Clinical and Translational Science Awards (CTSA) Program

- National consortium of medical research hubs
- Work together to improve the way clinical translational research is conducted nationwide
- Provide training for clinical translational researchers
- Evolved from GCRC and clinical training programs as part of NIH Roadmap for Medical Research
- The CTSA program was established in 2006 to re-engineer the translational research enterprise
National Center for Advancing Translational Sciences (NCATS) Mission

To catalyze the generation of innovative methods and technologies that will enhance the development, testing and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions.
Clinical and Translational Science Awards (CTSA) Program Sites (n=62)
CTSA as a catalyst
Matching scope and resources

CTSA program
~ 2% of NIH budget
~ 0.5% of total R&D investment  (Shekar 2014)

Clinical Research Enterprise
(public and private funders)

• CTSA program innovates
• Finds generalizable solutions

CTSAs $472M
CTSAs Support Spectrum of Translation

- Investigator Training
- Technology accelerator(s)/innovation incubator(s)/commercialization facilitation
- Translational genomics technologies
- Large-scale drug discovery program(s)
- Biobank(s)
- High through-put screening capabilities
- Large scale biomarker discovery/validation program(s)
- cGMP Facilities
  - Clinical Research Data Warehouses (i2b2)
  - Clinical Research Center(s)
  - Unique study population(s)
- Clinical Trials
- Health information exchange
  - Phase I
  - Phase II
  - Phase III
- CER infrastructure
- Research Networking Capability (VIVO, Profiles, Direct Network, etc)
  - Electronic Data Capture (REDCap)
  - Study Recruitment (ResearchMatch)
Examples of Cores Supported in the Past

- Investigator Training
- Technology accelerator(s)/innovation incubator(s)/commercialization facilitation
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Prevalence of Charge-Back Mechanism among CRUs/CTSAs*

SPARC: Services, Pricing, & Applications for Research Center
A Multi-institutional Integrated Web Based Research Management System

Center for Cellular Therapy (CCT)
The CCT is a GMP processing facility containing 3 ISO Class 6 processing suites available for the production of human cellular and tissue based products (HCT/P) for use in translational research protocols and clinical programs. In addition to aseptic processing, cryopreservation and immune monitoring capabilities, the CCT laboratory is also approved to work with Retro and Lentil based viral vectors.

Facility Fee
Quality Assurance Rate
Technician Rate

News
SPARC Request Blog Sign-Up Drawing – “Research Made Easy”
March 19, 2015

Three SPARC Request Hands on Trainings booked for Feb-March.
February 3, 2015

Calendar
No events scheduled within a month from today.
CATCHR: Catalog of Assets for Translational and Clinical Health Research

CATCHR is a resource (asset) identification tool that allows you to both browse and pinpoint diverse programs, infrastructure and services across the full clinical and translational science spectrum and across the entire CTSA Consortium. Use this page to view aggregate information on assets within the consortium, including questions used to collect data from sites. Select an asset from the menu below to view sites where that asset exists and to view questions and resulting aggregate data.

Choose an Asset
- Clinical Research Units
- Pilot Funding Programs
- Electronic Health Records and Clinical Data Reuse
- National and Regional Network Memberships
- Biobanks
- Clinical Trial Coordinating Centers
- High-Throughput Screening
- High End Instrumentation
- Non-NIH Lab Partnerships
- Medicinal Chemistry Facilities
- Unique Clinical Study Populations
- Drug Discovery Centers
- Nanotechnology Centers/Programs
- cGMP Facilities
- Expert Consults
- Community Engaged Research Infrastructures
- Trials of REDCap Adoption
- IND/IDE Support Programs

High-Throughput Screening by Institution
Points on the map below represent CTSA sites where this particular catalogued asset is present.

High-Throughput Screening
High-throughput screening (HTS) is a method for scientific experimentation especially used in drug discovery. Using robotics, data processing and control software, liquid handling devices, and sensitive detectors, HTS allows rapid conduct of tens of Learn more >>
Institute of Medicine (IOM) Recommendations

BOX S-1
Overview of Recommendations

The next steps for the Clinical and Translational Science Awards (CTSA) Program and opportunities for advancing clinical and translational research are as follows:

- Strengthen leadership of the CTSA Program by the National Center for Advancing Translational Sciences (NCATS).
- Reconfigure and streamline the CTSA Consortium.
- Build on the strengths of individual CTSAs across the spectrum of clinical and translational research.
- Formalize and standardize evaluation processes for individual CTSAs and the CTSA Program.
- Advance innovation in education and training programs.
- Ensure community engagement in all phases of research.
- Strengthen clinical and translational research relevant to child health.

*The full text of the recommendations appears throughout the summary and in Chapters 3 and 4 of the report.*
Formalize and Standardize Evaluation Processes for the CTSA Program

- Metrics introduced into new CTSA FOA: RFA TR 14-009
- NCATS CTSA working group has been formed to develop Common Metrics
  - NCATS staff, PIs, external consultant, etc.
  - Incorporate and leverage prior work on metrics
  - Minimize administrative/data burden on CTSAs
- New Domain Task Forces (DTFs)
  - Methods/Processes, Informatics, Workforce Development, Collaboration/Engagement, Integration Across the Lifespan
  - Includes representatives from all 62 CTSA hubs
New CTSA FOA Overview

RFA TR 14-009

Three Components

• **U award (cooperative agreement)**
  
  – *Overarching topics*: informatics, integration of health and research, diversity, community engagement, quality and team science
  
  – *Required modules*: Workforce development, BERD, regulatory knowledge, pilot studies, participant interactions, special populations
  
  – *Optional modules* in areas of institutional strength or opportunity
  
  – *Network support*: multi-site studies (IRB, contracting), and recruitment (EHR, on-the-ground recruitment support)

• **K award** – Mentored career development

• **T award** – NRSA Training Award
Multi-site trials are necessary to get from discovery to clinic

<table>
<thead>
<tr>
<th>Traditional model - CTSA 1.0</th>
<th>New model - CTSA 2.0</th>
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<tbody>
<tr>
<td>Trials re-built from the ground up each time</td>
<td>Prefabricated and funded clinical trial infrastructure with:</td>
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<tr>
<td>De-centralized IRB review and contracting</td>
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<tr>
<td>Splintered and complicated compensation</td>
<td>- Willing, veteran clinical sites</td>
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<tr>
<td>Trial participant estimates, gross overestimates common</td>
<td>- Master Trial Agreements in place</td>
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<td></td>
<td>- Central IRB (cIRB) with existing reliance agreements</td>
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<tr>
<td></td>
<td>- EHR estimates of patient availability</td>
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<td>- Means to introduce eligible, willing participants to investigators</td>
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Value of Regional IRB Reliance Agreement: Boston Marathon Bombing

- Several CTSAs in regions across the country have formed networks to collaborate on approving clinical trials - known as IRB reliance.
- Boston Marathon: Doctors at Mass Eye and Ear in Boston realized that they could learn more about the nature of blast-related ear injuries by studying bombing victims.
- Harvard CTSA already had an IRB reliance network in place with 7 other hospitals.
  - Rapid IRB approval was obtained to study a large number of ear injuries from the same blast, and to observe patients as they healed.
Building the Foundation: Pilot CTSA Network Initiatives

**cIRB** (Lead CTSA: Tufts)
- Reliance agreement drafted and under review
- IT platform under development (open source)
- Pilot project in planning phase

**Contracting** (Lead CTSAs: Mayo and Vanderbilt)
- Master trial agreement for CTSA/industry interactions drafted and executed at >2/3 of sites
- Subcontract template for NIH funded study under development
- Coordinating with PCORNet
Building the Foundation: Pilot CTSA Network Initiatives

- **EHR Recruitment**
  - Accrual to Clinical Trials - ACT
  - I2b2/Shrine technology implementation started at 11 sites (wave 1)
  - IRB approval obtained
  - Wave 2 sites identified
  - Governance, technology and regulatory workgroups have established infrastructure and SOP’s
  - Data harmonization group with PCORNet
  - Pilot query planned for June 2015

NOT-TR-15-001: Trial Innovation Centers (TICs)

- Customized clinical trial support
  - central Institutional Review Boards (cIRBs)
  - master trial agreements
  - streamlined organization, communications and oversight

- Innovative approaches to increasing clinical trial efficiency and effectiveness
NOT-TR-15-003: Recruitment Innovation Centers (RICs)

- Data-driven cohort discovery
  - use Electronic Health Records (EHR) to estimate the number of potential participants who meet the trial entry criteria with the CTSA network

- Development and implementation of recruitment plans
  - Innovative recruitment tools and strategies to connect participants with potential trial opportunities
Evolving the Program to Transform Clinical Translational Science

CTSA Hubs

TIC: Trial Innovation Centers
- Central IRB
- Contracting
- Budgeting
- Other support PRN

RIC: Recruitment Innovation Centers
- Feasibility Assessment
- Recruitment Plan and Implementation

Steering Committee with NIH members

Multi-site Study funded by NIH IC or others

Clinical Lead
Stats/Data Management

No need to re-build trial components each time
NOT-TR-15-005: Collaborative Innovation Awards

- Develop a new technology, method, or approach that addresses a general roadblock in science and/or operations that limits the efficiency and effectiveness of translation
- Demonstrate in one or more use cases whether the tool, method, or approach is effective in accelerating translation across multiple CTSA hubs
- Advance collaboration, building on existing strengths and resources of CTSA hubs
- Success of the proposed project can be defined and measured
Take-Home Messages

• The current pace of drug development cannot meet the needs and opportunities
• 21\textsuperscript{st} c. needs cannot be solved with 20\textsuperscript{th} c. structures
• The CTSA program has begun to transform itself and its programs to meet these opportunities and needs for the benefit of patients through
  ➢ Improved methods and streamlined processes
  ➢ Innovative training of the translational research workforce
  ➢ Collaboration with NIH partners