ALMAC

Partnering to Advance Human Health

Clinical Supply Chain Management

With the increased globalisation of clinical trials and development of biologics, the clinical supply chain can feel like uncharted territory.

Almac not only offers world class clinical supply operational capabilities, but our experienced supply chain consultants provide the insight needed to optimise your clinical supply.

We've been there

As innovators of the Supply Chain Management service offering, we have over 30 years of experience with multiple trial designs, phases and therapeutic indications. So when we talk about guidance, what we mean is an ability to anticipate supply chain needs, challenges and opportunities based on prior experience with a trial that's a lot like yours. Our Supply Chain Managers (SCMs) are experts in clinical supply process and IRT functionality.

Using innovative and fully integrated forecasting technology, dedicated SCMs draw on Almac's collective experience to Plan, Build and Manage your Clinical Supply Chain, ensuring that we make the most efficient use of available drug supply, without ever losing focus on the patient.

The service offering is flexible and completely customisable to meet your needs and compliment or enhance your current capabilities.

In some cases we provide a full end to end service, but in others we may augment your internal staff resources, so they can focus on more strategic activities.

It all depends on where we can provide the most help in overcoming your challenges.

Need help navigating the Clinical Supply Chain?

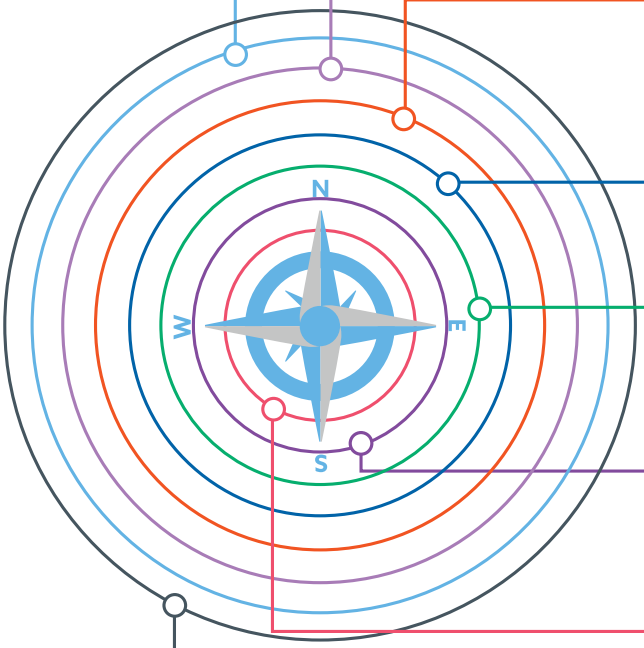
What if you were able to tap into the experience of **thousands** of clinical trials when designing your drug supply strategy?

What if you could see different ideas in practice and understand what works and what doesn't?

Let us guide you.

"Almac's staff worked closely with our personnel and demonstrated a high level of energy, enthusiasm and ownership of our clinical study. The Almac team become almost an extension of our company, and we sensed that our clinical study was their clinical study as well."

Vice President of
Product Development



Forecast and Simulation

Clinical material forecasting, forecast management and simulation tools along with SCM expertise, matches clinical supply to patient demand, ensuring optimised strategies to meet your trial needs.

Inventory Management

Almac SCMs continually monitor trial supply globally, trending study activities and adjusting future campaigns and material transfers to ensure that the right IMP is at the right place at the right time to meet study demand.

IRT Medication Management

Almac SCMs consult on the medication management IRT design to meet study needs. They set, monitor and adjust inventory management levels and system expiry strategies to ensure optimisation of IMP while reducing distribution costs where possible.

Label Development and Regulatory Vetting

Almac can oversee label text development, regulatory review, translation and artwork, ensuring that IMP labels meet clinical, regulatory, drug product and country specific requirements.

Temperature Services

Almac's innovative software program, TempEZ™, supports the full suite of Almac Temperature Services offerings, providing clients with a single central database to store temperature data while ensuring compliance to GxP and GDP regulations.

Bulk Drug Management

SCMs convert finished good demand into upstream manufacturing and API requirements, working with capacity and lead time limitations to avoid downstream supply interruptions and reduce over production and bulk waste.

Investigator Initiated Trials and Specialised Clinical Programs

Almac SCMs can provide full end-to-end planning, design and management of the clinical supply chain for Investigator Initiated Trials, Expanded Access and Named Patient Programs, designing flexible supply solutions and working directly with clinical sites where necessary to ensure continuous supply.

Pharmacy Services

Almac SCMs can serve as unblinded contacts for drug management and reconciliation, eliminating the need for additional unblinded site monitoring staff. We also have licensed pharmacists who can write pharmacy manuals, dose cards, patient and investigator educational materials; as well as provide input to clinical materials sections of trial protocols. These pharmacists can provide site personnel training at investigator meetings and can be on-call for dosing and drug compatibility questions throughout the trial.

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