

# Project Management in Clinical Research: Putting Out Fires and Starting Fires

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## FIRES - WHEN EVERYTHING IS A PRIORITY, NOTHING IS A PRIORITY

### Putting Out Fires

- Adaptable to changing priorities – sometimes day to day
- Adapting overall planning schedule for things that take longer than expected
- Focusing on on-fire issues while continuing normal work

### Starting Fires

- Recognizing when things are taking too long or are stuck
- Motivating others to focus on something
- Communicating when things are stuck
- Knowing when you can't handle the thing and who to bring in



As we go through the presentation -  
What are things that can help you navigate the forest fire that our jobs sometimes feels like?

Think about your daily work -  
What could you practice or implement to streamline or improve on current processes?

## PROJECT MANAGEMENT IN RESEARCH –

### DEFINING OUR SCOPE AND PERSPECTIVE

#### What is a project?

- Is it a study? Or is it a part of the study?
- What about projects that aren't studies? Systems change, new tech or platforms, process improvements?
- *For this presentation - a project is a study (development through analysis and publishing)*

#### Does it matter what type of study?

- Industry sponsor, external investigator-initiated multi-site study, internal study?
- Drug intervention, observational, chart review?
- *For this presentation - much of the discussion will focus on interventional studies but can be applied in part to any other study*

#### So, given those two things, what are you managing? What aren't you managing?

- Managing people
  - ✓ Direct reports or not, investigators, team members, monitors, sponsor contacts, lead teams, review groups, etc
- Managing processes
  - ✓ Feasibility, initiation, sponsor communications, required submissions and reviews, close-out, reporting, etc
- Not managing participants
  - ✓ Not screening, not recruiting, not consent, not enrolling (*probably – might still have to work as backup*)

## STORY TIME - OURS AND YOURS

*Sara and Rana tell their story about project management*

What qualities does a successful project manager have?

What have you seen in others or in yourself?

What does project management mean to you?

Does your work even have project managers or are coordinators doing this type of work?

**CHAT STORM**

# PROJECT MANAGEMENT - ESSENTIAL TRAITS

## SOFT SKILLS VS HARD SKILLS - ALL THAT USEFUL AS A TERM?

**Soft skills** - those that come naturally and uniquely to everyone. Personal qualities. Developed through experience.

**Hard skills** - those that can be gained through training or education. Competencies and abilities. Technical skills. Often include software ability or using specific methodologies or theories.

### LET'S JUST CALL THEM ESSENTIAL TRAITS

Some obvious overlap between these types of skills - sometimes no strong agreement about which “things” fit into which category. Some individuals will naturally excel at one trait but another person might need guidance and mentorship to become excellent at that same trait. These traits also complement and build off of each other.



Team management and effective communication



Time management, adaptable prioritization, setting and meeting deadlines



Task management, delegation, and understanding details and overall plan

## ESSENTIAL TRAITS AND ABILITIES

- ★ Communication
- ★ Leadership
- ★ Adaptability
- ★ Institutional Awareness
- ★ Time management
- ★ Organization
- ★ Confidence
- ★ Trustworthy
- ★ Proactive Approach
- ★ Expertise in Functional Area (?)



When we go into breakout rooms later, let's think about these traits. How could these help you navigate pain points or challenges?

## ESSENTIAL TRAITS AND ABILITIES - FOR REFERENCE ONLY

Communication: See specific slide

Leadership: See specific slide.

Adaptability: able to pivot to different priorities and able to pivot back - to understand on sometimes a daily basis, which different fire is burning the hottest. But also able to be adaptable to different and specific needs on studies - same needs but might each sponsor might want something in a very specific way. Understand when to provide them in that specific way but also able to push back and say no, this is how we do it.

Institutional awareness: understand where to go for questions and answers, understand which processes at the institution might be pain points or even easy wins, and also in which order to do things.

Time management: I think this is more specifically about you - about you managing your own time. But is also about understanding how long things take and being able to set deadlines that are realistic. You need to understand your role - how long you take to do things, how long the thing actually takes, and how long somebody else might take to get something done. And how do you manage ongoing needs with those things that seem to crop up every day - don't overschedule yourself with projects or meetings that you aren't able to deal with hot items.

Organization: this is a forest and trees skill - you have to be able to organize a team and the project into a set of steps but also yourself. Need to understand that what works for you may not work for others on your team. Shared calendars or shared process maps - do you have access to any online system that allows you to collaboratively work?

Confidence: Confidence is about knowing your job but also knowing how to say I don't know but I can find out. It's about what you project but also about how others view you. Are they confident in your ability? Are they confident that you are handling the thing you said you would handle? I'm also putting the "cool under pressure" in this category - able to handle difficult situations and conversations. Projecting confidence even when things might be chaotic or challenging, understanding what your stress triggers are. Maybe you're unfazed by deadlines, but you find it hard to say no to people in the moment. Understanding your personal pressure points will help you to be more aware of them going forward, so you can plan ahead and make better decisions

Trustworthy: don't make promises you can't keep. Understand that when you say you will do something, then you need to do it - and people will trust you more if you provide updates while you are working on that project, especially if you aren't going to hit your deadline. Being trustworthy is also about people being able to trust your answers, that you clearly state when you don't know the answer but can find out, don't guess at answers. But you need to follow-up with the person you said I don't know, with the answer. No point in saying "I can find out" if you aren't going to tell them what you find out - and make sure that you do follow up right away. If it seems like it will take longer than a day or two with the answer - tell the person that.

Proactive Approach: Proactive means not just knowing all of the steps but being able to anticipate the parts where things might go sideways and set up processes ahead of problems. It's submitting the things that take the longest or that other things depend on first. It's knowing to CC that manager when you submit something to that group. It's building your project to succeed from the beginning. Being proactive is really about efficiency.

Expertise: This is a tricky one - is this actually a "hard skill"? Lots of material online talk about having expertise and job postings certainly ask for experience in the disease group or human subjects. But I want to push back against that a little - Do you need to know that lymphoma is treated with a specific drug regimen or the progression of heart disease in women? What about research expertise? Do you need to be able to cite from memory pieces of the Common Rule? Do you know without looking your institution's policy on Consent Waivers? I would argue that your expertise has to be in what is essentially googling - can you find the answer? Do you have a strong understandings of the basics of research?

## ESSENTIAL TRAITS - COMMUNICATION

### Project Manager is the Communication Hub for all stakeholders

- Investigators
- Coordinators or others on the research team
- Sponsors
- Funders
- Monitors
- IRB and Institutional Approval Groups
- Data Management Staff
- FDA or other regulators
- *Who else could want something from you?*

Because you will be communicating with people at all levels and needs – consistently tailor your communication style and content to your audience

*“Project Management is a shift away from execution to instead how you are communicating. It goes from being about getting the work done to communicating effectively about what work needs to be done.”*

## COMMUNICATION - TWO KEY STEPS

### *Email - The Subtle Art of Being Obnoxious – Tailoring Your Obnoxiousness*

- When to send emails and how often
- When to CC a manager or supervisor (yours or theirs)
- Always think of the audience - how do they need that email written or sent

### *Meetings – Planning, Leading, Following Up*

- Knowing how to set agenda
- Sticking to agendas but also being able to go completely off-agenda if something comes up
- Providing that agenda ahead of time, providing notes or follow up steps afterwards
- Keeping everybody informed
- Discuss and share challenges and successes

## REMOTE OR HYBRID WORKING AND COMMUNICATION

*What does communication look like remotely?*

*How do you stay connected if you don't ever see anybody?*

### BE INTENTIONAL WITH CONNECTIONS AND YOUR TEAM

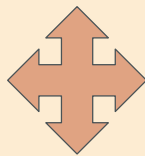
Save space for personal connections and sharing when it makes sense to do so. Some research groups may want to schedule monthly "coffee talks" or some dedicated non-work time.

Implement plan for using chat vs phone calls vs emails - do you have a chat system at work that you are allowed to use?

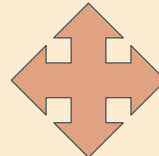
Make an effort when on campus to connect in person - within reason! Don't interrupt people while they are working.

## ESSENTIAL TRAITS - LEADERSHIP

*Project managers usually have no formal authority but they are often responsible for the overall success of the project.*



***Managing up and down***



- ★ *Learning other's management, leadership, and communication styles and preferences.*
- ★ *Make an effort to understand what others need from you and the ways they need it.*
- ★ *Using the essential traits to bring out the best in somebody.*

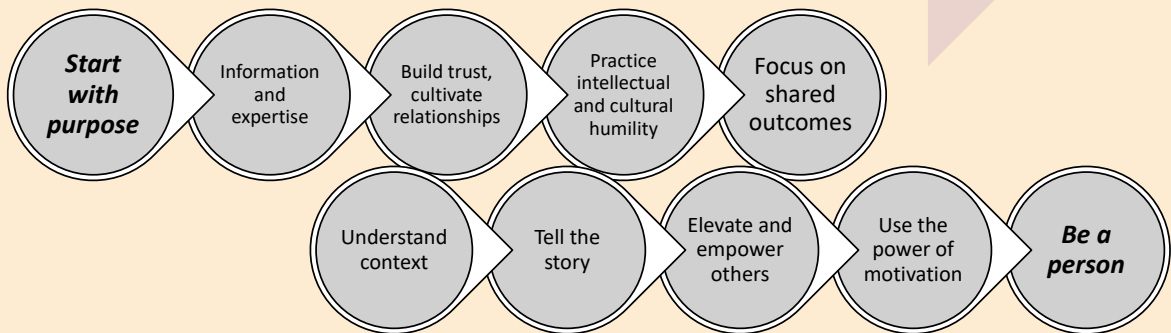
## LEADING WITHOUT AUTHORITY – YOUR SPHERE OF INFLUENCE

Most of us don't have actual "power", we aren't in management or leadership positions with the ability to drive culture change or have direct reports that we can actively mentor. We don't have any actual ability to make people do things.

So, how do we lead without actual power?

Influencing Without Authority

Indirect or intangible levers of influence



## LEADERSHIP BUILDING BLOCKS (OR AT LEAST TWO OF THEM)

### Trustworthiness

*Belief in abilities, integrity, and character of a person*

- Transparency
  - Share updates and info openly, candidly, regularly
- Authenticity
  - Show vulnerability and know who you are
- Reliability
  - Follow through on commitments, establish expertise

### Confident Humility

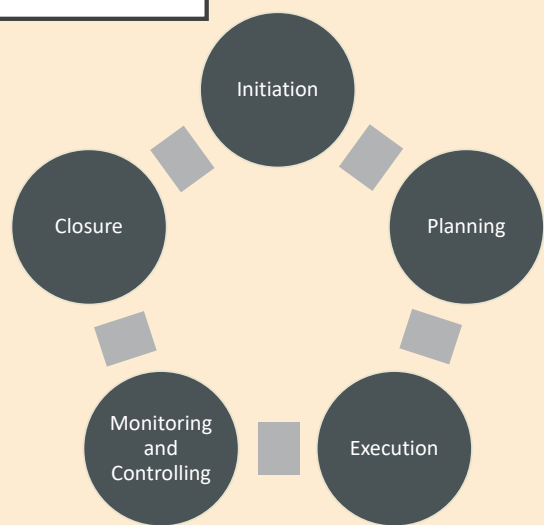
- Confidence in your abilities while showing humility to doubt your knowledge and your methods - understanding that others might have the solution or be better able to address a situation.
- Ask the questions you need to ask, admit without apology what you don't understand, and do the work to learn what you need to learn as quickly as you can.

- ★ Supports the strong communication and sense of well-being needed for a team to function effectively
- ★ Increases productivity and morale, creates a culture of teamwork and respect

## PROJECT MANAGEMENT CYCLE IN CLINICAL RESEARCH

### PROJECT MANAGEMENT CYCLE

The discipline of project management is gaining popularity and importance in all major industries, including clinical research!





## PROJECT INITIATION

Define the project at a broad level

Stakeholders–Investigator/Industry

Goals

Objectives

Timeline

Funding

Often within the Grant Proposal

High level feasibility determination



## PROJECT PLANNING

Overall Project Plan

→ Can occur at the study or site level depending on the project

Manual

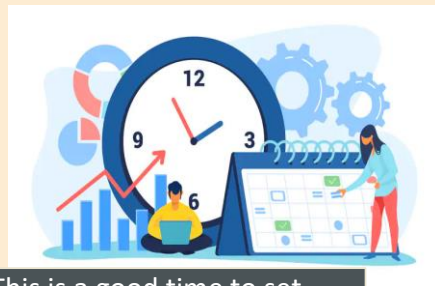
Communication Plan

Local stakeholders

Recruitment Plan

Initial IRB submission

Web-based platforms



Hint: This is a good time to set (reasonable) expectations

## PROJECT EXECUTION

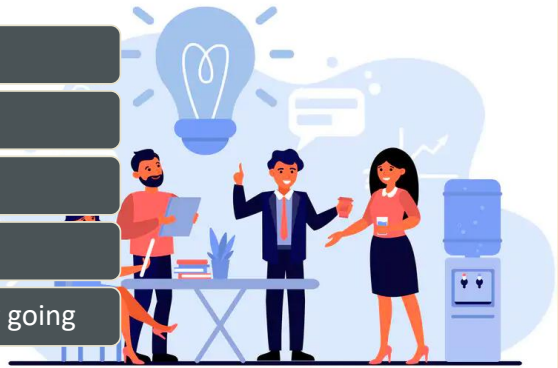
Open the study and establish workflow

Provide guidance and internal monitoring

Keep an eye on enrollment

Communicate with stakeholders regularly

Provide coverage your team to keep the study going



## PROJECT MONITORING & CONTROL

Occurs simultaneously with Project Execution

Reporting to oversight committees

Data monitoring and quality

Fixing problems with execution

→ Amendments

→ Changes to workflow

Check on Budgets & Timelines



## PROJECT CLOSURE

Site closure / Study closure

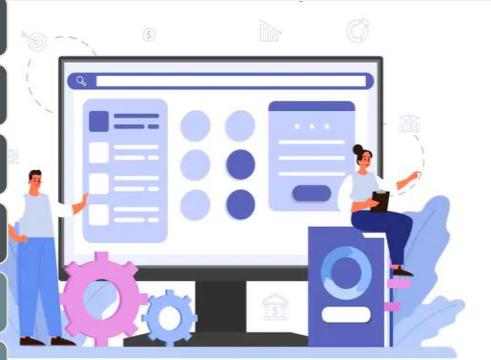
IRB closure

Data management

Publication or FDA approval

Reflect on outcomes – how did we do?

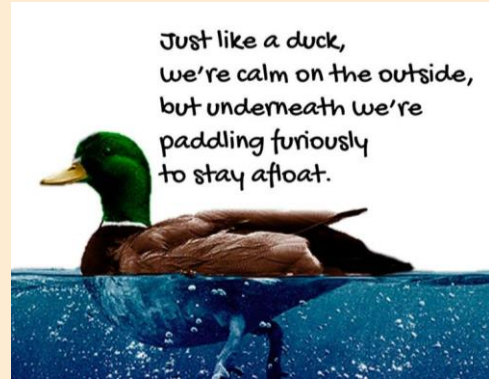
Plan future projects – would we do this again?



## PAIN POINTS AND ESSENTIAL TRAITS -- BREAKOUT ROOMS --

## PAIN POINTS IN PROJECT MANAGEMENT

- Research is HARD—and sometimes it's HARDER
- All projects have pain points
- How do you cope using essential traits?
  - Communication
  - Adaptability
  - Leadership
- Prior experience allows you to anticipate some problems and avoid them, but not all problems can be anticipated
- Don't panic—lead by example and your team will respond



**Paddling furiously =  
Using Essential Traits and Prior Experience**

## BREAKOUT ROOM - USING ESSENTIAL TRAITS WITH PAIN POINTS

### Directions and Expectations

- 10 minute discussion in breakout room
- 3-5 minute discussion in large room
- Discuss these pain points or identify and discuss others
- Focus on how you can use Essential Traits to anticipate / manage / prevent / cope with these pain points
- Focus on things that are Project Management tasks or activities and not activities that are coordinator-specific tasks (those that are directly participant-facing)
- Assumptions about the study are okay to make

### Pain Points

- Sponsor-related
- Investigator-related
- Study-related
- Institution-related
- Internal-related

### Scenario/Study

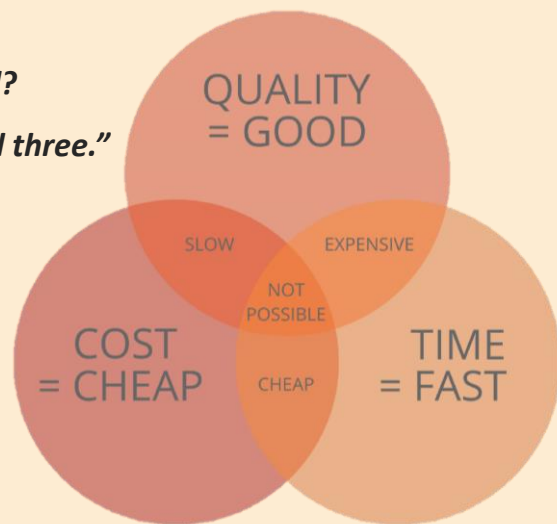
- Business-Industry sponsored study
- Phase 3, FDA-regulated (IND), randomized clinical trial - Drug ZYA45 vs SoC
- Colon cancer - Stage 1-3 only. No metastatic or Stage 4. Life expectancy greater than 12 weeks as determined by treating clinician.
- Screening run-in for safety and scans - 30 days, if eligible moves onto intervention period.
- Intervention is until disease progression
  - SoC according to treating clinician
  - Drug ZYA45 is daily infusion for 3 days, once weekly for 8 weeks, and then once per month until disease progression
- During first week of intervention, daily visits for blood draws related to safety. During Week 2-8, twice weekly blood draws for safety. SoC arm does not do these visits.
- Scans for both intervention and SoC every four weeks during intervention. Will use oncology-specific imaging criteria to measure disease progression (tumor growth).
- At disease progression - intervention stopped and then treated per SoC. At intervention stop, safety visit and scans and once again 30 days post intervention.
- Long term follow up for mortality data once annually post-intervention for up to five years.

## PROJECT MANAGEMENT CONCEPTS AND TIPS

### QUALITY PROJECT MANAGEMENT

***“Do you want it fast, cheap, or good?”***

***Pick two, because I can’t give you all three.”***



## MANAGING MULTIPLE STUDIES = PRIORITIZATION OF FIRES

Success usually leads to more work

- How can I make this work?
- Watch for signs of burnout and stress (yourself and others)

Apply a framework to your work so you are able to objectively PRIORITIZE

- Work with investigators to determine priorities – which projects are the most important and what are the hard deadlines
- Communicate daily with your team, weekly with your investigators (or whatever works – key is often)

Evaluate your resources regularly and reorganize workload across the team



## IMPORTANCE OF STAKEHOLDERS

Who are the stakeholders? Anyone who has roles & responsibilities

### Roles and responsibilities

- Clarity
- Communication Plan
- Capture requirements in the Manual of Procedures or Standard Operation Procedures

### Stakeholder Engagement - set the expectation

- Engage site PIs early and often – require attendance and participation at standing meetings
- Standing meetings for site coordinators for multi-site trials
- Standing meetings as a team with the sponsor or lead investigators

## ADDITIONAL KEY POINTS FOR STAKEHOLDERS

Managing relationships is everything

Good stakeholders become allies when things go wrong (and they will!)

- Keep them informed
- Keep them engaged
- Empower them to do their work and earn their trust—make sure they know that you are making good decisions and doing the best that you can
- Use your personal traits to build credibility

## THINGS WILL GO WRONG – FIRES WILL HAPPEN

Anticipate common problems

- Delays
- Some part of outcomes may not be possible
- Shortages
- Budget

Accept that things will go wrong and sometimes all you can do is respond

- Not all problems can be anticipated
- Your study will have to adapt and change



I attended the RPN Workshop on Project Management – I can handle this

## BE DELIVERY-FOCUSED – GOAL ORIENTED

NOT activity-focused – that is the coordinator’s responsibility and role

Strive to have every “deliverable” completed on time or early – even if you aren’t doing these activities

- Participants enrolled
- Study visits completed
- Data collected
- Queries issued and cleared
- Regulatory submissions

Keep your daily activities organized around moving the deliverables in the right direction

## TIPS FOR PROJECT MANAGERS

- Find a mentor and ask them what to do
- Don’t get bogged down with small problems
- Identify barriers early and address them
- If you don’t know the answer don’t make it up
- Know what success looks like
- Bring a sense of purpose to your work
- Develop a thick skin





## RESOURCES AND SUMMARY

### RESOURCES AND OPPORTUNITIES FOR LEARNING

#### Institutional

- BU: Terrier Hub – Online Learning Project Management Essentials Bundle
- BU - [Essentials for PROGRAM Managers](#)
- UVM - [Certificate in Project Management Practices](#)

Most institutions have courses labeled as “Project Management” - take time to see what is available locally.

#### External

*All have various resources (webinars, online or in-person conferences, courses, certifications, blogs, etc).*

- [ACRP](#)
- [SOCRA](#)
- [Advarra](#)
- [Florence](#)

*Conferences or courses often have materials that can be shared, create a library within your department of materials.*

## PROJECT MANAGEMENT AS A CAREER – A LONG AND WINDING ROAD

Project Management  
**roles in all types of  
organizations** -  
academic institutions  
and medical centers,  
cooperative groups,  
coordinating centers.

**Very little direct  
patient or participant  
interaction** - have to be  
willing to give up that  
aspect of clinical  
research.

Successful project  
managers are **excellent  
delegators** – have to  
understand and be  
comfortable with  
having others perform  
tasks.

Project Managers are  
**those who can see  
both big picture goals  
and the small interval  
goals** and understand  
how to move towards  
both of those  
simultaneously.

## FINAL THOUGHTS

- Project Management is both a skill and an art - and can be applied to your daily work, even if your job title isn't "Project Manager". It's really the activities and not the title or HR designation.
- A lot of what we work on - and what we are hearing from investigators and sponsors - is do it now now now. It's important to recognize that when all the things are on fire - none of them are. But it's up to you to figure out which ones are actually fires - which ones you can help put out, which ones you need to add wood to, and when to add that wood.
- Intentionally practicing those Essential Traits is key to the forest fire that clinical research can feel like.

Time for chatting?  
What are your questions or thoughts?

