WEP

With Every Patient.

CASE STUDY:
AUXILIARY MEDICINAL PRODUCT CLINICAL TRIAL SUPPLY & SOURCING FOR A PHASE III ONCOLOGY TRIAL

The Challenge

A CRO running a Phase III oncology study needed a partner to manage auxiliary medicinal product procurement and distribution to clinical trial sites in countries in Latin American, Central and Eastern Europe. The operating model relied on sourcing product locally in each country, shipping to a central depot for re-labelling and storage, ready for distribution to clinical sites.

The main risks were:

- **Regulatory and importation ambiguity:** Limited internal clarity on country-specific regulatory pathways, importation processes, and labelling requirements, creating risk of non-compliance and potential delays in study start-up.
- **Unpredictable and variable patient enrolment:** Unpredictable enrollment rates increase risk of stock (AxMP) variability and shortages, requiring rapid access to local stock to prevent site interruptions when enrolment exceeded projections.
- **Start-up pressure:** Supply continuity was needed before the Interactive Response Technology (IRT) platform was live.

Our Approach

We were engaged to run the end-to-end supply chain and provide consultative input to streamline operations and reduce avoidable cost and complexity. Our supply chain team aligned the model across procurement, labelling, QP release, and distribution, drawing on experience delivering into the countries in scope.

The Solution

Centralized coordination through Ireland:
All activities were coordinated through our Ireland warehouse location, creating a single controlled hub for program planning, labelling design & operations execution, and GMP QP release activities.

Clinical supply chain oversight:
The clinical supply chain team implemented a proactive, data-driven planning model that aligned procurement, inventory, and distribution decisions with the study's operational requirements, including strategic procurement planning, collaborative forecasting, production planning and bulk distribution.

In-country depot strategy for speed and flexibility:
Product was shipped in bulk to qualified in-country partner depots and held locally until site shipments were required, enabling rapid fulfilment in response to variable enrolment.

Quality release process implemented with local depots:
We worked with partner depots to put a Quality release process in place to support compliant release and distribution.

Custom label engineering for small pack sizes:
Where standard labels were not feasible due to packaging complexities, i.e. blister packs & vials, we designed and produced fit-for-pack labels to meet local requirements while maintaining legibility.

Manual ordering bridge to IRT go-live:
To avoid delays while IRT was being implemented, we introduced a controlled manual drug order process and then transitioned to IRT once live, supporting inventory release files to ensure systems were aligned for traceability.

The Results

- Supported the CRO in meeting Sponsor timelines and expectations by reducing regulatory and operational uncertainty in complex markets.
- Implemented a scalable distribution model with local depots to support rapid replenishment and reduce the risk of site stock-outs.

- Enabled product supply ahead of IRT go-live and transitioned to IRT without disrupting site operations.
- Provided a single end-to-end operational owner covering procurement, labelling, QP release and distribution, improving oversight and coordination.

Capabilities Demonstrated

- AxMP procurement and country-level sourcing coordination
- Clinical labelling design for constrained packaging formats
- QP release workflow design and implementation
- GDP-compliant bulk-to-depot and depot-to-site fulfilment
- Operational flexibility bridging manual and IRT processes
- Program Management for end-to-end clinical trial supply support

WEP provides high-touch, comprehensive clinical supply chain management solutions. We bridge the gap between large CDMOs and regional providers with limited capabilities, offering purpose-built designs that are focused on speed, flexibility, and expert oversight in complex clinical programs. Our approach integrates strategic supply chain leadership, comparator and R&D sourcing, GMP labeling & packaging, global warehousing, and worldwide distribution, all delivered through a single accountable partner.

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