ThermoFisher SCIENTIFIC

CASE STUDY

UNITED WITH AMBITION & ACCESSIBILITY

Accessing patient populations in remote locations presents challenges for ambitious new trial

Singapore team expertise paramount in trial success

Our client, a top major pharmaceutical company, approached us for guidance on how to run an ambitious clinical trial in the Asia Pacific region; a trial involving 10+ countries, 74+ sites with 400+ shipments across the region.

This trial presented many challenges:

- Cold chain Investigational Medicinal Product (IMP) that needed to be kept at specified temperatures from point of origin to site delivery
- Late stage labeling of supplies to accommodate adaptive trial timelines
- A need to access patient populations across many different countries in the Asia Pacific region and in many remote locations
- Multiple latent changes in client requirements
- Shortened timelines for fast drug approval

It became apparent that this Sponsor was going to totally rely on the Thermo Fisher Scientific team to manage this trial from start to finish.

Study planning and set-up

From the outset it was clear that the Sponsor was relying on Thermo Fisher Scientific to:

- Select the best courier companies with whom to partner across the region. To base this decision on its data driven objectivity and extensive statistics gathered on each distribution lane with multiple courier companies.
- Understand the customs clearance challenges across all countries in the APAC region. To mitigate risk of delays by choosing courier companies who had a history of effective customs clearance over time.
- Set up and perform late stage labeling to meet changing requirements and timelines of the trial.
- Suggest the best distribution plan to meet stipulated timelines and to get temperature sensitive supplies to remote areas.
- Give consultative advice on the possible risks and implications related to distribution into remote locations.

Temperature control challenges

South East Asia, in certain periods of the year, can experience extreme high temperature conditions, 32°C+. In addition, Pacifica zone and South Korea have different temperature climates which can affect the shipping conditions of cold chain clinical supplies. To help mitigate risk of temperature excursions on supplies during transit, the Thermo Fisher Scientific team:

- Carefully selected the most appropriate shipper box for the designated distribution channels, e.g. Summer versus Winter configuration, and/or specific technology enabled shipper boxes during seasonal change.
- Monitored and tracked shipments and gave guidance to appointed courier companies on how to maintain supplies within the correct temperature specification during transit.
- Pro-actively communicated with customs officers so as to limit delays in customs clearance.

Distribution model including remote locations

Many of the target patient population were living away from the big cities, in newly developed satellite cities and/or in more remote locations. Having thoroughly analyzed the patient reach and expected delivery schedule for the entire study, the Thermo Fisher Scientific team identified that:

- Longer timelines would be required to reach the more remote areas of Thailand, Vietnam, Malaysia, Indonesia and Philippines. In many cases an additional day was needed to reach sites located away from the main cities.
- An established understanding was needed with the Sponsor/CRO prior to study kick off - to allow longer lead time for the IMP to reach patient and to highlight in advance if a stressed timeline is required. Special arrangements were put in place in anticipation of urgent orders, e.g. sprinter services or dedicated truck services.
- All import documentation (e.g. import license) and paperwork had to be completed in advance of shipments across the region. Advance notification of impending shipments to multiple parties involved (Sponsor, importer, appointed clearance agent etc) would enable smooth customs clearance.
- Close communication with all parties was paramount. A proactive attitude in responding to any requests for further information, e.g. ad-hoc documents needed by the customs officials, would help to mitigate delays and maintains product integrity during transit.
- Up-to-date information on customs requirements and regulatory changes was essential.

In summary

The success of this trial was measured in metrics which the Sponsor reviewed and used when planning new trials in the region.

- Performance reviews with courier companies helped achieve above satisfactory service during the trial.
- Reduction in deviations and complaints through trending of incidences which then helped to prevent recurrence
- Overcoming cultural differences and language barriers ensured smooth distribution of supplies across the region

A 99% on-time delivery record to patients participating in this ambitious trial is a statistic to be proud of. We continue to work at achieving a 100% statistic. Let's never forget in our pursuit of performance perfection that at the heart of all we do is a patient.

+1 919 226 3200 • thermofisher.com/patheon • pharmaservices@thermofisher.com

COL34140 0921

ThermoFisher SCIENTIFIC