



CLINICAL
TRIALS
TRANSFORMATION
INITIATIVE

April 5, 2017

Optimizing Trial Execution and Conduct: Protocol Feasibility, Recruitment and Eligibility, and Working with CROs, Sponsors and Regulatory Agencies

Robin Douglas, RN, CCRC

QuintilesIMS

Overcoming Challenges



Strategies related to trial execution and conduct

Prepare prior to trial implementation

- Use knowledge and experience when reviewing protocols to identify time commitments and potential challenges
- Communicate with sponsor to prevent unanticipated time burdens
- Do not assign staff to trial until it is up and running

Reality check

- Accept time commitment
- Anticipate delays

“We have become more savvy at looking at protocols. We’re asking a lot more questions upfront before we select a study, and that helps us have a better understanding of what really is involved in doing the study..” - C

Strategies related to eligibility and recruitment

Plan appropriately

- Review protocol to assess its feasibility
 - Use multiple reviewers and perspectives (e.g., investigator and coordinator)
 - Use experience and knowledge of study population
 - Review existing patient database
- Become involved in protocol development: Adjust protocol
- Decline trials

Address potential barriers

- Recruit patients from own private practice
- Use a variety of recruitment strategies
- Listen to patients: obtain feedback, engage potential participants

I think that now that we have a better feasibility process and look more closely at these things, and we have more experience. It helps you understand how to better look at protocols in general, and so I think we can identify some of these issues upfront and raise the questions with the sponsors. And sometimes, like I said, it does result in a protocol change or modification or it results in us not selecting the studies now. —A

Strategies related to eligibility and recruitment

▣ Communicate

- Provide feedback on adjusting trial and criteria
- Ask sponsor questions about protocol and eligibility criteria
- Discuss recruitment and criteria challenges with sponsor
- Be upfront with sponsor about expected recruitment numbers
- Provide feedback to medical monitors and sponsors during trial

▣ Reality check

- This is difficult, requires knowledge of practice, and constant diligence
- Keep looking for more patients

That's part of the reason to look at the protocol and make sure you can [do it]—at least you have reasonable expectations.

So some of these we know it's an important question; the science dictates that it be a certain inclusion and exclusion.

So we just need to be clear how many people we can recruit, given those restrictions, to be successful at our level, at the site level. —A

Strategies related to working with CROs, Sponsors and Regulatory Agencies

▀ Challenges

- Quality and clarity of protocols
- CROs are barriers between sites and sponsors
- High turnover
- CRA's "hinder" study progress

▀ Reality Check

- Get involved early
- CROs are hired to be your single point of contact
- Current industry workforce challenges
- Difference between clinical practice and clinical research

▀ Strategies

- Prepare
- Communicate
- Prioritize

THANK YOU.



Robin Douglas
Site Solutions Director, Site and Patient Networks
QuintilesIMS
robin.douglas@quintiles.com



www.ctti-clinicaltrials.org