MEDICAL AFFAIRS RESEARCH AND REAL-WORLD OUTCOMES

PPD®

IMPACTFUL MEDICAL DATA

Investments for medical affairs/late stage research are increasing as companies need to predict more quickly and cost effectively how their products will perform and benefit patients in a real-world setting. PPD understands that developing and labeling a product doesn't guarantee a physician recognizes the value of treatment or that pricing and reimbursement organizations will agree on the product's value.

In the past 15 years, PPD has designed, conducted and reported more than 1,000 studies across all areas of medical affairs/late stage research, providing real-world evidence and data to evaluate the safety, effectiveness and economic value of our clients' products.

MEDICAL AFFAIRS RESEARCH OPERATIONS

Investigator-initiated Research

Risk Mitigation
- Risk Management Plan (RMP)
- REMS
- PAES/ PASS
- Regulatory Post-marketing Surveillance

Real-world Outcomes
- Health Economics & Outcomes Research (HEOR)
- Pragmatic Trials
- Patient-reported Outcomes
- Epidemiology

Observational Research
- Cohort Studies
  - Prospective
  - Retrospective
- Infant Follow-up Studies
- Registries
  - Disease
  - Pregnancy Exposure
  - Product Exposure

Database Studies

Expanded Access/ Compassionate Use Programs (EAP/CUP)
- Named Patient
- Treatment Use

Extended Access Program (XAP)

Interventional
- Phase II-IV
  - Practice informing
  - Publication
- Lactation/Placental Transfer Studies
- Consumer Health

COMMERCIALIZE, ACCESS PRODUCTS EFFECTIVELY

PPD offers medical affairs research and real-world outcome services to generate sufficient, timely and well-directed data that is critical to ensuring patient access and successful commercialization of products. Our experience and services span the product lifecycle across all therapeutic areas, geographical regions and all phases of research.

Extensive Partnership Experience

Capabilities Across the Range of USMA Indications

Specialist Medical Affairs Team

Integrated Partnership Model

Technology and Collaborations Innovations

COMPREHENSIVE SCOPE OF SERVICES

Interventional Late Stage/ Medical Affairs Research

PPD's research pr ce s g erat s fficient, timely and well-directed a a i or nt t the effective commercialization and access of your product. Through our ate tage r sear h we are able to:

+ Optimize data flow t answer key asset/brand questions in a timely fashion
+ Provide therapeutic expertise
+ Inform appropriate clinical practice
+ Enable optimal commercialization and market access
+ Improve the patient and customer experience

PPD has conducted

300+

interventional late stage studies

in the past five years.

Expanded Access/Compassionate Use Programs (EAP/CUP)

Our project management team has more than 25 years of collective experience managing global EAPs across all therapeutic areas. Through our inte nal center f e ce ence, we develop processes and techniques that ensure drug supply, regulatory management and our remote site monitoring and management staff are aware of program nuances. Our attention to detail and streamlined approach help ensure regulatory compliance.

PPD has enrolled more than

16,000 patients

2,200 sites

50 countries

in the past five years

35+ EAPs

globally in the past five years

Extended Access Program

Extended access programs (XAP) are designed to bridge the gap between the end of Phase III clinical trial participation and country-level product approvals for patients receiving new therapies.

By providing product until local country launch, PPD helps collect additional safety information, while maintaining patient access to therapies. Continuing with a therapy gives patients a link to the "parent" trial until the product becomes commercially available. This enables access to products with minimal data collection requirements, which eases subject participation burden.

PPD is experienced in implementing XAP master or platform studies as a way to provide post-trial access to a client's new product until it becomes locally available. This innovation helps build patient trust, investigator trust and fosters a culture of patient-centered commitments.

Observational Research

PPD supports peri- and post-approval studies and works with processes tailored for the real-world observational environment. Our expertise includes managing complex, dynamic programs with observational and post-approval safety studies ranging from a handful of sites and a few dozen patients to those involving thousands of sites and tens of thousands of patients. We have supported single-country and multi-national studies in compressed (one year) and extended (10 year) timelines and have worked on numerous global studies.

Pregnancy and Lactation Studies

As a global provider of pregnancy and infant follow-up studies, we bring more than 15 years of experience assessing the safety of exposure of medicinal products during pregnancy and postpartum. We have developed and implemented more than 40 pregnancy, infant and lactation studies that meet global regulatory agency requirements. Our experience includes meeting specific requirements outlined by the U.S. Food and Drug Administration's (FDA) Pregnancy and Lactation Labeling Rule. Using a customized approach, we provide study designs tailored to each client's needs. Our leaders have also served as invited consultants to the World Health Organization, the FDA, and the Centers for Disease Control and Prevention in developing best practices for conducting pregnancy and lactation studies.

Patient-reported Outcomes

PPD's patient-reported outcomes team has both qualitative and quantitative capabilities, with the expertise to create a strategy and develop and validate instruments through data analysis and reporting. Our team's experience spans all key therapeutic areas and includes rare and orphan diseases, as well as extensive experience with oncology development and interaction with the FDA for patient-reported outcome-labeling claims.

DRIVING RESULTS THROUGH PARTNERSHIPS

The PPD and HealthCore® partnership combines PPD's expertise in clinical trial design, health economics and outcomes research and medical affairs research with HealthCore's strengths in innovative real-world research designs and robust research-enabled electronic health care data environment. This partnership generates evidence that quickly demonstrates how products will perform and benefit patients in the real world, while covering product research in pre- and post-approval settings. We are setting new standards for quality, cost and speed of real-world evidence research to facilitate decisions and speed products to market.

HealthCore®

Our alliance includes more than 200 multi-disciplinary scientists, research/ data analysts and project managers dedicated to medical affairs and real-world outcomes research.

PPD has a team of experienced health economics researchers and strategists who map out and implement efficient strategy and research plans to help our clients achieve optimal market access. This team's experience spans all key therapeutic areas, including rare and orphan diseases. The combined PPD-HealthCore alliance team can leverage the large and rich data that resides in the HealthCore Integrated Research database to undertake research projects.

Through our alliance with HealthCore, PPD has access to large amounts of claim data and electronic health records. The linkage through HealthCore to the Anthem network allows us to conduct feasibility assessments on 70 million insured members of Blue Cross-Blue Shield and other health plans and target sites based on patient throughput or density. By providing de-identified aggregate data, we can link clinical data collected with other patient information, enabling us to address real-world effectiveness, safety research and cost effectiveness comparisons. PPD's team of epidemiologists undertakes both standalone and collaborative research with our HealthCore alliance partners. The team works closely with medical affairs and clinical development to design, implement and report on a wide range of peri- and post-approval study types.


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