Early Development Services for Neuroscience Studies

PPD® delivers complete neuroscience clinical trial solutions to help you get your life-changing therapy to patients in need as quickly as possible.

PPD’s integrated development solutions for neuroscience include access to the right sites and the right patients, an established neuroscience focused Phase I clinical research unit (CRU), a talented team of medical neuroscience specialists and long relationships with industry experts.

52 Phase I Neuroscience Studies Conducted in the Past Five Years

- 35 Neurology
- 7 Ophthalmology
- 1 Pain
- 9 Psychiatry/Psychology

Sites and Patients
- PPD’s patient database includes all key areas of neuroscience research—Alzheimer’s disease (AD), Parkinson’s disease (PD), amyotrophic lateral sclerosis (ALS) and multiple sclerosis (MS)
- PPD’s Accelerated Enrollment Solutions (AES) business brings together sites and patients from Synexus, Acurian and Optimal Research to deliver more patients from fewer sites in less time
- 55 PPD Select Sites globally
- The Synexus HealthyMinds Registry provides additional support for recruitment efforts

Neuroscience Expertise
- Experience across neuroinflammatory, neurodegenerative, epilepsy, movement, pain, psychiatry and neurobehavioral, sleep, ophthalmology, and rare disorders
- A dedicated team of 220 neuroscience PMs and CTMs focusing on our clients’ neuroscience needs
- Overcoming challenges in the neuroscience area through clinical trial simulation, industry leading patients registries, placebo response mitigation strategies and streamlined data platforms
- Innovative clinical trial design experience including Phase I/II and Phase II/III umbrella trials
- Worked on 7 of the 10 FDA-approved neuroscience therapies since 2016

Conducted 800+ Phase I studies in the past 5 years
30+ years of Phase I experience
750+ colleagues dedicated to early development studies
30+ global network sites and three PPD-owned CRUs
100,000+ households in our patient database
Orlando Phase I Clinical Research Unit

- Focused on Phase I, Ib, proof of concept (POC) and complex trials with in-depth neurology expertise
- A world-leading site in Alzheimer’s disease research
- In-house lumbar puncture capabilities for CSF collection
- Psychometric evaluations for study inclusion/exclusion and drug efficacy
- Private rooms for patients and caregivers
- Over 110 early phase clinical trials conducted since 2010
- Open since 2010, with a 32-bed inpatient unit with individual rooms and outpatient space separate from domiciling
- Concierge services for rare disease indication

Early Development Services

- PPD-owned Phase I CRUs in Austin, Texas, Las Vegas, Nevada, and Orlando, Florida
- On-site high-risk compounding pharmacies to facilitate single-ascending-dose (SAD) and multiple-ascending dose (MAD) trials
- Services from discovery through Phase Ib to support later phase programs and regulatory submissions
- Traditional, adaptive and complex study design expertise to facilitate rapid decision-making
- Dedicated bed space, experience and streamlined process delivers startup in six weeks or less

PPD’s Proven Early Development Process Accelerates Study Startup

Early Engagement - Protocol consultation facilitates project and resource planning
Rapid IRB Approval - Leverage PPDs relationship with dedicated early development IRBs
Streamlined Planning - Early phase specific templates established for a turnkey approach
Fast-tracked Recruitment - Sophisticated recruitment supplemented by Acurian
FSI in 6 weeks or less - Consistently achieve accelerated start-up leveraging dedicated service staff and CRU

Clinical Trial and Disease Simulation

- A suite of simulation tools to support trial design, health economic analysis and clinical trial outcomes assessments throughout the development process
- Clinical trial simulation (CTS) supports reimbursement and access by justifying clinical and economic value
- Disease simulation integrates existing data to inform key issues such as burden of illness and budget impact; post-launch differentiation; HTA/reimbursement submissions; and labeling strategies
- Alzheimer’s Archimedes condition-event (ACE) simulator covers the full disease spectrum from prodromal to severe
- Parkinson’s ACE simulator addresses the complex interactions between multiple components of PD pathology
- AD and PD ACE simulators have been validated against external and/or observed data sets

Delivering integrated solutions tailored to meet our clients’ specific needs to deliver life-changing therapies to nervous system disorders.

To learn more, visit ppd.com/services/early-development