

Clinical & Translational Science Awards (CTSA)

Consortium Strategy and Implementation Planning Meeting

October 6-7, 2008
Rockville, MD

Summary

The CTSA Steering Committee held a meeting on October 6th and 7th, 2008 to complete the CTSA Consortium Strategy and Implementation planning process. Over 120 CTSA PI's, Committee Chairs, administrators, NIH representatives and NCRR participants attended. Agreement was reached on a streamlined and consolidated list of priorities and on structural improvements to align the organization with these priorities.

This meeting was in follow up to a July 8, 2008 CCOC Operations Group meeting in Pittsburgh, PA, during which the group had created an interim list of 9 strategic priorities.

They were:

1. CQI Clinical Research Management System
2. Federated Career Support
3. National Resource Inventory
4. Clinical Trial "Network of Networks"
5. Data Sharing Network
6. National Phenotyping System
7. National Model for Community Engagement
8. Social Networking Initiative
9. Catalyze Improved Health Through Research

On October 6th, all participants engaged in a nine part facilitated strategic planning process in which implementation plans were developed for each of these priorities. In addition, the mission statement for the CTSA Strategic Plan was redrafted and agreed upon, as follows:

“The goal of the Clinical and Translational Science Award (CTSA) Program is to improve human health by transforming the research and training environment thereby enhancing the quality and efficiency of clinical and translational research.”

The PI members of the CTSA Steering Committee were then asked to review the draft planning results and reprioritize the goals where necessary in order to best achieve the mission of the CTSA Consortium. The PIs consolidated all nine priorities into four main goals as listed below:

Goal One

- ***Enhancing National Clinical and Translational Research Capability***

Including these elements:

- clinical research management
- research infrastructure
- phenotyping - human and preclinical models

Goal Two

- ***Enhancing the Training and Career Development of Clinical and Translational Scientists***

Goal Three

- ***Enhancing Consortium-Wide Collaborations***

Including these elements:

- social networking
- inventory of resources
- data sharing

Goal Four

- ***Enhancing the Health of Our Communities and the Nation***

Including these elements:

- community engagement
- public health policy

In order to support the successful accomplishment of these goals the CTSA Steering Committee also agreed to significant changes within the CTSA organizational structure, including:

- The CTSA Consortium Oversight Committee (CCOC) was renamed the CTSA Consortium Steering Committee (CCSC) to indicate its key role in Steering the consortium and setting priorities.
- The Operations Committee was renamed the CTSA Consortium Executive Committee (CCEC), as a subcommittee of the Steering Committee, to indicate its critical role in providing leadership.
- Previously titled “Steering Committees” were renamed as “Key Function Committees.”

In order to execute the strategic plan, the Steering Committee agreed upon the following next steps:

- Strategic Goal Committees will be created/assigned and will be responsible for the completion of each goal via coordination with appropriate Key Function Committees, Special Interest Groups and Working Groups. Three PIs, one of whom will be an Executive Committee member, will lead each Strategic Goal Committee.
- Strategic Goal Committee PIs will work with the Steering and Executive Committees in addition to content experts to devise a charge with deliverables for each of these areas, guided as needed by the implementation steps delineated in the strategic planning process.
- Consortium wide resources will be focused on the four key goals to ensure that the CTSA organization has identifiable objectives, milestones and outcomes.
- The existing committee structure will be systematically examined and reorganized so that it is optimized to support the strategic goals of the network while also providing important networking and synergizing functions to improve and support local CTSA operations.

Evolution of the Strategy

According to the CTSA Request for Applications¹, “the National CTSA Consortium Steering Committee shall be a forum for sharing policies, practices, and resources and for discussion of opportunities, impediments, joint agreement on broad issues impeding clinical research, government policies and practices, and other appropriate topics. The Committee will identify and approve best practices and policies that will advance clinical and translational research as a discipline and facilitate collaboration and sharing among CTSA institutions and with partners in clinical and translational research, e.g., industry, laboratories, hospitals.”

¹ RFA Number RFA-RM-06-002 <http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-06-002.html#SectionVI2>

According to the CTSA Governance Manual,² “A major goal of the CTSA program is to create an environment that will overcome challenges and impediments to clinical and translational science. The consortium will work towards adopting and implementing agreed-on best practices, policies, procedures, and other measures to advance collaborative clinical and translational research and reducing burdens on individual investigators at all institutions.”

The Steering Committee undertook the strategic planning process to optimize the fulfillment of these fundamental goals of the CTSA Consortium.

The CTSA Consortium represents an ever expanding group of stakeholders. The first 12 CTSA institutions received their awards in September, 2006. The second 12 received their awards in September, 2007. Fourteen additional institutions became part of the Consortium in May, 2008. An additional 22 institutional awards are planned by 2012. When complete, the Consortium will have linked together the capabilities of the much of the nation’s clinical research infrastructure. The complexity and potential of the organization demanded that a strategic plan be put in place to guide its development toward its fundamental goals.

While strategic planning is generally best performed with a static stakeholder pool, it became clear that a Consortium-wide strategic planning process was immediately necessary in order to optimize processes and collaboration among CTSA institutions even as the organization grew. This required a stepwise approach to strategic planning. This meant that in early 2008 goals were generally identified by the 24 existing CTSA members, meanwhile anticipating the need for full stakeholder participation and consensus development once 14 additional members were added to the consortium in the following months.

The following process was undertaken to accelerate progress toward the development of a full strategic plan:

1. CTSA Co-Chairs polled the then-named CTSA Consortium Oversight Committee (CCOC:consisting of 24 CTSA member institution PIs and NIH representatives; now known as the CTSA Steering Committee) to identify critical goals that would form the basis for a consortium-wide strategic plan.

Eight goals were identified as predominant. These were:

- a. “Develop a system of continuous quality improvement in clinical research management (IRB, contracts, grants management, Medicare and insurance payments, clinical site organization).
- b. Develop a coordinated/federated approach to career development, training and education across the spectrum of translational and clinical disciplines.

² CTSA Governance Manual http://www.ctsaweb.org/Docs/CTSA_Governance_Manual.pdf

- c. Create a national, searchable and interactive inventory of resources for translational and clinical research including people (e.g. clinical investigators, statisticians, etc.), technologies (e.g. genomics, proteomics, etc.) and services (data coordination, bioinformatics, etc.).
 - d. Develop a proof of principle approach through several clear examples of networks for enrollment and conduct of clinical trials that eventually could make the CTSA Consortium a “network of networks”, each focused on particular diseases/conditions, but also linked by common data systems and informatics.
 - e. Develop a national system of electronic data management and data sharing complemented by information technology tools.
 - f. Develop a national biobank.
 - g. Develop a national phenotyping system.
 - h. Develop effective national model for community engagement.”
2. After circulating these draft goals, the CTSA Co-Chairs requested additional feedback from the CCOC Steering Committee members, during which an additional four goals were suggested for consideration. These were:
- I. Clear cut conflict of interest policy
 - II. Develop a consortium-wide social networking initiative.
 - III. Support for regional and national health care reform.
 - IV. Develop a coordinated national comparative animal model core (and tissue biorepository).
3. The then-named CCOC Operations Group (now the CTSA Consortium Executive Committee, or CCEC) then held a facilitated strategic planning meeting in Pittsburgh, PA on July 8, 2008 that was also attended by two elected representatives on the 2008 awardees. The meeting was designed to clarify a mission statement for later CCOC strategy and implementation planning and also to clarify/refine the goals obtained through polling. The meeting was also designed to set the stage for implementation step identification and optimization of the CTSA Governance structure. In that meeting, the following approach to the creation of a draft mission statement was taken:

Since the RFA spelled out the broad aims of the CTSA, the Operations Group agreed that the following statement from the Governance Manual provided a base framework for the mission statement:

“The goal of the Clinical and Translational Science Award (CTSA) program is to transform the local, regional and national environment for clinical and translational science, thereby increasing the efficiency and speed of clinical and translational research.”³

³ CTSA Governance Manual http://www.ctsaweb.org/Docs/CTSA_Governance_Manual.pdf

The group then agreed that the statement should be modified as shown below:

*“The goal of the Clinical and Translational Science Award (CTSA) program is to transform the local, regional and national environment for clinical and translational science, thereby increasing the efficiency, **quality** and speed of clinical and translational research.”*

4. Using this draft mission statement, the Operations Group addressed the goals obtained through polling and also the suggested additional goals and refined them (with some nesting of goals) in the following way:
 - a. Develop a system of continuous quality improvement in clinical research management (IRB, contracts, grants management, Medicare and insurance payments, clinical site organization).

This was named: **“CQI Clinical Research Management System”**

- b. Develop a coordinated/federated approach to career development, training and education across the spectrum of translational and clinical disciplines.
 - i. New discipline of T1 Translation
 - ii. Clinical trials
 - iii. Health services and outcomes research
 - iv. T2 community research and community engagement

This was named: **“Federated Career Support”**

- c. Create a national, searchable and interactive inventory of resources for T&CR including people (e.g., clinical investigators, statisticians, etc.), technologies (e.g. genomics, proteomics, etc.) and services (data coordination, bioinformatics, etc.).

This was named: **“National Resource Inventory”**

- d. Develop a proof of principle approach through several clear examples of networks for enrollment and conduct of clinical trials that eventually could make the CTSA Consortium a “network of networks”, each focused on particular diseases/conditions, but also linked by common data systems and informatics.

This was named: **“Clinical Trial “Network of Networks”**

- e. Develop a national system of electronic data management and data sharing complemented by information technology tools.

This was named: **“Data Sharing Network”**

- f. Develop a national biobank.

This was named: **“National Biobank”**

In discussion with the Operations Group, the impression was that the National Biobank would be better classified as a strategic component of the National Resource Inventory and it was nested within that concept.

- g. Develop a national phenotyping system.

This was named: **“National Phenotyping System”**

- h. Develop effective national model for community engagement.

This was named: **“National Model for Community Engagement”**

- i. Develop a consortium-wide social networking initiative.

This was named: **“Social Networking Initiative”**

- j. Clear cut conflict of interest policy

This was named: **“Conflict of Interest Policy”**

In discussion with the Operations Group, the impression was that the Conflict of Interest Policy concept would be better classified as a strategic component of the Federated Career Support concept and it was nested within it.

- k. Support for regional and national health care reform.

This was renamed: **“Catalyze Improved Health Through Research”**

- l. Develop a coordinated national comparative animal model core (and tissue biorepository).

This was named: **“National Comparative Animal Model Core”**

In discussion with the Operations Group, the impression was that the National Comparative Animal Model Core would be better classified as a strategic component of the National Resource Inventory and it was nested within that concept.

The Final Set of Strategic Concepts and Their Underpinning Features

After naming and nesting of the strategic concepts, nine major concepts remained and all were deemed to be highly important elements of the mission. The final list and discussion bullets that illustrate their meaning are as follows:

a. CQI Clinical Research Management System

Key features of this strategic concept are:

- Study design
- Study start up
 - IRB
 - Contracts
 - Investigator orientation
 - Metrics
 - Systematic study recruitment
- Trial conduct
- Trial completion and reporting
- Financial issues
- Public trust maintenance

b. Federated Career Support

Key features of this strategic concept are:

- Efficient training of emerging investigators
- Standardization of all clinical education, support awards, etc.
- Structure exposure to complex, multiinstitutional research
- Include the international dimension
- Emphasize team building and management
- Consider business education or business school interface
- Define new training structures
- Define when investigators are “ready”
- Manage promotion policies and timelines for translational scientists
- Establish excellent conflict of interest policies
- Enhance basic researcher engagement with clinicians

c. National Resource Inventory

Key features of this strategic concept are:

- Enable outsourcing of research to other, more capable sites
- Locally and nationally searchable Google-like interface

Access to technical cores at other institutions

- Bioinformatics
- Biostatistics
- Data coordinating centers

National Comparative Animal Model Core

- There is an existing NCCR organization led by Dr. Grieder
- “Knowledge Environment” is key
 - Enabling model selection
 - Phenotyping
 - Correlation with human biology

National Biobank

- Systematic collection of biospecimens for common access and use
- Tissues and fluids
- Accessible network – not a single location
- IT enabled
- Quality and usability standards
- Standardized annotation
- Standardized consenting
- Policy focused
 - Inclusion criteria
 - Exclusion criteria
 - Handling

d. Clinical Trial “Network of Networks”

Key features of this strategic concept are:

Open access to CTSA-specific clinical trial support

Pilot mode first

Relationship to Social Networking Initiative

Visible single point of contact

e. Data Sharing Network

Key features of this strategic concept are:

Common, searchable website – University maintained

Development of a common informatics infrastructure

Clarify data sharing policies

Identify and support critical content for sharing

Social networking support

Consider privately funded opportunities

f. National Phenotyping System

Key features of this strategic concept are:

Need defined entry criteria
Informatics solutions required
Data broker/access
Establishment of phenotyping standards
Basic health care information present
Consider ongoing programs

g. National Model for Community Engagement

Key features of this strategic concept are:

T2 component

Community participatory research

- Design
- Participation

Identification of health disparities

Public assists in the delineation of unmet medical needs

Multiple programs require sharing – best practices

Interface with practicing community physicians

Increasing public trust

- Standards
- Public education

Creative financial sources for community research

- City
- State
- Foundations

Leverage other Federal organizations (CDC)

h. Social Networking Initiative

Key features of this strategic concept are:

Matchmaking/Facilitation

Specific needs to be identified

Development timelines critical

i. Catalyze Improved Health Through Research

Key features of this strategic concept are:

Guidance for research initiatives

Development of evidence to support health policies

Public policy engagement – more globally

Effectiveness of research as it deals with health care

5. A report of the July 8 meeting (see Appendix) was then circulated for review to all CCOC Steering Committee members, including the 14 newly added institutional members. A facilitated strategic planning meeting to identify implementation steps was planned for October 6 and 7, 2008 in Washington, DC.
6. In order to identify implementation steps (and their assigned committees) for the nine goals, a modified Hoshin facilitation process was designed and multiple PIs and NCCR staff were trained in the Hoshin facilitation process (see Appendix). In this process, a group creates a five year mission statement relative to the goal and then participates in parallel ideation, idea clustering and priority assignment in order to identify critical implementation steps, their durations and the degree to which progress has been achieved thus far. Nine such group meetings were planned (five in the morning, four in the afternoon), one to address each of the nine goals outlined by the Operations Group.
7. Approximately 120 persons participated in the strategic planning process with equal participation by PIs, their institutional colleagues and NCCR staff. As a result, a multi-stakeholder voice was captured. During this process, some renaming of the overall goals occurred, as indicated in the list of goals and key implementation steps outlined in the Results. Each implementation step represents the summation of a host of ideas offered by individual participants. These tactical suggestions are valuable for implementation planning and are listed in the Appendix (reachable via hyperlink from the implementation steps). These are provided to assist assigned committees in the stratification of immediate and longer range execution steps.
8. At the completion of the Hoshin planning sessions, the group redrafted the Mission Statement as follows:

“The goal of the Clinical and Translational Science Award (CTSA) Program is to improve human health by transforming the research and training environment thereby enhancing the quality and efficiency of clinical and translational research.”

This then became the working mission statement for the strategic plan.

9. On October 7, all nine previous goal groups met with their facilitators who assigned, where possible, responsible committees to the implementation steps. These can be viewed in the Results.
10. At this point in the process, the CCOC voting members were relocated together and a facilitated open forum discussion was held. Critically debated issues were:

- a. The number of goals and implementation
- b. The resources required to achieve the strategic plan
- c. The need to clarify the plan's objectives for a broader readership

After intense discussion, the group agreed to the following strategy:

- a. While all nine goals were ultimately deemed to be critical, four main goals were constructed from the original nine to illustrate the critical strategy of the CTSA, that is, *to streamline clinical trial systematics, optimize training and career development, organize national research resources to enhance collaboration and to strongly engage communities in the process*. This restructuring also enabled the rational timing of implementation of all goals.

The final four agreed upon goals were:

- **Enhancing national clinical and translational research capability**
 - clinical research management
 - research infrastructure
 - phenotyping - human and preclinical models
- **Enhancing the training and career development of clinical and translational scientists**
- **Enhancing consortium-wide collaborations**
 - social networking
 - inventory of resources
 - data sharing
- **Enhancing the health of our communities and the nation**
 - community engagement
 - public health policy

Implementation steps related to these goals are presented in the results.

- b. Each of the four final goal areas are to be governed by a "Goal Committee" that would be responsible for coordinating all other committee activities in the completion of that goal. Each Goal Committee will have one PI member from the newly named Executive Committee and two other PIs from the CCOC Steering Committee. All Goal Committees will report to the Executive Committee which will, in turn, report to the newly named CTSA Consortium Steering Committee.

Results

Goals and Their Implementation Steps

The Hoshin processes were applied to the nine goals specified by the Operations Group in their July 8 meeting. These were reassembled into the four main goal areas by the CTSA Steering Committee PIs in the following way:

- **Enhancing national clinical and translational research capability**
 - CQI Clinical Research Management System (former Goal 1)
 - Enhancing National Clinical Study Capability (former Goal 4)
 - National Phenotyping (former Goal 6)
- **Enhancing the training and career development of clinical and translational scientists**
 - Effective Innovative Training & Career Support (former Goal 2)
- **Enhancing consortium-wide collaborations**
 - National Resource Inventory (former Goal 3)
 - Data Sharing Network (former Goal 5)
 - Social Networking Initiative (former Goal 8)
- **Enhancing the health of our communities and the nation**
 - National Model for Community Engagement (former Goal 7)
 - Inform Public Health Policy Through Research (former Goal 9)

Implementation steps for the four main goals are accordingly grouped using the previous goal titles as subheadings. For ease of understanding and use, each implementation step is hyperlinked to the group of raw participant responses (in the Appendix) that were clustered within each implementation step. In addition, for execution planning, each implementation step was tentatively assigned a committee from the present governance structure (which may change with emerging governance changes). Finally, the relative priority in time of each step is indicated as well as its expected duration and the degree (scale = 1_{low} to 10_{high}) to which progress has already been achieved. *The Priority Strength listed in the results represents the proportion of times that implementation step is seen as needing to be executed early in the process.* All of this information is designed to guide the Strategic Goal Committees in the assignment of tasks to achieve the mission.

Goal:

Enhancing national clinical and translational research capability

- CQI *Clinical Research Management System (former Goal 1)*

Facilitators: Rebecca Jackson (PI) / Mary Purucker (NCRR)

Participants:

Carmen L. Ross	NIDA – NIH
Gerald Stacy	JHU
Robert Clark	University of Texas HSC San Antonio
Paymon Hashemi	Booz Allen Hamilton
Tesheia Johnson	Yale
Robert Sherwin	Yale
Lisa Guay-Woodford	UAB
Kenneth Polonsky	Washington University
Lars Berglund	UC Davis
Ira Wilson	Tufts
Mike McCune	UCSF
Dorothy West	NCRR
Mike Sayre	NCRR
Bonnie Ramsey	University of Washington
Regine Douthard	NCRR
Mary Samuels	Oregon Health & Science University
Shelia McClure	NCRR
Mike Alcorn	Scripps
Ana Austin	University of Michigan
Pablo Okhuysen	University of Texas – Houston
Steven Freedman	Harvard
Lili Portilla	NCRR
Donna Jo McCloskey	NCRR

Mission Statement: Establish innovative, dynamic and transparent systems that will promote efficiency, quality and safety in the conduct and life cycle of clinical and translational research within individual CTSA institutions and across the national consortium in five years.

Implementation Step	Suggested Committee	Priority Strength ⁴	Expected Duration (yrs.)	Progress To Date
<u>Establish standards and metrics</u>	Clin. Res. Mgmt. Task Force	83%	1	2
<u>Share best practices</u>	Clin. Res. Mgmt. Task Force	83%	2.5	1.2
<u>Training and quality of workforce</u>	Clin. Res. Mgmt. Task Force	33%	2	4

⁴ The implementation steps were compared in pairwise fashion to determine their relative priority in time. The Priority Strength represents the proportion of comparisons in which a particular implementation step was required to “start first.” This does not imply that other steps cannot be performed concurrently, however.

<u>Coordinate IRB processes across CTSA</u>	Clin. Res. Mgmt. Task Force	17%	>5	2.5
<u>Improve contracting processes</u>	Clin. Res. Mgmt. Task Force	17%	5	2
<u>Enhance patient recruitment and retention</u>	Clin. Res. Mgmt. Task Force	Pure Follower	5	1
<u>Inform national policy on clinical research</u>	Clin. Res. Mgmt. Task Force	Pure Follower	>5	1

- *Enhancing National Clinical Study Capability (former Goal 4)*

Facilitators: Julian Solway (PI) / Jody Sachs (NCRR)

Participants:

Deborah Roth	Duke
Lloyd Michener	Duke
Harry Greenberg	Stanford
Harry Shamoon	Einstein
Milton Packer	UT – Southwestern
Steven Hirschfeld	NIH/NICHD
Dan Rosenblum	NCRR
Jenna Goldstein	BAH
Pamela Davis	Case Western Reserve
Julianna I. McGinley	Cornell Medical College
Julie Earnest	OHSU
Rosemary Simpson	UNC – Chapel Hill
Shari Barkin	Vanderbilt
Betty Tai	NIDA/NIH
Ken Hargreaves	University of Texas HSC – San Antonio
Mary Ellen Michel	NIDA/NIH
David Stephens	Emory

Mission Statement: *Create links and common processes across CTSA's to amplify clinical study implementation and impact.*

Implementation Step	Suggested Committee	Priority Strength	Expected Duration (yrs.)	Progress To Date
<u>Create accessible catalog portal</u>	Communications, informatics, translational	80%	2	1
<u>Create operational standards</u>	Clinical Research Mgmt, Informatics	40%	3 - 5	1
<u>Capacity to match investigators with networks and populations (connect)</u>	Informatics, Communications, Community Engagement	40%	2	2
<u>Recruitment and engagement of special populations</u>	Community engagement, pediatrics	20%	1 - 33	1
<u>Integrating education in clinical studies</u>	Education	Pure Follower	1 - 2	4
<u>Mechanism for study of multi-site</u>	Clinical Research Mgmt, PEDs,	Pure		

coordination	PCIR, Informatics	Follower	2 - 3	1
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- National Phenotyping (former Goal 6)

Facilitators: Eric Orwoll (PI) / Anthony Hayward (NCRR)

Participants:

Mary Samuels	Oregon Health & Science University
Julie Earnest	OHSU
Mike Sayre	NCRR
Etta Pisano	UNC
Robert Clark	University of Texas HSC San Antonio
Betty Tai	NIDA/NIH
Mike McCune	UCSF
Lisa Guay-Woodford	UAB
Steven Freedman	Harvard
Bonnie Ramsey	University of Washington
Mary Purucker	NCRR
Liming Yang	NCRR
Kenneth Polonsky	Washington University
Anantha Shekhar	Indiana University
Robert Sherwin	Yale
Lars Berglund	UC Davis
Dorene Markel	University of Michigan
Paulette Sacksteder	University of Wisconsin
Bernard Talbot	NCRR
Anthony Hayward	NCRR

Mission Statement: *To develop appropriate standards and methods for phenotyping health and disease to facilitate clinical and translational research.*

Implementation Step	Suggested Committee	Priority Strength	Expected Duration (yrs.)	Progress To Date
Establish governance	PCIR w/ PEDs, Informatics, Regulatory	100%	0.5	1
Develop necessary regulatory compliance procedures	PCIR	86%	1	6
Develop methods, including analytic, databases, SOPs and informatics	PCIR	43%	2.5	5
Develop, define, and implement standards (including healthy "normals")	PCIR	29%	1	1
Choose priority projects	PCIR	14%	1	1
Leverage phenotypic annotation of bio-specimens	PCIR	Pure Follower	3	5
Secure acceptance and buy-in (education/communication)	PCIR	Pure Follower	3	3
Establish collaborations with existing databases, including National Records for secondary use	PCIR	Pure Follower	0.5	5

Goal:

Enhancing the training and career development of clinical and translational scientists

- *Effective Innovative Training & Career Support (former Goal 2)*

Facilitators: Steven Reis (PI) / Andrea Sawczuk (NCRR)

Participants:

Carol Shreffler	NIEHS
Guo H. Zhang	NCRR
Mohan Viswanathan	NCRR
Helen Lee	Booz Allen
Anantha Shekhar	Indiana
Paul Marantz	Einstein
Michael Lichtenstein	University of Texas – San Antonio
David Warner	Mayo Clinic
Ronald Sokol	University of Colorado – Denver
Lee Nadler	Harvard
Fred Meyers	UC – Davis
Don McClain	University of Utah
Rob Califf	Duke University
Mark Scheideler	NINDS
Harold Pincus	Columbia
Dan Clauw	Michigan
Louise Ramm	NCRR
Meryl Sufian	NCRR
Elizabeth Ofili	Atlanta CTSI (Morehouse School of Medicine)
Iris Obrams	NCRR
Valerie Lund	UT Southwestern – Dallas
Franziska Grieder	NCRR

Mission Statement: Develop a national coordinated approach to recruit, educate, train and promote the development of investigators across the evolving spectrum of clinical and translational research to improve human health.

Implementation Step	Suggested Committee	Priority Strength	Expected Duration (yrs.)	Progress To Date
<u>Develop core competencies for clinical and translational investigators</u>	Education	78%	1	4
<u>Continually improve trainee and program success</u>	Education	33%	3 - >5	2
<u>Ensure that institutions recognize clinical and translational</u>				

<u>investigation is a valuable enterprise with unique metrics & criteria for success and promotion</u>	Education	33%	1	1
<u>Develop policies and mechanisms for support for investigators across the spectrum of their career development and the range of clinical and translational research.</u>	Education	22%	2 - >5	2
<u>To establish core curriculum that will address the needs of clinical and/or translational investigation</u>	Education	11%	1 - >2	3
<u>Develop effective training and reward mechanisms for mentors</u>	Education	11%	2	1
<u>Develop, promote team building approach to research</u>	Education	Pure Follower	2	1
<u>To develop collaborative approaches regarding external partnership</u>	Education	Pure Follower	2	2
<u>To establish a common education platform of interdisciplinary science to instruct scientists about major problems of human health</u>	Education	Pure Follower	2.5	1
<u>Recruitment; to develop marketing strategies to attract outstanding trainees to clinical and translational research</u>	Education	Pure Follower	1	1

Enhancing consortium-wide collaborations

- National Resource Inventory (former Goal 3)

Facilitators: Gordon Bernard (PI) / Rosemarie Filart (NCRR)

Participants:

Jim Presson	University of Washington
Dorene Markel	University of Michigan
Susan Autry	UCSF
Barry Coller	Rockefeller
Harry Selker	Tufts University
Philip Greenland	Northwestern
David McPherson	UT – Houston
Dixie Baker	SAIC
Elaine Collier	NCRR
Diming Wang	NCRR
Gail Pearson	NHLBI
Gary Hunninghake	University of Iowa
Sheila Olson	Mayo Clinic
DeAnna O’Quinn	University of Iowa
Brian Athey	University of Michigan
Lori Mulligan	NCRR
Renee Joskow	NCRR
Amy Swain	NCRR
Doug Sheeley	NCRR
Henry Ginsberg	Columbia
Eric Topol	Scripps
John Gallin	NIH

Mission Statement: *Capitalize on the CTSA consortium to catalog existing specialized resources that will be available to all investigators and identify areas where new resources are needed to accelerate clinical and translational research and to improve human health.*

Implementation Step	Suggested Committee	Priority Strength	Expected Duration (yrs.)	Progress To Date
<u>Develop the project scope and process and ensure the project is adequately resourced</u>	New - TBN	100%	0.5	2
<u>Rules of engagement and operationalization</u>	New - TBN	75%	0.5	1
<u>Define resources to be listed and develop a catalog that is sustainable and accurate</u>	New - TBN	50%	0.5 - 2	1
<u>CTSA Consortium will mobilize their institutions to participate, organize and facilitate resource sharing</u>	New - TBN	25%	0.5 - 2	1
<u>Develop 1) an evaluation methodology that documents the impact of the catalog and the development of new collaborations 2) periodic gap analysis, 3) and assessment plan for existing and new needs</u>	New - TBN	Pure Follower	0.5	1

- Data Sharing Network Data Sharing Network (former Goal 5)

Facilitators: Eric Orwoll (PI) / Bernard Talbot (NCRR)

Participants:

Laura Weisel	Harvard
James Kushner	University of Utah
Havivah Schwartz	University of Washington
Paul Nakim	NIDA/NIH
Etta Pisano	UNC
Chris Kelleher	Oregon
Nora Disis	University of Washington
Robin Brey	UTHS CSA
Tom Inui	IU
Tom Karson	Einstein
Chris Webb	Stanford University

Mission Statement: *Create Data-Sharing Mechanisms to facilitate innovation, and the work of individual CTSA's and the consortium.*

Implementation Step	Suggested Committee	Priority Strength	Expected Duration (yrs.)	Progress To Date
<u>Governance</u>	Informatics	100%	0.5	3
<u>What's Out there? (Non-CTSA)</u>	Informatics	71%	1	6
<u>CTSA Inventory</u>	Informatics	57%	1	7
<u>Process Improvement</u>	Liaison with Evaluation, Informatics	43%	3	1
<u>Create Data Standards</u>	Informatics	43%	2	3
<u>Data-Use Policy</u>	Regulatory, Informatics	29%	2	1
<u>Communication/ Social Networking</u>	Informatics	14%	2	5
<u>Develop Tools</u>	Informatics	Pure		

		Follower	5	2
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- *Social Networking Initiative (former Goal 8)*

Facilitators: Rebecca Jackson (PI) / Jody Sachs (NCRR)

Participants:

Tom Karson	Einstein
Doug Sheeley	NCRR
Susan Autry	UCSF
DeAnna O’Quinn	University of Iowa
Gary Hunninghake	University of Iowa
Barry Coller	Rockefeller
Eric Topol	Scripps
Tesheia Johnson	Yale
Steve Dewhurst	University of Rochester
Dixie Baker	SAIC/NCRR
Dorothy West	NCRR
Laura Weisel	Harvard
Gerald Stacy	JHU
Havivah Schwartz	University of Washington
Henry Ginsberg	Columbia
Philip Greenland	Northwestern
John Choe	BAH
Chris Kelleher	Oregon

Mission Statement: *Build infrastructure to connect people to promote and support; collaborative multidisciplinary, clinical and translational research.*

Implementation Step	Suggested Committee	Priority Strength	Expected Duration (yrs.)	Progress To Date
<u>Feasibility & Needs Assessment – Scope Definition</u>	Communications - new PR Subgroup-Informatics Taskforce liaisons	100%	1	1
<u>Evaluation of existing approaches, tools, databases</u>	Communications - new PR Subgroup-Informatics Taskforce liaisons	86%	0.5	2
<u>Policies</u>	Communications - new PR Subgroup-Informatics Taskforce liaisons	71%	1	1
<u>Standards</u>	Communications - new PR Subgroup-Informatics Taskforce liaisons	43%	2 -3	1
<u>Create & Implement New Tools</u>	Communications - new PR Subgroup-Informatics Taskforce liaisons	29%	2 - 5	2
<u>Develop Metrics of Success and Evaluate</u>	Communications - new PR Subgroup-Informatics Taskforce liaisons	14%	2	1
<u>Federation of Tools</u>	Communications - new PR Subgroup-Informatics Taskforce liaisons	Pure Follower	5	1
<u>Adoption</u>	Communications - new PR Subgroup-Informatics Taskforce liaisons	Pure Follower	3 - 4	2

Goal :

Enhancing the health of our communities and the nation

- National Model for Community Engagement (former Goal 7)

Facilitators: Gordon Bernard (PI) / Rosemarie Filart (NCRR)

Participants:

Elizabeth Ofili	Atlanta CTSI (Morehouse School of Medicine)
Ken Hargreaves	University of Texas HSC San Antonio
Jane Atkinson	NIDCR
Regine Douthard	NCRR
Lloyd Michener	Duke
Donna Jo McCloskey	NCRR
Tom Inui	Indiana
Franziska Grieder	NCRR
Louise Ramm	NCRR
Amy Swain	NCRR
Don McClain	University of Utah
Shari Barkin	Vanderbilt
Dan Clauw	Michigan
Rob Califf	Duke
Lee Nadler	Harvard
Ron Sokol	University of Colorado
Nora Disis	University of Washington
Daniel Ford	Johns Hopkins
David Warner	Mayo Clinic
Meryl Sufian	NCRR
Michael Lichtenstein	UT Health Science Center – San Antonio
Tony Beck	NCRR
Steven Reis	University of Pittsburgh
Mike Alcorn	Scripps
Carol Shreffler	NIEHS

Mission Statement: To identify and develop effective partnerships between academic researchers and community stakeholders that allows for participation, discovery, application and dissemination of science that improves the public's health and reduces health disparities.

Implementation Step	Suggested Committee	Priority Strength	Expected Duration (yrs.)	Progress To Date
<u>Achieve and measure community outcomes that matter</u>	Community Engagement	60%	5	1
<u>Identify and disseminate, implement best practices within disparate communities</u>	Community Engagement	40%	2	3
<u>Health and science educational partnerships to earn public trust</u>	Community Engagement	20%	2	2
<u>Form and/ or facilitate practice based research networks</u>	Community Engagement	Pure Follower	1	2
<u>Develop and fund competency curricula and</u>	Community	Pure		

<u>training programs in community engaged research</u>	Engagement	Follower	2	4
<u>Advocate for community translational research</u>	Community Engagement	Pure Follower	1 - 5	2

- Inform Public Health Policy Through Research (former Goal 9: Catalyze Improved Health Through Research)

Facilitators: Julian Solway (PI) / Andrea Sawczuk (NCRR)

Participants:

Pablo Okhuysen	University of Texas – Houston
Ana Austin	University of Michigan
Harry Greenberg	Stanford
Pamela Davis	Case Western Reserve University
David Stephens	Emory
Julianne Imperato-McGinley	Cornell
David Wilde	NCRR
Carol Merchant	NCRR
Brian Currie	Einstein/Montefiore
Harry Shamoon	Einstein/Montefiore
Lori Mulligan	NCRR
Jim Presson?	University of Washington?
Enid Meyers?	UC Davis?
James Kushner	University of Utah
Robin Brey	University of Texas HSC San Antonio
Sheila Olson	Mayo Clinic
Harold Pincus	Columbis
Steven Hirschfeld	NIH/NICHHD
Dan Rosenblum	NCRR

Mission Statement: *Strengthen the scientific foundation to inform public policy and improve public health.*

Implementation Step	Suggested Committee	Priority Strength	Expected Duration (yrs.)	Progress To Date
<u>Engage community in public health policy and the research to develop public health policy</u>	Community Engagement	60%	2	3
<u>Identify public health priorities and the metrics to describe them based on data</u>	Community Engagement	40%	2	1
<u>Expand public health and public policy research among CTSA's by developing tools, mechanisms and funding</u>	Community Engagement with Informatics	20%	3 - >	1
<u>Expand CTSA training activities to include public health and policy;</u> - Curriculum development - Expanded Recruitment - Cross training between biomedical and	Education With Community Engagement	20%	1	2.5

<u>non-biomedical policy</u>				
<u>Partner CTSA investigators with policy planners and health care delivery systems</u>	Community Engagement	20%	1	2
<u>Disseminate information to public policy makers</u>	Communications with Community Engagement	Pure Follower	2 - >	1

Descriptive Statistics

The following represent the present state of the major goal areas with respect to the amount of progress thus far and their expected mean execution duration. Progress levels to date are to be expected at this early stage in the CTSA Consortium. Expected durations are within the framework of CTSA Consortium timelines. *In each case, those implementation steps having high priority strength (see above) should be used to guide committees toward accelerated execution.*

Main Goal and Subgoals	Duration Yrs. (Mean)	Duration Yrs. (Std. Dev.)	Base Progress (Mean)	Base Progress (Std. Dev.)
Enhancing national clinical and translational research capability				
<i>CQI Clinical Research Management System</i>	3.6	1.7	2.0	1.1
<i>Enhancing National Clinical Study Capability</i>	2.3	0.8	1.7	1.1
<i>National Phenotyping</i>	1.6	1.1	3.4	2.0
Enhancing the training and career development of clinical and translational scientists				
<i>Effective Innovative Training & Career Support</i>	2.1	1.0	1.8	1.0
Enhancing consortium-wide collaborations				
<i>National Resource Inventory</i>	0.8	0.4	1.2	0.4
<i>Data Sharing Network</i>	2.1	1.4	3.5	2.3
<i>Social Networking Initiative</i>	3.5	1.5	1.3	0.6
Enhancing the health of our communities and				

the nation				
<i>National Model for Community Engagement</i>	2.5	1.3	2.3	1.0
<i>Inform Public Health Policy Through Research</i>	1.8	0.8	1.8	0.9

Execution

In order to execute the strategic plan, the Steering Committee agreed upon the following next steps:

- Strategic Goal Committees will be created/assigned and will be responsible for the completion of each goal via coordination with appropriate Key Function Committees, Special Interest Groups and Working Groups. Three PIs, one of whom will be an Executive Committee member, will lead each Strategic Goal Committee. Strategic Goal Committee #2 will be the existing Education Committee and Strategic Goal Committee #4 will be the existing Community Engagement Committee. New Strategic Goal Committees will be formed for Strategic Goals #s 1 and 3.
- Strategic Goal Committee PIs will work with the Steering and Executive Committees in addition to content experts to devise a charge with deliverables for each of these areas, guided as needed by the implementation steps delineated in the strategic planning process.
- Consortium wide resources will be focused on the four key goals to ensure that the CTSA organization has identifiable objectives, milestones and outcomes.
- The existing committee structure will be systematically examined and reorganized so that it is optimized to support the strategic goals of the network while also providing important networking and synergizing functions to improve and support local CTSA operations.

In all cases, the priority strength of implementation steps (Results) should be considered as activity guides for the work of assigned committees.

Acknowledgements: The following Hoshin facilitators are warmly acknowledged for their effort in the creation of the strategic plan:

PI Facilitators: Gordon Bernard, Rebecca Jackson, Steven Reis, Eric Orwell and Julian Solway.

NCRR Facilitators: Andrea Sawczuk, Jody Sachs, Rosemary Filart, Anthony Hayward, Mary Purucker and Bernard Talbot.

Overall facilitation and report preparation provided by Scintellix, LLC using [Decide-S³](#)™ Analytics facilitation and decision support tools.

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Appendix

I. The Hoshin Strategic Planning Approach

The Hoshin Process

The Hoshin facilitation process is designed to support group strategic planning processes through the identification of a common goal followed by delineation and prioritization of the steps needed to achieve the goal. It is especially effective in disparate groups, as it is designed to maximize the sharing of ideas and active group participation.

The Hoshin Process is broken into multiple steps that are performed relatively rapidly (it is rare for the process to require more than 3.5 hours). These steps (and the approximate time required for their completion) are:

1. Mission creation (~45 min.)
2. Idea generation (~10 min.)
3. Idea reading (~10 min.)
4. Clustering of related ideas (~20 min.)
5. Naming of clusters as Group Ideas (~10 min.)
6. Break (~15 min.)
7. Comparison of Group Ideas to determine priority (~25 min.)
8. Assessment of progress to date (~10 min.)
9. *Reporting*

Materials needed to run the Hoshin process:

1. Pad of 3" x 5" Post-Its for each participant
2. Sharpie Fine Point black pen for each participant
3. Two easels with removable paper
4. A wall to which Post-Its can be affixed
5. One roll of masking tape

Group size: 8-20 person group size is ideal.

How to Facilitate the Process

1. Mission creation (~45 min.)

Ask your group to create a one or two sentence mission statement that illustrates a major five year goal of the organization. Using the Socratic Method, call on all members

present and generate ideas until a common conception is formed, write it on an easel and then iteratively improve it until the group is satisfied with it. Be cautious to prevent domination by one or more members and request input from quiet types in a balanced fashion.

2. Idea generation (~10 min.)

Ask all group members to silently write down ten steps (if group size is nearing twenty, ask for five steps from each person only) that must be completed in order to fulfill the mission. *Each step should be written on a separate Post-It note with a Sharpie pen so that they can be viewed easily later.*

3. Idea reading (~10 min.)

Gather all of the Post-It notes and without referring to whose ideas they are, read them all aloud and affix them randomly to the wall at reading height. *There will be many related ideas but do not attempt to sort them in any way.*

4. Clustering of related ideas (~20 min.)

Ask the group to all come forward and work together to sort the ideas into groups based upon their similarity. Encourage discussion and debate as to where the Post-Its should be assigned. When this step is completed, eight to ten groups of ideas are generally seen.

5. Naming of clusters as Group Ideas (~10 min.)

Based on observation during previous steps, ask two persons who are not highly acquainted with one another to assign a Group Idea heading for each cluster (using different pairs of people for each of the clusters and name them all simultaneously). The Group Idea heading should be very representative of the cluster of Post-Its that it describes. Have them make two copies of the Group Idea heading. One remains on the wall above the cluster it describes and the other is placed on an easel so that, together, all Group Idea headings form a circle.

Take a fifteen minute break here.

6. Comparison of Group Ideas to determine priority (~25 min.)

- Note: In The CTSA Strategy and Implementation Planning Process on October 6, this approach was modified and facilitators were asked to perform pairwise comparisons to determine the relative priority in time of one implementation step, compared to another. They were also asked to determine and estimate of the duration of the task -

With the entire group standing by the easel, the facilitator compares each Group Idea heading to every other Group Idea heading and asks if a relationship exists between

them (that is, do they depend upon one another at all). *If so, a line is drawn between them.* If not, no line is drawn. If a line is drawn, the facilitator then asks which Group Idea dominates or drives the other. Once this is identified, the facilitator adds a *one way* arrowhead (no two way arrowheads allowed) with the arrowhead pointing from the dominating idea to the submissive idea. This process is continued until all permutations of comparison between ideas have been completed. As there will be disagreements, simply settle all disputes with majority voting by a show of hands.

The following arrow counts are then made and written next to the Group Idea heading to which it pertains:

Idea relationship strength (R) = the number of arrows (in + out) between that Group Idea heading and all other Group Idea headings.

Dominance (D) = the number of outward arrows from the Group Idea heading

Submission (S) = the number of inward arrows toward the Group Idea heading

7. Assessment of progress to date (~10 min.)

The facilitator then asks the group with respect to each Group Idea heading how far along the organization is in the completion of that step. A one to ten scale is used, with an assignment of “one” meaning that essentially no progress has been made and an assignment of “ten” meaning that the step has been fully realized. This value is written as “P” adjacent to each Group Idea heading.

8. Reporting

Reporting is done after the fact but it is wise for the facilitator to list for the group the priority of Group Ideas based on their Dominance. The facilitator can then also divide D by P for each Group Idea to show how the priority of steps becomes realigned as a function of prior progress.

In the final report, the following are included:

- The mission statement
- Radar charts depicting (for all Group Ideas):
 - Relationship strength (R)
 - Idea dominance (D)
 - Idea submission (S)
 - Progress to date (P)
 - Normalized idea dominance (i.e., operational priority) (ND)
- Summary
- Appendix: All original ideas on Post-Its with their Group Idea headings.

Utility

The Group Idea headings and their quantitative parameters provide the skeleton of a strategic plan and the original ideas on Post-Its form the basis for tactical planning.

Some Important Issues

It is critical to retain for reporting:

1. The easel paper with the final mission statement
2. All original Post-Its in their categories, bound with their Group Idea Heading
3. The easel with the Group Idea headings in a circle *with the Group Idea heading masking-taped to the paper to prevent later confusion and misalignment during reporting.*

For questions, please contact:

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II. Post-It Data (Raw Implementation Concepts Contributed in Parallel by Participants)

Goal:

Enhancing national clinical and translational research capability

- CQI *Clinical Research Management System (former Goal 1)*

Establish standards and metrics [[Return to Document](#)]

- Publish a set of common standards for measuring institutional performance (speed?) in conducting Pt-oriented research
- Reward efficiency by ensuring that NIH ICs know where institutions stand on efficiency benchmarks (pharma, too)
- Look with ICs at internal processes required to implement research
- Engage CTSA institutions to collect standard metrics and permit transparency by disseminating data
- Use data to set national goal for IRB and contract timeline
- Re-evaluate measures
- Develop standard metrics across CTSAs to follow study initiation process and a central database for collecting metrics
- Establish metrics for IRBs that can be used across institutions
- Establish metrics for contracts that are/can be used across institutions
- Agreement on standardized metrics for contracts and IRB
- Metrics
- Obtain metrics across CTSAs for relevant outcomes (ex: time to IRB approval)
- Development of quality measures
- Measure time, cost, burden – IRB/contracts/ recruitment
- Share metrics for IRB and contracts to identify areas for improvements
- Develop standardized metrics
- Agreement to publicize institutional metrics
- Metrics transparency
- Develop metrics to monitor compliance and contractual approval process

- Identify items to measure: efficiency, quality, safety, speed, transparency
- Establish a national database of clinical trials
- Develop standards for data management to allow for interactions
- Develop a well coordinated system to track all start-up processes with one database (e.g. IRB→contract→packet registration)
- Develop model for databases to capture compliance and contractual review processes
- Inventory resources across CTSA to plan for multi-CTSA studies
- Establish common and reliable IT platforms for data management across all CTSA
- Create generic MTAs that will allow for interchange of IP's reagents between biotech/pharma and CTSA

Share best practices [\[Return to Document\]](#)

- Develop a catalog of best practices across institutions
- Develop "best practices" based on standardized metrics or benchmarks
- Establish a CTSA-wide protocol template
- Identify best practices within CTSA
- Engage IRBs & contact officer in following CQI and "lean" processes to improve efficiency. Encourage transparency in publishing run-around times.
- Establish national quality benchmarks for time to IRB approval, time to contract approval, % of planned enrollment achieved, and safety, and publish them annually
- Establish common review procedures, practices, and standards for review of clinical protocols from all CTSA
- Publish a catalog of CTSA institution performance, measured using a common rubric
- Establish guidelines for best practices of IRBs around protocol turnaround and participation in national studies
- Develop cross-CTSA standard contract language to decrease industry – institutional negotiation time
- Disseminate software that helps make IRB & contracting processes paperless
- Evaluate best practices and make changes that will speed up processes
- Establish best practices in patient enrollment processes, focus on programs or studies that successfully enrolled within proposed timeline
- Establish common procedures and practices for data management of all CTSA
- Set up repositories/information sharing for best practices (ex. study coordinator training and conduct)
- Standardized consent form language across institutions that are accepted
- Integrate all regulatory processes across partner institutions

Training and quality of workforce [\[Return to Document\]](#)

- Develop standardized training in regulatory issues for all staff conducting patient-oriented research
- Develop metrics to assess impact of compliance training on POR quality, efficiency and safety
- Develop "field guide" with individual requirements by CTSA. Then look at supplying systems on common areas.
- Establish core elements for educating IRBs about now issues in clinical and translational science
- Training of qualified/competent staff running CTSA research management offices
- Training
- Develop web-based national investigator and coordinator orientation and training programs
- Standardized education program for research associates and nursing staff to improve patient safety

Coordinate IRB processes across CTSA [\[Return to Document\]](#)

- Synchronization of scientific/IRB review
- IRB
- Develop national paperless IRB management system available to CTSA institutions
- Help local IRBs think through how they deal with multisite studies
- Establish a common consent document for all CTSA institutions
- Streamline IRB functions (electronic systems, standardized language and pathways)
- IRB reciprocity
- Create professional and appropriately-constituted IRBs that are able to review clinical protocols from investigators of all CTSA
- Integration or reciprocity of IRBs
- Develop trans-CTSA IRB for large clinical trials
- Work at national level with IRBs to address barriers

Improve contracting processes [\[Return to Document\]](#)

- Identify common barriers that exist in the process from protocol conception to IRB approval
- Develop a contracts source book
- Harmonize elements of contracts (content/review)
- Study workloads in contracting offices within CTSA institutions
- Define effective practices that bring the contract and IRB folks together to improve efficiency of protocol activation

- Contracts
- Develop principles to guide efficient contracting with industry
- Standardize contract language where possible
- Promote interactions between clinical investigators and IRBs around controversial issues, e.g. consent for DNA collection
- Establish a peer-to-peer master agreement among CTSA institutions
- Develop master agreements across CTSA consortium
- For contracts agree to set of metrics to track
- Establish quality improvement office to oversee clinical trials

Enhance patient recruitment and retention [\[Return to Document\]](#)

- Recruitment
- Identify barriers and mechanisms that affect subject enrollment
- Create participant recruitment cares that can be used by all CTSA
- Have a searchable national database of trials for potential trial participants
- Develop and disseminate standardized recruitment and enrollment practices
- Look at barriers to patient recruitment across research, include ICs
- Develop a system for indentifying potential clinical trials participants

Inform national policy on clinical research [\[Return to Document\]](#)

- Ensure outreach and dissemination of best practices/innovations to non-CTSA institutions
- Share, publish – to consortium, entire nation
- Open access to on-going clinical and translational studies within CTSA institution and across National Consortium
- Advise nation policy on research

- Enhancing National Clinical Study Capability (former Goal 4)

Create accessible catalog portal [\[Return to Document\]](#)

- Clearinghouse catalog of resources

Create operational standards [\[Return to Document\]](#)

- Systematically establish common systems and standards across networks
- Standard methodology and process for study coordinators so that they can effectively work across multiple sites
- Establish standardized policies and procedures for multi-site clinical research
- Standardization: databases, processes/procedures
- Identify top domain areas for data standardization and work with those stakeholders to achieve results in 5 years
- Best practice identification
- Definition agreement
- Partner with Cancer Institute to leverage tools and platforms for uniformity and information exchange (e.g. CA BIG, MediData)
- Get a national “opt out” for “subject” research
- Establish performance benchmarks
- Develop innovative methods to facilitate the process
- Develop methods of standardization
- Common policies for investigator qualifications
- Align technology
- Standardization across CTSA
- Implement standards for data acquisition, storage, interchange
- Standardization of research information such as imaging data, transcription
- Standardization between sites to include one common IRB, costs, etc.
- Assess current procedures for participating in clinical studies
- Set timeline for data standards
- Standardize informatics systems
- Require interoperable data standards
- Set up common training programs for networks – will be cheaper and help with standardization
- Continual assessment of performance benchmarks
- Work with bioinformatics committee to develop clinical trial/studies interface

Capacity to match investigators with networks and populations (connect) [\[Return to Document\]](#)

- Develop policies that support flexible assembly of CTSA partners to support research (i.e. develop many partial “networks of networks” depending on study)

- Develop supporting infrastructure
- test new electronic interfaces in terms of posting studies and accessing clinical studies

Recruitment and engagement of special populations [\[Return to Document\]](#)

- Establish coordinated recruitment strategies for clinical trials
- Develop methods of recruitment of
 - a) diverse populations
 - b) subgroups of populations
- Populations – assessment, identification , diversity
- Develop efficient recruitment
- Foster transition of children/youth trial participants→adult studies
- Create operational standards
- Data

Integrating education in clinical studies [\[Return to Document\]](#)

- Integrate CTSA scholars at CTSA sites into existing trials as training for trialists
- Meld education and research
- Need for a training program for CTSA staff involved in consortium network of network clinical studies
- Create method for leveraging CTSA-wide expertise for mentorship in study design
- Mechanism for study multi-site coordination
- Develop capacity to analyze multi-CTSA clinical research
- Create review board for proposed projects
- Create a network of the CRUs so that an individual protocol can be conducted at multiple-sites
- Establish central mechanism for development of novel ideas into multisite studies
- Multisite key
- Prioritize the clinical studies procedures that have been most effective
- Use the CTSA consortium as a network for studies of rare diseases for which an existing network does not exist
- Develop facile informatics communications among CTSA for those outside CTSA resources and institutional investigators
- Focus study on areas most generally found to be difficult by existing networks – two areas would be rare diseases or question related to underserved community
- Proactively eliminate redundancy
- Must work locally
- Be sure infrastructure locally makes easy (for the investigator) to follow; consortium best practice
- Develop a virtual “front door” to the resources of the CTSA
- Identify community/network concerns for investigation
- Function as “matchmakers” for C/T research projects
- Create “pilot” project to demonstrate multi-site collaborations

Mechanism for study of multi-site coordination [\[Return to Document\]](#)

- Sponsor forums on clinical trial ethics to gain visibility for role of CTSA
- Catalog resources available in the CTSA
- Each CTSA should ensure that information contained in the ICERN is accurate so that it is a living and useful tool
- Shared coordinating center
- Identify/list networks – within NIH, within CTSA sites, with partners AHRG/CDC/HRSA
- Sustainability direct resources leverage
- Enablers infrastructure linkage with other networks
- Provide additional funds for the informatics superstructure and for services to non-CTSA site investigators (may be from other ICs)
- Create a mechanism for the I/Cs to use the CTSA consortium as a one-stop shop for identifying sites for multi-site trials
- CTSA-wide method for funding multisite studies (IDC standards, etc)
- Identify cheaper, faster for whom?
- Create method for leveraging CTSA-wide expertise as mentors and integrating CTSA scholars as mentees for clinical research

- National Phenotyping (former Goal 6)

Establish governance [\[Return to Document\]](#)

- Establish user/operating policy
- Administrative requirements and governance

- Establish “baseline” specifics
- Survey users: what data do they currently acquire
- Identify existing phenotypic resources
- Develop preferred analytic methods for a group of diseases that are major health problems in the U.S.
- Develop standard operating procedures for analysis of parameters to be catalogued
- Develop methodology for building disease-related phenotype
- Link with research methods (genetics, trials, observational, etc.)
- Define how to update definitions of status of the phenotype as patient status changes (conversion from normal to abnormal)
- Develop procedures and practices that allow for specialized questions, i.e., the collection of certain phenotype parameters important for certain diseases, etc.
- Develop methods for consensus definitions
- Set up methods to define, test and refine disease and normalize phenotypes

Develop necessary regulatory compliance procedures [\[Return to Document\]](#)

- Devise means by which phenotypic parameters can be shared between CTSA's under current regulatory (e.g. HIPAA) constraints
- Data share policies
- Address informed consent issues that would allow subject data to be shared beyond single discrete study
- Standardized consent forms and protocol implementation documents across CTSA sites
- Agreement regarding access to phenotyping databanks

Develop methods, including analytic, databases, SOPs and informatics [\[Return to Document\]](#)

- Develop informatics methods to capture, analyze and report the data and to make it available publicly
- Create databases to coordinate the available standards of phenotypes
- Standardize databases to enter and store phenotype data
- Develop a relational database in which parameters can be listed and searched
- Develop database capabilities for entry, management and analysis of phenotyping information
- Develop tools to annotate existing data – images, genomes, microbiomes, proteomes, etc.
- Need informatics support to post standards/methods so they are widely accessible
- Define fields and appropriate values for all generic data items to be collected for all
- Digitized data entry
- Encourage collection of metadata along with data
- Incorporate baseline phenotypic informational (normal and disease-related) into framework database which then can be individualized for specific study

Develop, define, and implement standards (including healthy “normals”) [\[Return to Document\]](#)

- Develop list of parameters that should be catalogued
- Define “truth” re: presence of key disease states e.g. – when is diabetes present? lupus? breast cancer?
- Establish standards for phenotyping studies and analyses
- Develop standard criteria/definitions for all diseases or processes that are reasonably prevalent in the population
- Broad disease categories
- Establish standard dictionary for special disease conditions
- How can the CTSA set standards for data entry? (e.g. smoking – is it + cigarettes, +tobacco, no smoking, yes, smoking, etc.)
- Define and standardize behavioral phenotypes
- Define standard nomenclatures for phenotype definition
- Development of disease – specific parameter profiles
- Convene consensus panels of experts in a specific disease to develop standard criteria for that disease
- Define the phenotypic data elements that should be collected on all patients and research participants at CTSA sites
- Agree upon evaluation standards and procedures to allow for consistent data collection
- Define basic elements require to phenotype the normal population over time/age-specific
- Agreement regarding clinical and biochemical parameters defining healthy populations
- Common criteria for defining “normal” phenotype across all ages: infants, geriatrics
- Definitions and criteria for healthy subject cohorts of all ages, ethnicity and gender
- Establish age-appropriate elements for normal/healthy phenotype
- Systems for recruiting healthy subjects for phenotyping in different protocols
- Define demographic and laboratory analyses from healthy people across the age range
- Collect normative data across CTSA's for subjects enrolled as normal volunteers in clinical trials

Choose priority projects [\[Return to Document\]](#)

- Choose priority projects

- Encourage disease specific groups through pilot funding to develop more detailed phenotype descriptions and contribute these efforts to a national CTSA database
- Promote disease-focused phenotyping projects at smaller groups of CTSA sites dictated by interest/expertise
- Run a pilot study in a specific area
- Establish scope and use cases
- Decide upon high priority patient cohort areas for work on disease specific data collection items
- Develop collaborations between small groups of CTSA to demonstrate they can work together on a specific project focused on phenotyping

Leverage phenotypic annotation of bio-specimens [\[Return to Document\]](#)

- Develop standards to link phenotypic information to specimen identification and tracking across CTSA institutes
- Survey users: what variables should be characterized (phenotyped)
- Develop biorepository of serum samples and cells from normal individuals
- Establish standard protocols for basic collection of blood, body fluids, tissues

Secure acceptance and buy-in (education/ communication) [\[Return to Document\]](#)

- Develop standardized educational curriculum to inform investigators about phenotyping methodology and implications for genome-wide associated studies
- CTSA Institutes: buy in and participate
- Assess how ready individual investigators are to use agreed phenotypes
- To promote national research interactions, how can phenotype databases be promoted for broader use
- Agreement across CTSA of what the baseline data collection ought to be for every subject enrolled into a clinical trial
- Identify stakeholders

Establish collaborations with existing databases, including National Records for secondary use [\[Return to Document\]](#)

- How can clinical (e.g. hospital-based) records be tapped into for phenotype data on an ongoing basis?
- Standardization of clinical parameters included in medical records
- Implement collection of agreed upon data items into routine clinical care assessments
- Partner with other national efforts (e.g. NCI) to agree on CTSA-wide data platforms (e.g. CA Tissue) and make them uniformly available
- Identifying existing databases and standards that would be useful
- Identify other national groups with aligned missions and combine efforts (e.g. national efforts at defining “healthy normal”)
- Promote interactions with the pharmaceutical industry to facilitate pharmacogenomic studies
- Partner with NIST to develop standards and technologies with particular relevance to Clin/Translational Res.

Goal:

Enhancing the training and career development of clinical and translational scientists

- Effective Innovative Training & Career Support (former Goal 2)

Develop core competencies for clinical and translational investigators [\[Return to Document\]](#)

- Develop set of core competencies
- Define new “skills” that need to be developed
- Develop core “competencies” for graduates of translational training
- Develop competencies that stress what’s “new” about CTR
- Define competencies
- Standardized credentialing for clinical investigators
- Core training framework: Develop an overarching framework for describing the C/T disciplining and accompanying competencies (that can be regularly updated)
- Define core competencies for clinical & translational science
- Define “certification” criteria for clinical & translational investigators
- Rich interaction between other CTSA committees and the ETCD committee

Continually improve trainee and program success [\[Return to Document\]](#)

- Establish common conflict of interest policies
- Identify institutional (departmental) home, i.e. tenure granting department – within traditional structure

- Broad representation training/career development research areas across CTSA's
- Define how we can "retrain" established researchers into "translational science"
- Develop outcome measures relevant to "human health" (i.e., not just grants and pubs.)
- Measure self-efficacy
- Track outcomes
- Develop tracking system to measure long term & short term career outcomes
- Measure the efficiency of training in clinical/translational research
- Share outcomes
- Use evidence to adapt training program for new discipline
- Evidence-based understanding of what effectively promotes career development
- Restructure MD PhD training to focus on clinical & translational research
- Refine (new) approaches to interdisciplinary training
- Evidence based decisions

Ensure that institutions recognize clinical and translational investigation is a valuable enterprise with unique metrics & criteria for success and promotion [\[Return to Document\]](#)

- Identify benchmarks and timelines for Promotion Policies
- Identify reward gaps in migrating a career between basic & clinical research
- Develop national suggested criteria for academic promotion for translational/clinical research team members
- Develop program to educate deans/department directors about this new discipline
- Redefine promotion policies & requirements for clinical/translational investigators --- and team research

Develop policies and mechanisms for support for investigators across the spectrum of their career development and the range of clinical and translational research. [\[Return to Document\]](#)

- Funding for training programs
- Consistent NIH↔CTSA KL2 award policy
- Develop trans-institute funding mechanisms for transition to independence of trainees
- NIH policies for training grants that are consistent, that leverage resources, and that promote progressive career development
- New funding sources need to support Junior Investigators during training (KL2)
- Adequate funding for trainees once trained
- KL2 award - Flexibility
 - Leverage
 - Accountability
- Career Development Support: Develop recommended policies for NIH/other funders for a predictable, understandable (clear), competitive pathway for support of C/T investigators
- Business development effort to recruit sponsorships to training programs where gaps exist
- Loan repayment programs
- New first award grants for clinical investigators
- Fund training grants for the specific competences
- Coordinate with NIH ICS and career development program

To establish core curriculum that will address the needs of clinical and/or translational investigation [\[Return to Document\]](#)

- Common core curriculum for clinical investigators
- Focused but comprehensive curriculum
- Establish curricula that include business – public/private education and training
- Identify agreements needed to share curriculum, programs
- Standardize and structure mechanisms for multi-institutional research
- Animal/Human subjects/ethical conduct – Develop agreement on standards for training on ethical conduct of research and accompanying tools and tasks
- Develop team-building and organizational development curricula germane to C/T research
- Collaboration with educational professionals
- Develop web-based common tools for translational research available to investigators

Develop effective training and reward mechanisms for mentors [\[Return to Document\]](#)

- Mentor rewards
- Mechanism of funding support for mentor's time & effort devoted to mentees
- Training/incentives for mentors
- Formalize training of mentors and their responsibilities
- Develop training programs for mentors
- Dedicated mentors programs
- Shared best practices in mentoring

- Mentor training
- Develop common mentoring practices
- Develop a framework and associated tools for identifying, training, incentivizing and supporting effective research mentoring

Develop, promote team building approach to research [\[Return to Document\]](#)

- Develop and test novel ways of engaging non-clinicians in team science
- Develop institutional incentives for non-PI team members
- Create (?require?) team structures (basic-clinical, etc.) as part of training process
- Train non –clinicians in the basics of C/T research
- Training structure should promote team based research management skills

To develop collaborative approaches regarding external partnership [\[Return to Document\]](#)

- Develop collaborative approaches requiring external partners
- Develop and promote a team building approach to research

To establish a common education platform of interdisciplinary science to instruct scientists about major problems of human health [\[Return to Document\]](#)

- Standardized core curriculum
- Develop very basic core curriculum
- Aggregate existing curriculum across the consortium
- Define core curriculum
 - SHARED BEST CURRICULA
 - FOR BEST COMPETENCIES
 - FOR PROGRASSIVE, INDIVIDUALIZED CAREER DEVELOPMENT
 - FOR TEAM SCIENCE
- Develop common core curriculum
- Common MS & PhD education curriculum
- Common core curriculum
- Interdisciplinary training programs
- Identify effective processes (pedagogy) for education & training
- National “boot camps” for 2 – 4 weeks of intensive training

Recruitment; to develop marketing strategies to attract outstanding trainees to clinical and translational research [\[Return to Document\]](#)

- Identify reasons that CTR is a good career choice
- Recruit diverse trainees
- Coordinating and leveraging existing training programs
- Develop a set of strategies that encompass best practices (both nationally and locally) for recruiting potential investigators across the developmental spectrum
- Early integration of research project with curriculum to optimize competitiveness for research/indie career development grants

Goal:

Enhancing consortium-wide collaborations

- National Resource Inventory (former Goal 3)

Develop the project scope and process and ensure the project is adequately resourced [\[Return to Document\]](#)

- Support and develop new ideas and/or process
- Agree on scope and process
- Needs assessment
- Determine whether system will be federated or centralized
- Define and develop the catalogue
- Identify home to develop inventory
- Look at other similar efforts, e.g. CaBIG, GWAS data sharing to avoid reinventing wheels
- CTSA community identifies informatics support

Rules of engagement and operationalization [\[Return to Document\]](#)

- Once defined, ensure adequately resourced (or reduce scope)
- Update the catalogue at frequent intervals to keep it current
- Define expectations of the individual resources (if my core is listed, what's expected)
- Couple the resource database to a research database, to facilitate establishment of new partnerships
- Create rules of engagement for use of resource
 - Access
 - Payment
 - Credit/authorship
 - IP
- Survey CTSA members and beyond to identify specific resource needs and solicit novel concepts to use existing resources
- Prioritize resources for inclusion based on "users" (stakeholders) demand/needs
- Identify operational component responsible for establishing, updating, and quality control of the inventory, and provide adequate resourcing and staffing to this component
- Implement collaboration tools and KB intelligence
- Facilitate the users of the catalogue – national – local level
- Catalog: make it interactive to link to resource easily
- Interaction of CTSA sites to establish new collaboration inter-site, intra-consortium
- Define outside partners who can help fund this resource aggregation
- Develop a process to leverage existing core resources
- Define the types of resources to be included in the catalogue
- Outline process for each institution in submitting resources
- Define goals of use – how would we identify success
- Create priority systems for access to inventory and resources
- Have standard or common tools, e.g. consent forms for biobank specimens
- Identify processes and technology for facilitating licensing transfer of IP materials and/or securing of expertise
- Develop mechanism to review requests
- Pilot phase (small no. of centers)
- Define mechanisms for distributing information about resources and assign responsibility for sustaining the mechanisms
- Define mechanisms for gaining access to resources

Define resources to be listed and develop a catalog that is sustainable and accurate [\[Return to Document\]](#)

- Sustain catalogue
- Define resource requirements
- Matchmaking resources developers
- Define categories of resources:
 - Human
 - Instruments
 - Software
 - Etc
- Committee develops major categories of resources such as high tech equipment, etc.
- Define resources of highest priority that would benefit greatest # of investigators by sharing
- Establish a CTSA task force on clinical/translational research resource needs – work in concert with NCRR to create priority list
- Develop a needs assessment process to identify needed resources
- Develop standardized nomenclature for types and content of resources to use in compiling and searching the inventory
- Harmonize unique list
- CTSA community agrees on ontology – or nomenclature – for resources
- Define process for acquiring info re: available resources
- Develop and process and facilitate access to core resources
- Develop template to collect information
- Design shared resource entry website with searchable database format
- Create a template for entry into the catalogue to ensure consistency
- Creating catalog matrix
- By 2010, create a catalogue of specialized resources available to a broad group of investigators
- Create good IT interface for access to inventory
- Create templates for inputting resources uniformly
- Develop a common procedure for access or contracting resources
- Develop an IT mechanism to facilitate information exchange between institutions and other agencies interested in clinical and translational research
- Create informatics tool to support the established inventory/catalogue

- Develop web site to share results
- Create active queryable/updatable web-portal
- A searchable database platform is developed/purchased/chosen
- Catalogue is made available at some NIH CTSA site
- Design system – sustainable – works with other systems
- Develop software/visualization tools to effectively mine/search a resource database
- Develop data model for capturing information about resource and how to access it (agreements, etc.)
- Institution identifies resources
- Engage the local investigators to provide resources for the catalogue
- Survey CTSA sites
- Each CTSA lists all available resources by major category
- Do session to identify resources that if organized or developed at national level would have large positive impact on science
- Each CTSA site identifies valued, specialized assets
- Develop an inventory that includes patient populations, available investigators, and other core resources needed for clinical and translational research
- Work with phenotyping, data-sharing & career-support groups
- Institution identifies point of contact
- Determine who keeps catalogue up
- Survey quarterly of resources that are available to the network

CTSA Consortium will mobilize their institutions to participate, organize and facilitate resource sharing [\[Return to Document\]](#)

- Develop appropriate incentives for institutions to provide complete and accurate information to the inventory – e.g. terms include in terms and conditions of NIH grants
- Have CTSA consortium send message to all CTSA institutions that sharing of resources nationally is high priority and develop systems for sharing
- Clearly define who the stakeholders of this tool are (and how they measure success)

Develop 1) an evaluation methodology that documents the impact of the catalog and the development of new collaborations 2) periodic gap analysis, 3) and assessment plan for existing and new needs [\[Return to Document\]](#)

- Demonstrate that catalogue items are being used by investigators
- New collaborations based on specialized resources are measured (publications, grants) AND incentivized (added funding)
- First phase review and re-plan
- Evaluate process to date
- Create way to list specialized expertise within customary resources such as special statistical or informatics capacity within statistics or informatics components
- Determine metrics of success for use
- Define process for measuring value of this capability

- Data Sharing Network Data Sharing Network (former Goal 5)

Governance [\[Return to Document\]](#)

- Update mechanisms
- Federated vs. centralized approach
- Identify critical information to share
- Identify specific projects and scope of work that will test ability to achieve major goals
- Identify additional sources of funding to facilitate development of selected uniform systems across CTSA
- Incorporate appropriate CTSA working groups
- Prioritize needs for data sharing – at local and national levels
- CTSA agree that creating these mechanisms are a priority for their CIOs
- Identify “low-hanging fruit” – what can be accomplished in a 2-5 year time frame
- Define, in broad terms, the data sets we wish to share

What’s Out there? (Non-CTSA) [\[Return to Document\]](#)

- CA BIG has done good work on data standards sharing – could be used
- Link existent data warehouses and systems
- Survey other efforts in government and industry to do similar data-sharing work
- Identify other data sharing resources/mechanisms to help develop links among them
- Identify existing data systems and catalogue strengths and weaknesses

CTSA Inventory [\[Return to Document\]](#)

- Support the creation of a clearinghouse for information about CTSA infrastructure and research activities
- Build inventory of richly annotated populations to which CTSA have automated access
- Use the ibrz infrastructure to link patient databases among CTSA
- Create data and investigator registry
- Build national catalogue of CTSA investigators by domain of work
- Identify existing resources and tools that can be leveraged to support this mission
- Create a national database of translational research infrastructure
- Share tools for access to existent data across the consortium
- Inventory of efforts, databases
- Make available clinical trial data
- Create linked non-verbal data repositories – images, genomes, proteomes, microbiomes, other?
- Gather data
- Support the creation of inventories that are easily accessible by individual CTSA and prospective partners
- Identify types of data to be shared

Process Improvement [\[Return to Document\]](#)

- Facilitate research that creates best practices in charge back implementation
- Define what research, educational, safety goals can be achieved through sharing that cannot be achieved with current disconnected systems and decide to achieve 1 or 2 of them

Create Data Standards [\[Return to Document\]](#)

- Help standardize the posting of results in clinical trials. Gov
- Standardize methods for entry of data into the individual data sets
- Develop guidelines/recommendations for possible formats for data structure
- Support the development of specifications for data warehousing
- Define common vocabularies
- Harness standards (use what's there)
- Support the development of specifications for data sharing across the consortium
- Agree upon a common ontology

Data-Use Policy [\[Return to Document\]](#)

- Policy for sharing agreement required for CTSA sharing
- Develop rules for data sharing that ensures acknowledging efforts of those who contribute data
- Identify any regulatory or policy barriers and determine how to overcome
- Create common consent form for patient data entry that honors patient privacy and is approved by all IRBs
- Develop guidelines that help de-identify (make HIPAA-compliant) clinical data
- Harmonize HIPAA process to enable data-sharing
- Write data policies

Communication/ Social Networking [\[Return to Document\]](#)

- Build an easy way to allow investigators to communicate, i.e. chat rooms
- Implement a CTSA facebook site
- Assemble juicy accounts of translation acceleration from T1 to T3 (bench to trench)
- Build "classified ads" website for CTSA investigators searching for "scarce resources" (cases, populations, experts)
- Support the development of specifications for social networking across the consortium
- Build a facebook-like application to help C/T investigators find each other
- Create portals and data marts useful across centers (e.g. diabetes, AIDS, CF, cancers, etc.)
- Create a website that provides guidelines and links to other data share-related websites
- Link all CTSA websites
- Use social networking resources
- Clarify specific expected long term achievements attributable to local, regional, or national data management systems

Develop Tools [\[Return to Document\]](#)

- Create informatics resources needed
- Create realtime clinical feedback tool based on evidence-based medicine that would serve primary care practices and improve patient safety
- Data translation engines
- Search engine tool
- Build national tracking system for CTSA trainees-in training and into their careers
- Reports
- Apply informatics technology to allow access to specific data sets

- Social Networking Initiative (former Goal 8)

Feasibility & Needs Assessment – Scope Definition [\[Return to Document\]](#)

- Define info to be shared
- Define universe of investigators
- Develop a mechanism to describe research interests of investigators
- Define scope
- Clearly define scope
- Identify social networking needs for consortium
- What are the components necessary for a social networking initiative
- Define stakeholders & target audience
- Define potential applications
- Needs assessment and definition of priorities
- Identify the users
- Responsibilities of each institution defined
- Open up to non-CTSA communities with related interests
- Derive technical & operational requirements based on business objectives
- Prioritize social networks (btw scientists, scientist-mentor, industry, public-private, etc)
- If one central platform, how will it be managed what resources will be needed
- Define visualization fields to view
- Ensure project is resourced **adequately**
- Assess feasibility of federating existing research networks within and outside CTSA
- Evaluate **what** the CTSA could feasibly develop/create toward the goal of **connecting people**. If not significant, lets not spread ourselves so thin
- Research the feasibility of a federated social networking tool
- Assessment of feasibility of CTSA having achievable goals within our time frame

Evaluation of existing approaches, tools, databases [\[Return to Document\]](#)

- Database
- Build, buy, or collect tools – compare and choose one for the national long-term effort
- Identify scalable applications for active collaborative, e.g. – blogs, chat rooms, list servs., discussion groups
- Identify existing tools and conduct an analysis of the strengths and weaknesses of each and share this information among all CTSA
- Assess current social networking tools – will they work for CTSA
- Perform an evaluation of various social networking tools and identify a tool to meet consortium needs
- Construct a platform where the “connected” investigators can meet, chat, work
- Define datasets for inclusion
- Identify best practices and gaps among existing mechanisms for connecting individuals toward a defined purpose (e.g. a research goal, find a mentor)
- Identify and summarize best practices for using social networking tools and share this information among all CTSA
- Evaluate or have consultants evaluate existing tools – strengths and weaknesses
- Catalogue and assess all existing tools
- What is state of art for tools
- Shouldn’t “social networking” be part of the “National Resource Inventory” mission
- Develop an assessment of existing academic social network tools to be shared throughout the CTSA network
- Identify needed database and software tools/functionalities (including visualization)
- Look at past efforts to learn and improve models
- Find ways to use network tool on local, regional, national & international scale
- Define databases you want for you tool
- Identify existing social networking capabilities within CTSA – including collaboration tools
- What databases
- Define the social networks to be included
- Find ways to connect linking systems
- Define information fields for collection in system

Policies [\[Return to Document\]](#)

- Create consortium governance structure to lead social networking development
- How will programs interact to promote social networking
- Governance
- Create policies regarding “rules of engagement”
- Privacy policy

- If these tools could serve non-CTSA groups (such as industry, community, business...) – see whether these outside groups would be interested in partnering in the development and costs
- Develop privacy policy
- What are the tools necessary to make a social networking initiative
- Develop rules of engagement for use of network system

Standards [\[Return to Document\]](#)

- Standards creation regarding “social networking” data
- Set standards across network for social networking activities
- Publish a simple national data standard for a social networking environment
- Standards
- Evaluate whether common standards could be adopted to link social networking data from different CTSA
- Find unique identifiers in existing national databases that can enable connections of data
- Create standards for social networking
- Develop a critical mass of institutions who commit to a shared standard
- Get agreement from all CTSA to a common platform or interoperative platforms
- Develop list of characteristics of each investigator, i.e. name, pub. med. data – MESH terms, contact information

Create & Implement New Tools [\[Return to Document\]](#)

- Tools development for measuring effectiveness
- Monitor/evaluate connection made; assess outcomes
- Invest in the development or adoption of tools for supporting web-based collaborative work
- Develop an IT mechanism to link investigators and trainees at multiple sites
- Decide on approach for implementing capability
- Create ancillary tools around social networking which help drive individual participation
- Goal of “push” collaboration rather than “pull”
- Develop a mechanism to provide investigators from multiple sites to conduct clinical trials
- Build/obtain expertise mining tool
- Develop an IT mechanism to link trainees to investigators at multiple sites

Develop Metrics of Success and Evaluate [\[Return to Document\]](#)

- Identify metrics of success for social networking tools (short-term & long-term)
- How to judge success
- Develop a strategic plan for the IT part of social networking
- Assess impact
- Identify top 3 areas where social networking can be helpful (e.g. mentoring)
- Keep initiative current – re-evaluate
- Develop a consortium-wide agreement about best practices and tools for academic social networking
- Clearly articulate business objectives for social networks – including scope of networking
- Interest in social networking analysis capabilities
- Develop method to thank use of the social networking infrastructure, i.e. grants, papers
- What is evidence this approach is useful
- Pick one or more areas for “demonstration projects” – scientific (e.g. obesity) or administrative (e.g. training)
- Pilot phase with early adopters

Federation of Tools [\[Return to Document\]](#)

- Connect to existing social networking tools
- Link local social networks to national social networks
- Collaboration tools
- Build system prototype

Adoption [\[Return to Document\]](#)

- Think through low effort/efficient ways to enter data in scientist’s sites to permit sharing
- Educate potential users
- Align on one or more pilot projects to demonstrate value (early)
- Identify and publicize several examples of success stories from the use of social networking tools
- Get investigators and other possible collaborators to use the tool

Goal:

Enhancing the health of our communities and the nation

- National Model for Community Engagement (former Goal 7)

Achieve and measure community outcomes that matter [\[Return to Document\]](#)

- Measure outcomes and communicate successes to stakeholders, and incorporate finding into subsequent studies
- Adopt the elimination of health disparities as a strategic goal
- Put in standard health outcome measurement systems in CTSA communities
- Monitoring health outcomes on community level
- Develop precise, real-time, accessible measures of health in communities to evaluate program effectiveness
- Define desired outcomes of community based research
- Find or develop a capacity to track research – relevant “health facts” in your geographic community
- Develop standards for including the “end users” of the research into development of the study
- Develop clear metrics that define success in the various aspects of community engagement
- On an annual basis evaluate the utility of current medical research for various stakeholders

Identify and disseminate, implement best practices within disparate communities [\[Return to Document\]](#)

- Share/disseminate best practices – across CTSA, other academic health centers, other agencies and foundations
- Identify best practices in community and practice engagement
- Create a system whereby academic stakeholders can be linked with community stakeholders based on a shared vision or interest
- Develop and test innovative methods to engage the community
- Inventory and catalog existing research networks
- Provide meaningful incentives to community stakeholders
- Create a national website to facilitate community based research
- Develop templates for community based participatory research protocols
- Collect best practices for engaging community-based practices in clinical research
- Assess current approaches being utilized to develop partnerships between academia and the community
- Examine “found pilots” (where this is already working) for partnerships that effectively disseminate science
- Develop effective best practices for implementation of evidence-based practice in community settings
- Develop effective IRB and regulatory strategies for community research
- Define “effective partnerships”
- Develop a process to match academic partner with the community stakeholder
- Improve on IRB and review process for community research
- Promote concept of evidence based practice among physicians and other practicing health professionals
- Determine the qualities of an effective partnership
- Hold annual meeting to share best practices
- Develop system to prioritize and implement local or national CE project
- Establish a national health disparities consortium
- Evaluate success of different methods for engaging community stakeholders
- Information systems to support recruitment and retention of research participants
- Develop visualization maps of current and possible communities that interact with multiple CTSA
- Roles of individual (patient) oriented vs. public health (public practices) research in CTSA
- Establish effective multi-lateral communication among stakeholders
- Include community stakeholders in research design and implementation
- Separate real community –oriented “stakeholders” from those self-interested
- Hire and train, retain and promote community research implementation staff from community members
- Identifying the major barriers that inhibit public-private partnerships

Health and science educational partnerships to earn public trust [\[Return to Document\]](#)

- Improve health literacy
- Improve science literacy
- K-12 school teacher professional development
- Educate community about research and research process
- Health and research education messages for community partners
- Engage in “science” of science education
- Increase and ensure the public trust in research
- Educate the public about the nature of clinical and translational research
- Forums for community input

- Develop a capacity for reporting/disseminating research findings and research interest in plain, low-literacy language

Form and/or facilitate practice based research networks [\[Return to Document\]](#)

- Find, form, or facilitate community-based health coalitions interested in engaging with your CTSA
- Establish relationships with existing networks to partner for T2 translation efforts
CDC, ANRQ, HMO, RNs, HRSA, NIH Institutes and so on
- Facilitate participation of community-based practitioners in clinical research
- Identify and catalog existing community based research networks, including those funded by federal agencies
- Form or mobilize practice-based research networks
- Exclude specialty based hospital research networks
- Link practice based research networks across sites
- Link (network) community based research programs across CTSA sites
- Education and training of community physicians
- Identify and recruit practitioners willing to engage in practice-based research

Advocate for community translational research [\[Return to Document\]](#)

- Advocate for increased funding for T2 research
- T1↔Bidirectional↔T2
- Create incentives that recognize academic researchers performing “applied” or “community-based” research
- Increase funding for community based research
- Develop new approaches to fund community based research
- Create a report card for societal resources (?government) funding of research targeting each phase of translation
- Identify partners within other national/federal agencies, i.e. CDC, AHRQ, HRSA, UA, Indian Health Services
- Identify target groups that need to be involved in community engagement
- Advocate for policy reform at a local, state, and national level that will provide incentives for practitioners to implement best practices
- To third party payers & providers & University
- Economic models

Develop and fund competency curricula and training programs in community engaged research [\[Return to Document\]](#)

- Educate researchers about community based research
- Educate healthcare providers in a curriculum that facilitates their participation in safe and effective studies
- Increase quality and quantity of T2 research within CTSA
- Create a specific K12 program for community based research
- Develop national curriculum for community engagement
- Define core competencies in community based participatory research
- Develop training programs in community/practice engagement for IRBs, APT committees
- Train investigators to understand what “partnership” means, and promote real partnerships
- Define community based research hypothesis (?)
- Develop core competencies for research trainings in the areas of community engagement and practice-based research
- Develop & share core CTSA competencies in community and practice engagement with other CTSA
- Develop ed. competencies for community engaged research for training
- Train investigators at all levels in cultural and community competencies for conducting community research
- Culturally competent care

- Inform Public Health Policy Through Research (former Goal 9: Catalyze Improved Health Through Research)

Engage community in public health policy and the research to develop public health policy [\[Return to Document\]](#)

- Create a public health “messaging” marketing tool for the CTSA consortium
- Engage community in selection of research policy issues for CTSA focus
- Reach out to the lay public
- Develop models for best practices in public health research
- Hire a good lobbyist
- Give awards for CTSA contributions to public health policy
- Hold prioritization meetings on issues of public health importance
- Invite decision makers to CTSA sponsored events that highlight relevant research to particular public health topics
- Engage diverse community in research designed to develop health care policies

Identify public health priorities and the metrics to describe them based on data [\[Return to Document\]](#)

- Ensure that we can accurately measure public health in order to track our impact
- Metrics of success: how will success of this theme be evaluated

- Improve methods to measure public health impact
- Identify how to collect the data we need to begin our process
- Establish benchmarks for achievable health outcomes in each CTSA-served community
- Identify researchable issues that are critical for public health and incentivize their investigation
- Assess community (public) health issues: morbidity/disability, mortality, cost, productivity
- Develop some pilot projects aimed at reducing infant mortality – for example pertussis vaccination of pregnant women
- Identify one or two high-impact areas of public policy study that a CTSA consortium would inform
- Target specific policy for change based upon learned research data
- Create RFAs that address health 2010 disparities
- Identify top priority or focus areas that will greatly improve public health
- Agree on a process for prioritizing local and regional public health problems and guide research dollars to them
- Set priorities for current research needs that could drive policy
- Engage community in prioritize public health issues

Expand public health and public policy research among CTSA by developing tools, mechanisms and funding [\[Return to Document\]](#)

- Create informatics tools to manage the process
- Create a database of scientific studies already conducted that could inform public policy
- Expand funding support for T3 studies
- Create a system that allows for integration of research dive initiatives into regular patient care ala “ready to eat”
- Conduct outcomes studies to assess policy implementation results
- Develop methods to disseminate research findings to every day medical practice
- Make clinical and translational research part of day to day activities
- Develop incentives to health care delivery systems that incorporate T2 into their practices
- Vehicles of implementation: white papers, linkage of institutional economies, policy, public health programs
- Emphasize methods development aimed at improving acceptance of medical advances
- Complete regional health needs assessments or partner with other organizations doing this
- Improve informed consent/human subject protection for community health research

Expand CTSA training activities to include public health and policy:

- Curriculum development

- Expanded Recruitment

- Cross training between biomedical and non-biomedical policy [\[Return to Document\]](#)

- Expand CTSA training activities to include public health and policy:
 - Recruitment/training
 - Curriculum development
 - Cross-training (CT & policy)
- Develop cadre of interdisciplinary health care policy investigators/collaborators with CTSA
- Develop educational programs for policy makers
- Incorporate education in public policy area in our CTR trainee curriculum
- Include public health/public policy in our CTSA training programs
- Education
 - Policy education in clinical research training – why evidence based discoveries not implemented in policy
 - Interface education
- Develop effective training of CTSA health care professionals in development/implementation of health care policy
- Include health policy trainees in CTSA training programs
- Incorporate trainees in health policy into CTSA educational programs
- Recruit, train and engage scholars of policy, economics and public health within CTSA
- Create educational programs that are targeted at proven strategies to improve public health
- Utilize novel outreach methods to inform and educate the public about important health prevention methods

Partner CTSA investigators with policy planners and health care delivery systems [\[Return to Document\]](#)

- Incorporate non-biomedical expertise (law, business, economics) into the CTSA resource base
- Identify and develop collaborations with other stakeholders in quality of care research and implementation – IOM, IHI
- Coordinate efforts at each CTSA institution with their own health policy efforts, if applicable
- Unify health care funding and health care delivery
- Get CTSA researchers more engaged with activities in schools of public health
- Identify partners that generate data about improving the health of our citizens (CDC, etc.)
- Create opportunities for collaborative CTSA
- Create interaction with CTSA and public health departments in cities and within institutions
- Engage diverse communities in implementing existing health care policies
- Create partnerships with state and local public health agencies
- Lobby NIH to bring other federal agencies to table to fund unmet research needs in this arena within CTSA framework

- Develop linkages with initiatives to tracking public health impact – e.g. ICD 11, RHIOs, governmental surveys/pharmacovigilance, databases, e.g. census
- Create partnerships with other federal agencies
- Include community members in the development of new knowledge surrounding health policy questions
- Engage public health agencies in CTSA programming
- Partner with groups outside of CTSA to target needed policy changes
- Interface with public health organizations :
 - Schools of public health
 - Local and state health agencies
 - CDC
 - HRSA, others
- Create partnerships with payers ((insurance cos.) and purchasers (employers, Medicaid, Medicare)
- Build liaisons through shared visits between policy makers and scientists
- Create and sustain interface between CTSA and public health organizations

Disseminate information to public policy makers [\[Return to Document\]](#)

- Train CTSA trainees and faculty in government relations
- Identify method for conveying data to policy decision-makers
- Cultivate position as advisory board and establish CTSA as resource for external policy makers
- Develop curricula for state and federal policy makers and their staff that identify best practices in quality of care research and quality of care implementation

III. Hoshin Image Data

The following images depict the actual comparisons for temporal priority that were carried out by each Hoshin facilitation group with respect to the nine original goals. They can be enlarged manually, as needed.



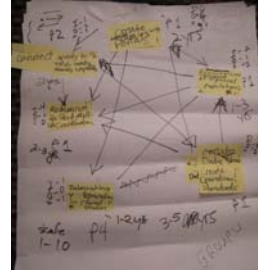
Goal 1



Goal 2



Goal 3



Goal 4



Goal 5



Goal 6



Goal 7



Goal 8



Goal 9