

CASE STUDY: LESSONS LEARNED FROM THE TRANSITION OF A LARGE- SCALE NIH COORDINATING CENTER

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Topics

- Program background
- Internal challenges
- External challenges
- Successes

Program Background

- 35 trials transitioned
 - 4 in protocol development
 - 21 actively enrolling or in follow-up
 - 10 closed
- Primarily investigator-led phase I/II studies
- Therapeutic areas
 - Transplantation
 - Autoimmune
 - Allergy
 - Asthma
- Rho is responsible for data management, product safety, and biostatistical support.

Internal Challenges

- Resourcing
 - Individuals with availability vs. long term commitment
 - Staffing during 'ramp-up' leads to initial budget overages
- Prioritizing
 - Upcoming deliverables, database activation, trial complexity
- Slowing down

Internal Challenges

- Communication
 - Meetings with all staff vs. core team
 - Core team: principal investigator, project director, product safety functional lead, data management functional lead, and biostatistics functional lead.
 - Resource expectations
 - How many staff can each functional area have?
- Organization
 - By therapeutic category?

Internal Challenges

- Minimizing impact of staff turn-over
 - Operations manual for statistical duties
 - Transition checklists
 - Communications log

External Challenges

- Clarify contractual obligations
 - Who is the archive?
- Prioritizing activities
 - Set clear priorities with the sponsor upfront and don't try to do everything
 - Communicate timelines for internal activities

External Challenges

- Communication
 - Don't make assumptions
 - Meet with the incumbent
 - Confirm information with sponsor

External Challenges

- Helpful questions to ask for each study
 - Is the IND closed?
 - Is the database locked?
 - Has the clinical study report been submitted to FDA?
 - What is the status of the SAP?
 - How many outstanding queries are there?
 - Are validation plans up to date?
 - Is there a CRF change log?
 - Is there a query frequency log?
 - Is there a decisions log?
 - Are there signature pages for finalized documents?

Successes

- 9 studies transferred from paper CRFs to eCRFs.
- Completed neglected tasks (SAP, CSR, DMP)
- Created guidance documents
 - Data requests
 - Unmasking
 - Subject ID naming
 - Safety management plan
- Had 1 lead for a set of tasks (e.g. protocol updates)
- Inventory

Successes

- Clarified data needs
 - Confirmed endpoint data
 - Confirmed stopping rule data
- Underwent major data cleaning efforts
- Created website
 - Houses study specific documents for study team
 - Create monthly reports tracking enrollment, CRF completion, AEs, protocol deviations, etc.

Questions?

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