CTSI: Driving Entrepreneurial Culture

Y2 Progress Report

Micheal Palazzolo, William Ouchi, Steven Dubinett
Discoveries to Products

Metric-Driven Translational Process

Linking research efforts, translational capabilities and program outcomes
Mar 4: The Business of Therapeutics
Apr 1: Process Mapping
May 6: Targets and Biomarkers
Jun 3: Therapeutic Antibodies
Jul 1: Small Molecule Drug Development
Aug 5: Strategic Planning
2013 Business of Science Venture Competition Finalists

• “Video-Guided Chest Tube Insertion System”
  - Robert Cameron MD

• “Improved Cast”
  - Ben Wu DDS, PhD; Emily Loughran, MBA

• “Superalarms - Predictive Combination of Alarms”
  - Xiao Hu, PhD

• “Breast Support and Immobilization Device for Radiotherapy”
  - Ke Sheng, PhD

• “3D Transurethral Catheter-Based Ultrasound System for Multi-Modal Fusion in Prostate Imaging”
  - Martin Culjat, PhD
• **CTSI’s Role: Drive Translation**

• **CTSI Interactions in Ecosystem**
  – Planning with William Ouchi and James Economou
  – Mentoring
  – Drug Discovery Seminar Series with other members of the CTSI
  – U54 Collaborators (Other UC campuses)

• **Approach**
  – Each partner is likely to want to choose its own business strategy but it is to everyone’s advantage to share information, insight, capabilities

• This presentation is meant to be informative and to stimulate discussion on how to collaborate within the CTSI
James Economou’s Vision for UCLA in the 21st Century

• Engines of scholarship, research, and teaching
  • Technology Transfer a major activity
  • Robust industry partnerships
  • Culture of entrepreneurship

Adapted From Presentation of VCR J. Economou
William Ouchi’s Analysis – UCLA Underperforming in Key Metrics of Entrepreneurship

<table>
<thead>
<tr>
<th>Invention Disclosures (#/$/1M research)</th>
<th>Industry Sponsored Research (% research expenditures)</th>
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<tbody>
<tr>
<td>CALTECH</td>
<td>COLUMBIA 16.1</td>
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<tr>
<td>STANFORD</td>
<td>USC 12.0</td>
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<tr>
<td>COLUMBIA</td>
<td>HOPKINS 7.9</td>
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<tr>
<td>MIT</td>
<td>STANFORD 7.2</td>
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<tr>
<td>UCLLA</td>
<td>MIT 6.8</td>
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<tr>
<td>USC</td>
<td>MICHIGAN 5.0</td>
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<td>MICHIGAN</td>
<td>UCLLA 2.9</td>
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## Ecosystem for Entrepreneurs

<table>
<thead>
<tr>
<th>Traditional View</th>
<th>New View</th>
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<tr>
<td>• Avoid Risk</td>
<td>• <strong>Manage Risk</strong></td>
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<tr>
<td>• Scientific Discipline</td>
<td>• Scientific Discipline plus <strong>Market</strong></td>
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<td>• Diffuse Accountability for Commercialization</td>
<td><strong>Discipline</strong></td>
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<td></td>
<td>• <strong>Board</strong> with Fiduciary Responsibility for</td>
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<td></td>
<td>Commercialization</td>
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Use Traditional Strategies but Incubate High Value Programs to a Point of Maximal Return

University Research

Tech Transfer Office

Venture Capital

Biotech

PHARMA

SOCIETY

TRADITIONAL HANDOFF

NEW VALUE TRANSITION POINT
Campus Share Xtandi Royalties

$141.5 Million over next 5 years from just one therapeutic
Implementing the Ecosystem

• User friendly conflict of interest guidelines

• 800,000 sq. ft. medical incubator on campus

• New nonprofit corporation recently approved by the UC Regents headed by business people to develop all UCLA intellectual property
<table>
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<tr>
<th>Into the Incubator?</th>
<th>Out of the Incubator?</th>
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<tbody>
<tr>
<td>• Major platforms</td>
<td>• Inventions with commercial value</td>
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<td>• Unanticipated breakthroughs</td>
<td>• Inventions that meet national priorities</td>
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Specific Aims

• Promote effective use of current cores
• Create new cores
• Educate CTSI user base
• **Strengths**
  – Voucher system for use of institutionally supported cores is reasonable and quite efficient

• **Weaknesses/Challenges/Opportunities**
  – Web portal user dashboards that enable faculty to track expenditures vs. awarded vouchers
    • Not feasible due to IT and accounting infrastructure limitations
Core Voucher Program

Shift from direct core subsidy to support for user defined need

• Process
  – Investigators formulate translational projects and apply for support
  – Applications are peer reviewed
  – Awards for requested core services made by merit
    • Emphasis on innovation

• Intent
  – Give investigators what they need ASAP
  – Quicken feedback loop between services/technologies being offered and what is needed
  – Incentivize investigators to engage in translational research
Successful Integration of the Application Process

Application process which was parallel in 2012 was successfully integrated in 2013

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<th>Jan</th>
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<th>Mar</th>
<th>Apr</th>
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<th>Jul</th>
<th>Aug</th>
<th>Sep</th>
<th>Oct</th>
<th>Nov</th>
<th>Dec</th>
<th>2013</th>
<th>Jan</th>
<th>Feb</th>
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<tbody>
<tr>
<td>Westwood</td>
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<td>CSMC</td>
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<td>LA-BioMed</td>
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<td>CDU</td>
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Scalable review process was developed

Phase 1 Review

Phase 2 Review

Centralized Intercampus Submission & Review Processes

384 applications received in 2012
112 proposals funded
$1,053,488 awarded
<table>
<thead>
<tr>
<th>Campus</th>
<th>Cumulative (2012)</th>
<th>Intercampus (2013 Round 1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Westwood</td>
<td>74 awards $686,613</td>
<td>34 awards $322,243</td>
</tr>
<tr>
<td>CSMC</td>
<td>16 awards $148,216</td>
<td>16 awards $157,880</td>
</tr>
<tr>
<td>LA-BioMed</td>
<td>17 awards $173,000</td>
<td>7 awards $68,950</td>
</tr>
<tr>
<td>CDU</td>
<td>5 awards $45,659</td>
<td>2 awards $20,000</td>
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### Vouchers Awarded – By Group

<table>
<thead>
<tr>
<th>Investigator Group</th>
<th>Fraction of Total Awards</th>
<th>Application Success Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Young Investigators</td>
<td>0.44</td>
<td>40.4%</td>
</tr>
<tr>
<td>Not-so Young Investigators</td>
<td>0.54</td>
<td>24.3%</td>
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**Fraction of Total Awards**

\[
\text{Fraction of Total Awards} = \frac{\text{# of awards by investigator group}}{\text{Total # of awards}}
\]

**Application Success Rate**

\[
\text{Application Success Rate} = \frac{\text{# of awards by investigator group}}{\text{Total # applied in investigator group}} \times 100
\]
Utilization of Cross-Institutional Core Resources

Number of awarded requests that utilized core resources at partner institutions

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2013</th>
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<tbody>
<tr>
<td>Westwood</td>
<td>1 (LA-BioMed core)</td>
<td>0</td>
</tr>
<tr>
<td>CSMC</td>
<td>2 (UCLA cores)</td>
<td>2 (UCLA cores)</td>
</tr>
<tr>
<td>LA-BioMed</td>
<td>12 (UCLA cores)</td>
<td>4 (UCLA cores)</td>
</tr>
<tr>
<td>CDU</td>
<td>8 (UCLA cores)</td>
<td>2 (LA-BioMed cores)</td>
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MOU in development to standardize pricing for CTSI investigators across all sites.
Utilization of Voucher Awards

Investigator follow up:
- Rate your core(s)
- Customer service awards

Utilization Rates
- 78% (WW)
- 89% (CSMC)*
Impact Assessment

• Individual Investigator level
  – Manuscripts, Abstracts, Presentations
    • Submitted
    • In print
    • Conferences
  – Patent applications
  – Grant applications/awards
  – Clinical Trials

• Research community level
  – Mine applicant/award information to trend shifts towards translational research
CTT Voucher Program Award Diversity at Westwood

Westwood Round 1

Westwood Round 2

Westwood Round 3
Development of New Cores

- Core Driven
  - Collaboration with Chancellor’s Shared Resource Consortium

- Investigator Driven
  - Identification through voucher review process
  - In development
    - Wireless Health Institute (Dobkin, Kaiser & Sarrafzadeh)
    - CURE: Digestive Diseases Research Center – Animal Core (Tache)
Educational Workshops

- 4 educational workshops in partnership with industry and technology cores were held at Westwood and videoconferenced at the partner institutions

- Over 150 investigators attended

- Opportunity to learn about latest technological advances in translational research, core services, and the CTT Voucher funding mechanism
Future Foci

• Decrease time from RFA end to Notice of Awards
  – Current: 6-8 weeks
  – Target: 4-5 weeks

• Devise mechanism for effectively providing investigator feedback
  – Stimulating innovation
  – Incentivizing translational research options

• Active tracking
  – Core/award utilization
  – Investigator impact
Pilot and Collaborative Clinical & Translational Studies Program

Y2 Progress Report

Leonard H. Rome, PhD
Program Area Leader, Pilot
Review of Program Area Goals

• Advance collaborative, translational research through broad-ranging funding mechanisms

• Develop novel clinical and translational technologies and methodologies

• Enable the next generation of faculty to establish careers in team-based clinical translational research

• Recruit at least 30 new CTSI translational research faculty over the next five years
## Pilot Programs

<table>
<thead>
<tr>
<th>Pilots</th>
<th>Team Building</th>
<th>Proposal Development</th>
<th>Proof-of-Concept</th>
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<tbody>
<tr>
<td>Junior Faculty Mentored Awards</td>
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<tr>
<td>Team Science Awards</td>
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<tr>
<td>Inter-Institutional Awards</td>
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<tr>
<td>Catalyst Grants</td>
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<tr>
<td>Novel Methods &amp; Technologies Award</td>
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<tr>
<td>Business of Science Prototype Grants</td>
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EAB Recommendations: Weaknesses/Challenges/Opportunities

Continuous review of incoming requests rather than periodic (e.g., annual) internal RFAs may better serve investigator needs, with review time proportional to size of resource requests (e.g., VU model of getting up to $2K overnight via administrative review)

- **Increased the frequency of review of our Catalyst Grant program to every 4 months.**

Consider incentivizing internal reviews by rewarding service with CTSI vouchers

- **Faculty have demonstrated compliance with our review requests**
- **Shared review responsibility with Team Science Partners**

Need to include both tech transfer (IP) along with publications as measures of success of pilot program

- **We will include IP progress and peer-reviewed publications in our measures of success**
Progress: Highlights of Y2 Activities

- Awarded 105 pilot grants in Y2

- $2.3 million direct CTSI and $1.5 million in institutional matching support

- Partnered with UCLA centers and institutes, both internal and external
  - offered 11 Team Science Awards
  - $605,000 direct CTSI support and $400,000 in institutional matching support
Progress: Highlights of Y2 Activities

- 23 Junior Faculty Mentored Awards

- 21 Catalyst Awards totaling $335,000. All catalyst awards were matched 1:1 or greater!

- Awarded $200,000 to the Rapid Response Team (RRT) to improve its grant-preparation software, catalyze collaborations and develop its administrative infrastructure

- $30,000 Prototype Award for the Business of Science program
  - supports technology development teams composed of UCLA faculty inventors and UCLA Anderson School of Management MBA students

- **Reached $26 million in new extramural funding resulting from Pilot investments**
Progress

Year 1 Pilots
- CTSI Funds: $612,275
- Other Funds: $1,066,738
- Total: 52

Year 2 Pilots
- CTSI Funds: $2,337,690
- Other Funds: $1,467,108
- Total: 105
Progress: Team Science Partners

- AIDS Institute
- JCCC
- Cardiovascular
- Cousins Center
- Psychiatry & Behavioral Science - CART
- Women’s Health Center
- RCMAR / CHIME
- School of Nursing - Patient Safety Institute
- School of Dentistry
- Center for Aging
- IMED
- OVCR Transdisciplinary Seed Grant Program
- Evolutionary Medicine
- Business of Science Center
- Department of Mental Health
- USC
- LA DHS
- University of Minnesota
Examples of Partnered Awards

• University of Minnesota CTSI & UCLA CTSI Cross Institutional Award for Health Disparities and Health Systems Change

• UCLA Clinical and Translational Science Institute—Los Angeles County Department of Health Services (LAC DHS) Collaboration Grants
  - Five one year awards up to $30,000 each

• Team Science Award in Translational Cardiovascular Science

• Business of Science Center Venture Team Competition (Prototype Grants)

• Novel Translational Technologies and Methodologies – RRT

• Developed a Team Science Award in Translational Neuroscience
  - Up to $200,000
• 11 CTSI Junior Faculty Mentored Awards were funded from 24 applications received - $30K awards

• 7 RCMAR-CHIME Scholars - $30-40K awards

• 3 DMH-UCLA Partnership Scholars – 3 fellowship positions jointly funded by DMH, UCLA and USC
Progress: Examples of Translational Research
CTSI Junior Faculty Mentored Awards

- Estrogen Deficiency and Cardiovascular Disease in Premenopausal Women.
- Acute Lung Injury and Effects of NAMPT and NAM in Modulating Lung Inflammation.
- The role of neuronal nitric oxide synthase (nNOS) in the pathophysiology of COPD skeletal muscle dysfunction.
- Metabolic Effect of Different Sources of Dietary Phosphorus.
- Investigating the Potential of Reprogrammed Pluripotent Stem Cells for Patient-Specific Cellular Therapies.
- Immunophenotyping to Differentiate Infection from Rejection in Intestinal Transplantation.
- Development of Peer-Led Smoking Cessation Intervention for Individuals with Severe Mental Illness.
- Inhibition of the lysophoshatidic acid signaling as a novel strategy for restoration of posttraumatic cartilage defects.
- Potential application of Irreversible Electroporation (IRE) in the treatment of pancreatic cancer.
- Functional Neuroimaging and Neuromodulation in Mal de Debarquement Syndrome.
- A Needle-Free Nanovaccine Against Melanoma.
- Fibrosis, Stress, and Ventricular Arrhythmias.
Year 3 Future Plans

• KL2 expansion leveraged through CTSI pilot funding, departmental and institutional matching – 5 additional junior faculty positions in Year 3, representing an expansion from 9 to 14 awards

• Philanthropic funding
Program Challenges

• Identify a sponsor for Technology Transfer and Prototype Grant program

• Help our faculty with shrinking NIH pay line (Seed Grants, Bridge Grants, Philanthropic Support)

• Identify new sources of support for Team Science Awards

• Identify new sources of support for research cores
Biostatistics and Computational Biology Program

Y2 Progress Report

Robert M. Elashoff, PhD - Leader
Steven Piantadosi, MD, PhD – Leader
David Elashoff, PhD – Leader
Andre Rogatko, PhD – Leader
## Program Organization

### Biostatistics and Computational Biology Steering Committee

<table>
<thead>
<tr>
<th>Consultations</th>
<th>Biostatistical Research</th>
<th>Biostatistical Education</th>
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<tbody>
<tr>
<td>Data analysis</td>
<td>Adaptive trial designs</td>
<td>Workshops</td>
</tr>
<tr>
<td>Study design</td>
<td>Novel statistical applications</td>
<td>Trainings</td>
</tr>
<tr>
<td>Grant-preparation assistance</td>
<td>Novel randomizations</td>
<td>MS in Clinical Research</td>
</tr>
<tr>
<td>Data management</td>
<td>Proteomic analysis</td>
<td>Dept. of Pediatrics</td>
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</table>

Biostatisticians onsite at partner institutions
June 2012 EAB Comments

• **Strengths**
  – Commitment to education and consultation is laudable (244 investigators and 260 projects in first four months), particularly for junior investigators

• **Weaknesses/Challenges/Opportunities**
  – Data management services are normally provided by Biomedical Informatics in CTSAs and potentially confusing to external reviewers
  – **Consider vouchers for biostatistical consult hours**
  – Model to build biostatistics tracking system outside of main CTSI portal with later plan to integrate into portal seems ill informed and will lead to additional R&D rework
  – **Consider initial ‘diagnostic consult’ CTSI supported, generates cost of services plan**
  – Need model for scaling up biostatistical services
• There is a very strong need for assistance with developing study databases

• Biomedical Informatics is focused on larger infrastructure database projects

• Our main service is database development in REDCap

• Having this service in Biostat makes sense as we can become involved at the earlier stages of projects to ensure proper research design, data collection tools and data management strategies
Response: Vouchers

• Partial implementation:
  – Adding biostatistics/computational biology support to high-throughput core vouchers
  – Vouchers for biostatistical services for projects exceeding threshold of free hours

• Administrative burden and time lag for smaller projects make this infeasible for all projects (~600 projects in 2012)

• Oversight of biostatistical support of projects performed by program leaders
Response: Tracking System

- TSS system developed by Biomedical Informatics program
- Biostatistics was first adopter of system
- Staff statisticians first users, providing feedback to improve implementation
- Current step: Training faculty statisticians
Typically we do have diagnostic consult at which time we identify:

- Appropriateness for CTSI
- Linking with appropriate statistical collaborator
- Possible co-funding
- Estimated hours and costs for hours above CTSI support threshold
- Prioritize junior investigators
Response: Scaling up Biostatistical Service

- Initial 3.5 FTE of staff support (UCLA/Westwood) now provides partial support for 6 newly hired statisticians.
- Partners primarily allocate support to faculty statisticians.
- Multiple models
  - Departmental support (Pediatrics)
  - Co-hiring with large projects (Rheumatology)
  - Recharge for projects exceeding free CTSI threshold
  - Inclusion on grant application budgets
Progress Aim 1: Consultation


- 580 Projects with 9372 consulting hours across four partner institutions
  - 4474 hours for data analysis
  - 824 hours for study design
  - 1763 hours for grant prep assistance
  - 1155 hours for data management

- 367 unique investigators: 31% trainees, 33% assistant professors, 36% associate or full professors

- Began computational biology consulting service
- Implemented a drop-in consulting service with an average of 2 new consults each week.
- Multiple cross-institutional consulting projects
- Collaboration between UCLA and Cedars (Elashoff/Victor) on multiple grants and manuscripts

- 427 Projects with 6355 hours for Nov. 1, 2012 through May 31, 2013

- Methods research including adaptive trials, computational biology, community studies
- **Computational Biology**
  - Co-expression network analysis
  - Integration of high-throughput datasets (miRNA and mRNA)
- **Community Studies**
  - Joint seminar series with CERP program
Progress Aim 3: Education


- Seminars on statistics in grant applications and statistical methods
- **Master’s in Clinical Research Program**
  - New course in grant writing
  - Most courses video-conferenced and archived on Moodle
  - 10 new students in 2011 and nine in 2012, along with many auditors
- **Computational Biology**
  - New course developed on microarray/Next-gen sequencing analytic methods
  - Next-gen sequencing workshop (With Pathology/Cancer Center)
- **BCB program representative on CREST committee**
- Assistance for KL2 awardees
CTSA Activities

• Consulted on projects that were joint collaborations with outside CTSI institutions.
• Participated in CTSA-BERD face-to-face meeting in April 2012/13 and BERD conference calls
• Collaborative meeting with other UC BERD programs
Future Plans

• Continue to provide collaborative services and expand the availability of our services to enhance the BSD-CDM user base

• Expand the availability of REDCap collaboration and contribute forms to REDCap library

• Continue to develop new educational materials/courses/seminars for computational biology education
Appendix: Education

MSCR program Course List

- **BIOMATH 170A**: Introductory Biomathematics for Medical Investigators (Fall, 4 units, Year 1) available via videoconference
- **BIOMATH 258**: Introduction to Clinical Trials (Spring, 2 units, Year 1) available via videoconference
- **BIOMATH 259**: Controversies in Clinical Trials (Winter, 2 units, Year 1) available via videoconference
- **BIOMATH M261**: Responsible Conduct of Research Involving Humans (Fall, 2 units, Year 2) available via videoconference
- **BIOMATH M262**: Communication of Science - Grant Writing (Winter, 2 units, Year 2) available via videoconference
- **BIOMATH M263**: Clinical Pharmacology (Spring, 2 units, Year 2) available via videoconference
- **BIOMATH 265A**: Data Analysis Strategies I (Winter, 4 units, Year 1) available via videoconference
- **BIOMATH 266A**: Applied Regression Analysis in Medical Science (Winter, 4 units, Year 1) available via videoconference
- **BIOMATH 266B**: Advanced Biostatistics (Spring, 4 units, Year 1) available via videoconference
- **Methodology in Clinical Research (3 quarter series)**
- **BIOMATH M260A**: Methodology in Clinical Research 1: Clinical Trials (Fall, 4 units, Year 2) available via videoconference
- **BIOMATH M260B**: Methodology in Clinical Research 2: Longitudinal and Community Clinical Trials (Spring, 4 units, Year 2) available via videoconference
- **BIOMATH M260C**: Methodology in Clinical Research 3: Observational Studies (Fall, 4 units, Year 1) available via videoconference
- **BIOMATH 299**: Special Topics in Clinical Research: Microarrays, Proteomics and Next-Gen Sequence Analysis (Fall, 4 units, Year 1) available via videoconference
Clinical and Translational Research Center (CTRC)
Clinical and Community Research Resource (CCRR)

Y2 Progress Report

David Martins, Leslie Raffel, Isidro Salusky, Christina Wang
Goals of the CTRC

• To broaden the scope and efficiency of clinical, translational and community research by implementing a CTRC without walls

• To promote collaboration across the CTSI partner institutions through integration of services

• To recruit junior professionals into careers in clinical and translational research
Integration of Services and Harmonization of Procedures

EAB Comment: “The services are still divided by campus; you need to develop ways for utilization of resources across the four partnering organizations.”

• Regular interactions implemented among CTRC leadership to facilitate harmonization
  – Monthly videoconference of program leaders and nurse and bionutrition managers
  – Regular face-to-face meetings of nursing and bionutritional managers
  – Increased collaboration among institutions at all levels
Integration of Services and Harmonization of Procedures

- **Standardized** nursing/bionutrition procedures/samples processing (e.g. OGTT) (website)
- **Common** cost-sharing models applied to services (website)
- **Single** utilization application process developed (website August 2013)
- **Unified** CTRC webpages live in June
- **CTRC personnel** and Office of Investigator Service facilitators assist investigators in locating CTRC services at all sites
- **Offering unique services** to serve the needs of investigators across all partners (e.g., de-identified access to umbilical cords, amnion, cord blood and placental tissue)
Examples of New Collaborations Using the CTRC

• Cedars/Harbor-LA BioMed/UCLA (Chew, Daar, Bairey-Merz, Hardy) Prospective longitudinal assessment of coinfected subjects with HIV/Hepatitis C for endothelial function study

• Cedars/Harbor-LA BioMed/UCLA (Cunningham, Hardy, Wang) Effectiveness of peer navigation to link released HIV+ jail inmates to HIV care


• Harbor-LA Biomed/UCLA (Shoptaw, Tsuang, Furst) Phase I Safety Interaction Trial of Ibudilast with Methamphetamine
Despite budget cuts (>30%) and staff reduction (9%), CTRC implemented cost-effective strategy and increased efficiency to create sustainable services.
EAB Comment: “With budget cuts likely in the future and with rapidly escalating costs of providing services, a plan for 50% cost sharing at five years may not be adequate.”

- Implement cost sharing up to 25% for 2013-2014; further increases in cost sharing based on budget estimates and number of studies
- Align service definitions and costs across all sites
- Post estimated costs for each service on the CTSI website
- Advise investigators to contact the CTRC for cost estimates before submission of grants or contracts
- Outreach to recruit industry-sponsored studies to defray costs of subsidized studies
CTRC: Safe, Efficient and Cost-Effective

• Increasing proportion of CTRC costs transitioned to non-grant sources
  – 44% of CTRC costs grant-supported (cost shifting to institution most apparent in sites with inpatient units)

• Creation of cost-effective, flexible units (e.g., 23-h unit at UCLA Center of Health Sciences)

• Partnerships developed with clinical trial units and community-based organizations
Improving Efficiency by Sharing Resources

- Harbor-LA BioMed CTRC partnered with Clinical Research Solutions (LA Biomed unit that assists investigators with clinical trial recruitment and conduct) to share resources

- CDU CTRC partnered with Community-Based Research Institute to foster community research collaboration and resource utilization for clinical trials
EAB Comment “Consider conducting a needs assessment and guide the alignment of services around that assessment.”

- Preliminary BIP and Evaluation survey in April/May 2012 showed CTRC is effective
- Work with Tracking and Evaluation and BIP (using examples from other CTSI clinical research units) to develop a UCLA CTRC specific survey to assess T1 to T4 investigators’ current and anticipated needs
CTRC and Community

- CTRC helped HCNI (70 block) project with pre-pilot, pilot and actual study resulting in 4 abstracts (Rachelle Bross, PhD, RD, Bionutritionist, Harbor-LA Biomed; L. Pitts, RN, Nurse Manager, CDU)

- Barber project involves R Victor (Cedars-Sinai), R Elashoff (UCLA), M Shapiro (UCLA), K Norris (CDU) and D Martins (CDU) and resulted in an R01 submission to the NIH in April 2013 (David Martins, MD, CDU)

- Participation in the Telemundo Salud y Bienestar (Health and Wellness) Expo organized by Spanish-language television station Telemundo to promote health and well-being for Hispanic and Latino families in LA (Leslie Raffel, MD, Cedars)
CTRC and Community

• Planning meetings underway to contribute to “UCLA – First 5 LA 21st Century Dental Home Project “ (PI Crall), which will establish dental homes in community health clinics. CTRC is exploring ways to provide research resources needed for community dental and medical research

(Carl Maida, PhD, School of Dentistry, UCLA)

• Collaboration with Weingart YMCA in South Los Angeles in development to establish a Lifestyle Intervention and Food Education (LIFE) Center

(David Martins, MD, CDU)
Recruit and Train Junior Professionals (with Education Program)

- Nurture scientists/physicians by providing varied opportunities in an incubator-like environment leading to new grant submission and awards
- Assist junior investigators with reduced cost sharing
- Recruit junior investigators into Training Program in Translational Science
- Engage medical students in Pathway on Clinical and Translational Medicine Education
- Mentor high school students in the CTRC Long Beach Polytechnic High School program
Recruit and Train Junior Professionals
(Nurture Scientists/Physicians in an incubator-like environment )

R. Edgerton PhD (Established neuroscientist) and D. Lu MD, PhD (Young neurosurgeon): Translational science project on “Spinal Cord Injury - Function of spinal cord can be modulated by neuro-enabling tools e.g., stimulation, medications, training”

- Neuromotor Recovery Research Center equipment at CTRC
- 3 CTRC-supported studies
- 1 U01 awarded and 1 R01 to be submitted 10/2013
- SBIR submission as well as grant submission to other foundations
Recruit and Train Junior Professionals  
(CTRC-Long Beach Polytechnic High School Program)

161 alumni, 99 (62%) completed survey  
77% under-represented minorities, 46% female  
69% are involved in research (majority in life sciences or medical)  
67% anticipate conducting biomedical research in the future  
78% influenced by program on choice of career

- Responded to survey: 99
- Enrolled Degree/Certificate Program: 95
- Master's Program: 11
- Medical School: 16
- Law School: 3
- PhD Program: 6

Number of Students

<table>
<thead>
<tr>
<th>Number of Students</th>
<th>Respondents</th>
<th>Degree/Cert.</th>
<th>Graduate School</th>
</tr>
</thead>
<tbody>
<tr>
<td>99</td>
<td></td>
<td>96</td>
<td>36</td>
</tr>
</tbody>
</table>
CTRC and CTSA Consortium

- Leaders participate in KFCs (Clinical Research Management, Clinical Service Core, Community Engagement and Education KFCs), national survey on CTSA clinical research units and in Annual Clinical Research Management Workshop

- CC-CHOC pediatric network for clinical trials

- CTRC laboratory and technical cores are members of the Southern California CTSI Laboratory Consortium
  - Listing of all clinical laboratory tests available at each core to be published, sharing resources within the CTSI Lab Consortium
CTRC : Future Plans

• Based on needs assessment survey, develop and prepare resources to meet the future needs of investigators

• Transform CTRC units into unique but flexible research resources to serve changing needs and environment of all our investigators

• Provide infrastructure to support multidisciplinary team science
Clinical and Translational Research Center (CTRC)
Clinical and Community Research Resource (CCRC)

Questions and Comments

David Martins, Leslie Raffel, Isidro Saluksy, Christina Wang
Goals

1. Harmonize regulatory mechanisms among the UCLA CTSI partners

2. Develop a Research Ethics Consortium
EAB Recommendations

• Uniform tracking and evaluation (with baseline data) of time to decision for IRBs and contracts for all consortium partners.

• Scheme for expediting contracting would be a useful component of CTSI.

• Consider evaluating all the steps in launching a new protocol (e.g., IRB approval, contract signature, etc.) so as to identify and correct sources of unnecessary delay.
Progress

• **IRB Harmonization**
  – multiple reliance mechanisms
  – increased use of reliance review
  – improved review time

• **Ethics** – expand consultation service, national involvement
  – 6 consultations before Oct 2012; 11 consultations since
IRB Review Statistics

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total Protocols</td>
<td>Average Days</td>
<td>Total Protocols</td>
<td>Average Days</td>
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<tr>
<td>Full review</td>
<td>495</td>
<td>75.2</td>
<td>318</td>
<td>68.6</td>
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<tr>
<td>Expedited</td>
<td>982</td>
<td>27.3</td>
<td>602</td>
<td>27.3</td>
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</tbody>
</table>

There has been a significant improvement in completion of full reviews.
CTSI Partner Relying Statistics

<table>
<thead>
<tr>
<th></th>
<th>Reviewing</th>
<th>Relying</th>
</tr>
</thead>
<tbody>
<tr>
<td>Charles Drew</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Cedars-Sinai</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>UCLA Westwood</td>
<td>8</td>
<td>4</td>
</tr>
<tr>
<td>LA Biomed</td>
<td>0</td>
<td>7</td>
</tr>
</tbody>
</table>

- 1/1/2012-9/30/12 - 4 approved reliance studies
- There has been a substantial increase in use of reliance
• **IRB of Record for Another Site**

• **Other Reciprocal Agreements**
  – UC, UC BRAID, Rand Healthcare, National IRB Share, USC, Long Beach Memorial, Research Centers for Minority Institutions

• **Relying on a Central or Other IRB**
  – WIRB, NeuroNEXT

• **IRB of Record for a Group of Studies**
  – Fast-AS, LA-Nett
**Contracts and Grants**

- **Joint project** between regulatory and evaluation programs and administration.

- Routine C&G activities are said not to be problematic. However, the **new computer system** at UCLA supports the generation of reports of throughput.

- Investigating and developing templates for the **process of funding multisite community research projects** to reduce barriers to translational research.
• Regular inter-institutional consultation discussions

• 6 before Oct 2012; 11 consultations since

• Finder now serves as a member of Cedars-Sinai's IRB Leadership Group (ILG) that deals with policy development

• Korenman and Finder are active in the national Ethics KFC
Future Plans

- Complete research Memorandum of Understanding with the West Los Angeles VA (largest VA in the US) and integrating the VA as a future CTSI partner

- Resolve the issues in funding multisite, community research

- Increase by 50% the number of approved reliance-review protocols
1. CERP/HSR Aims and Objectives
2. Responses to Selected EAB Recommendations
3. Updates on Regional and National Activities
4. Plans for Year 3
1. Promote and sustain bidirectional knowledge sharing between community and academia.

2. Strengthen academic and community infrastructure for sustainable partnered research.

3. Drive innovation in community engagement that accelerates the volume and impact of partnered research in diverse communities.

4. Build health services research (HSR) methods into partnerships to accelerate design, production, and wide adoption of evidence-based practice and behavior.
1. Opportunity to partner with LA County programs that could leverage resources for much greater impact.

2. Current metrics are mainly process, documenting infrastructure development and capacity building. What are the outcome metrics?

3. Increase focus on evaluation of programs, and identify specific metrics for success of community-engaged research partnerships, incorporating both quantitative and qualitative assessment methods.

4. Explore the role of CERP in the dissemination and implementation of evidence-based interventions; transferring knowledge from all forms of CTSA research to benefit community stakeholders and population health in a sustainable manner.
Leverage Relationships with LA County DHS & DPH for Greater Impact

**Health Impact Assessments (HIAs) with LAC DPH**
- HIAs evaluate the potential health effects of a plan, project or policy before it is built or implemented
- DPH project to streamline HIAs

**Department of Health Services RFAs**
- Joint DHS/UCLA CTSI grants to fund projects to improve population health outcomes without increasing costs

**Convened leadership of DHS (Katz), DPH (Fielding), and members of USC CTSA around high impact joint goal**
- Countywide Project on Successful Aging in Los Angeles
- Initial planning underway
Health Impact Assessments (HIAs) with LA County Department of Public Health

- Pew Charitable Trusts ($250K) – Teutsch, Kuo, Gase, USC CTSA
- The California Endowment – under review ($376K)
- CTSI proposal – Perry (DHS), Kuo, Gase ($30K)

- Goal: Streamline the HIA process through partnerships with academic institutions to obtain the needed expertise

- Objectives:
  - Conduct 2 HIAs in LA County in the next year
  - Develop infrastructure to conduct future HIAs through a partnership between UCLA CTSI, USC CTSA, DPH
### UCLA CTSI-Los Angeles County Department of Health Services (LAC DHS) Collaboration Grants

- Test approaches to allow DHS to improve and increase the delivery of high quality, patient-centered services without increasing costs
- Five awards of up to $30K each with Co-PIs at DHS and UCLA CTSI
- Potential for population health impact

<table>
<thead>
<tr>
<th>Number</th>
<th>Project Description</th>
<th>DHS PI</th>
<th>UCLA PI</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Implementation of a Primary Care-Based <strong>Teleretinal Screening</strong> Protocol for the Los Angeles County Safety Net</td>
<td>Daskivich</td>
<td>Mangione (UCLA)</td>
</tr>
<tr>
<td>2.</td>
<td>Los Angeles County <strong>Psychiatric Emergency Room Outcomes</strong> Study</td>
<td>Ochoa</td>
<td>Wells (UCLA)</td>
</tr>
<tr>
<td>3.</td>
<td>Prospective study of <strong>Asthma control, morbidity, quality of life (QOL), and health care expenditures</strong> in asthmatic children during transition from acute care at Harbor-UCLA Medical Center to community managed care organizations</td>
<td>Kwong</td>
<td>Fu (Harbor)</td>
</tr>
<tr>
<td>4.</td>
<td><strong>Obesity Group Visits</strong>: An innovative program to deliver obesity services at DHS facilities</td>
<td>Nossett</td>
<td>Friedman (CDU)</td>
</tr>
<tr>
<td>5.</td>
<td><strong>Health Impact Assessment</strong> (HIA) identifying on evidence-based programs to reduce school truancy</td>
<td>Perry (DHS) Kuo (DPH)</td>
<td>Gase (UCLA)</td>
</tr>
</tbody>
</table>
“Big Audacious Goal” for improving health in Los Angeles County

- CERP faculty convened meetings with leadership of Los Angeles County Department of Health Services (Mitchell Katz) and Department of Public Health (Jonathan Fielding)
- LAC DPH and DHS leadership decided to pursue goal of Healthy Aging in Los Angeles related to physical, emotional, and social health
- Working groups: conceptual model, interventions, funding
  - UCLA faculty, USC faculty, Community organizations, Stakeholder
- Domains to be addressed include social isolation, poor nutrition and lack of health food options, physical activity, mental health, substance abuse, prescription medication misuse, chronic disease management, built and social environment, etc.
Summary of Selected EAB Recommendations

1. Opportunity to partner with LA County programs that could leverage resources for much greater impact.

2. Current metrics are mainly process, documenting infrastructure development and capacity building. What are the *outcome metrics*?

3. Increase focus on evaluation of programs, and identify specific metrics for success of community-engaged research partnerships, incorporating both quantitative and qualitative assessment methods.

4. Explore the role of CERP in the dissemination and implementation of evidence-based interventions; transferring knowledge from all forms of CTSA research to benefit community stakeholders and population health in a sustainable manner.
Metrics: Process/Infrastructure vs. Outcomes
Expanded Outcome Metrics

Infrastructure / Process
• # of existing/new community partnerships
• # of conferences held and # of attendees
• # of training seminars/webinars on CEnR for faculty/fellows/students
• # of community research training sessions
• # of consultations*
• # of contacts/collaborations that evolve from consultations

Intermediate Endpoints
• # of research proposals led or partnered by CERP investigators
• # of awards to conduct community partnered research*
• # of scientific presentations, reports, and peer-reviewed publications
• # of products disseminated for broad community use
• # of lay health workers trained to work in underserved communities
• # of trainees, faculty actively involved in CEnR projects
• Perceptions of community partners of the CTSI’s effectiveness

Population Health Endpoints
• Enhancing DHS care and outcomes without increasing costs*
• Successful aging initiative – convened LAC DHS, DPH, USC CTSA
**Goal:** to help existing and new community partners and academic investigators incorporate community-based and health services research methods into their current and potential projects

- **Offer training and resources** in CBPR/CPPR, HSR, D & I, other methods
- **Connect** investigators and community partners
- **Advise** on study design, program implementation, and dissemination of results

<table>
<thead>
<tr>
<th></th>
<th>Year 2</th>
<th>Year 3 to date</th>
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<tbody>
<tr>
<td>Total # of consults:</td>
<td>48</td>
<td>15</td>
</tr>
<tr>
<td>General requests (intro to CERP services)</td>
<td>18</td>
<td>1</td>
</tr>
<tr>
<td>Grant or project specific requests</td>
<td>30</td>
<td>14</td>
</tr>
<tr>
<td>Number of project-specific consults per month</td>
<td>2.5 per month</td>
<td>4.7 per month</td>
</tr>
</tbody>
</table>
11 Awards (over $40 million in new funding) generated from investigators and projects funded through CTSI/CERP

- Federal Funding: CDC, NIH (NIA, NIMHD, NINDS), PCORI
- Foundation Support: California Community Foundation, PEW Charitable Trusts
- Intramural Funding: USC/UCLA Biodemography Center

- CERP co-funding for staff / community partners / projects

- Majority focus on improving health outcomes in LA County

- Topics: Disparities reduction, impact of community engaged research on chronic disease outcomes, training new investigators, community dissemination of evidence-based practices, etc.
• Funding Opportunities emphasize **improving health outcomes in public health systems, health care settings:**
  – LA County DHS and LA County DPH (6 funded projects)
  – University of Minnesota (3 funded projects)
  – New funding generated by CERP faculty and staff

• Return on Investment (ROI)
  – Component of the overall CTSI evaluation

• Social Return on Investment (SROI)
  – Seeking assistance with these analyses from the Anderson School of Management
Summary of Selected EAB Recommendations

1. Opportunity to partner with LA County programs that could leverage resources for much greater impact.

2. Current metrics are mainly process, documenting infrastructure development and capacity building. What are the outcome metrics?

3. Increase focus on evaluation of programs, and identify specific metrics for success of community-engaged research partnerships, incorporating both quantitative and qualitative assessment methods.

4. Explore the role of CERP in the dissemination and implementation of evidence-based interventions; transferring knowledge from all forms of CTSA research to benefit community stakeholders and population health in a sustainable manner.
Identified metrics for each program and project

• Impact
• Sustainability
• Scalability

Example: Hotspot analysis (Brown, Zingmond, Kominski, Shah)

• Provide reliable data to communities & investigators on chronic disease patterns and health services use at different levels of geography in LAC
• Support new funding and policy initiatives
• Linked data from:
  • Office of State Health Planning and Development (OSHPD)
  • U.S. Census
  • California Health Interview Survey (CHIS)
• Results made available to local governments and policy makers, community organizations, and residents
  • Fourteen presentations throughout LA County
L.A. County: 8 Service Planning Areas (SPAs) and 26 Health Districts

SPA 1 - Antelope Valley
SPA 2 - San Fernando
SPA 3 - San Gabriel
SPA 4 - Metro
SPA 5 - West
SPA 6 - South
SPA 7 - East
SPA 8 - South Bay
Hypertension Prevalence

Los Angeles County = 45%

California = 42%

Antelope Valley 40
San Fernando 38
San Gabriel Valley 49
Metro 50
West LA 38
South LA 54
East LA 42
South Bay 48

Definition: Ever diagnosed with high blood pressure among adults 45yrs and over; Source: CHIS 2009
Emergency department and hospital admissions for hypertension are **MORE THAN TWICE** as high in some LAC Health Districts than others.

<table>
<thead>
<tr>
<th>District</th>
<th>PQI #07 per 100,000 adults</th>
</tr>
</thead>
<tbody>
<tr>
<td>Southwest</td>
<td>381</td>
</tr>
<tr>
<td>Compton</td>
<td>349</td>
</tr>
<tr>
<td>Southeast</td>
<td>332</td>
</tr>
<tr>
<td>South</td>
<td>312</td>
</tr>
<tr>
<td>Inglewood</td>
<td>298</td>
</tr>
<tr>
<td>Bellflower</td>
<td>274</td>
</tr>
<tr>
<td>Northeast</td>
<td>270</td>
</tr>
<tr>
<td>Harbor</td>
<td>262</td>
</tr>
<tr>
<td>San Fernando</td>
<td>253</td>
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<tr>
<td>Pomona</td>
<td>246</td>
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<tr>
<td>El Monte</td>
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<td>Glendale</td>
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<tr>
<td>Long Beach</td>
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<td>West Valley</td>
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<tr>
<td>San Antonio</td>
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<td>Pasadena</td>
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<td>Alhambra</td>
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<td>Antelope Valley</td>
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<td>Hollywood-Wilshire</td>
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<tr>
<td>Central</td>
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<tr>
<td>Foothill</td>
<td>203</td>
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<td>East LA</td>
<td>198</td>
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<td>East Valley</td>
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<td>Whittier</td>
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<tr>
<td>Torrance</td>
<td>165</td>
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<tr>
<td>West</td>
<td>147</td>
</tr>
</tbody>
</table>

Definition: PQI #07 per 100,000 adults; Source: OSHPD 2007-2009
Hotspot Analysis
Dissemination and Evaluation Activities

Neighborhoods for CTSI Hotspot Analyses

- Health Districts 2012
- Service Planning Areas 2012

San Fernando Valley
- Sylmar
- San Fernando (CDP)
- Pacoima

Downtown Area
- Koreatown
- Westlake
- Magnolia Place
- Chinatown
- Boyle Heights (Building Healthy Communities)

Southwest LA
- 70 Block Project

SLACWI
- Chesterfield Square, Harvard Park & Vermont Slauson
- Manchester Square
- Vermont Knolls

South LA
- Gramercy Park
- Westmont
- West Athens (CDP)
- Vermont Vista
- Watts

South Bay
- San Pedro
- Wilmington
- Long Beach BHC (Building Healthy Communities)

Note: All areas except San Fernando, Westmont, West Athens and Long Beach BHC are part of the city Los Angeles.
Impact: Track data use (by whom, for what purposes, results)
   – Successful NIMHD R24 (Gallaway-Gilliam and Vargas; $750K)

Sustainability: Support to expand or incorporate into existing programs
   – New funding for public use small area estimates to inform local policy
   – Neighborhood Edition of Ask CHIS (California Health Interview Survey), [Kominski, $400K, California Endowment]

Scalability: Provide data/expertise for regions in and beyond LA County

Plans for Year 3:
   – Explore dynamic (interactive) mapping of estimates that can be linked to local resource availability.
   – Explore supplementation of Hotspot data with:
     • Mortality estimates from the state death master file
     • Cancer incidence rates from the state cancer registry
     • LA Data Repository (LADR)
1. Opportunity to partner with LA County programs that could leverage resources for much greater impact.

2. Current metrics are mainly process, documenting infrastructure development and capacity building. What are the outcome metrics?

3. Project Evaluation: Increase focus on evaluation of programs, and identify specific metrics for success of community-engaged research partnerships, incorporating both quantitative and qualitative assessment methods.

4. Explore the role of CERP in the dissemination and implementation of evidence-based interventions; transferring knowledge from all forms of CTSA research to benefit community stakeholders and population health in a sustainable manner.
Goals:
Expand UCLA capacity and activity in dissemination, improvement, and implementation (D&I) research in order to:
1. Enhance societal impact of UCLA research to improve health care quality, health behaviors and outcomes in and beyond LA — Harbor/LA Biomed Patient Based Research Network (PBRN)
2. Enhance UCLA competitiveness for funding in D & I
3. Contribution to national CTSA consortium

Activities:
• Education, Training, and Capacity Building
• Consultation and Technical Assistance
• Development of Tools and Resources
• Interface with other CTSI cores
Regional Collaborations

- Community Clinic Associations of California annual meeting
  - Symposium to highlight activities of the USC, UCSD, UCLA CTSA and how we can best work with community clinics
- EngageUC – UC-wide project on obtaining and sharing biospecimens
  - Deliberative Community Engagement events to obtain community perspectives on biorepositories (June 2012 in LA; Sept. 2012 in SF)
- Mental Health Fellows Program (DMH, USC, UCLA)
- Project on Successful Aging in LA County (DHS, DPH, USC, UCLA)

National Collaborations

- Exploring Trust via Concept Mapping (5 CTSA: UNC, Arkansas, Florida, Pittsburgh, UCLA)
- UCLA and University of Minnesota Cross-Institutional Award for Health Disparities or Health System Research
Future Plans

• Expand Consultation Service
  – Modify based on requested expertise, feedback from consultations
  – Develop and implement sustainability plan

• Funding Opportunities
  – Leverage CERP resources to support projects that can serve as local and national resources:
    • “Hotspot” analysis
    • EngageUC: Biobank governance project
    • Community-academic grant writing seminar
  – New collaborations with other CTSAs

• Publications
  – Process (e.g. Grant writing seminar, developing/refining consultation service)
  – Research results (Project-specific publications)

• Evaluation Metrics
  – Develop Social Return on Investment Metrics
Thank you!

Questions?
Program Goals

• Improve communication of science.
• Teach leadership to transform the health of communities.
• Improve cross-talk across the translational spectrum.
• Teach the skills needed to collaboratively accelerate drug development.
• Improve the quality of education and evaluation of the four CTSI institutions.
EAB Comments

- **Strengths**
  - Variety of training opportunities, particularly for pre-doctoral and early postdoctoral trainees.
  - Success in getting institutional support for Training Program in Translational Science (TPTS) continuity.
  - **Extension of KL2 support to other K awardees.**
  - Curriculum Tree distance education functionality is appealing.

- **Weaknesses**
  - Distance-learning technologies will need careful process and outcomes evaluation and monitoring.
  - Better internal communication plan for all programs, particularly KL2.
  - Opportunity for additional faculty-level consultation engagement in Implementation Science for projects that have a component of real-world organizational change-management.
  - Consider increased training curricula and opportunities for mid-career and senior investigators.
  - **Need to detect and compensate for ‘leaky pipeline’**
  - **Adaptive re-allocation of training resources over time.**
  - Better integration of training programs.
Extension of KL2 support to other K awardees

- Expand CTSI KL2 program with matching funds from sponsoring departments and CTSI funds to leverage resources.
- 13 KL2 Scholars after 3 years; one to be added for a total of 14
- Explore future partnerships with other health professional schools.
- PCORI/AHRQ institutional K award to expand number of faculty in CER.

<table>
<thead>
<tr>
<th>Scholars</th>
<th>Department</th>
<th>Institution</th>
<th>Type of Research</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y1</td>
<td>1 Internal Medicine, 1 Pediatrics, 1 Emergency Medicine</td>
<td>2 UCLA, 1 CDU</td>
<td>1 Basic, 1 Clinical, 1 HSR</td>
</tr>
<tr>
<td>Y2</td>
<td>1 Infectious Disease, 1 Hem-Onc, 1 Pulmonary</td>
<td>2 UCLA, 1 LA BioMed</td>
<td>2 Basic, 1 HSR</td>
</tr>
<tr>
<td>Y3</td>
<td>1 GIM/HSR, 1 Medicine, 1 Cancer Research, 1 Pediatrics, 1 Pulmonary, 2 Psychiatry, 1 TBN</td>
<td>4 UCLA, 2 Cedars, 1 CDU</td>
<td>2 Basic, 2 Clinical, 3 HSR</td>
</tr>
</tbody>
</table>
CTSI K Award Workshops

- **Objective**: To help junior investigators to learn how to prepare successful K award applications.
- Morning presentations from CTSI leadership.
- Afternoon review/discussion sessions for draft proposals.
- Next workshop scheduled for July 25, 2013 at UCLA.
- Rotate workshops among CTSI partner institutions.
- Mock study section with the UNC CTSA in the planning stage.
- Cost recovery plan will be implemented for future workshops.

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th># of Attendees</th>
<th># of Draft Proposals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jul. 26, 2012</td>
<td>UCLA Westwood</td>
<td>58</td>
<td>14</td>
</tr>
</tbody>
</table>
CTSI K Award Workshops

“I understand the different components of a NIH K/CDA grant proposal.”

Pre workshop

- Strongly agree
- Agree
- Neutral
- Disagree
- Strongly disagree

Post workshop

- Strongly agree
- Agree
- Neutral
- Disagree
- Strongly disagree
Need to detect and compensate for ‘leaky pipeline’

- High School Pipeline Working Group - common metrics for evaluation and tracking.
- Develop bridges for undergraduate students to be involved in research (model program: UCI EMRAP, Whittier BUILD application).
- Partnerships with the Undergraduate Research Center in Life Sciences to ensure a seamless pipeline to translational careers.
- Increased communication between MSTP and STAR with joint seminars. MSTP students see the pathway of how to reengage in research.
- Multi-level & daisy-chain mentoring.
- Mentors training program with the Dean’s Office is in the planning stage.
Research Associates Program (RAP)

• Established at UC Irvine Medical Center.

• A clinical research program for undergraduate students to work with faculty.

• Provides real-time experiences to educate and prepare students for a career in health care.

• Students receive academic credit, professional development and mentorship, and a valuable experience.

• Student researchers contribute to the infrastructure needed to conduct clinical research.
# CTSI Trainee Demographics

<table>
<thead>
<tr>
<th>Program</th>
<th># of Trainees</th>
<th>% Female</th>
<th>% Male</th>
<th>% Minority</th>
</tr>
</thead>
<tbody>
<tr>
<td>KL2</td>
<td>13</td>
<td>54%</td>
<td>46%</td>
<td>8%</td>
</tr>
<tr>
<td>TL1 Predoc</td>
<td>9</td>
<td>100%</td>
<td>0%</td>
<td>22%</td>
</tr>
<tr>
<td>TL1 Summer</td>
<td>40</td>
<td>68%</td>
<td>33%</td>
<td>45%</td>
</tr>
<tr>
<td>TPTS Workshops</td>
<td>103 (current)</td>
<td>53%</td>
<td>47%</td>
<td>12%</td>
</tr>
<tr>
<td>TPTS Certificate</td>
<td>36 (past 3 years)</td>
<td>56%</td>
<td>44%</td>
<td>8%</td>
</tr>
<tr>
<td>TPTS Master of Science in Clinical Research (MSCR)</td>
<td>19 (current)</td>
<td>53%</td>
<td>47%</td>
<td>5%</td>
</tr>
<tr>
<td>TPTS Pathway</td>
<td>49 (current)</td>
<td>41%</td>
<td>59%</td>
<td>14%</td>
</tr>
</tbody>
</table>
Adaptive re-allocation of training resources over time

- Planned use of TPTS evaluation and core competencies in guiding future adjustments to the TPTS curriculum.
- Received incomplete or low quality KL2 submissions during the first 2 cycles.
- Created K Award Workshops to help junior investigators improve the quality of their applications for the KL2 and other K awards.
- 5 of the 7 KL2 awardees this year participated in the workshops.
- Curriculum Committee is continuously evaluating the course offerings, Moodle platform and curricular tree will greatly facilitate this.
Training Program in Translational Science (TPTS)

- Important and highly successful curriculum for clinical research.
- Track 1 Workshops: 103 enrolled (current)
- Track 3 MSCR: 92 enrolled (2001-2012)
- Medical Student Pathway: 61 (2010-current)
- Originally funded by K30 but became an unfunded mandate when the UCLA CTSI was awarded.
- Currently this program is funded with institutional funds, but additional extramural funding to continue and expand this critically important educational program is needed.
Future Plans

• High school pipeline group is writing a best practices report.
• If the BUILD planning grant is funded, it will provide the UCLA graduate programs with a linkage to a non-research intensive college to increase the number of URM applicants to our graduate programs.
• Potential projects include submission of NSF grant for study in workforce development and implementation of EMRAP-type program at UCLA.
• Continue to expand and refine the TL1 and KL2 programs for our trainees.
• Continue the summer health equity training program (24 students have been selected for this summer).
• Continue the evaluation and feedback from all programs; this information is received by the CREST committee and real-time improvements are operationalized.
BIP Overview

• **Aim 1: Virtual Home**
  – Researcher Portal
  – Researcher Profiles

• **Aim 2: Research Data Repository**
  – Provision clinical data for research across institutions
    – CTMS
    – REDCap

• **Aim 3: Informatics Education**
  – Biomedical Informatics course
  – Moodle support for CTSI Training Program courses
  – Training on CTSI tools
2012 EAB Comments

Strengths

• Well-balanced plan for portal, Research Data Repository (RDR), and Education
• Implementation of Curriculum Tree, Interactive Survey Environment, UCRex
• HIPAA-compliant file-sharing utility
• xDR under construction; its connection to the proposed RDR is most important single new resource
• Ongoing census of investigator data needs

Weaknesses/Challenges/Opportunities

• Cost/benefit of VITAE investment and its sustainability needs careful assessment
• Build RDR incrementally on real-world research project needs, to build out initial research data dictionary rather than abstract notion of “all data for all CTSI needs”
• Failure to have a functional, clinically derived RDR at the end of the first CTSA award is a common feature of all current non-renewed institutions
• May need to decrease number of BIP projects in order to achieve highest priority
Aim 1: Virtual Home Redesign
Aim 1: Researcher Profiles

CTSI Directory

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About

John S. Adams, M.D. is Professor and Vice Chair for Research in the UCLA Orthopaedic Hospital Department of Orthopaedic Surgery in the David Geffen School of Medicine at UCLA. He is co-appointed as Professor in the Department of Molecular, Cell and Developmental Biology in the UCLA College of Arts and Letters. Dr. Adams is Director of the Orthopaedic Hospital Research Center, where he is charged with building an inter-school (the UCLA College and Schools of Medicine, Dentistry and Engineering), multidisciplinary program of training and research in developmental and regenerative musculoskeletal medicine.

His bench-to-bedside (translational) and clinical research efforts in the area of vitamin D have been continuously funded by the NIH for the last 30 years. These efforts are currently targeted at...
Aim 1: Team Science Workflow System

**CTSI Investigator**

I need help with:
- General questions about the UCLA CTSI
- Information about funding opportunities
- A grant proposal
- A clinical study involving human participants (beyond the proposal stage)
- Preparing a manuscript or other presentation of research results
- Other community-based activities, events, or products
- I’m not sure, I would like to personally speak with a research facilitator about the CTSI and my research needs.

---

**Request Workflow**

- INITIAL CONTACT
- IN SERVICE
- SERVICE COMPLETE
- FOLLOW UP
- OUTCOME
- END

---

**CTSI Facilitator**

**Facilitator Workspace**

- Requests
  - Grant proposal Dr. Smith

**Assign to Service Provider**

- Tickets

**Service Providers**

**Letter of Support (LOS) Admin**

- LOS Workspace
  - Tickets
    - Grant support

**Biostatistician**

- Biostats Workspace
  - Tickets
    - New power calculation
    - Statistical analysis
Aim 1: Team Science Workflow System

CTSI Investigator

**Workspace**

**Request Status**
- Complete - Notes
- Complete - Notes

Note
From: Biostatistician
Power calculation for is now complete.

CTSI Facilitator

**Workspace**

**Request Status**
- Complete - Notes
- Complete - Notes

Service Providers

**Workspace**

**Status**
- Service Complete

LOS Admin

**Workspace**

**Status**
- Service Complete

Biostatistician

**Notes**
Power calculation for is now complete.
Aim 1: Team Science Workflow System

CTSI Investigator

**Messages**
- **Service Satisfaction**

**General Questions**
Overall, how satisfied are you with how the facilitators coordi
- Extremely Satisfied
- Very Satisfied
- Moderately Satisfied
- Somewhat Satisfied
- Not at all Satisfied

CTSI Facilitator

**Workspace**
- **Questionnaire Status**
  - Service Satisfaction: Complete
  - Outcome Survey: Pending

Service Providers

- LOS Admin
- Biostatistician

**Request Workflow**
- INITIAL CONTACT
- IN SERVICE
- SERVICE COMPLETE
- FOLLOW UP
- OUTCOME
- END
Aim 1: Team Science Workflow System

Initial results

- Beta testing 11/14/12 to 5/6/13; live 5/6 - 5/30/13
  - 104 of 149 requests assigned to a service provider
    - 12 assigned to more than one service provider
    - The remaining 35 handled directly by OIS facilitators
  - 36 of 149 (24%) self-entered by the investigator
    - Last 2 months: 22 of 52 (43%)
• **Rebuilt and redesigned VH website**
  – Established weekly communications team meeting
  – Pilot, Voucher and Training Grant application system

• **Researcher Profiles**
  • Terminated VITAE
  • Researcher search still important
    • NCATS RFA: “Providing visibility of CTSA participating institution scientists and resources to facilitate communication and collaboration … is encouraged.”
  • Updated existing faculty profile system to encompass CTSI
    • Curated each CTSI researcher
    • Added MeSH terms based on publications and grants
    • Linked into Direct2Experts.org – CTSI now searchable among 41 CTSAs
    • Evaluating Vivo in conjunction with UCLA Upper Campus, esp. Vivo Harvester

• **Team Science Workflow System**
  – Service request, management and evaluation
Aim 2: UC-ReX
Aim 2: UC-ReX

• **Pilot results**
  – 15 users, 2 limited by performance problems
  – Data issues
    • Known: Low counts at UCSF; no pediatrics or procedures at UCSD;
      no imaging or E&M procedures (no CPTs in ontology)
    • Some UCLA counts seem high
  – 14 of 15 would recommend to a colleague

• **Additional data types to be added by Fall ’13**
  – Top 120 lab tests, culture and sensitivity results
  – Anticoagulant medications; maybe antibiotics, SCDs

• **Harmonizing honest broker and recruitment process**
Aim 2: Los Angeles Data Resource (LADR)

• **Initial Plan**
  – Link data at patient level, CTSI and other LA providers
    → More complete data sets than any single institution
    → No identification of care location by default
  – Authored governance process for participant autonomy
  – Developed 7 pilot study concepts with CTSI investigators

• **Revised**
  – Step 1: Cohort discovery for clinical research (“LADR-CR”)
    • SHRINE network, borrowing data standards from UC-ReX
  – Step 2: Data sets for clinical epidemiology (“LADR-CE”)
    • Initial test of Vanderbilt private record linkage software (SOEMPI) using LA County’s 6 million patient data set
Aim 2: Other RDR-related Activities

• **Support research use of UCLA’s “xDR”**
  – Epic EHR at UCLA is changing access to clinical data
    • “xDR” project: central source of valid, clean data to serve both research and health system administration
    • Many research studies depend on UCLA EHR data
    • Many investigators not familiar with IRB, compliance and security requirements to make research use of clinical data
  – BIP establishing function to assist investigators with defining their data needs, proposing feasible plans to IRB, compliance, and then setting up the data mart or extracting the data file they will need

• **Support CTMS selection process**
  – Now joint effort with Cancer Center, developing business model

• **Support investigators’ use of REDCap**
  – Installed at all 4 sites; usage accelerating dramatically
Aim 3: Informatics Education

• **Biomedical Informatics Module for TPTS**
  – 5/7 Part I: Informatics in healthcare and translational research (D. Bell, 1.5 hrs)
  – 5/9 Part II: Community-based informatics research (O. Ogunyemi, 1.5 hrs)
  – 5/14 Part III: Electronic health record systems (R. Jenders, 1.5 hrs)
  – 5/16 Part IV: Clinical decision support (R. Jenders, 1.5 hrs)
  – 5/23 Part V: Practical tools in biomedical informatics (W. Hsu/C. Arnold, 3 hrs)

• **Moodle Support for CTSI Training Program courses**
  – Hosted by UCLA’s central Moodle team
  – (Re)created new module mapping courses to competencies

• **Training on CTSI-supported tools**
  – So far: UC-ReX, REDCap, Team Science Workflow System
Scope Limitation

• **May need to decrease number of BIP projects in order to achieve highest priority**
  
  – Discontinued CTRC management system project
    • Exploring use of Harvard Catalyst scheduling and protocol systems
    • Other features redundant with CTMS
  
  – Discontinued cCloud file sharing project
    • A UCLA-wide service file sharing service is being designed
    • Also, now implementing HIPAA-compliant file-sharing for a Voucher Awardee; will scope out offering it as a service next year
  
  – Deferring work on a Common Terminology Service
    • No compelling application yet
    • Using individual tools successfully, e.g. RELMA for LOINC mapping
  
  – Postponing follow-up CTSI investigator survey to next year
    • 2-year interval will allow more time for services to mature
• Goals

• Progress

• Environment & Approach

• Future Plans
MCAH Goals

- Define MCAH strategic plan for CTSI
- Provide MCAH education and training
- Connect MCAH investigators with community partners
- Facilitate inter-CTSA collaborations
- Increase research opportunities across disciplines, departments & sites
Progress: Define MCAH Strategic Plan

• Held design meeting
• Constituted committee structure
• Formed 3 research nodes
  – Obesity, Mental Health, Fetal Programming
  – Facilitated grant submissions
Work is represented by:
T1 (Lab to Patient): PINK
T2: (Patient to Clinical): YELLOW
T3: (Clinical to Community): GREEN
T4: (Community to Policy): ORANGE

CTSI Research Network Design Meeting: November 22, 2011
The discussion then focused on network design elements such as: communication, training/mentoring, technology, grant production/funding, and vision and strategy development.

The group shared best practices from other networks they are involved in – including what works (above) and what to avoid.
Progress: Define MCAH Strategic Plan

• Mattel Children’s Hospital- UCLA Children’s Discovery and Innovation Institute
  – To connect research and training activities related to improving children's health;
  – Discovery from Bench to Community
  – Local, national & global innovation networks

• Focal Areas
  – Brain & Behavior
  – Nutrition & Metabolism
  – Cancer
  – Inflammation, infection & immunity
Progress: Facilitated Grant Submissions

- **R01 application in Obesity Epigenetics**
  - Collaboration among Pediatrics, OB Gyn, Genetics, and Molecular Biology

- **March of Dimes Discovery-based Multidisciplinary Center on Perinatal Outcomes**
  - Pediatrics, Ob Gyn, Genetics and others
  - To be Submitted?
Progress: Provide MCAH Education and Training

• Campus wide research seminar CDI

• CHRC K-12 child health training grant application

• T-32 child health training grant application

• KL2 scholar conducting MCAH research
  – Rebecca Dudovitz, MD, MSHS: *Understanding the Relationship between Adolescent Identity and Substance Use*
• Partnering with Northeast Valley Health Center, a PCORI grant was funded to adapt a behavioral and development screening via tele-health
  – Faculty from Pediatrics, Public Health, and Psychiatry

• Several CMMI Innovation proposals are being developed with community clinic networks to advance innovative models of delivery and finance
  – Proposals due August 15th
Progress: Facilitate Inter-CTSA Collaborations

• CC-CHOC-CTSA Child Health Oversight Committee
  – Organizing life-course focus to CC-CHOC activities

• Share MCAH design process with other CTSAs
  – Children's Hospital of Philadelphia may pilot

• MCH Life Course Research Network
  – Investigators from seven different CTSIs; UCLA leads
  – Developed 22 research-agenda-setting papers

• National Children's Study
  – Leading NIH funded Health Measurement Development Process across multiple sites
Environmental Scan

• To develop innovative translational research ideas

• To identify potential lead researchers for MCAH projects

• To take advantage of funding opportunities aligned with MCAH goals
  – Autism, Developmental Disabilities
  – Stress/Adversity/Depression/Epigenetics
  – Obesity/Nutrition/Epigenetics

• To expand existing and/or develop potential practice platforms for network-based research
  – AAP opportunities for QI/PBRN research in pediatric primary care.
GOAL

Build infrastructure that increases participation of CTSI investigators in translational research focused on maternal child and adolescent health

MCAH Driver Program

STRATEGIES

Assessment and Monitoring
- Conduct Environmental Assessment and Monitoring
  - Initial scan and ongoing tracking of internal and external resources

Administrative
- Establish Leadership and Structure
  - Recruit/sustain membership, establish meeting schedules and agendas
- Focus on value of participation
  - Provide concrete benefits of membership

Programmatic
- Catalyze novel MCAH studies
  - Prioritize topics for sub-groups, pilot funding, grant writing support
- Leverage LCRN Resources
  - Leverage people and ideas from Life Course Research Network through webinars, etc.
- Foster MCAH Practice networks
  - Link with existing and develop new relationships
- Link to related efforts
  - Other CTSI research efforts with potential application to MCAH

PRIMARY DRIVERS
- Effective MCAH leadership and administrative structure
- Robust communication and collaboration among MCAH investigators
- Diversity of MCAH-related practice-based networks that a research ready
- Opportunities to translate life course science into improved health outcomes
FIGURE 4: CTSI MCAH COMMITTEE / RESEARCH NETWORK ROADMAP

- **Data Collection**
  - Environmental Scan
  - Stakeholder Interviews
  - Internet Research
  - Ongoing monitoring

- **Analysis/Synthesis**
  - Synthesis of findings from Scan
  - Written report of Scan results
  - Revised Driver/Strategy Diagram
  - 2013/1 Work plan/Budget

- **Programmatic Strategy**
  - Refine research questions/methods
  - Invite members to LCRN Webinar
  - Reach out to practice networks

- **Administrative Strategy**
  - Prioritize Research topics of focus
  - Identify Collaborators
  - Link to other relevant CTSI efforts

- **Annual Workplan/Budget**
  - Identify Committee Chair
  - Recruit and convene members
  - Establish schedule of meetings
  - Monitor Metrics

- **2014/15 Work plan/Budget**
  - Revisit Driver Diagram
  - Update Scan

- **2015**
  - Submit grant proposals

- **2013/12/13**
  - 11/12/13
  - 2-3/13
  - 4-6/13
  - 7-9/13
  - 10-12/13
  - 1-3/14
  - 2014/15 Work plan/Budget
MCAH Year 3 Priorities

• Build and strengthen MCAH emphasis within CTSI
  – Leverage CTSI expertise in stress, nutrition, autism
  – Improvement prototype at Harbor and DHS

• Build and strengthen key community research partnerships
  – Community primary care networks as platforms
  – Build capacity for sustainable research with partner health systems including DHS and UCLA Health System
  – Magnolia Community Initiative
  – Healthy Community Neighborhood Initiative

• Expand MCAH Education and Training
  – CDI Research Seminar
  – Campus and Cross site Life Course Health Development Seminar

• Facilitate Inter-CTSA collaborations