Expansive Breadth Integrated Approach

Evidera | PPD

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

- Database, Social Media, and Post-Hoc/Exploratory Analytics
- Patient or Physician Surveys
- Hybrid Database and Direct-to-Patient Studies
- Time and Motion Studies
- Medical Chart Review Studies
- Disease, Product, and Pregnancy Registries
- Post-Authorization Safety and Efficacy Studies (PASS and PAES)
- REMS/RMPs Programs

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

Market Access

- Global Pricing, Evidence Generation, and Market Access Strategies
- Payer Landscape and Disease Area Strategy
- International Payer Advisory Boards
- Payer Engagement Plans
- Early Scientific Advice and In-Licensing Agreements

Interventional Studies

- Phase IIIb/IV Studies
- Expanded Access/Compassionate Use Programs (EAP/CUP)
- Extended Access Programs (XAP)/ Open Label Extension
- Lactation/Placental Transfer Studies
- Pragmatic/Adaptive Trials
- Investigator-Sponsored/Initiated Trials (IST/IIT)

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, including 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

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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."
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> Director, Health Economics and Outcomes Research, Top 10 pharmaceutical manufacturer