OVERVIEW

Government and Public Health Services

Since 1990, PPD has provided clinical, regulatory and quality support to government and public health clients around the world. These research programs require a diversity of full medical product development and clinical support services, including full-service clinical trials, regulatory support contracts, clinical site monitoring contracts, statistical and data coordinating centers (SDCCs) and clinical research operations and management support (CROMS) contracts. Our government and public health services group (GPHS) is a small, nimble, project-centric team of more than 150 dedicated personnel that benefits from access to our global organization.

PPD PROVIDES:

- Programmatic resources for broad portfolios or full clinical program capabilities
- Multiple contracting and partnering models
- Deep experience in navigating and upholding all Federal contract requirements as a prime contract holder and subcontractor
- A DCAA-compliant accounting system
- Government program management expertise, including Earned Value Management

70+ DoD projects over the past **10 years**

HOW OUR GOVERNMENT AND PUBLIC HEALTH EXPERTISE WILL ENSURE SUCCESS OF YOUR PIPELINE

1 Global Experienced and Passionate Workforce

In the past 5 years:

2,500+ trials in

100+ countries with

30,000+ dedicated team members

2 Patient and Caregiver Focus

Individual patient concierge

Patient pathway mapping

Patient advocacy groups support

- Vaccine priority network of 1,000 sites
- 300+ precontracted oncology research sites for rapid activation
- Pediatric groups
- Phase I units
- Training program for capacity building at site and general population education
- Up to 30% faster study startup and up to 10% faster study completion

Database of relevant patients

3 Innovative Design and Data-driven Analysis

- Virtual trials
- Digital platforms
- Data visualization
- Time-saving data access
- Adaptive protocol design
- Risk-based monitoring

Client Operations Dashboard

- **1,515+ government-funded clinical trials**, including **1,067** infectious disease and vaccines trials, across NIH, CDC, BARDA, and the DoD
- **Full-service support** for NIAID/DAIDS-funded ACTIV-2 COVID-19 Outpatient Platform Trial
- **Multi-service support** of the NIAID/DCR-funded ACTIV-3/3b COVID-19 Inpatient Platform Trials
- **1 of 4** CROs providing **global, full-service**, and **rapid response support** for all parts of NIAID.
- **Providing global, multi-service support** for the CDC's Tuberculosis Trials Consortium (TBTC)

Hematology/Oncology | Cardiovascular | Endocrine and Metabolic | Immunology | Ophthalmology | Transplant
Critical Care | Gastroenterology | Infectious Disease | Rare Diseases | Urology | Women's Health | Dermatology
Neuroscience | Respiratory | Vaccines

CONSULTING Regulatory Consultation | Therapeutic Expertise | Competitive Landscape Analysis | Rare Diseases And Pediatrics

PPD PROVIDES FULL DEVELOPMENT LIFE CYCLE EXPERTISE

DRUG DISCOVERY

- CMC consulting
- Clinical development planning
- Regulatory consulting
- Pharmacokinetic consulting

PRECLINICAL/ EARLY DEVELOPMENT

- Nonclinical development and chemistry
- Pharmacology and toxicology
- Epidemiology
- Gap analysis
- Pre-IND/IND support
- FDA support and representation
- Protocol development
- Payer/HTA strategies for value messaging

IND

CLINICAL (PHASE I-IIIB)

- Feasibility
- Regulatory
- Study startup
- Clinical supplies
- Recruitment
- Clinical research units (for healthy and patient volunteers)
- IXRS
- Monitoring
- Medical monitoring and PVG
- COA/PRO instrument development
- Patient preference studies
- Data management
- Biostatistics
- Pharmacokinetics and pharmacodynamics
- Quality
- Medical writing
- Medical communications
- Modeling and simulation
- Systematic literature reviews, network meta-analyses, simulated and indirect treatment comparisons

NDA SUBMISSION SUPPORT

- Full submission
- Programming and statistics
- Regulatory consulting
- NDA briefing packages

NDA/APPROVAL

PERI- AND POST-APPROVAL

- Evidence of value, effectiveness and safety to optimize market access
- Real-world evidence (e.g., data analytics, registries, observational studies)
- Interventional studies (e.g., Phase IIIb/IV, pragmatic/adaptive, EAP, XAP)
- Peri-/post-approval safety studies, REMS, RMPs
- Health care communications, medical writing

SUCCESSFUL PAYER/HTA SUBMISSION

PPD Laboratory services Central Lab | GMP lab - Bioanalytical Lab | Vaccine Sciences Lab | Biomarkers Lab

Our industry-leading scientific and medical teams design, plan and implement full-scale global programs to help clients reach key milestones. They develop and provide counsel on feasibility and protocol optimization across a range of therapeutic areas to drive patient and site enrollment and provide expertise in the conduct and management of clinical studies.

This expertise results in an understanding of the current challenges in the landscape, as well as established strategies and processes to assure efficient and cost-effective drug, device, and evidence-based care development.

30+ years
NIH history – all
27 institutions

Supported
46+
clinical programs to date with BARDA and BARDA-funded industry partners

Rebecca Harston, PhD | Executive Account Director | PPD Government and Public Health Services | Washington, DC |
Phone +1 571 310 1951 | rebecca.harston@ppd.com | www.ppd.com

PPD
Part of Thermo Fisher Scientific