

HELPING DELIVER LIFE-CHANGING THERAPIES





PPD® FUNCTIONAL SERVICE PARTNERSHIP (FSP) SOLUTIONS
SITE CONTRACTS AND PAYMENTS

CHOOSE PROVEN SOLUTIONS FOR FAST AND EFFICIENT SITE CONTRACTING AND PAYMENT PROCESSING



As biotech, biopharmaceutical, and medical device organizations face growing pressure to accelerate therapeutic development, accelerating site contracting cycle times helps you get your clinical trial sites activated and up and running sooner. Additionally, ensuring your site payments are accurate and on-time helps you become a sponsor of choice.

Whether you need a full site contracts and payments solution or highly skilled staff to complement your existing capabilities, **PPD FSP Site Contracts and Payments Solutions** delivers the right combination of contract best practices, local knowledge, and proprietary technologies — while providing muchneeded resource flexibility, reliability, and continuity.

Our site contracts expertise, by the numbers:

- **8,000**+ primary contracts
- **2,100+** ancillary agreements
- **7,000**+ amendments
- Approximately 600 trials supported in 66 countries

Our site payments expertise, by the numbers:

- **220,000+ payments** processed in 2023, totaling over **\$1.8 billion**
- Support for 85+ countries in ~40 currencies
- **700+ employees** worldwide

PROVEN BREADTH AND DEPTH OF EXPERTISE FOR YOUR SITE CONTRACTING NEEDS

Our solutions support tens of thousands documents annually for all clinical trial site contracting needs — from initial contracts to ancillary agreements and amendments. Our professionals bring expertise in areas including:



Legal language templates and documents

Preparation of contract documents using PPD templates and/or client templates, governmental, industry or sites' own templates



Clinical trial agreements (CTAs)

Generation of site-specific CTAs using previously generated contract documents, in addition to country budget information



Site-level negotiations

Management using minimal direct contacts with consideration for language, time zone, and local cultural and business practices



Escalation of site contracts

Establishment of clear communication and escalation pathways; accurate tracking of negotiations; review of site requests



Fair market value development/review

Determination of fair market value in grants using Medidata Edge Site Grants; fair market value considerations are based on demographics, geographic location, institution type and protocol-specific requirements



CONTRACTING BEST PRACTICES COMBINED WITH LOCAL EXPERTISE TO ACCELERATE CYCLE TIMES

We employ a mix of local specialists with in-depth country-specific knowledge and expertise, country-specific regulatory intelligence from PPD's proprietary RegView system, and oversight from regional generalists and centralized roles to accelerate your site contracting.

Contract Managers oversee the entire process



- Serve as a single point of contact for all contract-related items.
- Accountable for the work of the entire contracting team.
- Interact directly with your legal or contracting representative to aid decision-making and escalation.
- Selected based on their exceptional management skills.

Investigator Grant Analysts oversee budgeting



- Serve as a single point of contact for budget-related issues.
- Work alongside clinical management and legal staff on budgeting.
- Implement changes throughout a study, as needed.
- Collaborate with Contract Managers on escalations that arise from site negotiations, to appropriately address issues in a timely manner.

Contract Specialists manage site-level negotiations



- Reside in local countries, working in the site's time zone and local language.
- Provide real-time updates to key stakeholders and negotiate agreements on behalf of sponsors, as needed.
- Apply in-depth local knowledge to accelerate site contracting timelines.

DEDICATED TEAMS AND GLOBAL EXPERTISE DELIVER ACCURATE AND ON-TIME SITE PAYMENTS

Our site payments solutions employ dedicated teams with specialized functional expertise to deliver accurate and on-time site payments.

Through specialized support functions and hundreds of staff located throughout the world, our site payments group provides both payment processing and management services with the expertise needed to navigate the nuances of regional payment requirements. Using a unified and interconnected team structure, our site payment experts collaborate throughout the duration of a study to precisely and efficiently complete payment tasks on-time and provide support across functional areas including:



Site Payments Startup



Subject Visit Template (SVT) Review



Ethics Committee and Regulatory Authority Payments



Payment Processing



Payment Accruals and Reconciliation



Funds Management



Payables



Transparency Reporting



Administration

Our site payment solutions

Within our site payment solutions, well-established internal controls maintain separation between payment processing and payment approval tasks. Before payments can be issued, they must first undergo a formal review and approval process with multiple layers and system controls incorporated. Quality checks are also embedded throughout the payment processes to ensure our site payments team issues accurate and timely payments.

Extending to both the operational management and leadership levels, our two-pronged approach to the oversight of payment processes maximizes communication and escalation pathways to quickly engage leadership for assistance and support with issue management, contingency planning, and/or risk mitigation.

FLEXIBLE SOLUTIONS CUSTOMIZED TO YOUR REQUIREMENTS



Through best practices and lessons learned from our extensive site contracts and payments experience, we're able to quickly identify the best engagement model for each client's needs. Using a customizable mix of systems, processes, and oversight — yours or ours — our solutions offer the flexibility to either embed staff within your workforce using your existing infrastructure, SOPs, and processes or take the business fully in-house using PPD's SOPs, processes, and systems.

Flexible pricing models:

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

For engagements utilizing PPD systems and procedures, we leverage our knowledge and expertise to identify and utilize proven processes and tools to meet timelines and maximize speed and efficiency.

Our site contracting tools

Our in-house site contracting robotic processing automation (RPA), artificial intelligence (AI), and natural language processing (NLP)-based tools drive faster contract execution by more accurately predicting country-specific and site-specific contracting timelines and streamlining site negotiations, budget development and reporting, and risk identification and mitigation.

Digital Assistant (DA)

RPA tool

Oracle Activate

MAD DASH RPA tool

Examples include:

- Preclarus® for Site Contracting
- Site Contracts Analytics and Negotiation (SCAN) tool
- Medidata Edge Site Grants
- Budget Quality
 Assurance (BQA)

Our site payments tools

Our in-house site payments tools accelerate site study budget entry (ensuring compliance with Sarbanes-Oxley (SOX) controls timelines), payment inquiries response times, and payment processing cycle times by streamlining site agreements receipt by site payments team, site budget entry and approval, payment related tasks assignment, and payment details reporting.

Examples include:

- Preclarus® for Site Payments
- Ticketing system
- MAD DASH 2 RPA tool
- PDR (Payment Details Report) RPA tool
- · Admin RPA tool

- Budget Entry and Approval tool
- Reconciliation Tool
- Transparency Reporting Tool

Talk with your account representative or visit ppd.com/fsp-site-contracts-payments to learn more about how PPD FSP Site Contracts and Payments Solutions can help you accelerate site contracting cycle times and deliver timely site payments.



For more information visit our website at ppd.com/fsp-site-contracts-payments



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