

Streamline Your Clinical Trial Workload with Effective Project Management

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MEDICINE *of* THE HIGHEST ORDER



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Acknowledgement

- Forte Research



- Educational resources for the clinical research community

Objectives:

- Describe essential factors of clinical project management
- Assess your clinical trial workload to determine how to effectively tackle items
- Identify tools that can assist with streamlining tasks

Data should be ...

- ALCOA: Attributable, Legible, Contemporaneous, Original, Accurate
- CCEA: Complete, Consistent, Enduring, Available
- FAIR: Findable, Accessible, Interoperable, Reusable



What are the roadblocks?

- Limited resources
- Too many tasks
- Concurrent studies
- Need better organizational skills

Fundamentals of effective project management

- Project management = the practice of initiating, planning, executing, controlling, and closing the work of a team to achieve specific goals
- Important notes:
 - Encompasses many elements, including time, scope, quality, and budget
 - Have a defined end goal
 - Project manager normally takes on broader responsibilities, but individual contributors play a huge role

Principles of project management

- Planning
- Managing resources
- Communication

Stages of project management

- Initiating
- Planning
- Executing
- Monitoring
- Analyzing

Components of project planning

- Clear objective
- Set timelines
- Defined resources
- Staff accountability
- Communication details
- Associated risks

Clinical Research Management

Component	Trial Start-Up	Trial Maintenance	Weekly/Daily Tasks
Clear objective	Open the study to accrual on time	<ol style="list-style-type: none"> 1. Maintain regulatory compliance 2. 100% clean data by data lock 	<ol style="list-style-type: none"> 1. Attend to IND safety reports 2. Attend to subject visits
Set timelines	Anticipated Open to Accrual Date	IRB Expiration Date Enrollment Closure Date	Does it need to be done today? Tomorrow? End of the week? Next week?
Defined resources	What do I need to get the tasks at hand done? Are those resources available?		
Staff accountability	Who is in charge of each step?		
Communication details	<ol style="list-style-type: none"> 1. What do people need from me? 2. Who do I need to talk to in order to complete? 3. What is the most effective way to get items from involved people? 		
Associated risks	<ol style="list-style-type: none"> 1. What happens if the task doesn't happen in the set timeline? 2. Rank the impact of the effect 		

Tips and tricks

- Focus on the task, not the protocol
 - If you have lots of similar items for multiple protocols, bundle them up and do them at once
 - Be cognizant of repeated tasks and create checklists and templates
- Prioritize and manage daily tasks to stay organized to ensure everything is done in a timely and efficient manner.
- Organize what needs to be done and review daily
 - Today
 - This week
 - Next week
 - This month
 - Later

Apply project management

- Use your calendar!
- Once a deadline is received, schedule it!
 - IRB expiration dates
 - Data lock dates
 - Monitoring visits
- Add a reminder that is days or weeks in advance to prompt you to begin items
 - Schedule IRB expiration dates with a reminder to go off at the time when you should start the paperwork
- Even if you are not responsible for the task, know when key dates occur

Review, Analyze, Monitor, Communicate

- Review your information about what tasks get done
 - Item type
 - Number of items
 - Time it took to complete
 - Number of times something was moved / changed
- Review the strategy for managing workload
 - Do you have the resources you need?
 - What do you need to be successful
- Discuss with your manager modifications for better success
 - Be open to suggestions and constructive criticism

Tips for successful workflow management

- Make a “to-do” list
 - Electronic or paper; not just in your head
 - Today, this week, next week
 - Do not go too far out in time
 - Use your calendar – don’t just go off memory
 - Prioritize the list for the day
- Use the list
 - Put it where you can see it often
 - Modify it as priorities/abilities change during the day

Know your workload

- How many protocols are you overseeing?
 - Who is the PI on those studies
- What stage are those protocols?
 - Start-up
 - Actively enrolling participants
 - Follow-up of participants (data collection only)
 - Close-out
- When is the next major milestone for that project?
- What is that milestone?
- What do you need to do for that milestone?
- What do you need from others for that milestone?

Prioritize

- Be efficient, bucket review time for all things at once
- Block 30-45 minutes on the calendar to just do small tasks and bucket them together
- Pick a time that is usually quiet in the office (first thing in the morning or right before the end of the day)
- Intersperse items that take a lot of work with those that do not
- If you have been doing intense work for 4 hours, take 30 minutes to do some work that isn't as brain-intensive (e.g. copying, filing, making appointments)

Tips for successful workflow management

- Celebrate the wins!
 - Mark off items that are completed to gain a sense of accomplishment
- Don't be afraid to postpone items
 - Make sure they can be postponed
 - Recognize why the item is being moved
 - Ask “why wasn't this scheduled here originally?”
 - Know how many times something has been pushed back
 - Avoid moving items more than once
- Learn for the next time

Summary

- Daily preparation into your work portfolio will keep unnecessary surprises from occurring
- Utilizing a to-do list that is based on deadlines and projected time to complete the task will create realistic expectations for work that can be done
- Tracking time it takes to complete tasks at hand will allow for more efficient and effective future planning
- Knowing what tasks need to be completed and when they can get done will facilitate more effective communication with stakeholders and lower workplace stress

Questions / Discussion

- Do you have advice or learned tips that you would like to share?



Part II: SCORE Needs Assessment

Common Themes

- Positives –
 - Sharing updates, information, resources and research best practices
 - Networking and collaboration / group discussions
 - Educational content and training opportunity
- Negatives –
 - Topics are not relevant to my role

Breakout group feedback from our last SCORE meeting

- Breakout Group sessions
 - Certification Group
 - Experienced CRC
 - New CRC
- Goal = identification of your needs, the “big hitters” than can really help you now

Certification Group Breakout Session

- There are really no institutional incentives to obtain and/or maintain certification. Coordinators generally don't see a raise or change in title. It looks like a career ladder to...nowhere.
- Membership can be costly and there is no financial support for most coordinators.
- Getting to annual meetings is costly and difficult. We should have better coordination of knowing who is planning to attend, meeting in advance to review the schedule, and organizing into interest
- Groups who attend specific events to allow us to cover more territory. We should have a more formal re-grouping post-meeting with sharing of new ideas.
- SOCRA now allows participation via Zoom. We need to know more about meetings that can be joined remotely that provide credits.

Certification Group Breakout Session

- There is a lack of education about certification at the university level. Coordinators, PIs, Research Admins all need a better understanding of why certification matters
- Not enough people know about the certification test prep we offer.
- We should have more available/formalized ongoing and advanced mentorship opportunities.
- Thoughts on how to focus
 - Develop a path to certification and maintaining certification
 - 1. Why get certified?
 - 2. How to make the process easier?
 - 3. How to stay certified?

Experienced CRC Breakout Session

- Career development
- Courses for senior personnel - supervising opportunities / classes to improve those skills to excel - etc.
- Presentations from senior staff - to describe how their career path moved along in the institution
 - Where others have gone?
- Senior project coordinator career tracks - better opportunities
- What other roles / opportunities are above Sr. coordinator?
- Department structures are different –
- Looking at department structure, is it efficient or just because it's always been that way
- Centralized Office vs. individual departments shift within departments, not for everyone but a pool of coordinators to pick from when additional help is needed "UR connected"
- Retain our longevity
- Rewards for "additional opportunities" like training

Experienced CRC Breakout Session

- Career ladder discussion and ideas show opportunities of growth that people have experienced
- Training - monitoring, travel opportunities
- Clarification of job description - senior HS research coordinator I, II, III (series) versus senior HP coordinator
- Pay determines who/ where / what grants support their salary – limits
- What can CTSI do for us?
- Team building
- Workshop - how to engage PI's?

New CRC Breakout Session

- Networking
- Behavioral Health; Vulnerable population
- Informed Consent training
- How do I get my PI to pay for my conference
- Professional development
 - PowerPoint, Excel, RedCap
- Data management
 - Data entry and building data collection instruments and projects
- Management (team, if you are a lead coordinator how to achieve best from your team)
- Managerial positions on how to manage people and some level situations

Future Direction

- Next SCORE meeting – Wednesday, December 19th at 3pm – 4:30pm EST
 - Topic: Self Determination Theory presented by Dr. Christopher Niemiec
- We will roll out a 2019 monthly calendar for future SCORE activities using the track model
- ? Is there a need for sub-group informal meetings

Thank you!

