Navigating Lab Certifications in Clinical & Pre-Clinical Studies

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HOW TO CHOOSE THE RIGHT ONE

Most biomarker analysis work in Phase I and II clinical trials are exploratory research studies. The data will then guide future clinical development or plan subsequent studies. With the clinical impact of this work, it’s hard to know what level of lab certification you need. Sifting through the acronyms is confusing and time consuming. Here is a guide through the alphabet soup of lab certifications, to help you find the one that meets your needs.

1. What certifications are out there?

GLP, GCP, CLIA, and CAP are just a few of the acronyms out there describing lab certifications. But what do they all mean? How do they apply to your work? Below describes common certifications researchers in the clinical, pre-clinical, or research space will encounter. Sample type, study subjects, study aim, and function of the data will help drive the level of certification you should look for in a service provider.

- **Good Clinical Practice (GCP)** Standard for the design, conduct, performance, monitoring, analysis and reporting of clinical trials that assures the data and results are credible and accurate; that the rights, integrity, and confidentiality of the trial subjects are protected

- **Good Laboratory Practice (GLP)** Regulates the processes and conditions under which clinical and non-clinical research is conducted and abs are maintained

- **CAP Certification** Developed by the College of American Pathologists and basically expands on the CLIA regulations; CAP standards commonly exceed CLIA, FDA, and OSHA regulations
• **Good Manufacturing Practice (GMP)** Regulates the design, monitoring, and control of manufacturing processes and facilities. Biomarker analysis and lab testing don't involve manufacturing so GMP guidance isn't relevant.

• **Food & Drug Administration (FDA)** In the realm of clinical assays, it regulates the devices used in the diagnosis of disease and those used to cure, mitigate, treat or prevent disease.

• **Clinical Laboratory Improvement Amendment (CLIA)** Introduced in 1988 to ensure accurate and reliable testing for patients, the program holds testing labs accountable for quality procedures, safety protocols, documentation, and results reporting.

Now, let's break this list down and focus on the relevant certifications and quality levels for clinical and pre-clinical research. FDA and GMP are not likely to be applicable in the biotech space. GCP pertains more to the study design itself rather than the lab work to be completed. GLP, CAP and CLIA tend to be the more common certifications encountered, with CLIA being more prevalent. CLIA certified labs can perform lab services for research and pre-clinical projects and also for Phase I and II clinical trials. The stringent requirements for lab procedures, documentation and data security ensure alignment with the regulations of your clinical trial.

### 2. CLIA has its benefits

CLIA certification is a stamp of quality on the data resulting from a study. It maintains that the lab adheres to strict procedures and protocols for all sample processing. The lab is physically laid out to optimize workflow, protocols, and safety including placement of fire extinguishers. Personnel are required to maintain training logs and keep their training up-to-date on lab procedures, techniques, safety regulations and documentation requirements.
Documentation is a key part of CLIA certification. From sample in-take, processing, handling, analysis and data reporting—every step is documented. Lab maintenance is recorded; protocol steps are specified and checked off; access to instruments and the lab is monitored. All in accordance with CLIA guidelines to certify the quality and authenticity of the results.

CLIA certified labs are responsible for data security and required to follow specific procedures around handling human samples. Personnel and the lab overall is subject to HIPPA guidelines relating to data security and confidentiality. Subject information and sample data must be protected from fraud and theft via protocols limiting facility access, computer and instrument workstation access, and other measures to prevent inadvertent disclosure.

3. **What does this mean for your study?**

There is a wide variety of studies where CLIA certification suffices or is required. Sometimes researchers think they need a CAP certified lab when CLIA regulations facilitate the requirements of their project. And some researchers may be on the fence as to whether a CLIA lab is needed. How do you decide?

- If your organization has CLIA requirements that apply to the entire lab, regardless of whether or not the sample is a clinical patient sample that may be tested for patient outcomes— you should run the assay in a CLIA lab

- If your organization has service provider requirements such as lab layout, documentation, data safety and security, and personnel training— you should run your study in a CLIA lab

- If your project is looking at responders vs non responders to determine if the investigational agent is having the desired molecular effect— you should run your study in a CLIA lab
• If your assay development work could be used to develop a clinical test- you should run your assay in a CLIA lab

• If the data from your exploratory research study is going to guide future clinical development of a treatment- you should run your project in a CLIA lab

Initial exploratory work done in a CLIA certified lab is better suited for downstream inclusion in clinical studies. When done in a CLIA lab, this data can be used to guide future clinical development or plan subsequent studies. Your work is benefiting from the overall quality of the lab even if this level of certification isn’t explicitly required at this stage.

4. How to choose a Service Provider

Selecting a service provider is an important aspect of your study design. Mainly because you are looking for a partner in your trial; one that you can commit to long term for the duration of the study. This doesn’t mean you have to go to a large CRO. There are many small-to-mid-sized CROs out there with excellent records of quality and expertise. Things to keep in mind:

• A CRO that has the services you require for the experimental assay in your project

• A service provider that will provide feedback on sample quality and integrity prior to running to allow for replacement of poor quality samples and ensure maximum data points

• A CRO with project management and sample management to ensure samples are secure and organized

• A service provider that will be a partner in your study, rather than an instrument of your project
The alphabet soup of acronyms in lab certification was spelled out and defined and CLIA has been identified as the primary certification and quality level in the pre-clinical and clinical trial space. CLIA requirements include steps to ensure lab adherence to strict guidelines around lab safety, documentation, data security and overall excellence. Phase I and II clinical trials should be run in a CLIA certified lab, but this recommendation extends to pre-clinical and exploratory research work; especially when the work will have future implications on a clinical trial. Selecting a service provider to complete this work should focus on a CRO that will be a partner in your research, adding to the trial by performing the lab work with the utmost excellence, and collaborating with throughout, maximizing sample integrity and data quality.

Key Take Aways

The alphabet soup of acronyms in lab certification was spelled out and defined and CLIA has been identified as the primary certification and quality level in the pre-clinical and clinical trial space. CLIA requirements include steps to ensure lab adherence to strict guidelines around lab safety, documentation, data security and overall excellence. Phase I and II clinical trials should be run in a CLIA certified lab, but this recommendation extends to pre-clinical and exploratory research work; especially when the work will have future implications on a clinical trial. Selecting a service provider to complete this work should focus on a CRO that will be a partner in your research, adding to the trial by performing the lab work with the utmost excellence, and collaborating with throughout, maximizing sample integrity and data quality.