CASE STUDY

Driving speed and scale: More than 20 Phase I and Ib obesity studies completed on time

A KEY QUESTION

How did Fortrea and a leading sponsor deliver obesity studies on-time and accelerate NDA paths?

KEYWORDS Obesity Trials, Clinical Pharmacology Service, Phase I, GLP1

Introduction

Obesity research is entering a new era, with a high number of innovative therapies emerging, including GLP1 agonists and dual, triple and tetra agonists, as well as new therapeutic classes with a complementary mode of action to incretins. As the pipeline for obesity drugs rapidly expands, speed has become critical, especially for sponsors aiming to secure timely New Drug Application (NDA) submissions. In this competitive landscape, the ability to deliver high-quality clinical data efficiently can determine which therapies reach patients first.

Challenges

Executing more than 20 Phase I and Ib studies within a tight timeframe of one and a half to two years posed significant hurdles. The program faced aggressive timelines that required aligning all studies with the critical path for the Food and Drug Administration's (FDA) NDA submission. Other challenges included:

- Patient recruitment
- Regulatory complexity
- Infrastructure

Patient recruitment was a major challenge, as the team needed to enroll more than 500 obese patients across multiple geographies. Regulatory complexity added further pressure, with full responsibility of submission across the FDA, Medicines and Healthcare products Regulatory Agency (MHRA) and Pharmaceuticals and Medical Devices Agency (PMDA). Additionally, specialized infrastructure was essential, including securing sites equipped with advanced monitoring capabilities.

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Actions

To overcome these challenges, Fortrea leveraged its own Clinical Pharmacology Services (CPS) sites and external specialists to optimize timelines and maintain quality standards. The team implemented centralized program management to ensure consistency and efficiency across all studies. Regular team meetings were conducted to enable transparent communication and rapid decision-making. A dedicated project manager oversaw the established partnerships between the sponsor, industry experts and Fortrea.

CPS (Clinical Pharmacology Services)

Fortrea's four internal Clinical Research Units (CRUs) in the U.S. & UK, are purpose-built to deliver speed, quality and flexibility in obesity research.

Patient recruitment was facilitated across the Fortrea CRUs as the program required more than 500 obese patients across multiple geographies. Sites are equipped with advanced infrastructure to support complex study designs, long-duration confinement and obese patient populations. Our established relationship with expert partner sites provided the capabilities to assess energy expenditure in metabolic chambers under strict dietary control in a metabolic kitchen.

Key strengths include:

- **Experience:** Fortrea internal CRUs have extensive experience in conducting Phase I studies for obese, elderly and otherwise healthy subjects
- **Resources:** Dedicated teams, including experienced principal investigators, nurses and operational staff, manage all aspects of study execution, from recruitment to data collection
- **Volunteer databases:** Large, diverse volunteer and patient databases at each site enable rapid enrollment
- **Collaborative ecosystem:** Strategic partnerships with local hospitals, academic centers and medical providers enhance patient access and support hybrid or adaptive trial designs
- **Regulatory readiness:** Sites are accredited and experienced with global regulatory requirements, supporting seamless submissions to agencies such as the FDA, MHRA and PMDA

Fortrea CPS operational logistics and capacity

Leeds, UK CRU

- The Leeds unit is MHRA-accredited and features a total capacity of 100 beds and a volunteer/patient database of 14,023. Leeds has its own internal recruitment call center
- The Leeds CRU conducts studies in healthy, elderly and obese populations, including adaptive designs and hybrid protocols
- Over 170 studies during the last five years, dosing more than 1,000 subjects per year
- The unit is equipped for flexibility, safety and quality, with access to various labs on its campus. The unit has an established collaboration with the Leeds Teaching Hospital and their physicians' network to expand access to unique patient populations

Dallas, Texas, U.S. CRU

- The site features a total capacity of 100 beds and a healthy volunteer database of 63,457 individuals. All recruitment is conducted in-house with the help of a recruitment call center, located in the Dallas clinic for the U.S. Fortrea clinics
- The unit can conduct all Phase I study types, including studies involving special populations such as elderly and obese, otherwise healthy subjects
- The Dallas CRU doses approximately 1,200 subjects per year, with collaboration with local medical providers for outpatient procedures such as echocardiography, fluoroscopy, MRI, x-ray, ultrasound, ophthalmologist/retinal specialist and cardiologists

Daytona Beach, Florida, U.S. CRU

- The site features a total capacity of 88 beds and a healthy volunteer database of 27,457
- The unit conducts all Phase I study types, including special populations such as elderly and obese, otherwise healthy subjects
- Doses approximately 800 subjects per year, and collaboration with local medical providers

Madison, Wisconsin, U.S. CRU

- The site features a total capacity of 88 beds and a healthy volunteer database of 17,132
- Full clinical pharmacology capabilities and has extensive experience in radio-labelled studies
- Doses approximately 50 studies annually for Phase I study design

Table 1 - Database numbers for various weight ranges at the Fortrea CRUs

Sites	Age range	BMI 27-40	BMI 30-40	BMI 30-45
Dallas	18-65	24,065	13,560	15,037
Daytona Beach	18-65	10,303	5,400	5,876
Madison	18-65	5,823	2,936	3,225
Leeds	18-65	6,386	2,642	2,693
Total		**46,577**	**24,538**	**26,831**

External site partner network—global strength

- **Global reach:** Fortrea CPS maintains a robust network of 315 clinical pharmacology Phase I–Ib sites across 30 countries, ensuring worldwide access to advanced capabilities and diverse patient populations
- **Specialized knowledge:** Sites offer deep therapeutic capabilities and leverage extensive patient databases and physician referral networks to accelerate recruitment
- **Metabolic and obesity focus:** More than 50 partner sites specialize in Metabolic and Obese Phase I–Ib trials, supporting one of Fortrea's key strategic areas
- **End-to-end support:** Fortrea CPS delivers full-service management—including site identification, feasibility, country and site selection, operational logistics and risk assessment, site setup and ongoing oversight—when these partners are engaged in Phase I–Ib programs

Outcomes

The program achieved remarkable success, delivering on all critical objectives:

- **On time delivery:** All 20 studies completed on time
- **Regulatory milestones met:** Submission packages for FDA, MHRA and PMDA delivered flawlessly
- **NDA approval on track:** Enabled timely regulatory review
- **Market impact:** Two drugs approved and launched for obesity and diabetes, improving patient outcomes globally

Conclusion

Fortrea set a new benchmark for clinical research excellence, delivering a highly complex obesity program ahead of schedule through unmatched operational precision, strategic partnerships and unwavering patient focus. This achievement redefines industry standards for speed, quality and regulatory compliance.

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