

Coordinating complex obesity studies involving energy intake and energy expenditure assessments



A KEY QUESTION

How do you successfully recruit and engage patients with obesity in studies that require highly specialized procedures while maintaining study quality and consistency?

KEYWORDS

Obesity Research, Energy Expenditure Studies, Metabolic Chambers, Patient Recruitment, Site Engagement, Specialized Procedures, Metabolic Assessment, Operational Excellence, Long-Term Obesity Research

Obesity research is evolving with new compounds with complementary modes of action to incretins, targeting beyond hunger and satiety. These studies often require specialized procedures, dedicated facilities and experienced research teams capable of managing complex assessments while maintaining a positive participant experience.

Fortrea supported two obesity studies evaluating energy intake and appetite-related brain activity in adults with obesity, including one study conducted within specialized metabolic chambers. Despite recruitment and operational challenges during the COVID-19 pandemic, Fortrea successfully delivered both studies by combining proactive recruitment strategies, experienced sites and continuous stakeholder engagement.

Challenges

Limited recruitment environment during COVID-19:

- Recruitment activities were impacted by the COVID-19 pandemic, creating challenges in identifying and enrolling appropriate participants while maintaining study timelines

Restricted metabolic chamber availability:

- The studies required specialized metabolic chamber facilities, limiting the number of available sites and creating scheduling complexities across participating centers

Consistency across specialized procedures:

- The protocols involved site-specific assessments and specialized procedures that required robust training, standardization and validation to support consistent execution across study locations

Actions and solutions

Expanded site strategy to support recruitment:

- When recruitment challenges emerged, Fortrea proactively added two rescue sites during study conduct to expand participant access and support enrollment goals

Selected sites with obesity research experience:

- Site selection focused on centers with experience working with participants with obesity and access to established participant databases that included healthy individuals with obesity

Maintained continuous site engagement:

- Regular communication, site support and collaboration helped maintain momentum throughout study delivery and encouraged knowledge sharing across participating sites

Introduced targeted operational tools:

- To promote consistency and awareness across sites, Fortrea implemented:
 - Site newsletters
 - Competitive enrollment trackers
 - Specialized procedure trackers
 - Study-specific information sheets
- These tools helped reinforce procedural requirements and supported study performance throughout recruitment and execution.

Outcomes

Recruitment goals successfully achieved:

- The addition of rescue sites strengthened recruitment efforts and contributed to successful enrollment across the program

Enrollment targets exceeded:

- The studies met their enrollment targets of participants with obesity, supporting successful delivery of both protocols

Expanded sponsor collaboration:

- Successful delivery led to the award of a subsequent metabolic chamber obesity study evaluating calorie intake and energy expenditure under calorie restriction, involving 74 participants across three U.S. sites and supported by a proactive site strategy

KEY LEARNINGS

Several important operational learnings emerged from these studies:

- Specialized obesity research requires early evaluation of site infrastructure and facility availability
- Recruitment strategies should account for the complexity of study participation and patient burden
- Continuous site engagement is critical when studies involve specialized procedures
- Standardized training, validation and communication processes help maintain consistency across sites
- Flexible site strategies can help mitigate recruitment challenges and preserve study timelines



Conclusion

Delivering studies that assess energy intake, appetite regulation and energy expenditure requires careful coordination across sites, specialized facilities and study teams. Through proactive recruitment planning, experienced site selection and continuous operational engagement, Fortrea successfully completed two complex obesity studies involving 114 participants across three treatment arms.

As obesity research increasingly explores mechanisms beyond weight loss alone, including energy balance, metabolic adaptation and long-term outcomes, specialized operational experience will continue to play an important role in supporting successful study delivery.



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