CSM®
A CLINIGEN COMPANY

CASE STUDY:
INVESTIGATOR INITIATED STUDIES (IIS)

An investigator initiated study (IIS) involves the use of a product in a clinical trial initiated by an investigator, rather than a pharmaceutical company. Thus, an IIS is not the same as a regular phase I, II, or III clinical trial.

The investigator is responsible for the packaging and labeling, release, and distribution of the investigational medicinal product (IMP). The pharmaceutical company will usually support the IIS by providing its drug product at no cost.

Competent national authorities require independence between the pharmaceutical company and the investigator in an IIS, but ensuring that independence can be challenging.

This case study outlines how Clinical Supplies Management (CSM) provided smart and simple solutions to the investigators using a product from a top 10 pharmaceutical company.

CHALLENGES

The pharmaceutical company and the investigators faced different challenges. CSM leveraged its expertise to implement unique and flexible solutions for each.

For the Pharmaceutical Company:

1. The IIS's independence means the pharmaceutical company cannot directly monitor and supervise the packaging and labeling, QP (qualified person) release, and warehousing and distribution of its product. These activities are the responsibility of the sponsor.

2. Although the pharmaceutical company is not legally bound in an IIS, their QP usually feels uncomfortable about losing sight of its product's supply chain. Thus one major issue is how to ensure professional clinical trial supply (CTS) while respecting pharmaceutical/sponsor independence.

3. The pharmaceutical company in this case is providing 13 different products in more than 100 ongoing IIS. Most of these products are expensive oncology drugs, most of which are used in different IIS by different sponsors. Thus another major challenge is how to manage the CTS in a cost-efficient and quality controlled manner.

For the Investigator:

1. Studies involve not only the pharmaceutical company product, but other clinical supplies.

2. Usually the investigator has limited experience and knowledge about the packaging and labeling, QP release, and warehousing and distribution of IMPs. The investigator also needs to source other clinical supplies (such as comparator drugs or placebos, ancillary supplies, etc.) and coordinate their use with the IMPs.

3. This dual challenge means that the support of professionals to manage CTS is recommended.

CSM'S SOLUTION

CSM's team of logistics experts needed to develop a solution that would meet the specific needs of the study, meet the challenges faced by the pharmaceutical company, and provide the support required by the investigators – all while ensuring that the pharmaceutical company and the investigators remained independent of each other.

The solutions included:

- To ensure the pharmaceutical company and the sponsor-investigator remained independent of one another, CSM implemented service contracting solutions including:
  - One contract and quality agreement with the pharmaceutical company to store bright stock batches of its products.
  - One contract with the sponsor-investigator to manage packaging and labeling, QP release, and warehousing and distribution of the pharmaceutical company products and other clinical supplies needed for the IIS.

- To provide quality monitoring and oversight in the release and distribution of the CTS, the investigator subcontracted CSM to:
    - Ensure QP certification of final packed and labeled IMPs according to the regulations (Article 13.3 of Directive 2001/20/EC), based on batch certification forms, sponsor drug order forms, and technical agreements.
    - Ensure each instance of the final release of packed and labeled IMPs to sites, by verifying the regulatory release provided by sponsor prior to first shipment to a site.

- To minimize costs and often expensive product waste, CSM offered to store bright stock batches of the pharmaceutical product and implement the most appropriate packaging and labeling solution depending on the IIS and product specificities.
  Production was done in two ways, to ensure the ability to meet timeline and stock management requirements:
    - Mini-Stock Production – Labeling is done for quantities based on quarterly forecasts, which allows for short shipping timelines (normally five days or less) while minimizing production cost and stock loss. This solution is ideal for larger IIS with expensive drugs.
    - On-Demand Production – Labeling is done on a per-order basis, and stock is managed throughout the study. This solution allows for minimum stock loss and maximum flexibility while avoiding product waste. It is ideal for studies with limited or expensive drugs. On-demand production is supported by a specific functionality in CSM's proprietary ERP system.

- To further support investigators in their IIS, CSM provides end-to-end solutions including the sourcing of comparators and placebos, ancillary supplies, transport coordination, and the management of returns and destruction.

RESULTS AND OUTCOMES

This collaboration with one of the top 10 pharmaceutical companies has been a success. CSM is currently supporting more than 100 IIS involving 13 different products from that same pharmaceutical company.

ABOUT CLINICAL SUPPLIES MANAGEMENT

Since 1997, CSM has been providing innovative solutions to meet the complex clinical supply challenges that pharmaceutical and biotechnology companies face. CSM manages the clinical supply chain for hundreds of satisfied clients worldwide, providing services that keep clinical trials on time and on budget. CSM offers a full suite of cGMP-compliant services, continually delivering quality supplies to clinical sites and patients around the world. CSM's customer-centric approach, revolutionary processes, and state-of-the-art clinical services increase efficiencies, reduce costs, and improve outcomes for clinical trials.

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