

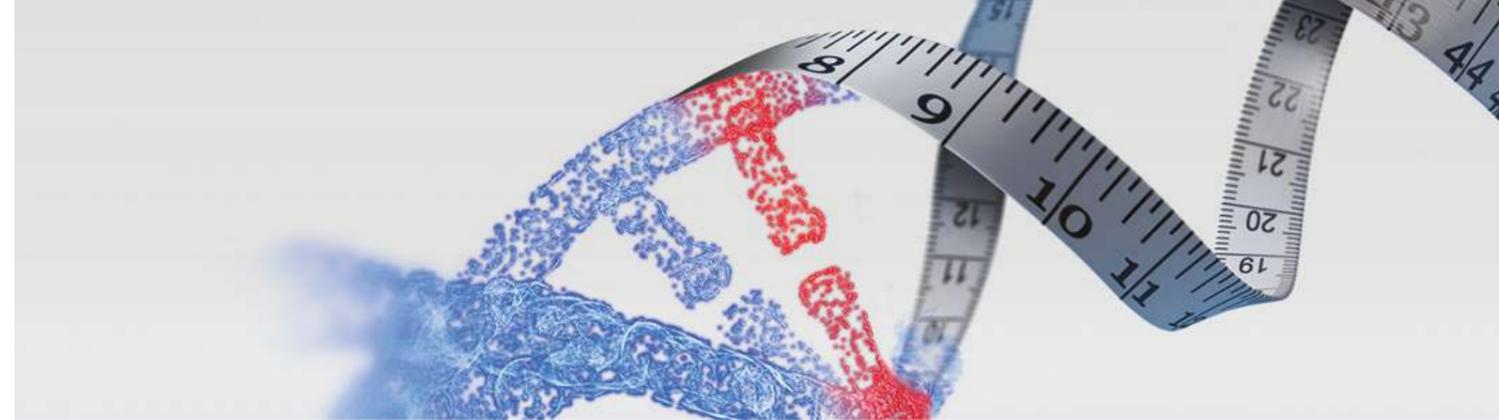
# An Overview of Almac

A Closer Look at Almac Group's Expertise



The Almac Group is an established contract development and manufacturing organisation that provides an extensive range of integrated services to the pharmaceutical and biotech sectors globally. The services range from R&D, biomarker discovery development and commercialisation, API manufacture, formulation development, clinical trial supply, IXRS® technology (IVRS/IWRS) through to commercial-scale manufacture.

The international company is a privately owned organisation that has organically grown over 50 years and now employs in excess of 5,000 highly skilled personnel. Almac is headquartered in Craigavon, Northern Ireland with additional operations in the UK, Ireland, across the US (Pennsylvania, North Carolina and California) and in Asia (Singapore and Tokyo).



# Diagnostic Services

Your Clinical Trial Diagnostic Partner

Almac Diagnostic Services is a stratified medicine company specialising in biomarker driven clinical trials.

The company is based in Craigavon, UK and Durham, USA, alongside a partnership lab offering diagnostic services for the APAC region. We have a strong and stable leadership team who have worked together for over a decade and are extremely well networked within industry and academia. Our diagnostic experience spans oncology, immunology, CNS and infective diseases.

In addition to supporting clients with their biomarker projects, Almac also has a portfolio of internally developed, novel biomarkers with predictive or prognostic utilities.

**Our global laboratories offer tailored solutions from discovery to commercialisation:**

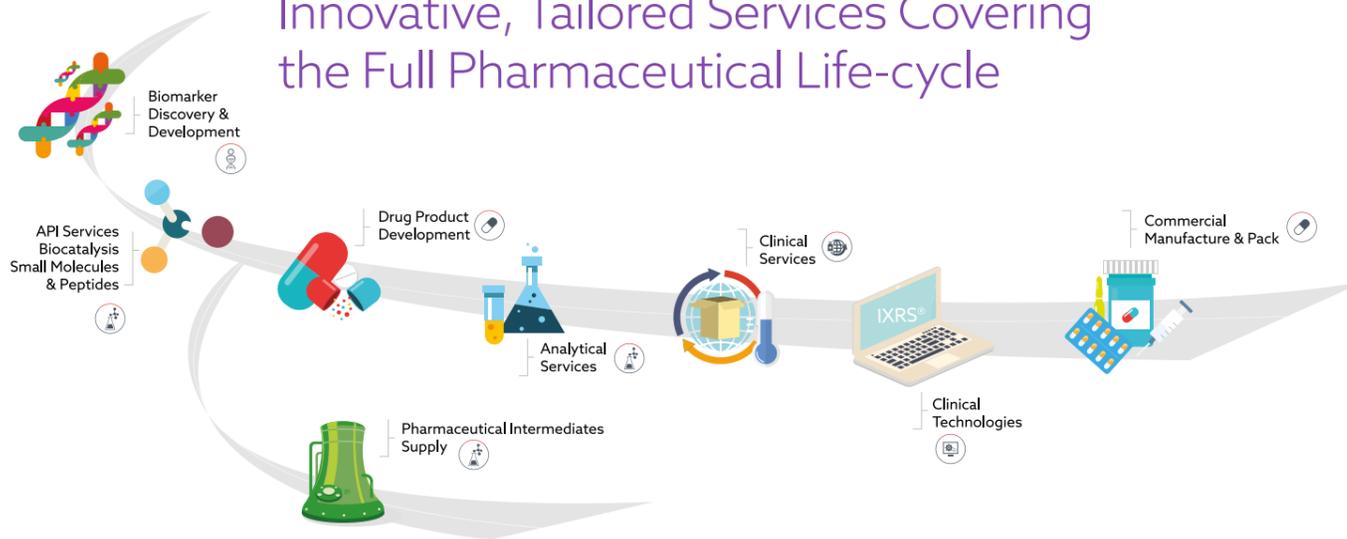
- Biomarker Discovery
- Custom assay development & validation
- DNA and RNA panel options for basket & umbrella trials
- Flexible CDx development & commercialisation
- Expert regulatory support
- Bioinformatics & software development

### Our CDx Approach

We know that when it comes to the discovery, development & commercialisation of companion diagnostics for future precision medicines, no two pharmaceutical or biotech companies will ever have the same needs.

Our CDx approach has been designed to offer you an intuitive partnership, with a range of flexible options and specialist supporting services tailored to your specific drug and companion diagnostic requirements

## Innovative, Tailored Services Covering the Full Pharmaceutical Life-cycle



### Specialised Services



## Leadership

Board of Directors



Alan Armstrong  
Chairman & CEO



Kevin Stephens  
Executive Director



Colin Hayburn  
Executive Director



Stephen Campbell  
Executive Director



Professor Paul Harkin  
President & Managing Director,  
Almac Diagnostics

Almac Diagnostic Services Professor Paul Harkin is founder of Almac Diagnostic Services. As President and Managing Director, he has overall responsibility for the strategic, financial and operational leadership of the company.

## Leadership & Events

- **AACR 2019**  
Mar 31 - Apr 3  
Atlanta, GA
- **World CB & CDx Europe**  
Apr 15 - 17 2019  
London, UK
- **ASCO 2019**  
June 1 - 3  
Chicago, IL
- **Biomarker & IO Congress**  
June 18 - 20, 2019  
Boston, MA
- **ESMO 2019**  
Sept 27 - Oct 1  
Spain
- **ASH 2019**  
Dec 07 - 10  
Orlando, FL



166+  
Clinical Sites

Received samples from 166+ clinical sites globally in last 12 months



5,000+  
Clinical Samples

Processed 5,000+ clinical trial samples in the same period



almacgroup.com

<https://www.linkedin.com/company/almac-diagnostics>



# Sciences

API Services and Chemical Development: your molecule, our expertise

Almac Sciences is a provider of integrated services from development to commercial scale of advanced intermediates and Active Pharmaceutical Ingredients (API). We provide a range of services for small molecules (including highly potent) and peptides. We have a proven track record of saving time and costs through the integration of our services and application of innovative biocatalysis and technology solutions. Our services are supported by global analytical facilities across UK, Europe & US.

Complementing Almac Sciences' range of services is its Arran Chemical Company Business unit. Arran manufactures products for diverse industrial applications, featuring a range of alkylamines, pharmaceutical intermediates, flavour & fragrance and other specialties. The combination of our exclusive biocatalysis technology platform with our large scale manufacturing asset allows fast supply of advanced intermediates from kg to multi-tonne scale.

We have responded to our clients' needs of leading their molecules through clinical development faster, smarter and cost effectively, ensuring projects are completed to the highest quality, on time and in full.

- API Development & GMP Manufacture
- Small Molecules and Peptides
- Biocatalysis Solutions
- <sup>14</sup>C Radiolabelling
- Analytical & Solid State Services



## Leadership & Events



**Dr. Stephen Barr**  
President & Managing Director,  
Almac Sciences

Dr. Barr has been Managing Director and President of Almac Sciences since 2001, with full responsibility for all technical operations and strategic direction.

- **DCAT Week 2019**  
Mar 18-21, 2019  
New York, NY
- **European NeoAg Summit**  
Apr 23-25, 2019  
Amsterdam
- **CPhI North America**  
Apr 30 - May 2, 2019  
Chicago, IL
- **MIXiii-BioMed Israel**  
May 14-16, 2019  
Tel Aviv, Israel
- **TIDES 2019**  
May 20-23, 2019  
San Diego, CA
- **BIO 2019**  
June 3-6, 2019  
Philadelphia, PA

**5,000+**  
Almac Group employees

**5,400+**  
Client locations across the globe



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

<https://www.linkedin.com/company/almac-sciences-limited>

# Pharma Services

Development to Commercialisation

Almac Pharma Services provide scalable drug product development to commercial manufacturing solutions, supporting all phases of clinical trials, through product launch and ongoing supply.

- Non-GMP and GMP pharmaceutical development
- Scalable development & manufacturing solutions
- Comprehensive analytical support
- High potent processing

## Pharmaceutical Development

Addressing the increasing pressure to bring clinical candidates through the pipeline faster and with greater efficiency, we provide expert development solutions. From developing a fit-for-purpose formulation for First-in-Human trials, to developing a more robust formulation and scaling up for late phase trials and ultimately commercialisation.

## Product Launch & Distribution

Having supported 15 orphan drug launches in the past 3 years, we pride ourselves on being the leader in understanding market requirements from product import analysis and country specific packaging to in-country distribution. Our expert product supply team ensure your launch dates are met and ongoing commercial supply is delivered on time in full.

## Commercial Manufacture & Pack

Whether we are scaling up from our development services to full scale commercial supply or transferring existing commercial products, we can meet your commercial solid oral dose manufacturing requirements.

With UK and US commercial packaging operations, we provide customised quality driven packaging solutions supporting both high volume marketed products and orphan drug launches.



**Graeme McBurney**  
President & Managing Director,  
Almac Pharma Services

Graeme oversees the operations and long-term strategy for the Pharma Services' development and has over 20 years' experience in the manufacturing and distribution of pharmaceutical products.

## Leadership & Events

- **DCAT Week 2019**  
Mar 18-21, 2019  
New York, NY
- **CPhI North America**  
Apr 30 - May 2, 2019  
Chicago, IL
- **Injectable Drug Delivery**  
May 15-16, 2019  
London, UK
- **Pre-Filled Syringes West Coast**  
June 3-4, 2019  
San Diego, CA
- **BIO 2019**  
June 3-6, 2019  
Philadelphia, PA
- **BOS Basel 2019**  
June 19-20, 2019  
Basel, Switzerland

**25/25**  
Worked with all 25 of the  
top Biotechs

**Phases I-IV**  
Experienced in phases one through four  
of pharmaceutical development



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<https://www.linkedin.com/company/almac-pharma-services>



# Clinical Services

Understanding and Delivering your Global Clinical Supply Chain

Almac provides the most comprehensive global clinical supply chain solution in the marketplace. Guided by our extensive clinical supply experience, we provide the physical resources and supportive technologies that ensure your clinical supply chain continually delivers across the globe. Clinical trial supply chains are becoming longer and more complex, while costs are rising and sponsors face additional challenges to reduce waste, cost and timelines. As trials become truly global, sponsors require partners that can provide the physical means of packaging and distributing their supplies, as well as providing the data to facilitate planning and enable decision-making.

- Commercial Drug Procurement
- Clinical Supply Chain Management
- Blinding of Clinical Trials
- Clinical Supply Packaging (Primary and Secondary)
- Clinical Storage & Distribution
- Next Generation Temperature Management

With over 30 years' experience, a history of innovation and a record of delivering 30,000 protocols for over 600 global clients, we have the experience to support you in your trial from beginning to end - with the ability to foresee any potential issues before they arise.



# Clinical Technologies

Real-Time Control of the Most Critical Elements in Protocol Execution

Almac Clinical Technologies is here to help the biopharmaceutical industry bring new therapies to those in need by empowering trial sponsors to proactively manage sites, patients, and clinical supplies through our industry-leading IXRS® Interactive Response Technology and expert consultancy.

The solutions we offer facilitate more than simplifying patient and trial material management - they engineer quality into the clinical trial process. Our technology provides sponsors and CROs with the visibility and control needed to make data-driven decisions by leveraging advanced supply management functionality coupled with real-time site and patient data in a closed-loop environment.

We employ more than 500 professionals dedicated to delivering high-quality solutions and reliable customer service. For nearly two decades, our expertise, energy, and commitment have earned us a reputation as a trusted ally in the drug development process.

### By the Numbers:

- 2,000 clinical trials performed with IXRS®
- Over 2 million patients supported
- Trials conducted in over 85 countries
- 65+ Language
- 10+ Rescue Studies

### Mega-Trial Experience:

- 510 studies lasting 5+ years
- 115 studies lasting 4+ years
- 44 studies with over 500 sites
- 170 studies with 200 sites
- 55 studies with more than 5,000 patients
- 34 trials with 10,000+ patients

## Leadership & Events



**Dr. Robert Dunlop**  
President & Managing Director,  
Almac Clinical Services

Dr. Dunlop is responsible for the strategic, financial and operational leadership of Almac Clinical Services in the UK, US and APAC and has over 25 years' experience in the pharmaceutical industry.

- **Outsourcing in Clinical Trials**  
Mar 12-13, 2019  
Tel Aviv, Israel
- **NECSO Spring 2019**  
Mar 14, 2019  
Boston, MA
- **Clinical Trial Supply Europe**  
Mar 13-14, 2019  
Milan, Italy
- **GCSG 2019 US Conference**  
Apr 28 - May 1, 2019  
San Antonio, TX
- **IQPC Clinical Trial Supply**  
May 20-22, 2019  
London, UK
- **Clinical Trial Supply Nordics**  
June 18-19, 2019  
Copenhagen, Denmark



**Valarie Higgins**  
President & Managing Director,  
Almac Clinical Technologies

Valarie directs Clinical Technologies' long-term commercial and operational growth strategies and has over 20 years' experience in the biopharmaceutical development industry.

## Leadership & Events

- **Outsourcing in Clinical Trials Southeast**  
Mar 26-27, 2019  
Durham, NC
- **Outsourcing in Clinical Trials Europe**  
May 14-15, 2019  
Milan, Italy
- **Outsourcing in Clinical Trials**  
May 21-22, 2019  
King of Prussia, PA
- **DIA 2019**  
June 24-26, 2019  
San Diego, CA
- **Clinical Innovation Partnerships**  
Sept 11-12, 2019  
Berlin, Germany



# 60+

Network of 60+ in-country depots for clinical supply



# 50%

Contributed to 50% of the FDA approved NMEs last year



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

<https://www.linkedin.com/company/almac-clinical-services>



# 2,000,000+

Patients in 2,000,000+ clinical trials supported with Almac's IXRS™ Interactive Response Technology platform



# 20+

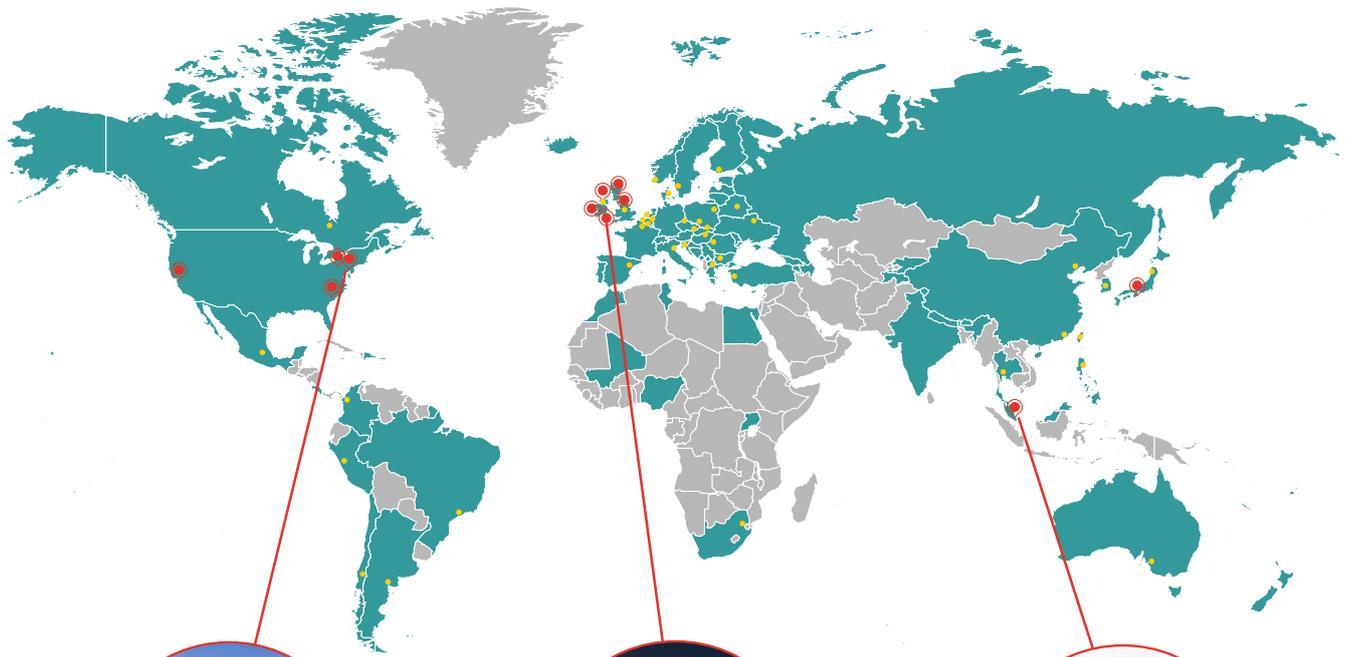
Years' experience offering technology support for clinical trials



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

<https://www.linkedin.com/company/almac-clinical-technologies>

# Almac: A Global Presence



ALMAC GROUP  
US HEADQUARTERS,  
PENNSYLVANIA



ALMAC GROUP  
GLOBAL HEADQUARTERS,  
UNITED KINGDOM



ALMAC GROUP  
ASIA PACIFIC HEADQUARTERS,  
SINGAPORE

 Countries we have provided services to in the last 50 years

 Our 60+ depots

 Our locations

## Get in touch

### US

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

+1 215 660 8500

### UK

Almac House  
(Global Headquarters)  
20 Seagoe Industrial Estate  
Craigavon BT63 5QD  
United Kingdom

+44 28 3839 5815

### EUROPE

Almac Group Ireland  
Finnabair Industrial Estate  
Dundalk  
Co. Louth  
Ireland

+44 28 3833 2200

### SINGAPORE

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

+44 28 3839 5815

 [twitter.com/AlmacGroup](https://twitter.com/AlmacGroup)

 [www.linkedin.com/company/almac-group](https://www.linkedin.com/company/almac-group)

For Media/Press or Public Affairs inquiries, please contact: [media@almacgroup.com](mailto:media@almacgroup.com)