NCATS Improving Health Through Smarter Science

CTSA Program Steering Committee

Monday, June 11, 2018

2:30 – 4:00 ET

CTSA Clinical & Translational Science Awards Program

NIH National Center for Advancing Translational Sciences

Agenda

2:30	Welcome	Kathleen Brady Christopher Austin
2:30 – 2:40	Director’s Update	Christopher Austin
2:40 – 2:42	Review Action Items List	Samantha Jonson
2:42 – 2:45	CLIC Un-Meeting Report Out	Martin Zand
2:45 – 3:00	iDTF and CD2H Update	Donald Lloyd Jones
3:00 – 3:30	Common Metrics: Informatics Update	Ann Dozier (CLIC)
3:30 – 4:00	Pod Feedback Round Robin	All

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Director's Update

- Both the House and Senate appropriation subcommittees held their hearings with NIH in preparation for their development of appropriation bills for FY19. Dr. Collins testified for NIH, but there was no mention of the CTSA Program.

- House and Senate markups and release of bills scheduled for last week of June

- Senate Majority Leader Mitch McConnell (R-KY) cancelled the August recess, in part to complete passage of appropriation bills prior to start of fiscal year

- NIH released its Notice of Fiscal Policies in Effect for FY 2018 (See NOT-OD-18-180).
  - Non-competing applications that were awarded at 90% under the CR will be restored to 100%.

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Other Resources

Director's Corner

June 6, 2018: Translating Translation

NCATS is unique at NIH in that the name in the Center's mission — "translation" — has a firmly established meaning that is generally associated with languages, not biomedical research. By contrast, other NIH components are named for widely known medical problems, such as cancer, diabetes and stroke. NCATS' outreach and education efforts are therefore especially complex. First, we must define what "translation" means as a biomedical research term. Second, we must convey why it matters. And third, we must explain what NCATS is doing to improve it.

To understand NCATS' definitional challenge, imagine for a moment that neither you nor anyone you know, including your scientist and physician friends, had ever heard of cancer. But you knew it to be an enormous and deadly problem, and you were working hard to find a cure for it. You would have a difficult time garnering interest in your work until your colleagues understood what "cancer" was. Substitute "translation" for "cancer" and you can better understand NCATS' challenge as well as its potential.

To help bridge this gap, I recently published a brief about three related terms — translation, translational research and translational science — in *Nature Reviews Drug Discovery*. I hope you will take a look at this freely available commentary and send me feedback.

"Translation" is firmly established as meaning the conversion of a message from one language into another. Biomedical translation, by analogy, is the process of converting a scientific or clinical observation into an intervention (e.g., drug, device, surgical procedure, behavioral change) that is shown to improve health.

Scientific translation is an exceedingly complicated process that involves dozens of steps. (See our Drug Discovery, Development and Deployment (4DM) Maps for a glimpse of just how complicated translation can be.) Imagine the child's game of "telephone," in which a message is translated into one person's language, and then another, and so on a dozen or more times. The likelihood that the original meaning of the message would be successfully delivered in the final person's language would be very small. Welcome to the world of biomedical translation!

Send Feedback

Share your thoughts about this message.

Director's Biography

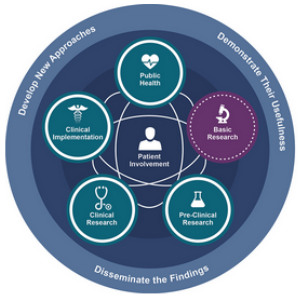
Read more about Christopher P. Austin, M.D.

More Messages

View past messages from the NCATS director:

- 2018 Director's Messages
- 2017 Director's Messages
- 2016 Director's Messages
- 2015 Director's Messages
- 2014 Director's Messages
- 2013 Director's Messages
- 2012 Director's Messages

Translating Translation



NCATS Director Christopher P. Austin, M.D., defines, distinguishes and explores the promise of translation, translational research and translational science.

https://ncats.nih.gov/director

COMMENT

Translating translation

Christopher P. Austin

The term 'translation' has emerged as a dominant concept in biomedical science over the last decade, but confusion around what the term means, and how it differs from translational research and translational science, is common. This article aims to help address this issue by clarifying the distinctions.

As director of the leading US public agency focused on translational science, the National Center for Advancing Translational Sciences (NCATS), I speak frequently to diverse audiences about translation and its relatives, translational research and translational science. Despite the widespread use of these terms, I have found widespread variation in their intended meaning, and frequent confusion among scientists, physicians, patients and policy makers about what translation is, how it differs from translational research and translational science, and how each relates to areas of biomedical research with which they may be more familiar. With the hope of advancing scientific and public discourse on translation and its potential and challenges, I offer here some definitions and distinctions.

Linguistically, the word 'translation' is derived from the Latin *trans* and *latus*, meaning 'to carry across'. Unlike terms that describe other areas of biomedicine (for example, 'cancer', 'diabetes' and 'musculoskeletal'), 'translation' has not only widely used non-medical meanings, such as the process of rendering one language

Several words or phrases in this definition are worth expanding on further. 'Process' reflects that unlike linguistic translation, biomedical translation is not a one-step event, but multistep and recursive. 'Observations' reflects that translation starts with the first-time perception of phenomena, which must be demonstrated to be reproducible and robust. 'Laboratory, clinic and community' reflects that (contrary to frequent parlance), translation need not start with a basic science observation and move towards the clinic and eventually public health; in fact, until relatively recently, most successful translation began with a clinical or public health observation that led to basic discoveries. Thus translation is bidirectional. Finally, with regard to 'interventions', translation is modality-agnostic; the translational process is conceptually similar whether its intended result is a small-molecule drug, a biologic (such as an antibody, oligonucleotide or aptamer), a device, a medical or surgical procedure, or a behavioural change (such as diet, exercise or smoking cessation). Thus 'translation' refers to an overarching conceptual and practical multistep process.

https://bit.ly/2sIfBZC

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Pending Action Items

(Not listed in priority order.)

Task	Description	Description	Action
1	CTSA Program U54 Review Processes	SC members brought up the issue of the review process in comparison to the Cancer Centers review and that no PIs are on the review panels.	DCI leadership will meet with the NCI Cancer Center Director regarding their review panels and report back to the SC on findings.
2	Future CTSA Program Meetings	Proposed for Fall: Day 1: Administrators and SC overlap; Day 2: Program Meeting	Revisions to the Program Meeting structure are underway. Details to be announced soon!
3	Workforce Development Concerns	Concerns: 1) the next stage of career for KL2s as NCATS does not have an R portfolio; 2) retaining physician scientists; 3) debt load of physician scientists;	Materials sent out to the SC on May 30, 2018. NCATS is seeking additional SC members to join the Ad Hoc SC taskforce on issues addressed during this session. Once a group is finalized, the SC will meet with the DTF lead team.
4	Support of administrators	SC recommended that we support the administrators	NCATS and CLIC will support the administrator meetings. CLIC will organize an in-person meeting in conjunction with the CTSA Program meeting this coming October.
5	FOA feedback	Develop a broad-reaching feedback mechanism on previous FOA	NCATS is developing a plan and will report back to the SC at a later time.
6	Suggestion Box	Need to have submissions and responses open to the consortium	All submissions are discussed on the SC calls and/or PI calls. CLIC will implement the discussion board which will allow for others to provide asyonchronous comments regarding topics.
7	Talking points for PIs for the institutional administration on the value of being a part of the CTSA Program consortium		NCATS will be developing revised talking points. NCATS staff will reach out to the SC for input. More details to come.
8	Steering Committee Task Force on the Domain Task Force		First call held on June 6.

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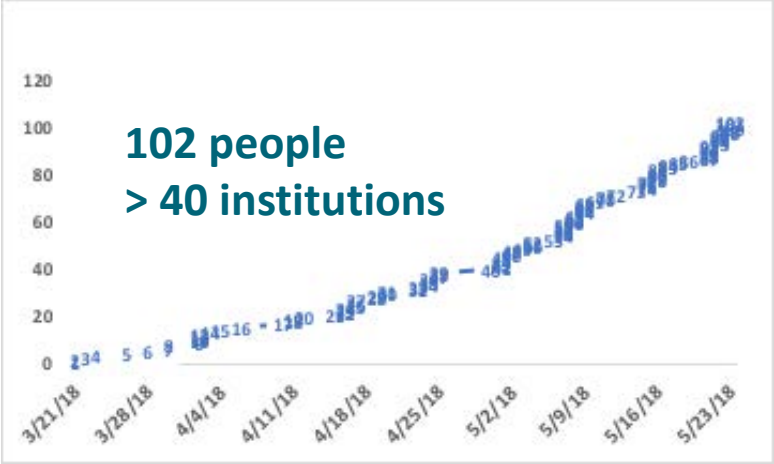
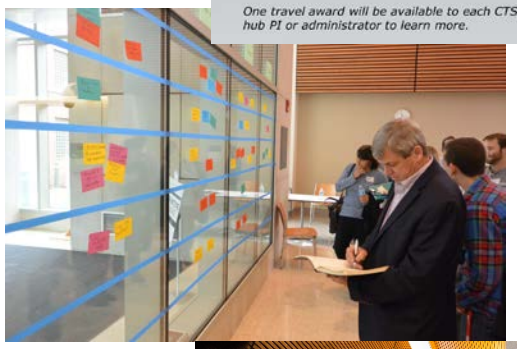
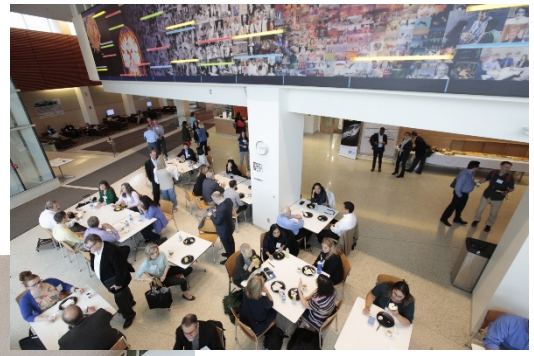
Un-Meeting

Speed dating for translational scientists:
"4 slides x 4 minutes, no exceptions"







RFA for future Un-Meeting proposals anticipated Fall 2018

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SCHOOL OF MEDICINE CASE WESTERN RESERVE UNIVERSITY
CTSC Clinical & Translational Science Collaborative
UT Health San Antonio Institute for Integration of Medicine & Science
UNIVERSITY of ROCHESTER MEDICAL CENTER | CLINICAL & TRANSLATIONAL SCIENCE INSTITUTE
CTS
ITHS Institute of Translational Health Sciences Accelerating Research. Improving Health.
HEALTH UNIVERSITY OF UTAH
NIH National Institute on Drug Abuse Advancing Addiction Science
THE OHIO STATE UNIVERSITY CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE
SC CTSI
Tufts CTSI Tufts Clinical and Translational Science Institute
CLINICAL AND TRANSLATIONAL SCIENCE INSTITUTE UNIVERSITY OF MINNESOTA Driven to Discover
EINSTEIN Albert Einstein College of Medicine
Montefiore
OHSU OREGON CLINICAL & TRANSLATIONAL Research Institute
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NIH National Center for Advancing Translational Sciences
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Breakout Sessions
(Actual Topics)

	A	B	C	D	E	F
Breakout 1	Rural Communities	Criminal Justice	Clinical Trials	Pediatric & Adolescence	Best Practices / late stage translation / quality and outcomes	Data Informatics
Breakout 2	Rx in Primary Care	Community Engagement	Pregnancy / Maternal / Neonatal / Child	Chronic Pain, Trauma, Suicide / Risk Prevention	Special Populations	Non-Pharmacological Complimentary Alternative Medicine
Breakout 3	Recovery and Resilience	Research Role of the CTSA	Infectious Diseases and Opioids	Strategies for reducing overdose deaths	Disparities in Addiction, Access to treatment	Prescribing Approaches
Breakout 4	Detox Centers	Community Outreach / Training	Mobile/Health Technology	Pharmacological Interventions	Health Insurance / Policy	

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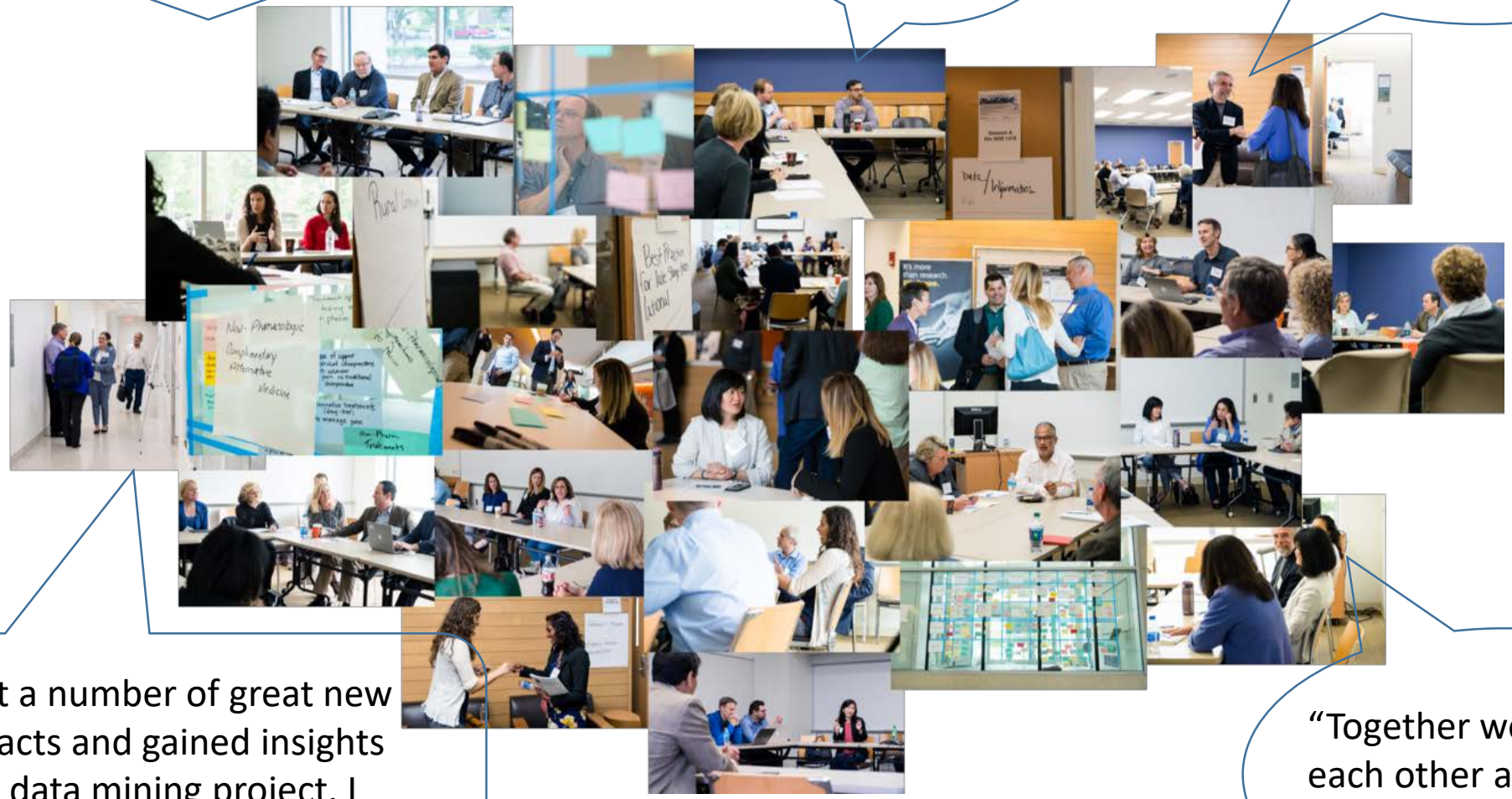
"There is more interest in community engagement than I expected. Also, participants reacted on a very emotional level to the opioid crisis."

"The NETWORKING was GREAT! It was the meeting."

"I learned a bit more about the landscape of opioid research and how it is getting framed."



"Met a number of great new contacts and gained insights for a data mining project. I learned a great deal from the meeting organization"

"Together we can educate each other and add to what we don't know."

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iDTF / CD2H WG / Project Process

- **Goals:**
  - To ensure that CTSA informatics workgroups and projects have critical mass of participation and adequate support from CLIC/CD2H
  - To ensure projects and working groups are chartered with clear deliverables aligned with NCATS priorities
  - To avoid overloading finite CTSA informatics capacity
- **Principles - endorsed by NCATS and iDTF:**
  - CTSA Informatics workgroups are open to everyone
  - In general CD2H to oversee work groups requiring funding & possible action by CTSA sites
  - In general CLIC to support policy-focused work groups from the sites and informatics communities
  - iDTF to be a venue where all CTSA informatics working groups report on progress to the broader CTSA community with a single list of CTSA informatics working groups accessible on both CLIC/iDTF and CD2H websites

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iDTF / CD2H WG / Project Process

- **Workflow for the Creation & support of work groups and projects**
  - CTSA informatics workgroup or project proposals are submitted to the iDTF Lead Team (which has iDTF, CD2H, CTSA, CLIC and NCATS members) for discussion and refinement prior to presentation to all iDTF members.
    - CD2H may bring forward projects created in the course of executing its mission for comment and review by iDTF
    - **NOTE: per NCATS**
      - Questionnaires to be **distributed to all iDTF members** must go through an iDTF Lead Team approval process (per NCATS Survey Guidelines, p. 2, Section A)
      - Questionnaires to be **distributed to all CTSA PIs** must go through an NCATS approval process (per NCATS Survey Guidelines, p. 2, Section A)
  - Finalized / Lead Team-approved proposals presented to iDTF Membership for discussion and voting on moving forward
  - For workgroups that will be chartered as an iDTF workgroup an additional step of CTSA Steering Committee approval is required (per CTSA policies)
  - iDTF Lead Team to then determine if the workgroup or project would be best served by CLIC or CD2H administrative support.

- **NOTE**: would aim for relatively quick turnaround as the Lead Team meets 2x a month between the All Hands Meeting

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

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Results of the Informatics Common Metric Pilot

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Informatics Common Metric (ICM)

- Purpose of the ICM:
  - Identify clinical research data gaps and opportunities for improvement
  - Improve local and network capacity to efficiently use data to conduct research
- Provide a baseline scan of level of coverage of the types of data hubs have in their clinical research data repository

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ICM Pilot Sites by Data Model

Data Model	Pilot Sites	
OMOP	Albert Einstein College of Medicine - Montefiore Health Columbia University Icahn School of Medicine at Mt. Sinai University of California Irvine	
PCORnet	Medical College of Wisconsin Ohio State University University of California Los Angeles	University of Chicago University of Kansas Medical Center Washington University
i2b2/ACT	Indiana University – Purdue University at Indianapolis University of Florida University of Pittsburgh University of Rochester	
i2b2/TriNetX	University of Massachusetts Weill Medical College of Cornell University	

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Queries / Scripts – Decrease the Burden of Collecting Metric Data

- Scripts were provided to hubs for OMOP, PCORnet and i2b2/ACT data models
  - Enable standardized automated query against the data repository (or repositories) at each hub
- Developed, tested, & approved collaboratively by the ICM Development Team and the iDTF
- Hubs using i2b2/TriNetX, sent request to TriNetX for data reports

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ICM Pilot Data Collected

Count of unique patients with:

- Age/DOB value
- Administrative sex value
- LOINC ID value
- Rx NORM ID value
- ICD9/10 or SNOMED value
- ICD 9/10 CPT procedure code
- Free text data
- Observations (present/absent)

Percentage calculated as:

$$\frac{\text{Count of unique patients with the standard value (numerator)}}{\text{Count of unique patients in clinical data repository (denominator)}} = \text{\% of unique patients with the standard value}$$

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Data at a Glance

- Range of number of pts in repository:
  - 589,903 – 5,663,620
- Range of date of data accessed by the scripts:
  - 5-32 years
  - 4 hubs did not indicate date range accessed

Date Range	# Years
2007 – 2017	10
2008 - 2017	9
2010 – 2017	7
2010 – 2017	7
2012 – 2017	5
2010 – 2017	7
DOB/Sex since 1980s	32
Others since 2012	5
2011 – 2017	6
2011 – 2017	6
2006 - 2017	11
2010 – 2017	7
2010 – 2017	7

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Completeness of Data

Domain	Results
Age/DOB	14 of 16 Hubs (88%) at 100%
Administrative Sex	13 of 16 Hubs (81%) at 100%
LOINC ID	Hub Results Range 17% - 82%
Rx NORM ID	Hub Results Range 7% - 78%
ICD 9/10 or SNOMED	Hub Results Range 31% - 97%
ICD 9/10 CPT Procedures	Hub Results Range 11% - 97%
Free Text Data	2 of 16 Hubs (12%) Had Notes
Observations	10 of 16 Hubs (63%) Observations Present

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Hubs that Identified Missing Data

Domains	# Hubs with Data
% of pts with an age or date of birth value	16
% of pts with administrative sex value	16
% of pts with LOINC ID value	**15**
% of pts with RxNorm value	16
% of pts with ICD 9/10 or SNOMED value	16
% of pts with ICD 9/10 or CPT Procedure value	16
% of pts with free text data	16
% Observations Present (Y=1, N=0)	**14**

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What did Pilot Hubs Learn from this Metric?

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Partners

In general, a wide range of local partners were identified for the individual pilots
Examples:

- Common data model expert
- Clinical data analyst
- Evaluation director
- Informatics program manager
- Hospital team members
- Researchers
- Data model users - community at large
- Other CTSA Program sites
- Information Services Division Integration Team - has role of administering i2b2 software and running the script to provide the ICM data
- Academic IT - has role of planning new directions for i2b2 software

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Strategies to Improve Interoperability & Data Quality

- Re-coding of values that were not previously coded to a standard
  - Find diagnoses not mapped to ICD 9/10 or LOINC (lab values)
- Increase the data
  - Bring in additional procedure codes
  - Add de-identified physician notes
- Investigate missing data
- Investigate if possible to harvest very old billing data on patients

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One Example Strategy

- Work with internal stakeholders to increase awareness of what is needed, so that when the hub transitions to i2b2, v2 will *have improved capability to gather data needed.*
- Consider what interpretations are most appropriate for the individual components
  - RxNorm - pts not on meds decrease percentage
  - Would it be more informative to either:
    - Reduce denominator to include only pts on meds, or
    - Include a code that indicates “no meds?”
    - Would this be part of the OG?
- For ICD performance measures, ascertain whether ICD 9 and/or ICD 10 should be included in the metric

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Recommendations and Considerations

Moving to Implementation Across the CTSA Program Consortium

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Recommendations to Enhance Operational Guidelines

- Limit hubs to collecting from primary databases/ warehouses used to support research only
- Clarify and enhance definitions:
  - Observation
  - Each data domain
- Describe how to interpret script output
  - Usefulness/meaningfulness in institutional context

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Enhancing the Operational Guidelines *(continued)*

- Add to inclusion/exclusion criteria – date range
  - Have hubs report date range included
  - Run script on full data repository, then
  - Run script again on more recent time frame
- Set a time to gather the data for the metric during the year
- Clarify expectations for achieving data completeness where script limitations exist
  - Should hubs perform additional queries if the scripts don't pull the data?

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Other Considerations for the Future

- Several hubs indicated they'd like to use a different data model in the future
  - Implications for data interpretation over time, for aggregation of this metric across the consortium?
- Variability in hubs' capacity for Informatics
  - Stretch Metric?
  - Engage iDTF to develop additional domains
- Incorporate other data models with this metric

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Pod Feedback Round Robin

Thank you!

Next call: July 16, 2:30 – 4:00