Fact Sheet

Tracking Clinical Trial Samples

The clinical trial ecosystem

The life cycle of clinical trial samples is complicated. Clinical trials are a distributed ecosystem with many interactive members depending on and supporting each other by sharing data and information. Each of these is critical to the health of the trial. The members within this ecosystem include the clinical sites, the laboratories, vendors handling the samples, and even a courier like UPS and repositories that store the samples long term. Finally, there are the samples themselves with any associated data.

Samples are the lifeblood of the entire enterprise for a study. To ensure success, the samples must be managed throughout the entire life cycle — beginning with the initial collection from the patient at the clinical site, to any movements of the samples from lab to lab for analysis, to the final submission of data and then storage. It can be challenging to follow the samples from lab to lab for analysis, to the final submission of data and then storage. It can be challenging to follow the samples through this life cycle in terms of integrating not just the physical samples, but also their associated data. When the samples are handled by multiple members within the ecosystem it becomes more complicated.

The sponsor must have full visibility of each sample as it moves from the patient, to the repository, to its end of life, as every sample must be accounted for. Visibility remains important after the intended study has ended. The samples enter another phase where they can be used for purposes beyond their original intent. This could include the development of diagnostic, or a novel assay within the same therapeutic area or in an area unrelated to the original.

In that case, careful consideration must be given to ensure that when the samples are being pulled from the storage repository for this future use or out-of-study

type of work they are properly consented, meaning the patient agreed that their samples could be used for purposes outside of the original study.

It's essential to ensure that both the sample and the data around the sample are both tracked and stored properly.

Questions for use

An investigator must determine:

- Can these samples be identified?
- Should they be identifiable?
- Should the samples be anonymized?
- How long have they been in storage?
- Could long term storage affect their viability?
- Is there any relevant information about the patients that these samples were collected from that could be important for new research?

Investigators can request both the physical sample itself, and data about the sample for new research. It's essential to ensure that both the sample and the data around the sample are both tracked and stored properly.

Chain of custody

As samples move from vendor to vendor, the chain of custody is the web connecting the different parts of the ecosystem. The courier is a critical control point. The courier records when they picked up a sample. As it's transported, the temperature may be recorded. Not every courier has that capability, but if you're dealing with a special rare sample, that information can be critical. The bottom line is the life cycle is the entire life history of a sample's collection, travels and use.

Varying approaches

Depending on the size and phase of the study, there may be up to hundreds of thousands of samples. In studies that have a large distributed ecosystem with multiple vendors touching the sample and movement from one place to another, one can expect that each vendor has their own procedures, data systems and approach to tracking their samples.

Some smaller specialty labs may not have a sophisticated data architecture in place for managing sample tracking. This is common with university labs, for example. They may have just a few staff members to manage all aspects of receiving and analyzing the sample. The focus is on the analytics and the assay, and less on the chain of custody.

Their approach to sample tracking and the data may not be as robust as the larger vendors. But the data from the smaller vendors is just as important as the data from large vendors and central labs because, in the grand scheme of things, every sample must be accounted for.

A clinical site may ship screening samples directly from their clinic straight to a testing lab, bypassing a central lab altogether. Most central labs are sending out data on a regular basis to the study team.

Samples for a screening lab may be going once every couple of months to a smaller lab. This means the study team doesn't have visibility of those samples until the smaller testing lab sends the analysis results, which could be a week or two after the sample has actually been received. Any delays in shipment or in receipt of the samples is unknown to the study team, and could compromise the quality or viability of the sample. Unfortunately, this could lead to a lost opportunity to test a valuable sample.

Having the chain of custody data together in one place on a regular basis is important for the study team to track their samples in nearly real time. This could ultimately save time and resources when they reconcile this information later on for final submission.

Risk of insufficient tracking

Most investigators will tell you that the sample itself is as important as the patient, especially in a rare disease study where one is working with a small number of patients. Each of their samples is a significant snapshot in the time course of the study that, from a biological chemical perspective, can't be duplicated. If these samples are critical in understanding the disease process, that would be a major loss. Not knowing where samples are could lead to missing the key insight of the study.

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Beyond a particular study, other investigators may want to use a portion of any remaining samples to perform unrelated research. Those rare disease samples may represent an important resource. In the spirit of advancing the scientific body of knowledge, there's a wealth of information stored in biorepositories. Somebody may have a life-saving idea. What if those samples can't be found? What if we can't answer the question? It's not only a waste of funding dollars and resources for storing thousands of samples that are unusable, but a missed opportunity for discovery.

Current practice

Everybody does it a little bit differently, but the picture in the same. It's spreadsheets, email manifests, vendor portals, study team calls and vendor team calls, There are a lot of moving parts not tightly woven together. Data managers and clinical trial leads are pulling information together manually to track their samples and to drive queries. Questions about things they're seeing on the sample data and even some of the patient data gets sent out for clarifications.

What is needed is an approach that pools disparate data sources in one place for investigators, sponsors and vendors to view and query. This must be accessible anywhere at any time, so that, for example, investigators in California have the same access to their sample data as their colleagues in Hong Kong.

In Part 2, we're going to cover consent management and tracking it along with the samples.

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