

# Pooled inventory and Just In Time labelling (JTL) meets demand for multiple channels



When a trial drug returns compelling results during early phases of a study, and when the drug has been developed to fulfil an unmet need and give patients with serious or life-threatening conditions an opportunity to improve their quality of life or extend their life expectancy, regulators may choose to fast track drug approvals.

Early commercialization provides evident benefits to patients in need of vital treatment but, when the drug is required for both commercial purposes and continued, extended clinical trial use, the impact on supply and demand processes can be overwhelming.

For one, small oncology-focused pharmaceutical company, the impressive results of its trial drug in a Phase 3 study led to the regulator providing fast track designation for review. This resulted in earlier than anticipated commercialization and to franchising of the trial to explore its performance, when combined with other therapeutics, across multiple disease types.



## **The challenge – balancing multiple demand channels with uncertain volumes and limited supply**

With a finite drug supply and the need to fulfil both trial and commercial demand, a standard manufacturing strategy that could contribute to excessive drug overage or missed patient visits simply wasn't an option. The sponsor needed to remove waste and optimize its operation.

The limited drug supply caused by demand exceeding supply meant that every unit was of pivotal importance. Running multiple, parallel trials to establish performance across several therapeutic areas – in addition to accommodating the demand for commercialized product – caused the already limited drug supply to be further constrained.

Coupled with a restricted supply of an expensive drug product, the level of demand required for newly established studies was uncertain: patient recruitment activity was limiting the ability for accurate forecasting to take place.

Furthermore, the same clinical site was being utilized by the sponsor to facilitate multiple trials, each evaluating response and efficacy against specific tumour types, using a combination of the sponsor's investigational product and existing therapeutics. A solution was needed that would ensure the scale and complexity could be accurately navigated and the drug correctly allocated to each study. These factors combined meant that there was very little margin for error.

## **The solution – pooled supply strategy, combined with Just In Time labelling (JTL)**

Under normal circumstances, a standard clinical packaging strategy would be employed to assign the drug supply needed for each individual study. Given the complex nature of this sponsor's requirement, especially relating to the need to adequately meet demand for several on-going trials using the same drug product against the backdrop of limited supply, the sponsor turned to Almac for its clinical supply chain and project management expertise.

Recognizing the need for a 'right the first time' approach, Almac's clinical services division recommended a pooled supply inventory strategy, combined with a Just In Time labelling (JTL) approach. This would enable greater supply chain agility and ensure the right drug was available for the right trial at the right time.

This strategy utilized a highly sophisticated and flexible IVR system, and saw the drug packaged in bulk before being stored within a pooled inventory. When an order was raised, appropriate volume could be picked from the inventory before a label – containing the protocol number – was applied to each unit at the point of distribution.

## **The results – right quantities, right place, right time**

With efficient and flexible clinical packaging and labelling, Almac was able to increase operational efficiencies, maximize drug supply and minimize drug wastage for this sponsor. The pooled inventory strategy proved effective in managing the complex set of challenges presented by the need to cater for the uncertain demand of multiple studies with a limited supply. This proved especially beneficial as each trial matured and expanded in scale.

Importantly, Almac's pooled inventory strategy – combined with Just In Time labelling (JTL) – proved a cost-effective means of making sure all studies received the drug quantities needed to best support patients, at the right time, in the right place and without waste.

[almacgroup.com](http://almacgroup.com)

---

## GET IN TOUCH

### UK

Almac Group  
(Global Headquarters)  
9 Charlestown Road  
Seagoe Industrial Estate  
Craigavon  
BT63 5PW  
United Kingdom

[clinicalservices@almacgroup.com](mailto:clinicalservices@almacgroup.com)  
+44 28 3836 2436

### US

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

[clinicalservices@almacgroup.com](mailto:clinicalservices@almacgroup.com)  
+1 215 660 8500

### SINGAPORE

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

[clinicalservices@almacgroup.com](mailto:clinicalservices@almacgroup.com)  
+65 63090720