CTSA Consortium Coordinating Center (C4)
Supporting the CTSA Consortium

FasterCuresTRAIN June 6, 2012
Gordon Bernard, MD
Program Director, CTSA Consortium Coordinating Center
Imagine rapid initiation and conduct of clinical trials by:
1. Quickly securing IRB approvals
2. Use of master intra-CTSA contracts
3. Easily locating necessary facilities
4. Use of standardized case report forms and data collection system for remote data entry
5. Quickly identifying potential participants
6. Having ready access to dedicated research space and high quality nursing care
IRB Share status

- Progress:
  - Reps from 37 CTSA sites met in person to discuss workflow (R13)
  - 22 CTSA sites agreed to participate in pilot
  - OHRP reviewed
  - Engaged KFCs and SGCs
  - Identified NIH-funded multi-site study

$84 Million Grant Awarded to Fund ISCHEMIA

The NHLBI has awarded an $84 million grant to fund the International Study of Comparative Health Effectiveness with Medical and Invasive Approaches (ISCHEMIA). The trial will randomize 8,000 patients with stable ischemic heart disease and moderate to severe ischemia. Two different treatment strategies for this patient population will be compared:

1. An **invasive strategy**, consisting of early routine cardiac catheterization followed by revascularization plus optimal medical therapy (OMT) and lifestyle changes.

2. A **conservative strategy** of OMT and lifestyle changes in which invasive procedures will be performed only after failure of OMT.

The primary endpoint is the combination of cardiovascular death, MI, and centrally adjudicated hospitalization for unstable angina, heart failure, or
VANDERBILT UNIVERSITY

Decision: approved
Review Cycle: 12 mo
Review Path: full
Submitted: 01/02/2012
Reviewed: 01/05/2012
Approved: 01/11/2012

IRB Number: 123456
# Following: 1

Documents:
- Protocol
- Determination Letter
- Meeting Notes
- IRB Application
- Consent Forms

MEDICAL UNIVERSITY OF SOUTH CAROLINA

Decision: approved
Review Cycle: 12 mo
Review Path: shared
Submitted: 01/17/2012
Reviewed: 01/17/2012
Approved: 01/17/2012

IRB Number: Pro00001234
# Following: 1

Base On:
[✓] Full Review of Vanderbilt University
CTSA 2.0: Establish the Consortium as a world class environment for high quality, multi-site C&T science

Envision rapid initiation and conduct of clinical trials by trained investigators who would:

1. quickly secure IRB approvals
2. **negotiate a site specific addendum to master contract**
3. determine which sites have necessary facilities
4. use standardized case report forms and data collection system for remote data entry
5. quickly identify potential participants
6. access research space and high quality nursing care
Expediting contracting

• Contract processes review and analysis (SGC1)
• Contract language comparisons e.g. IOM template (SGC5)
• Harmonizing language across sites (CC plans to support)
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Finding sites of interest (leveraging the CTSA established ‘entry points’)

HIGH-END INSTRUMENTATION
The NCRR High-End Instrumentation (HEI) grant program supported the purchase of a single major piece of research equipment that costs more than $750,000. Instruments in this price range include structural and functional imaging systems, macromolecular NMR spectrometers, high-resolution mass spectrometers, electron microscopes, and supercomputers. Many awards have been made over the past 6 years, and a subset of these are available for clinical and translational research.

PARTICIPATING INSTITUTIONS
Matching HEI: Spectrometers, Magnets/Microscopy, Computational, HTS/Genomics

University of Minnesota Clinical and Translational Science Institute
- 16.4 Tesla Animal MRM RP System
- High-Throughput Nanoliter Crystallization Facility

Note: symbol size reflects number of site awards.
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REDCap: ~50,000 users

Designed for RESEARCHERS
Flexible - supports any study
Fast setup and launch
Accessible – Web Based
Secure

Constantly evolving e.g.
Data De-Identification Services
Participant Scheduling Support
Data Transfer Services & API
Graphical Data Review
Double-Data Entry
Full audit trails and logging
Shared Library (efficiency, standardization)
Multi-site Collection (sequestered access)
Data quality reports
The REDCap Consortium is comprised of 335 active institutional partners from CTSA, GCRC, RCMI and other institutions, and it supports a secure web application (REDCap) designed exclusively to support data capture for research studies. The REDCap application allows users to build and manage online surveys and databases quickly and securely, and is currently in production use or development build-status for more than 30,930 projects with over 43,570 users spanning numerous research focus areas across the consortium. To find out if your institution is already running REDCap, you will find contact information on the Consortium Partners page.

Learn more about REDCap by watching a brief summary video (4 min).

Map of REDCap Consortium Partners
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Finding solutions, advancing health.
ResearchMatch.org

- Disease-neutral, institution-neutral, automated research matching service
- Over 140 liaisons actively engaged
CTSA 2.0: Establish the Consortium as a world class environment for high quality, multi-site C&T science

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Mapping of assets needed for a large, collaborative C&T project

Development of novel treatment for schizophrenia

CTSA RESOURCE IDENTIFICATION

Clinical and Translational science projects require a diverse set of resources that are available across the CTSA consortium. The CTSA Resource Identification Tool will link researchers with the resources, infrastructure, and expertise necessary to efficiently execute large-scale, collaborative C&T projects.

PARTICIPATING INSTITUTIONS

Matching CRC: ✔ Adult Inpatient Beds ✔ Subject Recruitment Support ✔ ECG ✔ Telemetry ✔ PK/PD

RESOURCES

- Medical Chemistry
- cGMP Manufacturing
- Preclinical Studies
- Imaging Technology
- IND/IDE Support
- CRC
  ✔ Adult Inpatient Beds
  ✔ Subject Recruitment Support
  ✔ ECG
  ✔ Telemetry
  ✔ PK/PD

University of Cincinnati Center for Clinical and Translational Science and Training

Register Study to Request a CTSA Consultation ➕ Export Institutional Resource & Contact List
All Initiatives Apparently are Priorities

- Streamlining (e.g. IRB Share)
- Value contribution
- Virtual Institute Drug Development
  - **87% yes**

N=61 so far
Drug development ratings

% of respondents

Impact
Feasibility
Urgency

High
Moderate
Low
<table>
<thead>
<tr>
<th>CTSA: INDIRECT SUPPORT</th>
<th>CTSA: DIRECT SUPPORT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Technology accelerator(s)/innovation incubator(s)/commercialization facilitation</strong></td>
<td><strong>Clinical Research Center(s)</strong></td>
</tr>
<tr>
<td>30/60 (50%) sites</td>
<td>60/60 (100%) sites</td>
</tr>
<tr>
<td><strong>Translational genomics technologies</strong></td>
<td><strong>Unique study population(s)</strong></td>
</tr>
<tr>
<td>57/60 (95%)</td>
<td>15/60 (25%) sites</td>
</tr>
<tr>
<td><strong>Large-scale drug discovery program(s)</strong></td>
<td><strong>cGMP Facilities</strong></td>
</tr>
<tr>
<td>25/60 (42%) sites</td>
<td>11/60 (18%) sites</td>
</tr>
<tr>
<td><strong>High through-put screening capabilities</strong></td>
<td><strong>Biobank(s)</strong></td>
</tr>
<tr>
<td>41/60 (68%) sites</td>
<td>9/60 (15%) sites</td>
</tr>
<tr>
<td><strong>Large-scale biomarker discovery/validation program(s)</strong></td>
<td><strong>Research Networking Capability (VIVO, Direct Network, etc)</strong></td>
</tr>
<tr>
<td>39/60 (65%) sites</td>
<td>5/60 (8%) sites</td>
</tr>
<tr>
<td><strong>cGMP Facilities</strong></td>
<td><strong>ResearchMatch</strong></td>
</tr>
<tr>
<td>11/60 (18%) sites</td>
<td>47/60 (78%) sites</td>
</tr>
<tr>
<td><strong>i2b2 Clinical Research Data Warehouses</strong></td>
<td><strong>Phase I</strong></td>
</tr>
<tr>
<td>27/60 (45%) sites</td>
<td>2349 studies/60+ sites</td>
</tr>
<tr>
<td><strong>Clinical Research Center(s)</strong></td>
<td>7286 studies/60+ sites</td>
</tr>
<tr>
<td>60/60 (100%) sites</td>
<td>12817 studies/60+ sites</td>
</tr>
<tr>
<td><strong>Data from ClinicalTrials.gov</strong></td>
<td><strong>Comparative Effectiveness</strong></td>
</tr>
<tr>
<td><strong>Biobank(s)</strong></td>
<td><strong>CER infrastructure</strong></td>
</tr>
<tr>
<td>9/60 (15%) sites</td>
<td>6/60 (10%) sites</td>
</tr>
<tr>
<td><strong>Research Networking Capability (VIVO, Direct Network, etc)</strong></td>
<td><strong>Phase II</strong></td>
</tr>
<tr>
<td>5/60 (8%) sites</td>
<td>25/60 (42%) sites</td>
</tr>
<tr>
<td><strong>REDCap</strong></td>
<td><strong>Phase IV</strong></td>
</tr>
<tr>
<td>55/60 (92%) sites</td>
<td><strong>Safety Surveillance</strong></td>
</tr>
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</table>
Program scope (and associated name) would be determined by Board

Virtual Institute of Drug Development...

Virtual Institute of Therapeutic Innovation?
Virtual Institute of Translational Science?
Virtual Institute of Drug Discovery, Development, and Dissemination?
Virtual Therapeutic Institute development next steps:

• **Progress**
  • Basic assets captured /framework created

• **Next steps:**
  • Refine and expand assets catalogue
  • Hold national design session
  • Develop governance structure