Leeds Clinical Research Unit

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Our Clinical Research Unit (CRU) in Leeds is located on the perimeter of the renowned Leeds General Infirmary and the University of Leeds. For more than 35 years, the Leeds CRU has conducted a range of clinical pharmacology studies from first-in-human (FIH) to registration enabling clinical trials, including drug-drug interaction, TQT, radiolabeled and microdosing studies. The in-house pharmacy prepares cGMP-compliant unit doses, including radiolabeled and sterile formulations. The Leeds clinic is one of our most experienced centers for complex study design and execution including adaptive, hybrid FIH and ethnic bridging studies.

Leeds CRU offers trials in obesity drug development with a state-of-the-art Human Appetite Laboratory enabling carefully controlled evaluation of appetite and food consumption. Our services also include the conduct of radiolabeled clinical trials with a radiation protection supervisor on-site and an external medical physics specialist working on our team. Real-time radioanalysis (for recovery) is performed at Labcorp to determine the exact day of discharge.

A new addition to the Leeds CRU is the introduction of new mobile, purpose built inhalation chambers, designed to offer variable air-flow technology and a flexible configuration for accurate delivery of IMP.

Site features

- Total capacity: 76 beds
- Participant database: 16,000
- Longest continuous in-house stay: 42 days
- Emergency response time: <5 minutes
- Adjacent to Leeds General Infirmary
- On-site cGMP-compliant pharmacy
- Two 10-bed high-visibility wards
- Pharmacodynamic (PD) assessment laboratory
- Clario Certified site
- Mortara Surveyor (48 channels)
- Physician team: combined 60 years of clinical research experience

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Drug Development

Hybrid protocol

“Go/no-go”
faster decision-making
for further development

Save
time and money while
enhancing opportunity

An adaptive design FIH immunology study

A small European biotechnology client approached Labcorp seeking the most efficient FIH adaptive trial design for an immunology drug study. Labcorp had already provided preclinical research on this molecule, so we had insight into the likely safety profile. Labcorp suggested a hybrid protocol—initially assessing the molecule in healthy volunteers and then evaluating results in patients—enabling the sponsor to include early efficacy data in the study. This approach would not only save time and money but also add significant value to the asset, as potential licensing partners could see data demonstrating both efficacy and safety.

Understanding the challenge

- Adaptive trial optimizing the ongoing study design
- Support for early “go/no-go” decision-making
- Continuity from preclinical to FIH clinical phases
- Hybrid protocol design, recruiting both healthy volunteers and patients

Hybrid, adaptive protocol accelerates “go” decision

Labcorp Early Phase Development Solutions (EPDS) offers the advantage of fast information flow between preclinical and clinical teams. For this client, a streamlined protocol design process allowed a finalized protocol within days of toxicology reports being available. The combined EPDS and clinical pharmacology team leveraged Labcorp late-stage clinical expertise, suggesting the inclusion of a small patient group in the FIH study to provide early proof of principle in this case. The approach was both practical and feasible, saving the time and expense of a separate study.

The Labcorp Leeds CRU conducted the healthy volunteer arm of the study, recruiting 48 volunteers in three months. The process included five dose-escalation steps, with up to two weeks between dose-escalation steps required to ensure sufficient decision-making data for this new biological entity. Along with safety, tolerability and PK evaluations following IV dosing, the team assessed subcutaneous administration, as this was the target dose route for subsequent clinical studies. With the use of optimized processes to access blinded interim data, the process enabled a rapid start to the patient portion of the study. To ensure robust patient recruitment, the team developed a network of four recruitment sites: the Labcorp Leeds CRU plus dedicated, experienced clinical pharmacology units in three U.K.-based hospitals—including the Royal Liverpool Hospital CRU. Among the 12 patients recruited within four months, efficacy signals were dramatic, delivering a strong “go” signal for further development.

This continuity of preclinical research to the FIH study—including early proof of principle—further streamlines the next phase of development. The generated data enabled a more efficient design and earlier initiation of a Phase II study. Our specialists’ understanding of this molecule and its development provided time and knowledge advantages to the client.

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