

# EPX™ ePRO Management System



## Overview

invivodata's EPX ePRO Management System is an easy-to-use Web-based system for monitoring key areas of study progress, including:

- Site management
- Patient management
- Data integrity
- System functionality

EPX creates efficiency in ePRO-related clinical trial workflows, freeing up users' time to attend to other trial-related activities. EPX takes the worry out of ePRO management for study sponsors, investigators/ study coordinators and CRAs/CROs.

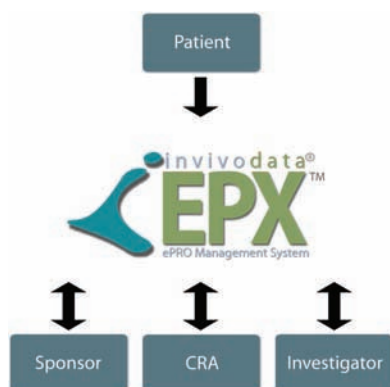
## Benefits

### For Sponsors:

- Provides a practical way to manage site performance
- Provides a real-time view of study progress, site performance and subject compliance
- Gives sponsors the information they need to monitor ePRO study progress in a single system, frees up time to focus on other areas of trial monitoring
- Assures focus is on areas of the study that need attention

### For Investigators and Study Coordinators:

- Guides investigators/study coordinators through their workflow in managing patients
- Makes ePRO management simple, highlights areas of importance and items needing further investigation
- Delivers timely resolution of data discrepancies via electronic Data Clarification Form (eDCF) system
- A few minutes reviewing the information in the system helps ensure desired subject compliance rates



### For CRAs and CROs:

- Up-to-date site and subject performance information is always available for CRO/CRAs
- Provides concise user dashboards (site and subject-based), and study reports (site and subjectbased) that provide clear views into study progress
- System is designed to facilitate site monitoring activities through the use of its reports, dashboard views and email alerts

## 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.

### Corporate Headquarters

2100 Wharton Street, Suite 505, Pittsburgh, PA 15203, USA  
+1-412-390-3000

[www.invivodata.com](http://www.invivodata.com)

### European Headquarters

Gainsborough House, 2 Sheen Road, Richmond, TW9 1AE, UK  
+44 (0) 208 973 2377

# EPX™ Key Solution Highlights

## Study Progress Reporting

### Study Health Report™

- High-level view of vital study metrics including:
  - › Subject Enrollment
  - › Subject Compliance
  - › Data Transfers
  - › Data Clarification Forms
  - › Help Desk Information
  - › Inventory Information
- Ability to drill-down to more detailed information in each category for further analysis

### Email Alert System

- Includes proactive alerts to study personnel to ensure that the right people are alerted to potential problems quickly

## Site Management

### Site Information Dashboard

- Performance information on a site-by-site basis, enabling remote site performance

### Site Reports

- Site-specific reports for each study that reflect overall metrics, tracking and performance information per site

## Patient Management

### Patient Management Dashboard

- Provides a dashboard of a specific patient's ePRO activity
- Hyperlinks to patient reports and patient data records

### Patient Reports

- Provides patient evaluability data and other patient-level reports for each study

### Patient Compliance Monitoring

- Provides real-time patient compliance reporting via patent-pending compliance algorithms

## Security and Regulatory Compliance

- Sponsors/CRAs can use EPX reports to determine if the site has interacted with the patient consistent with GCP practices
- Technology compliance
  - › Fully validated and 21 CFR part 11 compliant
  - › Includes full password encryption
  - › Complete data and access audit trails

## Data Integrity

### ePRO Data Listings

- Provides investigators with human-readable access to detailed patient data that meets FDA requirements
- Provides filter capabilities to display and sort desired data

### Electronic Data Clarification Form (eDCF) System

- Eliminates paper-based DCF systems

### eSignature System

- Provides audit information for eDCF resolution
- Eliminates paper-based authorizations

The screenshot shows the 'Site Information Dashboard' for Study 01: Protocol 2468 at Site 01001 - A Jones. It features a table with columns for Subject ID, Subject Status, Date of Last Visit, Date of Last Data Transfer, Open DCFs, Evening Report Compliance, and Study Medication Compliance. The table lists five subjects with their respective statuses and compliance percentages.

Subject ID	Subject Status	Date of Last Visit	Date of Last Data Transfer	Open DCFs	Evening Report Compliance	Study Medication Compliance
01001004	Run-in	16 May 2007	19 May 2007	No	96%	OK
01001005	Run-in	20 May 2007	23 May 2007	No	75%	REVIEW
01001002	Treatment	15 May 2007	18 May 2007	Yes	94%	OK
01001003	Treatment	24 May 2007	27 May 2007	No	82%	OK
01001001	Completed	25 May 2007	28 May 2007	No	96%	OK

Fig. 1 Site Information Dashboard: Summary view of patient status for each site

The screenshot shows the 'Subject Information Dashboard' for Subject 01001002. It provides detailed information including study ID, site ID, current date, subject ID, and subject status. It also includes a table for 'Subject eDiary Reports' with columns for DCF #, Date Posted, Status, and Summary.

DCF #	Date Posted	Status	Summary
3	13 Jun 2007	Open	Subject came into the office for visit 4, but investigator forgot to make an entry in DiaryPRO for the visit.

Fig. 2 Patient Management Dashboard: Detailed information for each patient