provides opportunities for sharing solutions to common problems; and (3) a peer mentoring program that seeks to facilitate the development of a professional community and decrease the isolation that many coordinators experience. To further expand the program, all seminars and lectures have been videotaped and made available through the CTSA Consortium's Virtual University.

Key Lessons: The program has been extremely well received by participants. However, a number of key lessons emerged. First, research coordinators fell into numerous university job classifications that varied across departments. Second, coordinators have a wide range of educational and training backgrounds. The needs of coordinators differed across coordinators with clinical (e.g., nurses, nurse practitioners, medical assistants) and non-clinical backgrounds. Third, garnering support from investigators was an important element in building interest in the program among coordinators, as was developing an advisory committee of respected senior coordinators.

Iowa

Abstract 2: Implementing a Multi-Method Evaluation System to Improve Clinical Research Unit Efficiency and Effectiveness

CTSA Institution: University of Iowa

Presenter: Gary E. Rosenthal, MD

Problem / Challenge: The University of Iowa Clinical Research Unit (CRU) provides an array of services to enable Phase I – IV clinical research studies and accounts for a substantial proportion of the CTSA budget.

Rationale / Approach: The Institute for Clinical and Translational Science (ICTS) developed a comprehensive multi-method system for evaluating the effectiveness and efficiency of CRU services. The goal of the system was to provide valid data to: (1) support quality improvement activities; (2) meet the emerging needs of investigators; (3) facilitate decision making surrounding resource allocation by ICTS leadership; and (4) enable the transition to a cost recovery model that offered value to investigators.

Methods: Seven complementary evaluation strategies were implemented over a two-year period, including:

- (1) quarterly review of utilization data (e.g., numbers of studies, visits, and laboratory test performed);
- (2) annual online needs assessment surveys of clinical investigators who did and did not use CRU services during the prior 12 months;
- (3) quarterly large-group meetings with investigators and coordinators to identify unmet needs and potential concerns;
- (4) focus groups of specific CRU users (e.g., junior investigators);
- (5) online surveys of investigators and coordinators to determine satisfaction with CRU services;
- (6) post-visit surveys of subjects to determine satisfaction and identify “critical incidents” (e.g., privacy concerns) that merit immediate review; and
- (7) Development of an online “dashboard” to summarize information on key indicators.

Outcome / Results: The evaluation system has provided an evidence-based approach for improving the effectiveness and efficiency of CRU services. For example, based on trends in utilization and the future needs of investigators, analytical laboratory and bionutrition services were eliminated, and resources were reallocated to other areas (e.g., coordinators to support studies outside of the CRU). Other utilization data revealed imbalances in subject scheduling (e.g. greater morning than afternoon volumes) that led to refining staff work schedules and strategies to incentivize afternoon subject scheduling. In addition, while 98% of research subjects were “satisfied” with their visit, subject satisfaction surveys identified specific areas in which to focus improvements (e.g., informing subjects prior to the visit on the anticipated length of the visit and of possible delays during the visit).

Key Lessons: Developing a robust CRU evaluation system required the development of several new tools and strategies. While maintaining the system requires considerable resources, the availability of empirical data has been invaluable in driving quality improvement efforts and communicating difficult decisions regarding resource allocations and cost recovery to investigators and staff.

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Iowa

Abstract 3: **Building Interdisciplinary Research Collaborations – The LINCC Pilot Grant Program**

CTSA Institution: University of Iowa

Presenter: Gary E. Rosenthal, MD

Problem / Challenge: The increasing emphasis of NIH and other funding agencies on translational research challenges many faculty in basic science departments to develop new collaborations with clinician scientists and move away from their traditional approaches and comfort zones.

Rationale / Approach: The University of Iowa Institute for Clinical and Translational Science implemented the LINCC (Looking Into Clinical Connections) Program to foster *de novo* collaborations between investigators in basic science departments and clinician investigators in clinical departments.

Methods: The LINCC Program brings together basic science faculty and clinician investigators who have not previously collaborated but who may share common scientific interests. LINCC strives to foster the development of: (1) new ideas and connections that bridge basic scientific investigation and clinical medicine; and (2) long-term scientific collaborations. LINCC provides up to \$50,000 over a 1-year period to support the work of the team with the expectation that the award will lead to at least one published manuscript, joint attendance at a national scientific meeting to present their work, and to a further grant application within 3 years of initiating the collaboration. Other activities include attendance by the clinical scientist at basic science seminars and shadowing by the basic scientist in a relevant clinical setting.

Outcome / Results: Eight LINCC teams representing five basic science and five clinical departments have been funded to date. Awardees include seven professors, three associate professors, and six assistant professors. The LINCC awards have had a significant impact. All teams have participated in translational research seminars. Five of the eight pairs have submitted external proposals to NIH and other entities using preliminary data obtained from their LINCC awards, while one team submitted a proposal to the American Heart Association. Five proposals submitted by four teams have been funded to date, including three NIH (R24, R21, and K08) and two foundation (March of Dimes and Thoracic Surgery Foundation) awards.

Key Lessons: Implementation of the program during the first year required significant matchmaking efforts and working with basic science department chairs to actively identify and facilitate potential collaborations. However, as recognition of the program increased, *de novo* collaborations surfaced easily and the quality of the applications increased. While the initial results are encouraging, the long-term collaborative impacts need to be demonstrated, particularly for pairs who have not yet been successful in obtaining new external funding.

Johns Hopkins

Abstract 1: **The Study Coordinator Apprenticeship and Mentoring Program (SCAMP)**

PI: Dan Ford MD, MPH - Vice Dean for Clinical Investigation, Johns Hopkins School of Medicine
Johns Hopkins Institute for Clinical and Translational Research (JH-ICTR)

Many investigators experience significant problems finding knowledgeable and experienced research coordinators, especially investigators who don't have enough funding to support an entire FTE. This problem is most acute for junior faculty who could most benefit from an experienced, well-trained coordinator, but typically have limited funding since they are just beginning their research careers. The ICTR hopes to solve this problem with SCAMP. SCAMP began in Oct 2012, enrolling a cohort of four trainees with little-to-no clinical research experience in a two-year intensive training and mentoring program in research coordination. These trainees have completed extensive educational training, well above the required human subjects training, and rotations in each of the ICTR's three Clinical Research Units. They have gained hands-on experience by shadowing experienced coordinators and by completing work assignments for investigators needing part-time coordinator support. SCAMP began accepting applications for work assignments in Jan 2013, and thus far has provided coordination to 15 studies for 12 different PIs in 7 different departments. Over the past 11 months SCAMP has become highly recognizable and trainees are greatly sought out, both for part-time work through SCAMP, and from PIs wanting to hire them out of the program. SCAMP is currently booked with work assignments through Jan 2014 and just matriculated its second cohort of trainees in September.

Lessons learned:

- The demand for coordinators is significantly higher than anticipated. As SCAMP grows, we will need to expand yearly cohorts beyond the current four trainees to meet anticipated demand. This will create new challenges, such as additional costs for increased supervision/management.
- Total work capacity of four trainees is roughly 2.5 FTE, allowing for time spent on continued training and education (1 day/week), weekly group and individual mentoring meetings with the program manager, and travel time to and from work assignments.
- We are discovering that we need an additional experienced coordinator to assist the program manager with course development, and to fill in as a kind of "float pool" for trainees when they are sick, on vacation, or are hired out of the program. We hope to add this position to SCAMP before Jan 2014.

Johns Hopkins

Abstract 2: **The Sharing Partnership for Innovative Research in Translation (SPIRiT Consortium)**

PI: Dan Ford MD, MPH - Vice Dean for Clinical Investigation, Johns Hopkins School of Medicine
Johns Hopkins Institute for Clinical and Translational Research (JH-ICTR)

While the latest RFA from NCATS has encouraged deeper coordination between the programs within a CTSA, this same paradigm is less evident across the national CTSA consortium. To successfully speed scientific translation in an environment of tightening resources, CTSA programs need to grow beyond the stand-alone model in which a common set of research resources are offered locally at each institution and instead become unique citizens of a coordinated national program in which each institution contributes specialized resources based in institutional strengths. While there has been significant regional collaboration amongst some CTSA programs, efforts constrained by geographic location may limit the benefits that can instead be derived from linking scientists, institutions, resources and innovative tools across an array of institutions with complementary capabilities. In an attempt to model this new paradigm, six geographically-dispersed CTSA sites (Johns Hopkins University, University of Chicago, University of Pennsylvania, University of Pittsburgh, Washington University at St. Louis, and Yale University) have formed a “virtual CTSA consortium” based on a shared vision for data sharing and prior collaborations focused on informatics initiatives: The SPIRiT Consortium. Initial goals of the program are (1) to develop a data sharing infrastructure for biospecimen-based research and deidentified clinical research data, and (2) to establish inter-institutional collaborations related to pilot studies, regulatory support, core laboratory facilities, and education and career development. During the past year, this consortium has deployed an informatics software and regulatory infrastructure to enable discovery and sharing of banked pathology specimens across three member institutions, has developed an inter-institutional pilot grant program to foster new scientific collaborations across sites, and has obtained supplemental funding to validate a novel technology for improving the diagnosis of malignant melanoma in multiple institutions. These examples of inter-institutional collaboration represent early initiatives to leverage infrastructure, link investigators and capitalize on clinical expertise across institutional and geographic boundaries. The founding of the SPIRiT Consortium on the basis of a common priority for data sharing, as opposed to geographic proximity, can serve as a paradigm for the development of other consortia of CTSA sites with common areas of focus.

Kansas

Abstract 1: Grant Writing Support

Kimber P. Richter, PhD, MPH, Richard J. Barohn, MD, and Lauren S. Aaronson, PhD, RN
University of Kansas Medical Center

Problem/Challenge: NIH grant review only permits two submissions and funding levels are extremely low. To help trainees find early success in funding, Frontiers has developed an intensive hands-on course in grant writing that takes students from conception to submission of their own NIH grant proposals to complement an existing traditional semester-based course on grant writing.

Rationale/Approach: Excellent materials and tips abound, but it is repeated cycles of writing and feedback, built on models from successful applications, that enables new investigators to quickly develop efficient and effective grant writing skills.

Methods: The course closely follows the *Grant Application Writer's Workbook: National Institutes of Health Version* (Russell and Morrison). The course is taught in an executive format, over an intensive introductory weekend and subsequent monthly meetings. Significant time in every class session is devoted to outlining and writing grant sections. Outside of class, students are required to perfect their drafted sections; trade sections and meet with peers at mid-month to trade critiques; and get regular feedback on application content from their career mentors. The introductory weekend focuses on understanding the NIH application and review process and drafting an initial hypothesis and specific aims section. Subsequent classes cover Significance and Innovation, Approach (2 classes), and ancillary proposal sections. The course is kept small (8-10 students) to facilitate a strong collaborative learning community. Handouts include the course syllabus, class agendas, and course handouts on writing style and the NIH application process.

Outcome: To date, 8 students, including a mix of faculty and students in KL2 and T32 programs, have completed the class. Student evaluations were very positive, and two submitted their completed applications to internal grant programs. Seven students are currently taking the course.

Lessons Learned: It is advantageous to have two courses to meet varying needs: a traditional, semester-based grant writing course with didactic lectures as well as student grant proposal presentations for critiques that focuses on programmatic as well as research grants, and an executive-style course that focuses exclusively on preparing NIH research grant applications and in which students primarily write in a supportive and time-limited environment.

Kansas

Abstract 2: **Pioneers Community Research Registry**

Patricia M. Kluding, PhD, PT, Richard J. Barohn, MD, and Lauren S. Aaronson, PhD, RN
University of Kansas Medical Center

Problem/Challenge: Many investigators struggle to access and recruit study participants, especially those who do not have a client/patient base from which to identify eligible study participants. For a multi-institutional CTSA, there are additional challenges posed by institutional health record access restrictions.

Rationale/Approach: *Frontiers: The Heartland Institute for Clinical and Translational Research* initially established a Research Participant Registry within the University of Kansas Physicians (UKP) practices using a HIPAA compliant information sheet where patients give permission to release their contact information to investigators with IRB approved studies. We wanted to reach beyond UKP clinic patients and offer this support to all Frontiers investigators.

Methods: We brought together the Frontiers key function cores on community engagement, ethics, informatics, regulatory support, communications, and clinical research resources. We engaged a design firm to develop a public website and created a REDcap health history survey for the website to provide initial screening data for investigators. We convened several community focus groups to help us develop, review, refine, and test the website content.

Outcome: We received IRB approval and then ran into a legal snag because we wanted to include an optional ask for permission to access health records from those who volunteer through the Pioneers website. This is being addressed. We also are creating brief descriptions of studies actively recruiting participants to the website so that community members may contact investigators directly if they wish. And, we developed a marketing brochure and are working on an overall marketing plan.

Lessons Learned:

1. Engaging patients and community members in the development process provides critically important information for the success of this effort.
2. The “lay” abstracts in www.clinicaltrials.gov are not always in language easily understood.
3. Without a marketing plan, if you build it, they won’t necessarily come.
4. Establishing resources to support investigators at multiple institutions remains challenging—particularly when institutions are located in two states.
5. Providing the “trusted” imprimatur for the public, as requested by our community advisors, is difficult when working with multiple institutions that have separate recognized ‘brands’ or logos.

Kentucky

Abstract 1: **Development of an Appalachian Translational Research Network**

Patrick Kitzman¹, Laureen Smith², Rebecca Jackson², Philip Kern¹

¹ Center for Clinical and Translational Science, University of Kentucky, Lexington, Kentucky.

² Center for Clinical and Translational Science, The Ohio State University, Columbus, Ohio.

Problem/challenge: In rural, medically underserved Appalachia, health disparities are severe, multidimensional, and cross state borders, and health research has not been viewed favorably by the community in the past. Both Kentucky and Ohio State CTSA's had independently proposed to develop resources and create a community of engaged investigators and community partners, which could lead to a fragmented approach.

Rationale/approach: Leadership of multiple institutions serving Appalachia reasoned that translational research efforts must be comprised of an integrated, cross-state, community engaged research network, founded on a culture of collaboration and equity between all stakeholders.

Methods: In April 2011, the foundation of an Appalachian Translational Research Network (ATRN) was formed. ATRN specific aims include identifying translational research priorities and developing effective engagement among the lay, practice, and academic research communities. In addition to an annual health summit held in either Lexington or Columbus, enhanced engagement of the ATRN partners include (1) a joint pilot program between many of the ATRN institutions targeting health conditions prevalent in Appalachia; (2) collaboration between the informatics programs where local expertise is leveraged and data management expertise shared for field studies in Appalachia; and (3) the development of unique resources that can be leveraged by any of the partners for the conduct of community engaged research. ATRN membership now includes more than 20 community partners and ten academic institutions (three of which have CTSA's), which participate in monthly teleconference meetings.

Outcomes: Multiple pilot studies totaling over \$500,000 have been funded involving partnered institutions, each with Co-PIs, involving collaborative studies that would not have otherwise occurred. Each institution has complemented its own research programs in health disparities with cross-institutional-community partner teams which serve as resources for investigators, supported by ATRN coordinators and dedicated faculty at each institution who serve as the local face of the ATRN. Investigators have used this infrastructure to support funded grants in smoking cessation, lung cancer, childhood obesity, and diabetes.

Lessons learned: It is paramount to build trusting relationships between fully engaged partnering entities. The health disparities in Appalachia do not respect state borders, and by working together we are stronger and can share expertise and resources and thus have a greater impact on improving the health of a region.

Kentucky

Abstract 2: Consolidated Pilot Programs at the University of Kentucky: Changing the Campus Research Infrastructure

Thomas E. Curry, Jr., Elodie Elayi, Philip A. Kern

Center for Clinical and Translational Science, University of Kentucky, Lexington, Kentucky.

Problem/Challenge: At the University of Kentucky (UK), pilot funding programs of different research centers and the Center for Clinical and Translational Science (CCTS) lacked standardized eligibility, requirements, timelines, and review mechanisms, leaving investigators confused about pilot programs. Pilot programs for cancer, aging, diabetes, and others, were siloed and discouraged novel research collaborations.

Rationale/Approach: CCTS proposed a consolidated pilot program with matching funds between CCTS & partnering research centers. Consolidated management by CCTS of pilot programs would facilitate efficiency, standardization, transparency, and collaboration.

Methods: The RFA and review of pilot programs involving other research centers were consolidated within CCTS, and matched funding was offered to partnering centers. This included the Cancer Center, Diabetes Center, Center on Aging, and Center for Pharmaceutical Research and Innovation. One RFA (with Center-approved language) is issued, and advertising of pilot opportunities is consolidated on the CCTS website. A standing committee of 15 NIH-funded experts representing various departments/colleges reviews proposals, providing NIH-format review and constructive feedback to applicants. Program management is consolidated within CCTS. A centralized database of UK researchers pools expertise and encourages networking.

Outcome: Matched funding and consolidated advertising of pilot opportunities have increased the number of awards. Transparency has increased due to review by a standing committee (with reviewers listed online) and disclosure of feedback and scores to applicants, who are eligible to resubmit applications for future funding rounds. The initial success of the consolidated pilot program led other research centers (Spinal Cord and Brain Injury Research Center and Center of Excellence in Emerging Tobacco Products) to request that their pilot programs be consolidated within CCTS process. The consolidated process allows CCTS to establish funding priorities and therefore push innovation and collaboration. Pilot management housed within CCTS increases awareness of CCTS and its resources among UK research centers and faculty/staff.

Lessons Learned: A collaborative and consolidated pilot program between various research centers can increase the amount, quality, efficiency, and innovative nature of research. Furthermore, matched funding and demonstration of successful collaboration can facilitate additional partnerships between research centers.

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Kentucky

Abstract 3: An Integrated Resource for Drug Discovery and Development at University of Kentucky

Linda P. Dwoskin, Jon S. Thorson

Center for Clinical and Translational Science, University of Kentucky, Lexington, Kentucky.

Problem/Challenge. The drug development process is not well understood by many investigators. Furthermore, drug discovery and development requires specialized tools and expertise to best assist investigators and recognize the potential of novel drugs and targets.

Rationale/Approach: The mission of the UK CCTS Drug Discovery and Development (D³) Core is to advance understanding of the drug discovery and development process and facilitate UK-based translational research through development of appropriate expertise, infrastructure, and pilot proposals.

Methods. A centerpiece of the D³ Core is the Therapeutic Advisory Committee (TAP) which is comprised of experts spanning the entire drug discovery and development pipeline and serves as an advisory panel for UK investigators interested in and/or engaged in translational research as well as the core 'study section' for CCTS D3 pilot project applications. The operational arm of D³ derives integration with the UK Center for Pharmaceutical Research and Innovation (CPRI), a shared resource with five drug discovery and development enabling cores: a) Organic synthesis (probe synthesis and medicinal chemistry), b) Chemoinformatics (virtual screening, rational design and predictive toxicology), c) Development (analytical/property analysis and preformulation), d) Translational studies (in vivo ADMET and efficacy support) and e) the UK natural products repository (>350 unique natural products, many from microbes isolated in unprecedented environments in Ky). The CCTS D³ Core interacts closely with CPRI and funds essential methodologic infrastructure and pilot proposals, and partners with other campus Centers and Colleges when appropriate.

Outcome: These cumulative resources and expertise has been brought to bear on many translational research projects relevant to cancer, infectious disease, neurodegenerative disease, metabolic disease and drug addiction. In addition, the CCTS D³ has engaged in advancing the local understanding via the development of a D³ seminar series and a new course on drug discovery and development.

Lesson learned. The process of drug discovery is relevant to all specialties and disciplines and employs a common set of tools. Hence, this activity represents an excellent opportunity for a CTSA to contribute infrastructure and coordinate expertise that will be beneficial to the greater community.

Supported by NIH UL1TR000117

Massachusetts

Abstract 1: **Facilitating the translation of discoveries into the clinic: the UMass CCTS experience;**

Katherine Luzuriaga, MD, PI and Director, UMass Center for Clinical and Translational Science

The UMass Center for Clinical and Translational Science (CCTS) has strategically harnessed an outstanding track record in engineering and basic science discovery to address the challenge of rapid translation of basic science discoveries into the clinic. To foster the assembly of cross-disciplinary teams to address the challenges of basic science translation, we issue an annual RFA for cross-disciplinary workshops at our annual CCTS retreat and have established a small conference/think tank grants program to catalyze the assembly of new teams with concrete deliverables. We also established the Life Sciences Moment Fund, a pilot grant program that requires an investigator from the medical school campus to partner with an investigator from at least one other UMass campus. Over the first 3.5 years of the program we have supported 22 multi-campus teams with numerous resulting publications and grant submissions. To specifically catalyze the development of biologics, we have partnered with Mass Biologics, which is the only non-profit, FDA-licensed manufacturer of vaccines in the United States. We established a new pilot grant program that received 20 pre-proposals in its first round; 8 full proposals were solicited and 4 projects were funded, with plans to offer this on an annual basis. To capitalize on institutional investments in gene therapy, we are collaborating with MassBiologics to develop a facility that would provide cGMP grade recombinant adeno-associated virus (rAAV) vectored products for early clinical trials. In the area of medical devices, we established the Massachusetts Medical Device Development (M2D2) Center, a collaboration that combines the clinical research strengths at UMass Worcester with the business and engineering expertise at UMass Lowell. This center has leveraged institutional and state funds to assist over 80 firms in the past year. Altogether, these initiatives and partnerships have resulted in increased capacity for speeding translation of discoveries to the clinic.

Massachusetts

Abstract 2: **Expanding career development options in translational research for PhD scientists,**

Katherine Luzuriaga, MD, PI and Director, UMass Center for Clinical and Translational Science (UMCCTS)

Recent biomedical workforce reports have estimated that fewer than 25% of PhD graduates end up in the “traditional” academic tenure-track. The remaining graduates eventually pursue any number of other important career tracks, but focused professional development and training is often lacking. We sought to capitalize on the combined strengths of our Graduate School in Biomedical Sciences (GSBS) and the UMCCTS to offer graduate students and post-docs greater exposure to translational research career options and opportunities. The potential benefits were twofold- trainees would gain a better perspective of the totality of career options and the university would serve its public institution mission to respond to local and state workforce needs. To accomplish this, the UMCCTS collaborated with the GSBS to support the development of new PhD career development programs under the direction of the Assistant Dean for Career and Professional Development. The CCTS initiated partnerships between the GSBS and key UMCCTS constituents, to enable the development of a comprehensive curriculum and career development activities. This allowed the preparation of a proposal ("An Integrated Curriculum and Community-Based Approach to Career Development") that was submitted in response to the newly-launched NIH Broadening Experiences in Science Training (BEST) grant opportunity. The GSBS proposal was one of ten funded nationally. We are currently working with the grant leadership to promote additional links to industry, trade associations, and government agencies to expand funding, experiential learning, and mentorship opportunities for these new career development programs.

Mayo

Abstract 1: **Extension of CRU Services to the Acute Care Setting**

PI: Dr. Sundeep Khosla, Mayo Clinic

Topic Area: Evolution of Clinical Research Unit (CRU) Services

Problem: In the past, CRU services and support staff were not accessible beyond the physical CRU setting. This created an access gap for all studies being conducted in the acute care setting.

Rationale/Approach: Expand services beyond the CRU physical facilities in order to diversify the range and types of studies supported.

Methods: A 24/7 extended staffing model was developed and put in place to ensure coverage of studies in the acute care setting. In addition, a “Real time” web-based scheduling system was designed and implemented to support the Extended CRU fast-path scheduling and printing of bar-code labels. CRU nurses and support staff assist in the conduct of research protocol activities including administering medications, securing specimens, and gathering clinical data at the bedside of hospitalized patients or in procedural areas. The availability of trained research staff ensures the integrity of the study while hospital nursing and technical staff focus on the provision of prompt, safe, and effective patient care.

Outcome: The Extended CRU now provides 24/7 coverage at both Mayo hospitals (Saint Marys and Methodist). The creation of the Extended CRU has greatly facilitated the ability to perform research activities in the acute care setting. The need for these services continues to grow as investigators become aware of the profound strength of having access to the Extended CRU resources.

PI's in the acute care setting are beginning to design studies and seek funding for proposals which take full advantage of the Extended CRU capabilities. Many of these studies are uniquely possible because of the Extended CRU services. Examples include studies conducted in the intensive care units, operating rooms, emergency room, catheterization laboratory and the closed Psychiatric Unit.

Lesson Learned: The Extended CRU permits CRU resources to be used throughout the institution and has helped to facilitate research to a wider range of clinical disciplines via the Extended CRU (virtual) unit.

Mayo

Abstract 2: **Optimizing the Efficiency of CTSA Educational Programs**

Mayo Clinic Center for Clinical and Translational Sciences (CCaTS)

Sundeep Khosla, PI

Problem/Challenge: As the popularity of our Masters and Certificate programs in clinical and translational sciences continues to grow, available faculty resources are under stress, and student demand for curriculum is outstripping capacity to provide it. In addition, it is increasingly difficult for learners to attend traditional in-person classes and seminars. Finally, existing degree and certificate programs exceed the needs of some learners.

Rationale/approach: To optimize the efficiency of these clinical research training programs, outcomes of the current programs needed to be measured. When combined with analysis of the program costs, program value can be estimated as a basis for rational redesign.

Methods: Using newly-developed evaluation tools, outcomes of current programs were assessed in terms of both traditional process measures of utilization and markers of career development such as publications and grant funding. Program costs were allocated across programs on a total learner-credit basis. The requirements for learner competencies are being defined by ongoing surveys of the learners, established faculty, and subject matter experts in clinical and translational research. Existing coursework is being adapted to an online learning format based on the highest priority competencies identified.

Outcome: Work to date has found that there is not a simple correlation between the intensity of training (e.g., 2-year masters vs. 1-year certificate) and outcome measures, such that the more brief experience may provide greater value for some learners. Based our analysis, we are refocusing our postdoctoral programs so that Master's degree targets those pursuing a career as leaders in multidisciplinary research, whereas the certificate aims at those who wish to be active participants in clinical research. We are also developing entirely on-line "certificate lite" programs for those wishing to learn more about clinical research, or increase their skills, but who do not have time or resources to pursue a classroom-based experience.

Lessons learned: As resources become more limited, educational programs must become more efficient and better meet learning needs in an individualized fashion with the appropriate content and delivery methods. Outcome- and competency-based approaches are well-suited to this task.

Mayo

Abstract 3: Accelerated Infrastructure Building for Rapid Drug Repurposing

Topic Area: Build on the Strengths of Individual CTSA's across the Spectrum of Clinical and Translational Research

PI: Jordan D. Miller, PhD (contact PI), Maurice Enriquez-Sarano, MD (co-PI), Hartzell V. Schaff, MD (co-PI)

The new UH2/UH3 mechanism for rapid drug repurposing combines the excitement of accelerated translation of basic science with challenges associated with building a substantial *de novo* support structure for clinical trials in a compressed period of time. Upon notification of the grant award, we paired the PI (a basic scientist) with our CTSA Research Operations Manager to ensure that there was a single point person for support and follow-up. After reviewing the grant and current laboratory staffing, we identified several key areas where the CTSA could lend support: 1) identification of qualified study coordinators for hire to assist with study recruitment and study scheduling, 2) identification of staff members with extensive experience in safety monitoring to serve on a DSMB, 3) referral of the investigator to key contact individuals in the research pharmacy, clinical research unit (CRU), and mobile CRU to develop drug dispensing protocols, logistics and support of study visits for tolerance testing, and sample acquisition logistics for efficacy testing in patients undergoing surgery, respectively. By providing individualized assistance to investigators, we were able to assemble a clinical study team to complement the basic scientific investigation during the early stages of this grant and establish procedures, protocols, and a safety oversight infrastructure within 3 months of receiving the grant award. In doing so, we were able to ensure that the CTSA/Institutional infrastructure for this UH2/UH3 grant was in place and that this infrastructure would not compromise milestones/timelines negotiated between the investigators and NIH. Collectively, we feel this study highlights the importance of quickly identifying unique studies that require substantial CTSA support and resources, as well as the effectiveness of providing individualized support to investigators involved with accelerated translational studies to ensure that key infrastructure and support pieces are not overlooked.

Medical College Wisconsin

Abstract 1: CTSI as a Common Platform for Multi-institutional Access

Challenge

The CTSI of Southeast Wisconsin is comprised of the Medical College of Wisconsin (MCW), four campus research partners, and three other major academic institutions. Consequently, clinical and translational research conducted here involves inter-institutional collaborations. A widely identified barrier to collaborative research is trans-institutional access; to systems (e.g. grant systems, IRB systems, etc.), information (e.g. medical records), research facilities (e.g. units, labs, etc.) and funds. Faculty and non-faculty scientists could not access the resources and support required to conduct research at institutions other than their own.

Rationale or Approach

Two pathways were created that enabled faculty and non-faculty scientists to access resources and support to conduct research: (1) CTSI adjunct faculty appointments and (2) CTSI scientist or senior scientist. Faculty status at MCW affords an individual privilege(s) to conduct research as a PI. Thus, adjunct faculty appointments grants faculty from other CTSI partner institutions access. CTSI scientist and senior scientist status was created for those individuals without a terminal degree who did not meet the eligibility criteria for faculty at MCW (i.e., nurses, engineers, etc.), but who CTSI determined can provide value in conducting research at MCW. Individuals in this category can only receive their appointment through CTSI.

Methods / Process

CTSI met with institutional leaders to discuss the need for non-MCW individuals to have access. Once CTSI gained buy-in from MCW leaders, a research resource manual was developed by the legal office to assist investigators and their staff conducting research at MCW and hospital partners. The manual recognizes the three statuses of individuals who are eligible to work as PIs.

Outcome(s)

Currently the CTSI has a total of 82 individuals that have gained access to systems, resources and support that was previously not available to them. Access to funding is also now available since adjunct faculty and CTSI scientists can respond to MCW RFAs as principal investigators. This group also qualifies to obtain a badge ID that allows them library and parking access, work space, as well as access to materials and core services.

Lessons Learned

To create a system that allows multi-institutional access all stakeholders need to play a major role in the decision making process and own the process. Once the process was in place communication and education was *a must* with people that own and controls the systems (IRB, Grants, Cores, etc.)

Medical College Wisconsin

Abstract 2: Towards Building a Bridge between CEnR and CER

Problem or Challenge

Approaching the intersections between Community Engagement in Research (CEnR) and Comparative Effectiveness Research (CER) is a national priority. A common aim is achieving meaningful engagement with stakeholders (patients or communities) but gaps in philosophies, approaches and competencies pose significant challenges. Transforming CER beyond successful recruitment or effective collection of patient input into a bi-directional, participatory research model warrants an exchange of assets and needs among CEnR/CER investigators.

Rationale or Approach

Neglecting to collaborate in expertise and skill when endeavoring patient-centered outcomes research, places risk for unintended negative consequences which would impact marginalized communities and the public's trust in clinical and translational research. The Bridge Building Day Workshop set a precedent for local CEnR/CER investigators to begin dialogue, establish a space for exploration of questions about discipline-specific attributes and needs, and catalyze transformative strategies.

Methods / Process

We convened CEnR/CER faculty, leadership who oversee translational research and community-academic partnership funding mechanisms, and staff to plan a workshop. We chose a case example approach with facilitation teams of CEnR/CER presenting a current research project, moderating dialogue, and identifying salient approaches to next step collaborations.

Outcome(s)

Participation included representation from 4 academic, 2 health, and 12 community serving institutions. Follow-up evaluations have identified several new collaborations and relationships. New activity includes CTSI members;

- in leadership roles of the CTSA SG4 Committee
- as reviewers for Patient Centered Outcomes Research Institute (PCORI) grants
- presenting nationally (invited) and at local PCORI consultation seminars
- as investigators on research proposals in response to new RFAs in CER
- attending CTSI-sponsored presentations and new proposal review committees

Lessons Learned

CTSI and the Community Engagement Key Function was a catalyst for groundbreaking dialogue to address national and local priorities in advancing translational research for CEnR-CER. We learned that overlap and distinctions exist between these two types of research and that there can be a process applied to making collaboration effective and beneficial. This workshop and subsequent activities that continue towards building a bridge have maintained dialogue and support for investigators as well as positively impacted research endeavors and new knowledge.

Medical College Wisconsin

Abstract 3: One City, One IRB

Challenge

Clinical and Translational Research by its nature is cross-disciplinary and frequently inter-institutional. Two widely identified barriers to conducting clinical and translational research are (1) siloed research infrastructure and (2) regulatory burden associated with conducting research.¹ These obstacles are often experienced by investigators through varied and conflicting policies, guidelines, and interpretations of research regulations across collaborating institutions. At the Medical College of Wisconsin, these obstacles were realized when conducting “Exception From Informed Consent” (EFIC)² ambulance-based interventions with patients who experienced out-of-hospital cardiac arrest, across the greater Milwaukee metro area which required access to patient records across six different hospital systems, 45 consent forms and approval by 16 different IRBs.

Rationale or Approach

In 2012 the Clinical and Translational Science Institute (CTSI) of Southeast Wisconsin began pursuing “One City, One IRB” - a metropolitan area-wide IRB Master Reliance Agreement with six, at times competing Southeast Wisconsin hospital systems, encompassing 31 affiliated hospitals. This meant a single IRB review for investigators pursuing research involving all 31 hospitals in the Milwaukee area.

Methods / Process

CTIS identified a problem and conducted a stakeholder analysis to better understand the context and groups involved. A collaborative approach was taken to analyze problems and possible downsides for everyone. While attending to the needs of investigators and safeguarding the institutions, CTSI created the necessary documentation and legal agreements to satisfy all parties involved.

Outcome(s)

The Medical College of Wisconsin executed a metropolitan area-wide IRB Master Reliance Agreement (dubbed “One City One IRB”) with six Southeast Wisconsin hospital systems encompassing 31 affiliated regional hospitals.

This agreement accelerates the pace of research. Evidence of the agreement’s success was demonstrated through the first study’s approval time which was reduced from 1.5 years to 6-7 months. All collaborating entities have access to and use a consent form that works for all 31 hospitals. This enables investigators to generate new ideas that can bring care delivery to larger environments with greater access to patient populations.

Lessons Learned

Ultimately, a collaborative process is key. CTSAs can be a catalyst for developing trust, improving relationships, and facilitating transparency due to the fact that they provide a neutral platform. These qualities help improve the web of systems and support for clinical and translational research.

¹ Heller, C. and Inmaculada de Melo-Martin. *Clinical and Translational Science Awards: Can They Increase the Efficiency and Speed of Clinical and Translational Research?* 2009. *Academic Medicine*: 84(4).

² Exception from informed consent applies because of life-threatening situation, intervention must be administered before consent is feasible and the research could not practically be carried out without the waiver of consent.

Medical Univ of South Carolina

Abstract 1: Tackling the Challenges of Entrepreneurialism at a Free-standing Academic Medical Center

CTSA Name: South Carolina Clinical & Translational Research (SCTR) Institute
PI: Kathleen T. Brady, MD, PhD

Problem: MUSC is a standalone academic medical center consisting of six colleges. While the university has robust relationships with private businesses, lacking the resources of a college of business and a law school presents challenges in the areas of: 1) catalyzing entrepreneurial activity; 2) developing comprehensive business plans; 3) resource faculty company formation; and 4) competitively marketing licensable intellectual property.

Approach: A 10-year strategic plan was launched with four main arms: 1) Interprofessional Development; 2) Technology & Innovation; 3) Globalization; and 4) Entrepreneurialism. SCTR leadership worked with the Entrepreneurialism Committee (EC) to develop a plan to create and sustain an entrepreneurial culture at MUSC with appropriate resources, infrastructure, education offerings, and to recruit an experience leader.

Methods: A multi-phased approach was taken to arrive at the structure and plan for the new Center for Innovation & Entrepreneurship (CIE) which resides within SCTR. Multiple listening sessions were conducted with faculty to fully understand company startup and licensing successes, what resources were lacking, and resources available throughout the region. Site visits were made to other universities with successful business and entrepreneurial models including Purdue, UAB and UNC's Carolina KickStart. Feedback was gathered from local retired Fortune 500 company senior executives as to the best approaches to establish the CIE, roles and responsibilities for efficient/effective operations, and an assessment of realistic timelines and expectations. The comprehensive plan was presented to the Board of Trustees for final approval. Once established, the founding director, a successful biotech entrepreneur, inventor and investor with real-world technology commercialization experience, was recruited. University policies concerning IP, start-up companies and COI were revised to encourage entrepreneurial endeavors.

Outcome: Within the first 9 months of operations, the CIE has doubled the number of IP disclosures on campus, tripled the number of technology related consults (215), assisted in 3 faculty startup companies, and is actively working to establish a Technology Accelerator Fund as a free-standing non-profit organization geared towards garnering SBIR/STTR extramural funds and new device prototyping.

Lessons Learned: Changing the culture to embrace an entrepreneurial spirit can be challenging. Faculty education and outreach concerning commercial potential of their discoveries, readily accessible consultation and revision of University policies to encourage entrepreneurial activities are critical elements.

Medical Univ of South Carolina

Abstract 2: **Integrated Learning and Programmatic Alignment for Multiple Institutional K12 Scholar Programs**

CTSA Name: South Carolina Clinical & Translational Research (SCTR) Institute
PI: Kathleen T. Brady, MD, PhD

Problem: Prior to MUSC receiving a CTSA grant, the institution held no institutional K12 awards. Building on success, our portfolio now includes 4 such awards with similar core programmatic expectations. As each award was managed in disparate departments, inefficiencies became evident, including: 1) inconsistent orientation to MUSC research environment/support 2) multiple approaches to Responsible Conduct of Research training (RCR); 3) multiple grant training forums; 4) lack of mentor training; 5) competing K12 Scholar research presentation forums; and 6) no catalyzing organization to promote interdisciplinary collaborations.

Approach: K12 PIs, Program Directors, and Program Managers established a Joint K12 Program and Curriculum Committee with the goal of discovering common programmatic elements that could be integrated and centrally administered.

Methods: The Joint K Committee systematically reviewed their program requirements to develop common core components that could be centrally delivered including: 1) common orientation program; 2) RCR training; 3) core clinical research training; 4) grant writing and budget development workshops; and 5) mock study sections. Next, joint program enhancements were implemented including: 1) annual mentor/mentee training retreat; 2) K-to-R Club for interdisciplinary networking; 3) coordinated research presentation to faculty mentors; 4) use of common instruments for needs assessment, scholar and mentor evaluation and 5) centralized navigation to CTSA resources for consultation in regulatory, research design, biostatistics, data capture, community engagement, and clinical research resources.

Outcome: The Joint K Program has resulted in consolidated RCR program delivery, increased faculty mentoring participation in grant training and mock study sections, Annual Mentor/Mentee Training Retreat, increased use of CTSA resources by K12 Scholars, unsiloed presentation of K12 research presentations, and establishment of a K-to-R Club.

Lessons Learned: Senior faculty participation in K12 activities is enhanced as requests are now coordinated across the previously disparate programs. Resources and evaluation instruments are more consistently applied/shared. Program management time has been reduced due to the development of central resources and coordinated planning sessions. The trainees' research presentations cross a number of disciplinary and therapeutic areas, so careful attention to the composition of the audience for each trainee presentation is critical to insure useful and appropriate feedback.

Medical Univ of South Carolina

Abstract 3: **Services, Pricing & Applications for Research Center (SPARC)** **Request: Streamlining the Research Process**

CTSA Name: South Carolina Clinical & Translational Research (SCTR) Institute
PI: Kathleen T. Brady, MD, PhD

Problem: With multiple and complex research resources provided, a system was needed to: 1) provide investigators with information and access to services; 2) track/invoice for services provided; 3) share /manage documents; 4) evaluate satisfaction with services and return on investment.

Approach: System functionality was conceptualized through collaboration between subject matter experts, graphic designers and informatics. Ease of use, training requirements, time saving (reduced duplicative entry) and value-added user and provider driven functionality were goals. An intuitive, fully integrated web-based system for requesting services and resources, obtaining pricing for budget development, sharing documents, tracking work fulfillment, audit trails, managing invoicing and payments, and evaluation survey tools was planned.

Methods: The software architecture is modular and flexible and leverages open source components that do not require additional licensing for redistribution. Add-value functionality such as pre-populated and pre-selected defaults and time saving quick click options create efficient processes, avoid entry duplication and non-added value steps. Billing functionality was built to replace the paper-based manual system, enhancing budget development, compliance and Medicare Coverage Analyze support.

Outcome: The system, released March 2012, included CTSA services and several other cores for piloting purposes. In January 2013, functionality to on-board other services and provide the code to other CTSA Institutions was released. An interface with Epic was developed to provide a process to set up studies and visit calendars in Epic. SPARC Request was offered to other CTSA Consortium Institutions in the spring of 2013. To date, 3 contracts have been signed. Pilot studies are planned to evaluate time and cost savings.

Lessons Learned: Maintaining engagement during development was difficult, with temptation to buy and install "off the shelf" systems which were not tailored to the needs of research facilities. Interfacing barriers with existing systems including difficulty obtaining necessary technical information. There was significant internal debate regarding licensing and uncompensated work required to support onboarding other sites locally and nationally. A REDCap-like license was adopted which is available at no charge to CTSA institutions but is not open-source. The issue of time dedicated to support the onboarding of other institutions remains under discussion.

Miami

Abstract 1: **Ensure Community Engagement in all Phases of Translational Research**

José Szapocznik, PI

Problem/Challenge: Investigators not versed in cultural competency, in general, and culturally-competent research, in particular, cannot effectively partner with minority communities in clinical and translational research.

Rationale/Approach: We must “*culturalize*” research and health care to fully embrace our diverse majority-minority population. To be fully effective in a community that is approximately 88% racial/ethnic minorities, the Miami CTSI adapts research methods, tools, and technologies to its cultural milieu.

Methods: Challenges faced in ethnically diverse regions dictate that to translate discoveries into effective practice, traditional approaches to conducting research need to be made culturally competent. While building personalized medicine, we must “*culturalize*” medicine and the discipline of clinical and translational research. We do this by:

1. Leveraging long-term community partnerships in planning, implementing, disseminating, and evaluating research.
2. *Culturalizing* CTSA services: Every CTSI program director has thought through what it means to “*culturalize*” science and service. A few examples follow.
 - a. Biostatistics – develop statistical models that can tease out effect of minority status on outcomes in a small sample size
 - b. PCIR – operate culturally-welcoming clinical research facilities in locations easily accessible to minority study participants, employ bi-lingual staff
 - c. Training and Mentorship – encourage minority investigators to apply for K12s, focus RFAs to areas related to minority health and community
 - d. Regulatory – help plan appropriate research protections in studies with vulnerable populations, *culturalize* the wording in consents
3. Effecting a fundamental shift among academicians in thinking of community and diversity as a means (e.g., recruitment) to an end (e.g., studies using majority minority community participants), to one of partnership in which each informs the other and contributes equally to improving community health, the *true* end.

Outcome: Our CTSI is advancing *culturalized* health sciences in word and in deed: institutional leaders now routinely use our newly coined term and investigators focus more and more on research that ultimately leads to health improvements in minority communities.

Lesson Learned: Fundamentally changing how we go about the business of research and transforming research infrastructure to sustain long-term participatory academic-community collaboration in research, education, and care can be accomplished using a combination of vision-directed service and participatory engagement.

Miami

Abstract 2: **Lessons Learned in Advancing Innovation in Education and Training**

José Szapocznik, PI

Problem/Challenge: Lack of career ladder and coordinated job descriptions, training, and hiring practices for clinical research personnel.

1. Decentralized clinical research positions functions without minimal job qualifications, training, and pay standards.
2. Mostly self-trained personnel are hired at different levels of proficiency and points of entry.
3. Lacking an organized career structure, we experience insurmountable difficulties in sustaining a top quality clinical research workforce.

Rationale/Approach: A major factor in sustaining scientific preeminence is the quality of clinical research personnel. Yet, while much attention is paid to building research capacity in faculty, we have no program to train and manage careers of this crucial workforce. In advancing the skill and professionalism of clinical research personnel, we advance scientific excellence.

Methods: Professionalizing the clinical research staff: Establishing a system to organize, train, and manage clinical research personnel are a primary strategy in our master plan. To clearly define eligibility requirements, job responsibilities, and career trajectories we are:

1. Organizing a Network of Clinical Research Professionals where personnel can interact and receive training and mentorship
2. Defining jobs categories and their primary responsibilities
3. Determining core competencies for each category
4. Making sure knowledge, expertise, practical know-how, and proficiencies match responsibilities
5. Mapping steps in career ladders that advance levels of:
 - a. Training, expertise, and skill
 - b. Responsibility and authority
 - c. Pay and benefits

Outcome: After a year of work, we have strong participation in the Network of Clinical Research Professionals, and have the endorsement of institutional leaders and investigators. We have constructed the career ladder framework, identified primary elements for job descriptions, and started teaching a curriculum of basic training that will be required for all clinical research personnel.

Lesson Learned: Building the capability to manage a major constituent of the clinical research infrastructure is a multifaceted process that requires careful orchestration of multiple organizational units, each with its own agenda, procedures, and timelines.

Michigan

Abstract 1: **Feasibility and Acceptability of Objectively Structured Clinical Examinations (Osces) For Assessment of Students' Research Competence in CTSA-Defined Domains.**

Shanley, T. University of Michigan.

Challenge: To develop high-quality competency assessments for use in MICHR education and mentoring programs.

Rationale/approach: Adapt some of the competency assessments developed and validated in health professions education for use in research education. OSCEs have been used extensively in health professions education and licensure examinations as one component of multi-source assessments to document student/graduate competence. OSCEs are performance-based assessments that require learners to integrate knowledge across domains and apply their knowledge and skills to a variety of situations and tasks encountered in “real world” practice. The purpose of this pilot study was to evaluate the feasibility and acceptability of an OSCE to assess progression toward competence of predoctoral students enrolled in three CTSA-sponsored summer research programs (clinical/translational, global and health disparities).

Methods: Within each summer program CTSA competencies were defined and five competencies common across the three programs were selected for inclusion in an end-program OSCE. OSCE scenarios required students to: 1) identify equitable research practices, 2) write clinical and translational research questions, 3) apply appropriate study design principles, 4) identify responsible conduct of research practices, and 5) obtain informed consent for participation in a research study from a standardized patient instructor. Student performance was rated on a 3-point descending scale: 3 – no errors, 2 - minor errors, 1 – critical errors.

Outcome: Twenty-three students (85%) completed the OSCE in two hours. Student performance varied within and across stations. In general, writing translational research questions appeared to be the most challenging task presented to the students in the OSCE and individual student performance appeared to be strongest on stations whose area related to the primary focus of the students' programs. This finding suggests that “in-program” learning was applied in responding to the situations and tasks presented in the OSCE scenarios. The OSCE was well accepted by students and feasible to administer in terms of time, cost, and personnel.

Lessons learned: OSCEs show promise for use in assessing the competence of scholars completing three CTSA educational programs. Studies to further validate the use of OSCEs for competency assessment in research education are ongoing.

Michigan

Abstract 2: Re-designing a subject recruitment tool (UMClinicalStudies.org) to promote enrollment in clinical research studies.

Shanley, T. University of Michigan.

Challenge: To develop a clinical research recruitment application to promote research participation and enhance communication between participants and research study teams.

Rationale/approach: UMClinicalStudies.org was developed in 2006 as a participant registry focused initially on women's health issues. The site expanded its research team focus and attracted over 10,000 registrants but did not reciprocally engage them. Communication between registrants and research teams was passive and inadequate to encourage and increase study enrollment.

Methods: UMClinicalStudies.org was completely re-designed using a human-centered interface. The new design reflected input from focus groups with potential participants from the U-M Health System and surrounding community as well as clinical researchers. Participants complete a brief personal profile, including current and past medical conditions (NLM SNO MED) and current medications (NLM RxTerms). Participants also indicate study types of interest to them and receive email recommendations on currently posted studies matching those interests. Participants can communicate their interest within the application to respective research teams using a new messaging feature. Conversely, research teams can screen individual profiles for eligibility and contact individuals meeting those criteria. Research teams may also receive recommended participants and contact them with the new messaging feature to inquire about their level of interest. The system is HIPAA-compliant and draws IRB approved studies from diverse disciplines and stakeholders across the clinical spectrum.

Outcome: The new application was released in late May 2013. There are currently 14,379 participants (14.6% increase since release); 293 active studies (128 posted since release); 13,018 instances of participants expressing interest in a study; and 11,165 messages exchanged between participants and research teams. A new 'mark as enrolled' feature activated by research teams at the time of enrollment serves as a new tracking mechanism, with 294 participants enrolled into an active study since release.

Lessons learned: The UMClinicalStudies.org re-design has shown early promise to engage potential participants and encourage their active communication with research teams, resulting in subsequent study enrollment. Collaboration between the MICHR Recruitment, information technology (IT), and Communication teams is ongoing to respond to user feedback, track metrics, and identify new system needs.

Minnesota

Abstract 1: **A Mentored Summer Research Program for Underrepresented Undergraduates: The University of MinnesotaCTSI and Center for Health Equity**

BLAZAR, BRUCE

University of Minnesota Clinical and Translational Science Institute

As outlined in the Advisory Committee to the Director Working Group on Diversity in the Biomedical Research Workforce June 2012 report, “achieving diversity in the biomedical research workforce is critical to the full realization of our national research goals and in the best interest of our country.” In line with the Working Group’s (DBRWG) findings, the UMN Undergraduate Research Program (URP) focuses on the first key transition point in the pipeline, entry into graduate degree programs.

CTSI runs a joint summer program with the Center for Health Equity (CHE – NIH P60 Center)) and provides funding for promising underrepresented undergraduate students, and those who aspire to become health professionals serving diverse urban or rural communities, for twelve-week mentored research projects. The goal is to inspire trainees to pursue doctoral degrees with an eye towards careers in academia. Trainees are introduced to careers and research experiences in CTS through weekly seminars, group discussion and activities, peer mentoring, a clinical research textbook, networking with senior faculty, and graduate students in the CTSI and CHE summer Advanced Research Program. As a capstone, trainees present a poster at the annual CTSI Research Conference with over 50 other CTSI scholars.

The program began in 2012 and just completed its second cohort in August. The 2012 cohort trained 10 scholars and the 2013 trained 11. Evaluation data from 2012 showed a statistically significant improvement in confidence in 7 out of 16 measures, and a high level of interest expressed in pursuing graduate degrees and conducting health disparities research. Scholars were most pleased with the seminar series, mentoring experience, research project, and group events. Mentors identified access to eager motivated students and support for the students both financially and through the structured training program as valuable program features. Analysis is being conducted on 2013 evaluation data.

Lessons learned: have shown this program is a valuable contribution to creating a diverse pool of students entering the CTS research pipeline. Adjustments thus far have focused on devoting program attention to individual scholars, increasing structured time for scholars to interact with each other, and tailoring seminars to an appropriate level.

Minnesota

Abstract 2: **Project Development Teams (PDTs) for Accelerating Therapeutics Discovery and Development**

Problem/challenge

- No single researcher possesses the regulatory, intellectual property, development, and commercialization expertise required to successfully translate research discoveries.
- Internal and external funding mechanisms often do not support the types of studies necessary to enable the development of new technologies.

Rationale/approach

- Establish a program to identify, accelerate and increase the number of scientific discoveries that are translated to products and services impacting human health.
- Provide project management expertise in therapeutics discovery and development.
- Develop individualized teams that expand beyond the scientific/technical aspects to development, commercial and operational areas.
- Partner with the university tech transfer office and develop relationships with community partners outside the University to bring necessary expertise to the team (e.g. industry experts, regulatory consultants, reimbursement professionals).

Outcomes

- Since initiation in early 2012, several projects have reached key translational milestones.
- The majority of investigators funded in the first year of the program have requested continuation of their PDT beyond the one-year funding period.
- This program has been recognized as a unique and effective approach that should be further developed and expanded (i.e. Medical School Strategic Plan).

Lessons learned

- Not all expertise required to effectively translate research discoveries can be found on campus. Effective engagement of the business and healthcare community is critical to the success these efforts.
- The need to educate investigators about the design and conduct of the appropriate studies and the commercialization processes that are required to transition a technology out of an academic lab should not be underestimated.

Mount Sinai

Abstract 1: **Design, Technology and Entrepreneurship (DTE): a new multidisciplinary training area.**

Geoffrey W. Smith, JD, Kevin Costa, PhD, & James Iatridis, PhD; Icahn School of Medicine at Mount Sinai, New York, NY

Problem/Challenge: Clinical and translational investigators do not have the technical expertise and practical experience to drive use-inspired basic research from original biologic insight through the commercial development process.

Rationale/Approach: DTE is a multi-disciplinary Ph.D. program involving advanced training in the discovery, design, development and delivery of technology-based solutions to critical biomedical problems. The goal of DTE is to foster the exploration and development of innovative technologies, models, techniques, designs and methods that have the potential to substantially advance biomedical research by infusing principles and concepts from the quantitative sciences to transform our understanding of biological, clinical, and translational science.

Methods: DTE students receive problem-based education in a combination of biomedical sciences, engineering design and entrepreneurship relevant to technology development. Many major biomedical research problems are best addressed using a multi-disciplinary approach, which bridges the life and physical sciences. Principles and techniques in quantitative sciences (e.g., physics, mathematics, chemistry, computer sciences, and engineering) are increasingly being applied to good effect in biomedical research. DTE will cut across traditional disciplines to provide each student with methods and tools for reliably producing creative solutions to nearly any biomedical problem. DTE's core curriculum is organized around six problem domains: basic principles of engineering, entrepreneurship and biology; medical devices and tissue engineering; diagnostics and imaging; biotechnology; pharmaceuticals; and information technology.

Outcomes: A specific example of a course being offered by DTE is the Q.E.D. Project -- a hands-on, team-based, technology development experience. Over the course of the academic year, student-led teams learn to define a specific problem, invent a technology-based solution to the problem, and build a prototype solution for it. These solutions are evaluated based on innovation, practicality, ease of use/adoption, economic impact and commercial potential. In the first offering of the course, 40 students combined to develop ten projects that were reviewed by a panel of VCs, entrepreneurs, engineers, and industry experts.

Lessons Learned: Graduate students are eager and willing to pursue translational research, and will be able to compete effectively for the best opportunities in academia, government, and industry.

Mount Sinai

Abstract 2: **Developing a Culture & Building Capacity for Clinical Translational Research in Pediatrics at Mount Sinai Leveraging Conduits.**

Rosalind J. Wright, MD MPH, Robert O. Wright, MD MPH, Philip J. Landrigan, MD, Hugh Sampson, MD, Bruce Gelb, MD, & Lisa Satlin, MD PhD.

Problem/Challenge: Identify key research priorities to advance pediatric research and identify gaps while leveraging existing infrastructure and strengths.

Rationale/Approach: Over the past 5 years, leadership involving the Department of Pediatrics, Mindich Child Health & Development Institute, and Department of Preventive Medicine in partnership with Conduits, Mount Sinai's Clinical & Translational Research Award (CTSA), has focused on enhancing capacity for pediatric clinical translational research.

Methods: This was accomplished through (1) establishing common goals to determine research priorities in child health; (2) recruitment of senior faculty to build research and mentoring capacity in priority areas; (3) developing efficient administrative research processes to enhance productivity (*Conduits Research Re-Engineering Project*); (4) building infrastructure to support cross-disciplinary collaborations with clinical and basic science departments and communities served by this urban medical center; (5) formalizing mentoring infrastructure for junior clinician scientists including establishing faculty advisory committees, establishing a Vice Chair for Research & Mentoring in pediatrics, establishing grant writing courses (*Conduits BERD & CEPPORTED*); and (6) solidifying bidirectional community engagement (*Conduits CCARP*).

Outcomes: Seminars targeting junior faculty on grant writing skills with initial focus on K awards. Establish a repository of funded and unfunded K awards in child health research. Develop and disseminate a Child Health Research Directory highlighting research faculty and potential mentors.

Development and submission of NIEHS Core Center (P30) "Transdisciplinary Center on Health Effects of Early Environmental Exposure" to build capacity for cross-departmental collaborations. Partnering with Conduits to expand pilot project funding that fosters collaborations between junior clinician scientists and senior mentors across at least two disciplines.

Submission of the New York State Empire Clinical Research Investigator Program (ECRIP) supporting training of physician scientists in child health research with anticipated matching Conduits funds.

Lessons Learned: Need for more up front preparation for trainees to enhance their ability to capitalize on the Conduits' Reach for your first K award' course. Need for career development programs that target mid-level faculty (i.e. Associate Professor) to increase probability of successful transitions from K to R awards. Need to increase infrastructure and core laboratory support in non-genomic biological sciences to add capacity in children's environmental health.

New Mexico

Abstract 1: **Regional Extension of CTSA Resources to Build Infrastructure for Clinical and Translational Research**

Richard Larson, MD, PhD
UNM CTSC

Problem/Challenge: How to effectively extend the reach of the UNM CTSA award to regional partner institutions that have little infrastructure for clinical and translational research

Rationale/Approach: To establish a network of institutions in western states without CTSA awards and provide training, expertise and the pilot grant support needed to develop new clinical and translational projects

Methods: An initial planning meeting was held in 2009, bringing together 20 administrators and scientists from each of the Western Institutional Development Award (IdeA) states (except Hawai'i, which joined later) and over 30 representatives from UNM. The primary outcome of the meeting was unanimous agreement to pursue formation of a consortium for the advancement of clinical and translational science in the Western IDeA states. An MOU was endorsed by officials from 11 institutions in 7 states agreeing to 1) Establish research infrastructure support mechanisms to share and leverage resources, 2) Develop pilot funding programs to stimulate collaboration between basic and clinical scientists and provide funding opportunities for junior faculty across the region, 3) Develop collaborations based on disease and clinical content areas with special consideration of unique populations in the region, 4) Develop websites, databases, and other collaborative tools to support the consortium.

Outcomes: UNM CTSC initiated and hosts an undergraduate summer immersion program in clinical and translational research, which has been attended by 90 students from all consortium states. UNM CTSC facilitated a pre-review system for NIH grant applications, inter-institutional pilot programs, and a collaborative mini-sabbatical program. To provide more support for these and other activities, all 11 consortium institutions contributed to an NIH U54 application to create a *Clinical and Translational Research Infrastructure Network*, which after two submissions will be funded in 2013.

Lesson learned: There is strong support from regional institutions to partner with our CTSA program and increase regional impact. Facilitating grant applications to support pilot costs and leverage resources is important to achieve the goal of developing new collaborative projects.

New Mexico

Abstract 2: Innovative Participant Recruitment Using an “Honest Contactor”

Richard Larson, MD, PhD
UNM CTSC

Problem/Challenge: Participant recruitment for clinical research remains a challenge that is complicated by HIPAA rules. Recruitment for using the Electronic Medical Record (EMR) is traditionally limited by the need to interact through a patient’s primary care provider or via a “Dear Patient” letter.

Rationale/Approach: The privacy statement signed by UNM patients states that “protected health information (PHI) may be used for research proposes.” With institutional authorities, we developed protections against coercion and misrepresentation, thereby allowing “cold calls” to potential participants. As a result, CTSC representatives may now call prospective participants to gauge their interest in participating in a clinical study.

Methods: The UNM CTSC Patient Recruitment Service (PRS) incorporates the following elements:

1. EMR search requests incorporating study inclusion and exclusion criteria are made using an online form. The resulting aggregated data may be used for feasibility testing, but PHI is not released to the investigator.
2. A check box on IRB applications acknowledges the intent to use the PRS.
3. After the study receives IRB approval, an EMR-derived list of potential participants is released to the CTSC Research Participant Advocate (RPA), who is trained on HIPAA, participant rights, and cultural sensitivity. A predetermined script for each study is reviewed by the patient literacy division at UNM Hospital. At initial contact, only general information about the study is provided. Patients requesting more information are subsequently contacted by a study coordinator within three days.
4. Patients who opt out from the contact list are added to a "do not call" list maintained by the RPA.
5. The UNM CTSC charges for this service in minimum increments of ten hours of work.

Outcome: Over the past year, the UNM PRS has proven very popular among investigators, with 1,302 potential participants contacted and 523 individuals agreeing to receive further contact.

Lessons Learned: The UNM CTSC has demonstrated that it is possible to query the EMR for the purposes of clinical research recruitment in a manner that is respectful of patient privacy rights and fully compliant with applicable laws.

New Mexico

Abstract 3: **Community Engagement in Translational Research**

Richard Larson, MD, PhD
UNM CTSC

Problem/Challenge: 1) Create a Community Engagement and Research Core (CERC) that enhances investigator capacity to conduct culturally appropriate clinical and translational research, 2) Strengthen research partnerships within UNM and among NM communities to build capability for addressing community health priorities through research, 3) Provide research expertise in the full spectrum of community engaged research.

Rationale/Approach:

- Form multidisciplinary leadership team from Medicine, Nursing, and Pharmacy in order to synergize team-science approach.
- Invite key UNM community stakeholders to cooperate with CTSC in translational research projects: HEROs (Health Extension Rural Offices), RIOS Net (practice-based research network), Project ECHO (remote education and disease management), NM Cares Health Disparities Center.
- Build CERC team of three CTSC research specialists to serve community engagement research needs.

Methods:

- Performed systematic review of all CTSC pilot funding requests for community-engaged research services and developed the following services for investigators: grant development, study coordination, survey administration and data management, subject recruitment, qualitative study data collection and analysis.
- Concentrated on submitting extramural grant proposals with partners.

Outcome: 1) Developed speaker series in community-engaged comparative effectiveness research, 2) Increased service hours provided by CERC from 600 to 1400 hours in one year, 3) Obtained funding for at least four extramural grant proposals: PCORI diabetes prevention in Native Americans; AHRQ-funded R24 study for dissemination of evidence-based information in rural areas; NIH-funded R21 Alcohol and substance abuse prevention in Native Americans; and American Cancer Society funded colon cancer screening decision aids in Hispanic.

Lessons Learned: The UNM CTSC developed a robust CERC by concentrating on the following key values: service, collaboration, integration, training, dissemination, and innovation. Strategic planning through an iterative evaluation of CTSC pilot grants helped to build needed services. Facilitating multi-disciplinary team formation to write grants has begun to expand CERC through successful extramural funding. Integration and coordination between internal community-oriented stakeholders led to expanding the research missions of each entity by building new research capacity in each of the following organizations: health extension agents (HERO program), practice-based research network (RIOS Net), and CTSC (evaluation core and CERC).

North Carolina

Abstract 1: **Improving the Grant Writing Experience for Junior Investigators: Two Strategies from the NC TraCS Institute**

Topic Area: Advance Innovation in Education and Training Programs

PI and Institution: Marschall Runge, PI, UNC Chapel Hill CTSA, North Carolina Translational and Clinical Sciences Institute (NC TraCS Institute)

Summary: A substantial investment has been made at the federal, foundation and institutional level to train the next generation of clinical and translational researchers. The leadership of the UNC Education, Training and Career Development (ETCD) Program recognizes the critical need to retain those we have trained in the clinical and translational research workforce. We have initiated two strategies to support retention of researchers in the workforce using a four phase development and evaluation model. The first phase is the identification of an innovative strategy, with the ultimate goal of disseminating effective strategies across the CTSA Consortium. The first strategy using this model, the R-Writing Group, is an intensive 9-month working group of 5-6 individuals who are preparing their first R-type award. As a result of the evaluation process, the program has evolved in the following ways: expansion of eligibility beyond K awardees to anyone preparing their first R-type proposal; separation of T1 and T2 groups; and addition of a junior faculty member to co-lead the program. A total of 37 individuals have completed participation: 16 funded as principal investigator, 5 funded but not as principal investigator, 9 submitted pending, 3 submitted not funded, and 4 who did not submit. The second strategy is the Mock Review Program which formalizes the process of pre-submission review for a grant proposal or resubmission. The ETCD Program identifies and contacts suitable reviewers and convenes an NIH-style study section panel to present the reviews. The diversity of science at UNC has directed our search for reviewers to other CTSA institutions. To date, we have conducted 6 cross-CTSA reviews. Applicants note that the enthusiastic involvement of researchers from other institutions emphasizes the “team approach” to career development available through the CTSA Consortium which significantly enhances their scientific network and increases their motivation to remain in research. This in turn has created further linkages across CTSA as reviewers have often subsequently served as mentors or collaborators on future projects. However, prior to broader translation and dissemination to the CTSA Consortium, we must develop protocols to protect confidentiality and information security.

North Carolina

Abstract 2: **Streamlining Oversight for Multisite Research: Lessons Learned in Moving from Innovative Concept to Real World Implementation**

Topic Area: Build on the Strengths of Individual CTSA's across the Spectrum of Clinical and Translational Research

PI and Institution: Marschall Runge, PI, UNC Chapel Hill CTSA, North Carolina Translational and Clinical Sciences Institute (NC TraCS Institute)

Summary: Oversight of multicenter clinical trials is complicated by the traditional approach of redundant review of the identical protocol by multiple local IRBs. There have been calls for streamlining this process, and academic institutions are increasingly relying on central IRBs for these scenarios. However, the "sole provider" model employed by most centers has its own drawbacks, and there are few data to guide their decisions. Our institution recently conducted a novel pilot study to compare local versus central IRB review, assessing both the efficiency and quality of the review processes through a randomized, controlled study design. The aim of the pilot was to assess the feasibility and acceptability of reliance on any central/independent IRB already involved with a multicenter trial, provided certain criteria were met. The pilot demonstrated that the quality of external review was good, and that use of a central IRB resulted in a potential time savings of 20 plus days per trial, provided that standing service agreements were already in place. There were 8 central IRBs utilized for the 22 protocols randomized to the external ("experimental") arm, reinforcing our hypothesis that reliance on a single IRB misses many opportunities to streamline. Multiple groups across campus are now establishing the systems and policies needed to adopt this as a permanent approach moving ahead. While this approach is conceptually appealing and supported by data, implementation is not without its challenges, and there are many lessons to be learned. Chief among them is recognition of the multitude of institutional reviews and control mechanisms that must still be addressed and coordinated, even if IRB review is outsourced. These include conflicts of interest, data security, HIPAA, radiation safety, institutional biosafety, investigational drug services, and clinical trial agreements with sponsors. These obligations are generally not transferred to the central IRB, and may necessitate a continuing role for the local IRB at many institutions.

Northwestern

Abstract 1: **Process Improvement: A Lean/Six Sigma Solution to Building a Research Cost Recovery Model for the Clinical Research Unit at Northwestern University**

Topic Area: Build on the Strengths of Individual CTSA across the Spectrum of Clinical and Translational Research

Northwestern University Clinical and Translational Sciences (NUCATS) Institute

PI: Donald M. Lloyd-Jones, MD ScM

The transition from the old General Clinical Research Center (GCRC) model to the more recent Clinical Research Unit (CRU) model has been difficult for many CTSA and investigators. In order to meet CTSA cost recovery expectations, Northwestern University (NU) needed to develop and implement a process to bill federally-funded studies for Clinical Research Unit (CRU) services.

These services were previously provided at no cost to investigators.

Challenges included:

1. Identifying a methodology to support the process improvement project;
2. Initiating the first cross-institutional process improvement project between NU and its major clinical affiliate, Northwestern Memorial Hospital (NMH);
3. Addressing organizational change management;
4. Bridging investigators from the old model to the new one and maintaining their engagement and participation in the CRU.

Lean/Six Sigma (DMAIC) methodology was chosen to support the project since it was widely and successfully used by NMH leadership. NMH provided training, a process engineer and an accountability structure comprised of senior leadership from both organizations to oversee and advance the progress of the project.

Implemented in 2010, the cost recovery project was a success, generating approximately \$500,000 annually, which has resulted in a sustainable financial model, a wider range of services offered, and actually expanded the usage of the CRU by investigators. This required careful work with investigators as they transitioned to the new financial model. Benefits of the project included improved processes for research billing compliance, resulting in zero billing compliance errors since its implementation. In addition, the CRU overhead cost model was restructured, resulting in an improved business model.

Lessons learned from the project are:

1. The value of process mapping, comparing the “Think it is”, “Should be” and “Actually is” state;
2. The importance of effective communication with all stakeholders; and
3. The value of building effective teams across departments and institutions.

This process improvement in a critical area of CTSA capabilities has proven to be a good model for other CTSA as well. We have shared the methodology, progress and lessons learned from the cost recovery process improvement project at the CTSA Clinical Research Management meetings.

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Northwestern

Abstract 2: Training the Clinical and Translational Research Work Force of Tomorrow

Topic Area: Advance Innovation in Education and Training Programs

Northwestern University Clinical and Translational Sciences (NUCATS) Institute

PI: Donald M. Lloyd-Jones, MD ScM

In 2008, the clinical and translational research workforce lacked qualified, uniformly trained research support staff with clear pathways for career development. A survey conducted at that time by the Consortium of Clinical Research Programs identified only 40 programs globally that offered some form of clinical research training. None of these programs was accredited, and many were not high-quality, standards-based educational programs.

In response to this need, the NUCATS Institute developed and implemented a Master of Science in Clinical Research and Regulatory Administration. The part-time program was the first of its kind offered by a CTSA nationally. It was designed to enable clinical research professionals to develop a complex knowledge base and skill set across areas from clinical trials management and implementation to compliance and regulatory affairs. The program curriculum was expanded in 2010 and renamed the Master of Science in Regulatory Compliance, which now allows students to specialize in quality systems, clinical research, and healthcare compliance. The course curriculum is based on competencies developed by the CTSA Education KFC.

The Masters programs admitted 115 students in the first three years (80 women, 35 men). The students comprise a diverse group including 17% African Americans, 11% Asian/Pacific Islanders and 2% Hispanic/Latinos. Participants also have diverse professional backgrounds and include nurses, pharmacists, orthotics/prosthetics professionals, research coordinators, research trial specialists, and project managers. Among current students, 35% have selected the quality systems, 47% clinical research, and 18% healthcare compliance tracks.

The program qualifies and prepares students to sit for industry professional certifications such as the Six Sigma Green Belt Exam or the Society of Clinical Research Associates (SoCRA) certification exam. Our alumni network and career development services provide career pathways for graduates. Thirty-seven students have completed the MS degrees as of Summer 2013. Fifty percent are currently employed in academic centers, 30% with pharmaceutical, medical device or clinical research organizations, and 20% with other employers.

The MSRC Program is successfully meeting one of the primary goals of the CTSA: to increase the skills of the clinical and translational research workforce and provide them with career pathways to retain them in industry and academia.

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NYU

Abstract 1: **CEPHR Consultation Service: an offering to community engaged and population health researchers**

**New York University School of Medicine
Clinical and Translational Science Institute**

CTSA PI: Bruce N. Cronstein, MD
CTSA PI: Judith S. Hochman, MD
Program Director: Marc Gourevitch, MD
Program Director: Mariano Rey, MD

Challenge: The Community Engagement and Population Health Research (CEPHR) core of the NYU-HHC CTSI identified two distinct challenges in 2009: 1) the importance of communityengaged research (CEnR) and population health-focused research (PHR) was unrecognized by many investigators; and 2) there was no formal mechanism for researchers to secure expert consultation in these methods and approaches. To address these challenges, we established the CEPHR Consultation Service (CCS).

Approach: The CCS provides guidance on methods/approaches in community-oriented and population health research to investigators across the translational spectrum. The goals of the CCS are three-fold: 1) to facilitate and support CEnR and PHR; 2) to support NYU and HHC (Health and Hospitals Corporation) researchers in securing extramural funding for CEnR and PHR; and 3) to advance knowledge aimed at improving community and population health.

Methods: Investigators seeking consultation submit a brief abstract of their proposed research. The CEPHR Program Manager facilitates an initial meeting with a potential consultant, assesses the scope of work and determines optimal fit between consultant and researcher. Consultants earn a credit that may be used for activities related to their research. Consultations may be subsidized by the NYU-HHC CTSI or supported directly by the investigator, depending on available resources.

Outcome: Faculty from across the translational spectrum have benefitted from CCS consultations, with examples including: guidance in developing a Community Advisory Board; methodological consultation in cost effectiveness; creation of quality of life measures, and many more. From 2009 to 2013, CEPHR made consultations available to investigators. Several faculty who received consults were subsequently successful in securing competitive extramural funding and others received CTSI Pilot awards, demonstrating the continuous nature of CTSI services. Additionally, CEPHR consults were provided to several extramurally funded projects.

Lessons Learned: Feedback reported by participants suggests that the CCS initiative has increased our research community's capacity to develop new areas of research, employ new methodologies, and improve methods and analytic strategies. Challenges have included fostering recognition of the existence of the service across NYU and HHC and managing the expectations of investigators regarding deliverables from the consultant. The CEPHR Consultation Service has succeeded in providing concrete results in facilitating and strengthening collaborations in CEnR and PHR.

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Abstract 2: **INTREPID: An intensive clinical research methodologies education program for senior housestaff and faculty**

**New York University School of Medicine
Clinical and Translational Science Institute**

CTSA PI: Bruce N. Cronstein, MD

CTSA PI: Judith S. Hochman, MD

Program Director: Michael Pillinger, MD

Challenge: Early-stage academic physicians, including trainees, often plan clinical research projects without formal training in relevant methodologies. Reliance on experiential learning may lead to less-than-optimal study design, recruitment, and implementation, and limit chances for project funding. Competing professional responsibilities limit the time that trainees and faculty have available for participation in extended full-time training programs. We hypothesized that a structured, short-term, program could address the need for rapid, early acquisition of core translational research skills and improve the probability of successfully conducting research.

Approach: We developed INTREPID (**IN**tensive **T**raining in **R**esearch **S**tatistics, **E**thics, and **P**rotocol **I**nformatics and **D**esign), a 24-day, full-time intensive program to provide training in clinical research methodologies to early investigators.

Method: Participants attend four integrated courses covering research methods, ethics, biostatistics, and bioinformatics with programming. Participants must secure 100% protected time from their departments for the duration of the program. Seminar-style teaching and didactic presentations are complemented by laboratory (“PASS” and “R” programming) and informal discussion sessions with “real-life” researchers. Assignments include readings (textbooks & online) protocol development, critiques of high-impact journal articles, problem sets, quizzes and exams, programming code to query databases, and oral presentations. Successful participants receive an NYU/NY State-approved *Certificate of Completion*, and 9 credit-hours applicable to the NYU CTSI MS in Clinical Investigation (Translational Medicine track).

Outcome: The inaugural class included 6 participants, four of whom were from NYUSoM academic divisions, one from the Health and Hospitals Corporation, and one from an international hospital. All participants had previously completed an MD or PhD degree; one additionally held an MPH. Academic rank ranged from fellow to assistant professor. Upon completion, trainees demonstrated the ability to write code in “R”, write a research protocol incorporating a research question and hypothesis, and critique peer-reviewed high-impact factor papers. All participants were surveyed and stated they would recommend the courses to their colleagues. We are planning to perform a follow-up survey six months post-completion.

Lesson Learned: An intensive program to build translational research skills for medical researchers across academic disciplines is feasible. INTREPID required a significant commitment of time and resources for participants and faculty. We plan to offer the INTREPID program annually.



Abstract 3: **CTSI Research Germination Program: A plan to accelerate the progress of translational research.**

**New York University School of Medicine
Clinical and Translational Science Institute**

CTSA PI: Bruce N. Cronstein, MD
CTSA PI: Judith S. Hochman, MD
Program Director: Mario Delmar, MD

Challenge: One critical obstacle for investigators is to expand a research question to the point at which it is structured as a project with potential for extramural funding. Since the goal of the CTSI is to incubate and accelerate outstanding translational science, we implemented two interventions: a “Pilot Project Program” (PPP) and a “Research Studio.”

Approach: The Pilot Project Program (PPP) supports one-year collaborative studies to develop pilot data; applications are invited once a year and evaluated by a panel of ad-hoc reviewers chosen from within our institution. Applications are judged on the scientific excellence, potential for future impact and, importantly, whether the project represents a collaborative effort and emphasizes a culture of team science. Departments are requested to support the initiative by contributing matching funds.

Method: One critical aspect of the program’s success is rigorous and ongoing monitoring of progress. We check-in with award recipients at inception and 4 times during the award period, either in the form of a presentation to leadership or progress report via REDCap. By requiring recipients to note progress on concrete milestones investigators are able to discuss progress and challenges, receive feedback from CTSI Leadership on overcoming obstacles, and facilitate collaborative relationships for the future.

Approach and Methods: Research Studios arise from the recognition that preliminary review of a proposal improves quality and potential impact. All investigators within the CTSI have the opportunity to request the formation of a panel of experts within our Institution that serve as a “study section.” The application is circulated to the panel to review in advance and the studio then consists of a 2-hour session during which the applicant describes the application and engages in a discussion as to how to improve the research plan.

Outcome: Key outcomes include extramural funding, peer reviewed publications and ultimately impact of the research. To date, the CTSI has funded 55 Pilot Projects of which 36 were T1/T2 and 19 were T3/T4. Additionally, the CTSI has funded 21 “Targeted Area” Pilot Projects for biorepositories and drug development, among others. This program has had a high impact leading to several dozen competitive, peer reviewed, extramural grants and dozens of original peer-reviewed publications, all of which acknowledge the support of the CTSI. In addition, these Research Studios have improved the quality of grants submitted, dramatically leading to a 50% success rate for investigators who have had a Studio.

Lessons Learned: In conclusion, CTSI intervention during the critical concept-to-conduct period has proven highly effective at increasing the number, quality and impact of collaborative translational studies. These results demonstrate the importance of institutional support frameworks in developing successful multi-disciplinary research teams to accelerate the progress of translational research.

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Ohio State

Abstract 1: **Enhancing Translation: Inspiring Entrepreneurship**

The Ohio State University Center for Clinical and Translational Science, Fisher College of Business and Comprehensive Equity at Ohio State/Advance

Over the past decade, there has been increasing evidence of an entrepreneurial gender gap. Not only are women more risk adverse, they also have smaller networks and choose areas of research less amenable to commercialization leading to less opportunity to learn about and pursue commercialization efforts. In response to these challenges, the OSU CCTS collaborated with the NSF -funded Comprehensive Equity at Ohio State (CEOS) program and the College of Business to develop programs and resources to introduce women faculty across the spectrum of translational science disciplines to the fundamental knowledge and skills needed to traverse the numerous pathways to entrepreneurship. Three approaches were utilized: a series of workshops on innovation, a campus cohort approach and a national conference. Major recurring themes for the programs included innovation, learning the landscape, team building and funding. To facilitate the participants' success in taking theory to practice, in addition to keynote addresses and panels, the programs provided access to self-assessment tools to evaluate readiness for engagement, exercises to enhance team building and leadership skills, small group activities that provided feedback on venture capital presentations and expert review of individual proposals to enable entrepreneurial efforts. Pre- and post-testing demonstrated that all 3 approaches were equally effective at increasing knowledge and confidence with engaging in the commercialization process. In contrast, the cohort approaches were most effective at providing sustainable networks. Longitudinal follow up demonstrated that attendees had greater entrepreneurial success as measured by invention disclosures and metrics of engagement in commercialization-associated activities.

Lessons learned include

- (1) the need for concerted ongoing support across the career as even faculty with previous commercialization experience felt that the programs provided them with needed knowledge and skills
- (2) Personalized feedback helped to initiate engagement more effectively
- (3) Entrepreneurial skills should be introduced in graduate training and reinforced throughout the career
- (4) There is a need for a readily accessible curriculum (distance-based) with dynamic components providing tools and resources. There is also a need to explore whether these programs perform as effectively for men and whether mixed gender cohorts have different outcomes.

Ohio State

Abstract 2: **Developing Resources that Build Upon and Extend Institutional Strengths:**

Collaboration with the OSU Comprehensive Cancer Center

One major center at The Ohio State University serves as a critical internal partner in creating the exceptional translational research environment at OSU. The OSU Comprehensive Cancer Center (OSUCCC) is one of 41 NCI designated Comprehensive Cancer Centers in the U.S. and one of only five institutions to hold both NCI Phase I (U01) and Phase II (N01) funding mechanisms for early phase cancer clinical trial development. With a collective vision of One University, the CCC and the Center for Clinical and Translational Science (CCTS) jointly build upon our expertise and scientific infrastructure to balance innovation with the OSU land grant mission to enhance Health and Wellness through ground-breaking research, knowledge dissemination, and community engagement. Over the past 5 years, there have been multiple areas of synergy between the CCC and CCTS, particularly in core integration (drug development shared resources such as medicinal chemistry and pharmacoanalytics, establishment of new translational technology cores such as laser capture microdissection and comparative animal models cores), shared informatics and biostatistics resources and initiatives, and collaboration with the cancer control program on the Appalachian Translational Research Network (ATRN). Benefits to collaborative integration include reduced duplication, improved efficiency, lower costs, and disease agnostic access to facilities and expertise for translational science investigators. Challenges to successful integration included different tracking and reporting mechanisms, prioritization schema, business models, and metrics of success.

Lessons learned include identify a common ground and implement approaches that are chosen because they ultimately better serve investigators. Examples of outcomes that reflect these tenets include: (1) migrating to a single ordering and billing system through adoption of the cancer center eRAMP; (2) planning for potential joint adoption of the CCTS- developed research project management system (CoRR); (3) organization of a single translational core oversight committee in partnership with the College of Medicine; (4) shared communications to investigators on core expertise and availability; and (5) development of a joint CCC-CCTS established training program on core management operations directed at core managers.

Oregon

Abstract 1: **Launching a biomedical device discovery program**

Oregon Clinical and Translational Research Institute
Oregon Health & Science University
PI: Eric Orwoll

Problem/challenge

To accelerate the delivery of healthcare technology from academia it is important to encourage bioengineering innovation, support commercialization and generate new revenue. In many AMCs this capacity is not well established. We postulated that an AMC represented a rich and untapped source of new ideas, particularly in the absence of an established device development process.

Methods

The Biomedical Innovation Program was designed to identify creative bioengineering solutions for important health care problems, to support the translation of an idea to proof of concept stage, and thus to enable the transfer of technology from the academic institution to a commercial entity and ultimately to positively affect human health. Concepts for novel, high impact biomedical devices were solicited widely from University faculty and staff. Using criteria of scientific excellence, feasibility, clinical impact, patentability and marketability, 5 projects were selected by a group of medical investigators, engineers and members of the biotech community. Each project was provided modest funding (\$10-40,000) with the expectation that proof of concept, early clinical validation of device effectiveness and second round funding (licensing, venture capital, biotech partnership, etc) would be achieved in 2-3 yrs. Substantial project management, engineering and tech transfer support is supported centrally. In the first year, three projects have yielded discussion with medical device companies for possible licensing or research funding and one of these has filed a provisional patent.

Key lessons learned

- For new biomedical device/diagnostics discovery there is a role for early stage concept creation at an AMC, which can be built upon by second round, outside investment.
- Partnerships with community engineers and biotech businesses contribute essential expertise as projects are being developed.
- The potential for economic development strongly motivates support from regional government and business organizations, including shared project financial support.
- Depending on the stage and type of the device, a small amount of funding can go a long way toward pushing an idea to prototype stage.

Oregon

Abstract 2: **Challenges in creating an AMC – HMO partnership**

Oregon Clinical and Translational Research Institute

Oregon Health & Science University

PI: Eric Orwoll

With CTSA support, the Oregon Clinical and Translational Research Institute (OCTRI) was founded in 2006 as a partnership between OHSU and the Kaiser Permanente Center for Health Research (CHR). The driving vision was the potential for stimulating a vigorous collaboration between an institution steeped in T1-T2 research (OHSU) and one with particular strengths in T3-T4 (CHR). There was real interest in the partnership from both sides and extensive effort and resources were devoted to developing the relationship, but major challenges prevented realization of the opportunity. Growth in joint publications and funding proposals was limited. After 5 years, and in the face of major CTSA funding reductions for grant cycle 2, the decision was reluctantly made to considerably reduce budgetary support for the partnership.

Unanticipated roadblocks included:

- Difficulty in stimulating new inter-institutional collaborations. Investigators were busy maintaining established research programs. The expectation that different kinds of research expertise would be complimentary and compelling was not realized.
- A difference in institutional compliance culture, methods and patient privacy expectations that required intensive efforts and an unflinching dedication to an efficient interface in order to overcome IRB and regulatory barriers.
- Institutional budget and resourcing models that were quite different, creating particular difficulty in developing the preliminary data needed to support new, collaborative research directions.
- Barriers to shared career development programs that arose because of limited indirect rates for K and T awards. The budget model of KP does not support training grants or mentorship because of the MDC low rate. This prohibited K or T scholars of using KP mentors or data resources for their research.

Individual research collaborations between OHSU and CHR faculty remain active, and partnership support from the CTSA grant continues in an area that has been quite productive – the development of the KP Northwest Biobank, which takes advantage of the collection and storage of specimens from the Kaiser patient population, and excellent clinical annotation from the EHR.

In retrospect, the barriers to collaboration, the time and resources necessary to overcome them, and the extent of interest in collaborative research were underestimated when the partnership was founded.

Abstract 3: **Development and Evaluation of a Process Model to Promote CBPR Partnerships with Rural Communities**

Oregon Health & Science University (OHSU)
Oregon Clinical and Translational Research Institute (OCTRI)

PI: Eric Orwoll, MD

Objective:

CTSAs have been challenged to speed the translation of research into practice and community settings. Most CTSAs are located in urban settings, and rural populations are often excluded from research initiatives due to lack of access, personal relationships, and perceived relevance. The Oregon Rural Practice-based Research Network (ORPRN) at OHSU implemented and evaluated a process to enable research partnerships with rural communities and address health disparities.

Methods:

The Community Research Enhancement & Education Development (CREED) project engaged four established county-wide health coalitions in rural Oregon and utilized childhood obesity, a community identified health concern, as a platform to provide research training, execute a community-based participatory research (CBPR) pilot study, and facilitate academic/community research partnerships. We used a mixed methods assessment including surveys, participant feedback, and observations to develop and evaluate the CREED project.

Outcomes:

Over an eight month period, community coalition members attended a symposium and translational research tour at OHSU, participated in eight research training modules, and worked in partnership with academicians to develop, implement, and analyze their CBPR study. Community members completed the pre-assessment survey and post-assessments. Participants demonstrated increased knowledge in research methods and increased trust in academicians. Members showed a significant increase in their confidence in participating in the research process including formulating a research question, defining study aims, gaining IRB approval, and collecting study data ($p < .005$). Each of the four coalitions completed pilot projects on local childhood obesity issues, and the data are being used to improve local programs and shape policy.

Lessons Learned:

CREED is a model CTSAs can use to engage existing community health coalitions in community/academic research partnerships by providing basic research training and conducting pilot studies. Establishing and sustaining trusting research relationships is time consuming and resource intensive. Our CREED model demonstrated that community participatory research is incremental and often does not have immediately identifiable outcomes. Without adequate support and commitment to an ongoing relationship, research with academic partners will fall off the radar of local community groups.

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Penn Hershey

Abstract 1: **EAB Directed CTSA Improvement**

PI: Lawrence I. Sinoway

University: Penn State University

All CTSA's are charged with demonstrating that the grant in fact advances clinical and translational research. We suggest that effective utilization of the CTSA External Advisory Board (EAB) is an important tool for raising the level of science.

The Penn State EAB was formed with input of our key function leaders. Our board includes a: 1) Vice President of Health Affairs; 2) College of Nursing Dean; 3) CTSA Director; 4) Clinical Research Educator; and 5) an expert in informatics and biostatistics. Our EAB has twice met at Hershey and provided reports. The April 2012 report highlighted our need for a CTSA strategic plan to determine areas of strength and uniqueness. Other concerns included website usability, the lack of an EMR cohort discovery tool, and a need to develop funding contingencies if the National CTSA program were eliminated.

Seven months later (November 2012) at our second EAB meeting, we presented the results of our strategic planning process. This plan emphasized the study of exercise, behavior and nutrition. This theme aligned University strength and community need. The EAB supported this disease agnostic direction but wondered if the future IOM report would endorse themes. The EAB urged accelerated development of cohort query capacity as well as new alliances with other CTSA's.

Since the 11/12 meeting, we held a thematic workshop for interested faculty. An RFA on this theme was released, new teams were created and 5 multi-investigator thematic projects were funded 6 weeks later. We have developed i2b2 for cohort discovery, have held seminar series on its use, and 100 investigators are registered to use it. Finally, we have met with another CTSA and a Memorandum of Understanding will soon be signed.

Based on our experience, we suggest that establishing an effective EAB and responding to their concerns in an aggressive fashion improves the quality of translational research within a given University. Methodology to measure the quality of the EAB input and associated responses should be considered.

Penn Hershey

Abstract 2: **Cross-campus face-to-face symposium to launch interdisciplinary pilot studies**

PI: Lawrence I. Sinoway

University: Penn State University

Creating a culture of novel interdisciplinary and translational research to improve health is a key goal of NIH's CTSA program. The principal tool to forge new collaborations has been a robust CTSA-supported pilot studies program. At Penn State, the medical school, the major laboratory for health research is separated from the university's considerably larger main campus by ~100 miles. Limited interpersonal connections and insight into unique areas of research expertise across the two campuses hinder collaboration. Furthermore, the ability of program leadership to directly identify and support potentially fruitful collaborative endeavors is subject to bias. To engage a critical mass of investigators, to exploit serendipity generated when researchers with disparate expertise and without prior knowledge of each other's work exchange ideas, and encouraged by the internal and external advisory boards, we developed an RFA for pilot studies around a broad theme (Behavior, Exercise and Nutrition Influences in Health and Disease). A one-day face-to-face symposium was held at Penn State University's main campus. Clinicians and faculty from multiple colleges with expertise in health research, engineering, informatics and others were invited and attendants assigned at random to discussion groups of 8-10 individuals. Following a brief presentation of the RFA, each group was asked, considering the theme, to define: 1) gaps in knowledge; 2) pertinent institutional strengths; 3) potential new scientific teams to address these gaps. CTSA-supported research tools (REDCap, I2B2, etc.) were also showcased. Symposium attendance was required by at least one investigator of each proposal. 102 Faculty (37 clinicians, 65 non-clinicians) attended the symposium, 24 letters of intent and 21 proposals by new teams of investigators were submitted and reviewed within one month, and 5 awards were made. All proposals represented teams of investigators who had not collaborated previously.

We learned the following lessons:

- 1) Despite widespread availability of videoconferencing, face-to-face conferences of potential collaborators generate enthusiasm, overcome barriers and spark new interdisciplinary research projects
- 2) RFA release in the context of a face-to-face brainstorming session engages investigators and helps articulate a broadly defined research theme;
- 3) Turnaround time (from proposal to award) previously thought unrealistic are achievable.

Pittsburgh

Abstract 1: **Pediatric Pittnet: A Practice-Partnered Research Network to Support Child Health Research**

University of Pittsburgh (Steven E. Reis, MD)

Challenge. To support child health research and dissemination of research findings through a practice-partnered research network.

Approach. Pediatric PittNet was created by partnerships among child health researchers and academic and private pediatricians. Goals are to: 1) educate children, parents, and pediatricians about research; 2) recruit study participants; 3) conduct studies in practices; 4) disseminate findings and health information; 5) investigate parental perceptions about research.

Methods. PittNet links 181 pediatricians and nurse practitioners in 35 primary care pediatric offices who serve >200,000 patients across six western Pennsylvania counties. PittNet research nurses based in practices recruit, screen and enroll participants, conduct protocols, and educate pediatricians and children/parents about studies. Clinical registrars recruit children/parents for the CTSI Research Participant Registry, which matches children with study inclusion/exclusion criteria based on ICD9 codes and demographics in their EHR and regularly sends information about these selected studies to parents. Methods to disseminate research opportunities and health information include videos, printed material, advertisements, and outreach by research nurses. Surveys are conducted to inform the pediatric research process.

Outcomes. Since 2007, PittNet has enrolled nearly 3,000 children in 120 pediatric and child mental health studies performed by 78 investigators. The CTSI registry enrolled nearly 4,000 children in the last four months. Investigators visit PittNet practices to present protocols, summarize findings, and network with pediatricians. Surveys identifying effective methods for communicating health information to parents and factors associated with study participation were performed.

Lessons Learned. A centralized approach that is respectful of clinical priorities and practice preferences and coordinates investigator access to practices effectively engages pediatricians and their patients in the research process. On-site research nurses facilitate participant recruitment and conduct protocols. Several methods are required to promote studies to children/parents and to address parental perceptions about research. A research registry that enrolls children at office registration and matches them with studies based on EHR data provides education about health issues and opportunities for study participation.

Pittsburgh

Abstract 2: **Center for Assistance in Research Using Erecord (CARE): Research Access to an Extensive Electronic Health Record**

University of Pittsburgh (Steven E. Reis, MD)

Challenge. To develop an institutional mechanism for comprehensive, regulatory-compliant access to electronic health record (EHR) data for research purposes.

Approach. EHR data have an important role in T1 through T4 research. Historically, Pitt scientists have had limited access to clinical EHR data from 20 hospitals and >400 practices of the University of Pittsburgh Medical Center. “Work arounds” to acquire data depended on researchers’ access to and funding of technical analysts. CTSI created the Center for Assistance in Research Using eRecord (CARE) to provide EHR data access to all researchers and the technical and regulatory expertise needed for EHR data extraction.

Methods. CARE provides a “knowledge engineer,” regulatory facilitators, project manager, and programmers to assist in hypothesis development/study design, compliance with IRB/privacy regulations, project planning, and secure data extractions, respectively. UPMC implemented a policy requiring all research involving EHR data be routed through CARE.

Outcomes. CARE has provided services to 786 studies including data extraction from multiple EHR sources, programming for PCORI projects, merging clinical and genomics data, and creation of alerts/decision-making tools in the EHR. Regulatory issues were addressed in 67% vs. 28% of studies during CARE’s first year vs. last eight months. Investigators requesting data for hypothesis development and study feasibility were not charged for CARE services. Externally funded studies requiring sophisticated data extracts were charged an average of \$9,202 for programming services (range \$120-\$65,726).

Lessons Learned. 1) Investigators assume that their clinical roles provide them with unfettered access to EHR data for research. Implementation of an institutional policy requiring the use of CARE necessitated development of an educational initiative. 2) EHR systems are constantly evolving. UPMC is investing >\$100 million to develop an enterprise data warehouse (EDW) to aggregate clinical, financial, and claims data across its extensive payer-provider health system. CARE is playing an integral role in the creation of an institutional research data repository within the EDW that will link and store research, clinical and financial data and provide a robust suite of research analytics tools within the secure EDW environment.

Pittsburgh

Abstract 3: Improving Minority Health through Partnerships with the Lay Press and Urban League of Greater Pittsburgh

University of Pittsburgh (Steven E. Reis, MD)

Challenge: Minorities face numerous health disparities, are underrepresented in research, and lack information about research opportunities. Increasing participation of communities of color in studies is critical to designing culturally-relevant research and translating findings to practice.

Approach: Pitt CTSI's Community Engagement Core (CEC) and the Urban League of Greater Pittsburgh (ULGP) partnered with The New Pittsburgh Courier, one of the nation's oldest and most prestigious Black newspapers (circulation≈10,000), to disseminate information about health disparities, research findings, and opportunities to participate in research studies through monthly newspaper and online segments.

Methods: Topics of interest to the African American community were identified by ULGP and Courier staff (e.g., HIV/AIDS, asthma, teen dating violence, adolescent mental health, infant mortality). CTSI identified researchers focusing on identified topics and trained them to create lay descriptions of their research. An interview with the ULGP Executive Director, who codirects the CEC, appeared with each segment to highlight key points and encourage readers to participate in research.

Outcomes: Full-page print segments highlight a health disparity and emphasize relevant research. Online versions on the Courier website had >75,000 hits. Many readers enrolled in promoted research studies. This sustainable and reputable partnership is entering its third year and, for the next five years, will be co-sponsored by the Center for Inclusion of the University of Pittsburgh Medical Center.

Lessons Learned: Creating partnerships with newspapers that reach specific communities of color is a sustainable model for promoting information about disparities, research dissemination and participant recruitment. Investigators are generally not trained on how to translate their research findings directly to the community. The opportunity to create health segments for the lay press increased investigators' enthusiasm for community outreach and research dissemination, and provided a new method to recruit study participants. Investigators are encouraged to use this approach to developing substantive community partnerships to translate their research.

Rochester

Abstract 1: **Building Community Interests into the Research Strategic Plan**

Submitted by the University of Rochester Clinical and Translational Science Institute

PI: Karl Kieburtz

As communities seek to “ensure community engagement across all phases of translational research,” CTSA’s must incorporate community needs into research priorities. This is critical to ensuring community support and diversity in research participants. In the Rochester community, multiple agencies and coalitions work together to improve health. However, only the academic medical center has the research capacity to test and disseminate new approaches to improve the health of the community and to develop national models. Therefore, it is important to harness the unique assets of the University of Rochester Medical Center in pursuit of community health goals.

We have defined research priorities through a multi-faceted approach that includes: analysis of local health data, including the support of a comprehensive community survey; partnership with the local health department’s community health planning process; integration of all hospitals into a collaborative addressing the ACA-required Community Health Needs Assessment and Community Health Improvement Plan; and through recommendations of the CTSI-supported Community Advisory Council.

These methods have resulted in a consistent focus on two areas of concern to the community: improving physical activity/nutrition and mental health. In response, the CTSI and the URMC are defining ways to develop research priorities that address these critical concerns. Prevention, including policy and behavioral interventions to support physical activity and nutrition, is now a key part of the URMC’s research strategic plan. The CTSI, using multiple interventions to support community engagement in research, will turn its attention to supporting these areas of research as well. The most important lesson learned is that institutional strategic plans need to reflect the interests and concerns of the communities they serve to build viable research, education and patient care strategies.

Rochester

Abstract 2: **Researcher Resilience through Multidimensional Mentoring**

Submitted by the University of Rochester Clinical and Translational Science Institute

PI: Karl Kiebertz

This project addresses common barriers to academic career success among women, underrepresented racial/ethnic minorities and people with disabilities: lack of quality mentorship, a sense of isolation and a 'hostile' environment. The goal is to investigate, by means of a randomized trial, two different mentoring interventions for graduate students, fellows and junior faculty in biomedical fields. The hypothesis is that mentoring interventions based on self-determination theory and peer mentoring practices will promote resilience of underrepresented minorities in biomedical researcher careers, resulting in greater career satisfaction, confidence and academic success.

Working with 12 academic institutions in Upstate New York, including members of the UNYTE Translational Research Network, investigators recruited 154 mentor-protégé dyads. Dyads were randomized to one of four groups: 1) mentor education based on self-determination theory; 2) peer mentoring groups; 3) both mentor education and peer mentoring; or 4) usual practice (control). The primary endpoints for this funding period across all four study groups will be comparisons of: 1) pre- and post-tests of trainees' psychological needs assessment using a standardized test adapted for the workplace; 2) productivity (thesis completion, publications, grants submitted); and 3) career trajectories. Participants were surveyed to gather data regarding perspectives on mentoring interventions and other aspects of the program. Mentoring interventions and data collection for the first 2 outcomes are complete and analysis is in progress.

Lessons learned:

- 1) Many underrepresented individuals in biomedical disciplines of academia lack mentors.
- 2) To reach minority populations, a broad recruitment strategy is important. Although initial plans involved only 3 academic medical centers, in order to reach enrollment targets, 9 additional institutions were invited to participate. Total enrollment slightly exceeded the original goal.
- 3) Mentoring educational interventions based on self-determination theory can be provided to a multidisciplinary group of mentors with protégés at various levels.
- 4) Findings may inform best practices for recruitment and retention of women and underrepresented groups, which in turn may reduce health disparities and speed the implementation of new clinical research findings in underserved communities.
- 5) Findings can be rapidly disseminated and adapted within the schools that have worked together for this grant.

Rockefeller

Abstract 1: **Bridging the T1-T4 Divide: The Rockefeller University-Clinical Directors Network Community Acquired MRSA Partnership**

Rhonda G. Kost¹, Andrea Leinberger-Jabari¹, Amanda Tsang², Chamanara Khalida², Nancy Jenks⁴, Shirish Balachandra³, Tracie Urban³, Claude Parola³, Brianna D'Orazio², Matthew Zeppieri⁵, Rhonda Burgess⁶, Mina Pastagia¹, Teresa Evering¹, Maria Pardos de la Gandara¹, Cameron Coffran¹, Herminia de Lencastre¹, Alexander Tomasz¹, Barry S. Collier¹, Jonathan N. Tobin^{1,2}

¹The Rockefeller University, New York, NY; ²Clinical Directors Network (CDN), New York, NY; ³Urban Health Plan, Bronx, NY; ⁴Hudson River Health Care, Peekskill, NY; ⁵Open Door Family Medical Center, Ossining, NY; ⁶Manhattan Physicians Group-125th Street Practice

Challenge: Community-Acquired Methicillin-Resistant Staphylococcus Aureus (CA-MRSA) is an infectious disease that has spread outside of the hospital/ healthcare facility setting to emerge as an important clinical and public health issue. Since CA-MRSA is of concern to community patients and their health care providers, but little is known about its precise mechanism of spread, we sought to catalyze collaborations between Rockefeller investigators studying the molecular epidemiology of MRSA (T1/T2) and community members and practitioners concerned with the health effects of CA-MRSA (T3/T4).

Approach: We created a series of MRSA-related opportunities for Rockefeller scientists, community engagement professionals, community-based clinical researchers, and Community Health Center (CHC) clinicians designed to align their efforts.

Methods: The Rockefeller University Center for Clinical and Translational Science (CCTS) and Clinical Directors Network (CDN), a Practice-based Research Network (PBRN), have convened project meetings, training workshops, and collaborative protocol development exercises for lab scientists, epidemiologists, infectious disease specialists, and community clinicians. Protocols were developed by CCTS, CDN and CHC clinicians to treat and assess patients in NYC CHCs presenting with skin and soft tissue infections (SSTIs), and to study the molecular signature and mechanism(s) of drug resistance of CA-MRSA.

Outcome: This project has:

- 1) optimized the standard of clinical care of patients with CA-MRSA
- 2) recruited, enrolled and followed 144 patients with CA-MRSA SSTIs
- 3) collected demographic, clinical history, physical exam, photographic, and quality of life data
- 4) developed methods for wound and nasal specimen collection and transport to clinical and research labs
- 5) conducted standard microbiologic culture/antibiotic sensitivity testing and whole genome DNA analysis
- 6) expanded the infrastructure to three additional PBRNs
- 7) educated barbers and beauticians to refer customers with suspicious SSTI lesions for care
- 8) Created a rich network of key stakeholders and a platform for new projects.

Lessons Learned: We were able to align community research interests and mechanistic basic science interests through the joint development of a partnership network and infrastructure. We now plan to expand the collaboration to a comparative effectiveness research (CER)/patient centered outcomes research (PCOR) study to prevent recurrence of CA-MRSA infection, a shared high priority for patients, clinicians, and researchers.

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Rockefeller

Abstract 2: A CTSA-wide Computational Biostatistics Resource to Identify Targets for Repurposed Drugs from GWAS Data in dbGaP

Knut M. Wittkowski and Benedetta Bigio (Introduced by Barry Collier). Rockefeller University Center for Clinical and Translational Science, New York, NY

Problem/Challenge: Almost a decade after the completion of the Human Genome Project, the scientific and medical advances hoped for from genome-wide association studies (GWAS) have not yet been realized. After early successes with diseases where a single haplotype confers all or most risk, the same statistical approaches have often produced ambiguous results when applied to complex diseases.

Rationale/Approach: Most statistical approaches to GWAS are based on p-values computed from individual SNPs. Isolated SNPs contributing independently to common diseases, however, would be selected against during evolution. Hence, statistical methods assessing the epistatic risk conferred by neighboring SNP are more likely to yield insights into the genetic risk factors of common diseases.

Methods: With the advent of massively parallel computing u-statistics for structured data can now be applied to structures representing linkage disequilibrium between neighboring SNPs. We developed the statistical methods to take advantage of this structural information and a computational infrastructure to take advantage of under-utilized computational resources across CTSA.

Outcome: In collaborations between Rockefeller, Mount Sinai, NYU, and Yale, we identified genetic risk factors for, psoriasis, epilepsy, and autism. Consistent with previous knowledge about disease etiology, genes along the same pathways were identified in epilepsies and autism, but not in psoriasis. For epilepsy, the results from a single study in only 185 subjects confirmed the aggregated results from several previous studies. A novel element suggested in the etiology of psoriasis is currently awaiting confirmation in laboratory studies. The results in autism consolidated previous findings suggesting an involvement of Ras/calcium signaling, and suggested a phase II trial to test a class of repurposed drugs not previously considered in autism.

Lessons Learned: The CTSA system provides a unique environment for utilizing computational resources and conducting collaborative trials towards fulfilling the 10-year old promise of genomic research to yield novel treatment strategies for common diseases. The major obstacles now are to expand the scope of the collaborating CTSA institutions to provide the computational resources and collaborative teaching efforts needed for finding the missing heritability and translating advances in genotyping and computational biostatistics into more successful treatment of common diseases.

Rockefeller

Abstract 3: An Electronic Graduate Training Survey System to Track CTSA Trainees' Careers

Michelle Romanick, George Lee, Kwan Ng, Barry S. Collier. Rockefeller University Center for Clinical and Translational Science, New York, NY

Problem/Challenge: CTSA educational programs are crucial components of the CTSA program. It is essential to track the careers and accomplishments of the graduates of these programs to assess the impact of these programs and to improve them. The major obstacle to systematic graduate tracking is the lack of a comprehensive and standardized data-gathering tool to aggregate data within and across institutions.

Rationale/Approach: We envisioned a comprehensive electronic questionnaire and database to assess whether trainees go on to improve human health and to document related surrogate indicators of career development.

Methods: The Graduate Tracking System Survey (GTSS) is a web-based questionnaire created by the Rockefeller CTSA with input from CTSA training program directors using open source technologies and advanced data security measures that pre-populates the graduate's information on publications, clinical trials, grants, and patents by downloading information in standardized formats from public databases. Graduates need only confirm that the information from the public databases is correct instead of entering the data manually. This simplifies completion for graduates and insures a uniform format that facilitates data aggregation. The questionnaire is divided into an *Initial Survey* and an *Annual Survey* to facilitate completion and minimize redundancy. The GTSS has a flexible design that allows it to be easily adapted for use with multiple training programs in a single center, as well as by multiple centers. In addition, questions can be added to the core questions by each site administrator. A manual for administrators provides detailed step-by-step instructions and the Rockefeller CTSA provides individualized training for new sites. A number of report formats are available.

Outcome: We have deployed the system to our KL2 Clinical Scholars and have analyzed 51 surveys. 16 CTSA's have adopted the GTSS. In a survey of 9 administrators from other CTSA's, 89% indicated that they would recommend the GTSS to other institutions.

Lesson Learned: With broad input from CTSA training program directors, we have created a standardized, pre-populated, web-based GTSS that can aggregate standardized data on CTSA training program graduates for reporting to NIH and the public and provide benchmarks for assessing the success, and improving, CTSA training programs.

Scripps

Abstract 1: **Bringing Whole Genome Sequencing and Omics to an Uninitiated Medical/Science Community**

The Scripps Research Institute CTSA: PI Eric Topol

The Scripps CTSA has built upon one of its core strengths in high-throughput sequencing and analysis to impact translational research from early stage research to clinical applications in man. Our initial challenge was to make high-throughput sequencing technology accessible to a diverse group of investigators, who are mostly focused on basic research, while capitalizing on the translational potential of whole genome sequencing. To do so, we have made available biomaterial and analytical resources which encourage and ease the use of this technology. First, we established the Wellderly cohort, over 1,500 individuals who are >80 years of age and have not developed any significant chronic illnesses or required any routine prescription medications. 1,000 of these individuals are undergoing whole genome sequencing to serve as both a whole genome reference control panel across the CTSA Consortium and as a resource for our efforts to understand the genomics of healthspan. This resource has encouraged investigators to utilize different omic technologies, including metabolomics and proteomics, in an attempt to identify potential molecular sources of longevity, and has encouraged the use of targeted sequencing studies in order to identify and characterize the genetic cause of various diseases. We have internally utilized this resource as a reference panel for various sequence-based studies, including its use as a control panel for the successful molecular genetic diagnosis of individuals with idiopathic disease. Moreover, we've begun to adapt the analytical tools built for idiopathic disease studies to aid investigators utilizing genome sequencing in other capacities. These applications include sequencing of pathogen genomes, antibody libraries, and even to establish the fidelity of man-made nucleotides. This has all lead to the use of high-throughput sequencing technologies in a wide range of research applications, and a heightened interest in the use of high-throughput sequencing for the characterization of the genetic determinants of disease and/or drug response across Scripps. These data intensive applications have been intimidating to most investigators, however, we've learned that the development and proof-of-principal application of analytical tools and close collaboration with those most interested in their use has encourages uptake of these complex technologies across a broad range of translation research.

Scripps

Abstract 2: **Supporting a Clinical Trial in Digital Medicine with Multiple Mobile Sensors**

The Scripps Research Institute: PI Eric Topol

Problem/Challenge: Our challenge is to determine if a multiple remote wireless monitoring interventions can reduce health service utilization and thus health care costs for the small number of patients who spend the greatest number of health care dollars (ie “hotspotters”). Until now there had been no randomized trials of mobile (smartphone) medical devices to test the ability of reducing health resource utilization and costs

Rationale/Approach: The Scripps Wired for Health study is focused on chronically ill individuals with diabetes, hypertension, and cardiac arrhythmias. Participants are equipped with state-of-the-field health devices, including the iBGStar (an iPhone enabled capillary blood glucose meter), the Withings Blood Pressure Monitor (an iPhone enabled blood pressure monitor), and the AliveCor (iPhone enabled ECG monitor). This project utilizes the concept of ‘hot-spotting’ in that we target individuals with the highest health care utilization rates based on reimbursement data from a large third party health administrator. This study is a collaboration between the Scripps Translational Science Institute, Scripps Wellness, Qualcomm, Healthy Circles, Accenture, Sanofi, AliveCor, Withings and Health Comp (third-party administrator for Scripps Health).

Methods: Using a prospective randomized controlled design. We have started recruiting a total of 200 participants who will participate (100 controls, 100 intervention) from among Scripps Health employees and dependents. Individuals in the intervention group are provided with an i-Phone and the wireless sensor device(s) most appropriate for monitoring their particular medical diagnosis. Participants use the devices for a period of six months. Health service utilization rates will be obtained and compared for the 6 months during which the wireless monitoring intervention occurred and the 6 months after the intervention is completed.

Lessons Learned: Getting this trial off the ground with so many institutions and industry partners was a herculean task. But now, for the first time, we have a dashboard platform of multi-sensors displayed on a single smartphone screen and in a position to test an important yet uncharted clinical question.

Stanford

Abstract 1: **IOM Recommendation: Advance Innovation Training in Education Programs**

Stanford Biodesign (Paul Yock, MD; Gordon Saul)

Spectrum—the Stanford Center for Clinical and Translational Research and Education

Problem/Challenge

Identify an approach to teaching that targets building skills in innovation and inventorship.

Rationale/Approach

We sought to develop a systematic educational approach to needs finding and the invention of new biomedical technologies. This approach uses multidisciplinary teams of trainees to increase the numbers of investigators capable of inventing novel medical devices and efficiently transforming these inventions into products. We took advantage of our local culture of innovation and technology transfer and leveraged expertise in neighboring Silicon Valley.

Solution/Methods

The Biodesign Program is an effective teaching methodology based on the concept of critical needs identification and rational selection of “high yield” innovation targets. This includes a oneyear fellowship training program, graduate and undergraduate classes, and training materials (textbook and video curriculum). A key element of the program is the Biodesign Fellowship, which affords MDs, engineers and MBAs a mentored team training launch pad for career development. Biodesign also established global programs in India and Singapore to enable emerging innovators to invent affordable technologies and export the training process to their home countries.

Outcome

The Biodesign program now has an established track record for developing young entrepreneurs and new companies that successfully address unmet medical needs. The program has spawned 28 start-ups and graduated 85 U.S. and 31 global (primarily India and Singapore) graduate fellows who have assumed leadership roles in academia and industry.

Key Lessons Learned

Establishing and sustaining a program like Stanford Biodesign requires a solid methodology that can be replicated in other interested institutions. We have disseminated our process of innovation training through a textbook, web-based materials, and consultations, and have created alliances with partner institutions across the U.S. and globe. Recent serious challenges are the radically changing start-up environment for medical devices in the U.S. and the relative absence of a start-up culture in India. Concern about cost escalation due to adoption of new technologies has created negative pressure on early-stage funding, significantly reducing the number of venture-backed start-up companies. In response, we incorporated explicit training in the basics of health care economics so that innovators can design and test new technologies with an emphasis on cost effectiveness.

9/13/2013

Stanford

Abstract 2: **IOM Recommendation: Strengthen Clinical and Translational Research Relevant to Child Health**

Spectrum Child Health (David Stevenson, MD; Christy Sandborg, MD)

Spectrum – the Stanford Center for Clinical and Translational Research and Education

Problem/Challenge

Integration of an excellent but somewhat “stand alone” Child Health Research Program into a broader pan-University Clinical and Translational Research (CTR) effort.

Rationale/Approach

We sought to ensure that child health investigators receive the optimal support to conduct their CTR studies, leveraging the substantial resources and expertise available across the university. Child Health support needed to be better integrated into CTSA-funded CTR support to minimize duplication of effort, yet be tailored to meet the specific needs of the child health community.

Solution/Methods

We developed effective programs focused on pediatric-specific support services and education within the larger CTSA program, including pilot funding programs, protocol development advice, research coordinator pool, budget development, mentoring and career development, and clinical lab services. Spectrum leveraged CTSA support to develop, help launch, and garner ongoing resources for new programs in neonatal device development, prematurity, mitochondrial disease, diabetes, and food allergies.

Outcome

Several supported child health focused research centers have progressed substantially in their respective areas:

- Neonatal Device Development Program: developed a neonatal isothermal warmer, an inexpensive neonatal hearing screening device, and a portable, point-of-care newborn jaundice screening device
- March of Dimes Prematurity Research Center: established collaborations with investigators at seven universities with CTSA
- Stanford Mitochondrial Disease Program brings together physicians, scientists and counselors to better serve the needs of mitochondrial disease patients and their families, with 134 patient visits among our five ongoing clinical studies.
- Stanford Alliance for Food Allergy Research program has applied translational research in clinical trials in 349 children and adults using the CTSA funded CTRU.

Key Lessons Learned

A key to the success was to include child health oriented CTR investigators in leadership positions in Spectrum: three of the five Spectrum directors/co-directors have major research interests in child health. Other important factors include partnership with a well-funded children’s hospital, important relationships with philanthropy, a growing faculty committed to child health research, and novel programs assisting junior faculty with CTR. Ongoing issues include continued pressure from Children’s health related leadership to demonstrate “independence” from the overall institution for a variety of reasons, including fundraising.

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Stanford

Abstract 3: IOM Recommendation: Build on the Strengths of Individual CTSA's across the Spectrum of Clinical and Translational Research

Spectrum Bioethics Program (David Magnus, PhD; Mildred Cho, PhD)
Spectrum – the Stanford Center for Clinical and Translational Research and Education

Problem/Challenge: Identify and resolve bioethical issues relevant to clinical and translational research (CTR) at Stanford and to export lessons learned.

Rationale/Approach: CTR investigators are most effective if they determine, early on, when to request consultations related to unresolved ethical issues in their CTR. Furthermore, it is important that novel approaches to new ethical issues arising during CTR be disseminated for broader discussion and refinement.

Solution/Methods: We developed a taxonomy for ethics consultations and the triggers to initiate such consultations. To assist investigators, specific questions were incorporated into an online clinical study registration tool. Certain answers result in an alert recommending an ethics consultation and an online scheduling option. So that other institutions might evaluate this approach, the taxonomy and triggers were published in *Science Translational Medicine*.ⁱ

To improve dissemination of informative case studies, we have worked collaboratively with other CTSA Ethics groups to develop common tools for consultation documentation and data collection, including generalizable guidance documents and educational materials, much of which we incorporated in Stanford's Responsible Conduct of Research (RCR) courses. The CTSA Ethics consortium has built a database of hundreds of cases for ethics consultants and also selects cases for quarterly publication in the *American Journal of Bioethics*.

Outcome: Ethics consultations have increased as a result of implementing the trigger questions in Spectrum's study registration tool. Furthermore, inclusion of case discussions in our RCR course has resulted in higher levels of trainee satisfaction. Our model of providing ethics consultations has been adopted at other CTSA sites, including standard data collection and sharing practices, policies, and tools. Our group helped lead efforts to establish national and international consultation practices. Stanford's consultation efforts have also helped identify emerging and important ethical issues faced by our investigators, producing generalizable knowledge on novel ethical issues.ⁱⁱ

Key Lessons Learned: Assisting investigators to identify CTR ethical issues at an early study design stage is difficultⁱⁱⁱ. We have attempted to mitigate this through intervention in RCR courses and a study registration system, and hope to address this further through educational opportunities and awareness campaigns. We also learned that routine consultations are a good source for identifying emerging ethical issues for scholarly research.

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Tufts

Abstract 1: **Quality Improvement: Can the requirement for resident QI be leveraged for good?**

PI Name: Harry P. Selker

Institution: Tufts Clinical and Translational Science Institute (CTSI)

Problem/Challenge: Tufts CTSI provides an array of services, including assistance with research design and analysis, quality improvement practices in research, and comparative effectiveness research. While our mission is to provide assistance to all levels of researchers, increasingly we have received requests from inexperienced medical residents, who must respond to a new residency requirement to complete a quality improvement practice study and yet, these trainees often have little or no prior research training. This has affected significantly the length of time and effort CTSI staff has had to spend assisting these residents. Consultations have become de facto (and not effective) research educational courses.

Rationale/Approach: We hypothesized that if we could strengthen the quality of resident training in the basics of research, our consultative assistance would be able to then focus on providing specific, more advanced advice to trainees for improving the study design and analysis, and quality improvement and comparative effectiveness research methods in their proposed studies.

Methods: To address the research education gap of trainees we needed to implement stronger research education within our affiliated medical partners' residency training, augmented by Tufts CTSI seminars and workshops in these areas. In order to accomplish this we have: (1) collaborated with medical education leadership at affiliated hospitals on the inclusion of such training within their educational programs; (2) conducted free on-site introductory seminars for residents regarding study design and analysis and quality improvement; (3) on the Tufts CTSI website, established an interactive learning ILEARN site to offer videotaped introductory research seminars; and (4) adopted a requirement that trainee requests must identify a mentor/experienced researcher for the study.

Outcome: This year we will be evaluating the effect of these changes on assistance requests from medical residents and on trainee research proposals and protocols. We will conduct surveys with trainees and CTSI faculty and staff who respond to requests, measuring improved trainee efficacy and capacity for developing research, and decreased time devoted to educating trainees on introductory research principles, practices, and methods.

Lesson Learned: Medical trainees need to have basic research skills before receiving more advanced expertise for improving their study proposals and protocols.

Tufts

Abstract 2: Quality Improvement in Research: Not Just for Medical Practice

PI Name: Harry P. Selker

Institution: Tufts Clinical and Translational Science Institute (CTSI)

Problem/Challenge: Tufts CTSI provides an array of services, including assistance in using quality improvement (QI) methods that have been used effectively in improving medical care, to increase medical *research* efficiency, effectiveness, and resolution of barriers to research goals. Tufts CTSI has taken on as part of its mission the development of ways to apply QI methods to research. This includes assisting research teams in understanding the basic QI tools and methods that can be effectively incorporated into new research protocols and ongoing studies. Without systematic processes for measuring and improving research study processes, problems remain unaddressed, studies' quality is compromised, milestones delayed, and goals not met.

Rationale/Approach: We hypothesized that if we could build researcher knowledge of QI methods and tools for improving research efficiency and measuring research process success, researchers could prevent inefficiency and address problems early on when they are less disruptive to the research process.

Methods: To address the gap in researchers' knowledge of QI methods, we developed a series of Tufts CTSI seminars in the fundamentals of QI and its application to common research problems. Examples of using QI methods to address barriers to patient recruitment, study protocol issues, and challenges in coordinating clinical research services illustrate QI tools such as cause and effect diagrams, flow charting, and run charts displaying study performance measures. The free videotaped seminars are available through our interactive, online learning website ILEARN at the Tufts CTSI website. Researchers seeking QI consultations are directed to the in person seminars to supplement their independent learning.

Outcome: This year we will be evaluating the effect of these resources on researchers' abilities to organize multidisciplinary research improvement teams for clinical trials in our clinical and translational research center, with the expectation that such practices and resources would then be applied to clinical trials within our nine other affiliated hospitals. Measures will include usual parameters of study processes and outcomes and a system to assess relationship coordination between research team members.

Lesson Learned: Knowledge of QI methods and the application to research processes represent an important opportunity to increase research process efficiency and effectiveness.

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U of Pennsylvania

Abstract 1: **Financial Challenges**

PI: Garret A. FitzGerald, MD, FRS

Problem/Challenge

Large, multi-institutional grants pose many challenges. Financial challenges are one of the greatest challenges confronting CTSA's. There are many different financial challenges such as aligning expectation with funding amount, obtaining additional financial support for the mission of the CTSA from internal and external sources and managing finances across multiple institutions. This abstract will focus on re-engineering, or a gentrification, of the old GCRC model in the new CTSA world.

Rationale/Approach

It was clear, with the award of the CTSA, that a new approach to managing clinical research would require a complete overhaul of the management of the Penn and CHOP GCRCs. These units would now be forced to manage resources and think in a much different manner. The CTSA afforded the opportunity for this timely change. The financial environment was changing, both with expanded expectations driven by the award and publicity of the CTSA and overall, decreased inpatient utilization of the unit.

Methods

The leadership team developed new methodologies to address ways in which the unit could support clinical research studies that were typically free of charge under the previous model. A reasonable cost sharing methodology was developed providing tiered support for various federally funded studies, full support for junior faculty, and full cost allocation for industry studies. Since we had to begin charging for services, the charges were offset with additional support for the investigator such as a navigator to assist with all aspects of conducting clinical research on the unit. Additionally, we conducted surveys to determine the services investigators were most interested in utilizing and how prepared they were to pay for them. A scattersite service was launched to assist investigators with critically ill patients who had enrolled in research studies but were not appropriate to be admitted to our Clinical and Translational Research Center (CTRC).

Outcome

Asking investigators to cost share service that was historically free caused some angst. The unit is now well positioned to support clinical research studies in the new environment. We demonstrate for each study how much support they are actually receiving from the CTRC.

Lesson Learned

It takes time, perseverance, and many mistakes to implement this new model. You have to be able to convince the institution to continue investment in these programs and demonstrate to everyone that they are receiving something for their contributions to this endeavor. This is not always an easy task.

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U of Pennsylvania

Abstract 2: Training the Next Generation of Translational Scientists: A Cost-Sharing Model

Emma A Meagher, MD
PI: Garret Fitzgerald, MD
University of Pennsylvania

Problem/Challenge

The Master of Science in Translational Research (MTR) at the University of Pennsylvania's Perelman School of Medicine began in 2004 with a mission to produce a workforce of translational scientists who are competitive in seeking research support and are knowledgeable about the complex issues associated with conducting sound translational research. To successfully complete the program, (coursework, execute a research project, write and defend a thesis) it was recognized that trainees needed protected research time and the degree program had to be cost neutral for the trainee. The challenge presented was 2-fold: (i) at the time of inception the program was challenged to identify sufficient funding to support protected time and cover tuition costs for all suitably qualified applicants and (ii) the program did not have a mechanism for supporting clinical fellows or postdoctoral trainees and was reluctant to place such junior research trainees on a K funding mechanism.

Rationale/Approach

Beginning in 2004, a competitive application cycle awarded funding to junior faculty on the NCCR K12 (which in 2006 was replaced by the CTSA KL2) held within the Institute for Translational Medicine and Therapeutics (ITMAT). Through this award mechanism 5 - 7 trainees received complete tuition and 80% salary support to provide protected time. To address first challenge the SOM/ ITMAT (via a partial reinvestment of generated tuition into further scholarships) offered a comparable funding mechanism (ITMAT Scholarships) for suitably qualified applicants who were not selected for KL2 funding. The MTR program was a highly successful academic model, however enrollment was low because participation was limited to these scholars. A new approach was needed to expand the program, make it more accessible for more junior trainees and increase the likelihood of training an adequate workforce.

Methods

MTR academic program leadership met with training program and fellowship directors and PI's of postdoctoral T32 training grants within the institution to explore options for a cost-sharing model. Leadership identified an opportunity to collaborate with other programs and leverage the preexistence of T32 grants. Trainees awarded postdoctoral T32 positions and entrance to the MTR program could be eligible for support from 2 mechanisms: Select T32s would support the trainee's salary (thus protected research time), while ITMAT/CTSA would support tuition costs. These trainees were also referred to as ITMAT scholars

Outcome

In 2004, 75% of MTR matriculates received funding from the KL2 with each K12 scholar receiving complete tuition and 80% salary support. The remaining 25% paid tuition using faculty tuition benefits but had variable protected time to conduct research. Now 9 years later we have evolved to 98% of MTR matriculates receiving funding from the KL2 or ITMAT departmental grant. Fifty five percent of these matriculates received support from the cost sharing model with tuition support being provided via an ITMAT scholarship and salary support provided from a postdoctoral T32. MTR class size averaged 6 students between 2004 and 2006. MTR class size averaged 14 students between 2007 and 2013. This enrollment increase is significantly attributed to the cost-sharing model.

Lesson Learned

As the funding landscape continues to evolve within the institution and the NIH, educators must prepare for change. We must continue to find creative ways to support as many trainees as possible while keeping the integrity of the program and protecting research time. This cost-sharing model between the CTSA-supported ITMAT and discipline specific T32s is a successful way to spread the wealth and fund more trainees.

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U of Alabama

Abstract 1: **Upending the Paradigm: Human to Model Systems (H2M)**

Robert P. Kimberly, MD

UAB Center for Clinical and Translational Science (CCTS)

The technologies available for human genetics have reached an unprecedented scale and power, and both large genotype-phenotype association studies and more focused deep sequencing in undiagnosed patients have identified plausible candidate genetic variants underlying disease pathogenesis. Molecular models, *in vitro* studies and *in silico* analyses of pathways support predictions about *in vivo* mechanisms, and a more complete understanding involves bringing such information from patients and patient populations into animal model systems for further investigation. Investigators often turn to the mouse as the mammalian model due to the advanced tools available to manipulate and analyze its genome. While mice may be preferred for some physiological systems, many other models offer considerable advantages for studying fundamental processes. Moreover, these models may offer significant advantages related to cost and generation times. To enhance the translation of knowledge generated in humans to model systems, the Human to Model Systems (H2M) Shared Resource brings together expertise within the CCTS Partner Network across model systems to provide a more comprehensive resource for all investigators – complementing rodent methods.

Bringing together a range of expertise in mammalian models, zebrafish, *Drosophila* and worms (*C. elegans*), H2M provides educational resources and training in the use of genetically modified organisms, as well as numerous computational and laboratory services for the creation of new animal models. It acts as a resource for how to most effectively translate human genetic and genomic insights into model systems, while leveraging existing and emerging tools and reagents for model development. All Shared Resource services are available to investigators across the Partner Network. With increased use of the H2M capacity across the Network in the development of vertebrate and invertebrate models to explore the biologic mechanisms underlying disease, models are exploring cystic fibrosis, coagulopathies, sickle cell disease, and ciliopathies in addition to metabolic and immunologic variants. While mice remain the more typical model system, adoption of other model hosts is accelerating through education, roundtable discussion and IDEAs (Individualized Design and Experimental Analysis sessions), as well as methods development.

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U of Alabama

Abstract 2: **Business Alliances: Seeing i2i**

Robert P. Kimberly, MD

UAB Center for Clinical and Translational Science (CCTS)

UAB has untapped potential for the translation of its ideas and its discoveries in research into implementation. A key goal in the Blueprint growth plan of the Birmingham Business Alliance (BBA) is to create opportunity in the Birmingham region. Molly Wasko, PhD, a CCTS Executive Committee member and Chair of the Department of Management, Information Systems and Quantitative Methods, developed the i2i (Invention2Innovation) program which links students and faculty in the UAB Life Science Entrepreneurship Program (LSEP) with local business mentors to develop UAB Research Foundation technology assets with high translational and commercial potential.

The year-long program began in September of 2012 with three main objectives: 1) to identify innovative inventions with strong translational and commercial potential; 2) to educate scientists and potential student entrepreneurs in technology innovation through instruction and experiential learning in the UAB LSEP; and 3) to engage mentors from local business networks to connect regularly with i2i teams. Mentors were chosen from 773 regional technology businesses inventoried by the BBA, vetted by the program and ranging from biotechnology to advanced manufacturing to IT and analytical services.

Project teams are comprised of students, faculty and business entrepreneurs. Participation of BBA enabled the involvement of Steve Ceulemans, former director of technology translation and commercialization for the New Orleans BioInnovation Center and current VP of Innovation and Technology for the BBA. The CCTS now has direct links to the IT portfolio, to entrepreneurial capacity building, and to the business community. Of the five initial teams in the program, four continue to develop the potential of their projects. The fifth was deemed a great idea but was eventually determined to be non-viable commercially. The i2i program has served as a feeder for the Alabama Launchpad, which provides a five-month program of coaching, support and fundraising opportunities for startups. With the help of i2i, two UAB startups recently won Alabama Launchpad awards and received more than \$120,000 in seed funding. The direct participation of business mentors has sharpened and accelerated the process of translation to application.

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U of Alabama

Abstract 3: **Productive Collisions through TIES**

Robert P. Kimberly, MD

UAB Center for Clinical and Translational Science (CCTS)

With a focus on assisting young investigators and pilot projects, our Nascent Projects Panel (NPP) includes a dozen faculty and staff experts who provide feedback in areas such as epidemiology, biostatistics, study design, health economics, outcomes, ethics, and health disparities. Meetings include presentations and Panel discussion, followed by a written summary of discussion points. Feedback has indicated that NPPs are extremely helpful for investigators seeking a broad, multidisciplinary view while preparing manuscripts and grant submissions. However, the NPP has also highlighted opportunities unaddressed, including a small-group review and strategy mechanism for all faculty and a forum for enhancing unconventional, productive “collisions” across disparate content areas.

To facilitate small-group review and strategy sessions, we have implemented Panels Done Quickly (PDQs). Each PDQ has 4-6 members with expertise tailored to the requested topic and organized through the CCTS Research Commons within 2 weeks of the request. There is an emphasis on multiple viewpoints in addition to content-specific expertise.

TIES (Translational Investigator Exchange Service), also organized through Research Commons, serves a matchmaking function to bring together complementary teams of investigators. For example, a clinical investigator with a need for basic science expertise can be matched with basic scientists – or a basic scientist with a finding that may be translatable to clinical application can be matched with clinician investigators. TIES is also used to bring together investigators across different schools and Partners. TIES discussions are convened upon investigator request and when opportunities that might benefit from “collisions” are identified through Research Commons. TIES has been particularly successful in facilitating collaborations between investigators who might not have otherwise met. The CCTS has brought together laser physicists with vascular surgeons to explore novel tissue preparation strategies; mitochondrial biologists with diabetologists to explore new insights in metabolism; and engineers, animal imagers and oncology surgeons to explore mass spectrometry, mAb-targeted fluorochromes and other strategies in defining tumor margins. Panels have led to pre-IND FDA meetings, investigator-initiated grant applications and new clinical initiatives. Investigator feedback and the continuing increase in the number of Panel requests indicate that new opportunities are being developed and important needs are being met.

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U of Illinois Chicago

Abstract 1: **UICentre (Collaborative Engagement in Novel Therapeutic Research and Enterprise): Drug Discovery @UIC**

Dimitri Azar, MD, MBA - Principal Investigator, University of Illinois at Chicago Center for Clinical and Translational Science

While many researchers and clinician-scientists uncover cellular targets driving disease states, they do not have the skills or resources to design and develop compounds that effectively intervene in their pathway of interest. To address this issue the University of Illinois at Chicago

(UIC) CCTS launched the UICentre in January of 2013 to create a collaborative, entrepreneurial environment that provides investigators with the resources needed for drug discovery and development research.

This innovative program brings together members from across UIC with varied skill sets and provides seed funding, external expertise, project management and core services to support milestone-driven drug development projects and the development of novel composition intellectual property. By pairing basic, clinical and translational investigators with faculty and external consultants with expertise in synthetic chemistry, medicinal chemistry, pharmacognosy, high-throughput screening, and pharmaceuticals, the UICentre strives to develop small molecule therapeutic agents whose clinical applications will improve human health.

Projects are identified from invention disclosures submitted to the Office of Technology Management (OTM). The UICentre sets milestones, organizes multidisciplinary project teams and provides seed funding to develop novel small molecules and test toxicology, bioavailability and targeted drug delivery for identified projects. Project Managers coordinate the projects and ensure milestones are met. Primary metrics of the UICentre include multi-PI research grant applications; novel composition patent applications and a pipeline of new invention disclosures. Out of the 9 projects currently under way, three lead compounds have been identified and 3 RO1s have been submitted using data generated by the UICentre.

UICentre is the result of a campus-wide initiative made possible through collaboration between the CCTS, the Colleges of Pharmacy, Medicine, and Liberal Arts and Sciences, with assistance from the Provost, the Vice Chancellor for Research, and the OTM. By successfully leveraging the expertise and resources available at UIC, the investment in the UICentre has been minimal compared to other drug discovery initiatives. Through this initiative we have developed a collaborative resource that allows discoveries at the university to move effectively and efficiently across the translational spectrum.

U of Illinois Chicago

Abstract 2: Ensuring Research Participant Protections in Community-Engaged Research: Improving Research Training of Community Partners

Dimitri Azar, MD, MBA - Principal Investigator, University of Illinois at Chicago Center for Clinical and Translational Science

The IOM review of the CTSA program recommends that the CTSA build partnerships with community groups and stakeholders to help ensure community engagement in all phases of the research process. Often such engagement involves community partners having direct interaction with research participants, such as with recruitment; obtaining informed consent, data collection and storage; and intervention delivery. A challenge, though, is that these “frontline” community partners are often new to research, have little or no training in human subjects research protections, and are vulnerable to protocol violations, breaches of confidentiality and the ethical implementation of research. Traditional trainings in human subjects research protections can be difficult for community partners, who may not have access to online resources, who may not find the material relevant or useful, or who may need tailoring to better fit community norms. Similarly, not all IRBs are familiar with the different challenges in community-engaged research. To help address this problem of frequent delays and lack of familiarity with community engaged research, Dr. Emily Anderson of the UIC CCTS, with input from a partnership of other CTSA institutions, developed the CIRTification: Community Involvement in Research Training Curriculum. The training program was developed after conducting several focus groups with academic researchers and community research partners, and is tailored to the unique roles of community research partners. This training program is meant to teach community research partners about the importance of protecting research participants and also, to enhance their ability to make contributions to the overall research team. Professionally designed materials for the training are available on the UIC CCTS website, with full-scale dissemination and evaluation underway. Partnering CTSA, including Northwestern University and University of Chicago have endorsed this certification as a substitute for community research partners required to complete human subjects training. Lessons learned: the input from multiple CTSA institutions was helpful in having IRBs accept this alternative training; for communities to accept this, project investigators’ involvement as role models was helpful to participation and endorsement; and continuing education and readily available support is critical for all research staff to avoid problems with subject protections.

U of Illinois Chicago

Abstract 3: **Collaborative Building of the Research Workforce in a Targeted Field of Investigation**

Dimitri T. Azar, MD, MBA (Director/PI), and Larry S. Tobacman, MD (Co-Director), University of Illinois at Chicago Center for Clinical and Translational Science

One of the important tasks of the CTSA program is to build, sustain, and improve the clinical and translational research workforce. The Master of Science in Clinical and Translational Science (MS-CTS) degree program at the University of Illinois at Chicago has educated trainees with both didactic content and mentored research experiences, since launch of the MS program in 2008. The MS-CTS has been particularly valuable for a unit that embraced a workforce-building strategy involving the MS program. The Nephrology section (i) used availability of the MS program to help recruit fellows and faculty with an interest in clinical research; (ii) supported participation in the program; and (iii) has now demonstrably provided the trainees with the tools to progress toward independent research careers. Prior to creation of this degree program by the Center for Clinical and Translational Science, Nephrology had a strong research program in renal epidemiology, led by senior faculty, but had limited success in building a future research workforce. Clinical fellows, for example, too often did not pursue research after completion of training, and some junior faculty felt gaps in their preparation for research. Since the inception of the MS program, four faculty members have completed their degrees, and another faculty member is expected to complete the program later in 2013. Importantly, four of these individuals are the recipients of career development awards (three K23 awards and one KM1 award) and three of these awards were awarded shortly after participation in a CCTS-operated grant writing course. In large part due to the vibrancy of the training offered by the Master of Science program, the Section has a very vibrant training and research program in chronic kidney disease epidemiology. Among the lessons learned was the requirement for effective partnership between the CCTS educational program and the academic unit. The two worked together to identify/prepare recruitment material and to meet with potential fellows and to then move them into faculty positions.

U of Washington

Abstract 1: Harnessing the electronic medical records (EMR) of diverse health care systems for research-Amalga Clinical Data Repository.

Shoonya Mohanrao, Peter Tarczy-Hornoch, Anthony Black, Marie Carter-Dubois, Paul Martin, Bonnie Ramsey, and Nora Disis. Institute of Translational Health Sciences (ITHS). University of Washington. Fred Hutchinson Cancer Research Center, and Seattle Children's Hospital.

At the time of the development of the ITHS, access to EMR data was not available in our institutions. Data needed to be pulled from multiple hospitals, clinic EMRs, and other data sources so that research cohorts could be identified, study feasibility determined, and datasets provided to researchers. Our ability to develop a comprehensive system was catalyzed by the institutions' need for assessment of quality improvement, patient safety, finance, operations. Our plan was to onboard a system for the functions as well as clinical data mining.

We piloted the implementation of a clinical data repository at the UW, Amalga, in partnership initially with Microsoft and subsequently Caradigm Corporation. The ITHS supervised, in partnership with the institution, hardware and software installations, data interfaces, and developed early reports and challenge queries from stakeholders. Key to the process, an oversight committee was formed to make a recommendation to senior leadership about proceeding to purchase licenses and fully adopt the technology.

We currently have an integrated clinical data repository on 3.8 million patients containing 20 billion facts. As examples we have further developed an automated clinical trials screening systems, saving research teams' significant time and allowing access to difficult to find research candidates and an Infectious Disease cohort discovery tool pilot, providing the ability to define disease cohorts and obtain longitudinal datasets.

Our challenges were creating a Data Access Policy group to ensure that appropriate law, policy, training, and data access was provided. Many policies had not yet been developed either locally or nationally. Further, many of the queries have to be completed by hand via a consultant service and prioritizing tool development to allow investigator-based queries has been difficult. Further, we still must unite additional databases from the FHCRC and SCH into an integrated system.

What was the lesson learned? Integrating data from multiple EMR, clinic and lab systems is a large and complex endeavor requiring significant resources, diverse skillsets, and most of all, institutional support. Key success factors include: the presence of an oversight committee, stakeholder involvement (senior leadership in finance, operations, clinical, and research domains), formal processes, and regular status reporting.

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U of Washington

Abstract 2: **Creating the IDEAL “LEAN” Organization.**

Bonnie Ramsey, Jennifer Sprecher, Lucinda Getz, Marie Carter-Dubois, Paul Martin, and Nora Disis. Institute of Translational Health Sciences (ITHS). University of Washington, Fred Hutchinson Cancer Research Center, and Seattle Children’s Hospital.

The ITHS is composed of 3 large partner institutions and collaborating organizations that span the 5 state region of Washington, Wyoming, Alaska, Montana, and Idaho. Developing a shared vision with shared goals that are important to and have been shaped by all stakeholders requires a structured process. Over the last 15 months we have been using the techniques of “Toyota Lean” to guide a strategic planning effort to bring ITHS’s numerous partner institutions together in forming shared 5-year goals.

The Lean concepts incorporated in planning included the definition of our customer and the assurance that the mission added value to that customer. Decision making has to be fact based which required preparation and data collection both locally and nationally to create a baseline or “Current State”. The steps include; (1) process mapping, (2) Current State mapping, (3) site visits to organizations with “best practices” to help us define an “Ideal State”, (4) Ideal State retreat, and (5) Future state goal creation and project prioritization.

Our challenges included the scope of our data collection. We defined our own Current State but it was difficult to obtain data to “benchmark” ourselves within the CTSA program. We also expanded our site visits to organizations we felt were innovative in specific areas including Google, a Health Metrics Institute, and a Global Health Institute. These outside organizations brought fresh ideas to our process. Another challenge was balancing between the number of people at each retreat and key representatives from our stakeholder organizations.

To date the process has resulted in a shared mission statement, definition of 5 key Ideal State goals focused on innovation, collaboration, creating value, and becoming responsive and effective, and the collection of numerous projects that will be the basis of our final step in the process; the identification of our Future State Goals. Most importantly, the process has given an in depth education about ITHS to the administration, faculty, community, and staff of our partners and collaborators. In addition, the exercise has generated significant enthusiasm to work together as a unified group to take ITHS into the next 5 years.

U of Washington

Abstract 3: **On the road to a “Research Ready” Hospital System.**

Michelle Doyle, Paul Martin, Ann Melvin, Kathleen Shannon-Dorcy, Bonnie Ramsey, Marie Carter-Dubois and Nora Disis. Institute of Translational Health Sciences (ITHS). University of Washington, Fred Hutchinson Cancer Research Center, and Seattle Children’s Hospital.

Hospitalized patients have increasing opportunities to participate in research studies, and best practices require appropriate integration of translational research with clinical care in hospitals. This need applies especially to research programs in our institutions focused on hematopoietic cell transplantation. Experience showed that deployment of research staff to the hospital from off-site research units was partially effective in solving the problem during standard work hours but not during other times of day.

We convened a steering committee with diverse representation from multiple disciplines and institutions with a clear goal: establish an easily accessible, sustainable program to support research for inpatients, while providing a high level of data integrity. A pilot project was initiated to recruit and train a pool of nurses from the inpatient oncology units to provide 24/7 on-call coverage for a defined set of routine research-related procedures. Key action items accomplished included

- The recruitment and training of clinical nurses for research
- Development of SOP surrounding research studies involving hospitalized patients
- Establishing a shared drive to house research support program information for nurses to access during off hours
- Development of an auditing approach to ensure data integrity

The new Inpatient Research Support Program has, so far, recruited 15 nurses and supported 3 clinical studies. The goal is to expand the program to support research in critical care and medical-surgical units throughout the medical center. We are also working with the community clinic system to develop a similar plan for integration of research into practice.

As challenges, we had to (1) articulate the need and obtain the necessary institutional administrative “buy-in,” (2) recruit institutional representatives who understood the need, wanted to find a solution and had the power approve the program, and (3) develop a tailored training program that could jump-start the project.

This process has allowed the ITHS to engage hospital administration, clinical faculty and hospital staff in a dialogue concerning the importance and necessity of supporting research throughout our health care system. Through this process, we have created enthusiasm for branding our health-care system as a “Research-Ready” organization.

U of Wisconsin Madison

Abstract 1: Review of Pilot Awards: A Shared-Power Mechanism for Community Engagement

Background: Major gaps exist between what we know and what we do in clinical practice and community health programs and narrowing this gap will require substantive partnerships between academic researchers and the communities they serve.

Objectives: We describe a research pilot award program that makes a unique commitment to community engagement, through the addition of an External Community Review Committee (ECRC) to the typical research review process, which gives external stakeholders decision-making power over research funding. Membership on the committee represented rural and urban voices, and different disciplines, perspectives, and races/ethnicities

Methods: Whereas engaging community reviewers in discussion and rating of research proposals is not novel, our review process is distinct in that it is subsequent to peer review and uses different criteria and methodology. This method of engagement allows for the community review panel to re-rank scientifically meritorious proposals—such that proposals funded do not necessarily follow the rank order from scientific peer review. The approach taken by us differs from those discussed in the literature, which present a model of community academic co-review.

Results: Our observations provide guidance for others interested in this model of community engagement and reviews and insights gained during the evolution of this strategy; including how we addressed conflict, how the committee was able to change the pilot award program over time, and individual roles that were crucial to the success of this approach. Over the first 5 years of the programs 141 Type 3/4 Translational Research applications were reviewed, 63 of which were scientifically meritorious and were re-reviewed by the ECRC. The opinion of the ECRC resulted in funding of 9 projects that would not have been funded otherwise. These 9 projects have provided a substantial return on investment – including 6 funded external peer-reviewed grant submissions, totaling \$4.5 million, as well as 7 publications in peer-reviewed journals.

Conclusions: The advantages of this approach include success through traditional academic metrics, while achieving an innovative shared-power mechanism for community engagement, which we believe is critical for narrowing the gap between knowledge and practice.

U of Wisconsin Madison

Abstract 2: **Development and Use of a Curriculum to Significantly Improve Mentoring Skills**

Background: Although research mentoring has long been considered a vital component of training for junior investigators, a standardized program to train mentors guiding scholars in biomedical, clinical and behavioral, and community-engagement research, has been a significant gap in clinical and translational science programs.

Objectives: Over the past 3 years, a multidisciplinary team has worked to adapt the programs for mentor training to make it applicable for the mentors of clinical and translational programs. Using this curriculum efforts were made to determine whether such a structured mentoring curriculum improves mentoring skills.

Methods: Over a 6 month period, the multidisciplinary curriculum team outlined, reviewed, and adapted learning objectives and core training activities to address 6 research mentoring competencies: 1) maintaining effective communication; 2) aligning expectations; 3) assessing understanding; 4) addressing diversity; 5) fostering independence; and 6) promoting professional development. Subsequently, a blocked randomized controlled trial was conducted at 16 academic medical centers, to determine if mentors training clinical/translational research scientists improved mentoring skills. Outcomes included a change in pre-test and post-test composite scores of the Mentoring Competency Assessment (MCA) and mentees' ratings of their mentors' competency before and after training.

Results: After adaptations of the mentoring curriculum, beta-testing followed and a final curriculum was published as *Mentor Training for Clinical and Translational Researchers*. Using this curriculum a total of 283 mentor-mentee pairs were enrolled: 144 mentors were randomized to the intervention and 139 to the control group. Self-reported pre-/post-test change in MCA composite scores was higher for mentors in the intervention group ($p < 0.001$). Mentees working with mentors in the intervention reported larger changes in retrospective MCA pre-/post-test scores ($p = 0.003$) and more positive changes in their mentors' behavior ($p = 0.02$) than those paired with controls.

Conclusions: Production of a new curriculum for training mentors overseeing clinical/translational research scholars has resulted in the first trial to demonstrate impact on research mentoring skills and practices in mentors. With documented success, the UW CTSA site has created a Web-based Legacy Resource for mentoring development, designed to serve national and international research mentor training programs.

UC Davis

Abstract 1: **Seeking Common Ground for Common Metrics**

Julie Rainwater, Ph.D., Stuart Henderson, Ph.D. Erin Griffin, Ph.D.,
Lars Berglund, MD, PhD
University of California, Davis Clinical and Translational Science Center

Since the inception of the CTSA initiative, the development of common metrics has been a desired objective. However, reaching consensus on the definition and measurement of comprehensive metrics that would apply across CTSA has been a challenge. Recently, in an effort to address this issue, the Evaluation Key Function Committee launched a pilot test of a small set of clinical research process metrics, such as IRB approval time and achievement of accrual targets. Concurrently, the regional coalition of University of California CTSA (UC-BRAID) has advocated for similar metrics at the UC level. Our challenges were to ensure that these dual metrics did not become “dueling” metrics and that they were compatible with previously identified institutional metrics. To address this problem, the UC Davis evaluation team took a proactive approach. First, the team joined the national CTSA workgroup to develop data collection protocols to help inform CTSA metrics. This required the evaluation team to work through critical steps in collecting CTSC metrics such as identifying data sources and resolving definitional issues. It also yielded a preliminary set of results for future benchmarking. Second, UC Davis CTSC evaluators convened the other UC evaluators in a collaboration to spearhead the metrics effort at the BRAID level and to insure that protocols, definitions, and data sources were consistent with the national effort. Finally, the local CTSC evaluation has begun integrating the metrics into its existing metrics to minimize the strain on local evaluation resources.

LESSONS LEARNED: Metrics have yet to be finalized or published at any of the 3 levels (institution, BRAID and national CTSA consortium). The effort underscores the need for a systems approach to CTSA evaluation that allows for interaction between national, regional, and local evaluations. Direct coordination of the effort at all 3 levels has moved us closer to utilization of evaluation protocols that inform our progress at CTSC and the UC BRAID and could potentially be adopted across all CTSA.

UC Davis

Abstract 2: **Building Bridges: An Engineering Capstone Experience in Translational Medicine**

Nicholas Kenyon, M.D., Cristina Davis, Ph.D., Alice Tarantal, Ph.D., Julie Rainwater, Ph.D., Lars Berglund, MD, PhD

University of California, Davis Clinical and Translational Science Center

Removing barriers between medicine and other disciplines is an ongoing challenge. The UC Davis Clinical and Translational Science Center (CTSC) developed a program to link faculty in the School of Medicine (SOM) and the College of Engineering (COE) through student teams focused on medical engineering projects. For the past 5 years, the COE *Capstone Senior Design Course*, with funding from the CTSC Pilot program (\$500-750/project), has brought together undergraduate engineering students and clinical faculty to develop device and therapeutic prototypes. A formal solicitation for project ideas is sent to all SOM faculty, and project concepts with the highest likelihood for success in five months are selected and offered as capstone opportunities to COE undergraduate seniors. COE and SOM faculty mentor student teams as they prototype an instrument from design to fabrication and testing.

To date, the program has included 40 faculty mentors, over 100 students, and 25 projects. Positive outcomes include a *New Technologies Summer Camp* for COE undergraduates to engage in clinically relevant translations of engineering innovations, as well as peer reviewed publications, patent disclosures, prototypes, and preliminary data to support grant proposals. Successful projects include an intensive care unit (ICU) patient self-hydration unit, an EMG-powered wheelchair, a mechanical walker for critically ill ICU patients, an endoscopic balloon drug delivery device, and a low-cost pediatric treadmill for home use by disabled children.

The program leaders, Drs. Kenyon and Davis, were finalists for the recent AAMC Award for Innovative Institutional Partnerships in Research and Research-Focused Training. The award recognizes creative, collaborative partnerships that have an impact on sustaining institutional partnerships in research and research-focused training.

LESSONS LEARNED: Minimal CTSC resources are required to design and prototype initial models of medical devices. Prototype development for medical devices outside of this Capstone experience required establishing a *COE Design and Prototyping Clinic*. The majority of new prototypes have been introduced into the clinics immediately to improve aspects of patient care, with a subset developed for commercialization. The UC Davis COE-CTSC-SOM Capstone collaborative shows that effective translational teams can be formed very early in the training experience, and have an impact on clinical care.

UC Davis

Abstract 3: **Establishing a Multiinstitutional Consortium and Federated Data Repository to Support Research**

University of California Research exchange (UC-ReX):

Kent Anderson (UC Davis), Lattice Armstead (UCSF), Douglas Bell (UCLA), Lars Berglund (UC Davis), Douglas Berman (UCSF), Daniel Cooper (UC Irvine), Lisa Dahm (UC Irvine), Steven Dubinett (UCLA), Gary S. Firestein (UC San Diego), Davera Gabriel (UC Davis), Michael Hogarth (UC Davis), Claiborne Johnston (UCSF), Mini Kahlon (UCSF), Mohammed Mahboub (UCLA), Michael Minear (UC Davis), James Murry (UC Irvine), Lucila Ohno-Machado (UC San Diego)

The increasing adoption of electronic health records (EHRs) presents an opportunity to establish large data sets to support clinical research. However, to develop a multiinstitutional clinical data repository is challenging on many fronts. We present an effort by the University of California (UC) to coordinate clinical data repository efforts across its five academic medical centers through the CTSA initiative. The UC-Research exchange (UC ReX) effort, funded by the UC Office of the President through the CTSA UC BRAID consortium, began in 2011 with a phase one goal of providing cohort discovery tools across 12 million patient records in the UC system. Three institutions already had i2b2 systems and two of them had experience with the i2b2 SHRINE (Shared Health Information Network) federated network architecture. UC-ReX initiated an implementation of a five-node i2b2 SHRINE network to support federated querying across sites. UC ReX working groups were formed to develop semantic interoperability of the data; implement technical deliverables and maintain systems; model and implement user support and develop a strategy to develop UC ReX into a valued shared UC service. Within 14 months, UC-ReX deployed “UC Data Explorer”

(<http://www.ucrex.org>) which enables queries for counts by a combination of diagnosis, procedures, and demographics. A key component of the project was data harmonization for data across the five repositories. The heterogeneity of source data and coding practices at each site tended to cause variations in query results due to semantic nuances.

LESSONS LEARNED: Having an uncomplicated, equitable shared governance structure was a key in establishing the consortium and enabling it to collectively deliver a working system in a timely fashion. Although the same EHR vendor system was present at 4 of the 5 consortium sites, local variations and documentation customs created differences in source data requiring adjustments to render semantically homogeneous federated data able to consistently answer queries across the federated network. We found a significant variation across the sites in implementation of health information technology ranging from recently implemented (within 12 months) to over two decades in operation, resulting in wide variations in the amount of site-specific data loaded.

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UC Irvine

Abstract 1: **Harnessing the Human Ventilome for Clinical Application– The Breath Biomarkers Project**

INSTITUTE FOR CLINICAL AND TRANSLATIONAL SCIENCE (ICTS)

PI: Dan M. Cooper MD and ICTS Steering Committee

(Chief Author-Dr. Pietro Galassetti)

Challenge: A major goal of NCATS is to create multidisciplinary partnerships for disease biomarker discovery. Measuring comprehensive biological gases in human breath (the *Human Ventilome*) is compelling and noninvasive, but clinical applications remain limited. We describe here our efforts to harness for clinical use the experience of a world renowned atmospheric chemistry lab at UCI founded by F. Sherwood Rowland (Nobel Laureate in Chemistry).

Rationale/approach: Our original vision formulated 8 years ago by the then UC Irvine GCRC rested on the earlier academic model of translational research. Targeted pilot funds were used to support proof-of-concept projects that were of biological and clinical importance. Little attention was paid to strategies and tactics necessary to implement breath biomarkers as a useful clinical tool. At that time, metrics of success relied predominantly on numbers of publications and extramural research grants.

Outcomes: ICTS pilot funds along with individual grants showed promising applications of human ventilome discovery in wide-ranging areas including: estimating blood levels of glucose and insulin; detecting volatile biomarkers of healthy and transformed leukocytes; and gauging pharmacokinetics of inhalants commonly used in asthma by detection of the aerosolizing agents in the breath. In the process, we also encountered **key obstacles to translation** that included: 1) diverse expectations among the collaborating clinician investigators and bench scientists; 2) the distinct practices and environments of a university atmospheric chemistry research unit compared with a clinical laboratory; 3) the lack of a clear commercialization plan; and 4) inadequate strategies to fund ongoing developments that addressed the challenges of bridging biomedical discovery and clinical application.

Lessons: For the clinical implementation of discoveries from multidisciplinary teams, a formal strategic plan that embeds pathways to application in the discovery process is needed. In our case, we must link the scientific goals of atmospheric chemists (focused predominantly on identification of novel volatile organic compounds) to clinical imperatives and disease pathophysiology. In the process, we need to encourage the team of investigators to think in non-traditional academic ways about issues such as analysis costs and access needed to actualize the biomedical discoveries; and early consideration of business models that will accelerate commercialization.

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UC Irvine

Abstract 2: **Challenges And Successes In Creating A CTSA-Allied Child Health Research Strategic Plan With A Community Children’s Hospital: The UC Irvine Experience**

INSTITUTE FOR CLINICAL AND TRANSLATIONAL SCIENCE (ICTS)

PI: Dan M. Cooper MD and ICTS Steering Committee

(Chief Author-Dr. Dan Cooper)

Challenge: In 2008, UC Irvine, an academic health center, and Children’s Hospital of Orange County (CHOC), a community children’s hospital, entered into a formal affiliation. This affiliation was seen as a major success since the history of the two institutions had been at times disharmonious. An immediate goal was to develop a formal strategic plan for translational research in child health. Issues of trust, authority, legitimacy, respect, and control loomed as potential difficulties.

Rationale/approach: An independent consulting firm was engaged and the UC Irvine CTSA (Institute for Clinical and Translational Science–ICTS) leadership was involved. The ICTS was viewed as “apolitical” in that it had NIH association and had provided CHOC investigators with support prior to the strategic planning activity.

Methods: A series of meetings (including day-long retreats, regular shorter brainstorming and review sessions) and much behind-the-scenes discussion occurred over a 4-month period. Research areas of interest were prioritized for investment by the two institutions; a fair and equitable governance infrastructure was created; and mechanisms put into place to manage and control charitable donations, institutional support for research, and indirect costs from research grants.

Outcomes: Some of the meetings were difficult and reflected other related issues that the two institutions were concurrently grappling with. The skills of the outside consultants and the UCI ICTS faculty and staff were essential in keeping the group on task. The plan was completed and was viewed as a singular success of the overall affiliation. The mission of the CHOC-UCI Child Health Research Institute is, “*To create a world-class child health center through innovation, research and discovery.*” An immediate goal was to implement a pilot grant program that emphasized UCI and CHOC collaborative translational research in line with the strategic plan.

Lessons: Creating formal strategic plans for translational research involving different institutions can be a difficult, time-consuming, and expensive task. CTSA’s tend to be viewed as “above the political fray” and, therefore, can play an essential role. Skilled consultants can substantially facilitate the process. A successful strategic planning effort can bring a multi-institutional, multi-disciplinary group of clinicians and scientists together in a way that can advance the goals of the CTSA’s and NCATS.

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UC Irvine

Abstract 3: **Bridging the Community–Academic Health Center (AHC) Gap in Clinically Relevant Biomedical Research**

INSTITUTE FOR CLINICAL AND TRANSLATIONAL SCIENCE (ICTS)

PI: Dan M. Cooper MD and ICTS Steering Committee

(Chief Authors-Drs. Kimberly Lakes and Lorena Teran)

Challenge: Linking AHCs with community partners to identify clinical research of particular relevance to the local community is difficult. Our community partners indicated their need for relatively small pilot project grants to help create effective partnerships. Here we describe our CTSA program using this mechanism to build sustainable collaborations in health care research.

Approach: The Community Engagement Unit (CEU) of the UC Irvine ICTS created the Campus-Community Research Incubator (CCRI) program. It was built as a true partnership between university-based investigators and community collaborators. Members included community health care advocacy groups [e.g., MOMS Orange County (OC)], governmental agencies (e.g., Children and Families Commission of OC), and nonprofit disease-focused charitable organizations (e.g., OC American Cancer Society).

Methods: The CCRI program invites grant applications for pilot health research from any partnership between university researchers and community organizations. Applications are reviewed by members of the CEU Community Action Planning Group. Awards are for \$4,000 to \$10,000 over one year. A new call for applications is released annually.

Outcomes: In the last five years, \$163,058 has been awarded to 28 CCRI projects. We overcame two key obstacles that have hindered these partnerships in the past by 1) creating new mechanisms to rapidly transfer funds to community partners; and 2) streamlining on-line human subjects tutorial for community partners. Results from a survey of a subset of 10 CCRI awardees (4 community and 6 campus partners) indicated that the projects: 1) were rated as successful (90%); 2) positively impacted health in the community (60%); and 3) led to sustained partnerships (70%). Moreover, 50% of respondents have subsequently received additional funding to further the research partnership.

Lessons learned: Providing pilot funds to support community-engaged research can lead to the development of research partnerships with practical significance to the community. Minimizing administrative hurdles is key to success. Identifying and addressing these effectively is imperative to the future of community health research partnerships. ***We would recommend working closely with our NCATS and NIH partners to ensure that mechanisms are in place at a national level that facilitate participation by community groups in AHC–Community partnerships in health research.***

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UCLA

Abstract 1: **Accelerating Team Science through Grant Submission Facilitation**

Authors: Lenore Arab (University of California – Los Angeles), Judith Gasson (University of California – Los Angeles), Robin Faria (University of California – Los Angeles), Anne Skinner (University of California – Los Angeles), Denise Gellene (University of California – Los Angeles), Steven M. Dubinett*(University of California – Los Angeles)

**presenter*

The Challenge: The complexity of medical science investigation requires multidisciplinary teams that collaborate across disciplines, departments, institutions and geographies. To support formation of sustainable teams, a central mechanism that matches investigators by research interest, project knowledge and complementary skills is needed to facilitate applications for large team science funding mechanisms.

Approach: To stimulate new team science collaborations and sustainable interdisciplinary research, UCLA CTSI established a Rapid Response Team (RRT) and software tool to facilitate team formation and support inclusive grant proposal development on tight timelines.

Methods: The UCLA CTSI RRT organizes, facilitates and hosts structured brainstorming sessions involving investigators across all CTSI partner institutions, consisting of more than 5,100 research faculty, to encourage cross-institutional collaboration and to develop the strongest possible responses to RFAs. The UCLA RRT facilitates the grant application process by providing the administrative infrastructure that investigators require to submit successful grant applications, with particular emphasis on large funding mechanisms that require additional administrative support. We streamline a complex process into workable pieces, pull together investigators for successful collaborations, and provide grant management support, tools, and software with the goal of helping increase the funding success rate.

Outcomes: In its first two years, RRT was involved with over 23 separate PCORI, NIH and DoD grant application proposals, resulting in more than \$13.6M in new extramural grant funding. For example, in the recently funded University of California Center for Accelerated Innovations (U54) grant application, the RRT invested over 500 hours of administrative time, including the coordination of more than 25 meetings and the collection or creation of more than 800 supporting documents, such as letters of support, biosketches, agendas, meeting minutes and e-mails. RRT has also been instrumental in launching three additional U54 submissions.

Lessons learned: The RRT continues to engage new CTSI research partnerships, locally, regionally and nationally, and to encourage large team science funding applications. Adoption and usage of the RRT grant management software is increasing. Grant submission support for team science funding mechanisms fulfills an unmet need.

UCLA

Abstract 2: **University of California Center for Accelerated Innovations**

Authors: Michael J. Palazzolo (University of California – Los Angeles), Denise Gellene (University of California – Los Angeles), S. Claiborne Johnston (University of California - San Francisco), Lars Berglund (University of California - Davis), Dan M. Cooper (University of California - Irvine), Gary S. Firestein (University of California - San Diego), Steven M. Dubinett* (University of California – Los Angeles)

**Presenter*

Challenge: The CTSA's at the five University of California medical schools constitute UC Biomedical Research, Acceleration, Integration, and Development (UC BRAID), a regional research network focused on translational science. To realize the full potential of this resource-rich network, UC BRAID must overcome institutional barriers to successfully compete for extramural funds.

Approach: UC BRAID leadership targeted an opportunity from NHLBI, "The NIH Centers for Accelerated Innovations," RFA-HL-13-008. The opportunity was selected because it (1) was focused on scientific translation, (2) was perfectly aligned with the resources and expertise of the University of California, which accounted for 7% of NHLBI's extramural grant funding in FY2012, (3) would seed creation of a regional CTSA mechanism to commercialize discoveries, and (4) would enhance integration of the UC BRAID regional CTSA network.

Methods: UC BRAID does not have dedicated infrastructure for identifying and seeking extramural funding. Thus, CTSA's across the five campuses collaborated to respond to the NHLBI RFA. Recognized experts in entrepreneurial education, management organization, project management and technology development led well-integrated, cross-institution design teams. A cross-institution CTSA administrative team developed budgets and collected supporting documents. Weekly conference calls and frequent e-mails kept the project on track. UC BRAID leaders set strategy and reviewed budgets and early drafts of the proposal. Senior CTSA investigators not involved in proposal development reviewed the final draft. The proposal called for leveraging and expanding the UC BRAID regional CTSA network by (1) integrating career development courses and trainings, (2) facilitating access to research resources across the network, and (3) fostering multidisciplinary, inter-campus collaborations to move discoveries toward commercialization. UC BRAID leadership obtained matching funds from business, engineering, and medical schools for the five campuses, demonstrating full institutional support and uniform enthusiasm across UC.

Outcome: The application was awarded \$12-million over seven years.

Lessons learned: The lack of infrastructure for identifying and responding to funding opportunities initially hampered the application process. However, the unanimity of the five CTSA PIs that form the UC BRAID leadership greatly facilitated the successful application. Frequent communication among writers and administrators was critical. A formal mechanism to support proposals will enhance future efforts.

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UCLA

Abstract 3: Establishing a University of California CTSA Biobanking Network that includes a Community Engagement Component

Authors: Sarah Dry (University of California Los Angeles), Julie Auger (University of California San Francisco), Lars Berglund (University of California - Davis), David Boyle (University of California San Diego), Elizabeth Boyd (University of California San Francisco), Arleen Brown (University of California Los Angeles), Dan M. Cooper (University of California - Irvine), Dan Dohan (University of California San Francisco), Gary S. Firestein (University of California San Diego), S. Claiborne Johnston (University of California San Francisco), Barbara Koenig (University of California San Francisco), Clara Magyar (University of California Los Angeles), Courtney McFall (University of California San Francisco), Dan Mercola (University of California Irvine), Hubert Stoppler (University of California San Francisco), Margaret Tempero (University of California San Francisco), Yvonne Wan (University of California Davis), Steve Dubinett (University of California Los Angeles)*

**Presenter*

Abstract: Translational research requires high quality human specimens. Hundreds of biobanks exist within the University of California (UC). Historically, no recommended standard operating practices (SOPs) existed and samples were not accessible across UC campuses. Community input on biobank governance has not been sought, despite known bioethical concerns. We seek to change this through the creation of a UC biobanking network that includes a community engagement component.

UC Biomedical Research Acceleration, Integration, and Development (BRAID), a CTSA consortium, addresses shared challenges of translational science across the UC biomedical system (Davis, Irvine, UCLA, UCSD, UCSF). BRAID's Biobanking group was tasked with creating harmonized operations/governance practices. Simultaneously, a NIH grant supplemental to the UCSF CTSA, EngageUC, has three goals: 1. Engaging UC stakeholders to improve informed consent processes for and handling of research specimens; 2. Comparing informed consent approaches in a controlled trial, and; 3. Implementing policies to sustain an exemplary system for biorespository research that respects our diverse patient base.

To engage Californians, EngageUC includes deliberative community engagement (DCE) events in LA and SF. Each event educates selected citizens on biobanking and informed consent, and seeks their input on the process and important bioethical issues, such as data/sample sharing. Dr. Dry ensures cooperation in these efforts as BRAID Biobank Chair and EngageUC Co-Program Director.

First year achievements include:

- A successful bilingual (Spanish/English) DCE in LA. Participants advocated for increased public UC-wide biobanking network structure
- Establishment of biobank SOPs
- Inclusive governance model for legacy/future collections with community involvement recommendations
- Initiatives in education and common data capture
- education about biobanks/biomedical research, believed citizens would participate and favored continued community involvement in governance.
- Successful recruitment for the SF DCE, including Asian populations underrepresented in the bilingual LA DCE.

LESSONS: Traditionally independent biobank leaders can agree upon harmonized biobanking practices/governance. Community members are enthusiastic about participating in governance. These broad, diverse accomplishments advanced the NCATS goals. Success required considerable time, effort, and resources. Additional funding and faculty effort are essential to continue community engagement activities and to ensure the UC-BRAID CTSA biobanking effort continues.

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UCSD

Abstract 1: **Larger than the sum of its parts: UC BRAID consortium within the University of California**

Authors: Gary S. Firestein (University of California - San Diego), Rachael Sak (UC BRAID), Lars Berglund (University of California - Davis), Dan M. Cooper (University of California - Irvine), Steven M. Dubinett (University of California – Los Angeles), S. Claiborne Johnston (University of California - San Francisco)

Abstract

Leveraging expertise and resources across academic biomedical institutions is key to CTSA success. UC Biomedical Research Acceleration, Integration, and Development (BRAID), a CTSA consortium of the five UC campuses was established to address University of California (UC) system-wide approaches to the shared challenges of translational science.

The consortium's goal is to catalyze collaboration, and reduce barriers for health research by taking advantage of shared policies across the UC system and the UC system benefit through improved competitiveness for large translational collaborative funding opportunities, attractiveness to industry partners, and improved access to resources and infrastructure. BRAID is led by an Executive Committee comprised of the PIs of the five UC CTSA's. Its network of campus leadership, faculty and administrators and UC Office of the President (UCOP) partners provides a powerful foundation for promoting and facilitating biomedical research.

BRAID was and continues to face a number of challenges, including cultures of scientific individualism at the institutional and investigator level; No history of sharing funds as a single UC entity; and institutional inertia in developing common IRB and contracting mechanisms. BRAID established an environment of collaboration across campuses by frequent teleconference and face-to-face meetings and selection of projects likely to have high impact and provide "proof-of-concept" across the UC system.

This approach has led to the following illustrative achievements:

- Funding from UCOP to support multiple projects.
- Implementing the first clinical query system including data from all 5 UC CTSA medical centers.
- Harmonizing IRB approvals and metrics across the UCs.
- Facilitating development of UC system wide master clinical trial agreements
- Creating a successful model for responding to cooperative grants

Challenges ahead include a source of sustainable funding for ongoing projects and for development of new ones.

LESSONS LEARNED: Multiple, traditionally independent and competitive health centers can develop effective networks and consortia that advance the NCATS goals. Considerable time, effort, discussion, and resources are necessary for success. Leaders at each center must be sufficiently confident and experienced that they can bolster both their individual institution and the consortium simultaneously. Regional mechanisms to support such networks are needed if these activities are to be sustained.

UCSD

Abstract 2: **Integrated service biomarker-based clinical trials: “UC San Diego CTRI Launching Pad”**

Authors: David L. Boyle and Gary S. Firestein, M.D. UC San Diego School of Medicine, La Jolla, CA

PROBLEM: Clinical trials focused molecular biomarkers, assay validation, and data interpretation can be challenging. Clinical biopsy procedures are not optimized for clinical trials and biomarker analysis is not readily available. Traditional core services are difficult to access for clinicians due to their specialized nature and specimen handling requirements. Scientific collaborations between basic and clinical scientists can be difficult to deliver as a core service.

RATIONAL: Our previous success with serial synovial biopsy studies in rheumatoid arthritis led us to create the “CTRI Launching Pad”, which offers integrated laboratory services, training, and consultation to clinical investigators. The goal was to provide design, laboratory, and statistical support that advance molecular approaches to interventional trials.

METHOD: To initiate the program, we provided Launching Pad collaboration to gastroenterologists to develop and validate sampling for molecular analysis approaches to inflammatory bowel disease (IBD) clinical trials. The CTRI integrated assistance to include study design, IRB application, sample acquisition, molecular analysis in the laboratory, and statistical modeling of the results as a suite of services. The study was designed as a cross-sectional evaluation of IBD with colonoscopy and colon sampling. Biopsies were processed and analysis performed, including application of quantitative PCR methods optimized for clinical trials to maximize analyte yield. Resulting statistical models yielded a power analysis for inter- and intra-patient sampling. A GI clinical fellow was trained in study design and data interpretation.

OUTCOME: Successful performance of a proof-of-concept study in IBD established a system that can now be applied to an interventional clinical trial to assess drug mechanism of action. The design includes baseline biopsy, therapeutic intervention, and follow up biopsy, which allows patients to serve as their own controls. Clinical fellows and faculty were mentored in molecular measures. Similar approaches are now planned for other specialties.

LESSONS LEARNED: CTRI Launching Pad delivered integrated collaboration in a service environment. To be successful these approaches require:

1. Institutional support at startup.
2. A leading collaborator within the CTRI.
3. Flexible cost recovery, including recharges and percent effort allocation.
4. Junior faculty or trainees as an interface between the CTRI and a senior investigator.

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UCSF

Abstract 1: **Catalyst Awards: a platform to enable innovation from research idea to health product**

Clinical and Translational Science Institute, University of California – San Francisco

Problem: Many academic discoveries do not successfully translate into health benefits because of the inability to identify development risks early and fund the most promising solutions.

Approach: The Catalyst Awards Program at UC San Francisco is a competitive intramural consultation and award mechanism that leverages the expertise of industry advisors and provides seed funding to support the early development of clinically beneficial and commercially viable products. The program is currently divided into 4 tracks: therapeutics, diagnostics, medical devices and digital health. Each track conducts its own reviews with awarded applicants matched to individual advisors for subsequent in-depth consulting. Upon completion of the consultation phase, the applicants compete for the financial award by presenting their revised proposals to a large group of expert industry affiliates.

Platform: The track-based structure of the Catalyst Awards program makes it feasible to grow and expand the program in response to new needs and opportunities. For example, due to the increased interest in digital interventions that impact health, we incorporated the Digital Health track into program in 2012. The track now has ~20 advisors and supports 5-10 applications per cycle. The track-based structure brings on board partners who are interested in a particular therapeutic modality or disease area. Partners can choose to sponsor an award within an existing track or to work with the Catalyst staff to develop a new, focused track -- e.g. a track for biologic drugs, for orphan diseases, or a track that is disease-specific.

Outcomes: 61 promising new interventions and technologies have been supported in the last two years in bridging the translational divide. With 100+ senior advisors from public and private spheres (pharmaceutical, biotech industries, law, clinical) most of whom participate as volunteers, Catalyst has been successful in reaching across the industry-academia divide. And, 100% of consultants and 95% of awardees would recommend the Catalyst program, as measured in a recent survey. Finally, Catalyst has evolved into a platform that enables the development of customized consultative tracks and has grown to match the increasing interest in new forms of public-private partnerships and translational science.

UCSF

Abstract 1: **CTSI Innovations in Distance Learning**

Clinical and Translational Science Institute (CTSI)
University of California, San Francisco (UCSF)

It's clear that major changes are occurring across the nation in education – from the Khan Academy and the flipped classroom to massive open online courses. CTSA's should incorporate the best of these new approaches to improve the quality, efficiency, scalability and impact of education, while focusing on the unique needs of motivated professional trainees. At its worst, online education means lectures videotaped in a traditional classroom and posted to a website. At its best, online education should provide highest quality content coupled with extensive peer interaction and mentored product development. CTST has developed several fully asynchronous courses that meet these standards for online education and tested them in a variety of audiences and settings:

- **Designing Clinical Research.** Provides lectures, readings and exercises focused on the theoretical and practical aspects of research design. Students develop a full-scale NIH-style protocol in an iterative process with extensive input from peers and faculty experts.
- **Responsible Conduct of Research.** Provides lectures, readings and exercises focused on ethical principles in human subjects research, conflict of interest, scientific misconduct and authorship. Student discussions of 14 controversial cases are monitored and directed by faculty experts, and students may produce the “Human Subjects” section of a research proposal.
- **Writing Clinical Research.** Provides lectures and readings focused on the elements of a research manuscript and good writing technique, demonstrates how editing improves manuscripts, requires students to edit poorly written manuscripts, and can provide peer collaboration and expert mentoring during development of a real manuscript.

We have delivered these courses to trainees at various levels at UCSF, and to trainees at Kings College London, Peking Union Medical College Hospital and Genentech China. These efforts have helped us refine the online courses with the aim of delivering them to clinicians and scientists in the US located at institutions with limited clinical research training resources. We also believe that this approach to online learning could be used across the CTSA consortium to develop research training programs, especially in areas where many CTSA's are not strong – such as early translational research, team science and biomedical informatics.

UCSF

Abstract 1: **Harmonizing Institutional Review Boards (IRBs) within Five Institutions of the University of California**

Authors: S. Claiborne Johnston (University of California - San Francisco), Rachael Sak (UC BRAID), (Lars Berglund (University of California - Davis), Dan M. Cooper (University of California - Irvine), Steven M. Dubinett (University of California – Los Angeles), Gary S. Firestein (University of California - San Diego)

Abstract

UC Biomedical Research Acceleration, Integration, and Development (BRAID), a CTSA consortium of five University of California (UC) campuses with medical centers, was established to identify system-wide opportunities to accelerate translational science. The consortium's goal is to catalyze collaboration and reduce barriers for health research by modifying policies, sharing expertise, and building common infrastructure across the UC system. It is led by an Executive Committee comprised of the PIs of the five UC CTSAs.

UC IRBs have traditionally suffered from institutional inertia, disparate administrative technologies, and historic cultures of independence and provincialism. BRAID selected projects likely to have high value, provide “proof-of-concept” and that would enable an environment of collaboration across the UC system. These projects focus on harmonizing processes to 1) enhance the UC mechanism for IRB reciprocity and expand its use in clinical research and 2) for metrics tracking and evaluation.

Initial efforts to facilitate IRB reciprocity approvals for industry sponsored clinical trials have reduced duplicative IRB reviews with resultant administrative efficiencies and improved approval times. Processes have been harmonized across campuses with a focus on reducing burden for the investigators and IRB staff alike.

In alignment with CTSA consortium activities, BRAID IRBs have begun to collect prospective data on common metrics. The data will be used to identify potential best practices, for local and system-wide process improvement projects, and to evaluate policy changes. IRB metrics will be analyzed periodically to identify trends and for predictive model building and will be made available to BRAID campuses, the UC Office of the President, and other interested groups.

LESSONS LEARNED: IRB committee chairs are fiercely independent and untrusting of the reviews of other entities. IRB program administrators rely heavily on input from the committee chairs and are also uniformly under-resourced. The institutional policies that govern IRB practices are not set by IRB chairs or administrators but rather by institutional officials responsible for research compliance. Advocacy from faculty and high-level administrators is necessary to overcome traditional barriers to shared or deferred IRB review. Ongoing communication and trust-building are critical to create systems that meet the needs of all constituents.

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Abstract 1: e-GATE: electronic-Grant Admistration and Tracking Environment

A Web-based solution for Funding Program Administration

PI and Institution: Thomas Buchanan, M.D.

Southern California Clinical and Translational Science Institute (SC CTSI)
University of Southern California and Children's Hospital Los Angeles

Authors: David Hellard*, B.S.; Praveen Angyan* M.S.; Aileen Orino, M.P.H.; Sarah Hamm-Alvarez, Ph.D; Melanie Funes, Ph.D. +□□ Authors contributed equally to the work; +Corresponding author (melanie.funes@usc.edu)

*We would like to acknowledge the contributions of John Burgos B.S., and Katja Reuter, Ph.D.

Abstract:

What was the problem/challenge?

A number of administrative challenges exist associated with managing a pilot funding program: email burden; application submissions; administrative triage; circulation of applications and reviewer scores and comments; compilation of statistical data; etc. Relying on email or document management solutions often results in loss or misdirection of critical documents.

What was the rationale/approach?

SC CTSI developed a web-based grant administration portal to provide a centralized solution for these demands. Off-the-shelf grant management packages were considered, but none met customization or start-to-finish solution expectations. A proprietary system, developed in-house, met those needs while allowing for future sharing of the open source code or system with other institutions.

What was done/methods?

e-GATE was designed and tested over two funding cycles with the goals of 1) handling program processes from beginning to end; 2) minimizing the learning curve for users through an intuitive interface; 3) reducing email burden for all; 4) sharing the system with others. Its key components include web-based: proposal submission, review and scoring; with easy information sharing across funding programs.

Unique features of e-GATE include: rigorous conflict of interest and confidentiality management; review committee meeting scheduling, live scoring, ranking, and comment-capture; and a user-permission hierarchy allowing selective access to applications and reviews by end users.

In development features of e-GATE include: integration with university, NIH and public data systems to enable post-award tracking of compliance and outcomes; budget management and tracking; statistical dashboard integration with the SC CTSI website; and a "My Award" feature summarizing key data for awardees.

What was the outcome?

e-GATE has been used during two funding cycles (Fall 2012 and Spring 2013); managing over 300 applications and 600 users (applicants and reviewers) and has significantly streamlined program processes.

What was the lesson learned?

Designed and tested by a team of developers with years of experience in managing pilot funding programs, e-GATE is a user-friendly system which ensures rigorous adherence with conflict of interest and confidentiality best practices. Proprietary development of e-GATE ensures SC CTSI can be responsive and adaptive to the needs of all end-users (applicant, reviewer and administrator).

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Abstract 2: **Promotoras (Community Health Workers) as Partners in Research: Lessons Learned**

PI and Institution: Thomas Buchanan, M.D.

Southern California Clinical and Translational Science Institute (SC CTSI)
University of Southern California and Children's Hospital Los Angeles

Authors: Katrina Kubicek⁺, M. A.; Marisela Robles, M. S.; Michele D. Kipke, Ph D

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We would like to acknowledge the contributions of Lourdes-Baezconde-Garbanati, PhD. Melinda Cordero-Barzaga, Mayra Rubio-Diaz and Rosa Barahona

Abstract:

What was the problem/challenge?

To address our national goal of “achieving health equity, eliminating disparities, and improving the health of all groups”, innovative approaches are needed to fully engage diverse communities in the conduct and dissemination of clinical and translational research. Community members can serve as catalysts and “change agents” in efforts to develop, evaluate and implement interventions design to improve human health across a wide range of human diseases and conditions. The challenge lies in developing community-partnered approaches that are both culturally relevant and appropriate, yet can be evaluated and ultimately broadly implemented for widespread adoption.

What was the approach?

The Community Engagement program of the SC CTSI facilitated the development an academic-community partnership focused on disseminating evidence-based guidelines related to cardiovascular health to Latino populations in Los Angeles, using *Promotoras de Salud/Community Workers*.

Promotoras are trusted volunteer community members who have a particularly close understanding of the community being served. This pilot project engaged *promotoras* in the delivery of an 11-session *Su Corazon, Su Vida* curriculum developed by the National Heart, Lung and Blood Institute.

What was done/methods?

A partnership was forged with *Vision y Compromiso*, an organization representing *promotoras* and community workers from across California who work and live in Latino communities, and provide support, information and training on health, education, and other issues important to the community.

Twenty-five *promotoras* were recruited and trained to deliver the 11-session cardiovascular health intervention to communities in urban Los Angeles and in California's rural Central Valley.

What was the outcome?

Promotoras conducted 49 workshops with 730 community members, maintaining a 73% retention rate throughout the 11-week course (without financial incentives for participation). Data indicate significant changes in: 1) the amount of physical activity participants perform; 2) knowledge of risks for heart disease and smoking, signs of a heart attack, and benefits of physical activity; and 3) the proportion of participants who have implemented lifestyle changes in their households to decrease their risk for cardiovascular disease.

What was the lesson learned?

This pilot study demonstrated that the use of *promotoras* is a potentially effective strategy to engage diverse communities in the dissemination and implementation of research findings to impact health, in this case to increase knowledge and improve the cardiovascular health of Latino populations.

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UT Houston

Abstract 1: **Creating a Cross-Institutional Core Laboratory Network Within the Texas Regional CTSA Consortium**

David D. McPherson, Patricia Hurn, and David G. Gorenstein

Center for Clinical and Translational Sciences (The University of Texas Health Science Center at Houston— University of Texas M. D. Anderson Cancer Center CTSA) (DDM, DGG) and The University of Texas System (PH)

In the current research funding environment, many institutions are having difficulty supporting research core laboratories and service centers, despite the increasing need for this critical research infrastructure. To address this issue, in 2012 the University of Texas (UT) System held iterative meetings, video conferences, and site visits across its 15 campuses and also with a team of external advisors from institutions with best-in-class core research facilities. This analysis led to an extensive set of recommendations for establishing a system-wide research core. UT System is currently working with the Texas Regional CTSA Consortium (TRCC, which comprises the Houston, Galveston, San Antonio, and Dallas CTSA) to explore ways that CTSA-affiliated research cores might leverage each other's expertise and assets. TRCC core directors met in July 2013 to establish a TRCC core laboratory network. In parallel, a Memorandum of Understanding (MOU) that defines the basic framework for investigator access to cores at UT institutions is awaiting approval from the TRCC institutions. This MOU provides "open access" for all faculty to the core lab network. Numerous advantages to such a core lab network have been identified: a) wider intra- or inter-institutional access to technology and expertise; b) access to efficiencies that promote financial viability and sustainability; c) increased likelihood service prices may be low relative to the external commercial sector due to growing capacity and economy of scale; d) leverage the collective expertise and capital investment to maximize technological capacity, e) enhanced competitiveness for research funding; f) enhanced user access; g) enhanced scope and quality of research; h) assurance of high standards of practice and benchmarking for quality assurance; and i) possible external non-TRCC markets for core services. Importantly, a core network may increase access to key technologies that can jump-start new investigators. As part of this process a UT System Core Network website (UT-CoreNet.edu) is being created through the TRCC leadership as the access point for investigators to locate existing core lab services. One of the lessons learned is that there is intense interest amongst core lab leadership, faculty, CTSA leadership, and university administration in creating this network.

UT Houston

Abstract 2: **Creating Research Teams to Leverage Hispanic Health Research**

David D. McPherson

Center for Clinical and Translational Sciences (The University of Texas Health Science Center at Houston— University of Texas M. D. Anderson Cancer Center CTSA)

Since its inception, the Center for Clinical and Translational Sciences (the University of Texas Health Science Center at Houston (UTHSCH)—M. D. Anderson Cancer Center CTSA) has had a Clinical Research Unit (CRC) in Brownsville, Texas (on the Texas-Mexico border). The CRC facilitates studies and interventions in the unique health issues of this medically underserved and understudied Hispanic population, including high rates of obesity and diabetes. With the Hispanic Research Center (HRC) in Brownsville's UTHSCH School of Public Health, the CCTS helped to create and sustain an extensively characterized population-based cohort of >2600 Brownsville Hispanics and to perform preliminary research on the cohort. However, the research potential of the cohort data and the local community exceeded the expertise of the HRC, so, the CCTS began to introduce Houston researchers to the HRC and CRU. Cardiologists, gastroenterologists, oncologists, and other specialists were apprised of the Brownsville resources and introduced to the HRC faculty. The most promising possible collaborators were flown to Brownsville for face-to-face meetings. (Brownsville is 350 miles from Houston but less than 1 hour by air, and airline schedules allow Houston researchers to fly to Brownsville in the morning and back by dinner.) These introductions have produced several papers and grant proposals on underdiagnosed high incidences of heart disease and fatty liver disease in Brownsville. The HRC recently received state funding to expand the collaborations and held a 2-day meeting with potential collaborators from across the state. Thirteen papers and 8 grant proposals are planned. Using institutional and state funds, the CCTS also supports a mobile clinic in the Brownsville area, providing free medical assistance to the indigent and uninsured. Plans are under way to use this van to collect research data. In addition, the University of Texas System funded an expansion of the Brownsville CRU to three communities, to extend research on the health issues of the Texas border communities, which are some of the poorest in the nation. This unique strength of our CTSA is a model for increasing research into the expanding Hispanic community—our largest growth population.

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UTMB

Abstract 1: Advance Innovation in Education and Training Programs

Advanced innovations in translational research education and training: integration of translational training programs with the Multidisciplinary Translational Team

Ameredes BT, Hellmich MR, Carter M, Cestone CM, Carr M, Watowich S, Anderson K and the UTMB CTSA (Brasier AR, PI)

Problem/Challenge: Translational biomedical science is an emerging discipline with the specific goals of speeding the discovery of novel treatments and advancing public health. An important challenge of this discipline is the education and training of the next generation of translational scientists.

Rationale/Approach: We postulated that the Multidisciplinary Translational Team (MTT) structure is essential for the execution of translational biomedical science, and serves as an optimal educational scaffolding for the development of translational scientists (see separate MTT abstract). To supplement this MTT-based training and focus on the acquisition of critical competencies, we implemented four specific training programs: 1) Human Pathophysiology and Translational Medicine (PhD); 2) the Translational Research Track (medical students); 3) Translational Research Scholars (postdoctoral/ junior faculty); and 4) Innovations in Entrepreneurship and Education Program (all ranks, from predoctoral students to senior faculty). A two-year Postdoctoral Fellowship in Clinical and Translational Research Ethics also broadens ethical competence and harmonizes the goals of translational science with societal expectations and concerns.

Methods: Embedding of trainees is a requirement for formation and CTSA support of all MTTs. Specific trainee participation and appropriate competency achievement was evaluated by selfassessment surveys and assessments by the program director. Translational teamwork competencies included building and managing an interdisciplinary team of scientists, advocating for multiple points of view, demonstration of group decision-making techniques, management of conflict, and management of a clinical/translational research study. The Education Key Resource also tracked and evaluated progress and success of trainees as measured by grant submissions and publication authorship.

Outcomes: In the first 3.5 years of CTSA funding, 222 trainees of all types were identified as participating in some fashion with the CTSA institution-wide. 110 trainees were directly associated with MTTs, 29 trainees were also involved in other CTSA-associated education and training activities, 12 trainees have obtained federal or other funding, 15 trainees have grants pending review, and a total of 80 CTSA trainees had 251 co-authorships across our 164 CTSA publications. All trainees indicated a high level of confidence that they had achieved the intended competencies.

Lessons Learned: We conclude that education and training within the MTT setting facilitates the attainment of important competencies and achievements in translational team science.

UTMB

Abstract 2: Formalize and Standardize Evaluation Processes for Individual CTSA and the CTSA Program

Creating a comprehensive evaluation process and model for Multidisciplinary Translational Teams

Wooten K and the UTMB CTSA (Brasier AR, PI)

Problem/Challenge: Assessing scientific teams has primarily involved analysis of bibliographic outcomes (i.e., impact of publications), patent applications, and grant funding. As team science becomes a critical approach in the evolution of translational science, there is a clear need for a better method of team evaluation, incorporating both scientific production and team dynamics.

Rationale/Approach: Much can be learned from social psychology and business management as they relate to the management of teams. Decades of research on team structure, context, leadership, dynamics, and the prediction of team effectiveness can aid our work. A significant body of such literature on team evaluation can also be used to develop metrics relevant to scientific teams engaged in translational tasks.

Methods: We employed a mixed-method approach to evaluate multidisciplinary translational teams, inclusive of traditional outcome evaluation (e.g., publications), process evaluation (e.g., team processes), and developmental evaluation (e.g., needs assessments of team members). Our mixed methods approach involved both quantitative and qualitative measures including bibliographic measures, team meeting notes, team process surveys, process observations by a team coach, scaled observations by observers, team development plans, and social network analysis. An expert panel was utilized to synthesize data. An evaluative model was developed, with a two-by-two matrix involving research/scientific factors (research plan, research generation, research communication, and progress across translational domains) as well as team development factors (team vision/clarity/goals, transformative and engaged leadership, meeting management and collaboration, and external communication and coordination).

Outcomes: A taxonomy of team types was generated, rating multidisciplinary translational teams as developmental teams, traditional teams, process teams, or exemplary teams. Of the teams evaluated, a distribution of teams was observed across all team types, with team lifetime exerting a major influence upon its classification.

Lessons Learned: Several important lessons were learned (Wooten, et al. *Evaluations in Health Professions*, in press). First, the use of multiple methods and appropriate evaluation criteria are essential in evaluating scientific teams. Second, many teams can be differentiated based on their team development/maturation, as distinct from their scientific capabilities and production. Finally, use of an expert panel to synthesize assessment information via a defined rubric is an invaluable tool in evaluating team science.

UTMB

Abstract 3: **Build on the Strengths of Individual CTSA's across the Spectrum of Clinical and Translational Research**

The Multidisciplinary Translational Team: a novel organizational structure to promote innovation in the CTSA

Calhoun WJ and the UTMB CTSA (Brasier AR, PI)

Problem: The spectrum of translational research, from T1 through T4, exceeds the skill set of individual investigators and demands contributions from a wide array of disciplines.

Rationale/Approach: We reasoned that a novel type of team structure, the Multidisciplinary Translational Team (MTT), which incorporates selected characteristics from multifunctional teams in industry, clinical medicine, and academics, could create organizational agility and accelerate the conduct of translational research in the setting of an academic medical center.

Methods: An MTT contains investigators from at least three disciplines and requires at least one trainee, leadership development plans, and a shared team vision (Calhoun et al., *CTS*, 2013). An MTT executes one or more projects that draw on the team's expertise and the CTSA's Key Resources. All groups include investigators with complementary expertise, junior members as trainees, and experts in Ethics and Biostatistics. Educational efforts are focused on the development of team competencies for all learner levels (see separate Education abstract). Team development goals and processes were established to facilitate the transformation of the group into a team with shared vision and goals, common language, and an integrative project. Some groups self-assembled with guidance and assistance from the CTSA, while others were assembled by the CTSA to address specific institutional strategic goals.

Outcomes: 13 MTTs have been developed in our CTSA's four-year history. Eight were 'legacy teams' formed at the inception of the CTSA, and five new teams have been added. The CTSA actively facilitated team development and the tracking/evaluation methods to monitor progress. In most cases, both the duration of the team and a source of stable funding were associated with scientific productivity. Team members reported acquisition of team competencies.

Lessons Learned: Based on initial efforts to promote team development, we restructured our pilot programs to provide longer-term support for MTT development, and created a mixed methods approach for evaluation and tracking (evaluating both scientific productivity and team development; see separate Evaluation abstract). Sustained MTT productivity requires the transition of project funding from the CTSA and its relatively limited resources to extramural sources of support. The MTT model fosters organizational agility and team function. Team leadership style is an important determinant of team functioning. Team membership and leadership may evolve as the needs of the project change.



UT San Antonio

Abstract 1: “Leveraging Resources for an Expanding Mission: or Doing More with Less”.

Contact PI: Robert A. Clark, MD

The University of Texas Health Science Center at San Antonio
Institute for the Integration of Medicine and Science (IIMS)

Authors: John D. Roache, Kenneth Hargreaves, and Robert A. Clark

Our GCRC grant operated within the VA Hospital for 25 years prior to CTSA funding. However, VA policies and restrictions, and the fact that it was a hospital-based unit, limited the range of investigators and research types able to receive GCRC support. CTSA funding allowed the IIMS to embrace a mission going beyond the GCRC model, but also envisioning the need to extend PCIR-like support to other clinical sites, other types of translational research, and other investigator groups not served by a VA hospital-based unit. This vision required a solution where, at diminished grant expense, we could maintain VA research while simultaneously diversifying support to other locations including a children’s hospital and other non-VA adult outpatient sites. Thus, we implemented a three-fold strategy of: 1) more transparently accounting for stakeholder resource costs and benefits; 2) negotiating with community partners to equitably engage and justify their resource contributions; and 3) instituting a Program Income System as a basis for clinical investigator service charges used to pay a portion of shared resource costs. This allowed the establishment of a CTSA-designed business model wherein resource utilization and cost are transparently accounted for so that proportional shares of resource costs could be paid from a combination of the CTSA grant, investigator service charges, and community partner stakeholders investing in research support cores at their sites. The net result was: a) maintenance of the VA-based unit with greater commitments of resource support from the VA due to the transparent recognition of research benefits to the VA; b) opening a children’s research unit at another hospital and two University-based adult outpatient units; and c) a greater than 60% reduction in NIH grant expenditure on PCIR-component support cores. Simultaneously, we surmounted the VA cyber-security restrictions on electronic data and HIPAA compliance by adapting our overall program procedures to be unique and appropriate for each clinical site and developing HIPAA and security-compliant authorizations within each institution. Lessons learned include the importance of transparent and accountable systems to rationalize resource allocation and justify resource expenditure while maintaining institutional compliance. Furthermore, these systems seem to motivate customer service, collegial support, and resource efficiency.

UT San Antonio

Abstract 2: A New Joint Translational Science PhD Program in the University of Texas (UT) System

Institute of Medicine Report Recommendation 5:
Advance Innovation in Education and Training Programs

CTSA: Institute for Integration of Medicine and Science (IIMS), San Antonio, TX
Contact PI: Robert A. Clark, MD

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Sharon P. Cooper, PhD – UT School of Public Health (San Antonio Regional Campus)

- **What was the problem/challenge?**

Translational Science (TS) graduate programs must train students to conduct research in ways that are not discipline-specific, yet tailored to research question complexities.

- **What was the rationale/approach?**

The UT System components with a San Antonio presence recognized that each had necessary, but insufficient, expertise to mount a TS PhD program on their own. In 2008, the faculty, deans, and staff from four geographically proximate UT components joined forces to develop a new joint program.

- **What was done (methods)?**

A pivotal 2009 facilitated meeting (34 faculty plus UT System representatives) identified 8 core domains:

1. Clear understanding of TS
2. Responsible research conduct
3. Expert research design and analysis in a scientific discipline
4. Collaborative team science: lead, motivate, manage
5. Multi-level cultural proficiency: organizations and communities
6. Effective scientific communication
7. TS business competence
8. Evidence-based implementation and policy

These domains and related competencies drive the TS PhD curriculum. Policies and procedures for multi-institution operations were developed and bound by an MOU, so as to facilitate smooth transitions as students move among campuses. In 2011, the TS PhD framework was approved in succession by the graduate faculty, deans, and executive leadership at each campus, the UT System Board of Regents, and the Texas Higher Education Coordinating Board.

- **What was the outcome?**

The TS PhD program's collaborative design mirrors the foundations of translational team science. New administrative procedures set precedents, providing efficient models for other distributed degree programs. Early on, formative evaluation metrics focus on student recruitment and diversity. The nine TS PhD students (2012 and 2013 cohorts) were selected from 47 qualified applicants, and include 2 physicians, 4 pharmacists, a kinesiologist, dentist, and social worker. Diverse high-quality students make the TS PhD very competitive, and assure training across the **full** TS spectrum.

- **What were the lessons learned?**

Graduate education cultures differ among schools and institutions. Patience, persistence, and network building resulted in harmonization of administrative and student policies and procedures among the partner institutions. Faculty buy-in ensures strong course offerings across campuses without compromising quality, standards, or service provided to students. Through monthly Committee on Graduate Studies meetings, faculty members learn, share, and adapt best practices to manage the TS PhD program.

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UT Southwestern

Abstract 1: **Advance Innovation in Education and Training Programs**

UT Southwestern Center for Translational Medicine
Robert Toto, MD

Challenge: Some of the major challenges in generating a robust and diverse clinical translational workforce are the training in clinical translational competencies, particularly for team based science, and supporting trainees' acquisition of mentored career grants and subsequent conversion to independent investigators.

Rationale & Approach: The UT Southwestern CTSA has previously focused on training clinician scientists who engage in patient oriented research at the mid to late phases of translation (T2, T3 and T4). In 2012, we introduced innovations in order to align with NCAT's new mandate to accelerate application of discoveries from basic laboratories into development of novel therapeutics and diagnostics.

Methods: We proposed the following:

1. Integrate and customize the existing MS in clinical science degree curriculum to include T1/phase I trial training, to align with our Institution's existing strength in T0 research, target identification and validation. We recruited many outstanding T0/T1 scientists as research mentors, allied with the Cancer Center to offer a campus-wide training colloquium on Phase I trials, and worked with the Office of Technology Development to provide introductory modules in key aspects of commercialization
2. Organize four thematic Accelerating Translation (ACTion) Affinity Groups as action "incubators" to catalyze transformative collaborations
3. Establish an integrated "mentored to independent investigator transition" program to promote the career advancement of the KL2 Scholars and their transition to independent investigators. We will intensify mentoring and formalize their experiential training as transdisciplinary mentors by pairing them with predoctoral PhD and medical students, and increase leadership training that includes negotiation, conflict management, resilience, work-life balance
4. Expand the TL1 program to train predoctoral PhD and medical students.

Outcomes: We have rallied the support of the entire Medical Center and are confident that we will be able to successfully implement the innovative changes outlined above.

Lessons Learned: (1) Align with Institutional areas of strength; (2) Increase flexibility to allow primary focus on research projects and early application for mentored career awards while in training; (3) Increase workforce diversity by including PhD translational scientists; (4) Support conversion from mentored to independent investigator through mentorship, leadership training and institutional changes.

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UT Southwestern

Abstract 2: **Formalize and Standardize Evaluation Processes for CTSA Program**

UT Southwestern Center for Translational Medicine
Robert Toto, MD

Challenge: The evaluation team addressed a long-standing tracking dilemma: investigators and students did not use a standard process to request grant-funded translational resources and services. Before this intervention, investigators could use an optional REDCap survey to request resources; however, due to survey design malfunctions, investigators rarely used this method. Requests were typically made in-person, while workflows and outcomes from requests were only tracked if the provider did so individually. In summary, no standard, automated system existed to log requests, manage workflow, or measure outcomes from CTSA resource and service requests.

Rationale & Approach: The evaluation team decided to build a software system to track progress of requests in real-time. This system would automatically track standard data points for each request, based on previously-defined metrics for all CTSA service providers.

Methods: First, the team conducted a needs assessment with students, investigators, and service providers. Next, we developed and pilot tested an internal web-based tracking prototype. Then, we developed the final product using feedback from the pilot test. After development, we marketed the tracking tool to our investigator community and offered training sessions. We also created monthly audit structures to define baseline measures for each CTSA service provider. Finally, we scheduled a six month follow-up for March 2014 to analyze audit data and compare tracking metrics to baseline measures for each provider.

Outcomes: The evaluation team now has a reliable data source to use for NCATS annual reporting and institutional benchmarking. Also, we defined standard tracking metrics to measure efficiency for all resource/service components of our CTSA.

Lessons Learned: The evaluation team learned valuable lessons from this project. In order to report trustworthy, standardized data, tracking tools must be easily accessible and user-friendly, and reporting metrics should be clearly defined. In addition, data systems should be relational to increase efficiency and reduce error. Providing a web-based resource request tool created a one-stop-shop for investigators to request CTSA services, a built-in workflow for service providers, and a centralized system to organize tracking information.

Utah

Abstract 1: **A Community-Based Partnership to Reduce Health Disparities and Promote Healthy Lifestyle Changes in Diverse Women: The Coalition for a Healthier Community for Utah Women and Girls**

Sara E. Simonsen, PhD and Kathleen Digre, MD
University of Utah Center for Clinical and Translational Science (CCTS)
PIs Don McClain MD, PhD and Carrie Byington MD

Participants:

Simonsen, Sara E.; Stark, Louisa A.; Davis, France; Lee, Doriena; Mukundente, Valentine; Napia, Ed; Nash, Ivoni; Rickard, Sylvia; Tavake-Pasi, Fahina; Alder, Stephen C.; Aiono, Heather; Ralls, Brenda; Sunada, Grant; Eisenman, Pat; Hoggard, Jenny; Johnston, Leanne; Keen, Kassy Noelle; Digre, Kathleen

Problem/Challenge: Utah women from disparity groups experience higher rates of overweight and obesity than non-Hispanic whites, with 36% of African American/Black women, 41% of American Indian/Alaskan Native women, 25% of Hispanic women, and 61% of Pacific Islander women suffering from obesity compared to 23% of non-Hispanic white women based on age-adjusted 2011 Behavioral Risk Factor Surveillance System data.

Rationale/Approach: To address lifestyle risk factors for obesity through a diverse partnership built on the foundations of community-based participatory research (CBPR), capacity-building, sustainability, and multi-directional learning.

Methods: A partnership was formed including University of Utah faculty and staff, leaders from five diverse communities (African, African American, American Indian/Alaskan Native, Hispanic, and Pacific Islander), Utah Department of Health staff, and members of the Utah Women's Health Coalition. Using an evidence-based program that has been effective in diverse communities (*A New Leaf*), we have recruited and trained community wellness coaches in each of the 5 communities, tailored coaching materials to address cultural and gender issues in these communities, and designed and implemented a randomized trial to compare the efficacy and cost-effectiveness of the coaching program. Women in the program are randomized to receive coaching through monthly activities vs. four times per year and are followed for a year. Outcomes measures include changes in clinical markers and self-reported behavior changes, self-efficacy, and changes in children's health behaviors.

Outcome: Currently, 144 women are enrolled in the study; the target is 400. Based on preliminary analysis of data from 105 women with complete baseline data, 64% of women were obese at baseline. Among 37 women who had reached the 4-month interview, 62% had lost weight, 54% reported an increase in their average weekly physical activity time, and 57% reported an increase in their average daily fruit/vegetable servings.

Lessons Learned: Use of community wellness coaches provides a promising, sustainable approach to support goal setting and healthy lifestyle change among women from disparity groups. Strong collaboration through a CBPR framework and a partnership between diverse communities, university and health department personnel and coalition members has facilitated multi-directional learning, capacity building, and the development of a promising community-based intervention.

Funding: Primary: HHS Office on Women's Health, grant 1CCEWH111018-01-00. Additional: NIH NCATS grant 8UL1TR000105 (formerly NCRR UL1RR025764) and the University of Utah.

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Utah

Abstract 2: **Development of an effort analysis tool for new protocol evaluation**

J. Robinson Singleton, MD

University of Utah Center for Clinical and Translational Science (CCTS) (PIs Don McClain MD, PhD and Carrie Byington MD)

Problem and rationale: The Utah CCTS Clinical Services Core (CSC) routinely operates near capacity with regard to both bed availability and nursing effort. The Utah CCTS Program Income Plan specifies that protocols supported by industry and extramural grants repay a portion of CSC cost based on hourly use. Investigators need to include these costs in proposed budgets, but are often unaware of, or dramatically underestimate the nursing effort and CSC bed time necessary for performance of their protocol.

Methods: The CSC developed a process for effort analysis now applied to every proposed CSC protocol. At the core of this process is a face-to-face meeting between the prospective Investigator and the CSC nurse manager to evaluate nursing effort, total CSC visit time, and other required services for the proposed protocol. Through an iterative process, the CSC developed an Excel-based Nursing Effort Analysis Tool (NEAT). The NEAT is comprehensive with regard to CSC services, and flexible enough to account for inpatient and outpatient protocols with multiple visit types and intensities. A NEAT meeting is now encouraged at the earliest stage for studies that may use the CSC, and required for Investigators seeking extramural support for their CSC protocol.

Outcome: Protocol effort analysis has been in use for six months, with 35 prospective CSC protocols reviewed using this mechanism. NEAT estimates are used by the PIP Administrator to estimate true cost for each study, and incorporated as promised CCTS subsidy to protocols seeking extramural grant funding in a CCTS Letter of Support. Total bed time and nursing hours estimates now constitute an important aspect of adjudication for prospective protocols by the Utah CCTS Internal Advisory Committee. Going forward, true CSC visit and nursing hours will be compared to NEAT estimates for new CSC protocols three months after study initiation to validate NEAT estimates and improve the effort analysis process.

Lesson learned: As more protocols are approved incorporating effort analysis, aggregate NEAT estimates will be used to model CSC capacity and nursing workflow. The Utah NEAT is available for use or modification by interested CTSA sites.

Utah

Abstract 3: Collaboration on Clinical and Translational Research Training for Basic Scientists

Carol Sweeney, PhD and Dean Y. Li, MD, PhD

University of Utah Center for Clinical and Translational Research (PIs Don McClain MD, PhD and Carrie Byington MD)

Problem and rationale: Basic scientists are vital members of translational research teams. Based on the premise that training in clinical research topics is needed to support basic scientists integrating into translational science, the Utah Center for Clinical and Translational Science (CCTS) collaborates with several academic departments at the University of Utah (UU) and with the Howard Hughes Medical Institute (HHMI) on the innovative UU Med to Grad Program (U2M2G). This program is designed to fill an unmet need to provide PhD-scientist trainees with sufficient background and experience to become translational scientists. The U2M2G mission is to transform basic-science graduate education by integrating medically-relevant courses and other experiences into pre-doctoral training.

Methods: Participants in the U2M2G are selected through a competitive application process. The 19 U2M2G scholars to date who have enrolled in the MSCI concurrently with their PhD are drawn from 7 different departments including Human Genetics, Pharmacology and Toxicology, and Neuroscience.

CCTS leadership worked to integrate the U2M2G with the CCTS-based MS in Clinical Investigation (MSCI) degree. Pre-doctoral students take certain courses, for example Biostatistics, Methods for Clinical Trials, and Biomedical Research Ethics, alongside physician-scientist trainees. Additional courses have been developed specifically for U2M2G scholars, including Physiology and Medicine for the Molecular Biologist and Animal Models of Human Diseases. The annual 2-day Translational Medicine Symposium sponsored by the CCTS, U2M2 and the UU Entrepreneurial Faculty Scholars is a novel strategy for innovation across disciplines. The theme for 2012 was *Bench to Business: Implementing the Problem to Product Paradigm*. Participating U2M2G and MSCI trainees attended sessions with mentors from medical, industry, regulatory, legal, and technology backgrounds to develop and present effective summaries of their translational research.

Outcome: The three students who have completed their PhD and MS in Clinical Investigation have all accepted post-doctoral positions with clinical and translational research groups, specifically two in pediatric research and one in a cancer center.

Conclusion: The CCTS and U2M2G have catalyzed an integrated translational training environment, involving clinician-scientists, basic scientists, and others to form new connections and synergy for translational research.

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Vanderbilt

Abstract 1: **BioVU: Tools for Building Genomic Medicine Infrastructure for Translational Science**

CTSA:Vanderbilt University

PI: Gordon R. Bernard, MD

BioVU is Vanderbilt University Medical Center's (VUMC) repository of DNA linked to de-identified clinical records. BioVU uses an "opt-out" model based on guidance from the federal Office of Human Research Protections that discarded samples can be used for biomedical research without prospective consenting if the clinical records are de-identified. Stakeholders across VUMC were engaged in development, including experts in biomedical informatics, ethics, research subject protections, privacy/security and clinicians as well as members of the community. Community engagement through surveys, focus groups, interviews and a Community Advisory Board provided crucial feedback regarding the opt-out mechanism. BioVU samples are accrued without an *a priori* disease focus, therefore reducing ascertainment bias and broadening the opportunities for research. There are **175, 000** samples linked to de-identified health records in the "Synthetic Derivative". The Synthetic Derivative (SD) is the de-identified version of the VUMC electronic medical records (EMRs). The EMR infrastructure at VUMC is a rich source of clinical data that includes structured and unstructured data, there are **2.2** million unique patient records in this database. Clinical data are de-identified to remove HIPAA identifiers and events are date shifted up to one year in the past using a randomly generated number, however temporal correlations within the same record are preserved by fixing the amount of date shift constant for any given record. Due to date-shifting algorithms, studies that have a seasonal component or are linked to an event in real time are not possible within the SD. The third component is the genotypic data. BioVU requires investigators to re-deposit all genetic data generated from BioVU samples so that the data are available to other investigators. A benefit of this policy is that all other VUMC investigators can access this existing genome-wide genetic data at no cost. There are 36 billion genotypes accumulated to date. These data can be used to generate pilot data to strengthen external funding applications and support participation in consortia that would otherwise require new significant resources. There are currently 54 active projects using BioVU/SD and 181 using the SD alone.

Vanderbilt

Abstract 2: **A systems-based approach for resource and publication tracking and monitoring to support compliance with the NIH Public Access Policy**

CTSA:Vanderbilt University

PI: Gordon R. Bernard, MD

Publications in peer reviewed journals provide one measure of scientific productivity. At the program level, publication tracking provides evaluative data necessary to guide prudent stewardship of federal, foundation, and institutional investments by associating scientific return with types and amounts of support provided. We developed a method for identifying and attributing recently published journal articles with a known pool of researchers receiving support from Vanderbilt's Clinical and Translational Science Award (CTSA) program grant (including investigators from Vanderbilt and Meharry Medical College). Since implementation, we have: 1) seen a marked increase in publications ascribing CTSA support; 2) captured at a more granular level the relationship between specific CTSA resources/services to scientific output; 3) maintained an increased awareness of our scientific portfolio; and 4) increased efficiency in compiling required annual NIH progress reports. Our publication-centric framework also facilitated rapid development and deployment of a new tool to assist investigators with the NIH Public Access Compliance policy. Although the policy has been in effect since April 7, 2008, recent changes aimed at improving compliance imposed new sanctions for non-compliance. With a new sense of urgency to assist investigators with publication tracking and monitoring we reviewed existing architecture to determine the best implementation strategy. Starting with data from the NIH Public Access Monitor, a web-based tool developed by the NIH and released in January 2013 to assist institutions with monitoring public access compliance, we compare and combine it with data available from Vanderbilt's CTSA portal (StarBRITE) and the Vanderbilt Office of Sponsored Programs, displaying it in a more user-friendly format and making it more readily accessible. We also pre-populate dashboards for PIs and designated Administrators displaying all publications and associated compliance status for their respective grants and allow individuals to sign up for weekly notifications of any non-compliant publications in their dashboard. This process is especially useful in order to rapidly become fully compliant with NIH rules at the time of grant submissions. At the in person meeting we will present our methodological framework and workflow, measures of impact, and a set of practical lessons learned to inform others considering a systems-based approach for resource and publication tracking including compliance status.

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Virginia

Abstract 1: **Creation of a consortia of informatics core resources for clinical research**

PI/ Institution: John Clore/Virginia Commonwealth University

Problem Challenge:

Need to collaborate with other Health/Research Institutions that utilize a common electronic medical record system (Cerner) to increase cohort discovery and enhance clinical and translational research collaborations opportunities. Partnering with other Cerner clients can be misinterpreted (or confused with) partnering with Cerner and becomes politicized.

Rationale/Approach:

Identify other CTSA institutions that utilize Cerner and lead efforts towards developing a Consortium dedicated to collaboration and developing new strategies to enhance research subject recruitment. This is of particular interest because Cerner is extremely customizable. Individual sites often develop unique applications and lessons learned in addressing those unique solutions toward a common platform would be of value to the entire CTSA consortium across other HER's.

Methods:

The VCU CTSA reached out to a number of Cerner-specific CTSA's and several agreed to enter into more formal arrangement including Penn State, University of New Mexico and Missouri to form a CTSA consortium. These sites were chosen in part because of common applications identified at all sites (e.g. Redcap, i2b2, DeID). Discussions included CTSA PI's, Medical School Deans, Informatics Core Directors, Administrative Directors, IRB Directors and CTSA Communication Specialists. Emphasis was placed on potential areas of collaborations.

Outcome:

MoU signed with Penn State to begin consortium collaboration and development. Collaborations with UNM on a Community Engaged Research (CEnR) proposal resulted in identification of new ways to standardize ambulatory EHR use at our site and enhance CEnR. An application for external funding is now pending from VCU, UNM and MU which will demonstrate our ability to recruit diverse patient populations to clinical research.

Lesson Learned: Efforts to identify common informatics infrastructure can result in enhanced collaboration and improved methods for conduction of clinical investigation.

Virginia

Abstract 2: **Establishment of a federation for community engaged research**

PI/ Institution: John Clore/Virginia Commonwealth University

A key CCTR CEnR activity has been to establish a Working Federation of leaders from VCU centers and institutes participating in CEnR. The impetus for developing the Federation came from the 2011 EAB visit. Initially the Federation was composed of high level faculty from the different schools at VCU.

Problem Challenge:

The CCTR and Division of Community Engagement (DCE) individually have limited resources to support CEnR. During the CCTR's annual review, the external advisory board recommended tripling the CCTR's CEnR budget. There is a tremendous amount of CEnR activity at VCU with a range of community partners, but projects are inadequately identified and coordinated. There is limited infrastructure outside of grant funded projects available to cultivate, support, and maintain relationships between researchers and community partners.

Rationale/Approach:

Combine resources across VCU to help promote, coordinate, and prioritize CEnR at VCU.

Methods:

The Working Federation has partnered with the DCE to promote CEnR, identify CEnR activities, and explore collaborative opportunities. These activities have included development of a pipeline of communication between VCU and community partners (e.g. establishing a Community Review Board, creation of a virtual community of partner organizations and researchers in VIVO), professional development and training (e.g. CEnR Mini Institute, IRB panel member training, CEnR Interest Group), and importantly the documentation of CEnR activities across VCU. Efforts to grow and maintain academic-community relationships through competitive internal pilot grants, infrastructure support, and bridge funding are taking place. The federation as also linked activities with public health improvements throughout the Commonwealth

Outcome:

CEnR is now one of a handful of high priority university strategies. Identification of CEnR investigators and community partners has resulted in focused efforts and application of robust research methodology.

Lesson Learned:

Attempts to be too inclusive result in an initial push-back by stakeholders which is best overcome by careful selection of individuals who are focused more on CEnR methods.

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Washington Univ in St. Louis

Abstract 1: Center for Applied Research Sciences Value Stream Mapping

Bradley A. Evanoff, MD, MPH
Institute of Clinical and Translational Sciences (ICTS)
Washington University in St. Louis

Challenge: The Washington University (WU) Institute of Clinical and Translational Sciences (ICTS) Center for Applied Research Services (CARS) supports interdisciplinary, translational research by operating three independent but interrelated research units: 1) a Clinical Research Unit, which includes the Lifestyle Intervention (diet and exercise) core, for complex in- and outpatient studies in adults; 2) a Clinical Trials Unit, an outpatient research facility for large volume, lower-intensity clinical trials; and 3) a Pediatric Clinical Research Unit. Increasing operation costs without a concomitant increase in funding makes it difficult to maintain or grow the number and quality of services available to investigators.

Approach: The CARS initiated a *LEAN* process improvement assessment (originally pioneered by Toyota manufacturing to preserve value with less work and cost).

Methods: The CARS organized a 2½ day *LEAN* event facilitated by two experienced *LEAN* coaches which brought together members of the CARS leadership team, research unit managers, nurses, dietitians, and technical support personnel to analyze the flow of materials and information and identify key action items to help improve work flow efficiency.

Outcomes: During the *LEAN* event, 22 action items (12 high priority to address immediately, 6 moderate and 4 low priority items to address in the future) were identified to help save time by streamlining work- and information flow, and eliminate waste (e.g., redundancy or misinformation) and improve quality of services. “Owners” responsible for the completion of each action item were assigned. Seven of the 12 high priority items were completed within 3 months, which included phasing out one technical support position and combining nursing and dietary resource request and scheduling systems. The *LEAN* event also boosted employee morale through engaging staff participation during the 2½ day event.

Lessons Learned: A relatively small investment of funding and time for the *LEAN* event resulted in significant workflow improvements and helped identify key performance indicators and areas for significant cost savings to help maintain value with limited financial resources. The process also provided the leaders with important management tools and metrics to repeat effective value stream mapping at regular intervals.

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Washington Univ in St. Louis

Abstract 2: **Community/University Health Research Partnership**

Bradley A. Evanoff, MD, MPH
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Washington University in St. Louis

Challenge: In open forums hosted by the St. Louis Regional Health Commission, community members expressed dissatisfaction with the relationships and power dynamics between university health researchers and local communities and community-based organizations (CBOs).

Approach: Informed by experiences at other CTSAs, ICTS partners Washington University (WU), Saint Louis University (SLU), and BJC Healthcare created an action plan based on key elements discussed in community forums, including:

- Building sustained relationships over time with CBOs
- Sharing grant resources when in partnership with CBOs
- Including community members in planning and decision-making as “co-creators” of research projects
- Sharing knowledge gained from research with CBOs post-grant

Methods: The ICTS, WU, SLU and BJC established and co-funded a new Community/University Health Research Partnerships program (CUHRP) to fund research on health problems of importance to St. Louis communities, and to foster collaborations between universities and CBOs. Applications required co-leadership and shared funding between an academic investigator and an investigator from a CBO. The St. Louis Regional Health Commission managed the selection process and awarding of \$1.5M in grant funds contributed by the ICTS, WU, SLU and BJC; the ICTS provided training and research resources to awardees.

Outcomes: Since 2010, 15 awards ranging from \$5,000 to \$200,000 have been made to 14 different CBOs and their academic partners. An external evaluation performed in 2011 concluded that CUHRP strengthened partnerships and facilitated the creation of new relationships, and that CUHRP demonstrated a significant effort to bridge the gaps between medical centers and CBOs in St. Louis. Funded projects have started to show findings relevant to community health, and some CUHRP grantees (and unsuccessful CUHRP applicants) have received external funding to continue these new partnerships and projects.

Challenges/Lessons Learned: 1) The multifaceted intentions of the CUHRP program resulted in confusion among applicants. 2) The logistics of establishing and managing such a program is time and labor intensive for all parties. 3) There was a large initial infusion of funds from ICTS partners to establish the CUHRP grants program, but sustainability of the program and of individual funded projects is uncertain.

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Washington Univ in St. Louis

Abstract 3: Human Imaging Unit

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Institute of Clinical and Translational Sciences (ICTS)
Washington University in St. Louis

Challenge: Access to specialized expertise and expensive technologies is often confined to relatively small and homogenous groups of researchers. In a local example, the Mallinckrodt Institute of Radiology (MIR) at Washington University (WU) is nationally recognized for medical imaging research; the vast majority of imaging research at WU was conducted by investigators in only two departments (Radiology and Neurology).

Approach: CTSAAs can efficiently promote interdisciplinary translational research by lowering barriers and “democratizing” access to existing research resources.

Methods: The ICTS created a new Human Imaging Unit (HIU) in partnership with MIR to improve access to imaging facilities and services, particularly for investigators lacking experience in medical imaging. The HIU provides a centralized imaging “portal” for investigators, enabling investigators with little or no imaging experience to incorporate imaging into their protocols. The HIU provides: 1) improved access to imaging technologies, services, expertise, and regulatory support; 2) tailored assistance with experimental design and protocol development; 3) simplification of data acquisition and analysis; 4) customized educational opportunities; 5) joint pilot funding through MIR and the ICTS.

Outcomes: Formation of the HIU has dramatically changed how imaging knowledge and expertise is shared across research disciplines at WU. Six years after formation of the HIU, more than 50 departments and divisions are using HIU facilities to incorporate imaging into clinical and translational research, with the most users coming from Internal Medicine (21%), Neurology (17%), Radiology (17%), Psychiatry (9%), Surgery (9%), and Pediatrics (7%).

Lessons Learned: Relatively small investments of funding and goodwill can dramatically broaden access to existing research resources and expertise, prompting a mutually beneficial collaborative cycle. The leadership of the WU HIU contributed to the CTSA Consortium Imaging Working Group (IWG), which was disbanded several years ago. The HIU leadership is now working to form a smaller consortium of imaging experts among the six CTSAAs that comprise the SPIRiT consortium. We hope that formation of a SPIRiT IWG will provide a forum for interaction between CTSA institutions to further promote collaborative research using imaging technologies.

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Yale

Abstract 1: **Empowering the Community to Improve Research**

PI: Robert Sherwin

Institution: Yale University

The Challenge: To build strong, mutually beneficial partnerships designed to actively engage the local community in clinical and translational research

Rationale: For many years clinical research at Yale suffered from lack of a positive relationship with the local community. Too often community relationships ended with the grant-funding period, creating additional divides with community partners.

Methods: The Yale Center for Clinical Investigation or YCCI) recognized that broadening community research participation involved not only linking investigators directly to resources in the community, but that a bidirectional dialogue was needed to ensure research was important to and addressed the needs of the community. To facilitate this, YCCI has partnered with JUNTA for Progressive Action, the oldest Latino community based non-profit organization in New Haven, and the African Methodist Episcopal Zion (AME Zion) Church, New Haven's oldest African American congregation, to ensure that clinical trial participation reflects the diversity of New Haven's population.

Outcome: Representatives of JUNTA and AME Zion Church serve as YCCI cultural ambassadors. They meet with Yale faculty and staff monthly to discuss issues important to the local community and act as expert resources, advising investigators on project development, protocol design, how best to raise awareness of clinical research, and to engage the community. Cultural ambassadors are available to: participate in projects, community engagement activities and community events designed to promote and increase participation in clinical trials; assist in the development of recruitment plans and protocols for specific trials; and provide translation services for informed consents and other materials into Spanish. For the past 3 years the YCCI and community leaders have been meeting monthly for two to four hours discussing community needs and/or upcoming projects.

The Lessons Learned: Open and continuing communication is required to maintain relationships with community leaders. YCCI first had to address many misperceptions about Yale and clinical research as well as address the history of research misconduct related to minority participants to gain the trust of the new partners. This was accomplished through an intensive training on topics such as the importance of clinical research, how it is conducted, and protections for human subjects.

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Yale

Abstract 2: **Breaking Down Silos**

PI: Robert Sherwin

Institution: Yale University

The Challenge: To build strong, mutually beneficial partnerships with other Yale programs actively engaged in clinical and translational research

Rationale: Partnerships offer the opportunity for the CTSA program to demonstrate both locally and nationally the benefits and strengths of CTSA's and NIH Institute/Centers working collaboratively to advance their research missions.

Methods: The Yale CTSA's (the Yale Center for Clinical Investigation or YCCI) has jointly funded research infrastructure and pilot grants with other NIH Centers.

Outcome: The most comprehensive collaboration has been with the Yale Cancer Center, which has many similar priorities and needs. The two centers have merged many aspects of their management structures for clinical trials, including financial administration (budgeting, contract negotiations, and billing systems) and staff support (protocol development, data management, and IND applications). There has also been a combined effort to implement electronic clinical trial management and data capture systems. Additionally, a joint quality assurance program is in place, and we have integrated support staff for scientific and safety review committees. Besides merging support functions, the two centers share faculty leadership and jointly launched and invested in core resources, including biostatistics, genomics, and *flow cytometry*. YCCI and the Cancer Center have further collaborated with the Yale IRB to streamline the protocol approval process; to fund pilot grants; to establish training programs for faculty, physicians, and staff conducting clinical trials; and are now working together to expand efforts in minority recruitment for clinical trials. Another example is the collaboration between YCCI and the DK-funded Diabetes Research Center. They are jointly funding new interdisciplinary pilot grants as well as a new Translational Research Core to provide nursing support and training for complex metabolic studies, a database for patient recruitment, and a diabetes-focused biostatistician.

The Lessons Learned: The best way to accomplish our mission in the face of current budget cuts, is to partner with NIH-funded Centers; university departments, centers, and schools; the community; foundations; and other CTSA's. Clearly, our ability to create and maintain such collaborations will depend upon YCCI's capacity to offer value-added resources and to be the "home" for clinical and translational research.

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