

# PPD's Government and Public Health Services



## PPD is a worldwide community of professionals committed to helping our clients deliver life-changing therapies.

Our industry-leading scientific and medical teams design, plan and implement full-scale global programs to help clients reach key milestones. Our medical experts develop and provide counsel on feasibility and protocol optimization across a range of therapeutic areas to drive patient and site enrollment. PPD's clients and partners include pharmaceutical, biotechnology, medical device, academic and government organizations.

## PPD offers its clients a wide array of pharmaceutical product development capabilities:

- **Early Development Services** – Expertise and infrastructure to deliver customized early phase strategies
- **Clinical Development Services** – Comprehensive product development services
- **PPD® Laboratories Services** – Global lab services—spanning small and large molecules
- **Real-world Services** – Research services to optimize the life cycle of a product
- **Consulting Services** – Diverse expertise across therapeutic areas and functional disciplines



## Government and Public Health

Since 1990, PPD's dedicated government and public health services group has successfully delivered clinical research services to the U.S. government, nongovernmental organizations and academia. We have worked in U.S. government prime and subcontracting models, public and private partnerships, and commercial subcontracting on U.S. government-funded projects.

Our ability to understand the needs of government agencies is indicative of our Federal Acquisition Regulation-compliant processes and program management skills.

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**PPD is a prime contractor under the DoD's medical product research and development (MPRD) program.**

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## PPD supports about 80 active ongoing projects for:

- Biomedical Advanced Research and Development Authority (BARDA)
- National Institutes of Health (NIH)
- Department of Defense (DoD)
- Nonprofits and academia

Under our prime BARDA Clinical Studies Network contract, PPD supports the design and conduct of clinical studies to develop medical countermeasures to protect against bioterrorism, pandemic influenza and other public health emergencies. PPD supports BARDA and its development partners in planning, performing, monitoring and interpreting Phase I-IV clinical studies.

Since PPD is a prime BARDA contractor, the "consent to subcontract process" by the BARDA contracting officer can

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potentially be expedited, saving valuable time in subcontract execution and study startup.

Our medical product research and development (MPRD) contract provides for services for the U.S. Army Medical Materiel Development Activity (USAMMDA), the U.S. Army Medical Materiel Agency (USAMMA), other subordinate commands of the U.S. Army Medical Research and Materiel Command (USAMRMC), and other DoD entities responsible for medical product R&D.

**In addition to our BARDA and DoD experience, PPD has provided services to NIH for the past 27 years.**

## Therapeutic Area Experience

We have more than 27 years of experience in managing all aspects of infectious disease trials, from design and conduct of studies and programs to operational execution and delivery of the final clinical report.

In the past five years, PPD has helped clients conduct 753 infectious disease trials involving 230,464 participants at more than 13,000 sites. This experience gives us familiarity with the most competent and experienced sites and access to experienced staff, which in turn allows us to support studies efficiently and effectively.

## Earned Value and Performance Management

PPD understands the importance of performance management, maintaining our Earned Value Management System in compliance with Federal

Acquisition Regulation/Defense Federal Acquisition Regulation Part 252.234-7002 and the American National Standards Institute/Electronic Industries Alliance (ANSI/EIA) 748-B standard guideline. PPD's contract administration team works with program and project managers on contract performance reports, review and earned value analyses to maintain program controls (i.e., schedule and budget).

## Record of Successful Project Execution

|                          | Government & Public Health Services | PPD Overall       |
|--------------------------|-------------------------------------|-------------------|
| Therapeutic Area         | Number of Studies                   | Number of Studies |
| Cardiovascular           | 11                                  | 190               |
| Critical Care            | 20                                  | 55                |
| Dermatology              | 12                                  | 113               |
| Endocrinology/ Metabolic | 25                                  | 395               |
| Gastrointestinal         | 2                                   | 196               |
| Genito-urologic          | 11                                  | 115               |
| Hematology               | 1                                   | 132               |
| Immunology               | 67                                  | 282               |
| Infectious Disease       | 289                                 | 753               |
| Injury and Poisoning     | 9                                   | 17                |
| Musculoskeletal          | 6                                   | 67                |
| Neurology                | 11                                  | 327               |
| Oncology                 | 4                                   | 1031              |
| Ophthalmology            | 0                                   | 141               |
| Other*                   | 31                                  | 638               |
| Pain                     | 2                                   | 79                |
| Psychiatry/Psychology    | 13                                  | 119               |
| Respiratory              | 73                                  | 327               |
| Women's Health           | 0                                   | 31                |

\*Includes studies in otolaryngology, dental, expanded access, cohort, case-control, surveillance, epidemiology, and other observational study designs

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