EARLY DEVELOPMENT CLINICAL DEVELOPMENT LABORATORIES POST-APPROVAL CONSULTING

PPD®

HELPING DELIVER LIFE CHANGING THERAPIES

HELPING DELIVER **LIFE** CHANGING THERAPIES

PPD partners with pharmaceutical and biotech companies to bring hope to those searching for a cure. We devote our global team of employees to achieve the goal of delivering life-changing therapies. We apply tailored solutions to the changing landscape with a clear focus on speed to market and are constantly innovating to enable advances in clinical development.

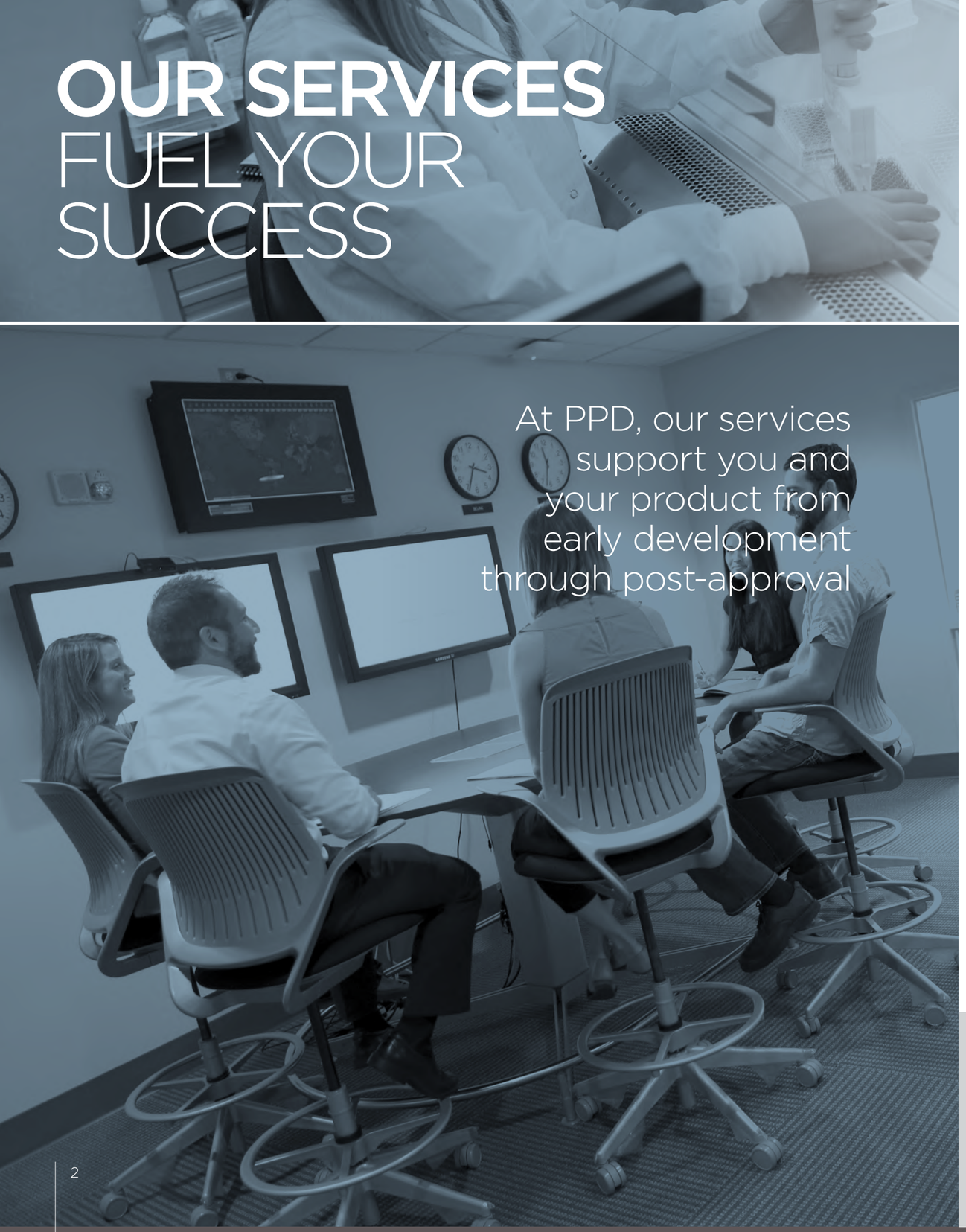
In the past 30 years, we've seen diseases that were once a life sentence become treatable with a once-a-day pill, conditions that were incurable become manageable, and shortened lifespans become longer and longer—proof that we are altering the future for the better.

PPD®

AT PPD, WE ARE FOCUSED ON CHANGING LIVES EVERY DAY

EARLY DEVELOPMENT | CLINICAL DEVELOPMENT | LABORATORIES | POST-APPROVAL | CONSULTING

OUR SERVICES FUEL YOUR SUCCESS



At PPD, our services support you and your product from early development through post-approval

POSITION YOUR PRODUCT TO REACH ITS MAXIMUM POTENTIAL

Early Development

Chemistry, Manufacturing and Control (CMC) Consulting
Manufacturing and Controls
Nonclinical Development and Chemistry
Pharmacology and Toxicology
Clinical Research Units
(for healthy and patient volunteers)
Patient Network
Translational Medicine

Clinical Development

Biostatistics
Clinical Supplies
Clinical Trial Monitoring
Data Management
Feasibility Studies
Global Pharmacovigilance
Interactive Response Technology Systems
Medical Communications
Medical Writing
Patient Recruitment
Pharmacokinetics and Pharmacodynamics (PK/PD)
Project Management
Quality and Compliance
Regulatory Affairs
Study Startup

Laboratories

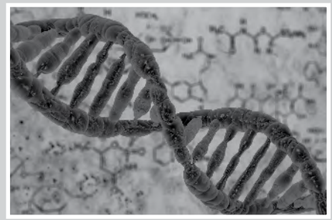
Bioanalytical Lab
Biomarker Lab
Central Lab
GMP Lab
Vaccine Sciences Lab

Post-Approval

Consumer Health
Early Planning for Post-Approval Research
Epidemiology
Expanded Access and Compassionate Use Programs
Extended Access Programs
Market Access Consulting and Communications
Data Strategy and Analytics
Global Pharmacovigilance
Health Economics and Outcomes Research
Medical Communications
Observational Studies
Phase IV Clinical Research
Patient Registries
Risk Evaluation and Mitigation Strategies (REMS) and Risk Management Plans

Consulting

Adaptive Trial Design
Biosimilars
Cardiovascular Outcomes
Medical Devices
Pediatrics
Product Development
Rare Diseases



PPD® Biotech

Operating as a company within a company, PPD® Biotech is a full-service CRO solely dedicated to biotech and small- to mid-sized pharma clients. With limited reporting layers, our team members are able to rapidly access executives to prioritize your needs. PPD Biotech combines the global power and capabilities of PPD with the personal attention, flexibility and extensive knowledge of biotech operations found at niche CROs.

Specialized Expertise in Early Development

PPD has full capabilities to meet the demands of small, yet complex, fast-paced Phase 0–IIa studies to help answer multiple safety, clinical pharmacology and disease/disorder activity questions in a single study. Our early development services team has managed thousand of studies from first-in-human through proof-of-concept.

Early phase specialists facilitate robust explorations of activity, dose and schedule. We also accelerate timelines by leveraging efficiencies through adaptive (i.e., Bayesian) or flexible trial design when applicable. Our insights—drawn from decades of experience—help minimize risks and improve the quality of decisions.

Better early decisions, in turn, improve the likelihood that the right dose is being studied for the right indication in the right patient populations, leading to downstream success.

Continued Investment in Early Development

PPD continues to demonstrate a strong commitment to early development. The past two years have seen:

+ Doubling of our dedicated cross-functional early clinical development operations team
+ Opening of a hospital-adjacent clinical research unit in Las Vegas, Nevada, for first-in-human through proof-of-concept trials in both healthy and patient volunteers
+ Continued investment in PPD's state-of-the-art 300-bed clinical research unit in Austin, Texas. In operation more than 30 years, the clinic has a staff of more than 500 people and has run thousands of protocols in normal healthy volunteers.
+ Ongoing rigorous development of quality audited global networks of high-performing early phase sites for special populations and early oncology development
+ Ground-breaking work using novel, flexible and/or adaptive trial designs to speed decision making
+ Ongoing cross-functional subject matter expertise (medical/therapeutic, scientific, regulatory, project management), providing end-to-end asset and portfolio management

In addition, PPD supports proof-of-concept studies, 3+3 designs, cohort expansion, comprehensive global bioanalytical, GMP and central lab capabilities, PK/PD dose escalation and biomarker studies.

Early Development Strategic Alliance Network

Specialized services include a global network of clinical sites to conduct early phase trials with a Phase I focus on healthy volunteers and patients/specialty populations across a range of therapeutic areas.

+ 30 sites in global locations across North America, Europe and Asia-Pacific audited for quality assurance
+ Global early phase oncology network with expertise across all facets of early phase oncology trials
+ Relationships with investigators for protocol and drug development expertise

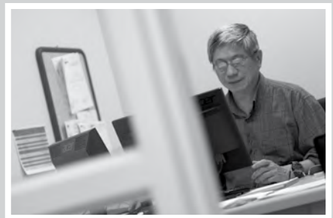
Our Early Development Model Delivers Results

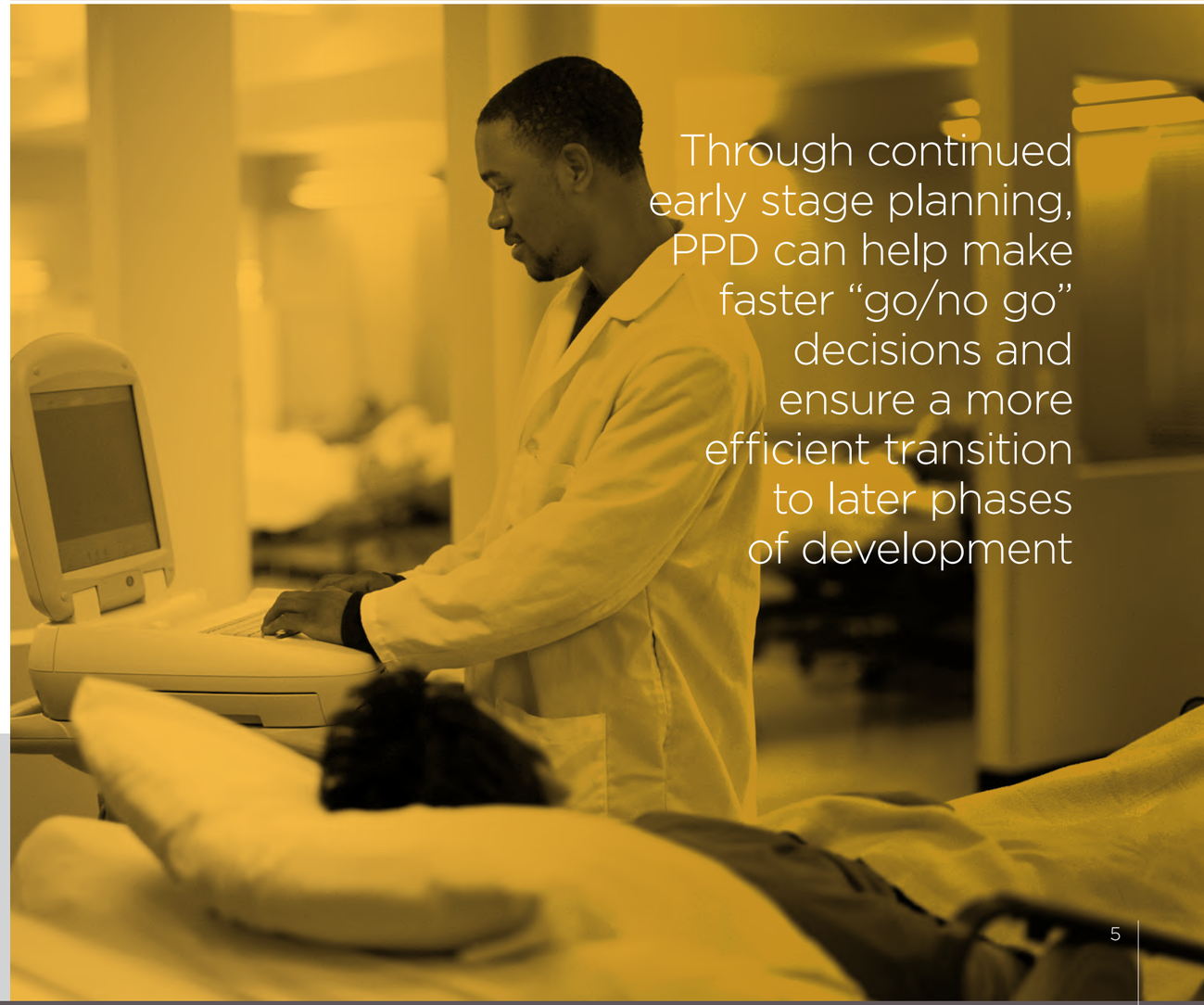
PPD deploys a fit-for-purpose operational model specific to early development. The model accommodates the complexity and rapid pace of early development, scaling to meet the unique needs of clients across multiple therapeutic areas.

"I really believe PPD is a pioneer in adaptive design."

Director of international business development
for a mid-sized Japanese nanotechnology company.

PPD proposed and developed a novel trial design for our client's Phase Ib-II lung cancer study. The novel design enhanced decision making and shortened the dose-escalation cycle time by five months, reducing the overall product development timeline.





LEADING DEVELOPMENT **AROUND THE WORLD**

Delivering therapeutic expertise and global reach to meet your needs

An expansive global footprint allows PPD to work with you in designing, implementing and managing your product development strategy in every corner of the world. From major markets to emerging ones, PPD ensures that you have immediate access to qualified patient populations, investigators and sites that meet your study parameters.

OUR AREAS OF THERAPEUTIC EXPERTISE INCLUDE:

+ Cardiovascular
+ Critical Care
+ Dermatology
+ Endocrinology/Metabolic Studies
+ Gastroenterology
+ General Medicine
+ Immunology
+ Infectious Diseases
+ Neuroscience
+ Oncology/Hematology
+ Ophthalmology
+ Pediatrics
+ Rare Diseases
+ Respiratory
+ Urology
+ Women's Health

Our experienced global team of physicians, scientists, product development experts, clinical personnel and regulatory professionals has many accomplishments:

+ Conducted approximately 2,400 studies in 100+ countries to advance therapies that lead to improved lives for patients
+ Worked with all top 50 pharmaceutical* companies and more than 750 biotechnology companies
+ Managed large, complex global studies with as many as 40,000 patients, 1,000 investigative sites and in 42 countries across all four major regions

Consulting

PPD® Consulting brings global expertise to develop custom plans that increase efficiency and reduce risks to help you realize your product's optimal value. PPD Consulting gives clients direct access to industry-leading experts to design and execute full product development programs.

Our consulting team is composed of physicians, scientists, regulatory professionals and biostatisticians with extensive small and large molecule development experience and diagnostic/medical device expertise—all with a focus on quality results. These experts have first-hand knowledge of state-of-the-art clinical, regulatory and commercial program strategies from first-in-human testing through registration, including post-approval studies and product optimization strategies.

*Ranked according to 2015 R&D spend

Rare Disease and Pediatric Center of Excellence

PPD's cross-functional Rare Disease and Pediatric Center of Excellence provides patient-centric solutions and disruptive approaches to recruitment. The center of excellence team works to address the strategic, operational, medical and scientific challenges presented by the small, widely dispersed patient populations that characterize rare diseases and drive trial participation and retention in this fast-growing area of drug development.

Expanding Our Therapeutic Area Capabilities

PPD is enhancing service delivery across several key therapeutic areas. In oncology, for example, we are developing a specialized, more highly trained oncology workforce and operating model, establishing a comprehensive offering for precision medicine trials and creating a patient-centric platform that includes exploring new ways to partner with academic medical centers.

Streamlined Processes and Proven Solutions to Maximize Product Value

PPD has the global knowledge and expertise required to design, plan and implement clinical development programs that help you reach key milestones on time and on budget. Through our expertise and knowledge of global regulatory guidelines, we can help ensure that your study meets applicable requirements. Our proven clinical development solutions span:

+ Biostatistics and Data Management
+ Clinical Supplies
+ Feasibility and Patient Recruitment
+ Medical Communications
+ Medical Writing
+ Clinical Trial Monitoring
+ Project Management
+ Quality and Compliance
+ Regulatory Affairs
+ Safety and Pharmacovigilance

Delivering Global Site and Patient Access

Reaching patients is the foundation of PPD's mission to deliver life-changing therapies. We meet our client's aggressive enrollment and retention goals through a custom patient and site strategy for each client program.

Patient engagement Our patient-centric trial capabilities empower clinical research participants and bring the trial closer to the patient. Collaboration with patient advocacy groups creates strong communications to support patient participation and provides home trial support to strengthen engagement. Through our acquisition of Acurian, the largest provider of enrollment and retention services, we have access to 70 million patients worldwide across many therapeutic areas.

Site engagement Strong partnerships with site networks across all major regions mean we can offer clients access to more than 100 million patients. We provide a comprehensive approach to site recruitment and engagement through access to high-performing sites. Preferred site networks include:

+ Synexus
+ Pediatric investigator network
+ Early phase oncology network
+ PPD® Select, a network of our highest-performing sites

Scientific engagement Our scientific, data-driven capabilities include innovative solutions to enhance our patient and site capabilities. We identify a medical oversight lead to oversee all aspects of a study, deploy a scientific steering committee with key opinion leaders to advise on protocol considerations and enrollment strategies, and conduct in-depth feasibility reviews to map patient pathways and evaluate the optimal method for engaging patients.

PPD® FSP

PPD® FSP delivers tailored outsourcing solutions that allow you to achieve higher quality, more measurable outcomes and greater cost savings. From traditional full-time equivalent (FTE) and output-based FSP models to units-based contracts and geographical-aligned outsourcing agreements, the PPD FSP team develops solutions to align with functional requirements.

New Approaches to Speed Development

PPD continually seeks to build innovative offerings that have a positive impact for our clients. Whether it's a new scientific approach, commercial model, technology, therapeutic advancement or continuous improvement, our focus is to bring efficiencies, advancements and differentiation to our business and get life-changing therapies to market faster by reducing the cost and time of drug development for our clients.

PPD® LABORATORIES GLOBAL, INNOVATIVE AND PROVEN **SOLUTIONS**

Leverage our extensive industry experience and scientific expertise to accelerate your product's development with consistently high-quality lab data

Greater Investment in Laboratory Data

With Preclarus®, PPD can easily combine central lab data with clinical management data in real time. We recently revolutionized sample accessioning, integrated our bioanalytical and vaccine lab data with central lab data, and created new pharmacovigilance tools to accelerate response to critical lab values. Near real-time integration with the clinical database saves up to 400 hours per study.

For nearly 30 years, PPD® Laboratories has been bringing clients world-class scientific expertise, innovative technology platforms, flexible service models and operational efficiencies at every stage of the drug development continuum.

Our comprehensive range of laboratory services spans small molecules, biologics, biomarkers and vaccines and allows us to reduce risk, increase efficiencies and ensure the highest safety standards for any project regardless of its complexity. We are equipped to work with client-transferred assay packages, or we can develop and validate customized assays.

Bioanalytical Lab

+ Precise, timely bioanalysis in a good laboratory practice (GLP)-compliant setting with expertise in many proven methods to quantitatively measure all types of compounds
+ Comprehensive immunochemistry services, cell-based assays and ligand-binding services
+ Substantial expertise in liquid chromatography/mass spectrometry (LC-MS/MS) for small molecules and biologics

Biomarker Lab

+ Comprehensive biomarker services and experience from early development to companion diagnostics
+ Integration of biomarker services into both the bioanalytical lab and the central lab to enable a tiered regulatory approach to development
+ A wide range of services including flow cytometry/cell-based assays, immunoassays, chromatography and genomics/molecular platforms

Central Lab

+ Standardized global testing platforms and a comprehensive quality assurance program provide consistent, high-quality lab results
+ Web-based database applications and innovative technologies, such as the Preclarus central lab database and the Preclarus investigator site portal, deliver secure access to lab data in real time
+ Strategic locations in Asia, Europe and North America dedicated to clinical trials and globally accessible to study sites

GMP Lab

+ Chemistry manufacturing and controls (CMC) pharmaceutical development services for active pharmaceutical ingredients (APIs) and all manner of pharmaceutical products independent of the chemical nature or dose formulation
+ Fully integrated analytical services across all phases of development and commercialization
+ The industry's most comprehensive and advanced instrumentation and technology to support method development and validation; stability, release and QC testing; extractables/leachables analysis, microbiological evaluation and physicochemical characterization

Vaccine Sciences Lab

+ More than 20 years of experience with a focus on quality and speed to support the introduction of life-changing vaccines
+ Capabilities include molecular, immunology and cellular/functional assays
+ Support for 15 U.S. Food and Drug Administration-approved vaccine development programs, more than any other CRO

Industry Leading Data Integration

+ The Preclarus central lab database creates a single global database for study definition, central lab data and lab process documentation
+ Interactive portals and dashboards enable real-time access to study-wide data and reduce data queries and inconsistencies by up to 70 percent
+ Online accessioning and sample tracking tools provide inbound sample visibility and improve chain of custody

Biopharmaceutical companies have a growing need for stronger evidence of how their products may perform in a real-world setting to determine and demonstrate value to payers and health technology assessment bodies. PPD delivers innovative, comprehensive development strategies to achieve regulatory approval, while simultaneously generating evidence needed to optimize market access for new products. Working in tandem with clinical development to optimize the life cycle of your product, PPD is able to maximize overall benefit to patients and help you maximize the return on your R&D investment.

With Evidera as part of the PPD family, we have created a global leader in real-world research and market access and are providing clients seamless, unmatched solutions across the product life cycle to generate outcomes-based evidence.

PPD and Evidera have designed, conducted and reported thousands of studies across all areas of medical affairs and post-approval research, including:

+ Investigator-initiated Research
+ Risk Mitigation
+ Real-world Outcomes and Observational Research
+ Expanded Access and Compassionate Use Programs
+ Interventional Studies
+ Patient-reported Outcomes
+ Patient Registries
+ Health Economics and Outcomes Research
+ Market Access Consulting and Communications
+ Data Strategy and Analytics

Scientific Leadership

We are the global leader in generating and communicating evidence of a product's value to inform health care decision making. With scientific thought leadership and expertise across all aspects of the post-approval space, we offer solutions that span real-world evidence, health economics, outcomes research, market access, epidemiology, modeling and simulation, and medical affairs studies.

Operational Excellence

We bring comprehensive medical affairs and real-world research experience across study design, site and patient recruitment, study execution, and analysis and reporting. Our experience incorporates investigator-initiated research, post-authorization safety studies, registries, interventional studies, expanded access and compassionate use programs, extended access programs, observational research and risk mitigation.

Data Insights

Our data insights include access to a variety of data sources, selecting the most appropriate sources and technical solutions based on the needs of the study. Data guide study design, execution, and analysis and reporting. Our expertise in this area includes database analytics, administrative claims, medical chart review studies, burden of illness studies, electronic medical records, longitudinal, linked patient-level data, hybrid database and direct to patient studies, coding algorithm development and Evalytica®.

Innovative Technologies

As pioneers in the industry, we have a long history of innovation. We continue to invest in R&D and develop numerous new capabilities and solutions, including innovative data and analytics platforms such as Preclarus and Evalytica.

Evidera: Generating Evidence of Value

Evidera provides evidence, value, and insight through health economics, outcomes research, market access, real-world evidence, and epidemiology research and consulting services. Evidera leverages expert knowledge of the global payer and regulatory landscape to help generate and communicate evidence of product value to inform decision making and optimize the commercial potential of products.

COMPREHENSIVE REAL-WORLD EVIDENCE AND MARKET ACCESS SERVICES

Delivering unmatched solutions across the product life cycle to generate outcomes-based evidence

TURNING INFORMATION **INTO KNOWLEDGE**

Combining the latest cutting-edge technologies with process improvement, real-time analytics and training for comprehensive solutions to business challenges

Technology Products and Services

Our technology, performance and innovation team partners with you to identify and address challenges and develop innovative solutions that improve business performance and deliver continuous improvement. PPD offers multiple technology solutions to address specific needs during the development process, including:

- Electronic Data Capture
- Electronic Informed Consent Form
- Electronic Protocol Inquiry Platform
- Evalytica
- Interactive Voice Response/ Interactive Web Response Systems
- Medical Imaging
- mHealth
- PPD® CTMS
- PPD® PatientView
- PPD® SponsorView
- Preclarus®
- Risk Evaluation and Mitigation Strategy (REMS)
- Virtual Investigator Meetings
- ARIS G/Argus
- Medidata Designer®
- Sequence WebEAS
- eTMF
- RegView
- Bioclinica ClinPay®

Data Access and Transparency

Data are critical in conducting clinical trials. PPD understands its clients' needs for rapid access and transparency in viewing study information, and we have developed Preclarus to facilitate access to operations, patient and lab data. Data views include:

- Adaptive and Intelligent Monitoring
- Corporate Experience
- Data Management
- Global Site Selection and Prioritization
- Patient Data
- Customer PPD Scorecard
- Study Management
- Study Startup
- Central Lab Data

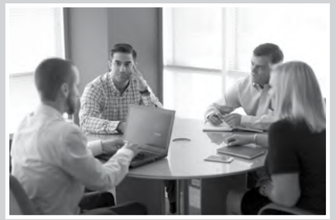
Training and Change Management

- Lean Six Sigma
- Learning Development
- Prosci Change Management Methodology

Award-Winning Innovation

PPD has received the Scrip Award for Best CRO and an award for deploying superior technological development in clinical trials. PPD was honored for its expertise and innovation in helping clients develop life-changing medical treatments. This expertise is consistently recognized by CIO Magazine with PPD's inclusion in the CIO 100 list, which honors organizations that have created business value through the innovative use of technology.

Additionally, in 2017, Evidera was named a Vault Top 50 consulting firm in its first year of consideration and among Vault's 2017 Top 25 best boutique consulting firms.



Delivery in Biopharma Partnerships

PPD has built best-in-class partnership models based on years of partnering experience with biopharma organizations. Our strategy includes fit-for-purpose governance and oversight, a single point of accountability, bringing innovation in unique ways across the partnership, and helping our client exceed its corporate goals across a portfolio of therapeutic areas.

ADVANCING
DRUG DEVELOPMENT

PPD's global resources are all pointed in your direction. We are ready to advance your research and development goals and achieve your product's full potential, putting it in the hands of those who need it most. Put our experience, our people and our vision to work for you.

TOGETHER WE CAN DELIVER LIFE-CHANGING THERAPIES

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