Knowledge and Skills our Evidence Suggests may be Needed to Perform Critical Tasks and Mitigate Risks to Quality Trial Conduct

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Question posed to expert interviewees

- Respondents were asked to identify the knowledge and skills required to conduct each of the top three critical tasks they identified.

- *Note: Many of the knowledge and skills identified as essential to conducting quality clinical trials apply to more than one critical task.*

Knowledge and skills required to perform critical tasks generally

- Knowledge of all protocol requirements
- Clinical knowledge of the disease and available treatments and skill at identifying safety issues
- Communication skills
- Attention to detail
- Knowledgeable about the need for informed consent and ability to administer informed consent in a variety of forms and contexts
- Detailed knowledge of GCP principles
- Technical knowledge and skills with data entry and electronic data collection systems

CTTI

Knowledge and skills needed for quality informed consent

- Communication skills -- ability to clearly communicate complex issues to subjects with patience, compassion and empathy
- Knowledgeable about disease state, pharmacology, investigational product and available treatments
- Understanding that informed consent is an ongoing process and ability to administer informed consent in various forms and contexts
- Ability to assess potential participants' compliance and understanding prior to enrollment
- Ability to assess patient eligibility given standard inclusion and exclusion criteria
- Ability to assess appropriateness of screening or enrolling vulnerable populations
- Comprehensive knowledge of informed consent requirements
- Strong knowledge of GCP
- Comprehensive understanding of the protocol

CTTI

Knowledge and skills needed for protocol compliance

- Knowledgeable about the disease state, pharmacology, investigational product and available treatments
- Ability to assess patient eligibility given standard inclusion and exclusion criteria
- Ability to escalate issues including protocol violations and adverse events and serious adverse events
- Comprehensive understanding of the protocol
- Ability to oversee that study procedures are consistently and timely executed
- Open communication between principal investigator, delegates and subjects
- Attention to detail and/or accuracy

Knowledge and skills needed for protecting participants' health and safety

- Knowledgeable about the disease state, pharmacology, investigational product and available treatments
- Clinical skills and experience to identify and assess causality of safety issues
- Ability to assess patient eligibility given standard inclusion and exclusion criteria
- Ability to escalate issues including protocol violations and adverse events and serious adverse events
- Ability to oversee that study procedures are consistently and timely executed
- Open communication between principal investigator, delegates and subjects

Critical Knowledge and Skills

Discussion