
ITHS
Institute of Translational Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.
NED 2020
Networking to Enhance Development
A Conference By and For Research Coordinators
iths.org/ned2020

Ensure a Successful Trial: Things to Think About When Establishing Timeline and Feasibility Assessments for your PI and Research Team

Lara B. Schiff, MPH
University of Washington

Scenarios

Has this happened to you?

Learning Objectives

1. Summarize key study start-up components and institutional/clinical involvement for feasibility considerations
2. Identify two considerations when communicating study timelines, needs and expectations to the study PI, research team and service areas
3. Determine two areas in which common unanticipated errors are made and the actions for addressing these errors

Component 1: Study Start-Up Considerations

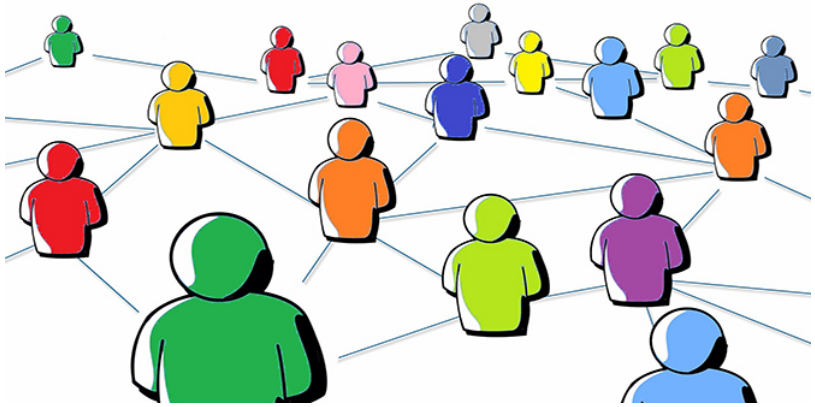
Brainstorm

- Who will be involved in the research and implementation of the study?
- Where will study activities occur?
- Which internal and external reviews do I need?

Component 2: Identify Stakeholders

Brainstorm

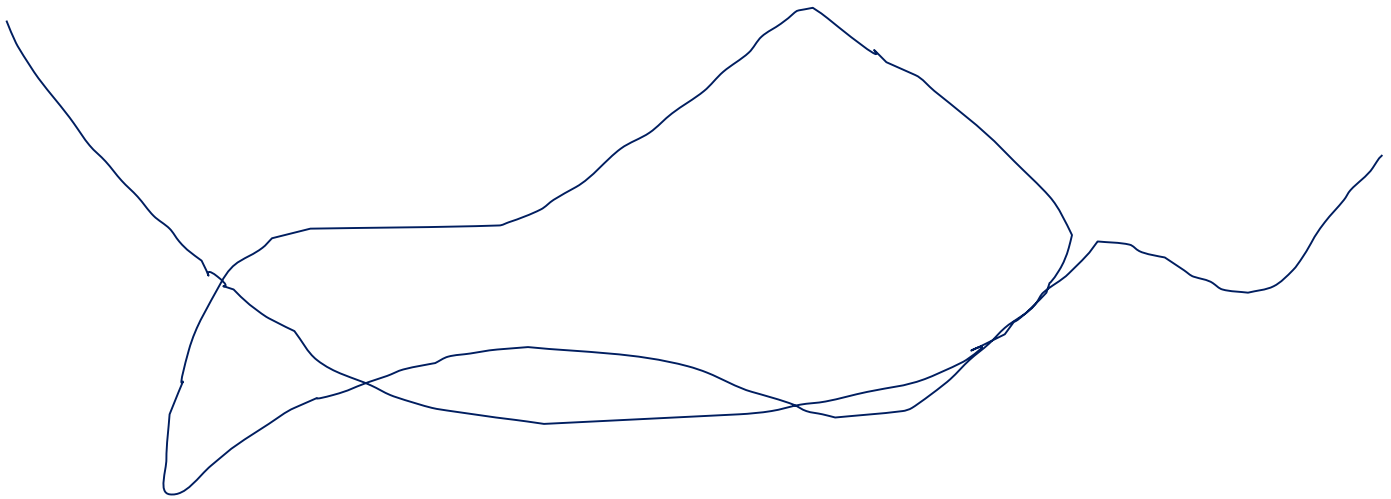
- Which internal departments/service areas do I work with?
- Who are the external groups/agencies that I will work with?



One Approach to Organizing

Sponsor/ Study	Regulatory	UW OSP	sRAMP	CTO/CRBB	Actions
-Pfizer, CRO Syneos (study #)	-UW HSD in review -ICF will be sent to Sponsor next -WIRB next	-Contract at OSP for review with CRO	-Budget negotiation stage	-MCA and pricing done	-Budget with Sponsor final review -Need to set-up RTS pricing -Sponsor to address remaining questions

Nonlinear Process



Feasibility

Determine

- Determine what is feasible
- Define what is not feasible
- Assess the different feasibility considerations or problems/issues

Tool to Examine Feasibility

UWXXXXX: Sponsor, Study Short Name, Group Short Name

PI Questions:

- How many patients do you think you will enroll over 12 months? -PI (8/5/18): 5, usually see this many or more in a year with indication
- How many cycles of treatment do you think most of these patients will complete? -PI (8/5/18): 10 cycles

Team questions:

- Dose based off BSA, if ±10% change in weight from BSA, patient dose will be recalculated (section 5.2.4.). Does this work for clinic? -IDS (8/30/18): Yes, document on PPO's
- Note -HCV and HBV collected at screening in research kit…add to HIPAA form? -Regulatory (8/10/18): Yes

Sponsor questions:

- Local ECG machine does not calculate QTcF, can site use QTcF online calculator?
- Duration of enrollment? Was originally informed enrollment would be 24 months. Per protocol (page 5) enrollment is 12 months. ? -Sponsor (9/5/18): The protocol, during feasibility and site ID was confirmed to be enrollment of >12 mos. We expect approximately 24mos overall

Budgeting clarification items:

1. Should we make the "Tissue Screening Cohort 1" invoiceable? Not all patients will fall under this cohort. -Sponsor (9/5/18): Yes, should be invoiceable.
2. Clarification on optional biopsy day, when does this apply? What type of biopsy performed/location? *Pending…*

Things to Consider When Establishing and Communicating Timelines

- Do you know what the expected timeline is?
- Do you know the timelines for the internal and external reviews?
- From your experience and workload, what is a reasonable timeline?

Example for Communicating Timelines

Where the study is currently	"I sent the Sponsor the initial budget on 11/05/19 and I received comments yesterday [11/11/19]. Will send the budget back with my edits by end of this week."
Expected timeline:	"With the Thanksgiving holiday, I expect to hear back within the next 2-3 weeks. If the budget is accepted, we can start to look for dates in early January to open the study."
Acknowledge timeline changes and re-establish expectations:	**"**This is later than the mid-December date you were anticipating, but with the holidays coming up and pharmacy not having availability in December, early January is more feasible." What do you think?

Steps to Communication of Study Needs/Setting Expectations

DEFINE: Need/Expectation

RESEARCH: Next Steps

SHARE: Need/Expectation and Next Steps

FOLLOW-UP

Example

Lara was informed that a study Sponsor is allowing local mutation testing for eligibility. However, Sponsor does not define the specific type of testing needed. Lara has almost completed her budget negotiation, and this new requirement may delay opening the study. PI expected this study would be open in a month.

Steps:

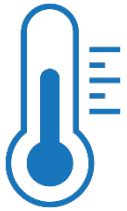
- Share with PI and research team new local testing requirement (SHARE)
- Contact local genetic testing group (RESEARCH)
- Determine timelines for setting-up local testing and having regulatory review (DEFINE)
- Share what you learned with PI and research team (SHARE)
- Communicate local testing method with Sponsor for approval (RESEARCH)
- Share status updates with the PI and research team (FOLLOW-UP)

Group Error/Problem Solving Activity

When research is needed	*Temperature excursion policy example*
Setting manageable expectations	*The CRO with a short study start-up timeline example*

Group Problem Solving Activity: When Research is Needed

Temperature excursion policy example



You are three weeks from the SIV for an investigational oral drug study, and the CRO shares the study specific temperature excursion form with you. Per CRO, all sites are to report temperature excursion on the study specific form. Per your local pharmacy policy, which Sponsor already approved, the pharmacy does not complete study specific temperature excursion forms. Pharmacy has a general excursion form that is used for all studies if a temperature excursion occurs. Pharmacy will not agree to complete the study specific form and refers to the local pharmacy policy already approved by Sponsor. You never asked about any study specific forms ahead of time and now the SIV is approaching, patients are waiting, and the pressure is on.

Group Problem Solving Activity: Setting Manageable Expectations

The CRO with a short study start-up timeline example

You just got a new study to start-up and you are informed by the CRO that the Sponsor wants the study up and running within 4 months at your site. The PI and research team are under the impression that this study can be opened in 4 months. A month into start-up, a new start-up portal is implemented at your site and you now need to have this study reviewed through this portal. You knew this portal was coming, but you did not give it much thought. You do not know now if it is reasonable to assume that you can get the study open in the 4-month period.

Any Other Examples?

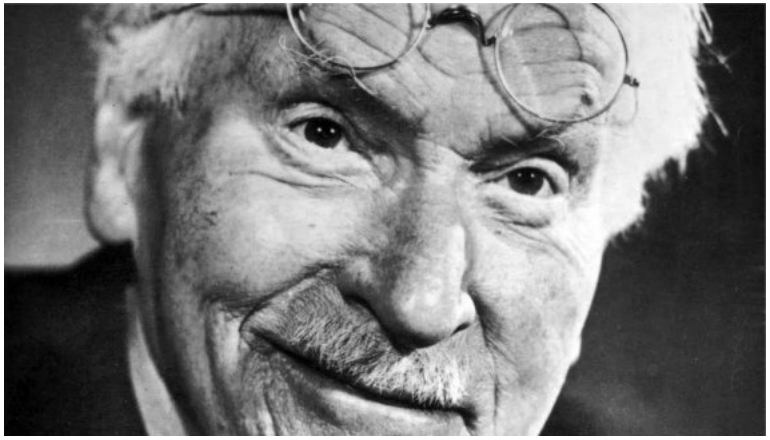
Any other examples of when errors were made during start-up you would like to share?

In Summary

- Do your research
- Identify internal and external reviews/stakeholders
- Identify/define the study feasibility, timelines, needs and expectations
- Communicate barriers and/or resource needs
- Follow-up and keep everyone in the loop

Most importantly: Find others doing similar work and share ideas/experiences

"Knowledge rests not upon truth alone, but upon error also."



- Carl Jung

Questions?

Thank You

Contact: Lara Schiff @ schiffl2@uw.edu


ITHS
Institute of Translational Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.
NED 2020
Networking to Enhance Development
A Conference By and For Research Coordinators
iths.org/ned2020