ALMAC

Partnering to Advance Human Health

Brochure

Optimising Global Clinical Trial Supply Solutions

Partnering for speed, cost and quality


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5
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ALMAC
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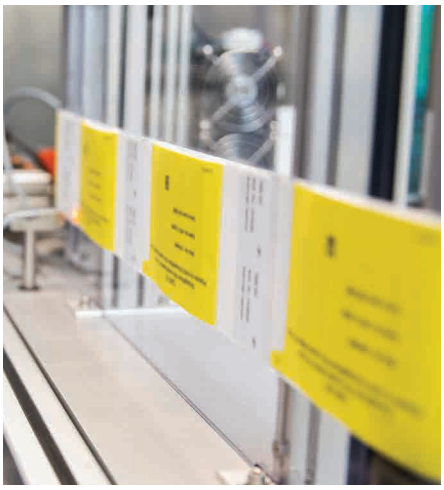

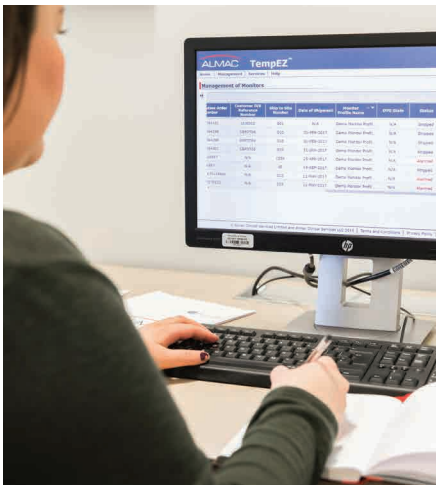
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Introduction

Taking a drug candidate from concept to commercialisation successfully in today's complex and competitive drug development market, hinges on a sponsor's ability to accelerate timelines, control costs and uphold quality assurance. Managing these challenges is paramount to ensure not only the best possible outcome for their clinical study, but more importantly for their patients. Here is a short summary from the Almac team, with key points and main areas to consider when planning a clinical trial.

The outsourcing partner a sponsor chooses to manage core aspects of their clinical supply must be considered with the end goal in mind. Significant experience managing primary and secondary packaging, labelling and distribution of clinical supply is fundamental to bigger-picture success. If these components are overlooked and not given the consideration they deserve early in the planning process it has the potential to compromise timelines, costs, quality and the success of the overall trial.

It is crucial to harness this best practice to overcome the nuanced complexities of trials, combined with the supportive infrastructure, network and expertise to scale up as IMP passes through its journey.

When it comes to trial timelines, timing is everything. Helping sponsors achieve optimised, flexible, and responsive supply operations, through early comprehensive planning translates to faster revenue streams and the delivery of critical milestones. However, throughout the clinical development process and as trials evolve through phases, change is inevitable. Our core service mix is often impacted by changes to the protocol; packaging requirements as an example, is impacted when there are changes to the expiry date, additional countries are added or change in drug volumes. Monitoring supply chains to accurately predict and identify challenges that could affect timelines is a necessity.

Managing study costs is a top priority when running a trial, particularly for the small and emerging biopharma companies who are often VC funded. For large pharma, selecting the right outsourcing partner, allows them to focus their efforts on other priorities, cost management should also be entrusted as part of that agreement.

Fundamental to success is embedding effective quality management systems into the clinical supply strategy. Quality if not managed correctly, can have a considerable cost and time impact to the study. With upfront planning on every detail of the packaging, labelling, distribution and design process, studies are kept on track and mitigations against risk are considered with action plans developed.

With over 30 years' experience in developing innovative clinical supply solutions to meet the needs of pharmaceutical and biotech companies worldwide, Almac is the trusted partner to manage time, cost and quality challenges.

Time Management - expertise to operate with speed and precision

Sponsors are under increasing pressure to deliver drugs to market faster and more cost effectively. Meeting targets on time can translate into securing essential funding, while faster product approvals expedite time to market; providing patients with access to vital medications sooner and sponsors with a timelier return on investment.

Almac helps sponsors achieve optimised, flexible and responsive supply operations through early planning and in-depth understanding of unique requirements.

When time is of the essence
Pressing Study timelines?

The global nature of clinical trials today, coupled with developments in biologics and other types of treatment, has introduced significant logistic-based complexities. Developing a robust packaging, labelling and distribution strategy to support specific protocol changes and avoid delay, whilst identifying and recognising processes that sometimes can be beyond our control, is critical to executing on time and at the right specification. Almac's Project Managers with the support of their teams will guide you through the entire project requirements phase establishing solutions that meets your exacting needs.

Almac will work with you to develop a plan you can trust, establishing study requirements across a number of areas:

Cost control solutions to todays pharmaceutical challenges

Maximising return on investment for sponsors is key, so it comes as no surprise that controlling costs remains critical and can be a daunting experience for first time trial sponsors. Almac works to understand unique requirements before developing robust plans and budgets, keeping costs in check and transparent is paramount.

For example, some of the areas that must be considered when developing your budget are:

- What materials are required to support the packaging of the drug? Does the drug require any special requirements for packaging purposes? If so, what is the lead time and who is responsible for sourcing the materials?
- How will the budget be managed?
- What site location is more cost-efficient for packaging the drug product when running a global trial, across multiple countries?
- Will the study be extended into additional countries mid-study? Are there any assumptions with regards to storage volumes and distribution channels?

Dedicated team of supply chain experts to manage cost

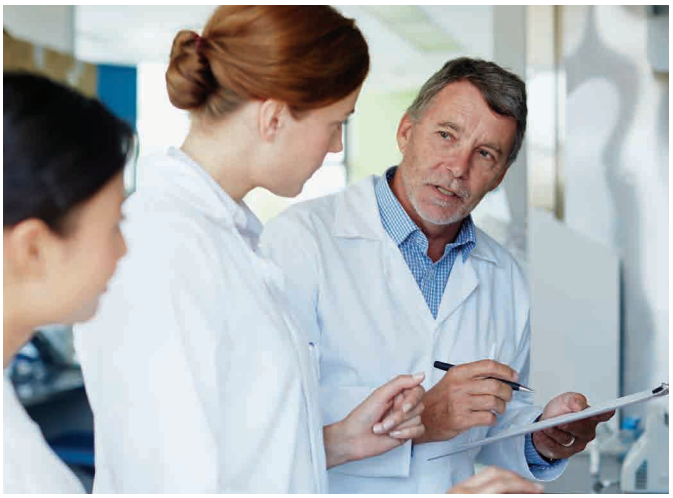
In order to manage costs Almac will work with a sponsor to understand the scope of the trial initially, applying accumulative experiences to create cost efficiencies.

Our Project Managers and Supply Chain Management teams bring significant value and experience in optimising the end to end clinical supply chain. While being accountable for the management of your budget and in support of forward planning, will continuously look to identify opportunities to add value.

Some of the ways Almac will look to achieve this:

- Production automation or semi-automation for packaging and labelling activity
- Pooling supplies across multiple programs
- Implementing LEAN production methodologies, including Just in Time Manufacturing and Just in Time Labelling
- Creating Integrations between the physical and digital components of the supply chain.
- A dedicated global procurement team to support with comparator sourcing, medical devices and ancillary needs.
- Our Project Managers will provide regular updates on your spend to allow better budget management through financial reporting.

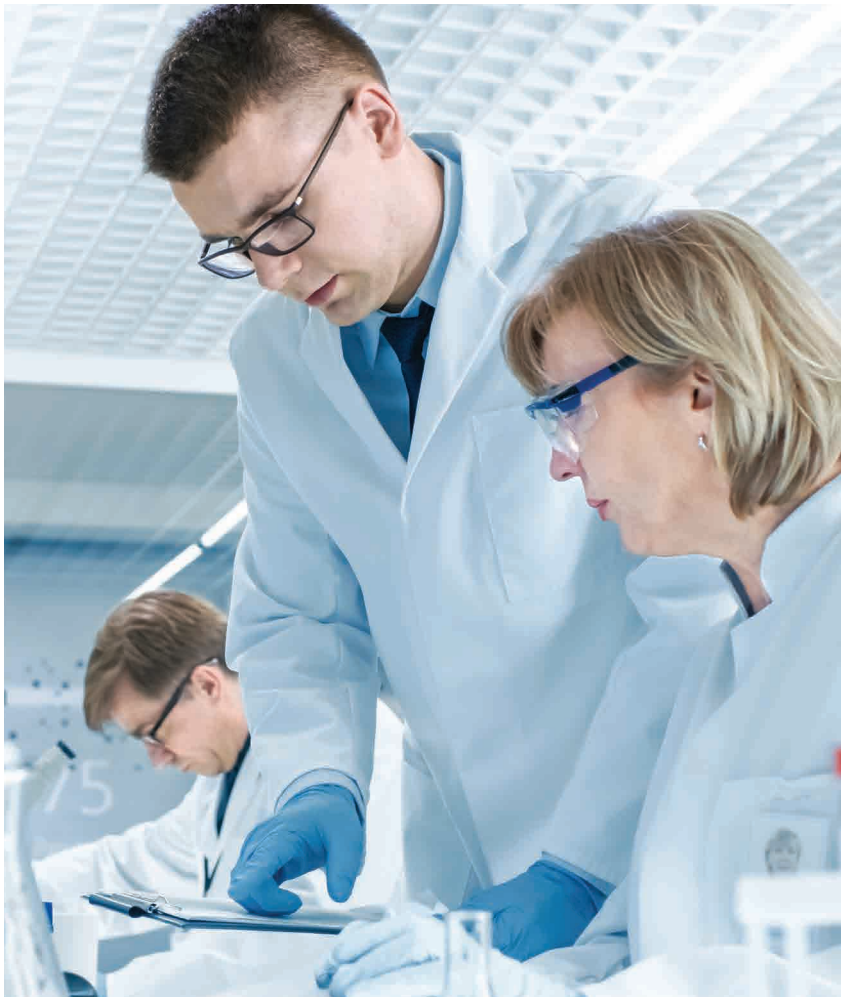

ALMAC
Clinical
Services
Almac Template – Blinded Drug Order Form
Customer Shipment Number: 010101
Site Number: Changi1234
Investigator: Khoonho Chnioh @ Almac Clinacal Services
Ship To: Almac gharmaceutical Services Pte. Ltd
Changi South Street 3
Unit 01-01
Singapore
486361
Phone: +65 63090720
Fax: +65 63090721
Email: Khoonho.chnioh@almacgroup.com
Special Instructions: N/A
Drug Order Type: Initial Re-supply
Total Number of Kits: 10



Quality assured - championing quality throughout the supply chain

Almac delivers quality and compliance by design. Patients are placed firmly at the centre of packaging and labelling operations, demonstrating best practice and managing risk. It is a fundamental aspect of every decision made and action taken. Right first time, no exceptions.

This is why it is crucial that robust quality systems and processes are implemented and maintained to avoid any compromises on patient safety and study delays.



Almac Offers Our Sponsors:

Robust, end to end quality systems across packaging, labelling, distribution network, comparator sourcing & procurement all overseen by a global team of quality personnel throughout the supply chain process.

Access to a **global team of +250 quality experts.**

Regular **internal self-audits** using our comprehensive Quality Management System (QMS) to ensure standards are maintained and global KPI's are set to ensure we stay on task.

Virtual auditing provision providing remote access to our teams and facilities when needed.

Rigorously defined and approved **Standard Operating Procedures,** across each of Almac's global facilities.

Continual drive to improve processes and systems through employee creativity, competency, and accountability.

Regular supplier audits to ensure all suppliers meet or exceed requirements set forth by the overarching **Quality Management System.**

The Almac Advantage

What makes us different?

Almac's base in Northern Ireland provides sponsors with a unique advantage. Northern Ireland's maintained alignment with specific EU rules relating to medicinal products not only delivers seamless regulatory movement into both EU27 and UK/GB markets but provides Almac sponsors with a 'business as usual' approach to QP release.

QP Services - a close look at Almac's extensive experience

To support sponsors with QP oversight and uphold quality and compliance, Almac offers a range of QP services. This includes management of product importation manufactured outside of the EEA, auditing of manufacturing sites outside of the EEA in support of QP declaration, QP certification of product trials conducted within the EU, and QP certification and collation of documentation in support of release for Israel.

Here are some of the services Almac can offer sponsors:

Easy to follow release procedures, which provide a consistent, secure, and structured approach that has been repeatedly reviewed during **MHRA inspections.**

The latest information regarding **current regulatory guidance** and expectations to proactively ensure continued compliance.

Global auditing of third-party manufacturing, testing, packaging, and labelling facilities as required in support of QP declarations for import into the EU.

On-site services, via Almac's **QP Facilitation Program**, that provide a deeper level of understanding of QP Services and the **release process** to supplement existing internal resources.

QP Services: An overview

Unrivalled expertise

With over 30 years' experience partnering with sponsors, from large Pharma to emerging Biotechs, across trials of all sizes and through all phases – Almac is the partner of choice for sponsors looking for a full suite of end-to-end, strategic and adaptable solutions, proven to optimise clinical supply, expedite trial timelines, control costs and champion quality.

Global Operations and Capabilities

	CRAIGAVON (UK)	DUNDALK (Ireland)	SOUDERTON (USA)	DURHAM (USA)	SINGAPORE
COMPARATOR SOURCING	●		●	●	●
BLINDING	●		●		●
PRIMARY PACKAGING	●		●		●
LABELLING & KIT ASSEMBLY	●		●	●	●
ALMAC ADAPT™	●		●	●	●
LEAN MANUFACTURING	●		●	●	●
LABEL PRINTING	●		●	●	●
ANALYTICAL SERVICES	●		●		
QP RELEASE	●	●			
GLOBAL DISTRIBUTION	●	●	●	●	●
SUPPLY CHAIN MANAGEMENT	●		●	●	●
IRT INTEGRATION	●		●	●	●
TEMPERATURE SURVEILLANCE	●	●	●	●	●
WebEZ	●		●	●	●
RETURNS AND DESTRUCTION	●			●	●

almacgroup.com

GET IN TOUCH

Global HQ
+44 28 3836 2436

EU HQ
+353 42 932 0718

US HQ
+1 215 660 8500

Durham, NC, USA
+1 (919) 479 8850

Asia HQ
+65 6309 0720

Japan
+81 3 4233 9178

clinicalservices@almacgroup.com