Critical Tasks that our Evidence Suggests Should be Well Executed to Drive the Quality Conduct of a Clinical Trial

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Questions posed to expert interviewees

- We asked our expert interviewees to share an exhaustive list of the critical tasks they believe should be conducted at research sites to ensure the quality conduct of clinical trials
- We then asked that the experts identify which of the tasks they shared were their ‘top three’ most critical tasks

All critical tasks

- Informed consent Protocol compliance
- Protecting participants' safety
- Staff qualified to perform assigned roles and responsibilities
- Ensure data quality, documentation, and accuracy
- Qualified physician responsible for study oversight and medical care of participants
- Quality assurance/quality control
- Reporting AEs, deviations, and responding to queries
- Adequate resources to conduct study
- Communication, among all levels of the team
- Creating a milieu that emphasizes ethical conduct
- Ensuring no misaligned incentives

Informed consent

- **Informed Consent -- most frequently mentioned critical task**
- Sponsor quote:

I'd say informed consent is very important, that the patient is educated on risks and benefits. I think one of the biggest abuses could be the desperate patient that is looking for a cure and has false expectations from the study, so patients need to be made aware that this is an investigational drug, and there's no guarantee that it's going to help them, and there are risks involved in participating in a study. I think that's number one.

Informed Consent

- Informed Consent -- most frequently mentioned critical task
- Investigator quotes: *Informed consent, because that's what starts the process. If it's not done correctly, then all of the other tasks you mentioned, we wouldn't have a study.*
  - *The more they know about the study and what the study is looking for and what to expect through the course of the study, the better their retention will be. A better informed patient is a better patient.*

Protocol Compliance

- **Protocol compliance -- most frequently mentioned critical task**
- Sponsor quote:
  - *…compliance to all the critical details [of the protocol], all the assessments, including any sampling that needs to be done, to really ultimately ensure patient safety.*
- Investigator quote:
  - *…[training] to make sure there's a good understanding of what's required*

Protecting Participants' Health and Safety

- **Protecting participants' health and safety -- 3rd most frequently mentioned critical task**
- Investigator quote:
  - *Data is important and studies are important, but individual lives are more important. So, if we see there is something unsafe, no matter how much the sponsor might want the study, we have to make sure the patient is taken care of first.*

Discussion