

Psychiatry

Your partner in successful psychiatry trial delivery

While medical and public awareness of the prevalence and burden of mental disorders has increased, there remains a high unmet medical need. Mental health and substance use disorders affect around 13% of the population globally. It is estimated that mental disorders are attributable to 14.3% of deaths worldwide (JAMA Psychiatry, 2015). There remains an urgent need to identify new, efficacious treatment options.

The PPD™ clinical research of business of Thermo Fisher Scientific has the right experience, medical/operational teams and data quality strategies to advance your psychiatry program.



40 psychiatry trials,
involving 5,032 patients



730 psychiatry site
investigators, including
those at dedicated sites



Digital trial technology
to reduce patient burden



Data integrity and
scientific surveillance,
critical for psychiatry studies

Confidently advance your psychiatry trial

High trial failure rates are believed to be largely driven by the significant placebo response rates observed in clinical trials in psychiatry. We understand how to minimize the risks inherent in psychiatry studies. Identification, recruitment and proper evaluation of the appropriate patients is a critical factor. We apply our deep understanding in this space to overcome issues which may negatively impact signal detection including:

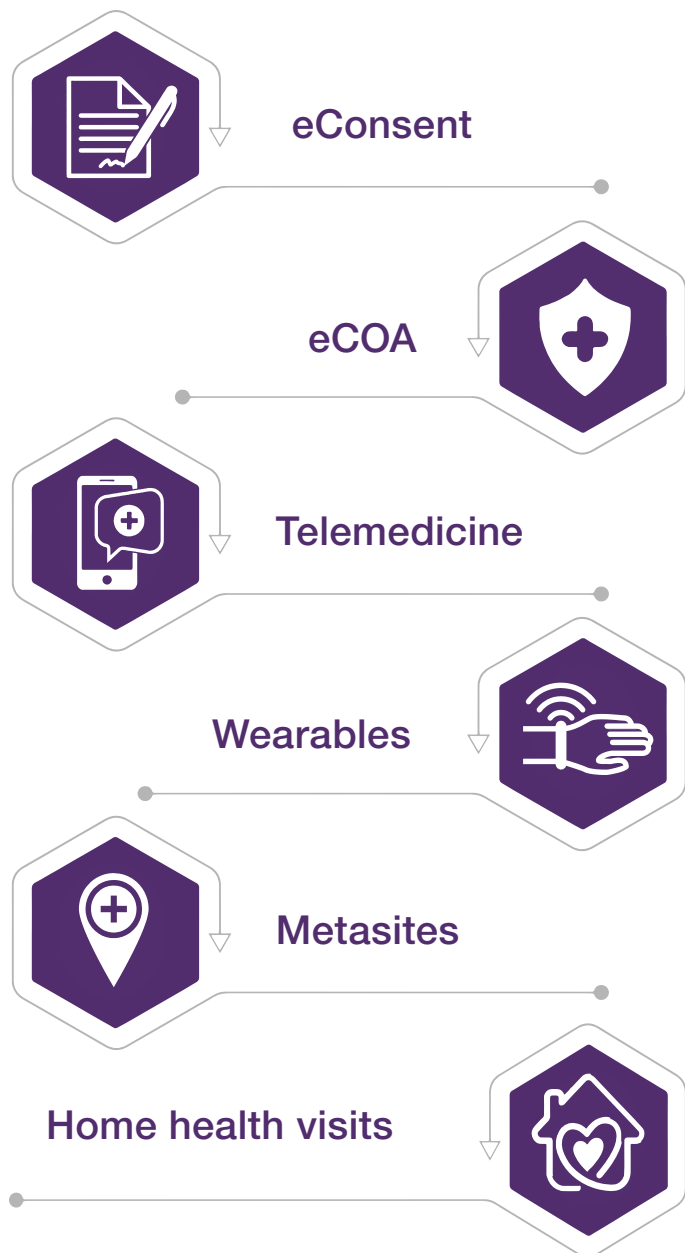
- Subjective endpoints
- Natural history of the disease
- Inconsistency in disease severity assessments
- Inaccurate diagnosis
- Misconceptions of treatment versus research
- Expectation bias

Our advanced patient enrollment solution is based on these key interconnected components:

- A global proprietary database of trial participants (100 million households)
- 160+ owned and partnered clinical research sites worldwide, including sites in over 10 countries worldwide with access to psychiatrists or neurologists
- A network of more than 700 traditional psychiatry sites
- The efficiency enabled by this solution gives us the ability to reduce study timelines and provide high-quality patients, budget certainty, operational efficiency, and complete accountability in achieving key performance indicators
- Additional benefits for psychiatry trials include:
 - Timely recruitment and retention without impacting data quality
 - Dedicated research sites and staff better understand the nuances of patient interactions and expectations in trials
 - A reduction in study site footprint equals fewer raters and reduced data variability

Reducing patient burden through PPD™ Digital and Decentralized solutions

Our teams offer digital and/or decentralized solutions to reduce patient burden based on an in-depth understanding of patient and caregiver needs in psychiatry studies, without jeopardizing collection of high-quality data supporting study endpoints/assessments of subject safety. **Our solutions include:**



Data integrity and scientific surveillance

Centralized statistical monitoring ensures scientific integrity by proactively mitigating risks, essential to identifying insights in psychiatry trials. Our data analytics group delivers a robust approach to data integrity protection, centralized statistical monitoring and scientific surveillance to better monitor and manage psychiatry clinical study data.

Scientific surveillance tools in neuroscience trials include Bayesian methods to predict risks. Multivariate methods coupled with clinical insights are used to detect systematic irregularities across and between clinical outcome assessments, patient reported outcomes and relevant safety outcomes, with appropriate multiplicity adjustments allowing us better management of scientific integrity at the site and study level.

Our teams are well-positioned to overcome the challenges of psychiatry programs



Our team of physicians, operations experts and leaders in statistical design are ready to leverage our proven strategies with specialized site networks to support your study. Together, we will bring new treatments to patients with psychiatric disorders who need them.

Learn more at thermofisher.com/ppd