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Solutions



A proven  
**partnership**  
to meet all your  
**ePRO needs**

# Your key to **successful** ePRO solutions

Perceptive Informatics and invivodata, the two industry-leading electronic Patient-Reported Outcomes (ePRO) providers, have established a worldwide partnership to provide customers with the power to choose the right ePRO solution for their trial based on objective science-oriented criteria, without having to compromise the quality of their research.

This partnership delivers to pharmaceutical and biotech companies best-of-breed offerings for the two most commonly used ePRO technologies – device-based and IVR (Interactive Voice Response).

The Perceptive Informatics and invivodata alliance provides sponsors balanced and science-based guidance in line with evolving regulatory considerations.

Each company's solutions are built on an in-depth understanding of regulatory and psychometric validation issues, coupled with proven clinical technologies and global support services.

Both Perceptive Informatics and invivodata have extensive experience in instrument design and possess strong relationships with industry thought leaders and instrument authors.

By bringing together leading-edge tools, systems and expertise, this unique partnership offers unparalleled options and total quality assurance for all your ePRO needs.



## Benefits

- Balanced and neutral advice for selecting the optimal ePRO approach
- Best-of-breed offerings from the two leaders of device-based and IVR ePRO solutions
- Expert guidance on regulatory compliance and psychometric validation
- Full visibility and management of real-time ePRO data for investigators
- Ability to readily combine IVR-powered instruments and device-based instruments within a single study
- Streamlined process management via seamlessly integrated clinical technologies

## Electronic Patient-Reported Outcomes

Patient-reported outcomes are increasingly important in clinical trials. As a critical component of many regulatory submissions, they are used extensively for efficacy and quality of life assessment, symptom and safety information, and medical compliance monitoring.

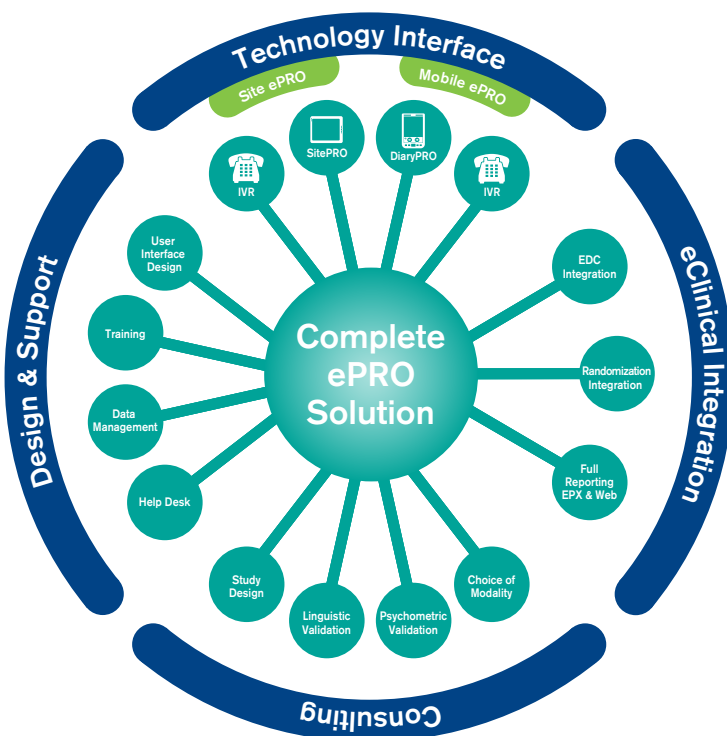
Compared to the well-documented limitations of paper-based methods, ePRO solutions enable biopharmaceutical organizations to gather key clinical data from patients while improving data quality and integrity.

When considering ePRO, sponsors must carefully evaluate key issues including the patient interface, instrument design, validation and regulatory implications.

## The Right ePRO Choice for Your Clinical Trial

Determining the right ePRO approach can be a critical factor in the success of a clinical trial. Each patient interface has particular applications and benefits, and therefore, some studies are more appropriate for device-based ePRO while others are best suited for IVR ePRO.

invivodata and Perceptive Informatics have jointly developed a decision modality tool as well as a white paper to guide sponsors in understanding which approach is best used for each study design.



## Capabilities

### ePRO Consulting and Design

- Unbiased guidance on the best ePRO solution to suit the study
- Solution development and consulting by PRO and ePRO experts
- ePRO instrument design
- Rigorous clinical, systems and linguistic validation
- Guidance on regulatory compliance

### Delivery

- Collection of patient-reported outcomes via IVR and/or device-based systems
- Suitable for both site-based and patient-based assessments
- Secure, real-time access to patient data
- ePRO compliance monitoring
- Access to study data and operational reports via invivodata EPX™ ePRO Management System
- Seamless integration with ClinPhone® RTSM (Randomization and Trial Supply Management) solutions, and EDC (DataLabs®) applications
- Multilingual, international delivery in unlimited languages
- Global, comprehensive trial support

To schedule a demonstration and review of the Modality Decision Tool,  
please contact us: [info@perceptive.com](mailto:info@perceptive.com), [info@invivodata.com](mailto:info@invivodata.com)

To submit your study characteristics for complimentary evaluation by the tool,  
please visit: [www.perceptive.com/modality-decision-tool](http://www.perceptive.com/modality-decision-tool)

## About Perceptive Informatics

Perceptive Informatics helps customers accelerate the drug development process through innovation. Our product portfolio is built on leading-edge technology and is combined with extensive medical and clinical expertise, as well as a deep understanding of the regulatory environment. Perceptive provides a powerful suite of integrated technologies and services that facilitate more informed and accelerated decision making throughout the clinical trials process. Our comprehensive product portfolio includes Randomization and Trial Supply Management (RTSM), Medical Imaging, Clinical Trial Management Systems (CTMS), Electronic Data Capture (EDC), Electronic Patient-Reported Outcomes (ePRO) and integration solutions.

Perceptive Informatics is the most experienced provider of IVR-based ePRO, having supported 250 studies spanning 64 countries in 82 languages and dialects. Perceptive Informatics' ePRO solution, powered by Perceptive Informatics' renowned, industry-leading IVRS (Interactive Voice Response System), offers an intuitive and easy-to-use solution for capturing patient self-reported data ranging from simple diaries to sophisticated clinical assessments. With extensive experience in linguistic and psychometric validation, Perceptive Informatics offers a comprehensive range of validated instruments for IVR use.

## About invivodata

invivodata combines behavioral science, information technology, and clinical research expertise to capture high quality clinical trial data directly from patients. invivodata's electronic Patient-Reported Outcomes (ePRO) solutions, which are based on over 20 years of research, deliver valid and reliable patient self-reported data by driving patient compliance with the protocol and eliminating recall biases that plague paper-based self-report data.

invivodata's solutions include comprehensive trial-support services that facilitate the collection of important ePRO data, and web-based access to study data plus operational reports that give researchers and sponsors visibility into study progress and improve trial efficiencies. invivodata's solution has been used in more than 200 trials and is the industry-leading ePRO system in delivering primary efficacy data for FDA drug approvals.

invivodata inc. is a privately held company with global headquarters in Pittsburgh, PA, USA; its European headquarters is in London, England; and its technology development center is in Scotts Valley, CA, USA.

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