

Update on the CTSA Program and the Office of Rare Diseases Research Toolkit Project

**NCATS Advisory Council and
CAN Review Board Meeting
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NCATS CTSA Program

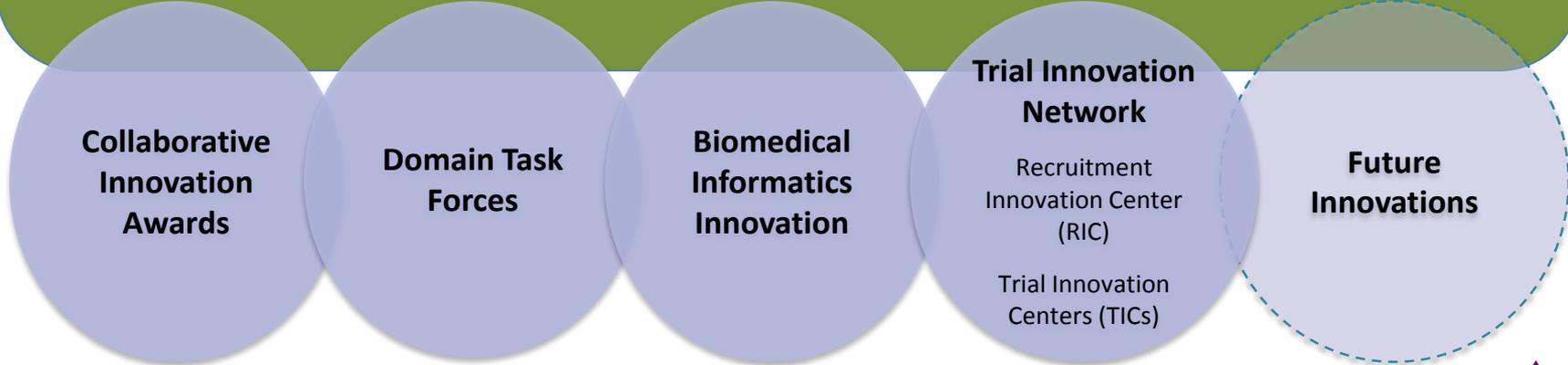
Local Strength
Collaborations
Organization Management

CTSA Program Hubs

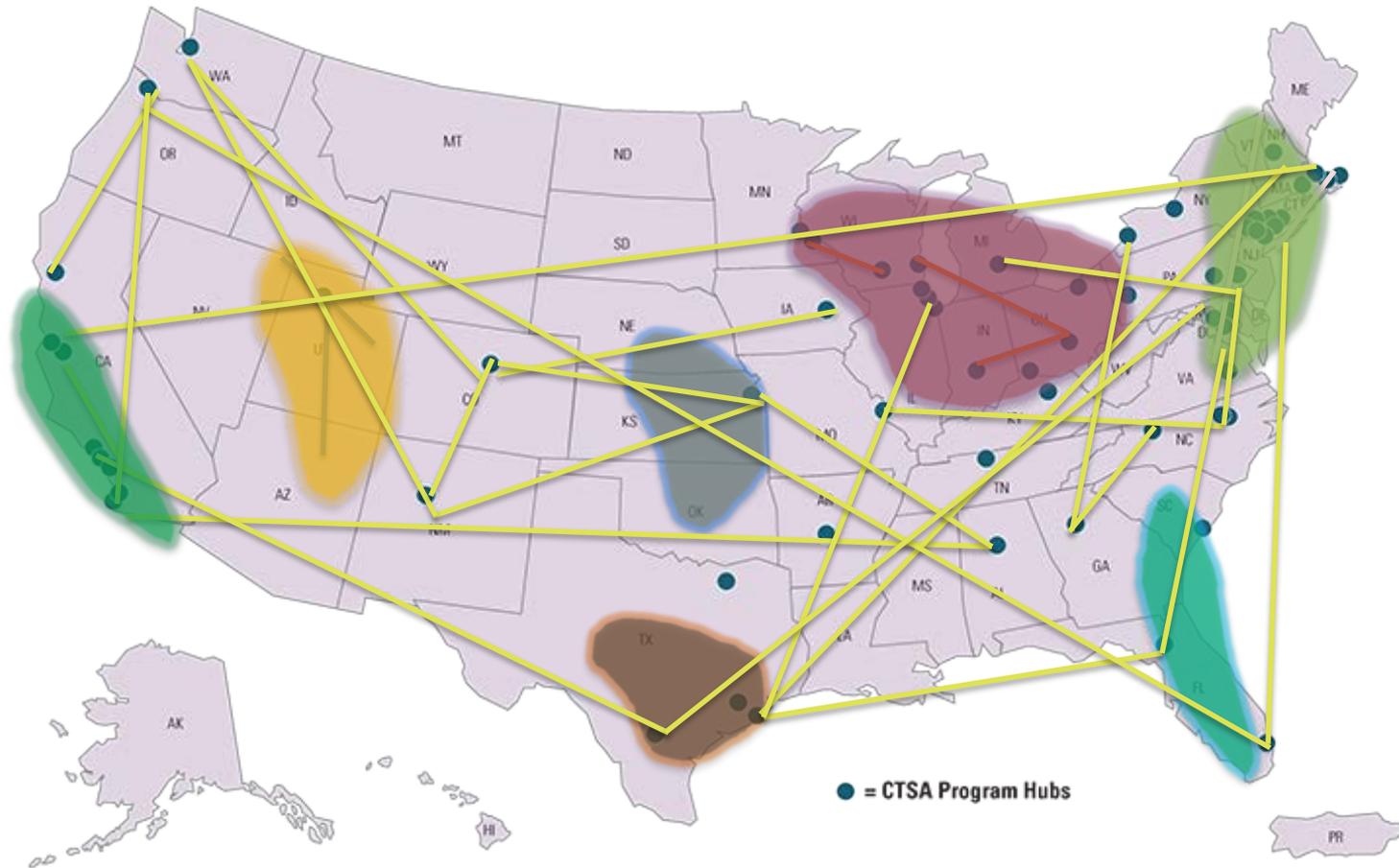
Leading excellence and innovation locally...

<i>Informatics</i>	<i>Training</i>	<i>Streamlining Processes</i>	<i>Community Engagement</i>	<i>Understudied Populations</i>
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... and collaborations regionally and nationally



Collaborative Consortium for Translational Research



Collaborative Consortium for Translational Research

Building on local and regional strength to bring more discoveries to health benefit:

- Form virtual teams
- Share information, practices, tools
- Connect data systems
- Implement efficient multisite studies
- Integrate care and research
- Have greater impact together

NCATS SMART IRB Reliance Platform

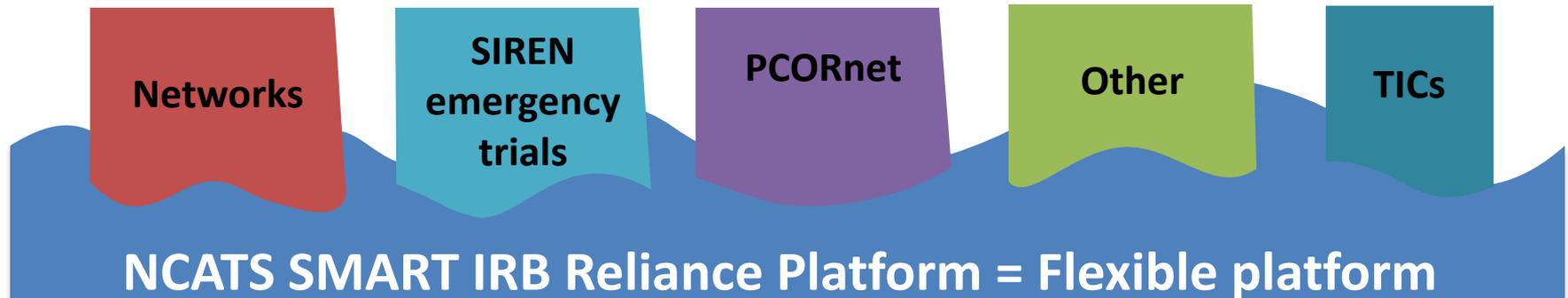
Streamlined, Multisite, Accelerated Resources for Trials

Why?

- Multisite studies are critical in getting from discovery to health benefit
- To streamline the process, research centers are beginning to rely on each other's IRB review

What's new:

- NIH policy for single IRB announced on June 21, 2016
- NCATS Single IRB Workshop took place on May 2, 2016
- IRB master authorization agreement posted on NCATS website, ready for signing on
- Current CTSA Program focus: workflow, training and IT processes
- Pilot proceeding: CARRA - Childhood Arthritis & Rheumatology Research Alliance; Phase II of SMART IRB Project to launch fall 2016



Streamlined Contracting

Why?

- Multisite studies require contractual agreements that are typically negotiated on a one-off basis
- CTSA Program investigators have worked on streamlining the process to avoid redundancies and delays

Accelerated Clinical
Trial Agreement
(ACTA)



Accelerated
Confidential Disclosure
Agreement
(ACDA)

What's new:

Accelerated (Federal) Subcontracting
(working with Federal Demonstration
Project – FDP)

<https://www.ara4us.org/>

Harmonizing Investigator Qualification for Clinical Research Teams

Why?

Streamlined qualification, decreased redundancy, reduced time to trial startup

What's new:

- Good Clinical Practice (GCP) recommendations for **clinical study investigators and coordinators** developed and adopted by CTSA Program consortium
- **Competency-based, clinical research professionals' training curriculum** developed for study investigators and coordinators
- **Social and behavioral research best practices e-learning course** developed for researchers and staff involved in social and behavioral clinical trials
- **Evaluation plan** for e-learning course under development by CTSA Program Workforce/Education Domain Task Force and University of Michigan CTSA
- Three manuscripts accepted to ***Journal of Clinical and Translational Science***

<http://www.ctsa-gcp.org/>

Trial Innovation Network

Why?

To optimize clinical trials enterprise to accelerate translation

- Data-driven “learning clinical studies system” so trials can recruit more quickly, retain participants, finish on-time and on-budget, and produce impactful, high-quality data
- Leverage the talent, expertise & resources of the CTSA Program to transform clinical trials

What's new:

- Key components were launched in July 2016
 - Trial Innovation Centers (TICs)
 - Recruitment Innovation Center (RIC)
 - Kick-off / introductory meeting to CTSA Program scheduled for Oct. 26, 2016

Common Metrics (CM) Initiative

Why?

To measure the impact of the CTSA Program on bringing discoveries to health benefit

What's new:

Supporting data-driven, results-based strategic decisions

- Not an evaluation, but a management tool
- **Measuring the *impact* of the CTSA Program**
 - At the hub
 - For the whole consortium

Each new topic area will have two components:

Supporting Excellence

Innovation

How:

- Collaboratively, fostering shared accountability
- Focus on usefulness for strategic management

Common Metrics (CM) Initiative

Implemented Topic Areas

- Careers in clinical and translational research
- IRB duration
- Pilot funding publications and funding

Topic Areas in Development

- Collaboration
- Community Engagement
- Hub Research Capacity
- Education and Training
- Accrual
- Informatics

Rare Diseases Toolkit



Why?

- Patient involvement and community engagement are vital throughout the translational research process
- A wealth of educational and informational tools have already been developed by and for rare disease community
 - Academia
 - Disease foundations
 - Government agencies
 - Industry
- **But** existing resources are dispersed, difficult to discover — especially for newcomers

What will the Toolkit project do for the rare diseases community?

- Collaboratively create a **well-designed source for online educational and informational research resources and tools**.
- Provide a **single online portal with resources** that patient groups can readily access along with context.
- **Improve coordination** rather than re-create existing resources.
- Facilitate opportunities to **bring groups together, identify gaps** in online resources, and **disseminate information** to patient groups.
- Promote **continuity across the lifecycle of the drug development process**.



Pre-clinical

Trial readiness

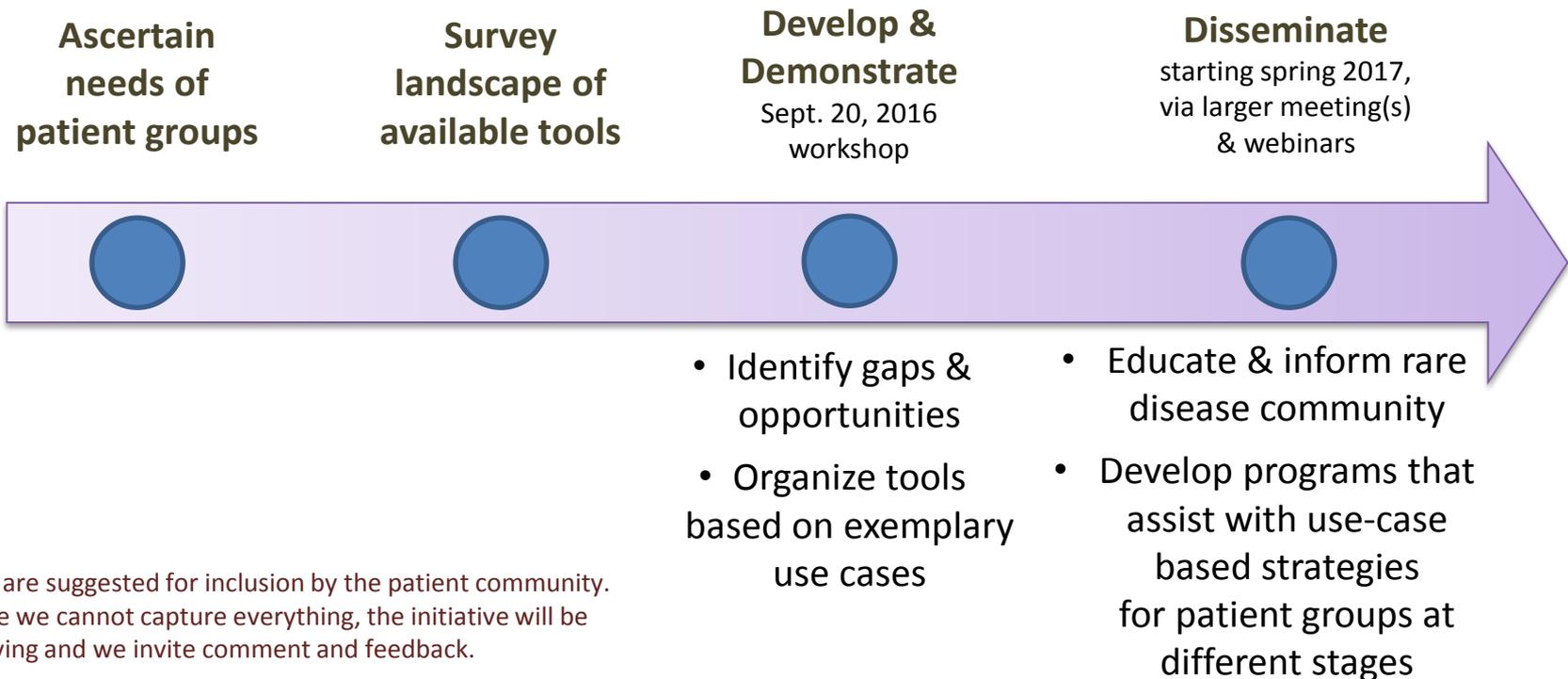
Trials

Post-marketing

How do we plan to develop the Toolkit?



- Planning group driven by patient group representatives
- Inclusive*, transparent, collaborative
- Focus on tools that are useful for research, easily accessible and practical



* Tools are suggested for inclusion by the patient community. While we cannot capture everything, the initiative will be evolving and we invite comment and feedback.