

Understanding Patient Experiences, Preferences, and Outcomes

Patients are key stakeholders in all aspects of medical decision-making, and there is a growing emphasis on patient engagement and patient-centered evidence among regulators and payers. Evidera's patient-centered researchers represent a unique combination of scientific disciplines, including psychometrics, economics, decision analysis, epidemiology, biostatistics, psychology, and public health. We develop and evaluate clinical outcome assessments to support labeling and promotional claims. We are your partner for evaluating patient, clinician, and caregiver outcomes, utilities and preferences, adherence, and other customized prospective observational study needs.

Clinical Outcome Assessments (COAs) and Patient-Reported Outcomes (PROs)

High quality, patient-centered data is becoming increasingly imperative for regulators and other stakeholders to understand whether a drug provides treatment or safety benefit. Evidera designs and implements strategies for outcome evaluation, including ClinROs, PROs, ObsROs and/or PerfOs that meet regulatory and stakeholder demands. We take an evidence-based approach to instrument development, driven by extensive experience measuring health outcomes across a variety of conditions and diseases. We help you understand the issues and design your program from concept identification and development through platform selection, instrument design, and psychometric testing, and we provide ongoing support during implementation and analyses.

COA/PRO Offerings

- Instrument Development and Psychometric Evaluation
- Outcomes Strategy
- Outcomes Evidence Dossier
- Health Utilities Studies
- Clinical Trials Support
- Electronic Clinical Outcome Assessments (eCOA)
- Technology (m/e-health) Validation Studies
- Advanced Psychometric and Statistical Modeling Services
- Regulatory Support
- Scientific Dissemination

Engaging Patients is Paramount for Improving Outcomes

Now more than ever, patients are active participants in their own care. Patient-centric healthcare models are becoming the new norm, with services designed to incorporate and embrace patients' wants, needs, and preferences. Evidera provides services that elucidate the patient experience at various stages in the product lifecycle to inform a patient-focused drug development strategy. Patient-centered services are designed around the unique needs of a program to facilitate the understanding of the patient experience as it relates to current unmet needs, the burden of illness, impacts of a disease, patient-defined meaningful endpoints, and patient-centered trial design. Evidera serves in leadership roles in several professional society and academic, special interest, working groups focused on developing best practices and recommendations for how to facilitate the engagement of patients in medical product development. We provide new and innovative approaches to working with patients and can help you design patient experience activities to ensure your medical product development strategy is patient focused.

Incorporating Patient Preferences into Decision Making

Most recognize that patient preferences have an important role to play in healthcare decision making, although it is only recently that decision makers have shown interest in quantitative methods for eliciting patient preferences. Data on patients' trade-offs can be used to generate decision-relevant information, including: the minimum acceptable benefit to offset treatment risks; the maximum acceptable risk that would be justified by treatment benefits; overall benefit-risk profile; willingness to pay; and, the probability that a patient selects or adheres to a particular treatment. With one of the largest in-house teams, and a unique combination of experience in both preference elicitation and decision analysis, Evidera has the expertise to ensure you generate preference information that meets the needs of decision makers.

Patient Preference Offerings

- Preference Elicitation (e.g., discrete choice, best-worst scaling, threshold analysis, swing weighting)
- Health Utilities Studies
- Patient-Centered Benefit Risk Assessment
- Uncertainty Analysis
- Experience Interacting with Regulators

Experienced Experts in Advancing Patient-Centered Research

With Evidera as your partner, you get a team of leading scientists who have developed innovative methods and instruments that are rapidly adopted by the field. For example, Evidera:

- Created one of the few PRO instruments recommended for clinical use in an international clinical guidance document: COPD Assessment Test (CAT)
- Developed the first multi-sponsor PRO consortium: The EXACT-PRO Initiative
- Developed the first PRO instrument to achieve FDA PRO qualification: The EXACT
- Supported a leading disease foundation in the development of evidence to support the first biomarker qualified for use by the FDA in COPD studies
- Designed two of the first condition-specific utility indexes: asthma symptom utility index (ASU) and rhinitis symptom utility index (RSUI)
- Partnered with the American Neurogastroenterology and Motility Society (ANMS) to develop the ANMS gastroparesis cardinal symptom daily diary, now an endpoint for clinical trials in diabetic and idiopathic gastroparesis
- Participated and chaired numerous methods task forces (e.g., ISPOR MCDA Task Force Chair, ISPOR Stated Preference Methods Special Interest Group Chair, ISPOR Patient Engagement Special Interest Group)

"[Evidera is] the leader in the development of PROs and so truly professional. Your work on the PRO has transformed our knowledge about how patients experience symptoms in [this] disease and the field will be indebted to you."

CEO, Biopharmaceutical Company