The Role of the Laboratory in Clinical Trials

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Laboratory role in CT

- Laboratory can play within a clinical study the role of:
  - **Local lab**: only testing
  - **Regional Lab**: testing and logistics
  - **Central Lab**: testing, logistics, data and project management
In clinical trials, lab tests are used to:

- Establish inclusion and exclusion criteria
- Determine baseline parameters
- Monitor the safety of the participants
- Demonstrate the efficacy of the investigational product
Where can the lab help in a CT?

**Sponsor level:**
study protocol design
- suitable blood volume
- selecting the proper analyzing method and equipment
- choosing proper test panels in relation to the study pathology
- study specific data base
- study specific report formats
- method development according to study goal
Where can the lab help in a CT?

Monitor and investigator levels:

- Professional expertise for pre- and post-analytical phases of testing
- Sample preparation
- Sampling kits
- Assembling logistics tasks (such as dry ice and courier providers, etc.)
- On site training for proper patient sampling
- Laboratory data interpretation referred to the study pathology
Important definitions

- Clinical means humans (GCP)
- GCP=good clinical practice
- GLP=good laboratory practice
- Laboratory means others than humans (GLP)
- GLP doesn’t apply to laboratory testing human samples
- GLP doesn’t apply to clinical trials
- GCLP=good clinical laboratory practice
- GCLP applies exclusively to clinical trials
1. Safety Resources
   - e.g. Is there a lab safety manual? what is the evacuation policy? emergency management policy?

2. Laboratory Housekeeping
   - e.g. Are walls and ceilings clean and well maintained?

3. General Safety Awareness
   - e.g. Have all employees completed/reviewed the Laboratory Safety Evaluation Form within the last year? Have all employees who work with human blood/products been offered the hepatitis B vaccine?
4. Personal Protective Equipment (PPE)
   - e.g. Do personnel decontaminate hands (i.e. handwashing) after removal of gloves? Is reusable clothing (i.e. lab coats) used for work with blood and blood products being collected in laundry bags that are either labelled or color-coded as “biohazardous”?

5. Biological Safety
   - e.g. Are surfaces on which work involving blood and blood products is performed routinely wiped down with an approved disinfectant at the end of the procedure or immediately following a spill?
6. Fire Safety
   o e.g. Are employees familiar with the location of fire extinguishers and pull alarms? Does the lab avoid placing electrical devices near water sources?

7. Chemical Safety
   o e.g. Are the containers for all hazardous chemicals properly labeled with the chemical name, hazard type, and what to do if accidental contact occurs?

8. Quality Management System
   o e.g. Are all relevant operations that are standardizable described in SOPs in writing? Describe, which operations are covered by SOPs. Is there evidence that all Individuals have access to the SOPs relevant to them and have they fully understand the meaning? Will internal audits be performed on a regular basis?
Clinical Laboratory Audit Checklist

9. Specimen Handling
   o e.g. Are there procedures for specimen transport? Is there unique identification of: the patient/ the specimen? date and time of collection? type of specimen? investigation requested? date and time of receipt? clinical information?

10. Examination Procedures & Equipment

11. Staff Training

12. Reporting Results
   o e.g. How results will be reported? For how much time will the lab keep the reports?
Talking about the past

• When a CT commenced and laboratory test data was returned, pharmaceutical companies would typically receive data with a 39% error rate

• Mislabeled test kits, incorrect tests, missing specimens caused data inaccuracies
During the time

- Analysis of CT data required months of work, with data having to be “cleaned” first before it could be analyzed.
- Data were gathered from multiple local laboratories, that used different methodologies, reference ranges and SOPs.
In order to deliver to study sponsors faster access to higher quality of data, faster receipt, analysis and a significantly reduced rate of error, the idea of CENTRAL LAB has been conceived.

Through the establishment of relationship with global logistics couriers, standardization in the production of sampling kits and the development of a single database, the CL industry has been able to deliver combinable data to CT sponsors.
Central Laboratory

- Investigators and sponsors expect lab results to be reported immediately after the central lab receives the samples.
- Result reporting within 12-24h may be easy to achieve for routine testing methods.
- For more complex and specialized methods, the frequency of running a specific assay in laboratory directly depends on the number of samples received.
- The high cost of instrumentation (up to $250,000) and reagents($1000 for a kit to test approximately 40 samples) in addition to qualified technicians, explain why laboratories need a minimum batch size to offer competitive lab fees to sponsors.
• A small laboratory processing 50 or 100 samples a day may only receive 5-10 samples for a specific immunology method

• This “imaginary” lab would only be able to run the immunology assay 2-3 times a month at a higher cost per unit

• A central lab with a capacity to process 5000 or more samples per day has the advantage of both offering competitive prices and reporting lab results with the shortest delays
Central Vs Local Lab.

• Smaller laboratories may be good for local studies where testing portfolio is not too demanding, but they will not have the capacity to cope with test panels that are becoming more complex.

• Central laboratories following the strategies mentioned previously may succeed in supporting global studies if they have an established worldwide infrastructure and a solid quality system in place.
Conclusion

• None of existing treatments result in a cure of all patients, nor are they without side effects, and doctors continue looking for better ways to treat the disease.

• Clinical laboratory plays a very important role in any clinical trial by offering reliable data for the patient’s diagnosis and the trial success.

• Only by common effort of all involved partners in the research field, better ways to treat disease will be developed and the patients health status will be significantly improved.

• Besides the other benefits reached by the participating into a clinical trial, none of us should ever forget that everything starts and ends with the patient!
THANK YOU