

UCSF CTSI
Overall Progress Report
Highlights, Milestones, and Challenges

A. Overall Objectives and Goals of the Program

The goals of the UCSF Clinical and Translational Science Institute are four-fold:

Goal 1: To enhance, support, and integrate existing training programs, thereby increasing the number and quality of programs and providing trainees from diverse disciplines with the knowledge, skills, and motivation to make significant contributions to clinical and translational research. This goal will be achieved through the Clinical and Translational Sciences Training Program.

Goal 2: To enhance, support, and integrate existing infrastructure, thereby implementing change required to foster the design and conduct of a diverse spectrum of high quality, original clinical investigation and translational research. This goal will be achieved through nine programs, including those in Novel Clinical and Translational Methods; Research Design, Biostatistics, and Ethics; Biomedical Informatics; Translational Technologies and Resources; Regulatory Knowledge and Support; Community Engagement; Global Health; and Health Policy; as well as by the CTSI Clinical Research Center.

Goal 3: To enhance career development of faculty and trainees involved in clinical investigation and translational research by providing mentoring, providing opportunities to catalyze original research, and changing the academic culture to appropriately reward original, multidisciplinary, collaborative work. This goal will be met through two programs: the Strategic Opportunities Support Center (the Pilot and Collaborative Translational and Clinical Studies program of the RFA) and Career Advancement.

Goal 4: To create a “virtual home” for clinical and translational researchers, thereby nurturing communication, encouraging collaboration, fostering original ideas, and catalyzing the successful conduct of clinical investigation and translational research.

As described in the original grant proposal, these goals are being addressed by a total of 11 program functions integrated across several clinical and translational research units supported by the four UCSF professional schools and the Graduate Division. Given the size and complexity of our environment, we knew from the outset that a major mission of the UCSF CTSI would be to serve as a facilitator: to help, wherever possible, to coordinate complementary (and, in some cases, redundant) clinical and translational efforts at UCSF in such a manner that “bench-to-bedside to community” research can proceed more efficiently.

B. Accomplishments

In our first 6 months, we have focused on the following imperatives:

1. Establishment of an administrative structure to sustain the stated goals of the CTSI
Clearly, the CTSI represents an organizational challenge. We recognize that each of the members of our Board of Directors (Deborah Grady, Dan Lowenstein, Mike McCune, and Joel Palefsky) brings certain skills, experience and motivation to the table. The same is true of the large number of senior faculty members who comprise the leadership and membership of our constituent groups. Given the historical structure of UCSF administration (usually led by research scientists who have moved directly from research into high level administrative roles that are often part-time) as well as the momentum underlying the CTSI grant, we will strive to sustain these leaders, including ourselves, in these roles. At the same time, we acknowledge that we need considerable full-time professional help in administration, program management, team building, and – in general – the complex art of managing geographically dispersed individuals working on a common but comprehensive mission.

To this end, we initiated a nationwide search using a professional search firm to find a full-time Executive Director (ED). We are pleased to report that we will soon be joined by Ms. Susan Autry. Most

recently, Ms. Autry has been Director of Administration and the Government Liaison of the Institute of Collaborative Biotechnologies at UC Santa Barbara. She holds an MBA and has many years of experience administering and implementing large, collaborative, government-funded research enterprises based in academia. Her full-time position with the UCSF CTSI and the creation of a full-time staff to assist her will help us to move to the next phase.

2. Creation of a financial structure to enable the work of the CTSI

With the award of the grant in October, our first goal was to reconcile the CTSI proposal to the final award and to discuss various scenarios for accommodating the cuts that were made to the budget (i.e., no funding in the proposed Global Health Program and, in Years 2-5, no cost of living increase in salaries, no increases in supplies and other expenses, and no expansion of training programs). Additionally, the existing Roadmap training and Clinical Research Center grants had to be transitioned to the CTSI financial structure, the total award had to be set up across the four schools and multiple involved departments/divisions at UCSF, and all cost sharing with the University needed to be reconciled and accounts established. With the assistance of Interim Executive Director Zoanne Nelson, the decision was made to decentralize the financial management of the grant and to organize the 11 programs funded in Year 1 into 24 accounts, each with a co-director, a financial analyst, and a department coder. Each of the programs was provided the full budget that it had requested (for the equivalent of the shortened 9 month Year 1) and each was asked to consider how to respond to the cuts implemented in Years 2-5.

3. Establishment of program management to enable CTSI teams to form and to operate most effectively

Upon the award of the CTSA grant, Interim ED Ms. Zoanne Nelson, joined the team for a predefined, limited period with the goals of establishing the financial structure of the CTSI and initiation of the program planning process. She was succeeded as Interim ED by Dr. Dan Santi, who expanded the program planning process and oversaw the recruitment of a permanent ED. In particular, Dr. Santi brought in a very powerful program management tool called SMART (for Specific, Manageable, Attainable, Realistic, and Tangible). The leaders of each group have been meeting with Dr. Santi, Dr. Claire Brindis (the director of the CTSI Tracking and Evaluation Program), and Mr. Rob Judd (a consultant who is an expert in the implementation of the SMART process). We anticipate that all CTSI programs will have completed the process of formulating SMART goals and accompanying metrics by this summer.

4. Initiation of process to better integrate clinical and translational activities across the UCSF campus

While writing the original CTSI proposal, it became clear that there were multiple interdisciplinary clinical and translational research units at UCSF with goals that overlapped and resources that are largely not shared or coordinated. A number of attempts were made to coalesce these entities prior to the submission of the grant. With the advent of the CTSI, these efforts have now expanded and have become an intense arena of campus-wide discussion, as reflected by: (a) a School of Medicine Leadership Retreat in January, 2007, which highlighted clinical and translational research and which heard from four of the major units on campus (the Comprehensive Cancer Center, the Immune Tolerance Network, Quantitative Biology 3, and CTSI); (b) the creation of a working group with the office of Executive Vice Chancellor Gene Washington (who will serve as the Chair of our Internal Advisory Board), enabling clinical and translational research efforts initiated and resourced by his office to be coordinated with those of CTSI; and (c) a campus-wide Strategic Planning Process which will culminate soon and which is likely to place clinical and translational research at a high priority for future development efforts.

In addition to the broad organizational steps described above, substantive and measurable efforts have been made by most of the programs proposed in the original grant. In some cases (e.g., training), this has meant continuation and expansion of previously successful programs. In others (e.g., the Clinical Research Centers), it has involved extensive reorganization of existing services and expansion to additional sites to enhance community-based research. In most, this effort has instead entailed the creation of wholly new services intended to facilitate clinical and translational research on campus.

Notable accomplishments for each of the groups are listed below (and described in more detail in the following group-specific reports):

1. Clinical and Translational Sciences Training

- Developed courses in T1 and T2 translational research for clinical researchers that will be offered in Y2
- Developed courses in T1 translational research for lab-based researchers that will be offered in Y2
- Developed a clinical and translational research training program for clinical residents that began in January, 2007
- Selected a new cohort of 6 new KL1 scholars from a wide range of disciplines
- Recruited the largest class ever of TL1 predoctoral trainees to take one year off to obtain training in clinical and translational research.

2. Biomedical Informatics

- Developed a database design consultation service that began offering services March 1, 2007.
- Developed a bioinformatics analysis service for high-level structured data that began offering services March 1, 2007
- Recruited full-time computer scientist to develop and manage the research data environment

3. Biostatistics, Research Ethics and Design (BREAD – formerly called Research Design, Biostatistics and Ethics)

- Developed a consultation service providing biostatistical, research ethics and design consultation and began offering services March 1, 2007
- Merged the Novel Methods program with BREAD, selected the first Director of Clinical and Translational Innovation, and are currently interviewing for the second

4. Regulatory Knowledge and Support

- Established a new business research unit to facilitate contracts and grants services
- Established a new service to facilitate IRB and Conflict of Interest review
- Established a new service to facilitate FDA submissions
- Established a new service to assist in design of pharmacokinetic/pharmacodynamic studies

5. CTSI Clinical Research Centers

- Consolidated 3 separate GCRCs into one new unit, the CTSI Clinical Research Center (CCRC)
- Added 3 new units to the CCRC- at Kaiser Permanente, the Veterans Administration Medical Center and a new adult unit based at the Children's Hospital of Oakland
- Reorganized services previously available to GCRC investigators such that they are enhanced through other CTSI programs and made available campus-wide

6. Translational Technology and Resources

- Initiated recruitment of an Academic Services Coordinator and a Technical Services Coordinator who will develop technology training programs and assist UCSF investigators in utilization of existing technology cores
- Funded the first round of technology-oriented pilot grants through the SOS program, in part to assist in development and adoption of new technologies for clinical use

7. Strategic Opportunity Support Center

- Defined six strategic areas for allocation of pilot funding in translational/clinical research to increase investigator participation in translational research and to enhance competitiveness for fully-funded grants
- Developed policies and procedures for submission, review and awarding of the funds
- Developed materials to inform availability of the pilot grants to the University community including written communications, posters, presentations, etc
- Created review committee(s) for each of the granting areas
- Assigned timelines for receipt, review and selection of letters of intent (LOIs) and full proposals

- Reviewed 260 LOIs followed by 98 full applications, with plan for issuing the awards in the latter part of April, 2007

8. Community Engagement

- Conducted a needs assessment of community partners and potential partners to identify prioritized needs
- Initiated community consultations with a “Hear from the Experts” speakers series, where UCSF faculty give talks to school personnel serving K-8 in the SF Unified School District
- Hired a “navigator” who will help guide investigators at both UCSF and Kaiser-Permanente (KP) in the design and implementation of collaborative research projects
- Hired a web-designer to help UCSF investigators learn about KP investigators and vice versa
- Continues to work in identifying incentives for and barriers to involving community clinicians in clinical research activities and partnerships, with the plan for developing training, consultation services, and outreach to community clinicians

9. Career Advancement

- Developed and presented three Career Development Workshops
- Developed Mentored Clinical Faculty Program which will begin training mid-level faculty in Y2
- Worked with the Deans for Academic Personnel of each of the 4 UCSF Professional Schools and the Committee on Academic Promotions to improve recognition of multidisciplinary, team-based clinical and translational research

10. Virtual Home

- Launched an initial CTSI website (ctsi.ucsf.edu), distributed information about CTSI activities, and added links to CTSI-program web sites.
- Coordinated the development of web-based tools for specific information systems and service of CTSI programs such as SOS, Regulatory Knowledge and Support, BREAD, and Community Engagement
- Installed the technical infrastructure for a production-quality web site, content management system, service-request tracking system and collaboration environment
- Created a CTSI-Announce email list that has provided an effective – if technically simple – means of communicating with the CSTI community
- Launched several pilot projects to explore the usefulness of various platforms for videoconferencing, and web streaming and archiving facilities to improve access to events such as seminars and lectures
- Conducted a pilot test, in partnership with Collexis, of a web-based program that provides profiles of publications and associated medical concepts for twenty-five of UCSF’s prominent clinical and translational investigators

11. Tracking and Evaluation

- Successfully integrated a Program Management process within the Tracking and Evaluation component of CTSI, including providing orientation on the concepts and utility of this approach in the academic environment
- Developed PM plans with 10 of the 11 existing Programs (the final one to be conducted by May 1, 2007) and established bi-monthly review process
- Initiated review of the CTSI portfolio to identify common areas for tracking and evaluation
- Participated in the National NIH cross-CTSA evaluation meeting and coordinated a cross-Program review of objectives, metrics, and sources of data for the national evaluation

(Note: As part of our original CTSA proposal, it was anticipated that a Global Health Program would be initiated in Year 1. In fact, this program was not funded because of restrictions in funding of foreign sites. The program has since been reconfigured and resubmitted to NIH for reconsideration of funding. Although a notice of grant award has not yet been issued, it is expected that this revised program will be funded and started by Year 2).

C. Challenges

In setting up the CTSI over the past months, a number of challenges have been met. Some of these were anticipated while others were not. All have had – and, in some cases, continue to have – real impact on the pace at which the Institute will grow in the future and, ultimately, on its success. Each will require significant attention going forward.

These challenges include:

1. The difficulty of breaking existing patterns of institutional behavior and organization
Many UCSF CTSI activities overlap with other campus organizations that conduct clinical and translational research. The CTSI will attempt to coordinate such activities to reduce redundancies and optimize efficiencies. It is challenging to modify existing patterns of individual behavior such that problems are approached as teams. We are creating infrastructure and planning approaches that encourage or demand teamwork.
2. The absence of adequate funding to achieve our stated goals
Given a flat or declining NIH budget, as well as the uncertainty of carry-forward funds to ensuing years, it will be a challenge to support continuing CTSI activities and assist faculty and trainees. We will attempt to raise funds or to reduce the scope of work, as necessary.

When we met with our External Advisory Board (4/2/07), this group also focused on the challenges of establishing an institute with such large scope. They discussed possibilities of the CTSI's performing an analysis of CTSI stake-holders priorities to ensure continued involvement, how to achieve efficiencies by the consensus-driven management of an academic environment, and actions/directions the CTSI might take to demonstrate impact of the Institute.

D. Program Integration and Innovation

See Section B above.

E. Proposed Modifications

Our future direction today is no different than that stated initially in our proposal. As above, we have devoted the preceding six months to building an organization that is now staffed with extraordinarily capable individuals. We believe that we have put in place a professional program management effort, each of the programs is fully staffed (or almost so), and the stated goals articulated in the proposal and the SMART process have clear timelines that we expect the programs to meet. There are no indications that any program will deviate from its stated course. We anticipate that we will fund each as per their original Year 2 projections. Predictably, differences will later emerge between programs, indicating greater progress in some than in others. Once these signs become more clear (most likely, after Year 2-3), we will assess the underlying reasons and, as necessary, make changes.

In addition to the 11 programs initiated in Year 1, we anticipate that we will also initiate programs in Global Health (see above) and Health Policy in Year 2.

F. Support Received under Institutional Commitment

A total of \$32M in commitments was made in the proposal from the Chancellor, the Deans, the Medical Center, and the Veteran's Administration Hospital. For this initial year, institutional commitment is approximately \$5.7 million with guarantees made to allow carry forward of unspent funds for use in the next project period.

G. Planned Institutional Commitment for the Coming Year

An annual total of \$6.0 million in commitments is planned for the coming year. These commitments include support for all 12 of our existing CTSI programs and will be critical to the overall success of our enterprise.