ClinEssentials

Study Transition

KEY QUESTIONS FOR CTMs

Are you inheriting a new project from an outgoing CTM? Here are some key questions to ask during your transition meetings to help set you up for success.

STUDY NUMBER

EXPECTED TRANSITION DATE

OVERALL STUDY STATUS

1. Stage of Study:

☐ Start-Up ☐ Maintenance ☐ Close-Out

What challenges are you experiencing on the study overall?

What are proposed risk mitigations to the challenges?

Are there any concerns/tasks needing to be prioritized or any that need to be addressed immediately?

2. What are 3 upcoming study deliverables for which I need to be aware? Where is the overall study timeline found?

3. Are there any other plans or guidance documents you refer to/rely on over the course of a day/week? Where can I find these documents?

4. Can you provide a copy of the PSV or SIV Slides? ☐ NA

If NA, your comments:

5. What systems do you access regularly over the course of the day or week?

6. What meetings do you regularly attend? Do you have to present or prepare any information for these meetings? If so, when are these due? 24 hours prior to the meeting, on the meeting day, etc?

Are meeting minutes generated for these meetings? When are the meeting minutes due following the meeting?

7. Which departments are you in close contact with?

SPONSOR

8. Who are the key contacts at the Sponsor? What time zone are they in?

9. Have there been any study escalations or issues previously reported by the Sponsor?

10. Any specific Sponsor expectations?

Are there any deliverables or reports that you need to provide to the Sponsor on a regular basis? *(e.g. monthly accrual reports, metrics, etc).*

Who receives these reports at the Sponsor? What is the process for generating these reports?

11. Are there any Sponsor/Vendor preferences for which to be aware *(responses within 24 hours or prefer meetings vs. emails)*?

SITES

12. How many sites do you have? What is the overall site goal?

13. Do you have challenges with a specific site?

Are there any concerns or issues with the sites *(low enrollment, high staff turnover, expired/missing drug)?*

GENERAL

14. Are there any deliverables or reports provided by ClinOps to other internal departments?

15. Are there any team member challenges?

16. Are there any key points or best practices that assist with keeping the study on track? Is there a key person you go to/rely on for specific information?

17. What SOPs or trainings do I need to take before starting this project?

18. Where can I find the site and study team contact list including the Sponsor?

19. Are there any other items of which I should be aware?

Additional Checkpoints

- [ ] Ensure you have received all study call invites from the outgoing CTM, so you can attend the calls once they have transitioned.
- [ ] Ensure you have received access to all applicable systems that are regularly used such as IRB portals, EDC portals, IRT portals, Central Lab portals, etc.
- [ ] Confirm you have received the link to the current Statement of Work and any Change Orders from the Sponsor and/or CRO including study vendor contracts.
- [ ] Confirm you have received the link to any invoice trackers.

All of these questions may be part of an official handover form between the incoming and outgoing personnel. However, if there is not an official transition and you only have one opportunity to speak with the outgoing personnel, the points in this checklist are essential to learn.

Additional Notes