

CTSA Program Common Metric for Informatics Solutions

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NCATS

Informatics Solutions

Metric Development Team

Informatics Metric Development Team
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Informatics for the CTSA Program

What is Informatics?

- The study and practice of creating, storing, finding, manipulating and sharing information

How does the CTSA Program Support Informatics Solutions? Through support and innovation in:

- Data Security - user friendly infrastructure to assist investigators in ensuring the security of their data
- Data Integration - integrating different types of data from different sources
- Data Standards - compatible research systems and use of standard terminologies
- Data Access / Data Sharing - ability to query across multiple units (at their institution), ability to respond to diverse queries; enable data access, integration and processing
- Data Quality - ensure data is fit for purpose

Informatics for the CTSA Program

Vision and Goal

Vision:

- The CTSA Program is a collaborative and interoperable national research network that will leverage resources across multiple systems and unique expertise within our institutions to connect research to health care that results in better health through research

Goal:

- Improve the interoperability of data within multiple systems by making the data adhere to the FAIR data principles so that they are machine readable:
 - Findable: data are assigned a globally unique and eternally persistent identifier
 - Accessible: data are retrievable by their identifier using a standardized communications protocol
 - Interoperable: data use vocabularies that follow FAIR principles
 - Re-usable: data have a plurality of accurate and relevant attributes

Rationale for Informatics Metric

- IOM report (2013) points to persistent data challenges that will need to be overcome in order to realize the full potential of clinical and translational science
 - eg. Interoperability and connectivity issues among data sources, along with privacy concerns, cultural barriers, and lack of incentives, impede data sharing among researchers and across sectors
 - Recent advances derived from data pooling and analysis could improve public health, enhance patient safety and spur drug development
- Need to move to a standards-based data warehouse harmonized with other federal agencies and CTSA Program activities [i.e. ONC, FDA (CDISC) and CTSA Initiatives like TIN]
- This harmonization will result in a common clinical research data model across all CTSA Program hubs

Rationale for Informatics Metric

- Lack of harmonization causes costly support of multiple clinical research data models (PCORI, mini-Sentinel, OMOP)
- Lack of semantic consistency (the *meaning* of the data) and syntactical (the *structure* of the data) across the CTSA Program
- Deep phenotyping potential is limited by multiple clinical research data models and lack of quality control
- Accrual to Clinical Trials (ACT) is a parallel initiative that is focused on cohort discovery - not data mining

Metric: Data Warehouse Harmonization

Metric:

- Improving discovery within and between CTSA Program hubs by improving data warehouse harmonization and quality across the CTSA Program

Process:

- Develop a baseline set of standards leveraging existing common data model for a CTSA clinical research data warehouse
- Develop or modify existing tools or scripts to support the characterization, quality assessment and visualization of CTSA clinical research warehouse databases
 - Script/Tool is to be developed in collaboration with the iDTF
 - Standards to be developed in collaboration with the iDTF
- Piloting of the metric will assist in testing the script/tool and the functionality
- Automation of the script/tool will lower burden for reporting of this metric at the CTSA Program hubs

Strategic Management

At the end of the implementation of the Informatics Solution metric:

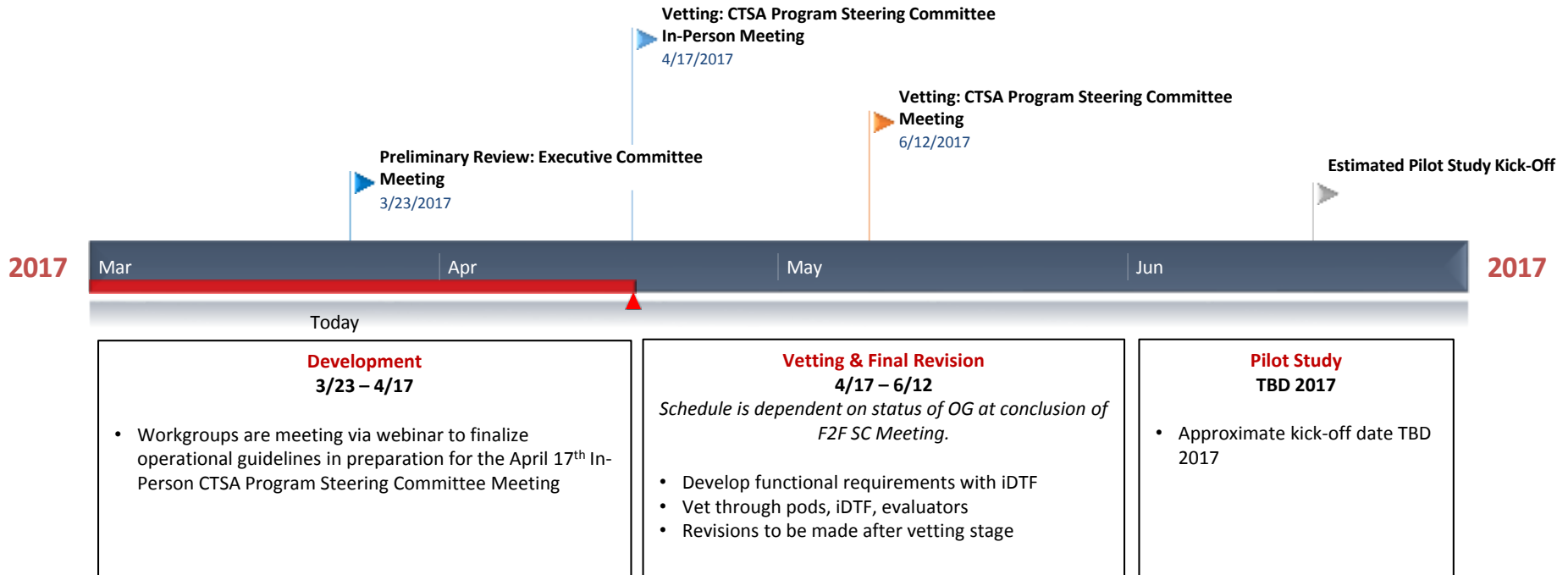
- The CTSA Program will have established a path toward consensus / standard of excellence / baseline value that reflects a minimal standard for a searchable, centralized electronic data warehouse at hub within the CTSA Program
- The CTSA Program will be able to track progress toward an **interoperable national research network** as it pertains to clinical data

This metric will provide **continuous improvement** for both the CTSA Program and individual hubs:

- This metric will provide continuous improvement for the CTSA Program by:
 - Enhancing interoperability by increasing different types of data in a hub's data warehouse
 - Adding new Tables/Fields/Data Types/Data Values
 - Adding different types of data: imaging, genetics, etc.
- Each hub will be able to strategically manage their data warehouse to:
 - **Enhance quality** of the data within the data warehouse
 - **Increase interoperability** within a hub and between hubs

Strategic Management: Timeline

CTSA Program Common Metrics Revised Metrics Development Timeline 2017



QUESTIONS?

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