

# DiaryPRO<sup>®</sup>

## cleaner data for better decisions



### Overview

invivodata has combined over 20 years of ePRO experience with innovative technology to provide DiaryPRO<sup>®</sup>, a simple-to-use patient eDiary that delivers unmatched data accuracy and patient compliance. DiaryPRO overcomes the poor reliability and biases inherent in paper diaries and other retrospective reporting methods through real-time data capture as required by your protocol.

### DiaryPRO Delivers Better Data

Poor or hastily designed and built ePRO solutions produce low rates of compliance, deliver poor trial data and put your study endpoints at risk. Whereas, DiaryPRO delivers patient compliance rates of **over 95%**. invivodata's patient interface, therapeutic best practice configuration libraries and extensive ePRO experience provide the most accurate test of trial endpoints.

### Real-time Study Insight with EPX<sup>™</sup>

DiaryPRO automatically uploads patient data into invivodata's ePRO management system, EPX. This Web-based system allows study sponsors, sites and CRAs to access and manage patient-based assessments and provides continuous, real-time visibility into the study's ePRO data.

### Industry's First NDA Utilizing ePRO

In 2003, the FDA approved the first drug for which the primary efficacy data in the sponsor's pivotal Phase III trials was collected using an electronic diary (invivodata's DiaryPRO). Since that time, DiaryPRO has been used as the basis for numerous additional successful New Drug Applications (NDA), including drugs for the treatment of breakthrough pain and diabetes.

### Benefits

#### For Sponsors:

- Improves data precision by collecting the right data at the right time
- Reduces study timelines by eliminating the need to transcribe patient diary data
- Increases patient compliance with programmed alarms

#### For Sites:

- Provides greater insight into patient behavior outside of the clinic, allowing sites to proactively manage patients
- Supports diverse patient demographics and accessibility requirements, thereby increasing the pool of patients available for enrollment

#### For Patients:

- Decreases time to complete diary assessments through a user-friendly interface
- Reduces training time with integrated "practice" feature
- Provides accessibility features including: enlarged fonts, oversized stylus and programmable alarm volume

### Why ePRO?

ePRO provides unparalleled advantages to trial sponsors who are collecting patient data. Among the technology's benefits are its ability to ensure legible, in-range responses; ability to utilize logical branching and edit checks to confirm data accuracy, and the ability to eliminate transcription errors from double-data entry.

### Why invivodata?

invivodata's eDiary system is based on a foundation of cognitive science, measurement theory, technology, research design, and psychometrics. This proven foundation enables the system to overcome the limitations of paper-based diaries and capture real-time data that meets the FDA's 2009 guidance regarding the reliability of PRO data in clinical trials.

# DiaryPRO® Highlights

## Functional Description

- Configurable data recording and format
- Patient-initiated assessments
- Dynamic sampling (changes based on patient's entry)
- Programmable Alarms
  - Fixed time alarms
  - Random prompt alarms
  - Alarms relative to specific events

## Types of Data Entry

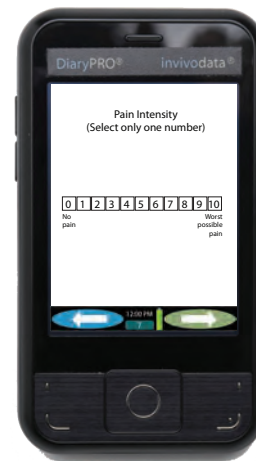
- Visual analog scales (horizontal & vertical)
- Ordinal scales
- Likert scales
- Pushbuttons (for exclusive answers)
- Checkboxes (for multiple answers)
- Free text entry
- Controls for numeric entry
- Time and date entry (duration, 24hr, AM/PM)
- Graphical figures (e.g., body diagram)
- Concomitant medications
- Adverse event reporting

## Flexible Branching, Per Protocol

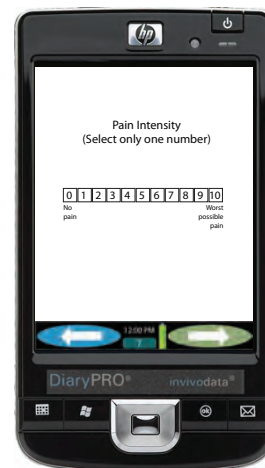
- Within-question edit and range checks
- Edit checks for logical consistency of answers
- Edit checks for consistency over time and assessments
- Tracks and adjusts to multiple phases of trial
  - Training, screening, baseline, treatment, open label extension, on/off monitoring, etc.

## Data Uploading

- Flexible upload options
  - Wireless: Automatic uploads from patients' homes silently and unattended
  - Wired: Automatic uploads from patients' homes via toll-free numbers
  - Site-based uploads
- Ability to update study software mid-trial on a per patient, per site, or per trial basis without site or patient intervention



DiaryPRO 170



DiaryPRO 210

## Integration with EPX™

- Web-based trial management system
- Customized reports for:
  - Individual patients
  - Investigative sites
  - Sponsor-only monitoring reports
- User e-signature for login and actions
- View into each patient's data with audit trail
- Automatic analysis of patient data for compliance metrics
- Electronic Data Clarification Form (DCF) management
- Patient enrollment tracking
- Patient visit tracking