

PPD FSP Clinical Operations solutions

The global expertise you need to ensure patient safety, data quality, and protocol compliance



It takes a wide range of resources to meet the challenges of conducting clinical studies. Whether you require specialized skills to complement your existing expertise or an outsourced solution to perform all aspects of clinical monitoring and site management, you need a partner that delivers customized clinical operations solutions that protect patients and keep your studies on schedule.

Through bespoke clinical operations solutions available in a flexible functional service partnership (FSP) model, **PPD™ FSP Clinical Operations solutions** helps biopharmaceutical, biotech, and medical device organizations ensure patient safety, data quality, and protocol compliance. With a proven track record built from decades of experience, we provide the right talent and expertise to help our clients meet their timelines — while providing much-needed resource flexibility, reliability, and continuity.

Faster staff allocation to meet timelines

More agile resourcing to keep pace with your changing needs

Better risk mitigation to minimize disruptions

Flexible clinical operations solutions deliver the breadth and depth of expertise you need

Backed by a 25+ year track record of FSP support, our comprehensive clinical operations solutions provide much needed resource flexibility, reliability, and continuity. Our experienced clinical operations professionals deliver a breadth and depth of therapeutic and functional expertise unmatched in the industry, uniquely positioning us to deliver the right experience and knowledge to fill your clinical operations gaps across a full range of services.



Bespoke solutions across a full range of services



Clinical monitoring

Blend of central, remote and onsite monitoring



Clinical oversight

Oversee all aspects critical to quality



Site management

From study startup through closure



Clinical support services

End-to-end site operational support



Develop and manage site relationships



How you benefit

- Greater patient safety, data quality, and protocol compliance
- Better resource flexibility, reliability, and continuity
- Better clinical oversight to drive standardization and consistency across studies/ countries/regions
- Strong, enduring site relationships
- More efficient and reliable management at the site

Problem-solving professionals & flexible models ensure you stay on schedule

Our clinical operations approach is driven by the understanding that it is difficult to fix a problem once it has occurred. With this in mind, our experts maintain a preventive focus on the front lines of new operating models rooted in risk-based quality management (RBQM) and data analytics.

Leveraging decades of clinical operations experience, we also partner with you to personalize the best outsourcing model for your needs. Our solutions provide the flexibility to embed our exceptionally trained staff within your workforce using a customizable mix of systems, processes, oversight, and reporting structures—whether yours, ours, or a blend—or we can take the work fully in-house using our innovations and systems.

Proactive teams

- Apply risk-based approaches, root cause analysis and problem-solving skills
- Align our experts to your internal structures through role mapping, which may include:
 - Clinical Research Associates (CRAs)
 - Clinical Trial Coordinators (CTCs)
 - · Country Approval Specialists
 - Site Contract Specialists
 - Site Engagement Leads
 - · Central Review Managers
- Drive accountability with our clientfacing people managers overseeing key performance indicators (KPIs), resourcing, and forecasting

Adaptable approach

- Embed our staff within your workforce using a customizable mix of systems, processes, oversight, and reporting yours or ours
- Or outsource the entire function and let PPD support your needs entirely in-house, using our systems, processes, and innovations
- Choose from flexible pricing models:
 - Full-time equivalent (FTE) models
 - Unit-based models
 - · Time & materials models
 - Hybrid models

Worldwide resources

 11,000+ clinical operations professionals worldwide:

• North America: 3,700+

• Latin America: 1.000+

• Europe, Middle East, Africa: 4,700+

Asia-Pacific: 2,400+



 $11,\!000 + \ clinical \ operations \ professionals \ worldwide$

From start to finish ensuring staff quality and continuity

With the number of registered clinical trials tripling in the last decade, the demand surge across the globe for talent is only growing more acute,¹ putting contract research organizations (CROs) and sponsors in a constant recruitment cycle for qualified resources in a hyper-competitive job market.

One of our priority talent sources is thousands of our own global internal pool of ready-to-deploy trained professionals. This allows us to allocate and onboard fully vetted staff very quickly—across multiple time zones—to keep your study on schedule. We also leverage the full force of our global infrastructure to take a three-pronged approach to attract, train, and develop diverse new talent pools to carry out your study from start to finish.



Our unique three-pronged approach to develop clinical operations talent pools



Global recruitment engine

- Established FSP recruitment model with dedicated recruiters and insourced contract labor program
- Targets experienced professionals as well as high-potential candidates for development



Forward-looking training

- Rigorous ongoing training for all clinical operations staff
- Innovative pathways into clinical research careers through our CRA Academy, Clinical Development Academy, and Clinician to CRA (C2C) Program



Development & retention

- Ongoing development programs, trainings, and coaching and mentoring
- Opportunities for advancement from CTC to CRA to Clinical Trial Manager (and more)
- Superior training, professional development, and support

Statista, Total number registered clinical studies worldwide 2000-2022

Why choose us as your FSP partner?



130+ recruitment professionals with dedicated FSP staffing team



Low 13.7% FSP staff turnover compared to industry average of 21% as of March 2023



Consistently low CRA turnover rates

15% in the US and 11.4% outside the US compared to 24% in US and 20% globally²



Excellent feedback scores on CRA recruitment effectiveness

Quality of hire: 92%
Manager satisfaction: 89%
New hire satisfaction: 90%



Centralized monitoring and risk surveillance analysis expertise

• 10+ years of experience

• 7,000+ analysis and review cycles



PPD is recognized as one of the best global enterprise learning and development programs in the world

by the Association for Talent Development³

² CenterWatch Weekly March 1, 2021 (BDO 2020/2021 CRO Insights Report)

³Thermo Fisher Scientific's Clinical Research Business Receives ATD Award for Employee Talent Development

Talk with your account representative or visit ppd.com/fsp-clinical-operations to learn more about how PPD FSP Clinical Operations solutions helps ensure patient safety, data quality, and protocol compliance so you can meet your timelines.