



Accommodating last-minute study changes without affecting drug supply

CASE STUDY: ON-DEMAND SERVICES

CSM's On-Demand methodology provides sponsors with a flexible and innovative tool that enables trial drugs to be packaged and labeled on short notice, without needing to commit the entire supply of drug up front. Unlike traditional packaging and labeling, CSM's On-Demand service concentrates on actual enrollment, meaning that trial drugs can be packaged and labeled specifically for, and immediately prior to, each shipment.

CSM can work with you to start a new clinical trial in just a few weeks, and can process new shipment requests or make changes to the trial within 48 to 72 hours. This flexibility allows you to save costs, use your drug product in multiple protocols, and avoid waste.

CHALLENGES

One recent trial that highlighted the strengths of CSM's On-Demand service involved an urgent request by a sponsor to package and label an investigational medicinal product (IMP). The sponsor needed a small number of kits to be packaged, labeled, and released for shipment to Belgium within 48 hours. If the kits could not be prepared within that period, patients in the trial would run out of the treatment medication.

In addition to the tight turnaround time, the project also presented several complicating factors.

- ▲ The sponsor had no additional stock of the drug product available for use in the program. This meant that the sponsor would have to repurpose drug product from another trial with the same product.
- ▲ The patients who needed the medication were located in a non-study country, so the sponsor had no printed labels immediately available for use.
- ▲ As the shipment destination was within the EU there were regulations that required certification by a qualified person (QP) for each packaged batch, putting an additional constraint on an already stressed timeline.

CSM'S SOLUTION

CSM helped the sponsor overcome each of these issues to create a successful program. Using its On-demand methodology, CSM:

- ▲ Took a supply of the drug product from one of the sponsor's other ongoing studies and printed new labels.
- ▲ Packaged and labeled the exact number of kits needed and dispatched them immediately, without warehousing, to the site.
- ▲ Dedicated a team to handling the request; the team met the deadline while performing the entire operation under cGMP conditions.
- ▲ Involved a qualified person (QP) throughout the entire process to ensure that the batch certification could be completed within the time limit.

These steps can be repeated to accommodate any number of clinical trial requests, and repeated as often as requested or needed.

RESULTS AND OUTCOMES

Thanks to CSM's On-Demand methodology, the sponsor's project was a resounding success. Patients received the kits in time, without any drug discontinuation period. The sponsor was pleased that CSM could provide coverage for the drug shortage until the normal resupply batch could be produced:

ADVANTAGES OF ON-DEMAND METHODOLOGY

▲ PACKAGING FLEXIBILITY

- Allows drug materials to be packaged and labeled on an as-needed basis
- Allows additional countries to be added mid-study without having to relabel
- Allows the use of multiple kit designs across protocols
- Significantly reduces waste of labels and subject randomization numbers

▲ STOCK MANAGEMENT

- Allows sponsors to run multiple protocols with seamless scalability
- Significantly reduces inventory, storage costs, and loss of drug stock

▲ IMP MANAGEMENT

- Requires no expiration updates
- Allows sponsors to receive overpack savings
- Allows sponsors to make rapid adjustments to their trials

▲ STUDY MANAGEMENT

- Eliminates need to commit entire drug supply to kits at the beginning of the study
- Reduces workload for reconciliation
- Eliminates need to rework packaged drug product
- Decouples the enrollment rate from scheduling
- Eliminates need for long-term forecasting of packaging and labeling



CSM On-Demand provides solutions to IMP challenges

- Avoid up to 50% drug waste and associated costs
- Work with the leading innovator: CSM has 16 years of experience with On-Demand production and produces up to 30% of its IMPs On-Demand
- Be agile: CSM's standard turnaround time is 48 to 72 hours



COULD YOUR STUDY BENEFIT FROM CSM'S ON-DEMAND METHODOLOGY?

Your study is unique, but regardless of its differences from the one outlined above, it too could benefit from the new level of flexibility that the On-Demand method offers. Learn more about CSM's On-Demand method and uncover the specific ways that your study can benefit from it.

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