

Clinical and Translational Science Award (CTSA) Program

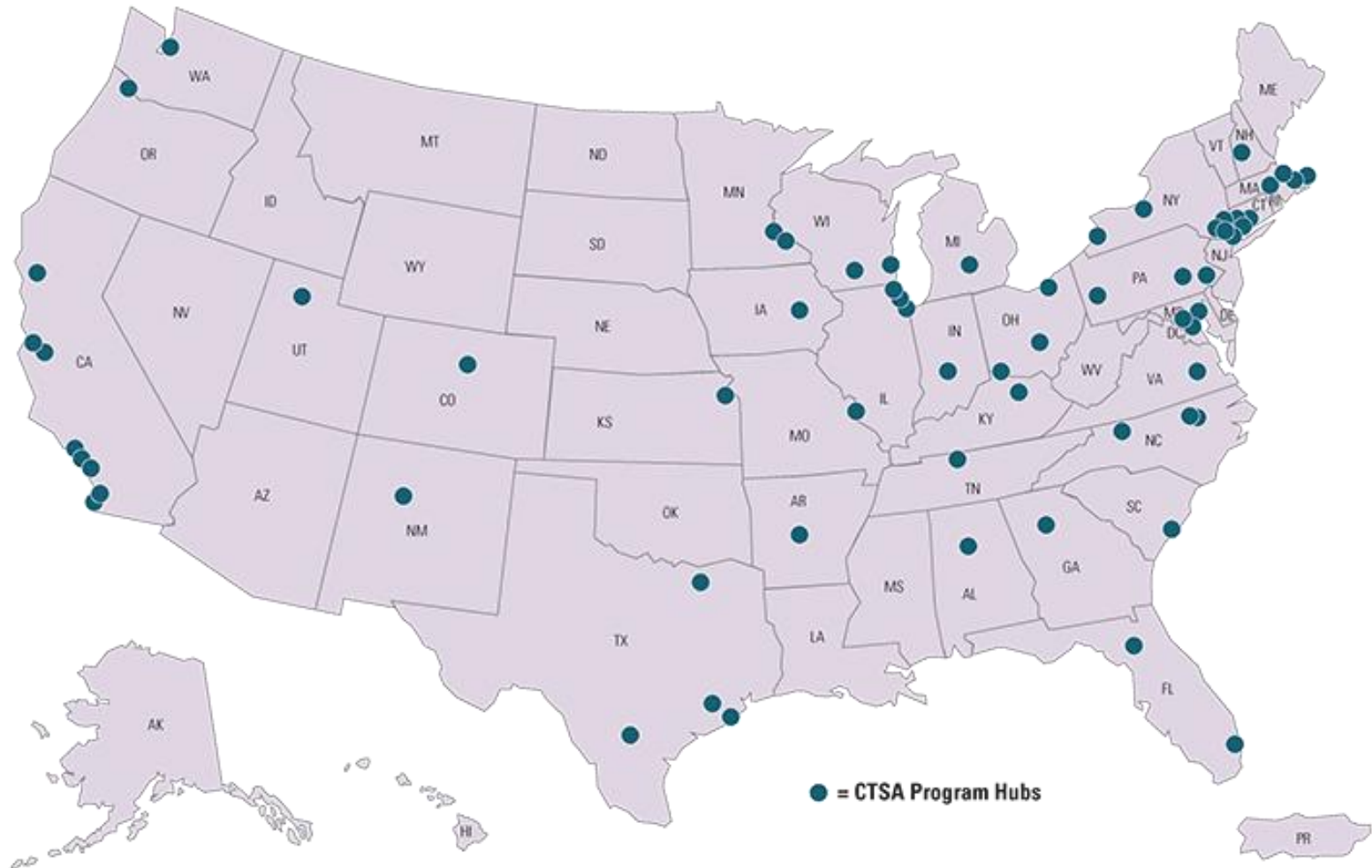
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APRIL 29, 2016

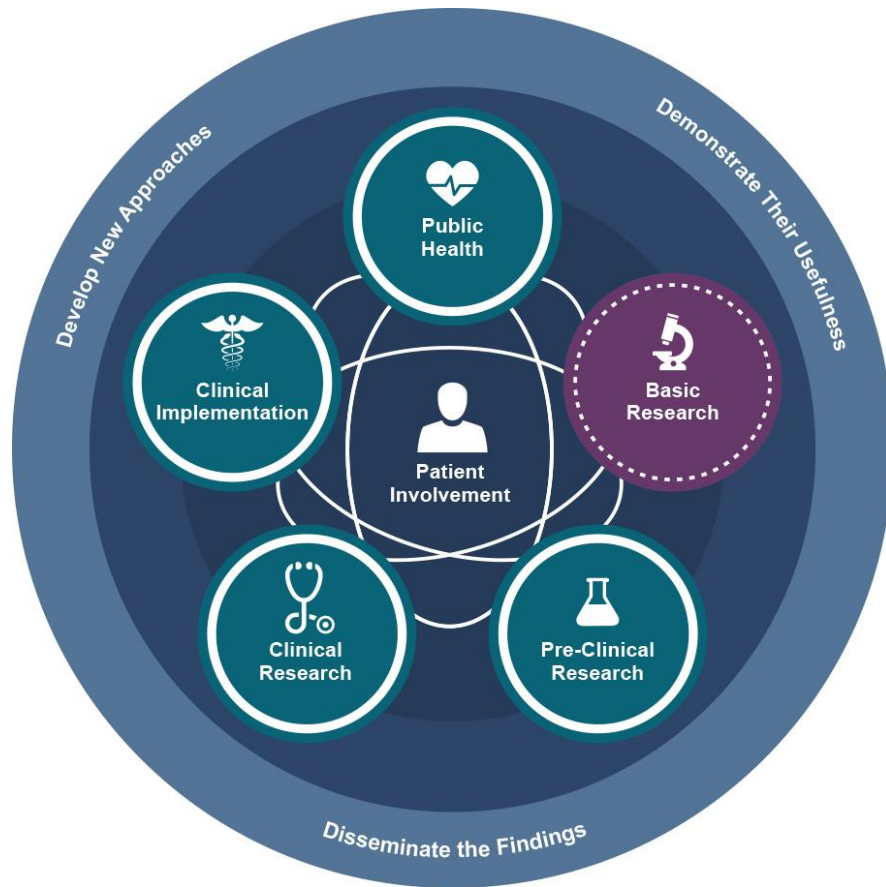
NCATS

Clinical and Translational Science Awards (CTSA) Program Sites

- Work together to improve the way clinical and translational research is conducted nationwide
- Provide training for clinical and translational researchers



Getting from Discovery to Health Benefits Faster



- Training and cultivating the translational science workforce
- Including patients and communities as active partners
- Improving tools and methods
- Focusing on understudied populations
- Harnessing the power of cutting-edge informatics

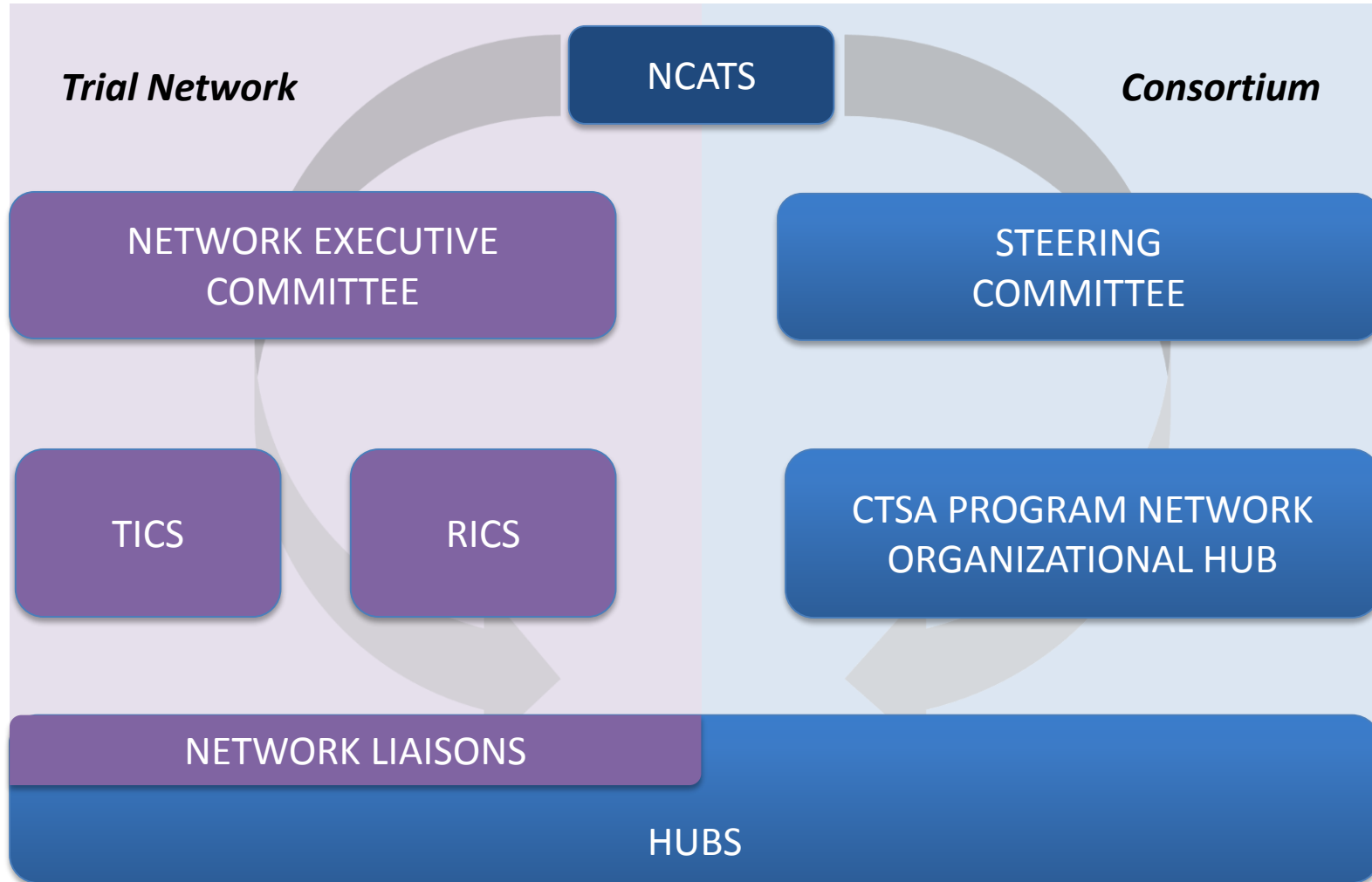
Promoting synergy among stakeholders

CTSA Program is Streamlining Multisite Clinical Studies

- The problem: Current fragmented system is inefficient, costly and often ineffective
 - Duplicative IRB reviews among sites
 - Subcontracting harmonization among institutions delays start-up
 - Duplicative investigator/site qualification
- Solutions in progress
 - Centralized IRB review (reliance agreements, IT solutions)
 - Streamlined contracting (pre-negotiated master agreements)
 - GCP training across CTSA sites



CTSA Program Network Functions



PCORnet and CTSA Network – Synergizing National Initiatives

PCORnet Overview: The National Patient-Centered Clinical Research Network

Rachael Fleurence, PhD

PCORnet Program Director, Research Infrastructure, PCORI

April 29, 2016



pcornet

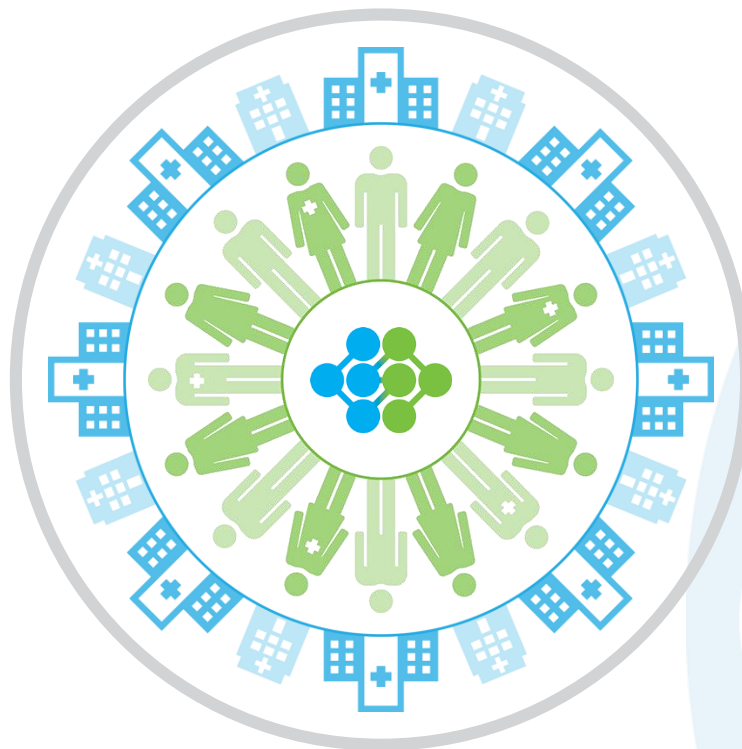
The National Patient-Centered Clinical Research Network

Vision for PCORnet

PCORnet brings together the expertise, populations, resources, and data of its participating organizations to create a **national infrastructure** that enables more **efficient, patient-centered research**

**“Research *Infrastructure*
Done Differently”**

PCORnet embodies a “community of research” by uniting people, clinicians & systems



21
Patient-Powered Research
Networks (**PPRNs**)

+

13
Clinical Data
Research Networks
(**CDRNs**)

=

PCORnet
A national infrastructure
for people-centered
clinical research

PCORnet is Growing

PCORnet

130 health systems across
the country

Over 60 data marts

Data on over
110 million patients

Research Demonstration Projects

- 1 Clinical Trial: ADAPTABLE
- 2 Observational Studies:
 - Antibiotic Use and Excess Weight Gain in Children
 - Bariatric Surgery: Benefits and risks of three main surgical treatment options
- 6 PPRN demonstration projects

Administrative Simplicity: *Streamlining Research Processes*

IRB

- Scalability
- IRB only and pilot

Data Sharing Agreement (DSA)

- Potential for use in demonstration projects

Master Contract

PCORnet/CTSA Dyad Initiative

- ✿ Bringing together PCORI and NCATS leadership to leverage work being done within PCORnet and CTSAAs
- ✿ Exploring pathways for collaborative national clinical research infrastructures
- ✿ Particular focus on advancing:
 - Contracting
 - IRB
 - Informatics

Implementing the PCORnet Data Strategy

Keith Marsolo and Lesley Curtis

PCORnet Coordinating Center



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The National Patient-Centered Clinical Research Network

PCORnet Data Strategy

- Standardize data into a common data model
 - Attention to data quality
- Build a secure querying infrastructure
- Build re-usable tools to query the data
- Send questions to the **data** and only return required **information**
- Learn by doing and repeat**

Standardize to a common data model

Fundamental basis

DEMOGRAPHIC

Records direct attributes of individual patients.

Data captured from processes associated with healthcare delivery

ENROLLMENT

Concept that defines a period of time during which all medically-attended events are expected to be observed.

DISPENSING

Outpatient pharmacy dispensing, such as prescriptions filled through a neighborhood pharmacy with a claims paid by an insurer. Not commonly captured within healthcare systems.

DEATH

Reported mortality information for patients

DEATH CAUSE

Individual causes associated with a reported death.

Data captured within multiple contexts: healthcare delivery, registry activities, or directly from patients

VITAL

Vital signs directly measure an individual's current state of attributes.

CONDITION

A condition represents a patient's diagnosed and self-reported health conditions and diseases. A patient's medical history and current state may both be represented.

PRO CM

Patient-Reported Outcome (PRO) Common Measures (CM) are standardized measures that are defined the same way across all PCORnet networks. Each measure is recorded at the individual item level.

Data captured from healthcare delivery, direct encounter basis

ENCOUNTER

Interactions between patients and providers within context of healthcare delivery.

DIAGNOSIS

Diagnosis codes indicate results of diagnostic processes and medical coding.

PROCEDURES

Procedure codes indicate discrete medical interventions or diagnostic testing.

PRESCRIBING

Provider orders for medication dispensing or administration.

LAB RESULT CM

Specific types of quantitative and qualitative measurements from blood and body specimens, standardized across all networks.

Associations with PCORnet clinical trials

PCORNET TRIAL

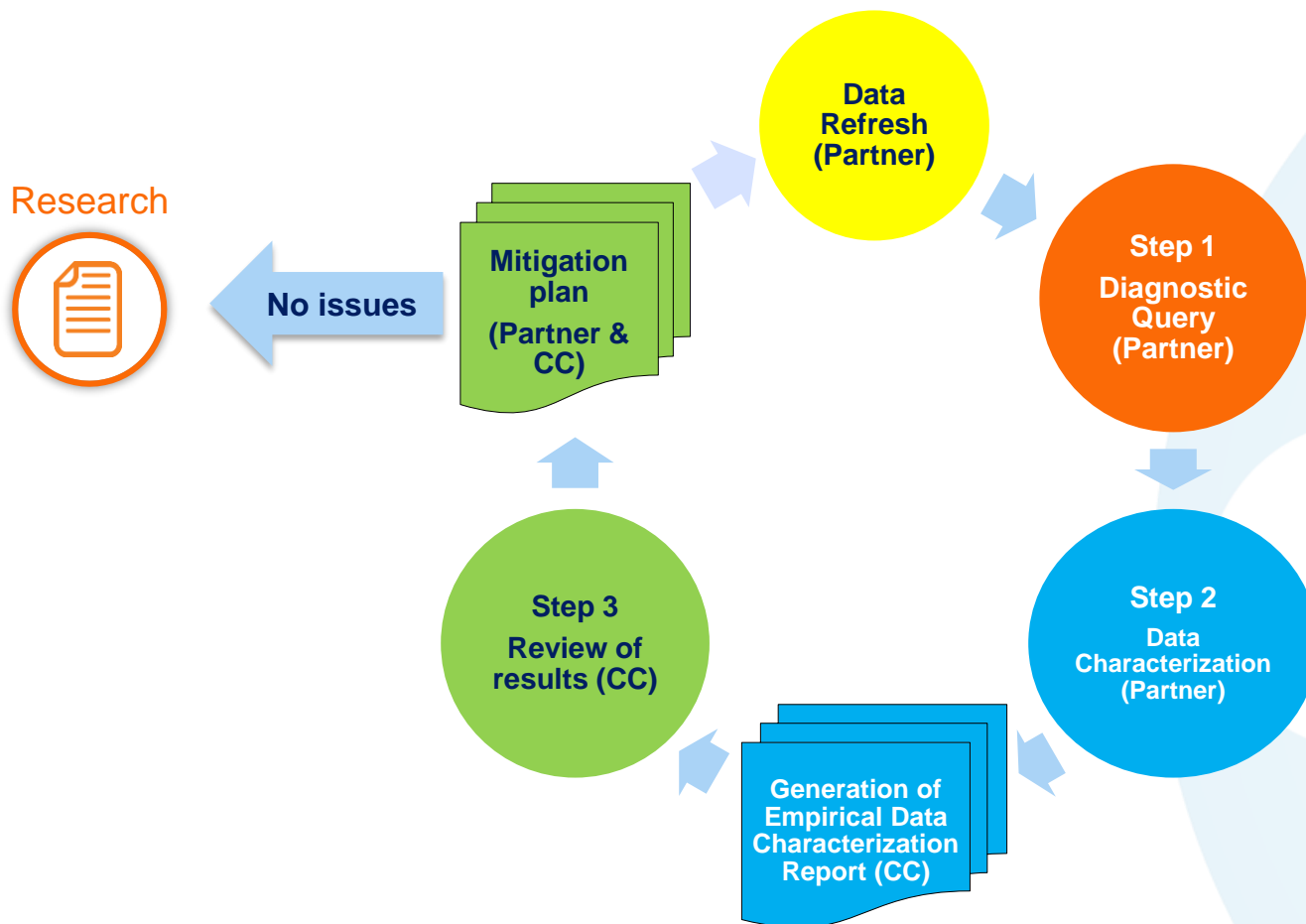
Patients with are enrolled in PCORnet clinical trials.

Process-related data

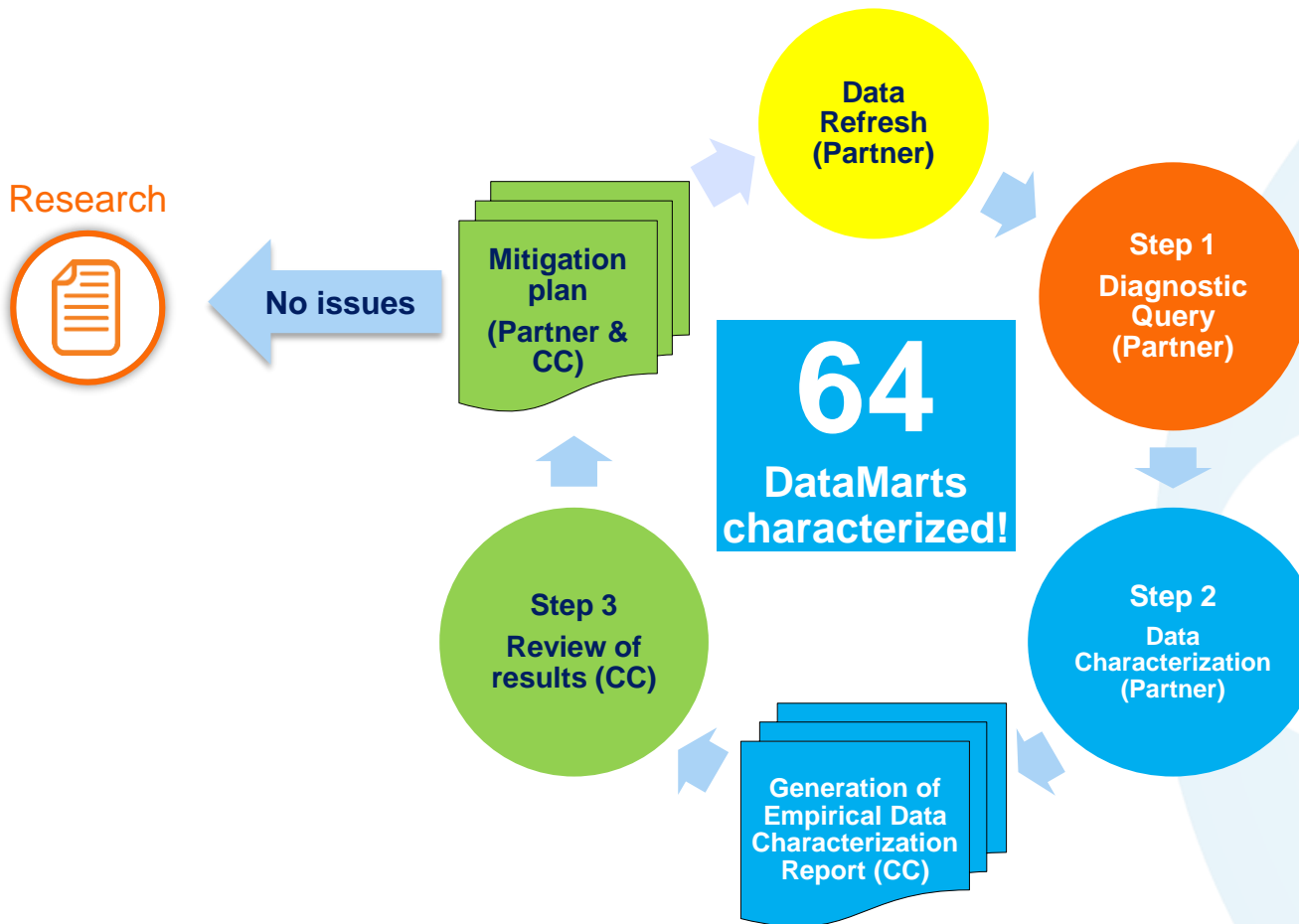
HARVEST

Attributes associated with specific PCORnet datamart implementations.

Attention to data quality



Attention to data quality

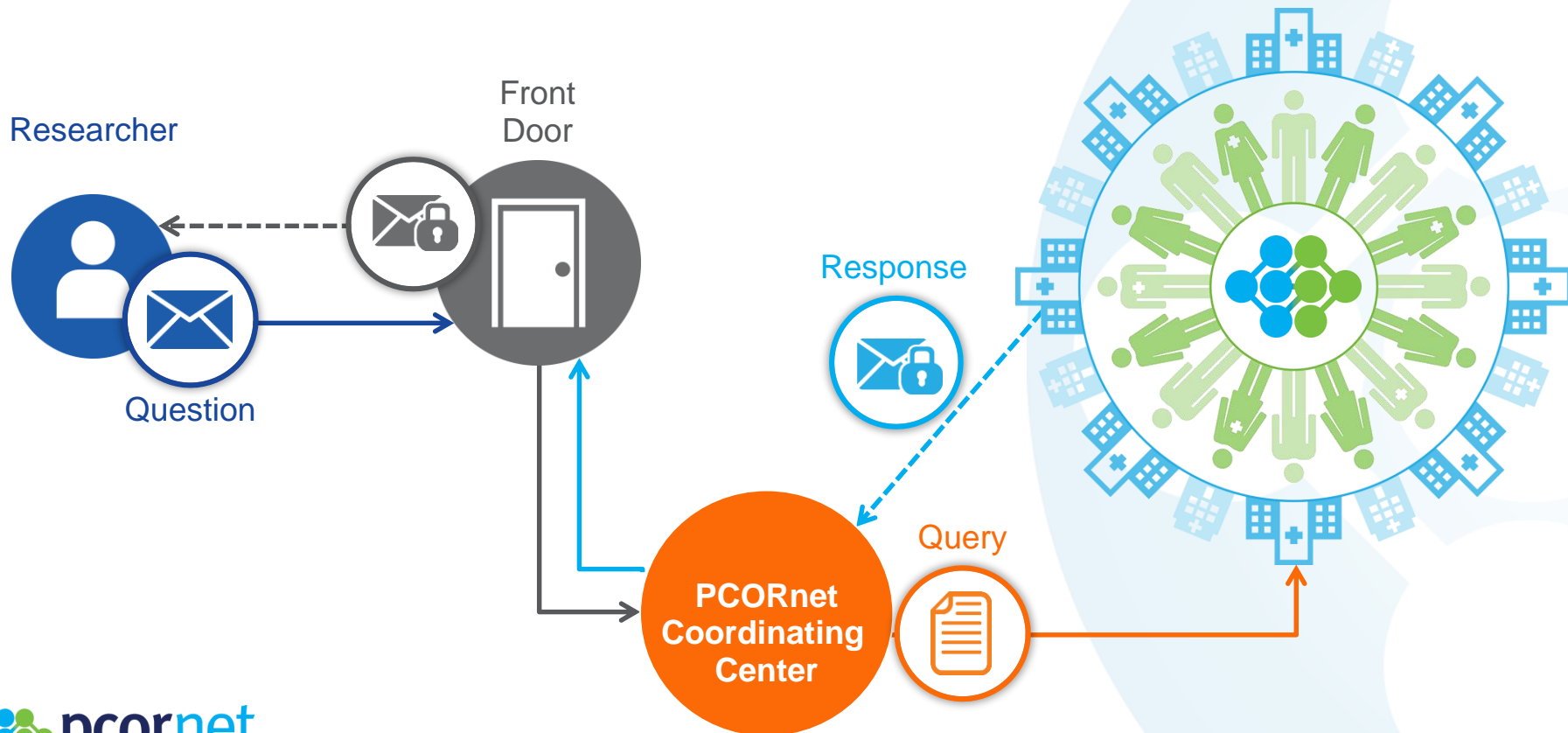


Here's how PCORnet's distributed research network works

The Researcher sends a question to the PCORnet Coordinating Center through the Front Door

The Coordinating Center converts the question into a query with an underlying executable code, and sends it to PCORnet partners

PCORnet partners review the query and provide a response, which is sent back through the Front Door to the Researcher



Build reusable tools to query the data

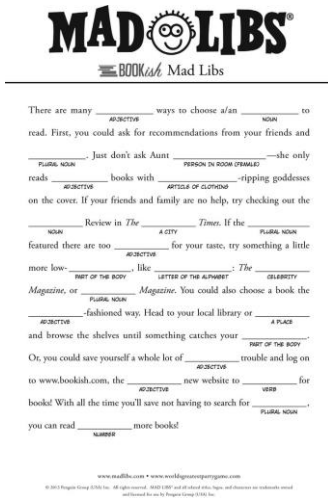


There are many _____ ways to choose a/an _____ to
ADJECTIVE NOUN
read. First, you could ask for recommendations from your friends and
_____. Just don't ask Aunt _____—she only
PLURAL NOUN PERSON IN ROOM (FEMALE)
reads _____ books with _____-ripping goddesses
ADJECTIVE ARTICLE OF CLOTHING
on the cover. If your friends and family are no help, try checking out the
_____. Review in *The* _____ *Times*. If the _____
NOUN A CITY PLURAL NOUN
featured there are too _____ for your taste, try something a little
ADJECTIVE
more low-_____, like _____: *The* _____
PART OF THE BODY LETTER OF THE ALPHABET CELEBRITY
Magazine, or _____ *Magazine*. You could also choose a book the
PLURAL NOUN
_____fashioned way. Head to your local library or _____
ADJECTIVE A PLACE
and browse the shelves until something catches your _____.
PART OF THE BODY
Or, you could save yourself a whole lot of _____ trouble and log on
ADJECTIVE
to www.bookish.com, the _____ new website to _____ for
ADJECTIVE VERB
books! With all the time you'll save not having to search for _____,
PLURAL NOUN
you can read _____ more books!
NUMBER

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Build reusable tools to query the data



Study Design:

Identify patients <AGE RANGE> with a <NEW / REFILL> dispensing of a <DRUG CLASS>. To be eligible, patients must have met the following criteria in the <LOOKBACK PERIOD> days before the index dispensing: (1) continuous enrollment in <TYPE(S) OF INSURANCE> benefits, (2) no prescription for <DRUG CLASS> or <DRUG CLASS>, and (3) no diagnosis of <DISEASE / CONDITION> in <INPATIENT / OUTPATIENT / ED> care setting.

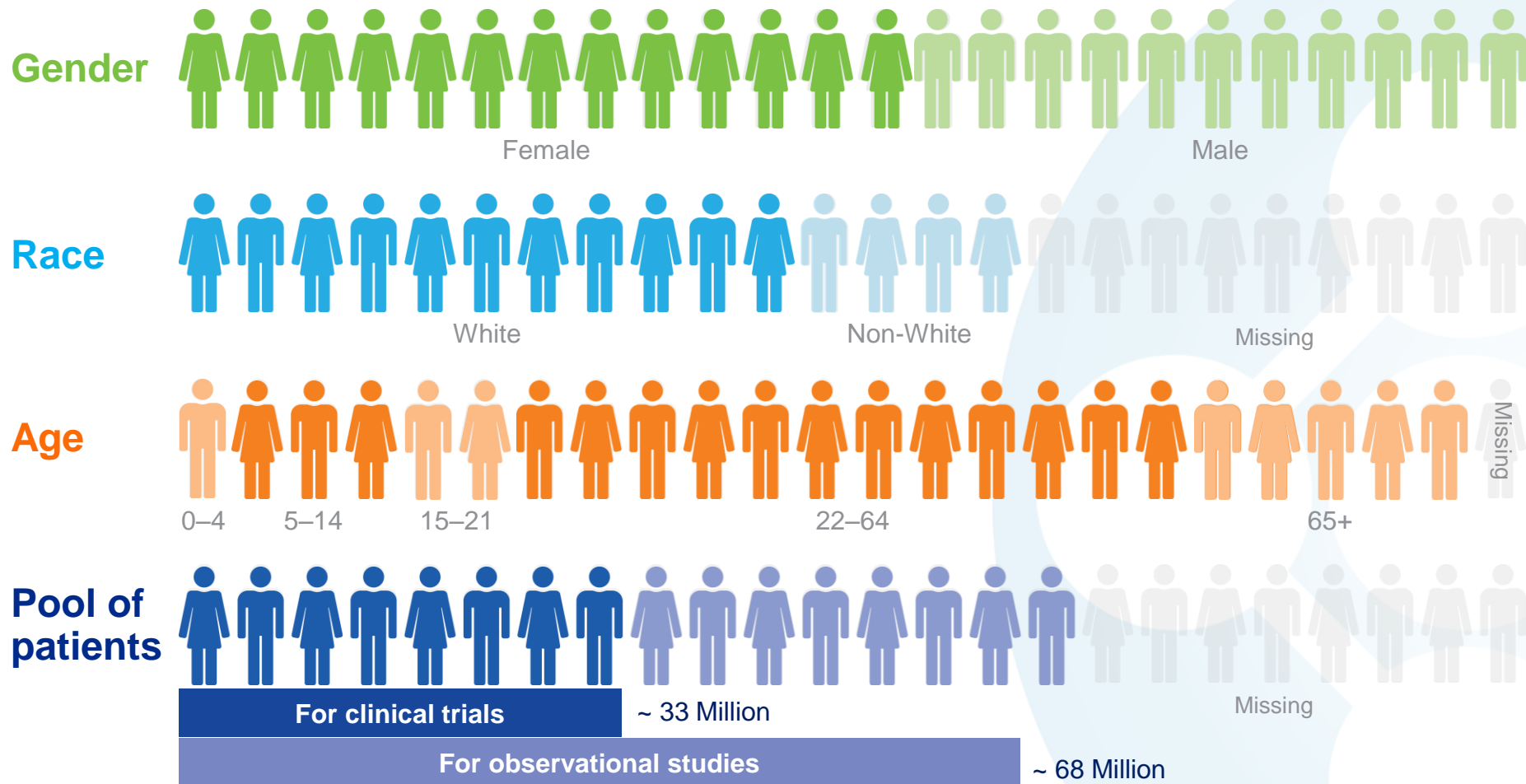
The primary outcome of interest is <EVENT> identified with <DIAGNOSIS CODE> in <PRIMARY / SECONDARY / ANY> position during an <INPATIENT / OUTPATIENT / ED> encounter.

Resulting in a national evidence system with unparalleled research readiness

People's data available in PCORnet to date:

~110 Million

Resulting in a national evidence system with unparalleled research readiness



Trial Innovation Network

Mission

- Create a national laboratory to study, understand, and improve multi-center research, (clinical trials, observational studies, etc.)
- Leverage, the talent, expertise, & resources of the CTSA Program to transform clinical trials
 - Collaborative national network
 - Accelerate planning & implementation of high quality multi-center trials
 - Provide more treatments to more patients
 - Learning health system

Trial Innovation Network

Network Accelerates the Translation of Best Practices and Novel Interventions to Evidence Based Treatments

Develop - Science/Create

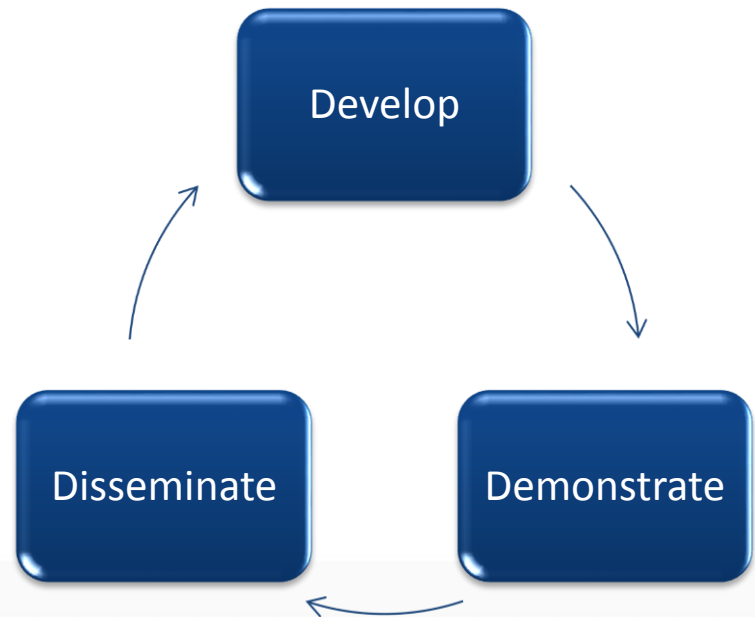
- Not enough to create another network

Demonstrate - Measure

- Evidence that Changes Practice

Disseminate - Care

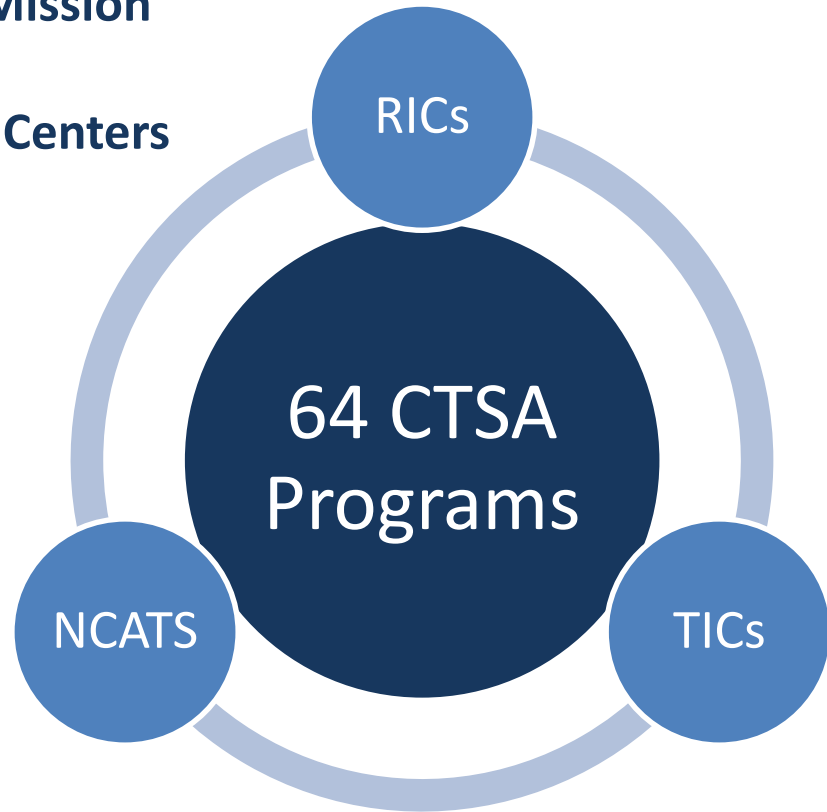
- Tools/Ideas that have an impact



Trial Innovation Network

Cooperative Network with a Unified Mission

- 64 CTSA Programs
- RICs Recruitment Innovations Centers
- TICs Trial Innovation Centers
- NCATS/DCI



Trial Innovation Network

Accrual for Clinical Trials (ACT) Accomplishments

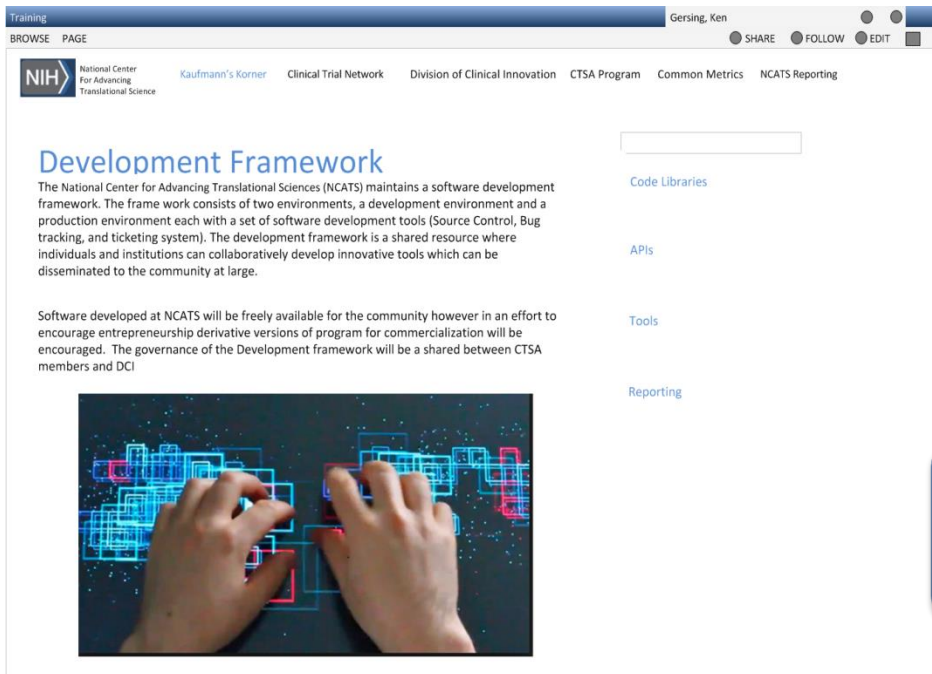
- Developed policies and procedures that govern identification of study participant cohort across multiple sites.
- Pilot project(s) that demonstrate that EHR-driven cohort exploration for multi-site research is enabled across the federated network.
- Steps toward making i2b2/SHRINE platform interoperable with PopMedNet, including the mapping of i2b2 to Common Data Model - SCILHS
- Effort, cost and time estimates for making two sites not using i2b2 interoperable with the ACT network.

ACT Team: Firestein, M.D, Toto, M.D., Reis, M.D., Nadler MD

Trial Innovation Network

Clinical Trials Bioinformatics Development Framework

- **Bioinformatics Innovation - Learning Health System for CQI**



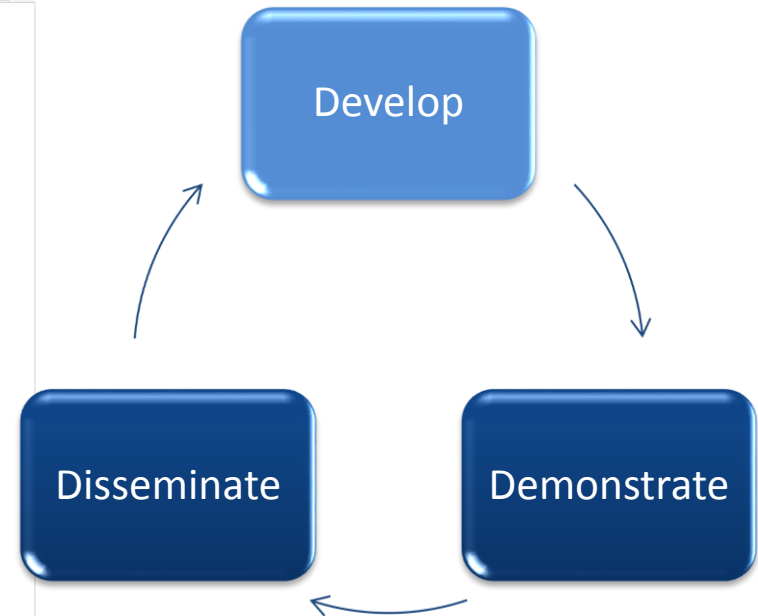
The screenshot shows a web browser window displaying the NCATS Development Framework page. The page header includes the NIH logo and navigation links: Kaufmann's Korner, Clinical Trial Network, Division of Clinical Innovation, CTSA Program, Common Metrics, and NCATS Reporting. The main content area is titled "Development Framework" and contains the following text:

The National Center for Advancing Translational Sciences (NCATS) maintains a software development framework. The framework consists of two environments, a development environment and a production environment each with a set of software development tools (Source Control, Bug tracking, and ticketing system). The development framework is a shared resource where individuals and institutions can collaboratively develop innovative tools which can be disseminated to the community at large.

Software developed at NCATS will be freely available for the community however in an effort to encourage entrepreneurship derivative versions of program for commercialization will be encouraged. The governance of the Development framework will be shared between CTSA members and DCI

Below the text is an image of hands interacting with a digital interface showing a network of nodes and connections.

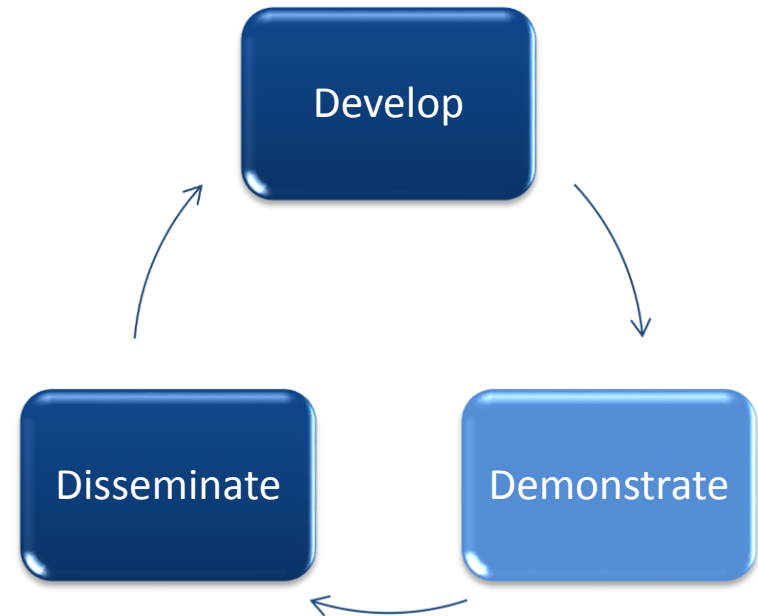
On the right side of the page, there is a search bar and a list of links: Code Libraries, APIs, Tools, and Reporting.



Trial Innovation Network

Learning Health System

- Evidenced Based Performance - Use Data to maximum value
- Help Clinicians to 'Work Smarter not Harder'



Trial Innovation Network

PCORNet / NCATS: Trial Innovation Network

Areas of Potential Collaboration

- Patients Centered Involvement
- Single IRB
- Governance in areas like Data Sharing
- Trial Design
- Common Data Elements
- Dissemination of Evidence: Best Practices, FDA
- PCORNet informatics Experience

Questions

