### **Endocrinology**

## An experienced endocrinology and metabolic partner

Bringing endocrinology and metabolic drugs to the marketplace comes with a unique set of challenges. The PPD™ clinical research business of Thermo Fisher Scientific has extensive global experience in planning, implementing, accelerating and delivering Phase I-IV metabolic and endocrinology clinical trials across a broad range of drug classes to help you overcome these challenges.

### Partner with us and benefit from our:

- Depth of experience across all stages of endocrinology and metabolic drug development, including two full drug development programs in T2 Diabetes
- Dedicated global team with deep experience providing consistent, quality delivery across all regions
- Investigator database of over 9,000 contracted sites
- Continuous Glucose Monitoring (CGM) offering with parsing and visualization of overall 'real time' data onto customized patient dashboards
- **Decentralized trial solutions** that accelerate recruitment and shorten timelines (by an average of 4.6 months)
- Emphasis on diverse recruitment of trial subjects who mirror the genetic and ethnic background of client's drug target population, including a proprietary database of 12.6M+ diabetes patients
- Customized digital solutions built around comorbidities such as cardiac outcomes and lipid trials
- Comprehensive laboratory services, including the PPD Laboratory services Bioanalytical and Central labs
- Our Cardiovascular, Kidney, Metabolic (CKM) collaborations support clients with seamless cross-collaborative operational, medical and scientific expertise

Our database contains 2,058 sites that have conducted endocrinology and metabolic studies with a global footprint:



**200+** Phase I-IV endocrinology and metabolic studies



**38,400+** patients across **3000+** sites in **81+** countries in last 5 years



300+ pediatric trials across all therapeutic areas

11 pediatric endocrinology and metabolic trials

**59** T1 and T2 diabetes studies

**30** obesity studies

42 metabolic rare disease studies

26 cell and gene therapy studies

### Endocrinology and metabolic clinical research experience

Our team has significant experience in conducting customized Phase I-IV endocrinology and metabolic clinical trials, ranging from a single protocol to full development programs with multiple protocols running concurrently.

T1 and T2 Diabetes • Complications of diabetes, including vascular and degenerative • Diabetic foot

- Pain-diabetic peripheral neuropathy Diabetic macular edema Obesity Inborn Errors of Metabolism (IEM)
- Metabolic Syndrome Organic acidemias (OA) Mucopolysaccharidosis (MPS) Lysosomal acid lipase deficiency (LALD)
  - Gaucher disease Fabry disease Glycogen storage disorders (GSD) Ornithine transcarbamylase deficiency (OTC)
  - PKU Wilson's Disease Pompe disease Acromegaly Hyperinsulinemia Ornithine Transcarbamylase Deficiency
- Hypoparathyroidism Congenital Adrenal Hyperplasia Dyslipidemia Metabolic Dysfunction-associated Steatohepatitis (MASH)

#### Easing enrollment and increasing retention with patient-centric services

We recognize how challenging managing clinical trial burdens can be for patients and their caregivers. We provide concierge services to **make it easier for patients to participate in trials** by offering:



Telemedicine, mobile units and home health care services



Digital and decentralized protocols



Transportation coordination and verification



eCOA/ePRO



Flexible reimbursement options



Wearables and mobile pages

These services help **produce timely and high-quality data** for our clients while saving patients time and cost. Our patient-centric approach has led to over **90% patient retention** over five years for a recent long-term follow-up trial.

To simplify recruitment, we offer accelerated enrollment solutions that give access to a robust and ever-expanding patient database including patients with rare conditions.



Scan to Learn More

# Leveraging technological insights for proactive study design

Our **clinical trial simulator** can help you identify potential gaps in your program ahead of time.

We help you use its insights to guide the selection of design parameters for clinical trials.

# Regulatory strategies to support successful filings

Our global regulatory experts have expertise in early and frequent collaboration with regulators to ensure successful submissions for metabolic and endocrinology indications.

We can support you with protocols for:

- Early planning
- Real World Evidence (RWE) generation
- Natural history, registry, and endpoint development and analysis