Applying result-driven rescue techniques to successfully transition (and save) a failing study

Have You Ever Been In This Situation?

"My CRO just told me they are going out of business in 2 weeks!"

"Patient recruitment has all but stopped.
Our CRO's focus has moved on to other things."

"My database did not open for 4 months and when it finally did thousands of edit checks fired. Now the sites are beyond mad!"

"My CRO charges me extra money for every last request and takes forever for the change order to be drafted!"

"The tables, listings and figures are not even close to what we wanted."

"The team my CRO promised all quit! Now I have an entirely new inexperienced team."

Indicators of A Project At Risk

Time

- Key milestones will be missed
  - Database Go-Live Date pushed out
  - Key site visits postponed or canceled (e.g., SIV)
  - DSMB meeting or interim analysis milestone delayed

Quality

- Poor Site Training
  - Too many protocol violations
- Poor Monitoring
  - Missing data (late-identified SAEs)

Cost

- Change Orders
- Rework
- Timeline Adjustments

To Rescue or Not To Rescue….?

…THAT IS THE QUESTION!

Where are you in your timeline?

What is the financial investment thus far?

- Does it make “cents”?

Did you meet your own obligations? Is it all the vendor?

Would a team change or retraining help?

First Things First

Know that a transition process will take time

Some “wheels” will have to be reinvented

- Teams will need to be retrained
- Database will need to be rebuilt
- Study Plans will need to be revised

Keep enrollment going or stop?

Contract considerations

- Cancellation clause?

Site and team morale and motivation impact

Affects on other ongoing collaborations

“Burned bridge”

Mutual Agreement – Moving Forward

- Transition Needs
  - Collaboratively develop a clear rescue bid (cost & scope)
- All Hands on Deck!
  - Involve new team as soon as possible
- Honest Communication – Build Trust!
  - Why didn't it work?
  - What happened?
- Understand Expectations
  - Timelines
  - Risks should be assessed for each step of the way
  - Required processes needed to move forward
    - Critical study-related documents/plans needed

Key Study Documents/Plans

DOCUMENTS	COMMENTS
CLINICAL OPERATIONS	
Clinical Monitoring Plan	Critical information for monitoring team (logistics)
Study Templates & Logs (Use by sites)	Save time by not reinventing – Reuse but also revise
Study Reference Materials (Regulatory Binder, Pharmacy Binder)	Save time by not reinventing – Reuse but also revise
Current Screening & Enrollment Log	Needed to continue site payment programming
All Regulatory Documents	Avoid recollection of documents
DATA MANAGEMENT	
DMP, Database Validation Plans	Critical information for database builders
CRFs, aCRF & Edit Checks	Streamlines database build
Listing of resolved and unresolved queries	Do not issue repeat queries
SAFETY SURVEILLANCE / PHARMACOVIGILANCE	
All Plans (SMP, Medical Monitoring Plan)	Listing of previous reports (expedited/periodic)
Safety database specifications and data	Historic information needed in safety database
BIOSTATISTICS	
SAP	What are the critical variable for the EDC
IxRS randomization schema	Needed for final analyses

Path To A Successful Rescue

Hold a transition meeting with the new team

Inform the sites!!

- Involve sites on the transition process
- Meet with sites in person
  - Consider a mid-study Investigator Meeting

Flexibility

- Be available for discussions and feedback
- Timely review of documents

Trust that your new team will not make the same mistakes

What To Look For In A Rescue CRO

- CRO that has successfully done this before
  - Knows what to ask for up front
  - Excellent track record with rescue studies
  - Established processes and systems
- Ability to define their timeline and scope-of-work
- Strong leadership
  - Interview the team, PM
    - Must have experience under belt
  - Support from senior management
  - Willing to work with previous CRO & other vendors

Final Thoughts…

To rescue or not - not an easy decision

Ask yourselves the right questions

- Know what will work best for your company's needs

Understand the commitment required

Find the right partner

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