

# Expansive Breadth Integrated Approach

Optimizing patient access with evidence of product value, effectiveness, and safety

## Services and Products Overview

Evidera, PPD's peri- and post-approval business, is a leading provider of evidence-based solutions to demonstrate the real-world effectiveness, safety, and value of healthcare products. We help biopharmaceutical, biotechnology, and medical device companies generate the evidence needed to optimize the market access and commercial potential of their products.

### Real-World Evidence & Data Solutions

- Database Study Designs
- Hybrid Study Designs
- LiveTracker®
- Data Science Applications
- Real-World Networks
- Integrated Evidence Generation Planning
- Trial Augmentation

### Non-Interventional Studies

- Disease, Product, and Pregnancy Registries
- Long-Term Treatment Durability and Safety Studies
- REMS/RMPs
- Chart Reviews & ClinicalLive™
- PASS/PAES
- Virtual/Decentralized Studies
- Early Natural History and Screening Studies

### Interventional Studies

- Phase IIIb/IV studies
- Open Label Extensions (OLE)
- Expanded Access Programs (EAP)
- Compassionate Use Programs (CUP)
- Extended Access Programs (XAP)
- Post-Marketing Commitments
- Virtual/Decentralized Studies
- Pragmatic/Adaptive Trials
- Investigator-Sponsored/Initiated Trials (IST/IIT)

### Patient-Centered Research

- COA/PRO Instrument Development and Psychometric Evaluation (including eCOAs)
- Health Utilities Studies
- Technology Validation Studies
- Preference Elicitation (e.g., Discrete Choice, Threshold Analysis, Swing Weighting)
- Patient-Centered Benefit Risk Assessment
- Uncertainty Analysis

### Evidence Synthesis, Modeling & Communication

- Economic and Epidemiological Modeling
- Clinical Trial and Disease Simulation
- Indirect Treatment Comparisons (e.g., Network Meta Analyses)
- Systematic, Targeted, and Rapid Literature Reviews
- Dossiers, Value Stories, and Submission Support

### Value & Development Consulting

- Global/Regional Regulatory Strategies
- Strategic Product Development
- Value and Access Strategy and Evidence Generation
- Program Design and Protocol Optimization
- Precision and Transformative Medicines Expertise

### Medical Writing and Healthcare Communication

- Manuscript, Abstract, and Poster Development and Planning
- REMS and RMP Document Support
- IIIb/IV Protocol/Study Reports
- Standard and Global Response Letters
- Product FAQ Documents
- Escalations/Out-of-Scopes, incl. Custom Responses
- Promotional Review Support

## How Can We Help You?



Understand the Market



Develop and Support Value and Safety



Build the Evidence to Demonstrate Value



Achieve Favorable Market Access



Preserve and Extend Product Reach

# Our TEAM

— 750+ —

Staff members internationally

— 35+ —

Countries where we have developed economic models; developed models for use in HTA submissions in 20+ countries

— 130+ —

Payer submissions across 20+ countries in the past 5 years, including reversal of multiple NICE decisions

— 150+ —

Drugs/Therapies supported in the past year

— 30+ —

Global Extended Access Programs in the last 3 years alone with thousands of patients transitioning smoothly from investigational to commercial

# Our EXPERIENCE

— Publications —

2,400+ peer-reviewed articles, averaging 130+ per year; 220+ research posters and presentations per year

— Influence —

Supported submissions to NICE, CADTH, IQWiG, FDA, PBAC, etc.; helped develop IQWiG economic evaluation guidelines

— Methods —

ISPOR Task Force participation on Meta-Analysis, MCDA, PROs and OBSROs, Modeling

— Ingenuity —

- Established EXACT-PRO: First consortium-developed PRO instrument with qualification statements from both the FDA and EMA in the area of COPD
- Next generation modeling and statistics: DICE simulation, AD ACE Simulator, Multi-Criteria Decision Analysis (MCDA), Simulated Treatment Comparisons (STC), and Matching Adjusted Indirect Comparisons (MAIC)

"...quality research, state-of-the-art methodologies, attention to detail, and flexibility...combine to produce important and credible findings."

Director, Health Economics and Outcomes Research, Top 10 pharmaceutical manufacturer