Biosample safety in clinical trial management

Effective handling, transportation, and storage of biospecimens must comply with the environmental conditions and timelines required by the study to guarantee trial validity. Inadequate biological sample management can lead to sample mix-ups, temperature excursions, and reporting delays, all of which can significantly delay important milestones, increase costs, and ultimately increase waiting time for patients in need. Here are some of the key considerations to mitigate these risks and how **Clinigen** can assist.

Biological samples for a study are often collected from around the world but will typically also need to be stored in one safe location. Transporting such samples safely on a global scale requires specific knowledge and expertise of the sector and should be handled by a biological sample logistics provider with the right capabilities. This can include the use of various technologies, such as live temperature monitoring devices on each individual shipment to ensure that any potential risk of temperature deviation is identified and notified immediately, allowing it to be proactively addressed as soon as possible.

For example, an unforeseen event (that goes on to result in an increase in temperature, for instance) may require an adjustment to the distribution routes, change in temperature-controlled packaging materials or the addition of dry ice. This capability can then go on to significantly reduce the risk of the biosamples being compromised in transit and give the sponsor peace of mind.

Sponsors should also consider costs associated with global distribution. Shipment and handling of biospecimens can be costly, especially for multi-centre studies. A partner with data-driven optimised distribution processes and facilities around the world can help sponsors reduce transportation costs and improve overall supply chain efficiency.

Ensuring full traceability at all times

Full traceability of biosamples is critical to guaranteeing the integrity of a trial. An experienced clinical supplies management partner will be able to guarantee the correct identification of biospecimens on an individual basis and maintain a compliant documented chain of custody for the entire journey. This provides a traceable record that guarantees uninterrupted control of samples from initial collection to final disposition, through strict Standard Operating Procedures (SOPs).

By working with a single provider for all of a trial's biological sample storage and handling requirements (storage infrastructure, flow management, and the location and management of sample demographic data), pharmaceutical and biotech companies will be able to optimise their entire supply chain and mitigate risk holistically. In particular, customer-friendly tools can provide access to biosample data at all times. For instance, client services might encompass a worldwide centralised database accessible to trial managers for reviewing sample location. Additionally, they can employ filters to refine the selection of samples, optimising batch size testing at central labs and consequently reducing their supply chain expenses.

Cost-effective storage for small-scale trials

Many larger sample management service providers do not have the ability to provide custom solutions and pricing for small storage projects. As a result, many small-scale trials with low quantities pay the premium to store their samples externally. On the other hand, they could choose to handle samples internally, which presents an alternative but costly approach. This option comes with the added risk of insufficient internal storage capacity and potentially inadequate monitoring technologies. Moreover, it may result in a loss of internal capacity that could otherwise be dedicated to research and development or core testing activities, which are essential for pharmaceutical customers.

While many suppliers offer one-size-fits-all storage packages, certain clinical supplies management organisations will provide customised solutions. The key is to find a provider that does not charge a premium for one-off or small projects. Clinigen offers biorepository services ranging from short and long-term storage of biological samples collected during a clinical trial to the management of a client's entire biorepository. Their services include ultra-low (<-60°C) and liquid nitrogen storage (<-150°C) with full barcode scanning and traceability and their unique over-tubing process. Specialists in cold chain management, maintaining sample integrity is the driving force behind all established processes.

With dedicated biological sample management facilities in Europe and the US, Clinigen delivers tailored solutions for clients to ensure their clinical trials are a success, regardless of the size, scope, or stage of the projects. Supporting their mission to accelerate clinical development to impact the lives of patients around the world, they offer competitive pricing and industry-best cycle times. ●

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