

# SitePRO®

## in-clinic patient reporting system



### Overview

invivodata's innovative in-clinic solution, SitePRO®, combines clinical science with technology to increase efficiencies in site-based patient reported outcomes (PRO) data collection in clinical trials. SitePRO collects accurate PRO data to deliver error-free data directly from the patient and eliminates costly transcription errors, out-of-range entries, illegible responses, and double data entry associated with paper-based studies.

### Cleaner Data for Better Decisions

When patients complete paper questionnaires they can easily miss questions, enter ambiguous responses or enter illegible text. SitePRO guarantees clear and complete responses with data entry controls and automated workflows, eliminating the need for data clarifications for these issues.

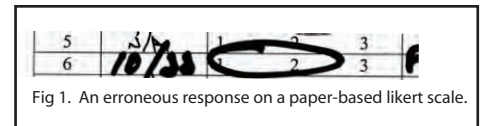


Fig 1. An erroneous response on a paper-based likert scale.

### Time and Cost Savings

With SitePRO, PRO data entered directly by the patient into an electronic device automatically produces data in an electronic format. When using traditional paper diaries, the same information must be transcribed from paper to an electronic format, then checked for accuracy. The process is time-consuming and expensive. On average, SitePRO has been able to save clients up to 50% in study costs.

### Real-time Study Insight with EPX™

SitePRO automatically uploads patient data into invivodata's Web-based ePRO management system, EPX, and elicits little to no data queries, or data clarification forms (DCFs). EPX allows study sponsors, sites and CRAs to access and manage PRO data and provides continuous, real-time visibility into the study.

### Proven Software Delivers Confidence

In use since 2004, SitePRO is the industry's only site-based ePRO solution to have collected primary efficacy data in support of a successful New Drug Application (NDA). SitePRO reduces risk and delivers confidence. Data quality and accuracy have been proven in dozens of trials.

### Benefits

#### For Sponsors:

- Improves efficiency by collecting clean, in-range, legible data
- Eliminates missing and inaccurate data which is inherent with paper-based PROs
- Reduces study timelines and costs by eliminating the need to transcribe PRO data

#### For Sites:

- Reduces the amount of paper that needs to be managed and stored at the site
- Simplifies administration of site assessments - a single device that houses multiple protocols and/or languages replaces mountains of paper-based assessments

#### For Patients:

- Easy-to-use patient interface translated into the local language eliminates patient confusion
- Intuitive user-friendly interface decreases time to complete assessments

### 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 ePRO 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.

# SitePRO® Highlights

## Functional Description

- Easy-to-use touchscreen patient interface
- Ability to capture more complex text-based questions including dynamic sampling (changes based on patient's entry)
- Study-specific data recording and formats

## Flexible Branching, Per Protocol

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

## 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)
- Wait screens (while patient completes an action)

## Data Uploading

- Ability to update study software mid-trial on a per patient, per site, or per trial basis
- Data replication - device data is stored for the life of the study and copied and verified with the EPX database upon each data transfer
- Wired and wireless data transfer options ensure timely data transfers from any site

## Device Specifications

### SitePRO® Tablet

- Size of unit
  - Weight: 3.6 lbs. (1.63 kg)
  - 12.67"W x 9.09"H x 0.90"D (323mm x 231mm x 23mm)
- Display
  - High-resolution, 12.1" AFFS+ LED backlight color display (1024x768)
  - Rotates to landscape or portrait
- Operating system: Microsoft® Windows® XP
- Power options
  - AC Adapter or rechargeable lithium-ion battery
  - ENERGY STAR qualified
- Functionality
  - Touchscreen display options for both finger and digitizer pen input
  - Ruggedized for heavy use in clinical setting
  - Allows for lengthier assessment text, similar to U.S. letter-sized and international A4 paper
  - Wired and wireless data transfer solutions



### SitePRO® 210

- Size of unit
  - Weight: 6.7 oz. (190 g)
  - 2.97"W x 5.27"H x 0.69"D (75.4mm x 133.9mm x 17.5mm)
- Display
  - 4.0" color display (480x640)
  - TouchScreen
- Operating system: Windows Mobile
- Power options
  - Rechargeable lithium ion battery
- Functionality
  - Allows for lengthier assessment text on a compact handheld device
  - Wired and wireless data transfer solutions

