



Almac Clinical Services

Supply With Care™





Who we are

Almac is a privately owned, global drug development services provider.

Our mission is to be your *partner of choice*, providing an expanding array of innovative Clinical Solutions worldwide.



Development
of your API

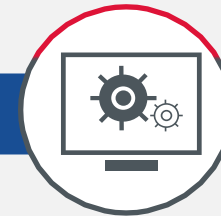
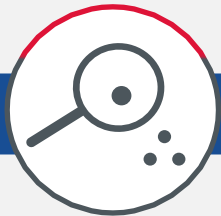
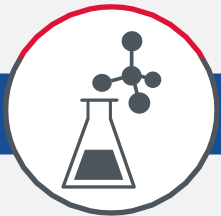
Manufacture of your
Solid Oral Dose

Analytical
Testing

**Clinical trial
Packaging and
distribution**

IRT
integration

Commercial
Development of
your approved drug



Almac
Sciences

Almac
Pharma Services

Almac
Sciences

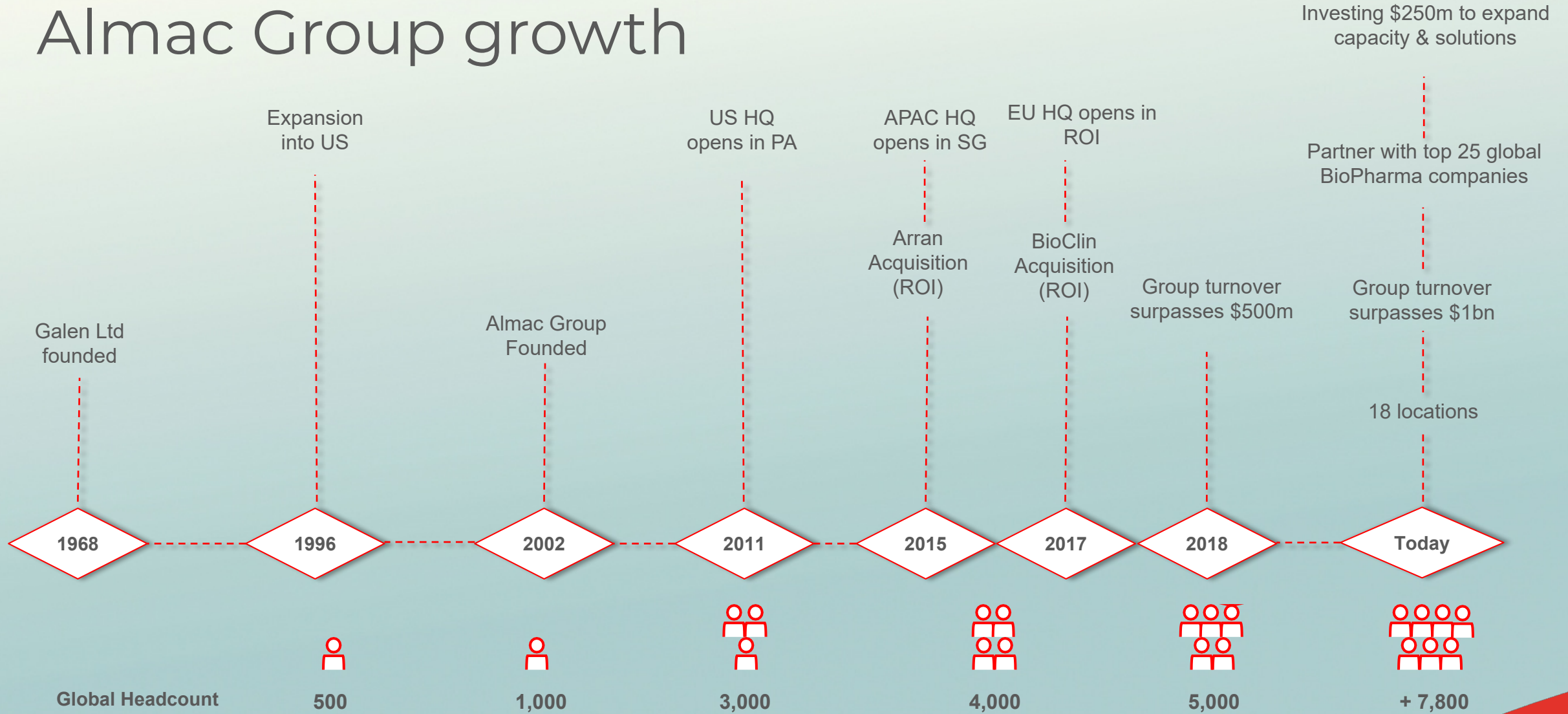
**Almac
Clinical Services**

Almac
Clinical Technologies

Almac
Pharma Services

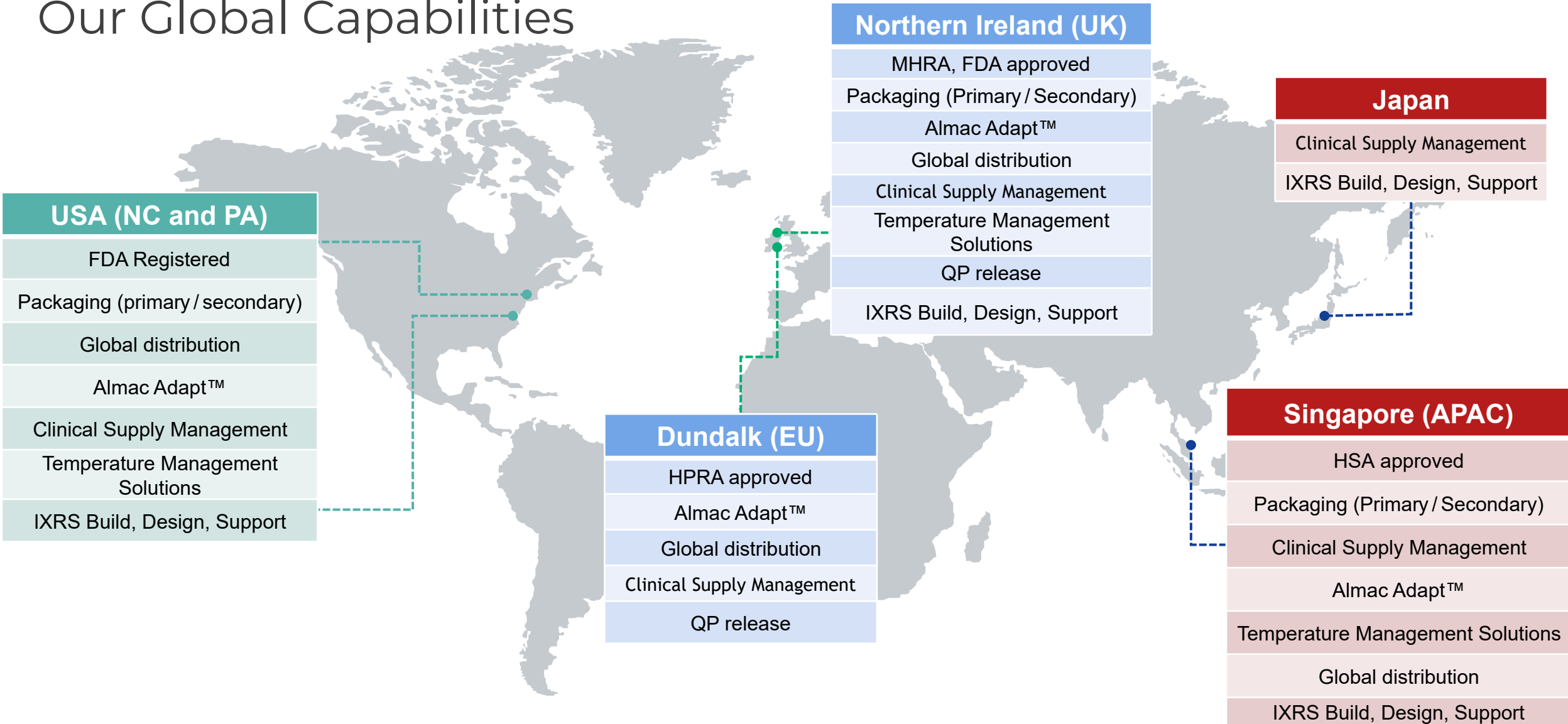


Almac Group growth





Our Global Capabilities





Almac Clinical Services

Our Capabilities and Solutions



Almac Clinical Services

Our full suite of clinical solutions supports your study from end-to-end

Our focused approach gives you the confidence that we can meet your goals with rapid and flexible deployment of solutions

Clinical Supply Oversight supported by our Integrated solutions



Quality Focus

Packaging, Labelling and Blinding

Our experienced Clinical Supply Managers offer alternative solutions, helping you to introduce cost efficiencies throughout your study.

Our Patient Centric approach ensures we:

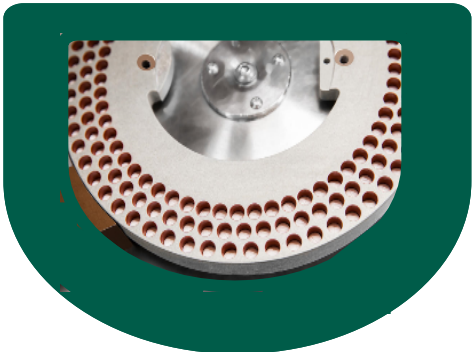
- Develop a packaging and labelling design to fit your protocol
 - Label design, translation and regulatory approval
 - Dedicated Packaging design team
- Our In-House tooling and engineering team can support your unique study needs
- Focus on Speed, Quality & Flexibility - whilst offering alternative solutions to traditional packaging
- Specialist solutions for cold chain handling – Refrigerated, Frozen, Ultra low and Cryogenic
- Wide range of Blinding solutions such as Vials, inhalers and Syringes



Our Primary Production Capabilities

Encapsulation

- Manually, semi-automatically and automatically
- Placebo, single and multiproduct fill capsules can be produced (with and without backfill)
- Check-weighing



Bottling

- Bottle cleaning
- Automatic tablet counter
- Cotton and or desiccant insertion
- Induction sealing
- UV printing and Inkjet code printing
- Bottling and on-line labelling where appropriate

Blistering

- Manually, semi-automatically and automatically
- Mixed blistering
- Thermoform and Coldform
- Vision systems
- Bespoke tooling in-house
- Contained Potent blistering is also available.



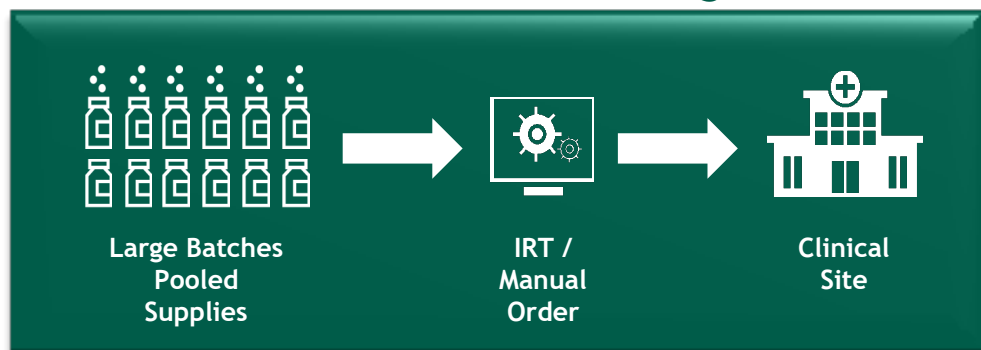
Walleting

- Manual, and semi-automated, walleting solutions
- Child Resistant and Non-Child Resistant wallet types
- Mixed walleting solutions
- Bespoke tooling in-house

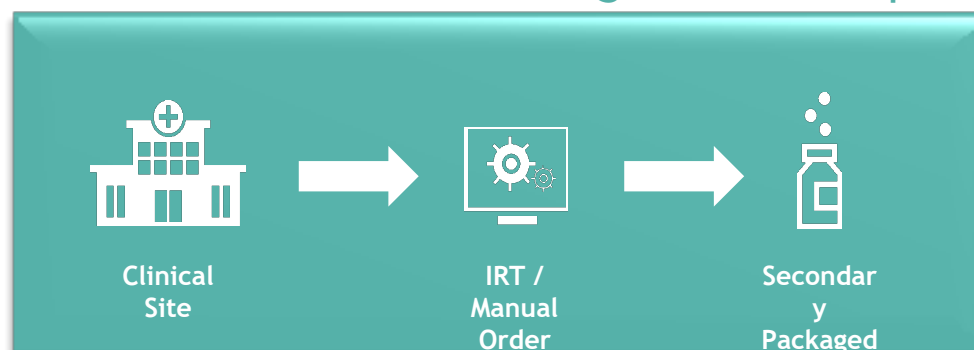
Global Secondary packaging and blinding

Solutions developed to fit your study needs and unique handling requirements
 - Vials, Syringes, Bottles, wallets, inhalers, pouches and stick packs

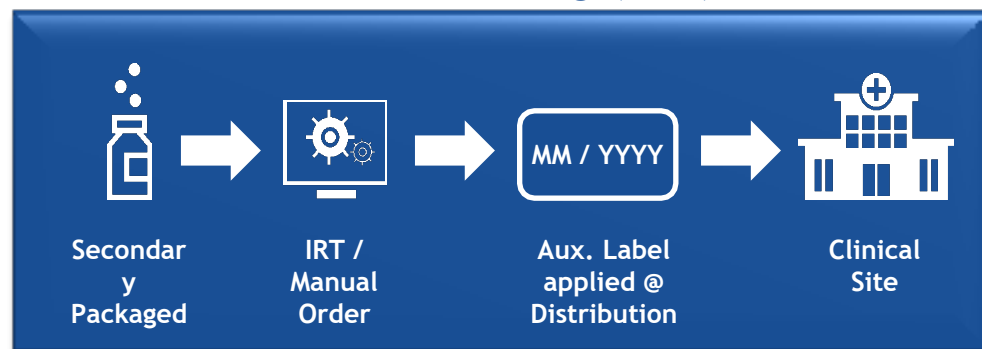
Batch Manufacturing



Just in Time Manufacturing - Almac Adapt™



JIT Labelling (JTL)



Product Release

Almac can provide Qualified Person Release for trials to be conducted in the EU/EEA and Rest of World as required.

- Almac holds two licenses, one for the Craigavon, Northern Ireland (UK) facility and one for the Dundalk (IE) facility.
- Only company with Regulatory alignment between Northern Ireland and the EU – robust Brexit solution
- UK QP verification takes place under our UK MIA (IMP) licence





Global Distribution

Our dedicated teams, strategic planning and full oversight of your shipments ensures your trial stays on track

- Global Depot Network with Integrated ERP System
- Leading Shipper and Monitoring Technologies
 - Pod™ & iTag Bio4
 - TempEZ™
- Experts in Biological and Demanding Product Delivery
- Import Services / Importer of Record
- Direct to Patient solutions – Site to patient, Depot to patient, Almac to Patient

300,000

SHIPMENTS
ANNUALLY
TO OVER 120
COUNTRIES



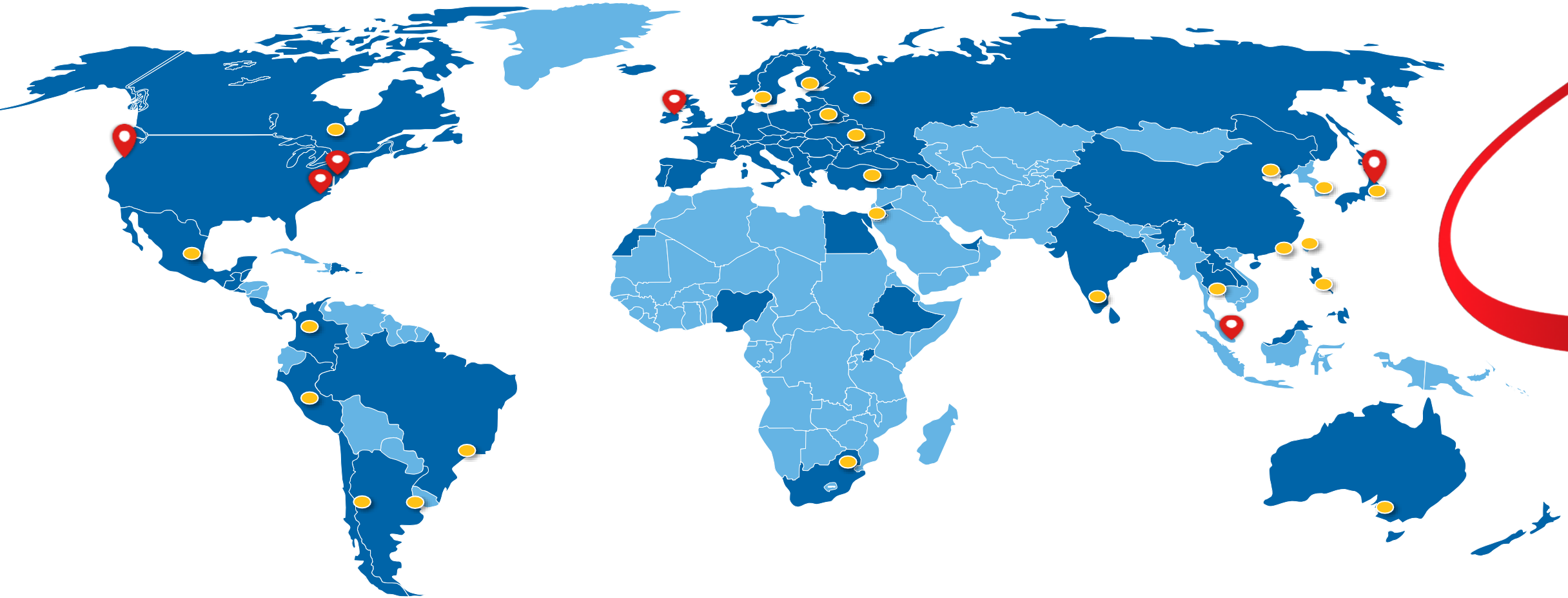
60

DEPOTS ON
6 CONTINENTS

MORE THAN **99%** OF SHIPMENTS ARE WITHIN SPECIFICATIONS

Ambient | 15-25°C | 2-8°C | -20°C | -70°C

Our Distribution Network



Integrated Operations Centers



Global Depot Network

Drug Returns and Accountability

Managing returns and destruction throughout the life of the study, helps to streamline the close out process, ensuring you avoid unnecessary costs

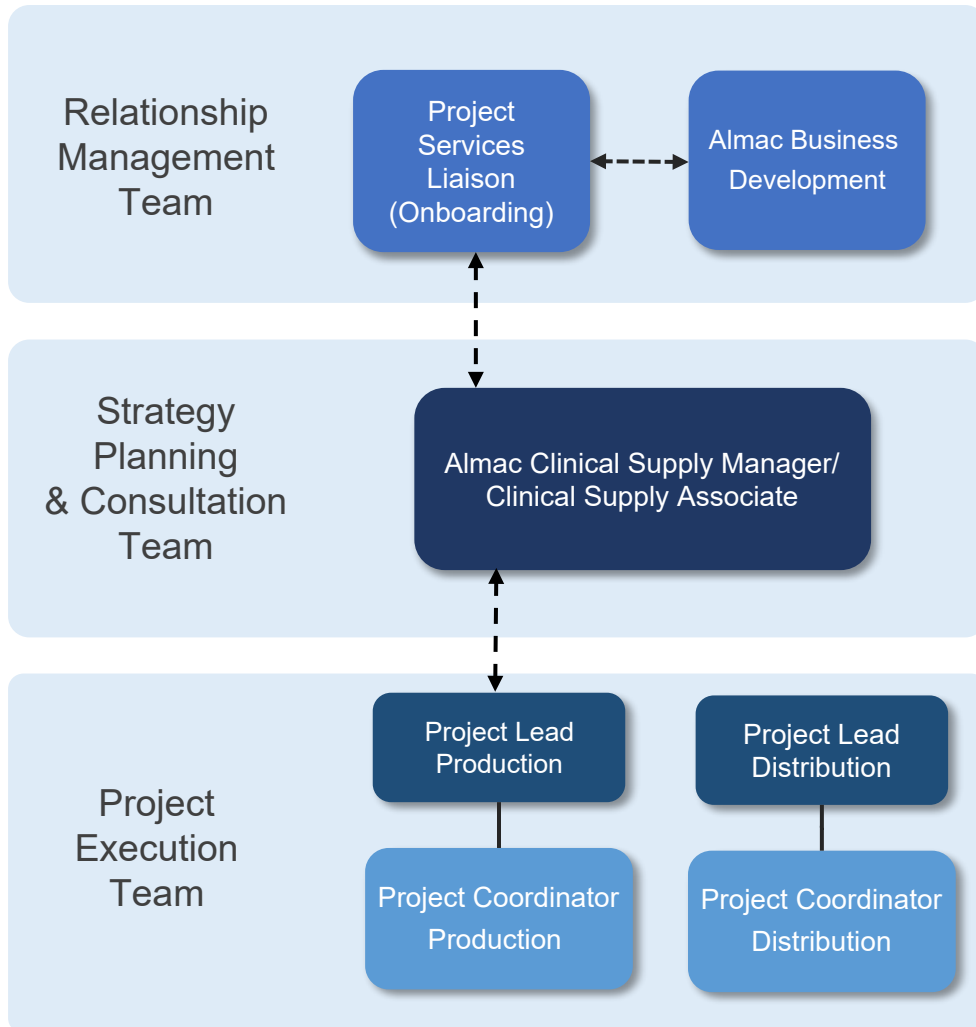
- Global Returns and Destruction solutions
- Non-Hazardous, Hazardous, or Controlled drug
- 2 Levels of accountability available
- Detailed reporting capabilities
- Remote drug monitoring solutions
- Almac DART – Online Drug Returns and Accountability





Who will manage the study?

Clinical Supply Management offering study planning and oversight



Strategic planning and forwarding thinking by our Supply Chain Management teams offers you flexible and proactive solutions ensuring your trial stays off the critical path.

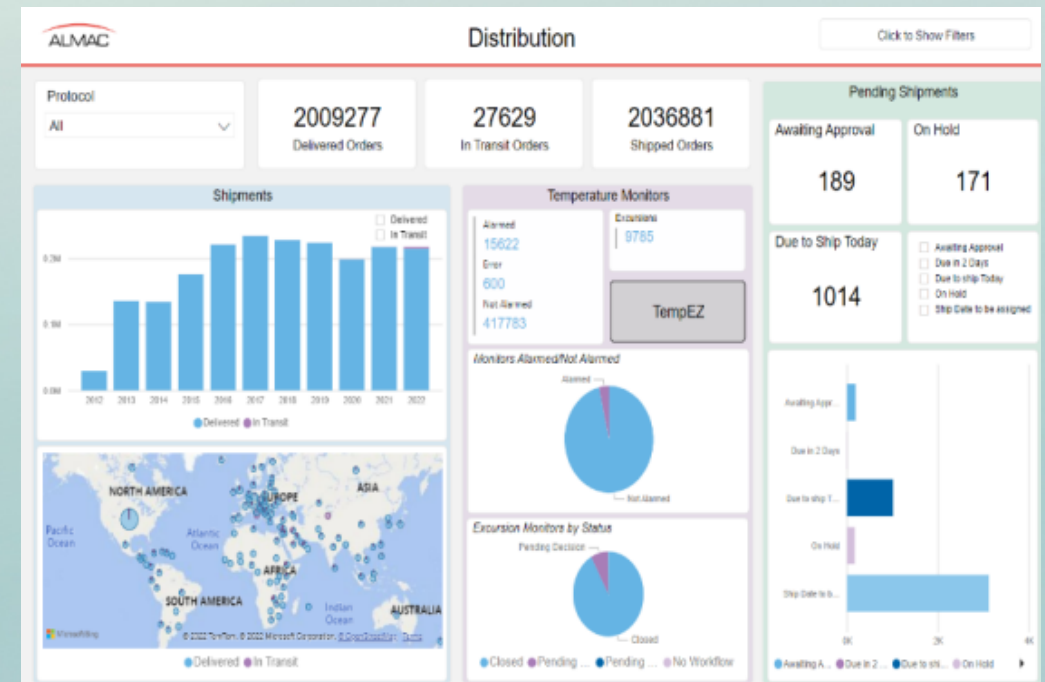
The Almac team will:

- Take responsibility for any supply chain activities contracted to Almac
- Work with/on behalf of your team to deliver correct drug to correct place at the right time
- Consult on production/distribution planning and forecasting
- Manage the internal delivery of the project to agreed specifications and timelines, globally.
- Analyze project risks and propose mitigation plans
- Facilitate communication on quality issues and reports
- Oversight of IRT set up and integration

Study and Timeline Management

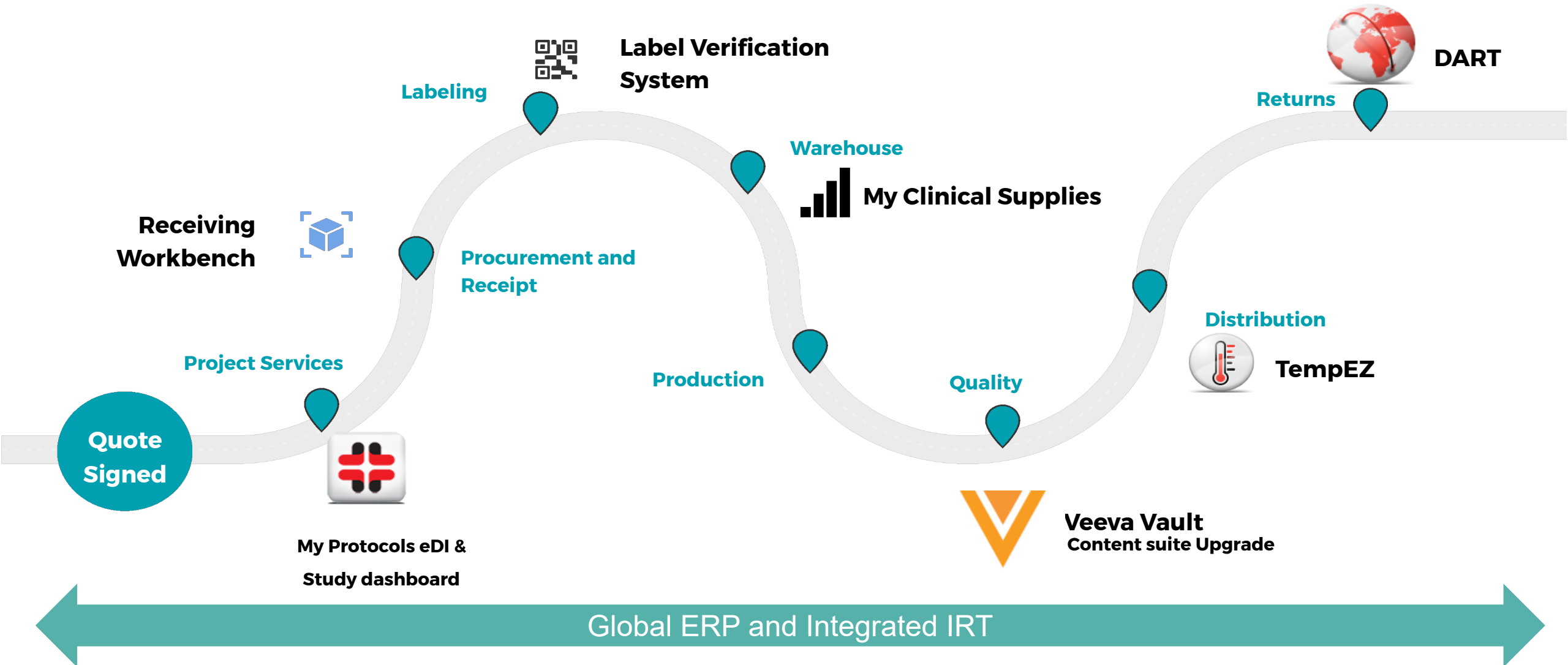
Our integrated systems and solutions ensure you have full oversight of your study from end to end

- Global ERP System (COSMOS)
- IRT System Integration (Almac One)
- Receiving Workbench
- Almac Gateway Application
 - Study Dashboard – including Budget management
 - My Clinical Supplies
 - Label approval System - LAS
 - WebEZ™
 - TempEZ™
 - Core Share
 - My Protocols
 - DocuSign
- Digital PQS - Vault



Study and Timeline Management

Our integrated systems and solutions ensure you have full oversight of your study from end to end



ALMAC

Corporate Social Responsibility



At Almac, we strive to take care of our **people**, protect our **planet** and make a positive impact to our **communities**

- ✓ Our pledge to be net zero by 2045
- ✓ Reduce Scope 1 and 2 emissions by 50% by 2030
- ✓ Engage our supply chain to tackle Scope 3 emissions
- ✓ Achieved ISO14001 Certification Environmental Management System (EMS) – at our UK, Ireland, US and Singapore sites
- ✓ Achieved ISO50001 certification – the international standard for energy management at our UK, Ireland, US and Singapore sites
- ✓ Achieved ISO27001 certification – the international standard for information security
- ✓ Achieved ISO 14064 certification for greenhouse emissions.
- ✓ Achieve ISO 45001 (Occupational Health & Safety Management System) Globally



People



Planet



Place



Supply With Care™

Almac Clinical Services





Supply With Care™

Why Almac?



Why Almac is your Partner of Choice?

FOCUSED APPROACH

Giving you the confidence that we can meet your goals with rapid and flexible deployment of solutions

TIMELINES AND LOCATION

Strategic planning and forwarding thinking by our Clinical Supply Management teams offers you flexible and proactive solutions ensuring your trial stays off the critical path, whilst our unique location give you flexibility and ease of supply

EXPERIENCE

Our reliability as a vendor is shown through the 95% repeat business that we achieve each year, achieved only through the use of our validated systems and processes as well as our approach to risk management, all fully embedded within Almac's culture.



COST MANAGEMENT

Our experienced Clinical Supply Management team offer alternative solutions, introducing cost efficiencies throughout the study, supported by real time study dashboards and transparent quoting.

QUALITY DRIVEN

End to end quality oversight supported by continuous improvement initiatives and KPIs. With over 230 client audits per year globally, you can be confident that we have a robust quality system in place supported by a global team of +350 quality staff.



Because everything we do, we

Supply With Care™