

ePRO

How will you ensure regulators and payors accept your PRO-based submission?

Key features

- **Collection of patient-reported outcomes via IVR, web, PDA or Tablet***
- **Expertise and Modality Decision Tool to help choose the best modality for your study**
- **Simple, intuitive user interface with built-in data validation checks**
- **In-house scientific support**
- **Date- and time-stamped entries**
- **Multilingual, global delivery**
- **24/7/365 toll-free help desk**
- **Cutting-edge reporting platform for secure, real-time access to patient data**
- **FDA and EMEA compliant, backed by rigorous clinical, linguistic and systems validation**
- **Seamless integration with ClinPhone® RTSM (Randomization and Trial Supply Management), DataLabs® EDC, IMPACT® and TrialWorks® CTMS, and other third-party systems**

* Offered in conjunction with invivodata inc.

Key Benefits

- Increased data integrity and quality
- Improved subject screening/recruitment capabilities
- Exceptional patient compliance and acceptance
- Full data visibility – real-time access to patient and compliance data
- Reduced need for data entry and lower data cleaning costs
- Enhanced trial efficiency through integration with RTSM, EDC and CTMS
- Unbiased, science-led advice from experts on the best ePRO solution to suit the study

Real-Time Data Capture

Patient self-reported data is increasingly important for efficacy and quality of life assessment, patient recruitment, symptom and safety information, and medication compliance monitoring. In fact, in some therapy areas, patient-reported outcomes (PROs) are the only means available to accurately assess the effects of treatment. Perceptive Informatics' ePRO solution is an intuitive and easy-to-use solution that has been used to deliver more than two million

patient assessments worldwide for every major therapeutic area. It has been used to capture patient self-reported data ranging from simple diaries to validated instruments such as health-related quality of life (HRQL) questionnaires to complex clinical assessments such as depression evaluation. Our applications are designed to facilitate rapid progression through the PRO assessments. We have extensive experience with a wide range of populations including elderly, adolescent and pediatric populations. Additionally, sites and sponsors can access patient ePRO data and diary compliance metrics in real time via Perceptive's secure, online web reporting capability.

Regulatory agencies have broadly acknowledged the many advantages of electronically collected patient-reported data (ePRO), including the importance of consistent, systematic assessment, instant validation checks and date/time stamping of patient responses. Further, ePRO data has already been accepted by the FDA as a primary endpoint in new drug applications (NDAs).

ePRO

The Right Tool at the Right Time

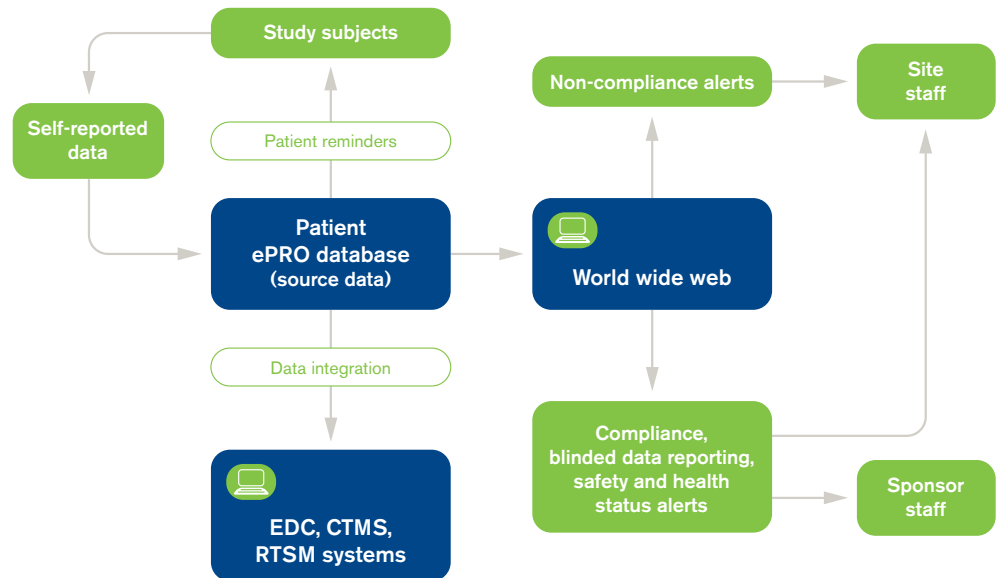
With Perceptive, you have the freedom to choose between the most commonly used ePRO methods: IVR, web, PDA and Tablet.*

- IVR (Interactive Voice Response) – Our leading, robust platform, ClinPhone IVR, enables ePRO delivery using the subject's own telephone, making the solution extremely cost-effective and simple to deploy
- Web/IWR (Interactive Web Response) – The web offers all of the advantages and benefits of IVR as subjects use any PC connected to the Internet to securely access the ePRO application and complete their entries
- PDA/Tablet – Depending on the specific characteristics of the protocol, a device-based solution may be best suited for your study

Choosing the right ePRO methodology and modality for your protocol is an important decision. Our *Modality Decision Tool* can help you decide which ePRO method is ideal for your protocol.

Types of PRO Instruments

Perceptive's ePRO is a powerful solution whose utility spans far beyond just registration data. It has been successfully applied to many key areas across the study life cycle including patient recruitment, eligibility determination,



efficacy and safety assessments, and protocol adherence. The types of PRO instruments we have delivered include:

- Health-related quality of life (HRQL) scales
- Disorder-specific symptom instruments and diaries
- Patient recruitment and screening questionnaires
- Safety/side effects data assessments
- Protocol and medication adherence questionnaires

Your Data is in Good Hands

Our specialist ePRO team has extensive clinical, regulatory, project management and tech-

nical expertise. With in-house scientific support, we can advise you with respect to industry best practices for ePRO validation. We will guide you through every step of the way including selecting the right ePRO modality, designing an appropriate user interface and compliance reporting. We will work closely with your study team through system development and monitor your data during your trial for total quality assurance. Our ePRO team is backed by Perceptive's robust global infrastructure, including live 24/7/365 help desk support. With rigorous clinical, linguistic and systems validation firmly in place, you can be assured that the information entered by study subjects and captured is accurate, reliable and valid.