



Clinical sample logistics
in a multicentre study

CASE STUDY: BIO-SAMPLING MANAGEMENT

This case study outlines how Clinical Supplies Management (“CSM”), a Great Point Partners (“GPP”) portfolio company, helped a trial sponsor to manage the logistics and sample management of its study with a smart and simple solution.

A multicentre study recruited patients at several sites in Europe and in the United States, with the aim of collecting plasma samples which would then be frozen on site.

There were 3 visits per patient and 10 time points per visit with 2 aliquots prepared at each time point in 2ml cryotubes: a primary sample for analysis and a back-up sample for long-term storage.

CHALLENGES

This study encountered at least 4 challenges. For each, CSM implemented a unique and smart solution, thanks to its integrated services and worldwide presence.

- 1 The study was multicentre; samples were collected on different continents
- 2 Samples had to be transported and stored at -80°C
- 3 A consolidated and verified list of all collected samples had to be established
- 4 Samples had to be dispatched according to their end use

CSM'S SOLUTION

Considering the study's specificities, CSM's team of logistics experts needed to ensure an efficient sample management solution. With its integrated services, CSM was able to provide solutions which included designing the collection kits and tube labels, organising kit & sample transports, storing samples and establishing a complete and verified list of collected samples.

- ▲ CSM took charge of the design of the collection kits and associated documents and labels, including the design of the identification of subjects and tubes and the design of the related requisition form: a unique identifier was assigned to each aliquot generated during the study.
- ▲ CSM provided clinical sites with sampling kits and complete instructions and documents (laboratory manuals, air waybills, PFI), ensuring easy blood collection and sample shipments.
- ▲ All samples were transferred to a centralised storage location, minimising shipment costs: (Exton for US sites and Brussels for EU sites). Upon receipt from sites, the samples were checked for integrity and counted. Information regarding each reception was documented.
- ▲ The smart design of the sample identification allowed the generation of an electronic list of samples prior to entering tubes in the system. This solution avoided the manual entry of data with only sample date and time having to be entered manually upon receipt. This type of entry reduces costs and the risk of data entry errors.
- ▲ CSM entered all tubes collected during the study and associated data in a validated database, using the unique identifier found in barcode form on the tubes, and performed a QC of the tubes and the requisition forms. A consolidated and verified list of samples was generated.

- ▲ In case of discrepancies/missing data, CSM was responsible for the data clarification process, managed directly with clinical sites.
- ▲ All tubes were uniquely identified in the system and precisely localised (freezer, rack, box and position). They were stored in qualified and monitored freezers. An alert system was put in place with staff on duty 24/7. Back-up freezers and back-up generators were also available.
- ▲ The primary samples were grouped and dispatched to 3 laboratories, accompanied by a packing list containing all data related to the samples which was required by the laboratory.
- ▲ Back-up samples were stored until the end of the study, to be destroyed upon request by the sponsor.



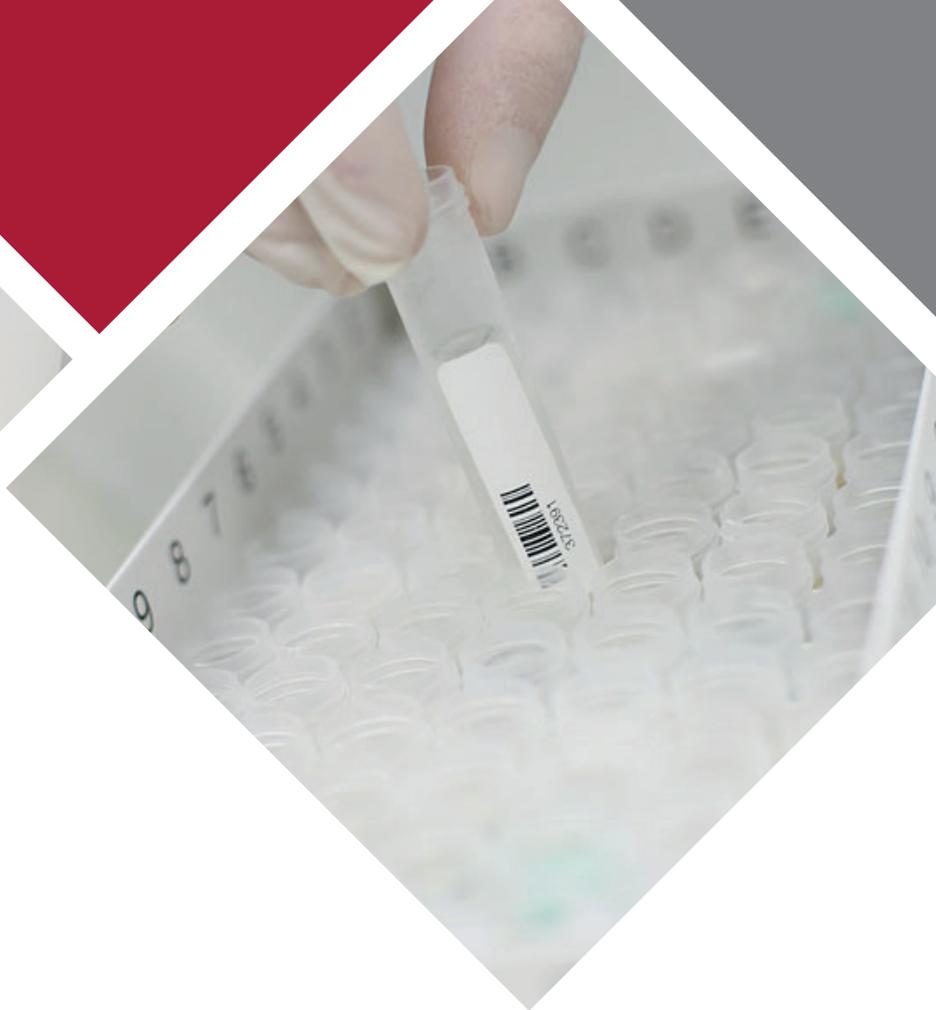
RESULTS AND OUTCOMES

By using CSM and its integrated solutions for collection kit design and supply, transport, storage and electronic verification, the client was able to limit risk, improve traceability and dramatically reduce costs.

CSM has dedicated bio-sample operations in both the US and Europe with over 130 freezers. The use of our dedicated sample management system supports millions of samples with over 10 years' successful management of client projects. CSM has proven expertise and delivers outstanding quality with a perfect track record of inventory management and the ability to consolidate samples from disparate central laboratories and clinics.

CSM's established capabilities and operations in the US and in the EU enable efficient and simplified biomedical sample management services. From the design & assembly of sample collection kits to the biomedical sample logistics and biorepository: you can use CSM to support your Ph. I to IV clinical trials with one contract and one solution...

- CSM's track record of millions of samples stored makes CSM the right choice with the right solution for your BSM
- You can trust CSM's logistical track record of 10,000+ shipments received from clinical sites and central laboratories worldwide when it comes to managing your study
- Over 250,000 biomedical sampling kits assembled since 2015 with only 0.002% incidents/deviations and sampling kits for 300+ clinical trials shipped to 86 countries worldwide since 2005



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