

# Customized Programs for Clinical Development and Global Regulatory Services

ProSciento provides scientific and operational expertise in the design and management of all facets of clinical development for NASH, diabetes, obesity, and related metabolic drug and device studies.

## Clinical Development Planning

ProSciento's clinical development services are tailored to the specific needs of our clients and typically begin with a well-defined target product profile and clinical development plan. Clients work with our team of seasoned professionals, comprised of PhD and MD level scientists, that have long-standing track records in metabolic drug development.

## Regulatory Strategy and Operations

Today's metabolic compounds and devices must be delivered in an environment of evolving regulatory requirements driven by the need for stricter safety guidelines and new therapeutic areas of interest. Regulatory agencies are seeking more data on safety and durability of drug effects, often requiring larger, longer, and more complex clinical trials, as well as in populations that are more reflective of real-world treatment. A CRO with therapeutic-specific scientific and regulatory expertise has a distinct advantage in navigating the evolving regulatory environment, as well as in identifying licensing opportunities.

ProSciento's regulatory services typically begin with assessing IND readiness, analyzing regulatory options, and researching marketing opportunities afforded by each regulatory path. The company's regulatory team then provides project management for all document creation, submission and representation of the client at meetings with regulatory agencies.

### *ProSciento's clinical development and regulatory services include:*

- » IND readiness, including pre-clinical, pharmacology, CMC, and clinical elements
- » Global regulatory considerations assessments
- » Target Product Profiles (TPPs) and Clinical Development Plans (CDPs)
- » Clinical study design and protocols
- » Global Regulatory Agency meeting preparation and facilitation
- » Scientific Advisory Board development and meeting management
- » Regulatory project management and representation through product life cycle
- » Final report publication, medical writing and presentation at medical conferences
- » Licensing strategies and management
- » Additional services customized for individual clients

### ProSciento's Track Record

**325+** Metabolic clinical projects conducted

**60+** Early clinical development protocols for biologics, small molecules, and devices

**100+** Submissions to FDA's Metabolism and Endocrinology Products (DMEP) and Gastroenterology and Inborn Errors Products (DGIEP) Divisions

Contributions to **17** drugs and devices on the market today

## CUSTOMIZED PROGRAMS FOR CLINICAL DEVELOPMENT AND GLOBAL REGULATORY SERVICES

### Reasons Why Clients Choose to Partner with ProSciento for Clinical Development Support

- » Scientific understanding and experience gained over 16+ years exclusively focused on diabetes, NASH, obesity and related metabolic diseases
- » Depth of clinical research and development services and seamless support from early development strategy to decision milestones
- » Team of experts at every level of client interaction and the adaptability to tailor individualized sponsor specific programs
- » Ability to navigate, guide and represent clients in regulatory decisions from early development planning through submissions, audits and meetings with regulatory agencies
- » Scientific services team to support the publication and presentation of outcomes at medical and scientific conferences worldwide
- » Commitment to upholding the highest level of quality assurance, operating at the highest level of compliance for GCP guidelines and FDA code of regulations
- » Relationships with distinguished industry and patient advocacy KOLs, relevant, among many reasons, for out-licensing and asset management support

### Access to Leading Clinical Development Experts

Another key component of ProSciento's clinic development services is access to a broad range of distinguished researchers and clinical development experts to advise on programs, as well as for the development of Scientific Advisory Boards. ProSciento has contributed scientifically and operationally to clinical development programs for metabolic diseases for 16+ years and more than 305 clinical projects and, as a result, has a deep network of relationships with leading researchers that represent cross-functional expertise in drug development and patient care and hail from prominent academic and medical centers in North America, Europe and Asia. More information about scientific advisory services is available by emailing [bd@prosciento.com](mailto:bd@prosciento.com).

Contact us at [bd@prosciento.com](mailto:bd@prosciento.com) to discuss your drug or device clinical development program



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