CASE STUDY

Fueling early-stage biotech growth with adaptive, patient-inclusive FIH trials

A KEY QUESTION

How can a hybrid, adaptive trial design improve early decision-making and reduce time and cost in FIH immunology clinical trials?

KEYWORDS First-in-human, Immunology, Adaptive trial design, Go/no-go decision-making, Hybrid protocol, Biotech

A small European biotechnology client approached Fortrea seeking the most efficient FIH adaptive trial design for an immunology drug study. We suggested a hybrid protocol—initially assessing the molecule in healthy volunteers, 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 effectiveness and safety.

Understanding the challenge

- Adaptive trial optimizing the ongoing study design
- Support for early "go/no-go" decision-making
- Hybrid protocol design, recruiting both healthy volunteers and patients

Hybrid, adaptive protocol accelerates "go" decision

Fortrea has deep experience of translating assets from preclinical to first-in-human studies. For this client, a streamlined protocol design process allowed finalized protocol within days of toxicology reports being available. Fortrea's clinical pharmacology team leveraged expertise from its late-stage colleagues who suggested the inclusion of a small patient group in the FIH study to provide early proof of principal in this case. The approach was both practical and feasible, saving the time and expense of a separate study.

A hybrid protocol offers faster **"GO/NO-GO"** decision-making for further development.

If a molecule is safe, well tolerated plus effective, there is a strong "go" signal for success. Accelerated decision-making saves time and money while enhancing opportunity.

Fortrea

The state-of-the-art Fortrea 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 is 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 Fortrea Leeds CRU plus dedicated, experienced Clinical Pharmacology Units in three UK-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 development success.

The deep knowledge of translating from pre-clinical to clinical streamlines the next phase of development. The data generated have enabled a more efficient design and earlier initiation of a Phase II study. Our experts' understanding of this molecule and its development provides time and knowledge advantages to the client.

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