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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by Jessica E. Shore PHD RN
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Facilitator: Santosh Basapur, IIT Institute of Design

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:

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. Educate the institution about CRO through regular updates, newsletters/flyers and short videos of endorsements
3. Amend Redcap survey 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”. This will bring CRO to the attention of proposal writers
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 start up, 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?
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Figure 1 Jessica E. Shore introducing the problem
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 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)
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Design Thinking Based Solutions:

Figure 2 Design Thinking Group working on the problem
Problem visualized with Insights
The group first discussed the problem and its context yielding the following context diagram as well as the stakeholder map:

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

- Studies are left Midstream
  - Red Flags are raised very late in the process
  - Even after having capable individuals, sometimes the budgeting issues are coming back work hand-off isn’t happening
  - PI is overworked/overwhelmed
  - There are no Research Administrators in clinical departments at Loyola
  - Feasibility study is not done correctly

- Faculty has enormous freedom but the risk is institutional
  - Training Resources aren’t available for every resident/junior faculty
  - Nobody has the expertise to approve the study except for the CRO
  - IRB is critical in addition to being difficult to understand since it doesn’t allow hands-on experience
  - Office of General Council takes care of assessment instead of Contract Office
  - Cost of failure is not appreciated

Figure 4 Insights into institution’s risks
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![Current Process Diagram]

- Outreach/Awareness is done
- Faculty signs the NDA
- IRB Approval is gained
- Resident is appointed
- Budget is approved
- Study is not conducted appropriately
- Lack of enough Resources
- Budget is not negotiated correctly
- Subjects are on drugs sometimes

Figure 5 Insight into current linear flow
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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. **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.
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<table>
<thead>
<tr>
<th>SOLUTIONS</th>
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<tbody>
<tr>
<td><strong>1. Analyze past failures and show the Risk for Institute</strong></td>
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<tr>
<td>Collect data from various sources</td>
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<td>Give Insights to the PI/Resident/Institute</td>
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<td>Quantify the results</td>
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<tr>
<td><strong>4. Redcap survey amendments</strong></td>
</tr>
<tr>
<td>Mandatory checkboxes to help the study and identify red flags earlier in the process for smooth study.</td>
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<tr>
<td>✓ The CRO has been consulted</td>
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<tr>
<td>✓ Study needs help/service</td>
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<tr>
<td><strong>5. Incentives</strong></td>
</tr>
<tr>
<td>Come early to the CRO and get a discount!</td>
</tr>
<tr>
<td>First Study is on us!</td>
</tr>
<tr>
<td><strong>6. Regular Updates</strong></td>
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<td>Regular Updates</td>
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<td>1 minute testimonial videos</td>
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Figure 6 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
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Appendix 3.
Actual pictures of white board from the studio session.
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