

PPD[®] – An Experienced Endocrinology and Metabolic Partner

Bringing endocrinology and metabolic drugs to the marketplace comes with a unique set of challenges. PPD 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 PPD 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**, global BioA and central lab services
- **PPD's Cardiovascular, Kidney, Metabolic (CKM) Centre of Excellence** supports clients with seamless cross-collaborative operational, medical and scientific expertise

PPD'S 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
- 16** obesity studies
- 42** metabolic rare disease studies
- 26** cell and gene therapy studies

ENDOCRINOLOGY AND METABOLIC CLINICAL RESEARCH EXPERIENCE

PPD 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 Healthcare 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, PPD offers accelerated enrollment solutions (AES) that give access to a robust and ever-expanding patient database including patients with rare conditions.



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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 gene therapies in rare neurological indications. We can support you with protocols for:

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