ALMAC

Partnering to Advance Human Health

CASE STUDY

MEETING REGULATORY REQUIREMENTS IN JAPAN: CUSTOMISED IXRS® MANAGES PATIENT-SPECIFIC DRUG ORDERS

Filling patient-specific drug orders requires thinking beyond an organisation's standard supply chain processes. For one sponsor undertaking a programme of trials across 30 countries, Almac had already re-configured their Interactive Voice and Web Response System (IXRS) with new features and functions to enable individualised ordering and customisation of the investigational drug for each patient upon enrolment. But Japan's regulatory environment posed unique challenges. The country-specific solution now manages and tracks the flow of drugs through an additional sub-depot for quality control before they are forwarded to the patient site—while capturing all related audit trails of what was shipped, when, how, and where.

THE PROCESS REQUIRED STRINGENT CONTROLS AND COMPLEX RECORD-KEEPING, INCLUDING AUDIT TRAILS OF WHAT WAS SHIPPED, WHEN, HOW, AND WHERE.

THE BUSINESS CHALLENGE: MANAGING PATIENT-SPECIFIC DOSING TO MEET LOCAL STANDARDS

A top-tier global pharmaceutical company had already implemented a highly customised version of Almac's supply chain management technology for a programme of clinical trials, to eventually include 30 studies across multiple countries. The trials involved a radioactive isotope with an extremely short shelf life of only four weeks, which was being tested as an anti-cancer therapy.

The current Interactive Response Technology (IRT) solution, which was up and running in several U.S. and European countries, incorporated sophisticated automated order processing. Each of the six doses required for the protocol had to be manufactured to specific requirements for each patient, based on the patient's weight.

Almac created the solution through a customisation of IXRS, which had originally been designed for automatic shipping according to precise demand projections—in essence sparing sponsors the need to fill patient-specific drug orders. In stark contrast, for this series of trials, the system had to be configured to trigger product shipments via direct requests from sites once each patient was registered and deemed eligible for participation.

In Japan, the sponsor required the same careful management of supply to avoid oversupplying sites and having the product expire. Again, dosing was patient-specific, with one or two vials dispensed, depending on the patient's weight. While some efficiencies could be gained by building on the original customisation to accommodate the trial in Japan, this would not be a simple replication. Japanese regulatory requirements stipulated that the shipment from an out-of-country originating depot had to first arrive at a sub-depot for quality control and only then could be sent to the site for administration to the patient. The process required stringent controls and complex record-keeping, including audit trails of what was shipped, when, how, and where.

THE ALMAC SOLUTION: REGIONAL DEVELOPMENT AND SUPPORT

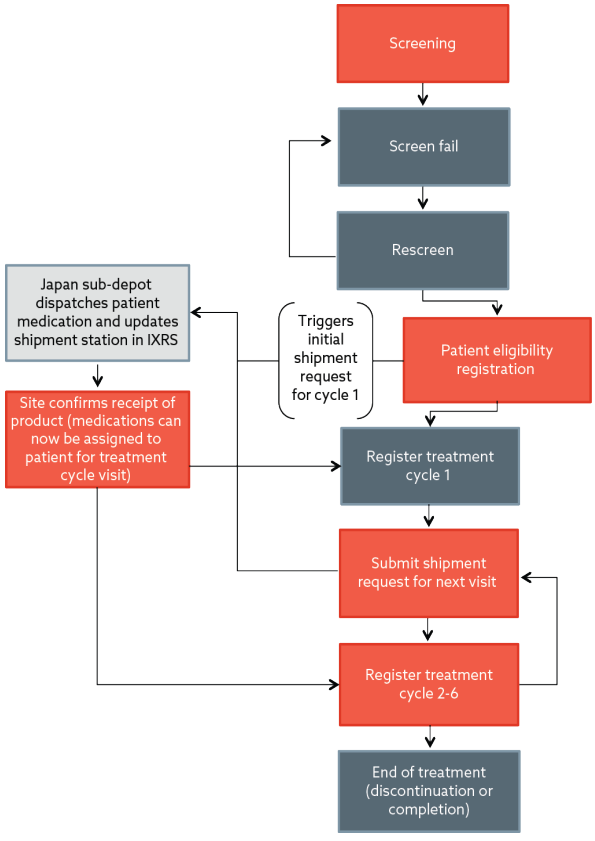
BY DEVELOPING AND SUPPORTING THE NEW SYSTEM WITHIN THE REGION, ALMAC ENSURED THAT NO TIME WAS LOST DURING THE ROLLOUT.

Almac's IXRS technology for patient and drug supply management offers a suite of intuitive alerts and reminders, information-prompting tools for patient and clinical supplies management, and reporting applications. Almac's Singapore-based developers further customised the existing system, creating made-to-order tables and views within the core platform.

For this study, IXRS had to accommodate the interim step of managing bulk drug supply as it was processed through the sub-depot in Japan for quality control. A qualified specialist at the sub-depot determines how much product should be shipped to the ultimate site for each individual patient, based on patient-specific shipment requests submitted by the investigative site via IXRS. In other countries, this step is performed by IXRS automatically at the main depot.

The solution also now includes a complete two-way data integration between the IXRS and the main depot with regards to requesting and releasing shipments to the Japan sub-depot, thus avoiding the potential human error with manual processing. When a request for a bulk supply to a sub-depot is made by the sponsor via IXRS, the system generates and triggers an electronic file to the main depot, which is then automatically uploaded to the main depot's supply database for processing. This integration eliminates the manual data entry step that is required by the depot personnel whenever a shipment request is received from IXRS. Similarly, when a shipment is released and ready to be sent to the Japan sub-depot, an electronic record is triggered from the main depot and sent to IXRS to update the status of the shipment. As a result, the main depot staff no longer need to log into IXRS to indicate that a shipment has been processed.

By developing and supporting the new system within the region, Almac ensured that no time was lost during the rollout. Working with sponsor contacts in their time zone, Almac staff was able to conveniently schedule meetings and provide same-day response to any issues that arose.



IN JAPAN, THE CLIENT HAS BEEN ESPECIALLY PLEASED ABOUT THE TIME SAVINGS AND RESPONSIVENESS MADE POSSIBLE THROUGH LOCAL SUPPORT BY SEASONED PROJECT MANAGERS AND CONSULTANTS.

THE CLIENT RESULTS: EFFICIENCY AND COMPLIANCE THROUGH RESOURCEFUL ADAPTATION

Now live and ongoing in Japan, the study adds to the series of successes that have been unfolding as Almac supports the sponsor's global programme of clinical trials. The new system that supports patient-specific and time-sensitive shipments for a potentially life-saving radioactive compound is working smoothly as planned.

The sponsor is delighted with the system performance and has experienced no outstanding issues from the depots or sites. In Japan, the client has been especially pleased about the time savings and responsiveness made possible through local support by seasoned project managers and consultants.

The system is a model of efficient supply chain technology for clinical trials, furnishing product optimally for minimal wastage and reducing the chance of human error through automatic order processing and notifications. It also exemplifies how, through a reliable system of checks and balances backed by sophisticated audit trails, a clinical trial sponsor can indeed achieve regulatory compliance as well as peace of mind.

GET IN TOUCH

UK
Almac Group
(Global Headquarters)
Seagoe Industrial Estate
Craigavon
BT63 5UA
United Kingdom

clinicaltechnologies@
almacgroup.com
+44 28 3835 2121

US
Almac Group
(US Headquarters)
25 Fretz Road
Souderton, PA 18964
United States of America

clinicaltechnologies@
almacgroup.com
+1 215 660 8500

SINGAPORE
Almac Pharmaceutical
Services Pte. Ltd.
9 Changi South Street 3
#01-01
Singapore 486361

clinicaltechnologies@
almacgroup.com
+65 6309 0720