



Biological sample  
management (BSM)

## CASE STUDY: CLINICAL SAMPLE LOGISTICS IN A MULTICENTER STUDY

Clinical Supply Management (CSM) understands that clinical samples are a key asset and is uniquely positioned to offer clinical sponsors with a set of comprehensive and integrated solutions for the management of biological samples from the design and assembly of collection kits, identification, cold chain logistic and biorepository. This case study outlines how CSM provided its integrated biological sample management (BSM) services to a global pharmaceutical company. The client develops medicines for chronic pain, cancer, asthma, and autoimmune diseases.

In his multicenter study, the client recruited patients at several sites in Europe and the United States. It collected plasma samples that were then frozen on site. The study involved three visits per patient and 10 time points per visit, with two aliquots prepared in 2ml cryotubes for each time point. The two aliquots included a primary sample for analysis and a back-up sample for long-term storage.

## CHALLENGES

This study encountered at least four challenges. For each, CSM was able to implement a unique and smart solution, thanks to its integrated services and worldwide presence.

- 1 The study was multicenter, with samples 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

CSM's team of logistics experts needed to ensure an efficient sample management solution that would meet the specific needs of the study. CSM was able to provide an integrated solution that included designing the collection kits and tube labels, organizing the transport of kits and samples, storing samples, and establishing a complete and verified list of collected samples.

- ▲ CSM designed the collection kits and labels (including the identification of subjects and tubes) and associated documents (including 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 shipment of samples.
- ▲ All samples were transferred to a centralized storage location (Exton for US sites and Brussels for EU sites), minimizing shipment costs while maintaining cold chain and keeping complete oversight by CSM. Upon receipt, the samples were checked for integrity and counted, and the receipt information documented.
- ▲ The smart design of the sample identification system allowed the generation of an electronic list of the samples prior to entering the tubes into storage. This solution, which meant that only sample date and time needed to be entered manually, reduced costs and the risk of data entry errors.
- ▲ CSM entered information on all tubes collected during the study and associated data in a validated database, using unique barcode identifiers on the tubes, and performed a QC of the tubes and requisition forms. A consolidated and verified list of samples was generated.

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



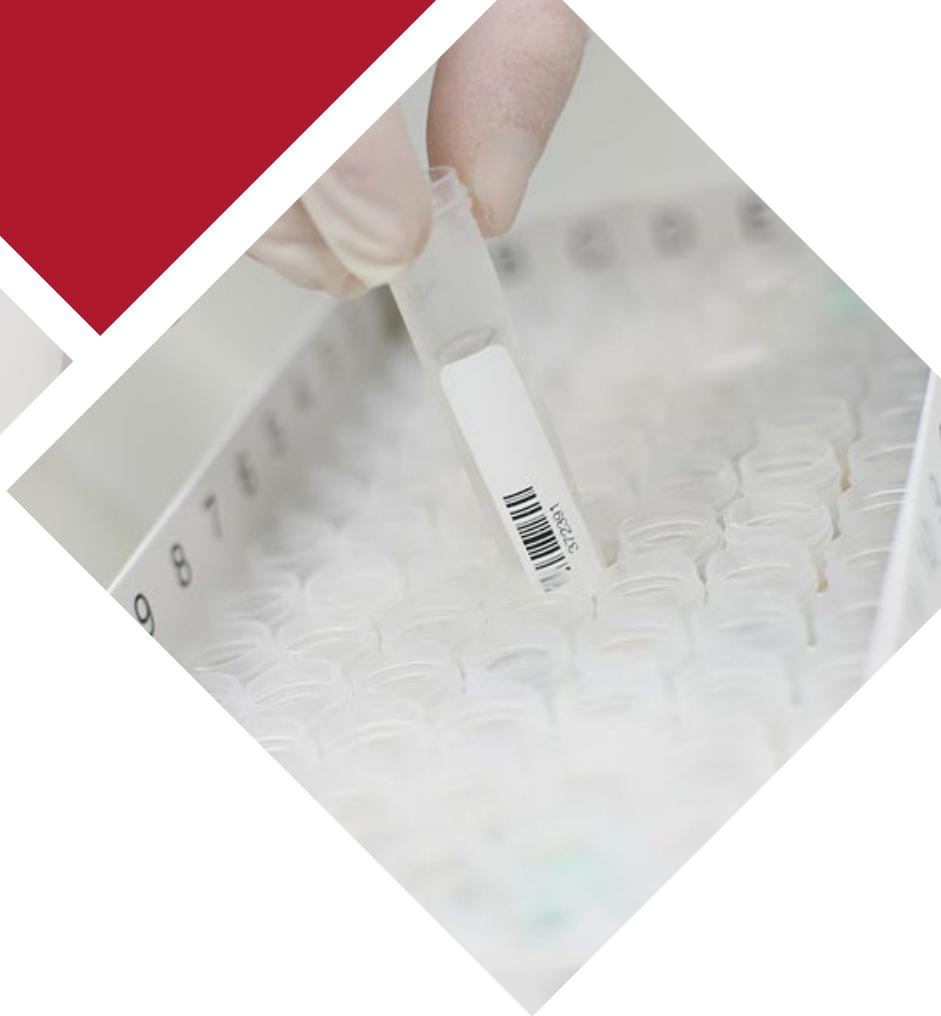
## RESULTS AND OUTCOMES

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's established capabilities and operations in the US and in the EU enable efficient and simplified biological sample management (BSM) services. From the design and assembly of sample collection kits to the biological sample logistics and biorepository, CSM supports your phase I through phase IV clinical trials with one contract and one solution.

CSM delivers outstanding quality with a perfect track record of inventory management, and can consolidate samples from disparate central laboratories and clinics. You can trust CSM's logistical track record:

- 10,000+ shipments received from clinical sites and central laboratories worldwide.
- 250,000+ biological sampling kits assembled since 2015, with only 0.002% incidents/deviations.
- 1,600,000+ samples stored.
- 300+ clinical trials involving kits shipped to 86 countries worldwide since 2005.
- 130 freezers at dedicated BSM sites in the US and EU.



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