



HELPING DELIVER LIFE-CHANGING THERAPIES



PPD® FUNCTIONAL SERVICE PARTNERSHIP (FSP) SOLUTIONS
STUDY STARTUP

GET THE RIGHT SOLUTION TO MEET YOUR SITE ACTIVATION TIMELINES



Launching sites on schedule is critical to meeting clinical trial timelines and ensuring strong relationships with sites. Doing so requires managing the complexities of regulatory requirements, essential documentation, systems and supplies, and countless other details.

The PPD clinical research business of Thermo Fisher Scientific leverages extensive study startup experience across more than 50 countries through PPD FSP solutions. Whether you need a team of country-specific specialists or help filling a specialized gap in study start up expertise, **PPD FSP Study Startup Solutions** help ensure smooth activation of your sites — while providing much-needed resource flexibility, reliability, and continuity.

Proven track record

- **30+ years** of study startup experience
- **450+ startup leads** supported by **1,400+ locally based startup specialists** across 50+ countries worldwide
- **30% faster site activations** and **2.5 times more patients enrolling** at PPD Select Sites compared to traditional sites
- Reduced site activation timelines, resulting in **as much as 10% faster times** than industry benchmarks in Final Protocol to First Site Active and Final Protocol to 50% Sites Actives

PROVEN STUDY STARTUP EXPERTISE TO LAUNCH YOUR SITES ON-TIME

Fast and efficient study startup begins with strong feasibility and site identification. With more than three decades of experience, our study startup solutions deliver the proven breadth and depth of expertise you need to identify the optimal strategies, countries, and site mix, streamline operational processes, optimize cycle times, and — most importantly — help launch your sites on-time. Our solutions are tailored to each client's needs to help ensure strong relationships with sites and provide support in areas including:

- **Startup strategy and planning**
To define the site profile and develop the path to site activation, utilizing data-driven forecasting for site activations
- **Site selection and activation**
To perform country and site selection, compile required documentation, and negotiate site contracts
- **Coordination of submission activities**
To submit necessary forms to the appropriate regulatory agencies and ethics committees, and draft master informed consent forms (ICFs)
- **Documentation support**
To collect and distribute project documents including protocols, Investigator's Brochures, informed consent forms, investigational medicinal product dossiers, etc.
- **IP, systems, and vendor setup**
To engage with project leads and clinical trial managers and meet timelines for investigational product, lab kits, ancillary supplies, critical path items, trade compliance, etc.

The PPD FSP Study Startup Solutions team has longstanding experience and expertise in activating studies that shows in our team's ability to accelerate timelines and increase efficiency.



EXPERIENCED PROBLEM-SOLVING PROFESSIONALS TO SOLVE YOUR STUDY STARTUP CHALLENGES

For every engagement we support, we bring together a team of experienced managers and country-based specialists, each of whom is dedicated to a specific role in study startup and brings a customer-first mindset to understand and overcome your specific challenges



Global startup team managers (GSTMs)

Support initial startup activities and ensure oversight of all study startup activities.

- Coordinate and develop comprehensive startup strategies
- Collaborate with project and functional leads
- Oversee development of study startup plan and site activation forecasts
- Build and leverage relationships with local experts and agencies



Regional startup team managers (RSTMs)

Drive regional site activation, working in tandem with GSTMs.

- Coordinate with local teams in the various regions (e.g., contract specialists and country approval specialists)
- Apply extensive knowledge of local languages, regulatory practices, and cultural needs
- Oversee at regional level the regulatory and ethics activities, collection of essential documents, and site contracts negotiations



Rapid onboarding and ongoing training

Ensures consistency and compliance, expands skill sets, and develops readiness for future needs.

- Standardized training curricula for every role on the team
- Processes for assessing training completion and compliance
- Specialized training around client systems and standard operating procedures
- Alignment of people managers to support resource and performance management

TAILOR-MADE SOLUTIONS TO MEET YOUR SPECIFIC STUDY STARTUP NEEDS

We apply best practices and lessons learned to create the best outsourcing model for your needs, including the flexibility to embed staff within your workforce or take the business fully in-house using our innovations and technologies. Whatever mix of systems, processes, oversight, and facilities we are working within — yours or ours — we provide dedicated resources aligned to your culture and values.

Examples of our systems and technologies:

- **Preclarus® Dashboards**
Cross-functional view of study startup activities and sites for tracking and communications
- **Oracle Activate**
Supports site startup collaboration and communication through a single source
- **Veeva TMF/ Quality**
Ensures eTMF compliance
- **Global Site Contracts Digital Assistant (DA)**
Provides standard information in country-specific templates
- **Budget Quality Assurance (BQA) tool**
Identifies discrepancies between site and country budgets using process automation
- **Predict Activation Dates tool**
Predicts when a site is likely to be activated based on current data and historical site performance

Flexible pricing models adaptable to your changing needs:

- Full-time equivalent (FTE) models
- Unit-based models
- Time & materials models
- Hybrid models

“One Team” approach drives collaboration and helps clients quickly and efficiently reach targets

- Strategies integrated with your goals and KPIs
- Clearly articulated roles, responsibilities, and communication processes
- Recurring governance meetings for proactive identification and mitigation of risks

Talk with your account representative or visit ppd.com/fsp-study-start-up to learn more about how PPD FSP Study Startup Solutions can help you meet your site activation timelines.



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