Webinar Tips

• Please mute your phone.

• Please do not put the call on hold.

• There will be time for questions after the presentation.
Carolinas Collaborative Pilot RFA Webinar

June 29, 2018
Partners
Overview

- What is the Carolinas Collaborative?
- Pilot RFA details
- Q&A
Traditional clinical trials are valuable, but have limitations...

- Too slow
- Too expensive
- Do not answer questions the right questions
- Health outcomes and disparities are not improving
EHR Data & Research
Research on clinical data can reduce these challenges.

- Locally through clinical data warehouses and i2b2
- Regionally and nationally through the Carolinas Collaborative (CC) and other clinical data research networks (CDRNs)
Developing a computable phenotype

Can you pull data from our EHR that will show me all patients between ages _____ and _____, who have been diagnosed with _______, but haven’t had a ________ in the last 6 months, but have had ___ visits in the ________________ clinic over the past year? I also need to know if they’re taking ________________, or have had any ___, ___, or ___ lab values over ___ mg/ml in the past year.
Now, what if you wanted to look at many patients at different health systems across the Carolinas?
Why look beyond your institution?

- Study rare diseases
- Increase generalizability
- Support study recruitment
- …it’s what your grant requires
But it can be hard...

- Study team may not know any potential collaborators at another site
- Data are formatted differently across sites making comparisons challenging
- Multi-site regulatory process is daunting and confusing
How Carolinas Collaborative (CC) Works

CAROLINAS COLLABORATIVE MEMBERS HAVE HARMONIZED THEIR PATIENT DATA TO ALLOW RESEARCHERS TO QUERY AND OBTAIN DATA ACROSS SITES.
CC is powered by 4 features:

1. Common Data Model (CDM)
2. Federated structure
3. Collaborator network
4. Shared governance

These features collectively reduce barriers and support inter-institutional data sharing and research.
The CC CDM allow data across sites to be compared.

- UNC’s data is optimized and coded for our organization. But what if we want to share it?
- If we just try to mash up the data in our warehouse with, say, the data in the Duke warehouse, we’ll be...
The CC CDM allow data across sites to be compared.

- But if we could agree with one, two, three, or more organizations to spin up a special instance of our data where we all agree on structure…
- …we’ll have an instance of our data that’s sharable in a number of ways.

(close enough)
Data federation allows for controlled data sharing.
Data federation allows for controlled data sharing.

Common data model

Data stored locally

Database 1

Database 2

Database 3

Database 4

UNC: 234 pts
Duke: 336 pts
HSSC: 502 pts
WF: 175 pts
Data federation allows for controlled data sharing.

Query for counts across sites

Common data model

Data stored locally

Federated Query Tool (Web-based)
CC connects researchers to collaborators.

- Expand the expertise of your study team:
  - Content experts
  - Methodologists
  - Engagement experts

- CC staff can help you find collaborators at other institutions.
CC has established oversight and governance process.

- Approval process for data requests
- IRB Reliance Agreements and guidance
- Templates for Data Use Agreements
Carolinas Collaborative
and Your Research
Carolinas Collaborative

- Partners:
  - Health Sciences South Carolinas (lead), including Medical University of South Carolina
  - UNC-Chapel Hill
  - Duke University
  - Wake Forest Baptist Medical Center
- Clinical data from ~11 million patient records
- Funded by The Duke Endowment
What research can CC support?

**Pre-research**
- Feasibility queries
- Engagement
- Match-making

**Interventional studies**
- Clinical trials
- Pragmatic randomized clinical trials
- Cluster randomization

**Observational studies**
- Cross-sectional
- Epidemiology
- Health services
- Comparative effectiveness or safety
Data Availability

Data are available in the following domains. Review the data dictionary for details.

- Patient Demographics
- Encounter Details
- Diagnoses
- Procedures
- Vitals
- Lab Results
- Medication
- Insurance Payor
- Tobacco History
- Patient Reported Outcomes (limited list of PROMIS measures)

CC Data Dictionary:
https://tracs.unc.edu/docs/bmi/CarolinassCollaborativeCDMDataDictionary_20180608.pdf
Carolinas Collaborative Services

- Consults to prepare for requests
  - Phenotypes, data quality and characterization
  - Example: what’s an encounter?
- Requests for feasibility counts of patients
- Requests for harmonized datasets
- Requests for network collaborators
Relationship to other data federation efforts

- The CC organizations also participate in other data federation efforts.
- The goals of these often loosely-organized efforts are similar, and usually involve the same faculty and staff
  - PCORnet: PCORI funded, moving to People Centered Research Foundation, common data model
  - Carolinas Collaborative: Duke Endowment funded, i2b2/SHRINE
  - Accrual to Clinical Trials (ACT): NIH funded, in start up phase i2b2/SHRINE
- Carolinas Collaborative pilots can work with any of these efforts
Carolinas Collaborative
Pilot RFA - 2018
Why support CC pilots?

- Large pragmatic trials and cohort studies are an increasing focus by NIH, PCORI and others
- The external awards are large (~$10M) highly competitive, complex to write and pull together teams
  - Preliminary data for sample size, data quality, number of outcomes are essential
- Faculty can currently use their ongoing pilot programs to conduct preliminary work using CC or another CDRN (e.g., PCORnet)
- Targeted pilot funding may stimulate cross-organizational collaboration
Previous CTSA-CC Pilots - 2016

- “Harmonization of Patient-Reported Outcomes Across CTSAs: Leveraging EHRs to Enable Comparative Effectiveness Research to Improve the Quality of Cancer Care”
  - Arlene Chung (UNC), Thomas LeBlanc (Duke), Phil Smeltzer (MUSC), Lynne Wagner (Wake Forest)
- “The HEART Pathway: a learning health system project, translating evidence to practice across the Carolinas”
  - Simon Mahler (Wake Forest), Christine Carr (MUSC), Alexander Limkakeng (Duke), Abhishek Mehrotra (UNC)
Previous CTSA-CC Pilots - 2017

- “Antibiotic prescribing in North Carolina before and after an FDA boxed warning on fluoroquinolones in 2016”
  - Zachary Willis (UNC), Deverick Anderson (Duke), Nicholas Pajewski (Wake Forest)
- “Pregnancies in women with Lupus in the Carolinas Collaborative (PLiCC) Cohort: Validation of computable phenotypes with existing Registries in order to study the role of socio-demographic disparities on pregnancies in women with lupus”
  - Megan Clowse (Duke), James Oats (MUSC)
CTSA – CC RFA Round 3

- Support preliminary data analyses, stakeholder engagement, piloting instruments, statistical consultation, etc.
- Each CTSA hub (Duke, UNC, WF, MUSC) can support up to three pilots with funding provided by The Duke Endowment and CTSA pilot programs
- Budget
  - Up to $25K per site per project; Total multi-site budgets from $50K to $100K
  - One year maximum timeline/budget period
  - Funds stay at each organization, no subcontracts
  - Check with your site regarding support for faculty time
- Peer reviewers contributed from each organization
- Awarded pilots will need to be approved by NCATS (formality)
CTSA – CC RFA Round 3: Key Components

- At least two CC members must participate in each application
- Current awardees ineligible
- Consult with CC analyst required
  - Arrange a consult: http://carolinascollaborative.org/researchers/
- Preference will be given to projects that exclusively utilize the Carolinas Collaborative CDM and do not require data elements outside of the Carolinas Collaborative CDM
  - Review the data dictionary: https://tracs.unc.edu/docs/bmi/CarolinasCollaborativeCDMDataDictionary_20180608.pdf
Pilot proposals

- Should have a clear path to a subsequent proposal for external support
- The more specific you can be regarding funder and next steps, the better. Agnostic regarding NIH vs AHRQ vs PCORI etc.
- Could be methods focus, but clinical trials and health systems interventions are also greatly desired.
- Need to ‘right size’ the work. Effort that is completed on time and leads to an external proposal is preferable to ambitious proposal that may be infeasible.
CTSA – CC RFA Round 3: Timeline

- RFA Released: June 18, 2018
- Application Submission Deadline: 5pm, August 15, 2018
- Selection of Awardees: By September 30, 2018
Q&A

- To reduce cross-talk, we ask everyone to please enter your question in the chat box and select send to “Everyone.”
- Please remain on mute, unless your are speaking, and do not put the call on hold.
- We may asks folks to explain their question verbally, and you are welcome to ask follow-up questions verbally.