

Update on the Clinical and Translational Science Award Program

PETRA KAUFMANN, M.D.
DIRECTOR, Division of Clinical Innovation

NCATS ADVISORY COUNCIL AND CAN REVIEW BOARD MEETING
JANUARY 15, 2015

NCATS

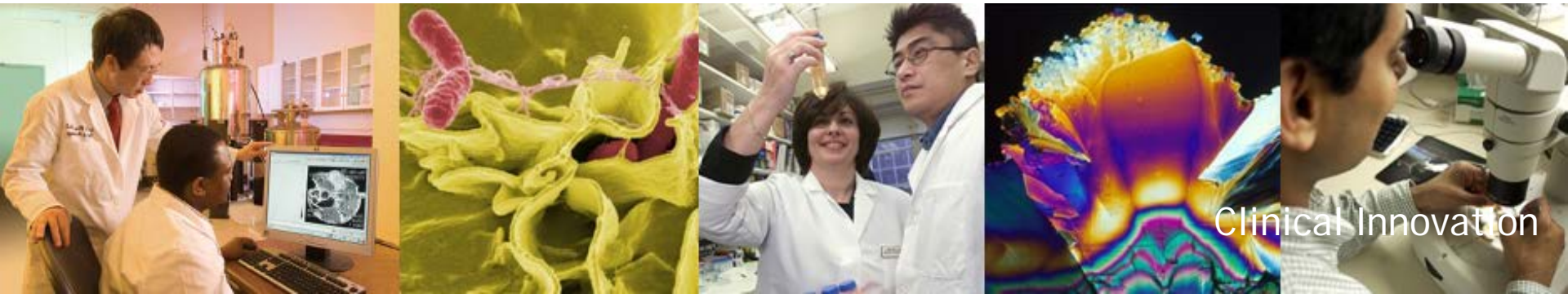
Division of Clinical Innovation Mission



The Division of Clinical Innovation catalyzes clinical and translational science by partnering with stakeholders through support of interdisciplinary research and training to improve individual and public health.

NCATS Division of Clinical Innovation Strategic Goals

1. **Train**, develop and cultivate future leaders in translational science
2. **Innovate** in translational science
 1. Engage patients and communities in every phase of the translational process
 2. Promote the integration of special and underserved populations in translational research across the lifespan
 3. Innovate processes to increase the quality and efficiency of translational research, particularly of multi-site trials
 4. Advance the use of modern informatics in translation
3. **Communicate** effectively with internal and external audiences using clear, timely, and consistent messages
4. **Measure** success of the CTSA program through a set of common metrics
5. **Partner** effectively with NIH and other stakeholders

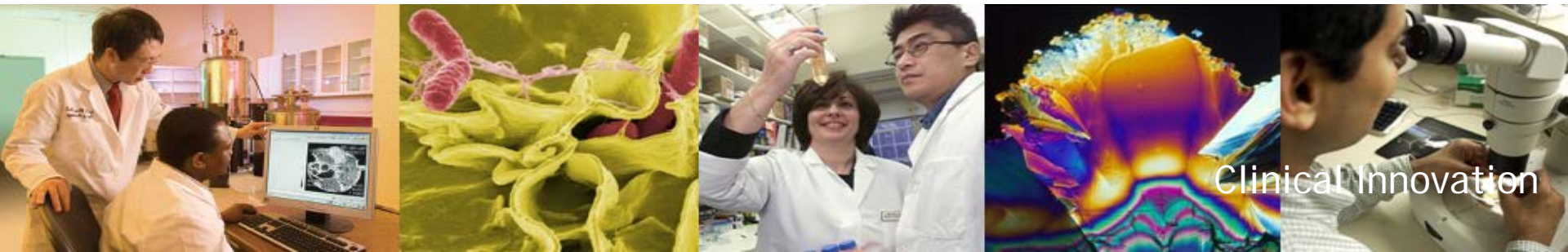


Promoting the Future Translational Research Workforce

- Non-traditional skills, such as
 - Regulatory sciences
 - Entrepreneurship
- Experiential learning experience
 - Internships in industry, government or other non-academic organizations
- Team science
 - Multi-disciplinary training
 - Incubator groups
- Making translational research an attractive career path
 - Promotion system
 - Broader range of mentors and training environments

NCATS Division of Clinical Innovation Strategic Goals

1. **Train**, develop and cultivate future leaders in translational science
2. **Innovate** in translational science
 1. **Engage patients and communities in every phase of the translational process**
 2. **Promote the integration of special and underserved populations in translational research across the lifespan**
 3. Innovate processes to increase the quality and efficiency of translational research, particularly of multi-site trials
 4. Advance the use of modern informatics in translation
3. **Communicate** effectively with internal and external audiences using clear, timely, and consistent messages
4. **Measure** success of the CTSA program through a set of common metrics
5. **Partner** effectively with NIH and other stakeholders



Engaging Stakeholder and Communities

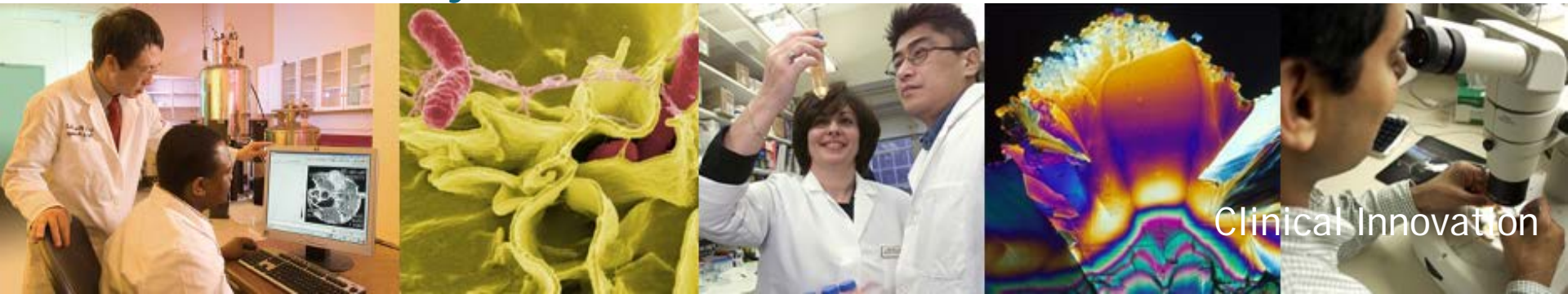
- Engaging stakeholder across the entire spectrum of translational research
 - Making sure that the research questions matter to patients
 - Ensuring feasible protocols with acceptable burden
 - Promoting stakeholder input into consent language
 - Including patients in implementation and safety oversight
 - Improving dissemination through communication with relevant communities
- **Example:** NCATS Rare Disease Clinical Research Networks

Including Populations Across the Human Lifespan

- Ensuring that children and the aging benefit from the advances of translational research
 - Point-person for pediatrics and gerontology
- Promoting the inclusion of special populations or underserved groups
 - Innovation in
 - Methods
 - Technology
 - Policy
 - Community and stakeholder outreach

NCATS Division of Clinical Innovation Strategic Goals

1. **Train**, develop and cultivate future leaders in translational science
2. **Innovate** in translational science
 1. Engage patients and communities in every phase of the translational process
 2. Promote the integration of special and underserved populations in translational research across the lifespan
 3. **Innovate processes to increase the quality and efficiency of translational research, particularly of multi-site trials**
 4. Advance the use of modern informatics in translation
3. **Communicate** effectively with internal and external audiences using clear, timely, and consistent messages
4. **Measure** success of the CTSA program through a set of common metrics
5. **Partner** effectively with NIH and other stakeholders



Ongoing Consortium-wide Demonstration Projects

1. Transforming Multi-Site Trials: Central IRBs for the CTSA Program
2. Innovating Research Participant Recruitment
3. Enhancing Clinical Research Professionals' Training and Qualification
4. Innovating Scientific Review for the CTSA Program



Streamlining Multi-Site Studies

The problem:

- Multi-site studies are a critical step in translation
- The current system is inefficient:
 - IRB review at multiple sites is associated with bureaucratic burden
 - Subcontracting between institutions delays start-up

The approach:

- NCATS is funding an initiative to build national trial support centers that
 - Centralize IRB review, and
 - Streamline contracting

IRB RELIANCE PROJECT - TOWARD A NATIONAL IRB

ALAN I. GREEN, DARTMOUTH COLLEGE
JOHN N. CLORE, VIRGINIA COMMONWEALTH UNIVERSITY
AND CTSA RESEARCH TEAMS

NCATS

Background

- Patients are frustrated with the slow pace of translational clinical research
- Research teams spend too much time on bureaucratic task
- Delays in trial start-up and during follow-up (amendments, renewals)
- Value of review by multiple IRBs is uncertain
- Thus need for collaborative IRB review models for multisite studies.
- Successful demonstration projects: NCI, NINDS (NeuroNEXT)
- December 3, 2014: NIH issues draft policy to promote the use of single IRBs in multi-site clinical research studies.

CTSA IRB Agreement Networks

UC BRAID

U Texas

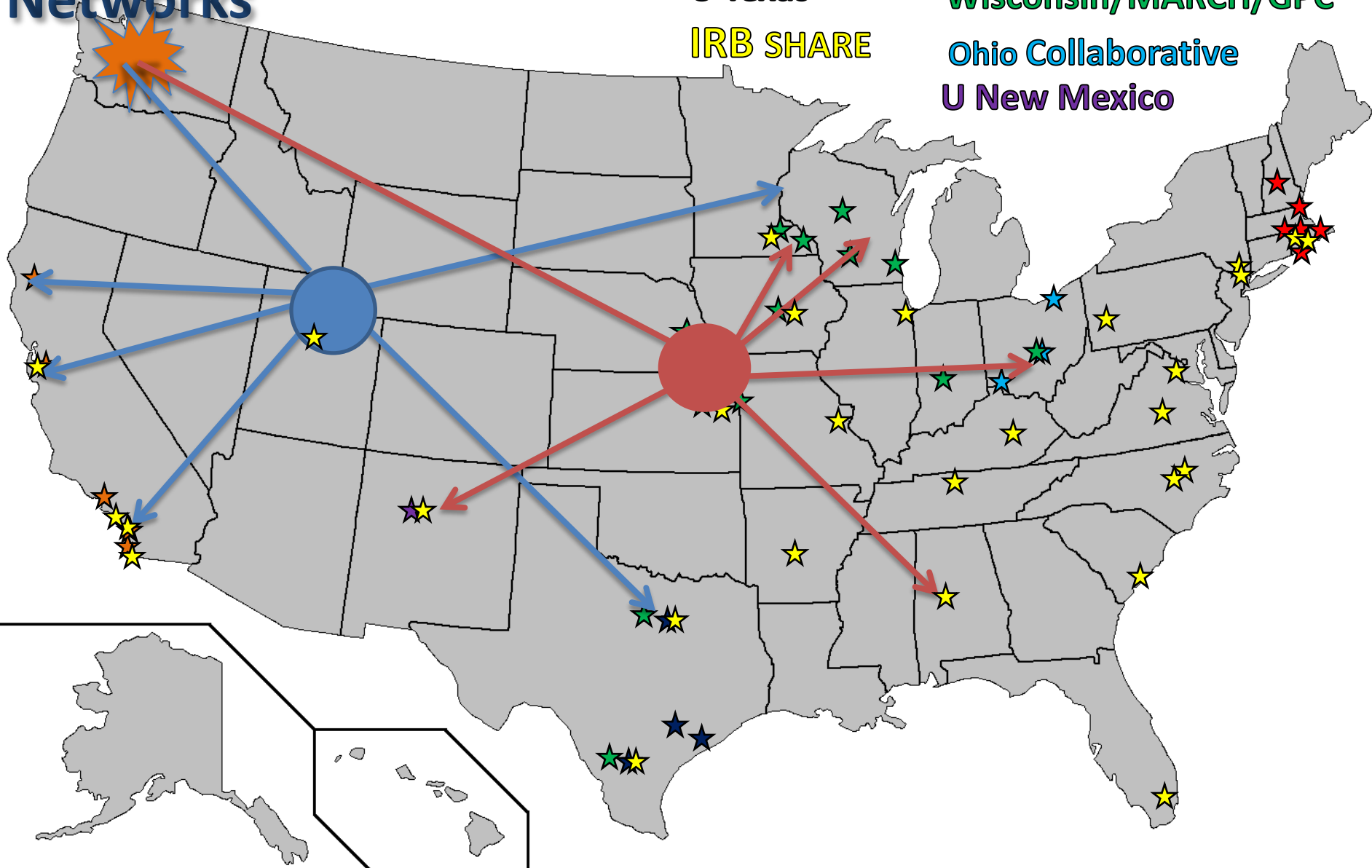
IRB SHARE

New England

Wisconsin/MARCH/GPC

Ohio Collaborative

U New Mexico



Value of Reliance Agreement and Network:

- Doctors at Mass Eye and Ear in Boston realized that they could learn more about the nature of blast-related ear injuries by studying victims of the Boston marathon bombing.
 - Harvard CTSA already had an IRB reliance network in place.



- With 7 other hospitals, rapid IRB approval was obtained to study a large number of ear injuries from the same blast and to observe patients as they healed
- See a video:
<http://catalyst.harvard.edu/programs/regulatory/>

Aims and Progress

- Draft national IRB reliance agreement, building on the expertise of existing regional IRB models
- Informatics infrastructure to support a national IRB reliance model
- Engagement with PCORI to harmonize efforts
- Outreach to wider community (PRIM&R, SCT)
- Next steps: Executing agreements and pilot project



ACCRUAL TO CLINICAL TRIALS (ACT)

LEE NADLER, HARVARD UNIVERSITY

GARY S. FIRESTEIN, UNIVERSITY OF CALIFORNIA - SAN DIEGO

STEVEN REIS, UNIVERSITY OF PITTSBURGH

ROBERT D. TOTO, UT SOUTHWESTERN, DALLAS

and CTSA research teams

NCATS

Improving Efficiency: Participant Recruitment

- The problem:

Slow recruitment delays most NIH-funded trials

- The approach:

NCATS funds initiative to build national recruitment capacity using data from the Electronic Health Record (EHR) to identify potential trial participants meeting entry criteria



Trial planning phase

Data-driven site selection

Feasibility analysis

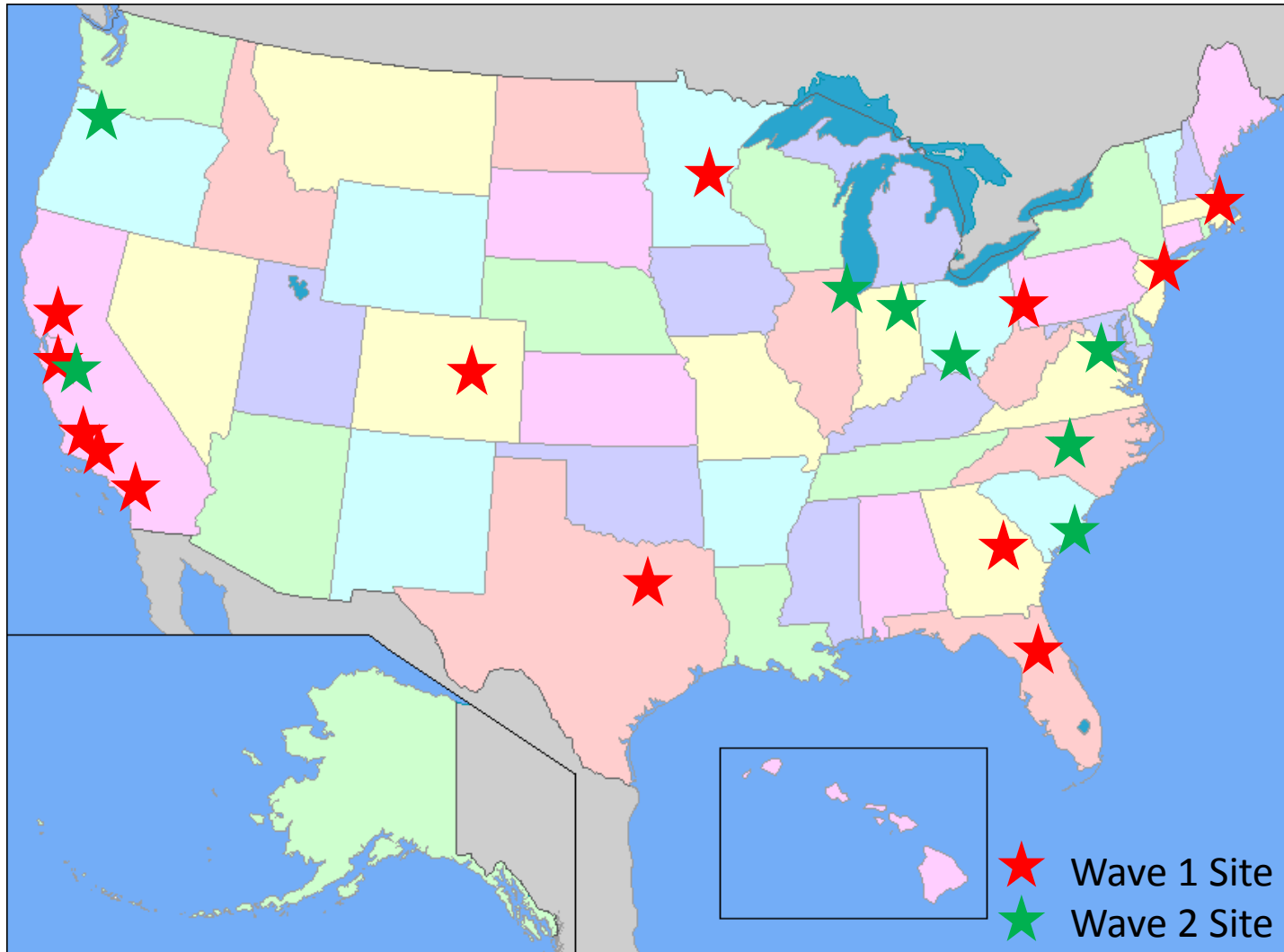


Trial implementation phase

Privacy and IRB compliant recruitment plan

Funded expert staff to help implement

Accrual to Clinical Trials – ACT



Progress to Date

- **Governance and working groups established:**
 - **Technology** - local software and network infrastructure
 - **Regulatory** - compliant access to EHR data across the ACT network and to contacting identified patients
 - **Governance:** Communication; Site Participation; Query Access ; SOPs
- **December 2014:** all NCATS 4 Month Milestones are met
 - IRB approval has been obtained for 11 sites (7 required)
 - 13 sites have been identified to participate in second wave (8 required)
 - 5 non-i2b2 sites have been identified (2 required)
- **Next steps:**
 - Pilot queries

Data Harmonization Work Group



Goal: Semantic compatibility with PCORnet which requires

ACT Ontology: Demographics, Diagnoses, Procedures, Visit Details, Medications, Laboratory Test Results

ACT works with PCORnet :

- Harvard, Pittsburgh & UCSD are also recipients of PCORnet grants
- Efforts towards a common ACT ontology semantically interoperable with PCORnet

ENHANCING CLINICAL RESEARCH PROFESSIONALS' TRAINING AND QUALIFICATION

THOMAS P. SHANLEY, UNIVERSITY OF MICHIGAN, ANN ARBOR
RICHARD BAROHN, UNIVERSITY OF KANSAS
AND CTSA TEAMS FROM ALL 62 HUBS

NCATS

Workforce and Site Qualification

The problem:

- Variable training leads to delays and errors
- Site qualification onerous for NIH and other funders

The approach:

- Create standards for research workforce training
- Good Clinical Practice certification as floor

The vision:

- Reduce burden
- Increase quality and efficiency

“Enhancing Clinical Research Professionals’ Training and Qualification”

Background

- Competency-based training for research personnel involved in executing clinical trials is inconsistent or absent

Aims

1. Standardize training in Good Clinical Practices (GCP) across the CTSA network (*Phase 1*)
2. Develop a competency-based, clinical research professionals’ training curriculum (*Phase 2*)

Scope

- All 62 CTSA hubs participating

Phase 1: Standardize GCP training

Project period: September 2014 to February 2015

Progress

Sept. - Oct. 2014

- Leadership team convened and performed background analysis
- Hub representatives engaged in planning process

Nov. 2014

- Meeting held in Chicago
- All 62 hubs represented
- Recommendations drafted and circulated for consensus by hubs

Dec. 2014

- Recommendations endorsed by all 62 hubs
- Formally presented to NCATS leadership

Phase 2: Develop a competency-based, clinical research professionals' training curriculum

Project period: December 2014 to May 2015

Progress

Dec. 2014

- Existing competency frameworks examined for potential adoption
- Working groups based on competency domains established
- Secured meeting site in Dallas for February 2014
 - identify those key competencies necessary for a research professional to be qualified to execute clinical trial work
 - identify anticipated evaluation metrics to be collected upon planned dissemination of curriculum

Impact

- Raises the clinical standards of the CTSA network
- Aligned with NCATS initiative to partner with industry on site qualification (IOM)
- Positions the CTSA network to better accommodate multi-site clinical studies
- Represents the first national CTSA initiative to include all CTSA hubs

SCIENTIFIC REVIEW

HARRY SELKER, TUFTS UNIVERSITY
AND CTSA INVESTIGATORS AND TEAMS

NCATS

Background

- Human subjects research using CTSA resources must uphold ethical and regulatory principles
- Scientific review of human subjects research proposals must ensure scientific validity and operational feasibility
- Proposals that exclusively use CTSA funding (pilot projects, KL2, TL1) should demonstrate a translational focus

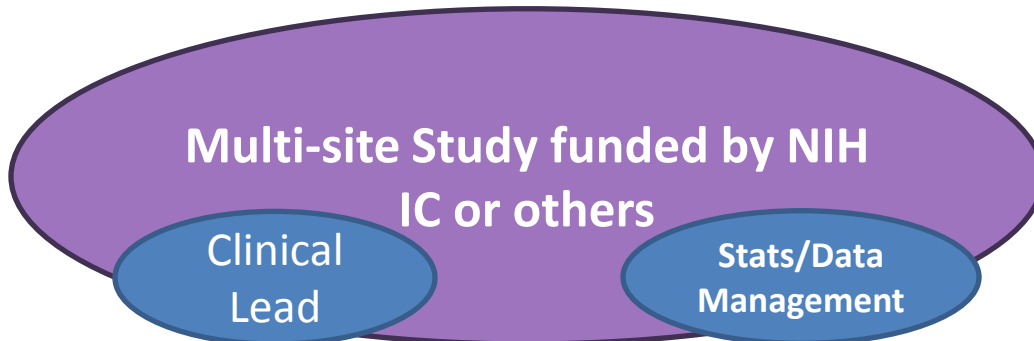
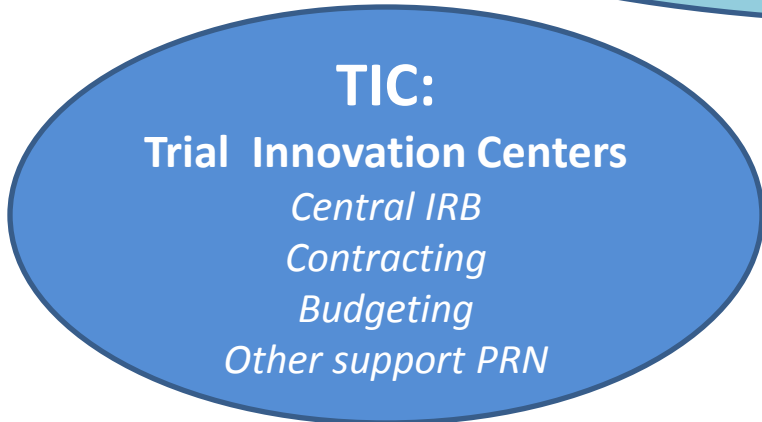
Progress to Date

- Broad stakeholder committee assembled
- F2F in Bethesda in December
- Drafts for
 - consensus document on review standards
 - recommendations on IT infrastructure
 - evaluation plan
- Next steps: demonstration and dissemination

EVOLVING THE CTSA PROGRAM

NCATS

Evolving the Program to Transform Clinical Translational Science

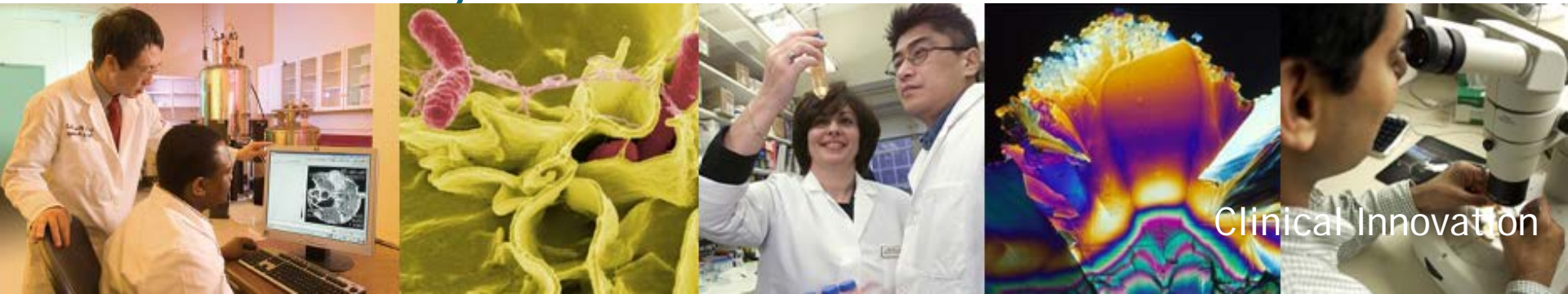


No need to re-build trial components each time



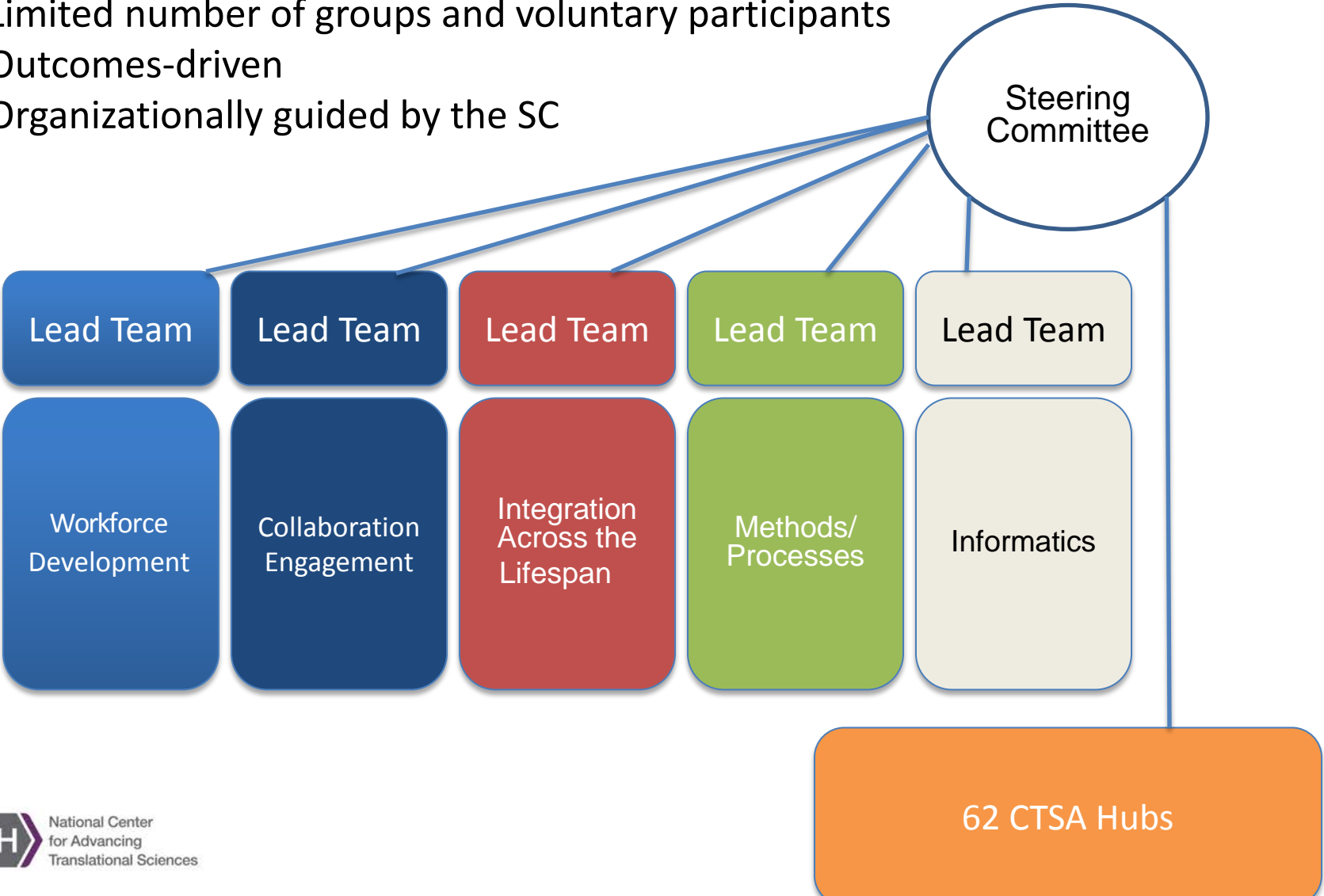
NCATS Division of Clinical Innovation Strategic Goals

1. **Train**, develop and cultivate future leaders in translational science
2. **Innovate** in translational science
 1. Engage patients and communities in every phase of the translational process
 2. Promote the integration of special and underserved populations in translational research across the lifespan
 3. Innovate processes to increase the quality and efficiency of translational research, particularly of multi-site trials
 4. Advance the use of modern informatics in translation
3. **Communicate effectively with internal and external audiences using clear, timely, and consistent messages**
4. **Measure** success of the CTSA program through a set of common metrics
5. **Partner** effectively with NIH and other stakeholders



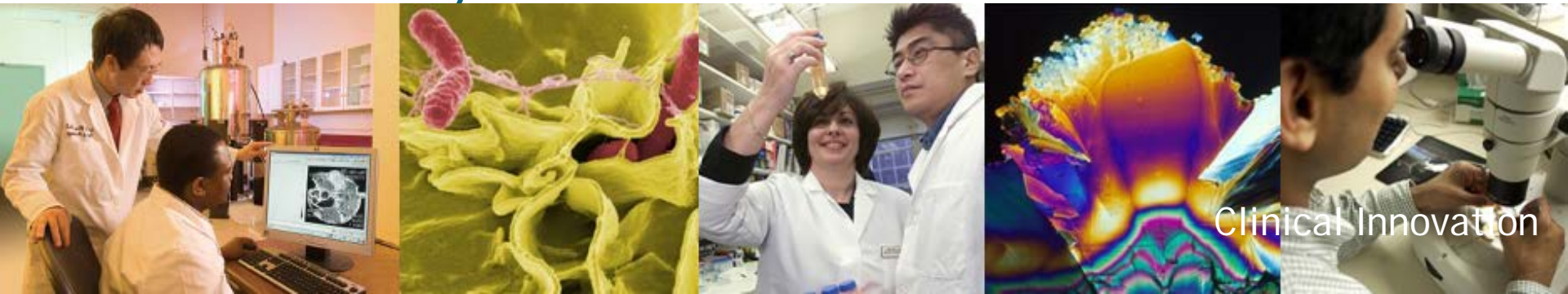
New, Streamlined CTSA Communications Structure

- Limited number of groups and voluntary participants
- Outcomes-driven
- Organizationally guided by the SC



NCATS Division of Clinical Innovation Strategic Goals

1. **Train**, develop and cultivate future leaders in translational science
2. **Innovate** in translational science
 1. Engage patients and communities in every phase of the translational process
 2. Promote the integration of special and underserved populations in translational research across the lifespan
 3. Innovate processes to increase the quality and efficiency of translational research, particularly of multi-site trials
 4. Advance the use of modern informatics in translation
3. **Communicate** effectively with internal and external audiences using clear, timely, and consistent messages
4. **Measure success of the CTSA program through a set of common metrics**
5. **Partner** effectively with NIH and other stakeholders



Evaluation and Metrics

- Need to develop a common set of metrics
- Limited number
 - Collect only what will be analyzed
 - Minimize burden
- Concise framework for regular reporting on the metrics, strategic analysis, and planning, including:
 - trend lines for the metrics with both historic baselines and forecasts;
 - identification of the factors/assumptions driving the trend lines;
 - strategies to address shortfalls.
- Communications strategy for metrics framework
 - Assumptions, timelines
 - Feedback on plan and regular review of results by external stakeholder group

Commitment to Local Research

- Most of funding goes to local activities
- Highlighting local success stories to illustrate local strengths (the first two “Ds”)
- Building on the existing local strength, we are adding network capacity
- Opportunities for successful local approaches to be more widely disseminated (for example, innovation fund projects)
- Opportunities for CTSA investigators to contribute to high priority NIH funded multi-site studies

CTSA Program FOA

- Applications will come in by January 15, 2015
- Broad interest, beyond the current CTSA program hubs
- At the next meeting, this will be discussed in the closed session of Council

Take-Home Messages

- The opportunities (and needs) in translational science are huge and systematic, so require *systematic* solutions
 - 21st c. needs cannot be solved with 20th c. structures
- The CTSA program has just begun to transform itself and its programs to meet these opportunities and needs for the benefit of patients.

Thank you

More Information

Petra.Kaufmann@nih.gov



Website: www.ncats.nih.gov



Facebook: facebook.com/ncats.nih.gov



Twitter: twitter.com/ncats_nih_gov



YouTube: youtube.com/user/ncatsmedia



E-Newsletter: ncats.nih.gov/news-and-events/e-news/e-news.html

E-mail us: info@ncats.nih.gov

