

CTSI Retreat 2014  
Program Proposals for 2016-2021

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## **Vision and Strategic Plan for CTSI 2016-2021**

### **Overall vision and strategic plan**

The UCSF Clinical and Translational Science Institute was founded in 2006. In the start-up period (2006 to 2011), we built an integrated home for clinical and translational research at UCSF, successfully improved, integrated and extended research services and infrastructure, and built a comprehensive research training program. As mandated by NCRRT, we developed several programs (pilot funding, consultation services, clinical research service, regulatory knowledge and support, training programs, etc.) to achieve these goals. In the second funding period, we focused on extending our services and infrastructure and collaborating with regional partners, most notably the other 4 University of California (UC) Medical Centers, and on making a measurable improvement in the health of disadvantaged residents in the San Francisco Bay Area. During this period, we continued to support discrete programs, but with marked integration of activities to support cross-cutting initiatives including the San Francisco Health Improvement Program and the Clinical Research Service.

In the coming 5 years, we propose to build on our prior work, take advantage of major strengths at UCSF, and to develop and link technologies to improve the quality, efficiency and cost of conducting multidisciplinary and multicenter clinical and translational research at UCSF, across California and across the nation. We believe this goal has become achievable through the confluence of widespread trends – the adoption of electronic medical records (EMR), the availability of large clinical datasets, access to web-based research platforms using computers and mobile devices, and the development of remote monitoring (eHealth) devices. We plan to develop and integrate these powerful technologies with a focus on team-based multidisciplinary research to support high-quality, efficient and cost-effective “NexGen” research that will scale to the 5 UC medical campuses and to others across the CTSA network. This effort will place UCSF at the forefront of developing a CTSA-wide multicenter clinical research and clinical trials network.

We will set two overarching goals: 1) to develop the infrastructure, services and training necessary to quickly and efficiently conduct high quality and low cost clinical and translational research at UCSF and across the CTSA consortium, and 2) to encourage and support innovative multidisciplinary team-based research. We will achieve these ambitious aims by creating a new program of “NexGen” research, aligning the activities of our current programs and filling identified gaps to create a seamless platform that can support a variety of types of studies, from observational studies to clinical trials, and from early to late translational research.

## Biomedical Informatics (BMI) Plans to support NexGen Research and Team Science

### **NexGen Research**

- NexGen research will be driven by data, and BMI aims to enhance the capacity for access and use of data resources by supporting 3 key initiatives:
  1. Build features in APeX that will support data quality & reporting
  2. Drive development of EDW with scientific research use-cases
  3. Improve processes/services for discovery and access of data resources
- BMI will also work to foster Digital Health innovation by supporting the dHealth Catalyst Award track and nurturing academia-industry-public sector collaboration on digital health sciences through jointly sponsored events
- BMI would like to work with Consultation Services to develop core services to support dHealth technical consults (to complement existing dHealth scientific consults), as well as facilitate a community of data concierge resources
- BMI will facilitate cross-institutional data collaborations related to UC ReX, PCORI CDRN, and PCORI PPRN efforts.

### **Team Science**

- Though there are no specific planned Team Science initiatives, BMI's work in supporting data resources and digital health will provide a rich environment for these scientific collaborations

## Career Development (CD) Plans to support NexGen Research and Team Science

- Aims:
- 1) To develop the infrastructure, services and training necessary to quickly and efficiently conduct high quality and low cost clinical and translational research, and
  - 2) To encourage and support innovative multidisciplinary team-based research.

The Career Development programs can assist greatly in the support of professional development for team-based research groups.

### **NexGen Research**

- CD supports faculty training through workshops developed in conjunction with the Office of Career and Professional Development and with the Office of Diversity and Outreach (Unconscious Bias). We could work with OCPD to develop workshops aimed at introducing some of the IT-based research methodologies to those who are not as familiar with this emerging field.
- We will continue to support the development and expertise of our mentors through the mentor development program as well as the diversity of our investigators through equity and inclusion efforts.

### **Team Science**

- Team Consultation - The CD Program will work in collaboration with the Strategic Opportunity Support funding award program to supplement the newly developed Team Science awards with a further opportunity for training in how to work effectively as a scientific team. We will coordinate these consultations through the Center for Health Professions, and will work with the teams of investigators to ensure the consultations address their specific needs and facilitate team effectiveness.

## Clinical Research Services Plans (CRS) to support CTSI “NexGen” Research and Team Science

Clinical Research Services (CRS) is a key component in maintaining and enhancing UCSF’s reputation as a leading research institution. We strive 1) to provide high quality, affordable, and expedient services to clinical investigators; 2) to be worthy of the trust of those who volunteer to be research participants; and 3) to inspire and engage research staff. We ensure financial sustainability through resources that are flexible, integrated within the larger UCSF system, and targeted to the appropriate level of care.

CRS assembled a Task Force of investigators representing a broad range of research interests (e.g., adult, pediatric, translational, clinical trials, and observational, comparative effectiveness, implementation research, and behavioral research) including both early stage and more senior investigators to conduct a systematic program review. Traditionally study participants have been seen in a dedicated facility, typically catering to a small number of investigators conducting resource and nursing intensive research that may require overnight stays. While access to such services is important to maintain, the Task Force felt that these should be allocated through a rigorous, peer review process to support the most innovative and highest quality research. The Task Force identified basic services and infrastructure that are most needed by investigators to quickly and efficiently conduct high quality and low cost clinical and translational research. Accordingly, more resources will be directed to essential services such as basic nursing, phlebotomy, and sample processing in an effort to expand and diversify the user base. CRS will continue to integrate its research services into clinical areas through mobile nursing models and in addition will pilot a program to leverage new technologies such as telecommunicating capabilities, internet interfaces, use of sensors and mobile devices to bring research to the participant whether in the healthcare or home environment.

CRS plans to build a Clinical Coordinator network sharing modeled after “eHarmony” matching service. This will enhance investigator teamwork through effort sharing and improve quality of service via training, community building, and sharing of best practices across clinical research.

To enable team science and interdisciplinary the CRS will offer services or funding opportunities for clinical and basic scientists to collaborate on pilot projects collecting data for future grant submissions. We will also host quarterly town halls highlighting groundbreaking science happening in both clinical and basic science.

## Clinical and Translational Science Training (CTST) Plans to support CTSI “NexGen” Research and Team Science

CTST will develop several new education and training initiatives to support NexGen research and team science.

### **NexGen Research**

- New courses:
  - “IT for Research” – to help investigators understand the structure of electronic databases, be able to speak “IT” with programmers and analysts, and understand the potential and pitfalls of using electronic data for research
  - “Research Using Electronic Platforms” - to make investigators aware of the range of “home grown” and commercial possibilities for supporting on line research
  - “Remote Measurement for Research “ - to make investigators aware of available mHealth monitors and apps, and to understand the steps in developing devices and apps
- Training: CTST will introduce modules in each of the level-specific training programs to reinforce the practice use, problems and capabilities of NexGen research

### **Team Science**

- New courses:
  - “Team Science” – to help investigators understand the challenges of creating teams of investigators with different backgrounds, language and goals, and how to bring these folks together to achieve a common goal. This course will also include organizational and management approaches to optimize the function of multidisciplinary teams.

## Community Engagement & Health Policy (CE&HP) Plans to support CTSI “NexGen” Research and Team Science

The CTSI Community Engagement and Health Policy Program (CE&HP) will build off the success of its current major initiatives (SFHIP and the SF Bay Collaborative Research Network (SFBayCRN)) and launch a new initiative on Early Life Experiences and Health Inequities (ELEHI) that advances NexGen research and team science. The ELEHI initiative will create an infrastructure that supports basic, clinical and population-based research on the social and behavioral determinants of health. By intervening early in the life course, interventions targeting social and behavioral determinants can alter lifelong trajectories of health and chronic disease. A wide variety of diseases and health conditions have common upstream risk factors linked to prenatal vulnerabilities and childhood exposure to adverse conditions in the social environment. Understanding and intervening on risk factors early in life can prevent disease and promote health throughout the lifespan.

### **NexGen Research**

- Integrate and enhance the usability of large electronic clinical and public health data sets in the Bay Area region to study the impact of existing community-based implementation science initiatives, with an emphasis on at-risk children
- Develop a standardized screening tool that assesses social vulnerability, based on recent IOM recommendations. The tool will be integrated into existing electronic health records (EHR) at the UCSF Benioff Children’s Hospitals in San Francisco and Oakland, and the San Francisco General Hospital. By doing so, we will create a platform for identifying at-risk children thereby supporting basic and applied research, as well as improvements in their clinical care
- Produce an EHR-ecumenical electronic registry containing a core set of basic demographic and clinical data for the diverse patients cared for in the hundreds of community-based practices participating in the SFBayCRN
- Use SFHIP and the SFBayCRN as “real world” testing sites for pragmatic applications of mHealth innovations (e.g., health monitoring apps, prenatal educational tools) and other innovations leveraging NexGen resources to promote improved health outcomes
- Create a comprehensive data base for a large birth cohort in California for ELEHI studies, including incorporating data from existing statewide surveys, school systems, and other data sources including biometric data that could form the basis of a more integrated cohort data base
- Through the use of the web, social media and other electronic forms for communicating health education information, engage community end-users as partners in the translational research enterprise

### **Team Science**

CE&HP is a transdisciplinary program and is well positioned to strengthen multidisciplinary team science. One of the signature efforts of CE&HP is to engage end-users of translational research—community based organizations, government agencies, local policymakers and community based clinical organizations—as partners in the research enterprise. Team science requires that these end users be engaged in the formative stages of research early on as active collaborators, not as passive recipients of research products. CE&HP faculty represent a broad swath of clinical and social science disciplines, including experts in health policy. The SFBayCRN is unique among practice-based research networks in the US because it not only includes community-based physicians, but also community based pharmacists, dentists, and nurses, with involvement of UCSF faculty in all four disciplines. The proposed new ELEHI initiative will embody the multidisciplinary team science approach of CE&HP, placing childhood experiences in a life course context that extends to adult health. All this work will be founded upon a conceptual framework developed by our multidisciplinary team of experts in child, adult and family health who work in an array of clinical, basic and social science disciplines.

## Consultation Services Plans (CS) to support CTSI “NexGen” Research and Team Science

CS will develop and expand the scope of CTSI-supported consulting services to support NexGen research and Team Science.

### **NexGen Research**

NexGen research will require new types of expertise that CS does not currently support. CS proposes to build the following capacity for consultation:

- Expertise in querying the APEX data stored in the Clarity database and creating analytic datasets for investigators from the clinical data
- Expertise in designing and implementing APEX-based interventions that are effective at changing practice patterns and clinician behavior without adding annoyance or inefficiency to clinician workflow
- Expertise in the range of mobile sensor technology that can be brought to bear for research projects
- Expertise in obtaining and analyzing data from Facebook and other social networking platforms
- Statistical expertise in handling and analyzing data derived from APEX, mobile phones and sensor devices
- Expertise in the ethical and regulatory issues that arise when designing studies that use NexGen data sources
- Expertise in natural language processing and other advanced methodology for analyzing medical record data

### **Team Science**

CS will encourage consultations to teams of investigators as they come together to achieve a common goal. With subsidy from CTSI, CS could offer an additional free hour of consultation from a given Unit when a consultant meets with a multidisciplinary TEAM of investigators rather than with a single investigator.



## Early Translational Research (ETR) Plans to Support CTSI “NexGen” Research and Team Science

ETR will develop and expand the scope of our translational research initiatives to support “NexGen” Research and Team Science.

### **NexGen Research**

NexGen research will require unique and customized support for early translational researchers:

- Identification, targeted support, and project management of early translation projects that propose to develop or use NexGen research tools.
- Identifying and recruiting academic and industry experts in NexGen research into the Catalyst advisor panel to support early development projects.
- Broadening the Catalyst fellows/interns program to include NexGen research education for early translational researchers and senior students and fellows
- Identifying and partnering with internal and external partners to provide infrastructure and resources to support NexGen research for early translational projects.

### **Team Science**

All initiatives within ETR emphasize the importance of team science in advancing early translational research. We will identify new opportunities to foster and encourage team science within ETR initiatives and create new mechanisms to promote and educate early translational researchers on the benefits, challenges and outcomes of team science.

## Regulatory Knowledge and Support (RKS) Plans to Support CTSI “NexGen” Research and Team Science

RKS will improve infrastructure to support NexGen research.

1. Continue the focus on improving operations of the CHR so NexGen research can be initiated more quickly.
2. Develop national network of CTSA IRBs allowing for reciprocal IRB approval.
3. Expand use of reciprocal IRBs for greater than minimal risk, industry sponsored multi-centered clinical trials.
4. Partnering with Kathy Giacomini’s Collaborating Centers of Excellence in Regulatory Science and Innovation, consult on regulatory issues and inform training programs relevant to collaborations with the FDA.
5. Develop and implement policies and procedures for patient contact for recruitment. Among issues to consider are: patients opting-out, sensitive diagnoses, multiple contacts and patients who have died.

## Strategic Opportunity Support (SOS) Plans to support CTSI “NexGen” Research and Team Science

Strategic Opportunities Support (SOS) will focus funding opportunities to support NexGen research and Team Science Proposals

### **NexGen Research**

SOS will place additional funding priority for innovating pilot research projects that facilitate NexGen Research (i.e. Electronic Health Records, Low cost/Innovative online recruitment strategies, etc.).

### **Team Science**

During Spring 2014 SOS launched the Team Science Grant, a funding mechanism focused on facilitating the development of new transdisciplinary research teams. We will continue to refine the Team Science RFA as well as recruit funders of this multidisciplinary funding mechanism to help promote team formation beyond UCSF.