The UCLA Clinical and Translational Science Institute (UCLA CTSI) provides the infrastructure to bring UCLA innovations and resources to bear on the greatest health needs of Los Angeles and the nation. It is a dynamic partnership among UCLA-Westwood, Charles Drew University of Medicine and Science (CDU), Los Angeles Biomedical Institute at Harbor-UCLA Medical Center (LABiomed) and the Burns and Allen Institute at Cedars-Sinai Medical Center.

The UCLA CTSI is organized into nine program areas through which the CTSI achieves its five main goals: (1) create an academic home for clinical and translational science, (2) build transdisciplinary research teams to accelerate and translate discovery, (3) transform educational and career development programs to promote the next generation of clinician-investigators and translational scientists, (4) build and expand strong bi-directional academic-community partnerships, and (5) serve as a national resource for collaborative research.

a. INTEGRATION AND INNOVATION

INTEGRATION

The geographic (Los Angeles driving distances and traffic) and cultural differences among our partner institutions provide numerous opportunities for integration, which is among our highest priorities. Many key initiatives are presented elsewhere in this document; thus, they are only listed here. These initiatives include Reliance-Review IRB (see Regulatory Program); Career Development Workshops (see Research Education, Training and Career Development Program); Team Science Awards (see Pilot Program); Metrics Gallery (see Evaluation Program); and the Los Angeles Data Resource (see Biomedical Informatics Program). Below we describe activities housed in the CTSI Office of the Institute.

Strategic Planning Initiative. In October 2013 we started work on a strategic plan to set the course for the CTSI as it emerges from its early development stage. We are being assisted by AMC Strategies of Los Angeles, which specializes in strategic consulting for academic medical centers. A steering committee of 17 representatives of the four CTSI partner institutions is guiding the planning process. The first phase of the process, a strategic and environmental assessment, will be completed before February 2013. During the second phase we will define the CTSI vision, goals and outcomes, and during the third and final phase we will develop a strategic roadmap and implementation plan. The process will be completed in April 2014.

Pediatrics Initiative. Led by our Maternal, Child and Adolescent Health (MCAH) Committee, our Pediatric Initiative leverages academic strengths in stress, nutrition and autism to ensure that child health is emphasized within CTSI. In June 2013 we co-funded three one-year pilots of $22,500 with the NIH-supported UCLA Center for Autism Research and Treatment to support research by new investigators or experienced investigators new to the field. In addition, we granted four KL2 awards and one TL1 award to scholars focused on pediatrics. In November 2013 we partnered with the UCLA Children’s Discovery and Innovation Institute (CDI) to offer three, one-year, $200,000 Team Science Awards for multidisciplinary, high-impact research focused on either brain, behavior and development; cancer and regeneration; infection, inflammation and immunity; or nutrition, metabolism and growth. Other activities include a pediatric health seminar series (2013-14) and a pediatric research day (May 2014)—both activities are in partnership with CDI.

Office of Investigator Services (OIS). CTSI has four research facilitators that direct investigators to resources and consulting expertise across our institutional sites. Requests for service are logged in an online ticketing system located on the CTSI website. From January to November 2014, 521 requests for service were received and 506 requests were filled. Of the 79 investigators who completed a satisfaction survey, more than 90%
were very or extremely satisfied with the quality and timeliness of the service they received and were very or extremely likely to recommended CTSI services to colleagues.

**Virtual Home/Communications.** We initiated a major redesign of the CTSI Virtual Home (website) to improve its usefulness to investigators. A comprehensive catalog of resources and services will be organized by research project “stage” i.e., planning, set up, conduct, closeout. Volunteer focus groups from all partner sites have been providing regular feedback on each phase of the redesign. We expect the site will become the leading guide to biomedical research resources at UCLA. The redesign will be completed in early 2014. A twice-monthly, opt-in newsletter initiated in 2012 now reaches 773 subscribers, a 40% increase over 2012, and has an above-average 33% open rate and a 36% click-through rate. The newsletter is an important driver of traffic to the CTSI site. Based on 11-month data, the site had annualized visits (defined by Google Analytics) of 86,326 in 2013, a 120% increase from 2012.

**Core Resources.** We completed an MOU between our four CTSI partner institutions in which each institution agreed to make research cores available at internal rates to researchers at other UCLA CTSI institutions. The agreement is expected to greatly enhance access to cores across the CTSI.

**INNOVATION**

Innovation is at the heart of the CTSI mission: Accelerating translation of UCLA discoveries to improve health and health care. Many innovations are presented in our program-area reports. These innovations include **clinical research seed grants** to support junior investigators and the launch of a **Neuromotor Recovery and Rehabilitation Center** (see Clinical and Community Research Resources Program); a **Healthy Aging Research Initiative** in partnership with the Los Angeles County Department of Public Health (DPH) and Department of Health Services (DHS) and the University of Southern California CTSI, and a **Dissemination, Implementation and Improvement Initiative** (see Community Engagement in Research Program); the **CTSI Seminar Series** (see Pilot Program); and publication of two **novel biostatistical methodologies**—one for analyzing genomic datasets and the other for analyzing data from community-based clinical trials (see Biostatistics Program). Activities described below are housed in the CTSI Office of the Institute.

**Grant Submission Facilitation.** UCLA CTSI supports submission of large proposals through a combination of direct facilitation and online tools. Direct facilitation includes administrative support (scheduling meetings, collecting supporting documentation); writing, editing and graphic design expertise; and support with budget development. Online tools available through the UCLA CTSI website include letters of support templates and document-sharing software. Our redesigned website will include grant-writing tips, funding search tools, sample grants, and boilerplate text. Since 2012 we provided direct facilitation to 39 separate PCORI, NIH and DoD grant application proposals and 24 K/Career Development Award submissions, resulting in more than $40.5 million in new extramural grant funding with $69.5 million pending. These results were presented during a poster session at the National CTSA Steering Committee meeting in December 2013.

**Pipeline Programs.** In December 2013 we initiated a pilot of the CTSI Research Associates Program (CTSI-RAP) to provide undergraduate UCLA students with the opportunity to gain exposure to hospital-based medicine as well as clinical research in an academic medical center. CTSI-RAP is designed to build a stronger support infrastructure for the research initiatives of UCLA faculty physicians. Research associates will make rounds with the medical team, observe common procedures, and experience didactic teaching sessions during the course of their research day. The blend of first-hand clinical experience and scientific research will give CTSI-RAP alumni a competitive advantage as they advance in their academic training. The program will initially be offered to student volunteers. We expect to offer academic credit beginning fall 2014.

**Entrepreneurship and Commercialization Initiative.** This multifaceted initiative provides resources to advance technologies toward commercialization while grounding innovators in the business-side of the product
development process. A description of the components of this initiative follows.

- **Drug Development Seminar Series.** Held in spring 2013, the five-part series covered the business of therapeutics, process mapping, targets and biomarkers, monoclonal antibodies, and project management. An average of 20 people attended the late-afternoon lectures; Dr. Michael Palazzolo, a professor of medicine with experience in industry and venture capital, was the presenter. The purpose of the seminar series was to educate faculty and introduce the consultation program (see next item).

- **Consultations.** In fall 2013 Dr. Palazzolo began offering one-on-one consultations to faculty on many of the topics covered in his lecture series, including drug development, intellectual property, negotiating agreements with industry, and raising venture capital. He held 29 consultations and facilitated a patent filing, initiation of two industry-sponsored research contracts, and negotiations for venture investment by two separate faculty innovators. These consultation services are now a permanent feature of CTSI.

- **University of California Center for Accelerated Innovation (UC CAI).** The UC CAI, a consortium of the CTSAs at the five UC medical campuses (Davis, Irvine, Los Angeles, San Diego and San Francisco), is administered from UCLA. In 2013 the UC CAI received a seven-year, $12-million award from NHLBI to speed translation of academic discoveries to benefit patients. In December 2013 UC CAI issued an RFA soliciting applications from faculty innovators across all five campuses. In 2014 we will select three technologies for incubation under this RFA and another six technologies under a second RFA to be issued in mid-2014. Selected technologies will receive up to $200K over one or two years and project management support. The UCLA CTSI provides the administrative infrastructure, including communications and financial oversight, for the CAI.

- **Incubator for Biomedical Start-ups.** UCLA is renovating 800,000 square feet within its existing Center for Health Sciences building to provide incubator space for start-up companies formed by faculty innovators. The facility, which is being financed with $400 million from an $850-million University of California taxable bond issue, will support technology transfer across the CTSI. In 2013 UCLA, in collaboration with CTSI, identified six areas of expertise (cancer, cardiovascular, immunology, metabolism, neuroscience and regeneration) and charged faculty teams with generating specific research challenges within each area. It is our expectation that these research objectives will drive the future of translational research for UCLA and our CTSI partner affiliates. CTSI has already worked with four of the six themes (cancer, cardiovascular, immunology and neuroscience) on strategic pilot projects and an RFA for a pilot in regeneration, degeneration and repair will be announced in January or February 2014. We anticipate offering a pilot in metabolism later in 2014.

- **Institutional Research and Academic Career Development Award (IRACDA).** In fall 2013 UCLA and Charles Drew University of Medicine and Science (CDU) submitted an application for UCLA-CDU IRACDA, a novel career development program to prepare minority post-doctoral scholars for productive academic research and teaching careers. The proposal leverages CTSI resources to provide scholars with career development workshops, hands-on research facilitation and assistance with grant preparation. Because translational science faculty of tomorrow will need to understand how to commercialize innovations, scholars will participate in a set of informational programs and immersion experiences in research-related fields, such as regulatory science, intellectual property and therapeutic development. CTSI Grant Submission Facilitation assisted with the application.

- **Entrepreneurial Education.** CTSI supports two programs in the UCLA Business of Science Center designed to give academic inventors hands-on experience with advancing innovations toward commercialization. The CTSI-Business of Science Venture Team Competition pairs biomedical faculty with graduate students from the UCLA Anderson School of Management. Competition winners receive $30K in proof-of-concept funds to advance innovations toward licensing. Advanced Bioengineering Innovations, a two-semester course for graduate students from any UCLA doctoral or professional
program, provides lectures and hands-on, mentored training in medical device development. Students invent practical devices to address problems they identify in the UCLA Health System.

b. ACHIEVEMENT OF MILESTONES

CTSI programs have met or are expected to meet or exceed the majority of their milestones for year 3. (Please see the program-area reports elsewhere in this document for more details.)

Our External Advisory Board reviewed our progress during a face-to-face meeting in June 2013. In response to its thoughtful recommendations, we have initiated a number of CTSI-wide improvements. They are listed below. (For program-specific improvements, see program-area reports elsewhere in this document.)

- **Entrepreneurial Climate.** In 2014 we will expand the number of experts available to provide consultations to faculty on start-up formation, intellectual property, scientific translation and other areas critical to advance innovations toward commercialization. In collaboration with UC CAI we will develop a “technology commercialization primer” covering such topics as technology readiness, market research and risk mitigation. To complement this effort, we will work with CAI to develop an online catalog of workshops and materials related to entrepreneurship in the biomedical sector. In addition, we are in discussions with the Anderson School of Management about a collaboration in which MBA students will create databases of market prices for therapeutics, digital health devices and predictive algorithms for medical treatment. This information will assist UCLA in negotiations with licensees.

- **Bioinformatics.** Dean’s Office at the David Geffen School of Medicine convened a Biomedical Informatics Task Force to make recommendations regarding the creation of a department or organized research unit for biomedical informatics. We expect that the resulting unit will strengthen the role of BIP in providing training and support for translational research. We also expect to be creating an ACGME-accredited clinical informatics fellowship in 2014.

- **Leadership in Community-Engaged Research.** We are leveraging our strengths in community engagement with the goal of becoming a national leader in this area. As noted above and discussed in the CERP report, we are intensifying and expanding our **collaboration with Los Angeles County DPH and DHS through the Health Aging Initiative and the CTSI-DHS Collaboration Grants.** Five projects were awarded one-year collaboration grants to advance asthma care, retinal screening, obesity prevention, psychiatric care and adolescent health in low-income populations without increasing costs. We expect these pilots will lead to larger collaborations that will ultimately yield improvements in health care delivery. In 2014 we expect to advance our Dissemination, Implementation and Improvement (DII) initiative through a **partnership with the UCLA Health System.** CTSI and the UCLA Health System would co-fund up to three $30K seed grants for quality improvement projects designed to build institutional capacity for improvement research and culture change. As noted above and detailed in the Biomedical Informatics Program report, we expect to pilot the **Los Angeles Data Resource** in March 2014 with data from UCLA-Westwood and Cedars-Sinai. We anticipate our negotiations with the University of Southern California (USC), Children’s Hospital Los Angeles, Los Angeles County, CDU and LABiomed will result in their participation in 2014 or early 2015.

- **Governance.** We expect our **strategic planning initiative** will lead to a stronger, more streamlined governing structure that allows the PI to delegate operational management so the PI can focus on strategic decisions. We anticipate implementing a new governance structure in 2014.

c. CHALLENGES ENCOUNTERED AND ADDRESSED

In 2013 UCLA began a major restructuring of its systems for managing clinical trials. A Clinical Trials Informatics Office was created, with responsibility for the selection and implementation of a clinical trials management system (CTMS), an effort initiated by CTSI. The new campus informatics office selected OnCore by Forte Research Systems, with full implementation expected in June 2015.
With institutional funds, we more than doubled the number of new KL2 awards in 2013 to support the translational science careers of our most promising junior faculty.

We continued to implement cost-sharing in our CTRCs while providing support for junior investigators. The UCLA CTRC successfully piloted a seed grant program for junior faculty in 2013 that will expand to Cedars, CDU and LABiomed in 2014.

To reconcile our budget, we asked our programs to make cuts in year 3 and year 4.

d. PLANS FOR SHIFTS IN ACTIVITIES WITH RATIONAL FOR MODIFICATIONS. None.

e. INSTITUTIONAL SUPPORT

In our 2010 submission the four CTSI partner institutions committed a total of $73.25 million. The amount included team-based research staff and faculty support, a research data repository commitment, and commitments for faculty recruitment, a clinical trials management implementation system, clinical research, bio-banking, research imaging and informatics infrastructure, and space commitments of $202.2 million. Based on our year 1 figure of $44.5 million and our year 2 figure of $72.2 million, we will far exceed our original plan.

f. IMPACT OF THE ACADEMIC HOME WITHIN PARTNER INSTITUTIONS AND HOW CTSI FACILITIES MULTISITE RESEARCH OF INVESTIGATORS IN THAT HOME.

Our academic home integrates and builds on the many strengths of our four institutional partners to advance translational and clinical science and facilitate multisite research. Our nine program areas report elsewhere in this document how their specific components contribute to a flexible, cross-institutional research infrastructure. The achievements listed below show how our infrastructure supports research across institutional boundaries.

Patient-Oriented Scalable National Network for Effectiveness Research (p-SCANNER). P-SCANNER, a collaboration of UCLA CTSI; the CTSAs at UC Davis, Irvine, San Diego and San Francisco; the Veteran Health Administration; San Francisco State University; USC and RAND, received a $7-million, 18-month award from the Patient Centered Outcomes Research Institute in December 2013. The project will integrate data from three networks covering 21 million patients. UCLA CTSI will participate in developing novel methods for distributed analyses that can take place without moving patient data to a central location.

Barber-Pharmacist Coordination to Improve Blood Pressure Management in Black Men. UCLA CTSI provided biostatistical, community-engagement, grant-submission facilitation and regulatory support to this proposal to train barbers to detect untreated hypertension in African American clients and then to refer those clients to local pharmacies for treatment. The proposal calls for an intervention study at 20 Los Angeles barbershops. If results are positive, an implementation pilot will be conducted in California, Mississippi and South Carolina in partnership with Kaiser Permanente and Walgreens. The $8.5-million proposal to NHLBI received a fundable score in the 5-percentile range in October 2013. The proposal uses preliminary data from a $200K CTSI pilot award to the PI (R. Victor).

University of California Center for Accelerated Innovation. UCLA CTSI Grant Submission Facilitation coordinated the preparation and submission of the five-campus application to NHLBI. Upon receipt of funding, UCLA CTSI Communications and Biomedical Informatics Program (BIP) built a website for the CAI that provided information about the grant, funding opportunities and research resources. After three weeks, the site had 1,400 visitors, including more than 800 unique visitors. An e-mail newsletter prepared by CTSI and distributed to 241 opt-in subscribers at the five campuses drove traffic to the site. CAI applications will be submitted and reviewed online using an RFP tool developed by BIP. Successful applicants will be able to access research cores on any campus through their respective CTSAs.

g. NOTE IF SHIFTING FUNDS AMONG LINKED AWARDS.

We have no plans to shift funds among our linked awards.