Opportunities for Cooperation and Synergism between PCORI – NIH Collaboratory – CTSA consortium

Gordon R. Bernard MD
Director CTSA Consortium Coordinating Center (C4)
Vanderbilt University
Nashville, TN
## Overlap of CTSA and PCORI CDRN SITES (not counting affiliates)

<table>
<thead>
<tr>
<th>Albert Einstein College of Medicine (partnering with Montefiore Medical Center)</th>
<th>Northwestern University</th>
<th>University of Iowa</th>
</tr>
</thead>
<tbody>
<tr>
<td>Columbia University</td>
<td>The Rockefeller University</td>
<td>University of Kansas Medical Center</td>
</tr>
<tr>
<td>Harvard University</td>
<td>University of California Los Angeles</td>
<td>University of Minnesota Twin Cities</td>
</tr>
<tr>
<td>Johns Hopkins University</td>
<td>University of California, Davis</td>
<td>University of Pittsburgh</td>
</tr>
<tr>
<td>Penn State Milton S. Hershey Medical Center</td>
<td>University of California, Irvine</td>
<td>University of Texas Medical Branch</td>
</tr>
<tr>
<td>Medical College of Wisconsin</td>
<td>University of California, San Diego</td>
<td>University of Wisconsin - Madison</td>
</tr>
<tr>
<td>Mount Sinai School of Medicine</td>
<td>University of California, San Francisco</td>
<td>Vanderbilt University (partnering with Meharry Medical College)</td>
</tr>
<tr>
<td>New York University School of Medicine (partnering with New York City Health and Hospitals Corporation (HHC) )</td>
<td>University of Chicago</td>
<td>Weill Cornell Medical College (partnering with Hunter College)</td>
</tr>
</tbody>
</table>
Collaboration with the Clinical Decision Support Consortium (CDSC)

28 Institution and Industry members including Vanderbilt as the Coordinating Center (Blackford Middleton)

Collaboration and leadership to expand best practices and service to a network of institutions including those in PCORnet
## Overlap of CDSC sites and PCORI CDRN sites

<table>
<thead>
<tr>
<th>Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>CIRD at Partners HealthCare</td>
</tr>
<tr>
<td>CQA at Partners HealthCare</td>
</tr>
<tr>
<td>DGIM at Brigham and Women's Hospital</td>
</tr>
<tr>
<td>Kaiser Permanente</td>
</tr>
<tr>
<td>Mount Sinai Medical Center</td>
</tr>
<tr>
<td>Oregon Health &amp; Science University</td>
</tr>
<tr>
<td>Mount Sinai School of Medicine</td>
</tr>
<tr>
<td>The University of Texas Health Science Center at Houston and Oregon Health Sciences University</td>
</tr>
<tr>
<td>Vanderbilt University</td>
</tr>
</tbody>
</table>
Overlap of eMERGE sites And PCORI CDRN sites

<table>
<thead>
<tr>
<th>Children's Hospital of Pennsylvania (CHOP)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cincinnati Children's Hospital Medical Center/Boston's Children's Hospital (CCHMC/BCH)</td>
</tr>
<tr>
<td>Geisinger Health System</td>
</tr>
<tr>
<td>Group Health Cooperative in conjunction with the University of Washington and the Fred Hutchinson Cancer Research Center</td>
</tr>
<tr>
<td>Essentia Institute of Rural Health &amp; Marshfield Clinic (Marshfield)</td>
</tr>
<tr>
<td>Mayo Clinic</td>
</tr>
<tr>
<td>Mount Sinai School of Medicine</td>
</tr>
<tr>
<td>Northwestern University</td>
</tr>
<tr>
<td>Vanderbilt University</td>
</tr>
</tbody>
</table>
The eMERGE Network

Electronic Medical Records & Genomics

A consortium of biorepositories linked to electronic medical records data for conducting genomic studies
CTSA (and now PCORI & NIH Collaboratory): Vision to create a platform for more efficient conduct of clinical trials

LaunchPad

Note: These efforts have various sources of support

- Institutional
- Federal
- Industry
- Foundation
- PCORI
LaunchPad

- National Studios
- Expert Collaborator Identification
- Educational Resources
- Resource & Infrastructure Identification
- Document Sharing & Collaboration
- IRB Streamlining
- Contract Streamlining
- Participant Recruitment
- Data Collection & Management
- New Components as Needed

**REDCap (Research Electronic Data Capture):** an electric data management system utilized by **941** institutional partners and over **127,000** users working across **75** countries.
REDCap is a secure, web-based application for building and managing online surveys and databases

Features include:

- 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
- Auto-validation
- Calculated fields
- Branching/skip logic
- Randomization
- FDA Part II compliance
#2 Registries + Longitudinal Studies

1. REDCap User Maps Data Warehouse Fields to REDCap Project Database

<table>
<thead>
<tr>
<th>External Source Field</th>
<th>Map to REDCap Event</th>
<th>Map to REDCap Field</th>
<th>Map to REDCap date/time field</th>
<th>Remove mapping</th>
</tr>
</thead>
<tbody>
<tr>
<td>name “Medical Record Number”</td>
<td>Enrollment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Source Identifier Field</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>gender “Gender”</td>
<td>Enrollment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>race “Race”</td>
<td>Enrollment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>dob “Date of Birth”</td>
<td>Enrollment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>firstName “First Name”</td>
<td>Enrollment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>lastName “Last Name”</td>
<td>Enrollment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitalis weight “Weight”</td>
<td>Event 1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>weight “Weight”</td>
<td>Event 2</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. REDCap Users Are Made Aware of Data in Warehouse

3. REDCap Users May Adjudicate Data Into REDCap Project Database
PROMIS Short Form v1.0 – Physical Function 12a

• Are you able to walk a block on flat ground?
  - Without any difficulty
  - With a little difficulty
  - With some difficulty
  - With much difficulty
  - Unable to do

• Does your health now limit you in doing strenuous activities such as backpacking, skiing, playing tennis, bicycling or jogging?
  - Not at all
  - Very little
  - Somewhat
  - Quite a lot
  - Cannot do

• Are you able to get in and out of bed?
  - Without any difficulty
  - With a little difficulty
  - With some difficulty
  - With much difficulty
  - Unable to do
OHRP/FDA/AAHRPP-acknowledged shared IRB review model designed to streamline initiation of multi-site studies by:

- Reducing duplicative IRB reviews of multi-site studies
- Accelerating IRB approval and study start-up
- Facilitating document sharing
- Promoting consistency
- Facilitating collaboration across IRBs

35 participating institutions, 4 active studies
IRBshare

- **Single, one time universal agreement**
- Open to any institution with an active Federalwide assurance with OHRP
- Open to any disease network
- Does not require a single IRB of Record for the life of the study
- All sharing sites do not have to choose the same IRB of Record
- Free to join; minimal start up and overhead costs

**Required IRB documents:**
IRB application, study protocol, consent form, meeting minutes (redacted), and determination letter
A newer initiative called ContractShare to streamline the contracting process for multisite clinical studies. 25 institutions have created a master accelerated clinical trial agreement.
The Master Contracts Working Group from the 25 CTSAs below is collaborating to develop efficient models for Clinical Trial Agreements for multi-site study initiation.
ROCKET (Research Organization, Collaboration, and Knowledge Exchange Toolkit): a free web-based HIPAA compliant tool to facilitate collaboration
ROCKET is a web-based sharing and collaboration software platform

- Allows creation of virtual workspaces and rapid dissemination of information and documents
- Permits sharing of documents for collaborative review and editing
- Useful for assigning and tracking completion of tasks and makes tasks visible to all
ResearchMatch is a free, secure registry that connects people who are trying to find research studies with researchers who are seeking people to participate in their studies. Can be used to create sub-registries.
ResearchMatch.org

The ResearchMatch Registry is:

• Free
• Secure
• Making it easier for the public to volunteer for studies
• Making it easier for researchers to find participants
Launched: Autism, HIV, Intellectual Disabilities, Ehlers-Danlos Syndrome, Eosinophilic Esophagitis and Postural Orthostatic Tachycardia Syndrome (POTS), Food Allergy

In Development: Huntington’s Disease (working with researcher Dan Claassen Vanderbilt), Neuropathy (Neuropathy Association partner)
Role of the Vanderbilt eMERGE Coordinating Center

- multi-party data use agreement
- transportable algorithms, computable phenotypes; [http://phekb.org/](http://phekb.org/)
- data exchange capabilities
- data standards
- privacy