LabConnect

Top Takeaways

from our webinar series addressing key challenges to reaching clinical trial milestones.

Part 3: How to Prepare and Analyze Lab Samples

Key Insights Covered

Importance of choosing a laboratory to optimize capabilities with protocol needs

Considerations in choosing the right laboratory for downstream analysis

How to ensure that samples are prepped and analyzed in a timely manner

Ways advancements in molecular diagnostics, testing methodologies and automation can accelerate progress

What is unique about your lab and how are you uniquely positioned to support current and future clinical trials?

Both laboratories provide patient care testing, as well as clinical trial testing, that delivers unique prospective allowing the laboratories to be cutting edge and have an in-depth view into testing.

Labor Dr. Wisplinghoff

- Seamless integration of workflows
- Broad spectrum of diagnostic capabilities
- Supports more complex trials

Cleveland Clinic

- Supports varies clinical care settings globally
- Extensive depth of clinical care critical for research testing
- Reseach center and education center

As a top clinical research and patient care testing lab, what do you think is important in how clients choose a central lab partner?

- ✓ Deep understanding of logistics and functional components
- ✓ Pre and Post analytics are key
- ✓ Knowing the laboratory itself can provide insights to how the testing can impact research
- ✓ Breadth and depth of experience
- ✓ Focus on patient care
- ✓ Access to scientific expertise
- ✓ Understanding the workflow and mechanics to relate to the doctors and patients
- ✓ Support the planning and trial setup to ensure studies integrate seamlessly
- ✓ Efficient processes to reduce errors in collection which helps reduce site burden
- ✓ Robust lab strategy
- ✓ Ability to provide customized kits makes it easier to implement clinical trials

How does your lab continually review the market demand for testing to expand your testing menu?

- Review the complexity of trials to provide a broad spectrum of clinical diagnostic tools to support them
- Understand and develop specialized tests as needed
- Support the co-development of tests to help with regulatory and data requirments
- Insight into patient care realities drives the development of tests as needed to optimize patient care – providing the right test at the right time for best outcomes
- Being integrated with clinical teams nationally and internationally assists in understanding demands globally
- Look at overall demands to understand how to support tests in the research setting

How important is securing a reliable sample management flow from collection to delivery to analysis for sample viability?

Ensuring samples gets to be where they need to be can be challenging especially if delivery scope is global - having a seamless integrated logistics process inside the laboratory is beneficial for sample viability.

- ✓ Once the sample enters the laboratory the process is streamlined for sample viability –knowing where the sample is at all times, and knowing the next steps, provides the best results
- ✓ Strategic location is beneficial
- ✓ Strong logistics support is needed
- ✓ Turnaround times on reporting is critical

Is having different platforms available to run the same tests important? If yes, why?

- Different platforms can be useful in more domain dependent studies
- Different platforms can also provide different results in clinical settings – some platforms perform better than others and it can be helpful to have a mix
- Comparing different instrument sets can control variability
- It is important to have more than one type of platform because no two tests test the same and this is a huge benefit in a clinical trial setting
- Leveraging a central lab in a consultative way helps to understand which platform to use in clinical trials

What are the pros and cons of automation and innovation in lab testing?

Automation has advanced in the last decade and is a key component in the clinical lab setting.

Helps streamline, improve and accelerate throughput

Ensures samples are tested more efficiently

Improves quality and turnaround time

Increases traceability and eliminates human error

What types of innovation in testing are you finding to be transformative?

- New automations of tasks that have not yet been automated
- Rapid development of molecular testing
- Software advancements and AI to compute algorithms
- Genetic disease and CAR-T targets are more specified
- Decentralized models for clinical trials

Can you share with us why access to routine and specialized testing globally is a benefit in the clinical trial space?

- Broad spectrum and expertise in different specialties – i.e. patient care, regulatory, safety testing, planning
- Delivering the best available test and result is the least amount of time
- Testing is a spectrum, and the scientific and clinical experience provides insight and input for the next level of support

How are you connecting scientific input within the lab to the testing?

Linking the Science to the Patient...

- All scientific experts are connecting with the patient - linking patient care with the clinical experience
- Always providing excellence in clinical care with the aim to meet or exceed standards for the best patient care
- Optimizing how clients can work with your lab by connecting routine and specialized testing

How is pathology and laboratory medicine vital in diagnosing, treating, and monitoring outcomes in clinical trials?

- Pathology is slightly different than clinical testing and dependent upon physicians and experts that support the high complexity of care
- Cleveland Clinic Laboratories has a foundation of complex cases over the decades with pathologists handling and supporting clinical trials establishing valuable IP for supporting highly complex patient care
- Experts in specialties and sub-specialties globally provide input to WHO and other bodies to inform and support the best possible care and outcomes

Summary

Laboratory diagnostic testing guides clinical decision-making for patient treatment and clinical trial outcomes. Access to routine and specialized testing can be a crucial factor for successfully meeting the analytical requirements of your clinical trial protocol.

- Understanding the full capabilities of your lab partner helps you match your protocol needs with your choice of lab
- Your lab is a valuable resource for understanding innovation in lab testing
- Labs are a valuable resource in strategies to reduce patient and site burden in considering protocol design
- Advancements in testing are a constant: do regular check ins to understand capabilities

Thank You!