Clinical and Translational Research Institute [CTRI]

Funded by: UCSD institutional funds, CTSA, UCOP, industry and NHLBI U54
- CTSA: $37.2 M (2010-2015); $52 M (2015-2020)
- CTRI Supports:
  - Informatics and biostatistics
  - Clinical research infrastructure
  - Pilot project grants
  - KL2/TL1/CREST programs

>1000 members
- 900 UCSD
- SDSU, Sanford Burnham, Salk, LIAI, Venter, others

To develop innovative solutions that will improve the efficiency, quality, and impact of the process for turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public.
**Altman CTRI — shared clinical & research space**

![Diagram of Altman CTRI with labels for 'Open dry lab', 'Shared Clinic', and 'Shared Auditorium']

**Community Engagement Unit, CTRI**

**2010 to 2015:**
Focus: Resources that explain research to the community

Developed:
- Research-relevant Training for CHW/Promotoras — [http://ctri.ucsd.edu/community/Pages/Community-BasedOrganizations.aspx](http://ctri.ucsd.edu/community/Pages/Community-BasedOrganizations.aspx)
- High school: Interactive class (research principles: purpose of research, control group, randomization, informed consent, etc).
- Courses in Community Engagement (targeting Researchers to learn about community) [http://ctri.ucsd.edu/education/Pages/CoursesCE.aspx](http://ctri.ucsd.edu/education/Pages/CoursesCE.aspx)
- ResearchMatch.org [http://ctri.ucsd.edu/clinical/Pages/using-ResearchMatch.aspx](http://ctri.ucsd.edu/clinical/Pages/using-ResearchMatch.aspx)

**Community Engagement Unit; Videos that Explain Research (example: what is randomization)**

![Image of people reading a book, possibly illustrating a video on randomization]
Community Engagement Unit, CTRI
2010 to 2015:
*Developed bilingual videos*
  - Videos that explain research:
    - What is random assignment?
    - What is a control group?
    - Who can participate in research?
    - How is research made safe?
  [www.youtube.com/user/HealthResearchUCSD](http://www.youtube.com/user/HealthResearchUCSD)

Community Engagement Unit, CTRI
2010 to 2015:
*Focus: develop resources that explain research to the community*
  - Posters promoting research participation –
    (note: Spanish posters are not yet shown on this page. But we have some)
  - [http://ctri.ucsd.edu/community/Pages/HealthCareProviders.aspx](http://ctri.ucsd.edu/community/Pages/HealthCareProviders.aspx)
Change of Focus for CTRI (although not for CTSA/NIH):
- Get community input into academic research
- Improve recruitment/accrual efficiency**
- Dissemination and implementation research
Community input into academic research

1. Community members review all CTRI-funded pilot awards, (even complex early stage science), and will review many awards for community relevance.

2. Community Advisory Board

3. Web Portal for local health indicators

4. Community input into large health record data base analyses

More on the web-portal

San Diego County Report Card on Children and Families

SUBSTANCE
Community Engagement Unit, CTRI

2016-2020

Change of Focus:
- Get community input into academic research
- Improve recruitment/accrual efficiency**
- Dissemination and implementation research

Participant Recruitment Resources [with BioInformatics]

Current Resources to be improved
a. Research Match
b. UC ReX
c. Data concierge [identify
d. pSCANNER
e. Introduction of Investigators to community agencies
**UC Research eXchange (ReX)**

**Federated Clinical Data Repository**
- Funded by UCOP
- 13.5M medical records
- Cohort discovery
- Quality improvement and research

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**UC Research eXchange (ReX): Cohort feasibility**

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**Participant Recruitment Resources [with bioinformatics unit]**

**Planned Resources**
- Mobile Blood Units distant from UCSD as research clinics
- Eisenhower Medical Center
- “MyChart” for research patient preferences
- FACTS (Find the Appropriate Clinical Trial)
- NIH–NCATS: “Recruitment Innovation Centers”
Community Engagement Unit, CTRI

2016-2020

Change of Focus:
- Get community input into academic research
- Improve recruitment/accrual efficiency
- **Dissemination and implementation research**

CTRI: Dissemination and Implementation Research

1. Pilot funding specific to dissemination and implementation research:
   - $60K per year, (each grant ~ $15K to $30K)
   - prioritize new research / researchers that would not have engaged in T3 research

2. Increase capacity of investigators to conduct implementation science
   - consultation to investigators
   - encourage participation in existing seminars/courses
   - provide scholarships to national courses
   - technical assistance for applications to national courses
   - ? UCSD host one annual UC-implementation science symposium
Other pilot project grants

- Focus on junior investigators
- $15-50 K per 1-year grant
- Traditional categories
  - Clinical and Translational research
  - Innovative technology
  - Galvanizing Engineering in Medicine (GEM)
  - Pilot Academic—Community partnership research
- New categories
  - Lifespan research
  - Clinical research processes
  - Science of Team Science
  - Dissemination and Implementation Science

More CTRI resources to facilitate research

- Administrative support to develop and launch clinical studies
  - Rapid Research Trial Teams (R2T2)
  - Clinical Trial Project Organization (CTPO) teams
  - Workflow, Outcomes and Quality Improvement Office (WOQI)
- CTRI Center for Clinical Research
  - Project Manager Service
  - Clinical research space
  - Infusion center
  - Sample acquisition
  - Clinical cores (exercise, echo, DEXA, skin biopsy)
  - Phase I unit
  - Nurses, coordinators, phlebotomy
  - Experimental pharmacy
Clinical and Translational Research Institute

- Clinical services since 2011, including:
  - 148 protocols currently active in CCR
  - ~3000 visits/year
  - 238 infusions since 2013 (179 in 2014)
  - 418 skin biopsies since 2012 (36 in 2014)
  - 72 IRB submission consultations since 2012
  - 90 consults to facilitate recruitment and enhance diversity

CTRI coordinates specialized research centers

- Center for Health Research: Pediatrics, Orthopedics, Neurosciences
- Center for Women's Health: Obstetrics, Gynecology, Reproductive Health
- Center for Aging: Geriatrics, Neurosciences
- Center for Rare Diseases: Genetics, Neurosciences

Project Manager Service

- Review, triage and track service requests
- Coordinate and manage pre-launch (RED team) and post-launch activities (CTPO)
- Develop timelines and track milestones
- Manage regulatory and administrative hurdles
- Track enrollment and institute action plan if needed
- Assure high quality and timely data collection
Clinical trial workflow

- R2T2 Members
  - Project Manager
  - Feasibility
  - Safety and ethics
  - Biostatisticians
  - Regulatory
  - Budget and contract
  - Pharmacy
  - Nursing
- CTPO Members
  - Project Manager
  - Recruitment
  - Amendments
  - Adverse Events
  - Safety Tracking
  - Nursing/Pharmacy
  - Monitoring
  - Information
  - Database

Clinical Trials Project Operations
Clinical Research Performance

RED Team
- Project Manager assigned after request from research team or notified by contract office or HRPP
  - Organizes team and tracks progress
  - Identifies roadblocks and facilitates solutions
- RED team members vary depending on protocol needs
  - Regulatory analyst
  - Contracting and budget specialist
  - Nursing and safety assessment
  - Pharmacist
  - Informatics consultant
  - Biostatistics consultant for design and feasibility
  - Ethics consultant
- Team meets with investigator to initiate pre-launch
Performing studies:
Clinical Trial Operations Teams (CTPO)

- Project manager transitions project from R2T2 to Clinical Trial Project Operations (CTPO)
  - Assembles CTPO team members and resources
- CTPO manages Center for Clinical Research (CCR) resources
  - Space
  - Coordinators/Nurses
  - Infusions
  - Experimental pharmacy
  - Phlebotomy
  - Sample collection and processing
  - Informatics assistance
  - Biorepository services
  - Biomarker services

CTRI informatics tools for clinical research

- Velos
- REDCap
- iDASH and HIPAA-compliant data storage
Tools for clinical trial accrual

- Study feasibility and participant recruitment services
  - UC ReX
  - ResearchMatch
  - Data concierge
  - New tools that use the EMR to match patients with studies

CTRI biorepository support

- Sample processing
- Biorepository services
- Velos eSample for tracking and linking to the EHR

CTRI: beyond San Diego; a collaborative hub

- UC BRAID
- “Engage UC” for Biorepository consents
- NCATS Accrual to Clinical Trials
- NCATS IRB Reliance
- NCATS Good Clinical Practice project
- NCATS Scientific Review project
CTRI as a collaborative hub: UC BRAID

• Created in 2010

• Shared Vision: to integrate resources and talent across UC to accelerate research that improves health

BRAID and improved clinical trial efficiency

UC BRAID and improved IRB efficiency

• IRB reliance agreement between UCs
• 39 studies with duplicate IRB reviews across UC
Center for Accelerating Drug Development

- Multi-disciplinary early proof-of-concept clinical trials
- Improve drug safety, efficacy and dosing assessments
- De-risk trials with clinical endpoints
- Novel study designs, e.g., n of 1 studies
- Key elements
  - Phase I Unit
  - Biomarker Laboratory
  - Center for Computational Biology

CADD: CTRI biomarker laboratory

Biomarker studies in RA and IBD

CADD: Center for Computational Biology

Network-based stratification of somatic tumor mutations:
Survival in ovarian cancer subtypes
CTRI education and training: Integrated program for learners

CTRI education and training—CREST

404 enrollees since 2010
Core curriculum includes:
- Biostatistics
- Epidemiology
- Patient-oriented research
- Bioinformatics
- Health services research

Master of Advanced Studies Degree
with additional coursework and practicum

Future CTRI plans:
Master of Drug Development Science Degree

CTRI Mentored Career Development Program (KL2)

- 2-3 years funding for research, instruction, career mentorship training
- Leads to individual K or R award
- 14 awarded since 2010
- 80-90% receive significant funding within 2 years
- New areas of emphasis:
  - Increased number of scholars from 3 to 8
  - Improved diversity
  - New courses (Masters in Drug Development Science)
  - Mentoring Core
  - Mini-sabbaticals
**CTRI Pre/post-doctoral Training Program (TL1)**

- 100 enrollees since 2010
- 3 month (8 positions) and 1 year (10 positions) curriculum for MD and PharmD students
- 1 year program supports MAS degree
- Recent changes:
  - Expand to UC Riverside
  - New tracks with MAS in Clinical Research program
  - New MS degree in Drug Development Science
  - Mentoring from K awardees
  - New post-doctoral trainees for team science (2 positions)

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**CTRI science: Disruptive innovation**

Stamp-sized patches of circuits, sensors, and wireless transmitters to monitor the brains immediately after birth

Todd Coleman—engineer
MJ Harbert—pediatric neurologist

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**Disruptive innovation—Tricorder XPRIZE**

International teams compete for novel home-use diagnostic device