Study Transition

KEY QUESTIONS FOR CRAs

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

STUDY NUMBER	INVESTIGATOR	EXPECTED TRANSITION DATE

1. What issues or concerns have you identified with this site? *(Items to consider: Visit Scheduling, Documentation of ICF Process, PI Oversight, Drug Accountability Issues, Regulatory Issues, Lab Results Not Reviewed Timely, Source and CRF Discrepancies)*

- [ ] NA

2. Are there actions with the site which need to be addressed immediately?

3. Can you provide me with:

- [ ] Key Contact Info Sheet
- [ ] Tips for Visiting Site (airport, hotel, parking)
- [ ] Last Regulatory Review Spreadsheet or Notes
- [ ] NA
- [ ] PD Review Log
- [ ] Enrollment Status Notes
- [ ] Other items you have created to date for the site?

4. Who completes the source and performs eCRF data entry at the site *(is it the same person or different people/departments)*?

5. When was drug accountability last completed?

- [ ] Has not been completed to date.

6. Is filing up to date in the Regulatory Binder/Investigator Site File?

7. When was the last time an eTMF to Regulatory/Investigator Site File reconciliation was performed for this site?

- [ ] Has not been completed to date.

8. Are queries and/or action items addressed in a timely manner?

9. Do you have the current Protocol Deviation listing for this site? Have CAPAs been implemented? Any follow-up action needed?

10. Have there been any site escalations from you? Has the site escalated any issues to the Sponsor or CRO such as payment delays or other issues?

11. What topics have you re-trained the site on?

☐ NA

12. Do they have Electronic Medical Records? If so, what is the procedure for access?

13. Do they have paper source, electronic source or a combo of both?

14. What are the site's preferences *(Items to consider: How to Schedule Visits, Are Co-Monitors Allowed? Is Remote Monitoring Possible?, etc.).*

15. Is there anything else that would be good to know? *(Items to consider: Where Should You Park When Arriving on Site? How Long is the Walk from Parking Lot to Monitoring Room? Are all locations: Monitoring, Regulatory, Pharmacy, and PI in the Same Building or Do You Need Time to Commute? What is the Best Airport to Fly into? Do you need One or Two Days on Site?)*

16. Do they have specific medical or procedural requirements *(such as for COVID-19)*?

Additional Checkpoints

☐ Ensure you have received all study call invites from the outgoing CRA, 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.

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