

CTSA Program Steering Committee

Monday, May 14, 2018

2:30 – 4:00 ET



UNIVERSITY of
ROCHESTER
MEDICAL CENTER

CTSA

Clinical & Translational
Science Awards Program

Center for Leading Innovation & Collaboration

CLIC Updates

Steering Committee

14 May 2018

Deborah J. Ossip, PhD

Martin S. Zand, MD, PhD

Serving the CTSA Program through coordination, transparent communication, actionable metrics, network analytics and innovative collaboration tools.



Center for Leading
Innovation & Collaboration

Spring CTSA Program Meeting Evaluations

CTSA

Clinical & Translational
Science Awards Program

Results: 276 Registered – 79 evaluations collected (29% response rate)

Questions:	"Agree (3)" or "Strongly Agree (4)"
This meeting covered topics I found valuable.	68.83%
This meeting addressed my expectations.	71.05%
There was adequate networking time allotted.	66.23%

On a scale of 1 – 10, please rate the meeting overall: (1 = lowest rating, 10 = highest rating)	
1 – 4	15 of 74 (20.27%)
5 – 6	10 of 74 (13.51%)
7 – 10	49 of 74 (66.21%)
Overall Meeting Average Score	6.78

Positive Themes

- Presentations from Dr. Kurilla and NCATS leadership were well received
- CLIC/Common Metrics presentations were helpful
- Linking the meeting with ACTS/DTF meetings helped participation in both meetings and created synergy

Areas of Improvement

- Include DTF updates
- Vote on topics/ put out a call for presentations
- More networking/ Roundtable discussions/ Smaller groups to share best practices
- Engage audience/ polling
- Offer best practices presentations

Agenda

Open Discussion on the following topics:

- **Continued discussion:** Reflections on the 2013 IOM Report on the Program
- **Decision Making:** Role of interest groups, i.e. Administrators
- **Funding Opportunity feedback:** What worked? What did not work?
- **Bidirectional communication:** How to encourage the use of the suggestion box



National Center
for Advancing
Translational Sciences

Suggestion Box Submission

Steering _Commi ttee	Date Rec'd	Who	Affiliatio n	Hub/ location	Suggesti on for	Suggestion	Date Sent to NCATS	Sent By	Date of Response from NCATS
Steering Commit tee	4/23/20 18	John Buse	CTSA Institio n	Universit y of North Carolina, Chapel Hill	Steering Committ ee	<p>It struck me that the recent CTSA PI meeting was pleasant enough but too short to really be useful. Or put another way - the travel time and expense was not optimally leveraged with productivity. It seems that perhaps it is time to untie the ACTS meeting from the CTSA consortium activities. The ACTS meetings have their value and their place, but it is inappropriate how the meetings were held last week.</p> <p>E.g., we had a "PI meeting" attended by PI's and administrators and KL2 and TL1 leads for 4 hours. It was functionally a meeting where reports were presented. Some people flew in exclusively for that meeting. Very nice snacks were provided.</p> <p>The next day there were some DTF meetings for ~3 hours with breakfast.</p> <p>The administrators and evaluators had to register for the ACTS meeting to be able to meet and they did not get breakfast or snacks until two people chipped in to buy them food (a CTSA and a non-CTSA institution).</p> <p>The optics of bloviating (for lack of a better word) PI's getting free breakfast and no registration fees while the administrators pay registration fees and get no breakfast was unfortunate.</p> <p>My proposal is that the CTSA Steering Committee should take control of our meetings to ensure that the right people are meeting for the right reason at the right time in the context of a CTSA meeting.</p>	4/30/2018	TD	Response not requested



Thank you!

Next call: June 11, 2:30 – 4:00



The 2013 IOM Report and 2014 NCATS Council Working Group Report

Retrospectives and Moving Forward

Christopher P. Austin, M.D.
Director, NCATS

CTSA Program Steering Committee Meeting
April 18, 2018



June 2013

The CTSA Program at NIH: Opportunities for Advancing Clinical and Translational Research

**IOM Committee to
Review the CTSA Program at NCATS**



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Elizabeth O. Ofili, Morehouse School of Medicine

Bray Patrick-Lake, Clinical Trials Transformation Initiative

Doris Rubio, University of Pittsburgh



Statement of Task Highlights

The IOM committee was convened to provide an independent appraisal of and advice on the NIH's CTSA Program as it will be implemented by NCATS.

The committee was specifically asked to

- make recommendations on the appropriateness of the program's current mission and overarching goals
- explore the contributions of the CTSA's in
 - accelerating the development of new therapeutics,
 - facilitating disease-specific research and pediatric research, and
 - enhancing the integration of programs funded by the categorical NIH Institutes and Centers.

Recommendation 1 (continued)

Strengthen NCATS leadership of the CTSA Program

As it implements CTSA 2.0, NCATS should:

- Form strategic partnerships with NIH institutes and centers and with other research networks and industry;
- Establish an innovations fund through a set-aside mechanism that would be used for collaborative pilot studies and other initiatives;
- Evaluate the program as a whole to identify gaps, weaknesses, and opportunities and create mechanisms to address them; and
- Distill and widely disseminate best practices and lessons learned by the CTSA Program and work to communicate its value and accomplishments and seek opportunities for further efforts and collaborations.

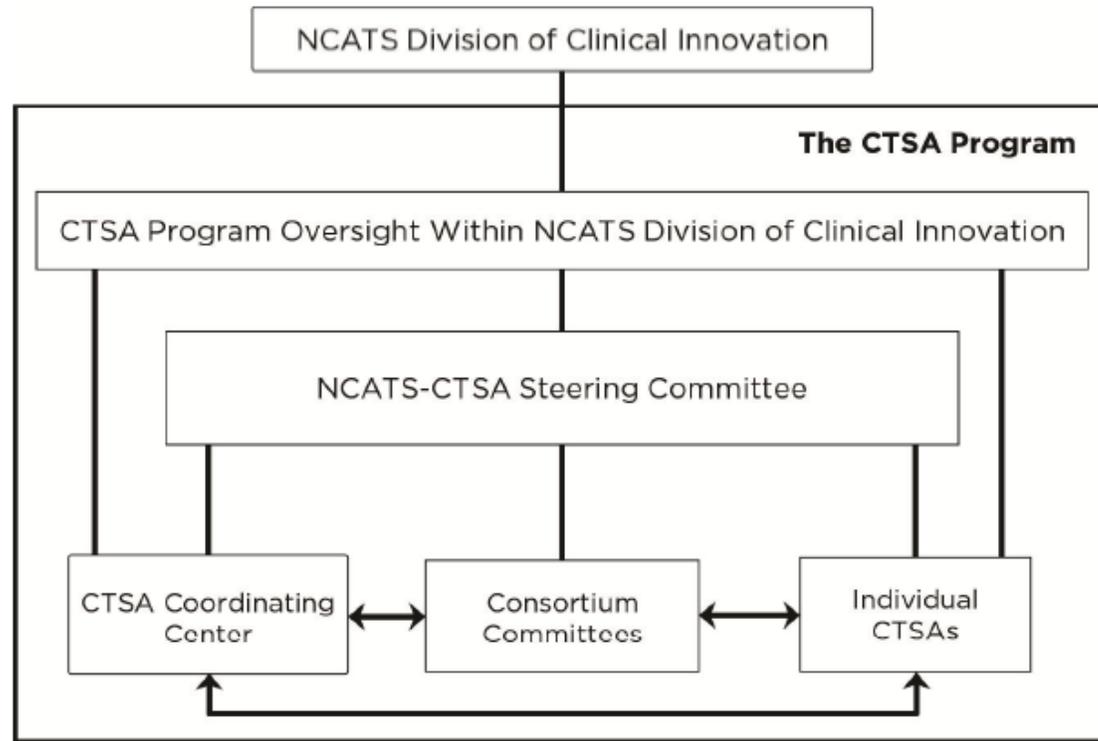
Recommendation 2

Reconfigure and streamline the CTSA Consortium

NCATS should reconfigure and streamline the structure of the CTSA Program by establishing a new multi-stakeholder NCATS-CTSA Steering Committee that would:

- Be chaired by a member of NCATS leadership team and have a CTSA principal investigator as vice-chair, and
- Provide direction to the CTSA Coordinating Center in developing and promoting the use of available shared resources.

Proposed Revised Structure



Recommendation 3

Build on the strengths of individual CTSAs across the spectrum of clinical and translational research

Individual CTSAs, with the leadership of NCATS, should emphasize their particular strengths in advancing the program's broad mission and goals. In doing so, CTSAs should:

- Drive innovation and collaboration in methodologies, processes, tools, and resources across the spectrum of clinical and translational research;
- Emphasize interdisciplinary team-based approaches in training, education, and research;

Recommendation 4

Formalize and standardize evaluation processes for individual CTSA's and the CTSA Program

The evaluations should use clear, consistent, and innovative metrics that align with the program's mission and goals and that go beyond standard academic benchmarks of publications and number of grant awards to assess the CTSA Program and the individual CTSA's.

Recommendation 5

Advance innovation in education and training programs

The CTSA Program should provide training, mentoring, and education as essential core elements. To better prepare the next generation of a diverse clinical and translational science workforce, the CTSA Program should:

- Emphasize innovative education and training models and methodologies, which include a focus on team science, leadership, community engagement, and entrepreneurship;

Recommendation 6

Ensure community engagement in all phases of research

NCATS and the CTSA Program should ensure that patients, family members, health care providers, clinical researchers, and other community stakeholders are involved across the continuum of clinical and translational research. NCATS and the CTSA Program should:

- Define community engagement broadly and use this definition consistently in RFAs and communications about the CTSA Program;
- Ensure active and substantive community participation in priority setting and decision making across all phases of clinical and translational research and in the leadership and governance of the CTSA Program;

Recommendation 7

Strengthen clinical and translational research relevant to child health

NCATS should collaborate with CC-CHOC to strengthen clinical and translational research relevant to child health through efforts to:

- Identify and designate CTSAAs with expertise in child health research as leaders in advancing clinical and translational research relevant to child health and as coordinators for CTSA programwide efforts and other collaborative efforts in this research; and

NCATS Advisory Council Working Group on the IOM Report: The CTSA Program at NIH

A Working group of the NCATS Advisory
Council to the Director

May 16, 2014

(Slide presentation at NCATS Council by Ron Bartek, Nora Disis, and Scott Weir)

NCATS Advisory Council Working Group on the IOM CTSA Report

Co-Chairs

- **Ronald J. Bartek**
FARA/Friedreich's Ataxia Research Alliance
- **Mary L. (Nora) Disis, M.D.**
University of Washington School of Medicine
- **Scott J. Weir, Pharm.D., Ph.D.**
University of Kansas Cancer Center

Members

- **Ann Bonham, Ph.D.**
Association of American Medical Colleges
- **Matthew Davis, M.D., M.P.P.**
University of Michigan
- **David L. DeMets, Ph.D.**
University of Wisconsin

- **Gary H. Gibbons, M.D.**
National Institutes of Health
- **Robert A. Harrington, M.D.**
Stanford University
- **Philip L. Lee, J.D., M.P.M.**
Results Leadership Group
- **Lynn Marks, M.D.**
GlaxoSmithKline
TransCelerate Biopharma
- **Sharon Milgram, Ph.D.**
National Institutes of Health
- **Louis J. Muglia, M.D., Ph.D.**
Cincinnati Children's Hospital
- **Fernando Pineda-Reyes**
CREA Results
- **Robert I. Tepper, M.D.**
Third Rock Ventures, LLC

Acknowledgements

- This report draws on the experiences and insights of many and we owe them our thanks for sharing their ideas, particularly the NCATS leadership and staff, and members of the translational science community.
- To our colleagues and members of the Working Group, we express appreciation for the breadth and depth you brought to the project. Your range of experience and perspectives were indispensable to addressing the Institute of Medicine (IOM) Report recommendations.
- We acknowledge Working Group member Phil Lee's very special role in providing our introduction to the [Results-Based Accountability \(RBA\) tool that guided our deliberations](#) and in steering us through the process. His kind but forthright critiques and probing questions repeatedly improved this report.
- An essential part of our deliberations flowed from the exceptional, in-depth review of the CTSA Program by the IOM committee. The superb work of the members and the many who participated in that process provided a rock-solid foundation for the Working Group deliberations.
- We also acknowledge our debt to NCATS leadership for encouraging the Working Group to make its own assessments, draw independent conclusions and express them in a report of its own creation.

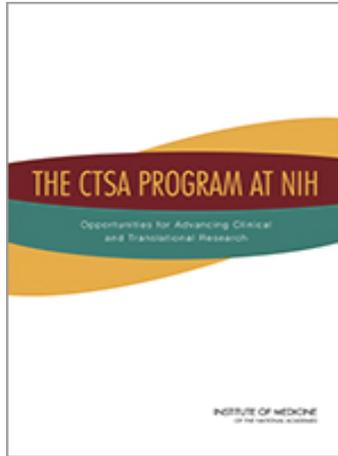
Working Group Charge

NCATS Advisory Council Working Group (WG) on the IOM Report was given the charge to:

1. Develop meaningful, measurable goals and outcomes for the CTSA program that address the recommendations of the IOM report, and;
2. Speak to critical issues and opportunities across the full spectrum of clinical and translational sciences.

Implementation of IOM Report Recommendations

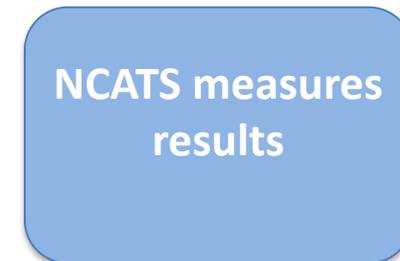
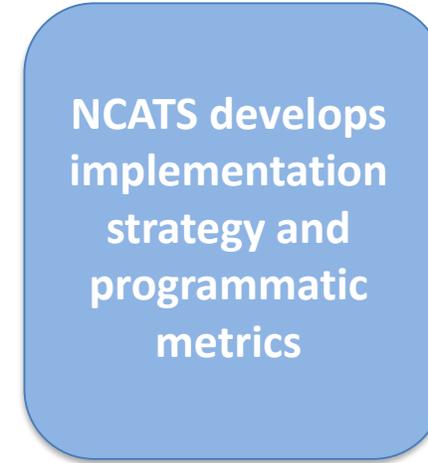
Overview of the Process



**IOM Report
Recommendations
June 2013**



**WG Report
Recommendations
May 2014**



IOM Report Recommendations

IOM Report Recommendations

- Strengthen NCATS leadership of the CTSA program.
- Reconfigure and streamline CTSA consortium.
- Build on the strengths of the individual CTSA's across the spectrum of research.

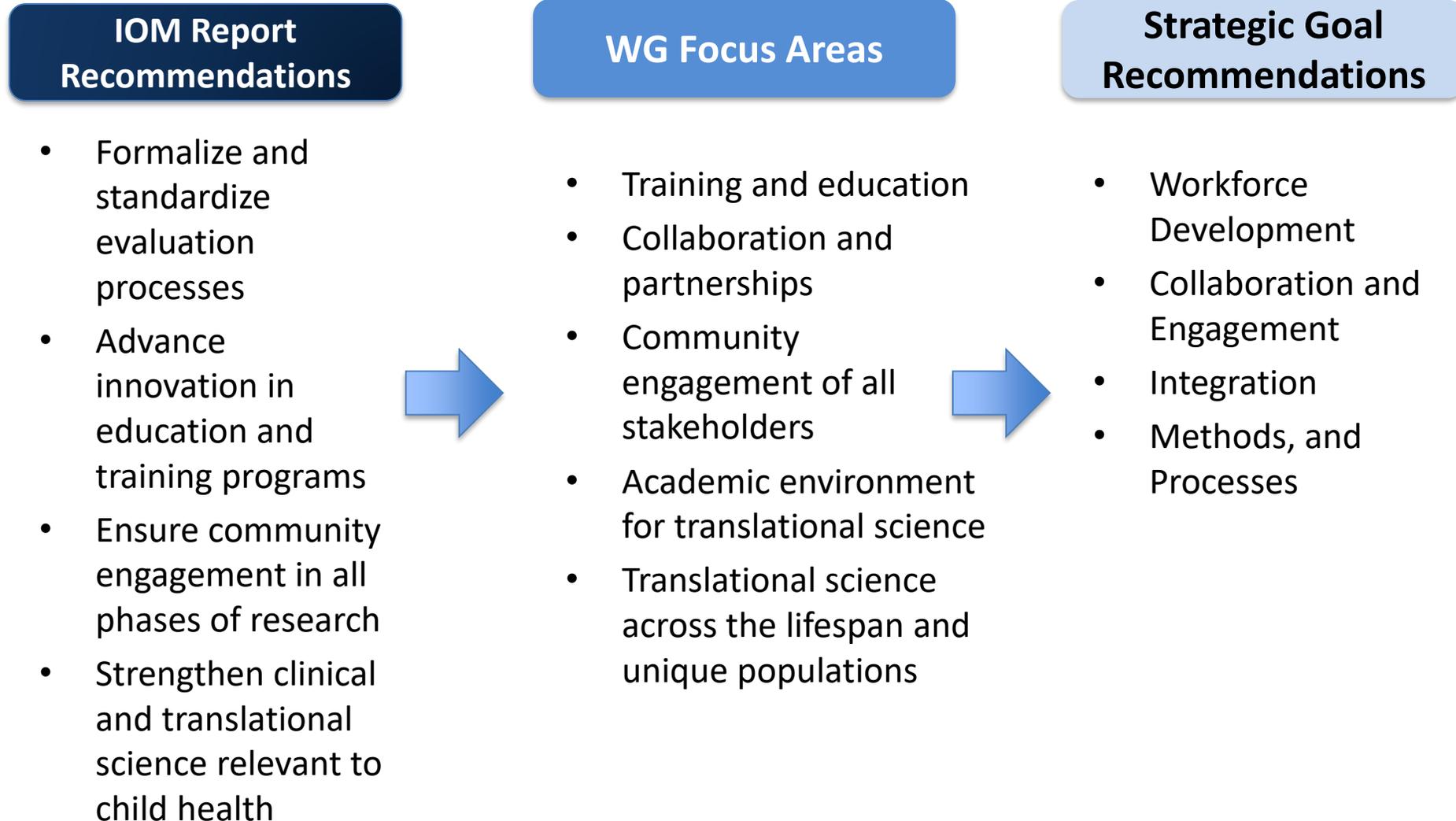
**Being addressed by
NCATS Staff**

- Formalize and standardize evaluation processes.
- Advance innovation in education and training programs.
- Ensure community engagement in all phases of research.
- Strengthen clinical and translational science relevant to child health.

**Considered by
NCATS Advisory
Council Working
Group**

Development of Strategic Goals

WG Focus Areas → Strategic Goal Recommendations

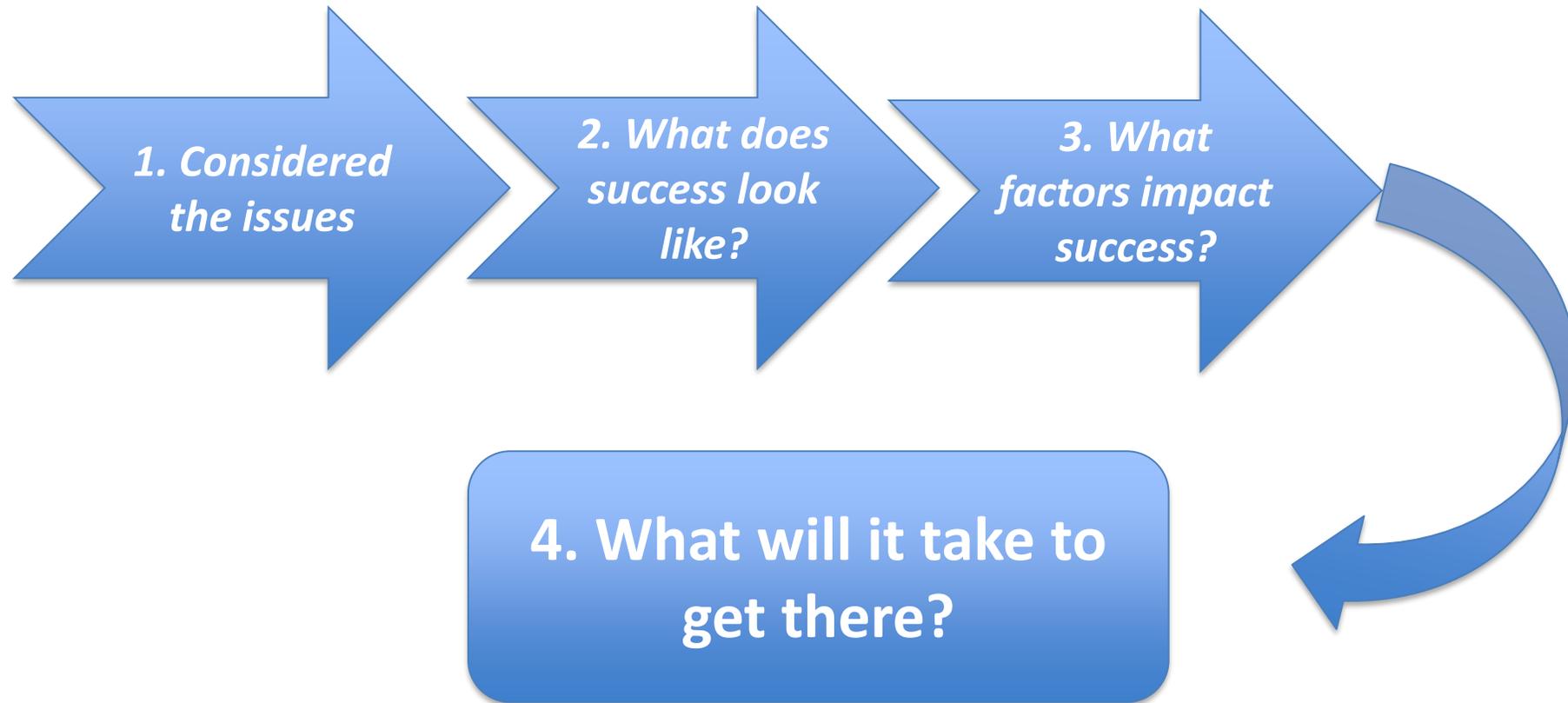


Strategic Goals

WG Recommendations

- **Workforce Development**
 - The translational science workforce has the skills and knowledge necessary to advance translation of discoveries.
- **Collaboration/Engagement**
 - Stakeholders are engaged in collaborations to advance translation.
- **Integration**
 - Translational science is integrated across its multiple phases and disciplines within complex populations and across the individual lifespan.
- **Methods, and Processes**
 - The scientific study of the process of conducting translational science itself enables significant advances in translation.

Elements For Each Strategic Goal



Strategic Goal: Workforce Development

What does success look like?

- Translational science is viewed as “the place to go” by those who want work to pursue high-impact careers in health sciences.
- The translational science workforce will meet the recognized needs of today and emerging needs of tomorrow and shape the vision of the future.
- The translational science “workforce” is broadly defined and includes researchers, clinicians, practitioners, patients, patient advocacy organizations, industry, community members.
- The curriculum needed to train a world-leading, globally connected, continually learning workforce with the skills to excel in translational science has been established.
- The sub-disciplines within translational science are well defined. The steps to advancement within each translational science sub-discipline are well defined.

Strategic Goal: Collaboration/Engagement

What does success look like?

- Collaborative team science becomes the norm rather than the exception; translational science is the model.
- Diverse stakeholders would be engaged as full partners in translational science and involved in shared leadership roles throughout the entire process.
- Communities involved in all aspects of the translational science spectrum contribute to the development of all aspects of translational sciences.
- The value of collaboration is enhanced while the cost and difficulties of collaboration are reduced by methodologies and approaches emanating from CTSA programs.
- Translational science is governed by collaborations and partnerships that reward all stakeholders (e.g., researchers, patients, and the community).
- Patient advocates, community members, and citizen scientists have the tools and infrastructure in place to participate fully as partners in all phases of translational science.
- Funding agencies, such as NIH, routinely collaborate in translational science initiatives and effectively engage other federal agencies, industry, academia, and philanthropic organizations as partners.

Strategic Goal: Integration

What does success look like?

- If translational science always includes efforts to study special populations, differences in the progress and treatments of disease processes would be identified.
- Translational science efforts lead to quantifiable improvements to the health, healthcare outcomes, and quality of life for people living with chronic disease and for racial, ethnic, and underserved populations.
- Laboratory and clinical advances are translated rapidly into lifesaving and life-prolonging interventions in both the young and elderly without unnecessary delay.
- New models (including regulatory, ethical, or policy considerations) exist that include all patients in biomedical research.
- Opportunities to prevent, postpone the onset, or otherwise alter the natural history of acute and chronic conditions through interventions early in the life course are examined by translational science researchers.
- Data across the entire lifespan is integrated, analyzed, displayed and exploited as relating to translational science.
- The translational investigation of health conditions that are specific to different life stages (childhood, adolescence, early adulthood, reproductive ages, pregnancy, and older adulthood) are emphasized.

Strategic Goal: Methods and Processes

What does success look like?

- The program functions individually and together as a research engine transforming the way translational science is conducted.
- Programs would routinely establish new scientific fields and paradigms and develop technologies and methods that change the way scientists approach their work.
- By changing methods and processes, translational science dramatically improves translation of discoveries into practice in real world settings.
- Key roadblocks that impede the translation of science into improved impacts on human health have been identified and eliminated.
- New tools, technologies, datasets, and models are widely available to enable translation across organizations; accelerate translation of science; and test new approaches that foster innovation in real world settings.
- Translational science uses digital technologies to create scientific information and to communicate, replicate, and reuse scientific knowledge and data.
- Data sets are integrated and data sharing and access to secondary data is the norm across the translational spectrum.

ModPod

Bruce Blazer

Barry Coller

Marc Drezner

Alan Green

Sundeep Khosla

Anantha Shekhar

NCATS Advisory Council Working Group on the IOM Report

Results Based Accountability (RBA)

**Principle: *Engage Stakeholders
collaboratively by making the
decision-making process transparent***

CTSA External

Clients/Customers/Stakeholders

- **NIH Institutes and Centers**
- **Governmental Agencies- FDA, CDC, AHRFQ, PCORI, CMS**
- **Biotechnology and Pharmaceutical Industries**
- **Congressional and Executive Branch Policy Makers**
- **Hub Institutional Leaders**
- **Hub Hospital/Health Care Systems Partners**
- **City and State Agencies**
- **Philanthropic Organizations and Foundations**
- **Patient Advocacy Groups**
- **Community Healthcare Providers**
- **The Press**
- **The Public**

CTSA Internal Stakeholders

- **NCATS Leadership**
- **NCATS Staff**

- **CTSA PIs**
- **CTSA Hub Teams**

CTSA Strategic Planning

- The CTSA program comprises a large number of elements.
- To guide future planning it would be valuable for CTSA PIs and NCATS leadership to rate each element for its:
 1. Importance
 2. Success to date
 3. Value relative to its cost
- Elements can be categorized by whether they operate primarily at the Institutional or National level, recognizing that there is considerable overlap (e.g., strengthening institutional research infrastructure strengthens the TIN).

CTSA Strategic Planning

Institutional Level

A. Culture change

- 1. Creating a home for translational investigators**
- 2. Enhancing the status of translational research and gaining a greater voice in high level institutional policy making, as for example, with IT deployment**
- 3. Enhancing support from technology transfer office**
- 4. Enhancing support from grants and contracts office**

CTSA Strategic Planning

Institutional Level

- 5. Enhancing support from legal department for protocol-specific contracting**
- 6. Enhancing support from public affairs department for publicizing translational advances by faculty and trainees**
- 7. Enhancing IRB focus on, and support of, translational studies and single IRB**
- 8. Modifying appointments and promotions policies to better recognize translational research**
- 9. Enhancing student and housestaff interest in translational research careers**

CTSA Strategic Planning

Institutional Level

B. Support and creation of programs

1. Education

a) KL2 degree-granting program

b) Other non-degree translational educational programs (e.g., ones for high school students, undergraduates, medical students, PhD students, and/or post-doctoral fellows)

2. Translational research infrastructure

a) IT support of translational research

b) Biostatistical support of translational research

CTSA Strategic Planning

Institutional Level

- 2. Translational research infrastructure (cont'd)**
 - c) Bioinformatics support of translational research**
 - d) Research coordinator support of translational research**
 - e) Protection of human subjects support of translational research**
 - f) Nursing support of translational research**
 - g) Research pharmacy support of translational research**
 - h) Monitoring and auditing support of translational research**
 - i) IND/IDE support of translational research**
 - j) Other**

CTSA Strategic Planning

Institutional Level

- B. Support and creation of programs**
 - 3. Pilot project support of translational research**
 - a) CTSA-supported**
 - b) Institution-supported**

 - 4. Collaborations with other Hubs**
 - a) Education-related**
 - b) Programmatic**
 - c) Administrative**

CTSA Strategic Planning

National Level

A. DTFs (each judged on the basis of collaborations sparked, best practices identified, and collective activities initiated).

- 1. Informatics**
- 2. Methods and Processes**
- 3. Collaborative Engagement**
- 4. Workforce Development**
- 5. Integration Across the Lifespan**

CTSA Strategic Planning

National Level

B. Translational Innovation Network (TIN)

- 1. Protocol development assistance**
- 2. Protocol siting assistance**
- 3. Protocol recruitment assistance**
- 4. Protocol conduct**

C. CD2H

D. Technology Transfer

E. Communications