TRIO STUDIO: How Do We Effectively Respond to the Trial Innovation Network (TIN) Requests?

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August 8, 2018
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By Sherry Robison
TRIO Manager, Institute for Translational Medicine
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Research Assistants: Divya Jain, Abhignan Sai Godha and Yun Yang (MDes Students)

Attendees:
Design Thinking Team: Kelly Shaffer Loyola Medical University, Elizabeth Kirwan Loyola Medical University, Denise Voskuil-Mane RUMC, and Nurie Dervishi ITM, U of Chicago

Quality Thinking Team: Kate Haas U of Chicago, Kirsten Hendrickson RUMC, Gerald Stacey ITM U of Chicago, and Drew Simon ITM RUMC.

Summary
Sherry Robison, University of Chicago Institute for Translational Medicine, introduced the Trial Innovation Network (TIN) requests for quantitative data from ITM and the subsequent challenges of obtaining the data from ITM’s six member institutions. She gave background information on ITM, CTSAs and TIN including TIC (Trial Innovation Center) and RIC (Recruitment Innovation Center) and introduced the challenges of communication and informatics to the studio.

Design Thinking approach and Quality Thinking were both used to solve the problems faced by Sherry and her team at ITM. Many suggestions, based on experiences at different institutions, were made.

Top 3 Actions Proposed by the Studio Participants to Sherry:

1. **Point of Contact at Each of the ITM Institutions:** Establish a point of contact at each institution to route these requests.

2. **Decision tree:** Establish a decision tree at each institution for the point of contact and the bio-informatics point of contact with delegated back up and for the PI to get back to the point of contact if they are interested or not in the proposed study.

3. **Point of Contact have Access to Informatics:** Giving the point of contact access to informatics will make it easier to pull the data the TIN is requesting and should speed up the process as it won’t have to be routed to informatics.
TRIO Studio Problem Description:

The goals are to create a process with a logical flow for responding to TIN requests within the time frame given.

Sherry Robison from University of Chicago ITM TRIO introduced the problem. The TIN sends requests to the liason person listed on the TIN website along with the CTSA Engagement Package. The Engagement Package gives a brief description of the study, a very detailed inclusion/exclusion criteria, and when the informatics information is due. The due date can range from one week to four weeks. Requests from TIN are either not responded to or the responses are not coming in prior to the deadline. Several factors may impact why all ITM instutions do not respond to the current requests: short time to respond, potential PI may not be interested, multi-institutional requests (6 institutions) and requests are not reaching the correct person at each institution (informatics, PIs, coordinators, etc).

TIN sends out requests for potential studies with a very detailed inclusion/exclusion criteria and deadline. The requests are sent to each institution with a due date. TRIO at University of Chicago can run their own informatics while other institutions don’t have access to running their numbers. This results in requests going unanswered or responses coming in after the deadline.

Sherry’s call to action: “Do you have suggestions on how do we effectively respond to the Trial Innovation Network requests?”

Figure 1 Sherry Robison presenting TIN Requests and TRIO’s perspective on challenges associated with the requests
Main problem for the studio participants to solve:
Does the TRIO studio audience have suggestions for responding effectively to Trial Innovation Network requests?

Studio Methodology
Design Thinking approach as well as Quality Science approach was used as part of the studio to solve this problem. The attendees were split into two groups. One group was assigned to Divya and Abhignan to use Design Thinking method and Santosh lead the other group with Quality Thinking approach. Final solutions were documented from both teams and provided to Sherry Robison.

Design Thinking Method
We used the Design thinking approach with five steps:

1. Created a free form mind map of the problem and identification of issues – Mind Mapping technique
2. Actionable insights were identified
3. Generated ideas to address issues
4. Synthesized solutions from the smaller ideas – Creative integration of smaller ideas led by Design Thinking Expert facilitator was done using white boards.
5. Solutions were proposed and were rated by the team on implement-ability (0-4 scale)

Quality Science Method
The Six Sigma Quality Science approach was used which consisted of five steps:

1. Problem definition and mapping of actual structure of the process
2. Identify issues and analyze causality using Fishbone analysis
3. Generated ideas to address to issues – Brainstormed using SCAMPER method
4. Merged smaller ideas and scale ideas to create bigger solutions
5. Actionable insights and solutions were proposed and solutions were rated by the team on implement-ability (0-4 scale)
Design Thinking Based Solutions:

Problem visualized with Insights
The group first discussed the problem and its context yielding the following context diagram:
High level insights:
Following the context discussions, insights were generated as follows:

Figure 3 Insight into lack of systems in place at Clinics

Figure 4 Insights Generated during Discussion
Solutions Generated by Design Thinking Approach Team:
Six relatively implementable solutions were created to solve the issues of getting a study started. They are as follows:

1. **Point of Contact at Each of the ITM Institutions**: Establish a point of contact at each institution to route these requests.

2. **Decision Tree**: Establish a decision tree at each ITM institution for the point of contact and the bio-informatics point of contact with delegated back up and for the PI to get back to the point of contact if they are interested or not in the proposed study.

3. **Point of Contact have Access to Informatics**: Giving the point of contact access to informatics will make it easier to pull the data the TIN is requesting and should speed up the process as it won’t have to be routed to informatics.

4. **Email Communications**: Email communications need to be more clear as to the deadlines.

5. **Educate About the Process**: If points of contact know the process and what is involved, they may be able to speed up the process.

6. **Follow up Emails/Email Updates/Newsletter**: Follow up emails to determine the status of the request, email updates as to what is going on with the potential study (was it funded) and a newsletter talking about successful recruitment would be beneficial to the sites.
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**IDEATION**

- System within clinics
  - Make a site-based list of priority research plans
  - Focus on P.I. engagement
  - Sherry could always respond with a default "NO"
  - Weekly in-person meetings with the team across clinics
  - Surrogate P.I. to help communication
  - Training for ‘local’ contact initially

**SOLUTIONS**

- Know point of contact at each of the institutions
- Decision tree for point of contact with designated back-up (need to have bioinformatics P.O.C.)
- P.O.C. should have access to informatics
- Email communications to be clearer with deadlines
- Introduction/Education about the process to each of the institutions
- Follow up emails/ email updates/ newsletters talking about successful recruitments in the past

**Figure 4 Ideas and Solutions after discussion of ideas**
TRIO STUDIO: How Do We Effectively Respond to the Trial Innovation Network (TIN) Requests?

Figure 5 Possible Options for TRIO Communication Flows
TRIO STUDIO: How Do We Effectively Respond to the Trial Innovation Network (TIN) Requests?

Quality Science Based Solutions:

**Problems Analysed to Identify and Define Issues.**
The group discussed all the problems in the TIN request related communications.

![Diagram](image)

**Figure 6 Problems as discussed by Quality Approach group**

**Analysis of Issues and Causes**

Causes for the issues found in step one were discussed as a group. Here is the summary of that discussion:

Requests from TIN are not responded to and the responses are not coming in prior to the deadline. The TIN sends requests to the liaison person listed on the TIN website along with the CTSA Engagement Package. The Engagement Package gives a brief description of the study, a very detailed inclusion/exclusion criteria, and when the informatics information is due. The due date can range from one week to four weeks. Several factors may impact why all ITM institutions do not respond to the current process: short time to respond to TIN, potential PI may not be interested, multi-institutional requests (6 institutions) and not contacting the correct person at each institution (informatics, PIs, coordinators, etc).
TRIO STUDIO: How Do We Effectively Respond to the Trial Innovation Network (TIN) Requests?

Figure 7 Current Process Flow with issues highlighted

TIN sends out requests for potential studies with a very detailed inclusion/exclusion criteria and deadline. The requests are sent to each institution with a due date. TRIO at University of Chicago can run their own informatics while other institutions don’t have access to running their numbers. This results in requests going unanswered or responses coming in after the deadline.

Solutions Generated by Quality Science Approach Team:
Five relatively simple solutions were created to solve the issues of the TIN requests. They are as follows:

1. **Identify Data Person at Each ITM Institution**: Carbon copy the honest broker (if possible so that they can expediate request) and carbon copy personal contact currently in place.

2. **Clearly Document “PROCESS”**: So that all institutions are aware of what needs to be done and submitted, clearly document the process for obtaining the informatics data.

3. **Buy-in from Infomatics**: Identify contacts, approve process and resource constraints to hire more honest brokers. Availability of self service tools for Sherry (TRIO) to access at each member institutes will solve many of the communication problems as well. It eliminates the middle person completely saving time.

4. **Spin this with CaPRICORN Lingo**: Work with CaPRICORN to see how they set up the informatics requests they receive for studies. CaPRICORN is a well established program so using it as analogy or as an inspiration for communication process is good idea as well.
5. **Work with TIN to Improve Incoming Requests**: Determine when ICD 10 does with be on the requests as opposed to ICD 9 and requesting queries to be returned to them as soon as possible.

![Diagram of TIN request flow]

*Figure 8 Future Flow of TIN requests with TRIO responding on time*

<End of Document. Thank you.>
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Appendix 1.
Slides used by Sherry Robison, ITM, TRIO, University of Chicago for the studio kick off.

Appendix 2.
Session Pictures

Session Pictures – Design Thinking
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Session Pictures – Quality Thinking Approach
Appendix 3.
Actual pictures of white board from the studio session.
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Quality Science Team Pictures
TRIO STUDIO: How Do We Effectively Respond to the Trial Innovation Network (TIN) Requests?
TRIO STUDIO: How Do We Effectively Respond to the Trial Innovation Network (TIN) Requests?
Solutions for Shenvy

1. Identify “Data Person” at each institute
   - % Honest ground (if available to put in place)
   - % Personal contact currently in place

2. Clearly documented/communicated/signed off
   “PROCESS”
   Shenvy → Institute → Request → Response
   → Approval

3. Buy in from “Informatics Security”
   - Identify contact
   - Approve process
   - Resource constraint to hire more honest bodies

4. Spin this w/ Capricorn Lingo & Scale
   help w/ data counts return

5. Work w/TIN to improve incoming request
   - ICD10 codes
   - Ready “queries” to run through SAP
Addendum 1 – 30 Day Follow up
Effectively Responding to the Trial Innovation Network (TIN) Requests

Suggestions Proposed by Design Science Team:

1. **Point of Contact at Each of the ITM Institutions**: Establish a point of contact at each institution to route these requests.

**Implementation and Results:**

Since Design Studio on August 8, 2018, Sherry has been working with the Informatics team to establish a point of contact at each institution. Together they have established a Standard Operating Procedure (SOP) for processing TIN requests. She has names at Rush and Loyola to act at the primary point of contact. Sherry pulls the data from U Chicago so a point of contact there is not needed. Contacts are pending at Advocate and Northshore.

2. **Decision tree**: Establish a decision tree at each institution for the point of contact and the bio-informatics point of contact with delegated back up and for the PI to get back to the point of contact if they are interested or not in the proposed study.

**Implementation and Results:**

A decision tree has yet to be established at the 6 ITM institutions. Once point of contacts are established at each institution, a decision tree with be established.

3. **Point of Contact have Access to Informatics**: Giving the point of contact access to informatics will make it easier to pull the data the TIN is requesting and should speed up the process as it won’t have to be routed to informatics.

**Implementation and Results:**

The three institutions where there are point of contacts established, the point of contact has access to informatics. The SOP has been shared with all institutions and with the point of contacts at the 3 institutions. With the contacts having the SOP and access to informatics, the process should run smoothly.
Suggestions Proposed by Quality Science Team:

1. **Identify Data Person at Each ITM Institution**: Carbon copy the honest broker (if possible so that they can expedite request) and carbon copy personal contact currently in place.

   **Implementation and Results:**
   
   Since Design Studio on August 8, 2018, Sherry has been working with the Informatics team to establish a point of contact at each institution. Together they have established a Standard Operating Procedure (SOP) for processing TIN requests. She has names at Rush and Loyola to act at the primary point of contact. Sherry pulls the data from U Chicago so a point of contact there is not needed. Contacts are pending at Advocate and Northshore.

2. **Clearly Document “PROCESS”**: So that all institutions are aware of what needs to be done and submitted, clearly document the process for obtaining the informatics data.

   **Implementation and Results:**
   
   Sherry has been working with the informatics team and they have created a Standard Operating Procedure (SOP) for processing TIN requests. This process is clearly documented and has been shared with all sites.

3. **Buy-in from Informatics**: Identify contacts, approve process and resource constraints to hire more honest brokers. Availability of self-service tools for Sherry (TRIO) to access at each member institute will solve many of the communication problems as well. It eliminates the middle person completely.

   **Implementation and Results:**
   
   Contacts have been identified at 3 of the institutions. Sherry is working closely with the informatics team to identify contacts at the other institutions. Due to budget constraints, hiring more honest brokers at each institution is not feasible. Sherry has access to self-service tools at UChicago.
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Addendum 2- 90 Day Follow up
Effectively Responding to the Trial Innovation Network (TIN) Requests

Solutions Generated by Design Science Team:

1. **Point of Contact at Each of the ITM Institutions**: Establish a point of contact at each institution to route these requests.

   **Implementation and Results:**

   Sherry is working with the informatics team to establish contacts at each ITM institution. Northshore will be providing a contact. We’re still attempting to establish a contact at Advocate.

2. **Decision Tree**: Establish a decision tree at each ITM institution for the point of contact and the bioinformatics point of contact with delegated back up and for the PI to get back to the point of contact if they are interested or not in the proposed study.

   **Implementation and Results:**

   Once contacts are established at each ITM institution, a decision tree will be established.

3. **Point of Contact have Access to Informatics**: Giving the point of contact access to informatics will make it easier to pull the data the TIN is requesting and should speed up the process as it won’t have to be routed to informatics.

   **Implementation and Results:**

   All institutions, where a point of contact has been established, have access to informatics data. The process is running smoothly with the SOP in place and the contacts having access to informatics.

4. **Email Communication**: Email communications need to be more clear as to the deadlines.

   **Implementation and Results:**

   Email communications are clearer; they list a deadline date to the TIN and a date when Sherry would like to have the response.

5. **Educate About the Process**: If points of contacts know the process and what is involved, they may be able to speed up the process.
Implementation and Results:

Sherry is working with the point of contacts to educate them on the TIN and the process.

6. **Follow up Emails/Email Updates/ Newsletters:** Follow up emails to determine the status of the request, email updates as to what is going on with the potential study (was it funded) and a newsletter talking about successful recruitment would be beneficial to the sites.

Implementation and Results:

Follow up emails, newsletters and updates as to the studies have not been established. This will be done as we learn of the funding for the various study requests.

Solutions Generated by Quality Science Team:

1. **Identify Data Person at Each ITM Institution:** Carbon copy the honest broker (if possible so that they can expedite request) and carbon copy personal contact currently in place.

Implementation and Results:

Sherry is working with the informatics team to establish contacts at each ITM institution. Northshore will be providing a contact. We’re still attempting to establish a contact at Advocate.

2. **Clearly Document “PROCESS”:** So that all institutions are aware of what needs to be done and submitted, clearly document the process for obtaining the informatics data.

Implementation and Results:

The process has been clearly documented in an SOP which has been shared with all sites. The process is also documented in the emails sent requesting informatics data.

3. **Buy-in from Informatics:** Identify contacts, approve process and resource constraints to hire more honest brokers. Availability of self-service tools for Sherry (TRIO) to access at each member institution will solve many of the communication problems as well. It eliminates the middle person completely saving time.

Implementation and Results:
Sherry is working with the informatics team to identify contacts. Unfortunately, budget restrictions do not allow for more honest brokers to be hired. Sherry has access to the self-service tools at University of Chicago, therefore, a contact does not have to be established there.

4. **Spin this with CaPRICORN Lingo:** Work with CaPRICORN to see how they set up the informatics requests they receive for studies. CaPRICORN is a well-established program so using it as analogy or as inspiration for communication process is a good idea as well.

**Implementation and Results:**

Sherry met with the CaPRICORN team prior to staff turnover. She has received some good advice from CaPRICORN and will use their ideas to help with the TIN requests.

5. **Work with TIN to Improve Incoming Requests:** Determine when ICD codes need to be included on the request and request these from the TIN.

**Implementation and Results:**

Sherry is working with TIN, sending emails, communicating via telephone and attending the TIN monthly calls to help with the TIN requests to make sure we get what we need to process them.
Addendum 3 - One Year Follow up
Effectively Responding to the Trial Innovation Network (TIN) Requests

Solutions Generated by Design Science Team:

1. **Point of Contact at Each of the ITM Institutions**: Establish a point of contact at each institution to route these requests.

   **Implementation and Results:**
   
   At the one year follow up, Sherry has established a contact at each ITM institution, with the exception of Advocate.

2. **Decision Tree**: Establish a decision tree at each ITM institution for the point of contact and the bioinformatics point of contact with delegated back up and for the PI to get back to the point of contact if they are interested or not in the proposed study.

   **Implementation and Results:**
   
   A decision tree is established at all institutions, with the exception of Advocate.

3. **Point of Contact have Access to Informatics**: Giving the point of contact access to informatics will make it easier to pull the data the TIN is requesting and should speed up the process as it won’t have to be routed to informatics.

   **Implementation and Results:**
   
   All institutions, where a point of contact has been established, have access to informatics data. The process is running smoothly with the SOP in place and the contacts having access to informatics.

4. **Email Communication**: Email communications need to be clearer as to the deadlines.

   **Implementation and Results:**
   
   Email communications are clearer; they list a deadline date to the TIN and a date when Sherry would like to have the response.

5. **Educate About the Process**: If points of contacts know the process and what is involved, they may be able to speed up the process.
Implementation and Results:

Sherry is working with the point of contacts to educate them on the TIN and the process.

6. **Follow up Emails/Email Updates/ Newsletters:** Follow up emails to determine the status of the request, email updates as to what is going on with the potential study (was it funded) and a newsletter talking about successful recruitment would be beneficial to the sites.

Implementation and Results:

Follow up emails and updates are sent as we learn of the funding status for the various study requests.

Solutions Generated by Quality Science Team:

1. **Identify Data Person at Each ITM Institution:** Carbon copy the honest broker (if possible so that they can expedite request) and carbon copy personal contact currently in place.

Implementation and Results:

At the one year follow up, Sherry has established a contact at each ITM institution, with the exception of Advocate.

2. **Clearly Document “PROCESS”:** So that all institutions are aware of what needs to be done and submitted, clearly document the process for obtaining the informatics data.

Implementation and Results:

The process has been clearly documented in an SOP which has been shared with all sites. The process is also documented in the emails sent requesting informatics data.

3. **Buy-in from Informatics:** Identify contacts, approve process and resource constraints to hire more honest brokers. Availability of self-service tools for Sherry (TRIO) to access at each member institution will solve many of the communication problems as well. It eliminates the middle person completely saving time.

Implementation and Results:

Informatics contacts have been established. Budget restrictions do not allow for more honest brokers to be hired. Sherry has access to the self-service tools at University of Chicago, therefore, a contact does not have to be established there.
4. **Spin this with CAPriCORN Lingo:** Work with CAPriCORN to see how they set up the informatics requests they receive for studies. CAPriCORN is a well-established program so using it as analogy or as inspiration for communication process is a good idea as well.

Implementation and Results:

Sherry is using ideas she received from the CAPriCORN team to help with the TIN request.

5. **Work with TIN to Improve Incoming Requests:** Determine when ICD codes need to be included on the request and request these from the TIN.

Implementation and Results:

At the one year follow up, Sherry continues working with TIN, sending emails, communicating via telephone and attending the TIN monthly calls to help with the TIN requests to make sure we get what we need to process them.

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**About the Institute for Translational Medicine (ITM)**

The ITM is a partnership between the University of Chicago and Rush in collaboration with Advocate Health Care, the Illinois Institute of Technology (Illinois Tech), Loyola University Chicago, and NorthShore University HealthSystem that’s fueled by about $35 million in grants from the National Center for Advancing Translational Sciences at the National Institutes of Health through its Clinical and Translational Science Awards (CTSA) Program.

We’re part of a network of more than 55 CTSA Program-supported hubs across the country working to slash the time it takes to develop and share new treatments and health approaches. We work with you and for you to make participating in health research easy, so that together we improve health care for all.

Join the movement and learn more about how we help researchers, physicians, community members, industry, government organizations, and others. Visit us at [chicagoitm.org](http://chicagoitm.org) and connect with us on Facebook, Twitter, Instagram, YouTube, and LinkedIn @ChicagoITM.

**TRIO** is supported by the National Center for Advancing Translational Sciences (NCATS) of the National Institutes of Health (NIH) through Grant Number UL1TR002389 that funds the ITM. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH. Please cite the grant in your publications to ensure **TRIO** can continue helping researchers like you.