Selecting a CRO Partner

Navigating Laboratory Accreditation

Pre-clinical and clinical trial studies have the potential to help guide future medical advances to improve human health. As such, it is important to consider how and according to what standards these research studies are conducted. Laboratory accreditation can help to ensure high-quality data and reliable results and should not be reserved for clinical trials alone. Researchers conducting pre-clinical studies should also consider working with a CLIA-certified CRO partner.

1. What is CLIA-certification?

Congress enacted the Clinical Laboratory Improvement Amendments (CLIA) to ensure the accuracy and reliability of all laboratory testing. Laboratories that are CLIA-certified meet certain standards around personnel training, documentation, and data storage. They follow detailed wet lab protocols and maintain logbooks to document instrument maintenance. These labs also ensure patient information is protected from fraud, theft, or inadvertent disclosure with specific laboratory floor plans that limit computer and instrument workstation access. In summary, CLIA-certification is an important and high standard to ensure the accuracy and reliability of lab testing of human samples.

2. What are the common acronyms?

CLIA is just one standard for laboratory testing. Other standards and governing bodies that are most relevant to pre-clinical and clinical laboratory work include:

- Clinical laboratory improvement amendment (CLIA) is a federal quality standard for accurate and reliable testing human specimens for health assessment or to diagnose, prevent, or treat disease
- College of American Pathologists (CAP) accredits laboratories performing testing on humans or animals, the standards often exceed those of CLIA and FDA
- Food & Drug Administration (FDA) regulates medical devices used in the diagnosis, prevention, or treatment of human disease
- Good clinical practice (GCP) is an international ethical and scientific quality standard for designing, recording, and reporting trials involving human subjects
- Good laboratory practice (GLP) is a scientific quality standard for test data related to non-clinical safety studies and is developed by OECD

At least a broad awareness of these acronyms and what they stand for is essential for researchers working on pre-clinical and clinical trial studies.

3. Which certification is best?

There is no easy way to answer which certification or accreditation body is the right one for your research. In some cases, an Institutional Review Board (IRB) or other governing body may require work to be performed in an accredited laboratory. In other cases, certification may not be explicitly required, leaving it up to researcher discretion. In our experience, CLIA-certification stands out as one of the more important quality standards for accurate and reliable testing human specimens. However, it can also be extremely applicable in pre-clinical studies as well.

4. Why choose a CLIA-certified lab for pre-clinical work?

The results of early-stage work performed in a CLIA-certified laboratory are better suited for inclusion in later clinical studies. Conducting these studies in a CLIA-certified laboratory provides anyone reviewing the data with the confidence that the work was done with integrity and meets a level of standard deemed important by the federal government. If your exploratory research has the potential to guide the development of a treatment, the work should most likely be performed in a CLIA-certified laboratory. This includes studies investigating responders vs. non responders to determine the molecular mechanism of treatment and work on biomarker or assay development which could result in a clinical test.

5. How should I choose a CRO partner?

Selecting a CRO partner with the appropriate accreditation is an important step. However, it's not enough to select a CRO partner based on CLIA-certification alone. A good CRO partner also has experienced scientists who bring expertise to the facility. Additionally, good sample management and sample tracking is critical, especially for studies following subjects over time and collecting samples at multiple time points. Canopy Biosciences has significant experience with sample tracking for longitudinal and complex projects. Prior to running the assay, we perform a sample quality control step. During this time, we notify the research if any samples did not pass quality control. We care about helping you maintain a robust sample size to aid in statistical analyses, so we provide the option to send us a replacement sample if available.

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