

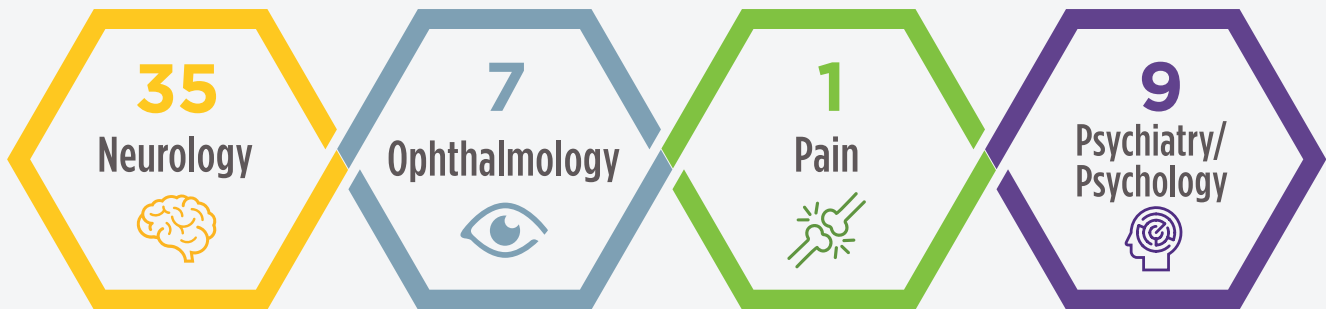
# Early Development Services for Neuroscience Studies



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



### 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**

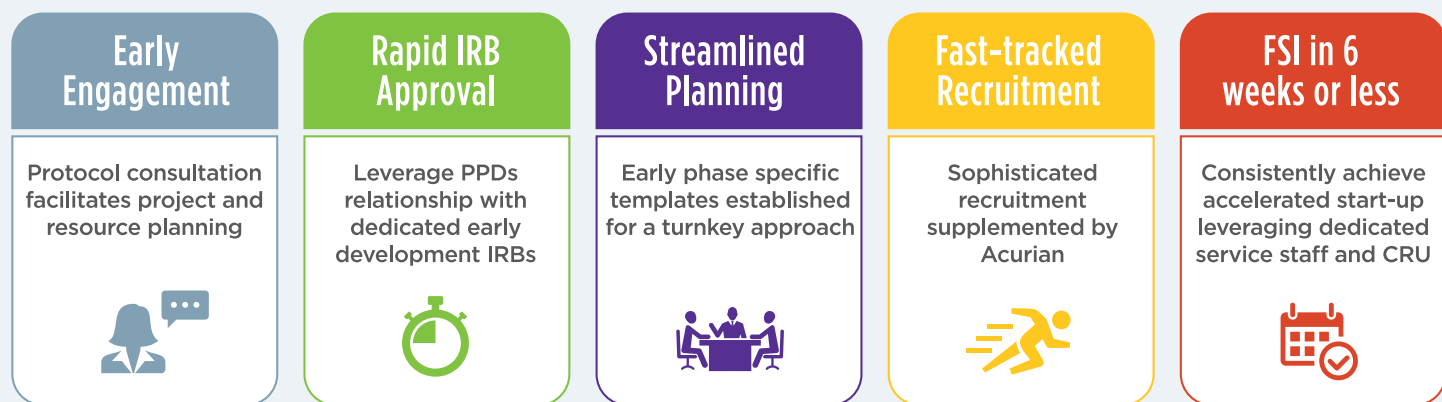
## Orlando Phase I Clinical Research Unit

- 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



## 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](http://ppd.com/services/early-development)**