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Clinical ancillary management

Tackling the complexities of a global diabetes trial

Diabetes: A killer that must be stopped

According to the World Health Organization, around 1.6 million people worldwide died due to diabetes in 2016. It is estimated that 425 million people are living with diabetes all over the world. As the disease is often undiagnosed, projections indicate that by 2045 this number may reach 629 million. Given it is one of the leading causes of death worldwide, it is no surprise that diabetes research has become highly competitive. In mid-2018 there were over 1,600 ongoing interventional diabetes-related trials, with some large manufacturers sponsoring over 30 trials simultaneously.

Clinical ancillary challenges for diabetes trial

A diabetes trial is inherently complex. Patients must track blood sugar levels which introduces the need for glucometers, test strips, and a long list of additional supplies such as lancets, alcohol swabs, syringes, needles etc. Each trial is somewhat different with respect to the number and frequency of tests, and whether nutritional supplements will be required. Patients are typically maintaining supplies at their homes, requiring materials be transported in a convenient 'kit' that maintains product integrity. Determining the 'master' list of supplies, and developing an accurate demand forecast can be challenging.

Given a highly competitive enrollment process, supplies need to be readily available in support of investigator sites and in time for first patient visit. In today's environment, where later stage trials involve large patient populations in multiple countries around the globe, materials must have labels and instructions in local languages or the sponsor risks having a patient that is non-compliant because they simply don't understand the directions. Worse yet, they might be unaware of their actual health and put themselves at risk.

The global nature of these trials introduces import / export challenges that must be taken into account when planning lead times for delivery of materials. Each country has its own regulations and customs practices. They may also mandate minimum expiry dates which can significantly impact demand planning.

This level of complexity can quickly outstrip the sponsor's available resources. Even the largest of manufacturers have realized the value of outsourcing ancillary materials management to experienced clinical supply service providers.

Working with outsourced providers

A large manufacturer engaged the Thermo Fisher Scientific Ancillary Management team in support of their global diabetes trials. The scope of a single trial often included as many as 1,500 to 2,000 patients in 15 to 20 countries across all geographic regions (US, EU, Asia, Middle East). The geographic reach of the trial and the number of items that had to be sourced required working with 3 to 5 suppliers and an average of 15 to 25 manufacturers.

The sponsor relied on their Clinical Supply Chain Project Manager to support with:

- Identifying the required supplies
- Calculating demand
- Developing a sourcing strategy that included both centralized and local suppliers to address all regulatory and language requirements
- Access to regionalized / local storage facilities with associated inventory management, distribution and logistics support to streamline the supply chain while enabling rapid response in the context of a competitive patient enrollment profile
- Providing ongoing operational execution and oversight to ensure everything required to support the protocol was at the investigator site in time for each patient visit

Representative list of required ancillary supplies

Item	Expiry Date?	Shelf Life?	Procurement	Sent with Patient?
Alcohol Preps (200/box)	No	Yes	Bulk	Yes
Sharps Container	No	Yes	Bulk	Yes
Ice Packs	No	Yes	Bulk	Yes
Pen Needles	No	Yes	Bulk	Yes
Syringe, 1mL (100/box)		Yes	Bulk	No
Needle, 27G (100/box)		Yes	Bulk	No
Insulin syringe and needle combination		Yes	Bulk	No
Insulated bag	No	No	Bulk	Yes
Tote Bag	No	No	Bulk	Yes
Glucometer	Yes	No	Region of use	Yes
Test Strips (50/box)	Yes	No	Region of use	Yes
Lancets	Yes	No	Region of use	Yes
Control Solutions	Yes	No	Region of use	Yes

Developing and actionable plan

The Clinical Ancillary Management team was able to navigate the inherent complexities of a large-scale global trial on behalf of the Sponsor.

Given their depth of experience with diabetes trials, there was an existing checklist of supplies that are typically required to support such a trial. This allowed them to quickly develop the 'master' supply list with the sponsor so they could begin the demand planning process.

Calculating demand is always a tricky process.

- Accurately determining the number of sites and the rate of patient enrollment is challenging, especially in a highly competitive process. The Clinical Supply Chain Project Manager worked closely with the Sponsor and CRO to develop best possible forecast.
- Overage must factored into the plan to enable flexibility and rapid response to support newly enrolled
- Items with expiry dates add another level of complexity as replacement supply must be accommodated. As example, the batteries in a glucometer have expiry dates, as do some of the components within a test kit. Each requires detailed tracking within the inventory management system.
- There are often different units of measure for a given item. For example, test strips may be in packs of 50 in one country but in packs of 100 in another. Patient visits by site and dosing schedules must be translated into number of packs / boxes / cartons to be ordered, and at what frequency.

Part of defining the demand plan is understanding the available capacity at the investigator sites. Will they be able to accept some materials in bulk and use them across multiple patients? Or will pre-packaged kits be supplied in support of each patient visit? The Ancillaries Clinical Supply Chain Manager created a plan that defined what the investigator sites needed between visits and what to send home with the patient. The sites were supplied with a tote bag for each patient to transport materials. This level of detailed planning optimized patient compliance and investigator site convenience.

Once the demand plan was fully defined, the team began work on designing the supply chain.

- With access to a vast database of quality-approved suppliers, combined with their experience with global trials, they identified the most appropriate sourcing approach for each item required in support of the trial. In some cases items were sourced centrally where, in other situations, local in-country sourcing proved to be the best approach.
- Using their global network of GMP facilities, they identified the most appropriate locations where supplies could be staged to support in-country / regional sites, enabling rapid response to support newly enrolled patients.
- Item-level lead times were established that incorporated the time required to procure and distribute materials. When combined with the demand plan, which also addressed management of expiry dates, the Supply Chain Project Manager was able to finalize a master schedule for the trial.

When supporting a global trial, individual country regulations and customs rules can quickly derail the best laid plans. To mitigate that risk, the Thermo Fisher Scientific team leveraged their in-country experts and logistics specialists to ensure all regulatory requirements were met, and that required import/ export documentation was in place to minimize customs clearance delays.

Benefiting from expert planning and execution

Planning for ancillary materials in support of a global trial is complicated. Investigator sites must focus on patient enrollment and retaining the patients that are already participating in the trial. The Sponsor is most focused on their Investigational Medicinal Product (IMP) and typically don't have the bandwidth or expertise to take on the administrative burden of managing the myriad of ancillary supplies that might be required for a successful trial.

By leveraging the expertise of a trusted clinical supply provider, this Sponsor benefits from:

- A comprehensive regulatory-compliant supply management program that reduces their administrative burden;
- Support of investigator sites, eliminating their need to separately procure, store and dispose of ancillary materials;
- The Thermo Fisher Scientific team leveraged their in-country experts and logistics specialists to ensure all regulatory requirements were met, and that required import/export documentation was in place to minimize customs clearance delays.
- Distribution expertise, with global GMP-compliant locations that provide flexibility and responsiveness to meet the demands of a competitive patient enrollment process;
- Reduced waste due to a centrally managed program that can optimize the end-to-end supply chain; and
- Improved patient compliance as materials can be pre-packed in support of each patient visit, ensuring everything is in place to support the dosing schedule.

As the Thermo Fisher Scientific team continue to work with this sponsor, they explore ways to further refine the process, especially as it relates to support across multiple studies. But at the end of the day it comes down to this singular focus: getting the right material in the right quantity at the right place, and at the right time, every time.

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