

Implementing and Managing Statistical and Data Coordinating Centers (SDCCs)



Statistical and data coordinating centers (SDCCs) are key to implementing large clinical research programs and providing centralized scientific leadership and oversight, study design and protocol development, statistical design and analysis expertise, project management, data management, decentralized data collection, safety, biospecimen repository and specimen tracking, DSMB support, clinical site monitoring, regulatory affairs, quality assurance, and training and certification across all phases of clinical trials and observational and non-interventional studies.

Let PPD's dedicated Government and Public Health Services group (GPHS) help you achieve your clinical research goals

Since 1990, PPD has provided full-service, multi-service, and single-service clinical, regulatory, and quality support to the U.S. government and commercial clients around the world working with global non-profit organizations, DHHS, and the DoD. Our dedicated government and public health services group (GPHS) supports all our government and non-profit clients. They provide a small, nimble, project-centered team of 150+ dedicated personnel that benefits from access to PPD's strong global footprint.



Global Capabilities with SDCC Expertise

We offer global solutions and exceptional quality to successfully oversee broad programs of clinical trials and studies from concept development to final deliverables (e.g., CSR, manuscripts, regulatory submissions, public data sharing, and more). GPHS has successfully supported more than 1,500 clinical trials and projects for the U.S. government resulting in long-standing relationships with numerous established NIH research networks and consortia.

Global Therapeutic Experience

As one of the most experienced CROs working directly with the US Government or providing subcontractor support for biopharma, academia, and non-profits on government-funded contracts, we have worked in a variety of research programs requiring a diversity of full medical product development and clinical services, including full-service clinical trials, regulatory support contracts, clinical site monitoring contracts, SDCCs, and CROMS contracts



End-to-End Protocol Development, Statistical Support, Data Management, and Support Services

- Concept Development & Study Design Support
- Protocol Development Support
- Protocol-Related Document Development
- Biostatistical and Programming Support
- Traditional & Adaptive Designs
- Data Management Support
- Compliance With Data Security Standards
- Decentralized/Digital and Hybrid Trial Capabilities
- Regulatory Support
- Clinicaltrials.gov Registration and Reporting
- Medical Writing Support for Final Study Reports
- Manuscript Writing Support
- Public Data Sharing
- Patient Management

PPD's Government Experience

Providing strategic partnership and local expertise in trial operations, human subject protection and regulatory affairs, data management and analysis, and quality control/quality assurance to protect and enhance global public health.

Global Regulatory Professionals

- 900+ global regulatory professionals across 50+ countries (300 regulatory affairs personnel & 600 site intelligence /activation country approval specialists)
- **Our regulatory experts have delivered more than 95,000 regulatory submissions across 164 countries in the past 10 years (i.e., INDs, CTAs).**
- PPD has supported more than 150 FDA drug approvals in the past 5 years alone
- **Our regulatory experts know the intricacies of providing regulatory support to researcher-initiated and other grant-funded NIH projects and investigators who are sometimes unfamiliar with regulatory authority pathways and timelines.**

Digital & Decentralized Trial Experience

In the past 3 years, PPD has supported 240 studies that included digital solutions. Specifically, we supported the following:

- 2019 = 17 studies
- 2020 = 66 studies
- 2021 = 110 studies
- 2022 (through May 2022) = 47 studies

Out of the 240 studies supported, the **Top 5** therapeutic areas for digital solutions deployed included:

1. Vaccine = 47 studies
2. Neuroscience = 41 studies
3. Oncology = 25 studies
4. Infectious Disease = 22 studies
5. Dermatology = 19 studies

US-Based SDCC Personnel Depth & Breadth

- 85+ PhD-level epidemiologists, 20+ PhD-level Implementation Scientists, 10+ Qualitative Research Scientists, 503 NA-based Data Management Personnel, 115 US-based PhD and Master's-level Statisticians, 300 US-based Statistical Programmers.
- **PPD has a separate, 10-member statistical science group that supports studies with complex statistical designs and analysis methodology. In the past 5 years, our experts have managed more than 90 adaptive design, 11 platform, 87 basket, and 5 umbrella studies.**
- PPD's 85+ epidemiologists and real-world evidence researchers publish 130+ peer-reviewed manuscripts annually.

In-House Lab/Biorepository Capabilities

- Reduced program, quality, and financial management burden with our in-house central labs and biological specimen repositories in Rockville, MD, and Highland Heights, KY (Cincinnati metro area) that provide central repository and tracking support for off-site, decentralized specimen repositories.
- Our leading LIMS, Preclarus Lab Data Portal, provides secure 24/7 access to real-time biospecimen data. A virtual biorepository with real-time visibility to specimen storage location and chain of custody, Preclarus Lab Data Portal allows full integration with multiple commercial off-the-shelf EDC systems (e.g., Medidata Rave EDC, Veeva Vault EDC, etc.).

Statistical Innovation

In the past five years, PPD has conducted 103 studies under a master protocol:

- 92 studies in oncology
- 5 studies in COVID-19
- 4 studies in central nervous system (CNS)
- 1 study in immunology
- 1 study in pediatric patient population

Study Phase	Basket	Umbrella	Platform
Phase I	9	1	1
Phase II*	75	2	9
Phase III**	3	2	1
Total	87	5	11

*Includes Phase I/II studies
**Includes Phase II/III studies

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PPD provides strategic partnership and local expertise in clinical research to protect and enhance public health. As a global provider of clinical development and laboratory services, focused on operation excellence, we improve health by helping customers deliver life-changing medicines. Our services support organizations in conducting therapeutic, vaccine, and medical device studies on a global scale across all trial phases and therapeutic areas.