

NCATS CTSA Program Data Governance for the Common Metrics (CM) Initiative

The purpose of this document is to describe the:

1. Background and Purpose
2. Roles and Responsibilities of Participating Groups
3. Use and Management of Data Generated

1. Background and Purpose

The Institute of Medicine report on the CTSA Program at NIH (2013) recommended that NCATS formalize and standardize its evaluation processes for individual CTSA Program hubs and the CTSA Program Consortium. In response to this recommendation, NCATS embarked on a collaborative process with the CTSA Program hubs to develop the CM Initiative. Subsequently, the NIH research strategic plan for Fiscal Years 2016-2020 was released with a primary objective to excel as a federal science agency by managing for results. Thus, the CM Initiative is a high priority for the NCATS CTSA Program and aligns with the NIH Strategic Plan.

The CM Initiative is guided by the Results-Based Accountability™ principles which are described in *Trying Hard is Not Good Enough: How to Produce Measurable Improvements for Customers and Communities*, Mark Friedman (2005). (See <http://raguide.org/>)

To realize the IOM recommendation, the CTSA Program funding opportunity announcements indicated that CM would be developed across the CTSA Program (PAR-14-009, for May 2015 Council and beyond). Subsequently in the re-issue of the funding opportunity announcement (PAR-15-304), applicants were scored on their use of CM in the management of hub and network activities.

The vision for the NCATS CM Initiative is to use specific CM to demonstrate and improve the impact of the CTSA Program.

The CM Initiative is guided by the following principles:

1. CM will:
 - Be useful to – and used by – the CTSA Principal Investigators (PIs) and NCATS staff;
 - Foster continuous quality improvement by using metric data collected to support the strategic management of the activity; and
 - Facilitate collaboration and shared accountability for improving and maximizing the impact of the CTSA Program.
2. The CM Initiative is developed and implemented in collaboration with NCATS staff, the PIs and their CM teams, and the CTSA Program Evaluators.
3. Whenever possible, the development and implementation of any metric will strive to build on and leverage existing or prior metrics, data collection methods and processes that exist within the community or at the hubs. To maximize interpretability, effectiveness and utility, explanations of CM data should, where appropriate, be integrated with CTSA Program hub evaluation data.
4. Common Metric data will not be used by NCATS to make funding decisions or to rank the performance of one identified hub against any other.
5. Common Metric data will not be used by CTSA Program hubs to support public representations of performance compared to other hubs.

6. Aggregate data from across the hubs will be used to demonstrate the impact of the CTSA Program to stakeholders. Any publicly available visualizations of aggregated CM will not provide the identification of any individual hub.
7. The sharing of common metric deidentified and aggregated data, with the relevant context of the data collected, will stimulate a learning environment within the CTSA Program and beyond.

The goals for the CM Initiative are to:

1. Develop and implement specific metrics across the CTSA Program using a collaborative approach that includes CTSA Program hub investigators, evaluators, administrators, coordinators, NCATS staff, and other stakeholders.
2. Harmonize specific metrics data across the CTSA Program hubs to describe the impact of the CTSA Program locally and nationally.
3. Use CTSA Program hub evaluation data to better understand the patterns in CM data locally and to provide a more locally-relevant “Story Behind the Curve” for specific metrics.
4. Use data from specific metrics to strategically manage activities at the hub and across the CTSA Program.
5. Implement a common strategic-management framework to enhance the development of best practices for the CTSA Program Consortium and to disseminate these practices to the larger biomedical research enterprise.

2. Roles and Responsibilities of Participating Groups in the CM Initiative:

2.1. CTSA Program hubs:

- Various Program hub members actively participate in the development, testing, implementation, dissemination and reporting of CM. (See the CM Implementation Overview in Appendix A).
- The CTSA Program award is a cooperative agreement that involves substantial NIH programmatic involvement with the awardee during the performance of the activities. Consequently, the hub PI(s), and their CM team, are expected to discuss hub specific metrics during standard hub collaborative discussions with their NCATS Program Officer. To facilitate this discussion, the hub may wish to provide hub data and the story behind the data via a live webinar and/or a PDF print-out.
- Participation in the CTSA Program CM Initiative is an expectation for hubs across the consortium. Currently all CM are collected during the calendar year: January 1 – December 31. In addition, all CM data collection, entry into Scorecard (or other selected web-based platform), and the development of Turn-the-Curve plans are due August 31st of the following calendar year (this date is subject to change). During the time that data are collected, reported and Turn-the-Curve plans are developed, CTSA Program hubs may be in one or more of the following categories: 1) an active project period, 2) a no cost extension (NCE), or 3) not receiving any NCATS funding (and not in a NCE).

Hub status during a funding period will impact the level of participation in the CTSA Program CM Initiative as follows:

1. CTSA Program hubs that are in an active project period (defined as hubs that have an active UL1, linked KL2, and optional TL1 awards):

- It is **expected** that the hub will participate in data collection, enter data into its Scorecard (or other hub-specific section of the web-based platform), use as appropriate local hub evaluation data to better understand the factors affecting the metric, strategically manage CM data and the activities that CMs measure at their hub, and participate in calls with their Program Officer to discuss their strategic management plans.
 - It is **expected** that the hub will participate in CTSA Program activities related to any new CM.
2. CTSA Program hubs in a No Cost Extension (NCE) (defined as hubs that have extended their final budget period of a previously approved project period one time for a period of up to 12 months, without additional NIH funds):
- As no additional funds are provided during a NCE, a hub is **encouraged, but not expected** to continue to participate in data collection, enter data into their Scorecard (or other hub-specific section of the web-based platform), use as appropriate local hub evaluation data to better understand the factors affecting the metric, strategically manage CM data and the activities that CMs measure at their hub, and participate in calls with their Program Officer to discuss their strategic management plans. Any data collected voluntarily will be included in the CTSA Program aggregated dataset for that calendar year.
 - A hub in a NCE could **voluntarily participate but not be expected** to participate in any activities related to existing or new CM. Data collected voluntarily from hubs in a NCE will be included in the CTSA Program aggregated dataset for that calendar year.
 - A hub whose status changes from active to a NCE during a calendar year would be considered to be in a NCE for the purposes of participating in the CM Initiative.
3. CTSA Program hubs that were once funded but that no longer receive funding and that are not in a NCE:
- Hubs that are neither receiving NCATS funding nor are in a NCE are **not expected** to continue to participate in the CM Initiative. As such, any data that they collect will not be included in the CTSA Program aggregated dataset for that calendar year.
 - A hub moving from being in a NCE without a new award of NCATS funds during a calendar year would be considered to be in the category of no longer receiving funds.

2.2. CTSA Program Coordinating Center or other entity funded to implement the NCATS CM Initiative:

- On behalf of the CTSA Program, the coordinating center, or other entity funded to implement the NCATS CM Initiative, will be responsible for the collection and management of data to gauge and improve the impact of the CTSA Program hubs and the evolving CTSA Program Consortium, including:
 - Collecting the data, assuring data completeness, and working with hubs on the training and implementation of the operational guidelines for metrics and developing strategic management plans.
 - Analyzing, and displaying data related to the strategic management of the CTSA Program and CTSA Program hubs through the use of CM.
 - Developing, disseminating, and implementing strategic management for the CTSA Program through the use of the Results-Based Accountability framework (<http://raguide.org/>).

- Contributing to establishing harmonized common metric data.
- Collaborate with the CTSA Program Evaluator’s Group on developing and disseminating resources and supplementary material on how to effectively integrate use of local CTSA Program hub evaluation data in understanding the performance of the common metric data.
- Assessing the accuracy and thoroughness of the common metric data, and assessing the common metrics initiative overall.
- Aggregating consortium-level data and providing visualizations in a manner consistent with CM Data Governance rules, taking into consideration the context and story behind the curve of the data with input from hubs.
- The coordinating center will act as an honest broker between the CTSA Program hubs and the NCATS CM Team.
- The coordinating center adheres to procedures to manage the data in a secure and confidential way and agrees not to share identifiable information, beyond providing hub-specific data back to the originating hub only.
- The coordinating center will work with NCATS and the CTSA Program investigators to develop, implement and collect data related to consortium-level performance. The coordinating center will also coordinate the development of strategic management plans for the CTSA Program Consortium and track the implementation for consortium-level metrics.
- The coordinating center will collaborate with CTSA Program hubs to support innovative approaches to use of CM data, evaluation data, and strategic management plans.

2.3. NCATS Lead for CM Initiative:

- Responsible for oversight of all activities associated with the CM Initiative.
- Responsible for ensuring the CM Initiative is being implemented in a way that is aligned with the vision of the initiative, developed to be responsive to IOM recommendations, and meets stated goals.
- Assist the coordinating center in distilling best practices in hub-specific strategic management plans based on qualitative data.
- Provides oversight to the coordinating center in their access and use of the quantitative and qualitative data collected as a part of the initiative.
- Ensures that the common metric data are used to aggregate consortium-level data by the coordinating center for visualization in a manner consistent with CM Governance rules, taking into consideration the context and story behind the curve of the data, and are not used in any way to rank one hub against another nor in any inaccurate or unapproved manner.
- Will receive reports from the coordinating center that provides a summary of the CTSA Program hubs that have provided their CM data into Scorecard (or other selected web-based software platform) to ensure that the data set is complete.

2.4. NCATS Coordinating Center Project Scientist:

- Provides oversight to the coordinating center and any hub in their access and use of the quantitative and qualitative data collected as a part of the CM initiative.
- Assists the coordinating center in distilling best practices from qualitative data.

2.5. NCATS Coordinating Center Program Officer:

- Evaluates the coordinating center's progress and enforces terms and conditions of the award.

2.6. NCATS Lead(s) for the CM Development:

- Works with the CM development team to develop, pilot, and implement CM.
- May have identifiable hub-specific data from CTSA Program hubs piloting a new metric with permission from the pilot hub. Data would be shared with the NCATS Lead(s) for the purpose of providing technical assistance to the hub and/or assessing the operational guidelines for the metric.

2.7. NCATS Program Officers/Project Scientists:

- The CTSA Program award is a cooperative agreement that involves substantial NIH programmatic involvement with the awardee during the performance of the activities. Consequently, the NCATS Program Officers will discuss hub specific metrics during standard hub collaborative discussions. To facilitate this discussion, the Program Officer may wish to receive hub data and the story behind the data via a live webinar and/or a PDF print-out.
- NCATS Program Officers will be expected to limit sharing of hub-specific data to discussion with and support to hubs for their local strategic management.

2.8. CTSA Program CM Executive Committee:

- The CTSA Program CM Executive Committee provides feedback to NCATS and the CTSA Program Coordinating Center on the activities related to the CM Initiative. Among other activities, feedback is provided regarding the project planning, stakeholder engagement and communication strategies related to the CM Initiative.

2.9. CTSA Program Evaluators Group:

- The CTSA Program Hub Evaluators Group connects evaluation experts across the CTSA Program. The evaluators provide input and feedback to NCATS on the CM Initiative and have representative membership on the CM Development teams and the CM Executive Committee.

2.10. CTSA Program Steering Committee:

- The CTSA Program Steering Committee (SC) provides feedback on activities relevant to the CTSA Program. This includes the activities associated with the NCATS CM Initiative.

2.11. CTSA Program CM Development Team:

- CM Development Team is comprised of the following CTSA Program members: 2 PIs, 2 Evaluators, 2 Administrators, 1 Subject Matter Expert and 1-2 NCATS Lead Team member(s).
- This team is responsible for development and refinement of metrics, drafting the operational guidelines, finalizing the operational guidelines based in feedback from the CM Executive Committee, the Steering Committee and through piloting the metric.
- Responsible for assisting in providing technical assistance and answering questions related to the metric's operational guidelines.

Table 1: CM Participating Groups and Access to Types of CM Data

Source of CM Data:	All Hubs	Single Hub	All Hubs
Type of CM Data:	Aggregate / De-identified	Identified	Identified
CM Participating Groups:			
2.1. CTSA Program Hub	x	x	
2.2. CTSA Program Coordinating Center*	x	x	x
2.3. NCATS Lead for CM Initiative	x		
2.4. NCATS Coordinating Center Project Scientist	x		
2.5. NCATS Coordinating Center Program Officer	x		
2.6. NCATS Lead(s) for CM Development	x		
2.7. NCATS Program Officers/Project Scientists*	x	x	
2.8. CTSA Program CM Executive Committee	x		
2.9. CTSA Program Evaluators Group	x		
2.10. CTSA Program Steering Committee	x		
2.11. CTSA Program CM Development Team	x		

**See 3.2. Protection of Confidentiality*

3. Uses and Management of Data Generated from the CM Initiative

3.1. Ownership of Data:

- Data describing performance of specific hubs remain the property of the hub to which the data pertain.
- Each hub agrees to designate the CTSA Program Coordinating Center as its agent for collecting, managing, analyzing and reporting on CM data.
- The CTSA Program Coordinating Center, as NCATS agent, will act as honest broker and have authorized access to all identifiable CTSA Program data. The CTSA Program Coordinating Center will produce information and reports on the performance and impact of the CTSA Program and CTSA-Program hubs within the governing agreements to ensure confidentiality of identifiable hub-specific data.
- All data and information produced from hub-specific CM data not containing hub identification will be the property of NCATS and the CTSA Program.

3.2. Protection of Confidentiality:

- The CTSA Program Coordinating Center, and any other entity designated as NCATS' agent for management of CTSA Program CM data, will act as an honest broker and will only release identifiable CTSA Program hub data as authorized by governing agreements.

Appendix

Appendix A:

Tufts implementation - <http://www.tuftsctsi.org/wp-content/uploads/2016/08/Implementation-Group-3-Team-Building-and-Training-Overview.pdf>