

INVESTIGATOR QUALIFICATION SUMMARY OF INTERVIEW FINDINGS

We appreciate your input on our evidence-gathering activity on identifying key learning objectives for preparing investigators and their delegates on the quality conduct of sponsored clinical trials. This letter shares the main findings from the study interviews.

The objectives of this evidence-gathering activity were to:

- 1) Describe the impact GCP training has on the quality conduct of clinical trials.
- 2) Identify gaps and redundancies in the current training of investigators in preparation for the conduct of clinical trials.
- 3) Identify key learning objectives for training to qualify investigators for the quality conduct of clinical trials.

We conducted **23 semi-structured interviews** with 13 investigators with various trial experiences and specializations, and with 10 sponsors from pharmaceutical, device, and biotech organizations.

MAIN FINDINGS:

Definition of and Concerns About Quality Conduct

The majority of respondents' definitions of quality conduct of clinical trials were associated with more than one of the 13 principles of ICH-GCP, with the **top three most frequently mentioned principles** being:

- 1) Compliance with a scientifically sound protocol.
- 2) Accurate reporting, interpretation, and verification of study data.
- 3) Informed consent freely given from every participant prior to participation.

The need for metrics, a non-GCP principle, was also mentioned by many sponsors when asked to define the quality conduct of clinical trials.

The most frequently mentioned **concern** about quality conduct of clinical trials pertained to data quality; concerns about informed consent were also frequently noted.

Critical Tasks

Respondents described what they consider to be the critical tasks associated with the quality conduct of clinical trials at research sites, and linked these tasks to GCP principles. The **top three critical tasks** most frequently named were:

- 1) Informed consent,
- 2) Protocol compliance, and
- 3) Protecting participants' health and safety.

Respondents described a variety of **knowledge and skills** as being essential to conducting the top three critical tasks, as well as for the quality conduct of clinical trials in general.

Most Valuable GCP Principles and Additional Suggested GCP Content

Most respondents said that the GCP domain “Ethics” is central to the quality conduct of clinical trials and serves as the foundation for all of the other GCP principles. Many respondents also noted the importance of the GCP domains “Informed Consent” and “Responsibilities,” as well as that of domains pertaining to data integrity and quality control.

Suggestions for improving GCP training with respect to the top three critical tasks focused on adding to existing guidance, definitions, and training. For example, respondents proposed better defining what **informed consent** involves and providing training on writing clearer consent forms; aiding **protocol compliance** by better defining protocol deviations/violations and clinically significant events, and emphasizing training on all aspects of the protocol; and promoting **participant safety** through clearly defining specific endpoints, adverse events, and monitoring periods, and providing training on how patient data may be used in the future.

Training—Unmet Needs, Changes Needed, and Potential Solutions

Respondents described a lack of research training for physicians, leading to investigators who are well trained in medicine, but poorly qualified to lead research.

Mentorship, as well as having more opportunities to engage in ongoing real-world training, were seen as important means of supporting investigators.

Several investigators proposed that GCP training be conducted less frequently, particularly for non-critical elements such as historical information, which was viewed as redundant. Numerous other suggestions were provided.

These data will be used by the CTTI project team to develop recommendations on investigator qualifications.

Thank you for sharing your thoughts with us!

If you have any questions about this study, please contact CTTI Project Manager
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