

Early development

Early development services for neuroscience studies

The PPD™ clinical research business of Thermo Fisher Scientific delivers complete neuroscience clinical trial solutions to help you get your life-changing therapy to patients in need as quickly as possible. Our 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

- Our 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)
- Our Accelerated Enrollment Solutions (AES) business brings together our unique combination of global site locations, patient-centric and digital solutions to deliver more patients from fewer sites in less time
- 55 select sites globally
- The 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
wholly 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

- Wholly 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

Our proven early development process accelerates study start-up

- **Early engagement** - Protocol consultation facilitates project and resource planning
- **Rapid IRB approval** - Leverage our relationship with dedicated early development IRBs
- **Streamlined planning** - Early phase specific templates established for a turnkey approach
- **Fast-tracked recruitment** - Customized patient recruitment strategies
- **FSI in six 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

 Learn more at thermofisher.com/ppd

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