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Fact Sheet

Clinical Research Strategies to Drive Advances in Obesity Drug Development

Obesity is one of the most prevalent health problems of the 21st century. Global levels of obesity have more than doubled since 1990. According to 2022 data from the World Health Organization, more than 2.5 billion adults, ranging between 18 years and older, are overweight. Of these, roughly 850 million are obese (defined as a body a mass index >30 kg/m^2). The Centers for Disease Control (CDC) reports that the prevalence of obesity in U.S. adults increased from 30.5% to 41.9% and the prevalence of severe obesity increased from 4.7% to 9.2% in less than a 20-year period (from 1999–2000 through 2017–2020).

Clinical Research Considerations for Obesity Drug Development

The complexity of obesity-associated pathophysiology extends beyond the metabolic and endocrine actions of white and brown adipocytes to the gastrointestinal tract and the brain's role in maintaining energy homeostasis. Moreover, comorbidities that are often associated with obesity, including type 2 diabetes, multiple cardiovascular risk factors, and metabolic dysfunction-associated steatotic liver disease, may alter risk-to-benefit considerations of anti-obesity pharmacotherapy. A clinical development partner with a deep expertise in obesity and comorbidities and relevant research methodologies is important for a streamlined study that provides a sponsor actionable data at every step of development.

ProSciento's Therapeutic Expertise in Obesity and Other Metabolic-Related Drug Development

ProSciento provides scientific and operational expertise in the design and management of all facets of obesity-related clinical drug development. Moreover, ProSciento's proficiency in obesity pathophysiology and expertise in drug targets is combined with state-of-the-art clinical research capabilities for detailed proof-of-concept and mechanistic studies.

Differentiating insights provided by advanced methodologies include impact on body composition, carbohydrate and lipid metabolism and turnover, adipose and hepatic fat, regional metabolism and multiple cardiovascular risk biomarkers.

Key aspects of ProSciento's obesity clinical research methodologies

- Mechanistic insights into mode of action, including effects on appetite regulation and regional brain activity responses to food
- Comprehensive evaluation of effects on body weight and body composition (DEXA)
- Indirect calorimetry to determine energy expenditure and substrate utilization
- Doubly labeled water technique to measure energy expenditure
- Advanced imaging techniques including MRI, PET/CT, PET/MRI to elucidate
  - Visceral and subcutaneous adipose tissue volume and activation
  - Ectopic fat deposition (including liver, muscle, and pancreas)
- Tissue biopsy (fat, muscle, liver) and cellular enzyme activity
- Stable isotope techniques to investigate adipose tissue lipid turnover, tissue-specific insulin sensitivity and hepatic de novo
- lipogenesis QT and electrocardiographic telemetry
- Standardized and specific meal tests, hunger/satiety assessments, weight tracking/food intake and counseling

Unparalleled Expertise in Metabolic Clinical Research

450+ metabolic clinical projects conducted

Contributions to **20** drugs and devices on the market today

220+ clinical trial sites across the Americas, Europe and Asia-Pacific

Fact Sheet: Driving Advances in Obesity Drug Development

ProSciento's specialized methods provide early evidence of differentiating effects on comorbidities, including decreased insulin resistance, improved glucose metabolism, decreased hepatic steatosis, improved cardiovascular risk profiles, regional metabolism (liver and muscle), and substrate utilization. Moreover, ProSciento's science-driven approach enables simultaneous comprehensive profiling of multiple safety and efficacy signals and helps to minimize risk by maximizing the actionable data generated in clinical trials.

Premier Provider of Clinical Research Support for Obesity Drug Development

Obesity-Related Compound Experience:

Drug Class	Disease(s)*
DGAT inhibitors	Obesity; type 2 diabetes; MASLD/MASH
GLP-1 receptor agonists	Type 2 diabetes; obesity
Leptin agonists	Obesity; lipodystrophies
FGF21 analogs	Obesity; type 2 diabetes; MASLD/MASH
Centrally acting small molecule appetite suppressants	Obesity
Peptide YY	Obesity
Amylin agonists	Type 1 diabetes; type 2 diabetes; obesity
Dual incretin agonists	Type 2 diabetes; obesity Antipsychotic-associated obesity
Glucocorticoid receptor antagonists	

The above table highlights compound experience related to obesity drug development. Contact ProSciento at bd@prosciento.com for a full list of compound experience spanning more than 450 clinical research projects for diabetes, MASLD/MASH, obesity and other related metabolic diseases.

Specialized Metabolic Clinical Research Unit

ProSciento has a state-of-the-art, early phase clinical research unit (CRU) in Chula Vista, California. Many clients choose to include ProSciento's CRU as a site in a global, multi-site program or as the sole facility for a single-site project. The CRU has on-site clinical, subject recruitment, pharmaceutical and research nutrition teams with deep expertise in early phase studies for metabolic-related diseases. The 21,000 sq. ft. facility includes 30+ treatment beds, CLIA-certified laboratory, USP 797/800 standard clean room, and a dedicated glucose clamp unit. To learn more about ProSciento's scalable clinical R&D services for single and multi-site studies, contact bd@prosciento.com or visit www.prosciento.com.

Related Publications

Obesity-related publications authored by ProSciento scientists:

1. Krentz AJ, Weyer C, Hompesch M; Translational Research Methods in Diabetes, Obesity and Nonalcoholic Fatty Liver Disease Focus on Early Phase Clinical Drug Development. SPRINGER 2019
2. Krentz AJ, Fujioka K, Hompesch M; Evolution of weight reducing drugs: a perspective based on adverse effects. DIABETES OBESITY & METABOLISM 2016;18:558-70
3. Krentz AJ, Fujioka K, Hompesch M; Anti-obesity drugs: the intercontinental regulatory divide. DRUGS 2015;75:931-933

Contact us at bd@prosciento.com to discuss your obesity drug development program

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