CLINICAL DATA RESEARCH NETWORKS (CDRNs) - LEVERAGING THE VALUE OF EHRs

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presented by:

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Agenda

• Describe what a Clinical Data Research Network (CDRN) is and the benefits of CDRNs
• Review Duke’s involvement in CDRNs
• Review the underlying technology
• Identify the value of CDRN
What is a Clinical Data Research Network (CDRN)?

A group of health care delivery organizations that have agreed to aggregate their clinical data in a federated manner for the purpose of supporting clinical research.

- Enables sharing of de-identified clinical data, i.e., the provision of counts, for patient populations as defined by specific criteria to aid cohort identification

- If appropriate cohort size is identified, the CDRN can also provide more detailed dataset with appropriate IRB approval

- Respond to
  - Requests for data – counts and datasets
  - Requests for research collaborators/study participants
CDRNs are Vendor Agnostic

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“Once you close a paper file it's dead. You’re not able to move it or learn from it.”

Dr. Farzad Mostashari – Former Office of National Coordination Chief, DHHS

• CDRNs represent a paradigm shift for clinical and health services research which leverages the proliferation of electronic health records (EHRs)

This data acquisition process is:
• Timely
• Less costly
• More efficient
• Leverages existing EHR data
Some Key CDRN Advantages

Secure access to Broader Patient Base for Research
- In the federated data sharing model, the actual patient clinical record never leaves the health delivery organization.
- Assists researchers in identifying cohorts of potential participants in research study.
- Enables Pragmatic Clinical Trials and Cluster Randomization

Standard Data Model
- Many participating organizations implement the same common data model allowing for data harmonization across different health care organizations with different EHRs.

Institutional Support
- Potentially reduces the cost of research by eliminating or minimizing need for chart data abstraction and subsequent data entry.
- Organizational leadership buy-in for secure data sharing process for research is ensured.

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Active CDRNs at Duke Health

ACT

Mid-South CDRN/PCORnet

Carolinias Collaborative

Duke Health

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Carolinas Collaborative

- **Overview:** 3-year grant project funded by The Duke Endowment
  - Create data and IT infrastructure
  - Use data/infrastructure to improve the health of Carolinians

- **Number of Patient Records:** 9M+

<table>
<thead>
<tr>
<th>Year 1 Accomplishments</th>
<th>Year 2 Goals</th>
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<tbody>
<tr>
<td>Received IRB approval for the required data and technology infrastructure</td>
<td>Lead Health Equity initiative in Collaborative with UNC-CH</td>
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<tr>
<td>Created the common data model</td>
<td>Fulfill requests for count data and approved datasets for research projects</td>
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<tr>
<td>Implemented the required i2b2/SHRINE technology platform</td>
<td>Refine our internal Duke CDRN operations</td>
</tr>
<tr>
<td>Defined needed processes for reviewing/fulfilling approved requests for counts and datasets</td>
<td>Promote use of CDRNs by Duke researchers.</td>
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<tr>
<td>Created i2b2 training for Duke researchers.</td>
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<tr>
<td>Established proper agreements among participating institutions.</td>
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Mid-South CDRN/PCORnet

- **Overview:** 3-year PCORI grant to be a node on the PCORnet (Patient Centered Outcomes Research network) via our participation in the Mid-South Alliance CDRN

- **Number of Patient Records:** 25M+

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<thead>
<tr>
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<th>Year 2 Goals</th>
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<tr>
<td>• Created the common data model</td>
<td>• When requested by the PCORI Coordinating Center, provide count data in response to specific research questions posed to all nodes on the network – “rapid responses”</td>
</tr>
<tr>
<td>• Implemented the required PopMedNet/SAS technology platform</td>
<td>• Support research studies by providing datasets, co-investigators, and/or study participants upon request and subsequent to review/approval process</td>
</tr>
<tr>
<td>• Defined needed processes for reviewing/fulfilling approved requests for counts and datasets</td>
<td>• Promote use of CDRNs by Duke researchers.</td>
</tr>
<tr>
<td>• Established collaborative partnership with the Duke Recruitment Center operations to support CDRN requirements.</td>
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<tr>
<td>• Established proper agreements among participating institutions.</td>
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</table>
ACT CDRN

- **Overview:** Accrual to Clinical Trials is a Clinical and Translational Science Awards (CTSA) sponsored initiative which aims to improve the success of U.S. clinical trials by developing a nationwide network of sites that share EHR data.

- **Number of Patient Records:** 40M+

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<td>• Data harmonization (using the same term for the same type of data) across EHR platforms.</td>
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</tr>
<tr>
<td>• Technical needs assessment and implementation of i2b2 and SHRINE technology platform.</td>
<td>• Regulatory approaches to ensure compliance with protocols for data access and participant contact.</td>
</tr>
<tr>
<td></td>
<td>• Establish proper agreements among participating institutions.</td>
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Benefits to Duke for CDRN Participation

- Allows Duke researchers access to clinical data outside of Duke Health System
- Expands Duke researchers opportunity to participate in studies as co-PIs
- Provides opportunity to generate research revenue
  - CDRNs position health care organizations to participate in major NIH studies, e.g., Precision Medicine Initiative (PMI)
- Ensures continued Duke presence on national research stage given new paradigm for accessing clinical data for research – both as a provider of clinical data and a receiver of clinical data for research.
- CDRNs are a required element for our Clinical and Translational Science Awards (CTSA) renewal, all major center grants, PCORI and Duke Health Chancellor’s strategic planning for population health.
Duke Goals and Key Aspects

Goals:
• Make CDRNs part of the “organizational fabric”
• To the extent possible, leverage existing technology, resources, policies, procedures, etc.

Key aspects:
• Provision of clinical data – counts and datasets
• Recruitment of co-investigators for studies
• Recruitment of study participants

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CDRNs Functional Overview

Data Provision Functions
- Maintain technical data infrastructure
- Ensure data quality
- Perform data extraction
- Serve as Honest Broker

Administration
- Oversight of data provision and recruitment functions
- Develop/maintain operating policies and procedures for CDRN
- Ensure operation consistent with Duke policies for data release and with external governing CDRN policies/procedures
- Tracking and administrative reporting of requests
- Promote use of CDRNs by Duke researchers

Recruitment Functions
- PI and study participant recruitment support strategy and operations
- Database/registry maintenance

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Effective CDRN operations require strong interdisciplinary collaboration and coordination within the organization. Some of these units include:

- IRB
- Security
- IT
- Governance
- Communications/Outreach
- Training and Education
Vanderbilt Medical Center: hospitals, >100 clinics engaging 2 million patients. Meharry/Metro General Hospital: 100,000 patients

VHAN: 7 health systems, 34+ hospitals, 350+ clinics engaging >3 million patients

Greenway: 1600 clinics engaging 14 million patients

Carolinas Collaborative with > 6 million patients
Data Aggregation Across Mid-South CDRN

1. Queries and Analytic Software Packages from PCORI
2. CDRN returns Counts and Aggregate resulting data
Mid-South CDRN Profile

PCORnet Coverage Map
This map depicts the number of PCORI-funded Patient-Centered Clinical Research Networks who have coverage in each state.

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Data and Technology Overview
#PCORI Common Data Model V 3.0

<table>
<thead>
<tr>
<th>Category</th>
<th>Version</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CONDITION</td>
<td>v2.0</td>
<td>A condition represents a patient’s diagnosed and self-reported health conditions and diseases. The patient’s medical history and current state may both be represented.</td>
</tr>
<tr>
<td>DEATH</td>
<td>v3.0</td>
<td>Reported mortality information for patients.</td>
</tr>
<tr>
<td>DEATH_CAUSE</td>
<td>v3.0</td>
<td>The individual causes associated with a reported death.</td>
</tr>
<tr>
<td>DEMOGRAPHIC</td>
<td>v1.0</td>
<td>Demographics record the direct attributes of individual patients.</td>
</tr>
<tr>
<td>DIAGNOSIS</td>
<td>v1.0</td>
<td>Diagnosis codes indicate the results of diagnostic processes and medical coding within healthcare delivery.</td>
</tr>
<tr>
<td>DISPENSING</td>
<td>v2.0</td>
<td>Outpatient pharmacy dispensing, such as prescriptions filled through a neighborhood pharmacy with a claim paid by an insurer. Outpatient dispensing is not commonly captured within healthcare systems.</td>
</tr>
<tr>
<td>ENROLLMENT</td>
<td>v1.0</td>
<td>Enrollment is a concept that defines a period of time during which all medically-attended events are expected to be observed. This concept is often insurance-based, but other methods of defining enrollment are possible.</td>
</tr>
<tr>
<td>ENCOUNTER</td>
<td>v1.0</td>
<td>Encounters are interactions between patients and providers within the context of healthcare delivery.</td>
</tr>
<tr>
<td>HARVEST</td>
<td>v3.0</td>
<td>Attributes associated with the specific PCORnet datamart implementation.</td>
</tr>
<tr>
<td>LAB_RESULT_CM</td>
<td>v2.0</td>
<td>Laboratory result Common Measures (CM) use specific types of quantitative and qualitative measurements from blood and other body specimens. These standardized measures are defined in the same way across all PCORnet networks.</td>
</tr>
<tr>
<td>PCORNENT_TRIAL</td>
<td>v3.0</td>
<td>Patients who are enrolled in PCORnet clinical trials.</td>
</tr>
<tr>
<td>PRESCRIBING</td>
<td>v3.0</td>
<td>Provider orders for medication dispensing and/or administration.</td>
</tr>
<tr>
<td>PRO_CM</td>
<td>v2.0</td>
<td>Patient-Reported Outcome (PRO) Common Measures (CM) are standardized measures that are defined in the same way across all PCORnet networks. Each measure is recorded at the individual item level: an individual question/statement, paired with its standardized response options.</td>
</tr>
<tr>
<td>PROCEDURES</td>
<td>v1.0</td>
<td>Procedure codes indicate the discreet medical interventions and diagnostic testing, such as surgical procedures, administered within healthcare delivery.</td>
</tr>
<tr>
<td>VITAL</td>
<td>v1.0</td>
<td>Vital signs (such as height, weight, and blood pressure) directly measure an individual’s current state of attributes.</td>
</tr>
</tbody>
</table>
PCORnet data characterization process

- Extensive review process to ensure quality data
  - Review benefits our Carolinas Collaborative datamart also because of same common data model being used
- Every 6 months process for entire datamart data
- Study specific data characterization to be done as needed
Carolinas Collaborative Technologies

i2b2
Informatics for Integrating Biology & the Bedside

SHRINE
Shared Health Research Information Network
Typical i2b2 Workflow

Step 1: Data Collection
- EMR
- Claims
- EMPI
- Schedule
- Etc.

Step 2: Clinical Data Warehouse (PHI)
- Integration ETL
- IRB-Approved PHI is retrieved

Step 3: Research ETL (PHI Removed)
- i2b2 research mart populated (anonymized data only)

Step 4: i2b2 research mart populated
- IRB approval
- Re-issue query to data mart with patient IDs
- eIRB request for PHI data
- Submit

Step 5: i2b2 queries

Step 6: Research data (PHI) to researcher

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I2b2 and Data Warehouse
The Duke i2b2 Interface
PopMedNet Network Workflow

1. Query created and submitted by authorized user on the secure network portal
2. Data partners notified of query and retrieve it from the secure network portal
3. Data partners review and run query against their local data
4. Data partners review results
5. Data partners securely return results to the secure network portal for review by requestor

Figure 1: Network Workflow
1. Query Metadata

Query 1, Tool = PMPI, MetaData

- Name: PCORI_PMPI_WP001_NS06_v01
- Priority: Normal
- Due Date: August 1, 2016
- Purpose of use: HRESCH (Health Research)
- Level of PHI Disclosure: Aggregated
- Description: (NOTE limited to 400 characters)

Query 1 calculates background rates in 2014 for ICD-9 and SM diagnosis-based conditions of interest. Executes against PCORnet SAS CDM v3.0 compliant tables (demographic, encounter, diagnosis). Aggregate output produced. SAS code should only be modified when specified. Report will be public facing and aggregate for all responding CDRNs/DataMarts. See Additional Instructions and Work Plan.

- Additional Instructions: (NOTE limited to 3000 characters)

Requester: PCORI

Confidentiality: The request topic should be treated as confidential pending final release of public report.

Planned Use: Report will be a public-facing description of the aggregate PCORnet population represented by responding PCORnet DataMarts. This report will appear on the PCORnet public website, aggregated across all CDRNs (one aggregate report across all responding CDRNs/DataMarts).

Program Package Contents: 1 work plan and 4 folders serving to organize program inputs and outputs. Program folder structure described in more detail in the work plan. Instructions to execute the master.sas program are located in Section 4 of the work plan.

This program will identify cohorts of patients in 2014 who have the following conditions:
* Diabetes (as defined by Charlson)
* Chronic Pulmonary Disease (as defined by Charlson)
* Any Malignancy (as defined by Charlson)
* Myocardial Infarction (as defined by a validated medical claims algorithm)
* Stroke/TIA (as defined by a validated medical claims algorithm)
* Rheumatoid Arthritis (as defined by medical claims algorithm)
* Ulcerative Colitis (as defined by medical claims algorithm)
* Hypertension (as defined by Charlson)
* Renal Failure (as defined by Charlson)
* Influenza and Pneumonia (as defined by medical claims algorithm)

Please follow internal governance/policy for returning query output to the Coordinating Center.

This program package counts as three PCORnet queries.

Output: This program package requires one SAS program to be run and will generate 10 output files. SITES SHOULD ONLY RETURN THE FOLDER LABELED 'DRN OC' TO THE COORDINATING CENTER.
CDRNs Critical Success Factors

- Timely response to requests for data, Co-PIs and/or study participants
- Release of quality, well-described data
- Ongoing effective communications re:
  - benefits and availability of CDRNs
  - processes to request data from CDRNs
- Effective user training of tools for researchers
- Buy-in of organizational leadership and belief in the security of the process
Next Steps for Duke

• Continue to:
  – build out the data and technology infrastructure for CDRNs
  – refine our data request fulfillment processes

• Fulfillment of requests for data and recruitment of Co-PIs/study participants

• Continue to manage our relationships with other internal Duke organizational units that are important for CDRN participation success
Why are CDRNs even important?

- Informs the health care delivery process
- Aligns with “learning health system” framework
- Informs transition to value based payment environment
- Leverages existing EHR data
- Less costly approach for data collection for research compared to traditional means
- Provides larger base of data records/study subjects thus influencing generalizability of study results
- Enables more regional and national focused studies
Thank you!!

Contact:
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Dr. Iain Sanderson at iain.sanderson@duke.edu