

Life Science Sector Opportunities Northern Ireland

Clinical Trials



Introduction

- **Clinical trials commonly refer to testing the effectiveness of experimental drugs and are typically categorised into four phases; I, II, III, IV.**
- **The global clinical trials market is currently estimated at £29 billion¹.**
- **It is estimated that the global out-sourced clinical trials market will be worth £19 billion by 2015.**
- **Clinical trials are conducted by government departments, charities, universities and healthcare companies.**

Key facts in the UK

- **£5 billion is spent on research and development in the UK Life Sciences sector every year².**
- **Approx 25% of the world's top medicines were developed in the UK.**
- **The establishment of the Health Research Authority in 2011 has streamlined the regulation of research within the UK.**

Areas of Strength in NI

- **NI has significant experience in providing clinical trials specialising in oncology, cardiovascular, respiratory and anti-infective diseases.**
- **Almac is one of the top three clinical trials supplies company in the world.**
- **With 1.8 million inhabitants and one unique healthcare system NI is favourably positioned to take advantage of its demographic makeup in terms of clinical trial networks.**
- **NI has complete health and social care records which provide anonymised and aggregated data for ethically approved health and social care related research.**

1. House of Commons, Science and Technology Committee, Clinical Trials Third Report of Session 2013-14

2. Department for Business, Innovation and Skills, Office for Life Sciences, Strategy for UK Life Sciences, December 2011

Business



Almac Clinical Services has over 25 years experience in clinical supplies and has successfully packaged distributed and delivered supplies for thousands of clinical protocols. It works with small and large organisations alike, providing consulting services such as Drug Supply Management and Qualified Person release that enhance and supplement the global clinical supply chain, alongside its core manufacturing, packaging and distribution activities.

Almac Clinical Technologies is a global leader that has conducted more than 1900 clinical trials worldwide. It helps pharmaceutical and biotech companies get new drugs to market faster by increasing productivity in the management of sites, patients, and clinical supplies through their industry-leading IXRS® integrated IVR/IWR technology.



AxisBioServices

Axis Bioservices provides pre-clinical drug development services with specialist capabilities in oncology and angiogenesis. Services range from in vitro efficacy and mechanistic studies, through pharmacokinetics and in vivo target engagement, to efficacy studies in subcutaneous and orthopicxenpgrafts.



BioKinetic Europe manages Phase I-III clinical trials with particular experience in women's health, pain management, respiratory, diabetes and vaccines. The company operates a GCP and GMP compliant, 30-bed inpatient clinic with MHRA Supplementary and Standard Accreditation.



Celerion offers one of the most experienced clinical pharmacology research networks in the industry with a global capacity of more than 730 beds (24 in-hospital), efficient bio-analytical laboratories and experienced scientific staff. The Belfast facility is a member of the UK's Translational Research Partnership in Respiratory Disease which enables faster access to target patient populations, specialists and techniques in Phase I and IIa studies.



Venn Life Sciences

Think Research

Venn Life Sciences (NI) Ltd is a regional centre for parent company Venn Life Sciences European which has over 24 years' experience in the management and resourcing of clinical trials. Venn Life Sciences has a close relationship with hospitals, investigators, regulators and key opinion leaders across a range of 16 therapeutic areas.



O4 Research offers a range of personalised, high quality and cost effective services across Phases II-IV, non-interventional and investigator initiated studies. The company has an excellent track record in conducting clinical trials across a broad range of therapy areas with a particular focus on analgesia, cardiovascular, CNS, dermatology, endocrinology and vaccines/anti-infectives.



Cast Healthcare provides an unrivaled service both in terms of quality re-packaging and turnaround times to Parallel Importers ensuring continuity of supply and reduced costs.

RANDOX

Randex manufactures custom biochips to aid identification of patients for inclusion on clinical trials and also to allow specific testing on clinical samples.

Academic and Clinical



Northern Ireland Clinical Research Network is funded by NI's Health & Social Care R&D to provide a single-point access to the NHS including hospitals, community and primary care sectors with the objective of developing high quality clinical research studies.



Northern Ireland Clinical Research Facility was established in 2013 to perform early phase clinical trials in areas such as cancer, diabetes, eye disease and respiratory diseases. It is a joint venture between HSC, Queen's University Belfast and the University of Ulster.



Clinical Translational Research and Innovation Centre (C-TRIC) is a unique facility partnered with the Western Health & Social Care Trust (WHSC) and Derry City Council aimed at facilitating translational and clinical research to reduce time to market and R&D associative costs. WHSC has undertaken Phase II-IV studies and can accommodate Phase I studies if required.



Northern Ireland Cancer Trials Network co-ordinates and promotes cancer clinical trial activity throughout Northern Ireland and drives the development of early phase cancer clinical research. NICTN integrates with Queen's University Belfast and the University of Ulster translational research programmes.



Belfast Experimental Cancer Medicine Centre (BECMC) is jointly supported by Cancer Research UK and health departments for England, Scotland, Wales and Northern Ireland. The BECMC further facilitates effective translational research in experimental cancer medicine within the Centre for Cancer Research and Cell Biology (CCRCB) at Queen's University Belfast. This enables doctors to have access to the very latest new drugs to test in clinical trials.

Case Studies

Wellcome Trust-Wolfson Foundation Northern Ireland Clinical Research Facility (NICRF)

The progression of research projects from lab to clinic is facilitated by NICRF's proximity to two major Belfast hospitals. The capacity to deliver Phase I to Phase IV clinical trials in areas such as cancer, diabetes, eye disease and respiratory disease is of benefit to industrial collaborations. For example, the Northern Ireland Clinical Trials Centre, Almac and Centre for Cancer Research & Cell Biology at QUB are currently collaborating on a pilot study in patients receiving neoadjuvant therapy.

Biomarker focused clinical trial

This is a Phase I clinical trial for ovarian cancer involving ALM201, the first novel cancer drug fully developed in Northern Ireland. This £13m collaboration between Almac and CCRCB represents a major investment by Almac, QUB and Invest NI in translational life sciences research. The investment will combine the strengths of the academic and industrial partners to focus on novel therapeutic target identification and validation, medicinal chemistry and companion biomarker discovery.

If you require this brochure in an alternative format (including Braille, audio disk, large print or in minority languages to meet the needs of those whose first language is not English) then please contact:

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