TRIO STUDIO: How do we establish a process to complete feasibility assessments for studies at initial contact and throughout the life cycle of project?

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TRIO STUDIO: How do we establish a process to complete feasibility assessments for studies at initial contact and throughout the life cycle of project?

TABLE OF CONTENTS

Topic of Studio: Loyola University’s CRO and its feasibility assessment process .................. 3
Attendees ........................................................................................................................................ 3
Summary ....................................................................................................................................... 3
Top 3 Actions Proposed by the Studio Participants ................................................................. 3
TRIO Studio Problem Description: .......................................................................................... 4
Main problem for the studio participants to solve: ............................................................... 6
Studio Methodology .................................................................................................................. 6

Design Science Method .............................................................................................................. 6
Design Thinking Based Solutions: .............................................................................................. 7
Problem visualized with Insights ............................................................................................... 8
High level insights: ..................................................................................................................... 9

Solutions Generated by Design Science Approach Team: .................................................... 11
Appendix 1 ................................................................................................................................... 13
Appendix 2 ................................................................................................................................... 13
Appendix 3 ................................................................................................................................... 15
Addendum 1 – 30 Day Follow up ............................................................................................... 19
Addendum 2 – 90 Day Follow up ............................................................................................... 20
Addendum 3 – 1 Year Follow up ............................................................................................... 22
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Research Assistants: Divya Jain, Abhignan Sai Godha (IIT ID MDes Students)

Attendees:

Summary
Jessica E. Shore, Loyola University, introduced the process of feasibility assessments for studies at initial contact and throughout life cycle of project. She described how Clinical Research Office (CRO) should ideally be engaged at the beginning of the research project during the proposal stage, when CDA/Site feasibility is not yet complete with industry sponsor. But, this much needed early feasibility assessment does not always occur, especially at the initial contact stage of the project proposal. Jessica asked the studio to focus on ideas that help address the feasibility issues at the initial stage of contact rather than mid-cycle or even later.

Design Thinking approach was used to solve the problems faced by Jessica and her team at Loyola. Many suggestions, based on experiences at different institutions, were made.

Top 3 Actions Proposed by the Studio Participants to Jessica Shore:

1. Audits can go beyond analysis of immediate failure and show the institute’s exposure to risk due to studies that don’t go through CRO

2. Testimonials and Informative advertisement material on multiple platforms – Custom flyers targeted to different adult demographics can help bring a broader participant pool. Video message from the Principal Investigator and reading testimonials from previous study participants can also help engage those interested. Have social networking site advertisements embedded with an influencer will also be a good idea.

3. Give participants a personal report on sleep and food habits – For the participants that are not solely motivated by the monetary incentive, the educational portion of the study and learning something new about themselves can become a more desirable reason to participate. So enable a "sleep" report that can be given to participants along with a thank you note.
TRIO STUDIO: How do we establish a process to complete feasibility assessments for studies at initial contact and throughout the life cycle of project?

TRIO Studio Problem Description:

The goals are to generate ideas to enable CRO at Loyola University to establish a process to complete feasibility assessments for studies at initial contact and throughout the life cycle of project.

Jessica E. Shore from Loyola University, Chicago introduced the problem. The Clinical Research Office (CRO) is a central resource for faculty at the Health Science Campus, providing biostats, biobank, regulatory and study coordination, and budgeting services. CRO should ideally be engaged at the beginning of the research project; at proposal stage when CDA/Site feasibility is being worked out with industry sponsor, but, this does not always occur.

When engaged in the early stages there is time to assess the study and overall fit for the institution. CRO is a central resource, not departmentally based in medicine, surgery, etc. They provide support across entire Health Science Division. Request for services are currently made via REDCap survey. The team being requested will respond and set up time to meet with the faculty member seeking help. CRO works on all projects and the expectation is to be funded on the project for staff effort.

Past Experience has been that there is always a push to get studies up and going quickly, but there is limited time to truly assess if we can make the project successful. This hampers informed decisions being made about feasibility of a study. Request for resources in the middle of project are even harder to address. There can be (or are) regulatory issues, staffing and also complicated changes in study design/conduct middle of project pivots. For instance, CRO picked up a project in the middle of startup, pre-site visit occurred with sponsor, regulatory and contract documents were shared with department months prior to when CRO started to work on study. The hospital was not engaged for feasibility of work flow at the clinical end. Sponsor was eager to get going but CRO ended up being constantly behind on timeline for study activation. Study opened to enrollment but PI lost staff and the study got stuck. The PI, eventually, transitioned the study to the CRO. Consequent issues identified include consent issues, budget is not covering costs, poor enrollment, and the sponsor was not happy. CRO conducted an audit of the study and its issues and made recommendations to the PI and study team. CRO struggled to correct all errors when the study was transitioned over and to get enrollment going in time.

Jessica’s call to action: How can CRO team better assess, at the early stages of the project, how feasible it is at Loyola? Feasibility assessment that includes regulatory, budget, consent, study design changes, and how it was affecting staffing. Also, how can CRO improve processes when they are pulled into the project midstream?

Current problems involve recruiting individuals that fit within the inclusion/exclusion criteria and who are willing to complete the full study. There is a loss of participants at each stage of scrutiny that is affecting overall numbers in terms of throughput.
TRIO STUDIO: How do we establish a process to complete feasibility assessments for studies at initial contact and throughout the life cycle of project?

Figure 1 Jessica E. Shore introducing the problem
TRIO STUDIO: How do we establish a process to complete feasibility assessments for studies at initial contact and throughout the life cycle of project?

Main problem for the studio participants to solve:
How can CRO team better assess, at the early stages of the project, how feasible it is at Loyola? Feasibility assessment that includes regulatory, budget, consent, study design changes, and how it was affecting staffing.

Studio Methodology
Design Thinking approach was used as part of the studio to solve this problem. Santosh, Divya and Abhignan used Design Thinking methods to facilitate the groups ideation session. Final solutions were documented and provided to Jessica E. Shore.

Design Science Method
We used the Design Science 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)
TRIO STUDIO: How do we establish a process to complete feasibility assessments for studies at initial contact and throughout the life cycle of project?

Design Thinking Based Solutions:

Figure 1 Design Thinking Group working on the problem
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Problem visualized with Insights

The group first discussed the problem and its context yielding the following context diagram:

![Mind Map of Issues and Stakeholders](image)

*Figure 3 Mind Map of Issues and Stakeholders*
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High level insights:
Following the context discussions, insights were generated as follows:

Figure 2 Insights into institution’s risks
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Figure 3 Insight into current linear flow
TRIO STUDIO: How do we establish a process to complete feasibility assessments for studies at initial contact and throughout the life cycle of project?

Solutions Generated by Design Science Approach Team:

Six relatively implementable solutions were created to solve the issues of getting a study started. They are as follows:

1. **Audits can go beyond analysis of immediate failure and show the institute’s exposure to risk due to studies that don’t go through CRO**: Collect data from various sources on past study failures and the risk institute was exposed to by the PI and study design without CRO help. Analyze and give insights to the P.I./Resident/Institution. Quantify the results in terms of risk, lost time, lost funding, lost revenues, lost opportunities in doing other studies etc. Either the CRO or department chair has to accept the cost and risk associated with failure.

2. **Take the risk of failure and show why studies fail when CRO doesn’t help**: Do not help studies that come too late to CRO. Let them fail and make a case of why they should have come to CRO for help at the beginning of the process. Don’t be mean but make a point about things that cannot be helped when it’s too late.

3. **CRO based Training for people writing proposals**: Require a training program with the CRO before being eligible for help. Implement the CRO as a part of the training process. All decisions to be CRO first and faculty exceptions come later.

4. **Amend Redcap to ensure CRO is brought to attention of proposal writer**: Redcap survey amendments to include a checkmark question on whether “The CRO has been consulted”. Mandatory checkboxes will work to help the study and identify red flags earlier in the process for smooth study. Study needs help/service can be another check box. Yes, will mean CRO can be flagged as a resource.

5. **Incentives**: Early contact with CRO in proposal writing should get the PI/Resident some discount or voucher of service. Something like “Your first study is on us” would also be worthwhile to try to introduce CRO services to all the faculty PIs and Residents.

6. **Educate the institute about CRO through regular updates and short videos of endorsements**: Follow up Emails/Email Updates/Newsletters/ Flyers around the institute will all be useful. Email updates as to what is going on with the potential study (was it funded or has begun enrollment) and a newsletter talking about successful recruitment would be beneficial to know about. Video recommendations / endorsements by people who have used the CRO services could also be developed and used in communications and on website. Keep the videos short – 1 minute videos to keep them exciting and easy to consume.
TRIO STUDIO: How do we establish a process to complete feasibility assessments for studies at initial contact and throughout the life cycle of project?

1. Analyze past failures and show the Risk for Institute
   - Collect data from various sources
   - Analyze past study failures
   - Give Insights to the P.I./Resident/Institute
   - Quantify the results

2. Take the risk of Failure
   - Either the CRO or department chair has to accept the cost and risk associated with failure

3. Training to help CRO
   - Require a training program with the CRO before being eligible to help the CRO
   - Implement the CRO as a part of the training process
   - All decisions to be CRO first, faculty exceptions come later.

4. Redcap survey amendments
   - Mandatory checkboxes to help the study and identify red flags earlier in the process for smooth study.
     - The CRO has been consulted
     - Study needs help/service

5. Incentives
   - Come early to the CRO and get a discount!
   - First Study is on us!

6. Regular Updates
   - Regular Updates
   - Regular Reports
   - 1 minute testimonial videos

Figure 4 Ideas and Solutions after discussion of ideas

<End of Document. Thank you.>
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Appendix 1.
Slides used by Jessica E. Shore, Loyola University Chicago.

Appendix 2.
Studio session pictures
TRIO STUDIO: How do we establish a process to complete feasibility assessments for studies at initial contact and throughout the life cycle of project?
TRIO STUDIO: How do we establish a process to complete feasibility assessments for studies at initial contact and throughout the life cycle of project?

Appendix 3.
Actual pictures of white board from the studio session.
TRIO STUDIO: How do we establish a process to complete feasibility assessments for studies at initial contact and throughout the life cycle of project?
TRIO STUDIO: How do we establish a process to complete feasibility assessments for studies at initial contact and throughout the life cycle of project?
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Addendum 1 – 30 Day Follow up
Suggestions Proposed by Studio Participants:

1. **Audits can go beyond analysis of immediate failure and show the institute’s exposure to risk due to studies that don’t go through CRO:** Collect data from various sources on past study failures and the risk institute was exposed to by the PI and study design without CRO help. Analyze and give insights to the P.I./Resident/Institution. Quantify the results in terms of risk, lost time, lost funding, lost revenues, lost opportunities in doing other studies etc. Either the CRO or department chair has to accept the cost and risk associated with failure.

   **Implementation and Results:**

   Since TRIO Design Studio on September 12, 2018, Jessica and her team are reviewing all studies within the past 2 years that fits the audit criteria. Jessica will discuss with her team, in a staff meeting, what they will audit within that criteria/area.

2. **Take the risk of failure and show why studies fail when CRO doesn’t help:** Do not help studies that come too late to CRO. Let them fail and make a case of why they should have come to CRO for help at the beginning of the process. Don’t be mean but make a point about things that cannot be helped when it’s too late.

   **Implementation and Results:**

   Jessica and her team are currently looking at all studies as to what has been successful and what hasn’t. This review will make it easier to determine what they can do as far as feasibility. Cardiology and thoracic surgery recently came in to the CRO group. The CRO teams’ workload is increasing, and they are bringing in 5 new research nurses to their group to assist with the feasibility and workload. They are also reviewing cardiology and thoracic surgery studies for feasibility.

3. **CRO based Training for people writing proposals:** Require a training program with the CRO before being eligible for help. Implement the CRO as a part of the training process. All decisions to be CRO first and faculty exceptions come later.

   **Implementation and Results:**

   Jessica and her team are currently re-evaluating the training process. Loyola University Health System Division has a Clinical Research Forum scheduled in January and will attempt to incorporate the CRO training to the forum.
Addendum 2 – 90 Day Follow up
Suggestions Proposed by Studio Participants:

1. **Audits can go beyond analysis of immediate failure and show the institute’s exposure to risk due to studies that don’t go through CRO:** Collect data from various sources on past study failures and the risk institute was exposed to by the PI and study design without CRO help. Analyze and give insights to the P.I./Resident/Institution. Quantify the results in terms of risk, lost time, lost funding, lost revenues, lost opportunities in doing other studies etc. Either the CRO or department chair has to accept the cost and risk associated with failure.

   **Implementation and Results:**

   Since the 30-day follow up, Jessica and her team have performed audits to determine any risks, lost time, lost funding or lost opportunities with doing the study without CRO support. They are also looking at studies being started by investigators and then transferred to CRO. They have compared numbers with quantify results. Jessica and her team are also looking at studies not enrolling to determine what the CRO can assist with to increase enrollment or close the studies.

2. **Take the risk of failure and show why studies fail when CRO doesn’t help:** Do not help studies that come too late to CRO. Let them fail and make a case of why they should have come to CRO for help at the beginning of the process. Don’t be mean but make a point about things that cannot be helped when it’s too late.

   **Implementation and Results:**

   Since the 30-day follow up, there is a new CRO Advisory Council being established. They will look at risks involved in not involving CRO. They have also determined that any study regulated by FDA needs full-time support from PIs, not just students.

3. **CRO based Training for people writing proposals:** Require a training program with the CRO before being eligible for help. Implement the CRO as a part of the training process. All decisions to be CRO first and faculty exceptions come later.

   **Implementation and Results:**

   Jessica and her team conducted a Clinical Research Forum on 1/23/19 which provided training on FDA regulated research. A PI from the Cancer Center provided a training session.

4. **Amend Redcap to ensure CRO is brought to attention of proposal writer:** Redcap survey amendments to include a checkmark question on whether “The CRO has been consulted”. Mandatory checkboxes
TRIO STUDIO: How do we establish a process to complete feasibility assessments for studies at initial contact and throughout the life cycle of project?

will work to help the study and identify red flags earlier in the process for smooth study. Study needs help/service can be another check box. Yes, will mean CRO can be flagged as a resource.

Implementation and Results:

Jessica and her team are looking at updating the IRB submission as opposed to the Redcap. This will make it easier to catch the study at time of submission prior to the investigators starting the study.

5. **Incentives:** Early contact with CRO in proposal writing should get the PI/Resident some discount or voucher of service. Something like “Your first study is on us” would also be worthwhile to try to introduce CRO services to all the faculty PIs and Residents.

Implementation and Results:

The CRO currently offers 1-2 hours of free statistical support and regulatory consultations are offered for no charge. Block rates for services are also being established.

6. **Educate the institute about CRO through regular updates and short videos of endorsements:** Follow up Emails/Email Updates/Newsletters/ Flyers around the institute will all be useful. Email updates as to what is going on with the potential study (was it funded or has begun enrollment) and a newsletter talking about successful recruitment would be beneficial to know about. Video recommendations / endorsements by people who have used the CRO services could also be developed and used in communications and on website. Keep the videos short – 1 minute videos to keep them exciting and easy to consume.

Implementation and Results:

Jessica and her team used the Research Forum to educate research teams on the CRO. They have also established a clinical research listserv to update researchers and their team. Regular listserv emails are sent to investigators and their teams with updates and changes.
TRIO STUDIO: How do we establish a process to complete feasibility assessments for studies at initial contact and throughout the life cycle of project?

Addendum 3 – 1 Year Follow up
Suggestions Proposed by Studio Participants:

1. **Audits can go beyond analysis of immediate failure and show the institute’s exposure to risk due to studies that don’t go through CRO:** Collect data from various sources on past study failures and the risk institute was exposed to by the PI and study design without CRO help. Analyze and give insights to the P.I./Resident/Institution. Quantify the results in terms of risk, lost time, lost funding, lost revenues, lost opportunities in doing other studies etc. Either the CRO or department chair has to accept the cost and risk associated with failure.

Implementation and Results:

Since the 90-day follow-up, Jessica and her team do feasibility assessments on any new study to the CRO. Feasibility assessments done on a monthly basis with all team members including the PI, CRO, nurses, research coordinators, budget and contracts to make sure the study can be done and to identify the problems up front to see if there are any concerns.

**Take the risk of failure and show why studies fail when CRO doesn’t help:** Do not help studies that come too late to CRO. Let them fail and make a case of why they should have come to CRO for help at the beginning of the process. Don’t be mean but make a point about things that cannot be helped when it’s too late.

Implementation and Results:

Jessica and her team in the CRO don’t let studies fail, especially if there are patients on study. They do pause to do an assessment if there are additional risks to patients or problems with the study.

2. **CRO based Training for people writing proposals:** Require a training program with the CRO before being eligible for help. Implement the CRO as a part of the training process. All decisions to be CRO first and faculty exceptions come later.

Implementation and Results:

Since the 90-day follow-up, Jessica attends all new faculty orientations to train and the Vice-Dean for Research in the School of Medicine has taken on the PI training.

3. **Amend Redcap to ensure CRO is brought to attention of proposal writer:** Redcap survey amendments to include a checkmark question on whether “The CRO has been consulted”. Mandatory checkboxes will work to help the study and identify red flags earlier in the process for smooth study. Study needs help/service can be another check box. Yes, will mean CRO can be flagged as a resource.
Implementation and Results:

IRB outreach coordinator alerts the CRO of new studies and amendments that need CRO help.

4. **Incentives:** Early contact with CRO in proposal writing should get the PI/Resident some discount or voucher of service. Something like “Your first study is on us” would also be worthwhile to try to introduce CRO services to all the faculty PIs and Residents.

Implementation and Results:

The CRO does not offer incentives for using their services.

5. **Educate the institute about CRO through regular updates and short videos of endorsements:** Follow up Emails/Email Updates/Newsletters/Flyers around the institute will all be useful. Email updates as to what is going on with the potential study (was it funded or has begun enrollment) and a newsletter talking about successful recruitment would be beneficial to know about. Video recommendations/endorsements by people who have used the CRO services could also be developed and used in communications and on website. Keep the videos short – 1 minute videos to keep them exciting and easy to consume.

Implementation and Results:

Jessica and her team participate in clinical research grand rounds and research forums to educate various departments on the CRO and how to engage them.
TRIO STUDIO: How do we establish a process to complete feasibility assessments for studies at initial contact and throughout the life cycle of project?

**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.

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