

7 REASONS TO CHOOSE ePRO OVER PEN AND PAPER

Clinical trials prioritize data quality, operational efficiency, and patient-centricity. Electronic patient-reported outcome (ePRO) solutions enable patients to directly report outcomes data digitally, offering significant advantages over pen-and-paper-based collection.



01 BETTER DATA QUALITY, RELIABILITY, & INTEGRITY

An effective ePRO solution prevents missing, conflicting, ambiguous, and out-of-range data. It also ensures on-time assessment completion, minimizes recall bias, and prevents the "parking lot" effect. Finally, electronic solutions provide a reliable and complete audit trail, attributing entries with date, time, and user stamps for transparency and traceability.

Day 10 Morning diary. Please complete at 8:00 am

1 Please write today's date ← 1 **MISSING DATA**

2 Did you take all your study medication this morning? Yes No
Take one box Take one box

3 Please rate your pain this morning:
 No pain
 Mild pain
 Moderate pain ← 2 **AMBIGUOUS DATA**
 Severe pain
 Extreme pain

I had a really bad headache and saw the doc ← 4 **EXTRANEANOUS DATA**

4a Did you wake up in the night due to your pain? Yes No
Take one box

4b If yes, how many times did you wake up because of your pain? 3 ← 3 **CONFLICTING DATA**



THE PARKING LOT EFFECT

The parking lot effect refers to patients completing missing diary entries just before their next study visit instead of when directed to by the clinical trial protocol.

When this occurs, patients may not recall or report their health accurately, or their perception may be influenced by their current status, reducing data accuracy and integrity.

Regulators recommend that steps be taken to ensure that patients make entries according to the clinical trial design and not, for example, just before a clinic visit when their reports will be collected.

ePRO is a simple way to ensure timely assessment completion.



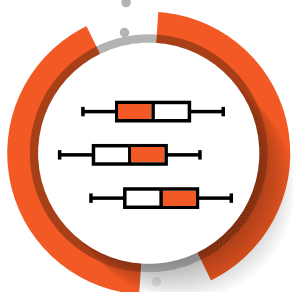
02 ENHANCED PATIENT OVERSIGHT

With ePRO, investigators have real-time access to data between clinic visits, enabling better and more frequent patient monitoring and oversight. Automated notifications can alert sites to patients that may need follow up.



03 REDUCED SITE BURDEN

Electronic COA administration facilitates remote data collection, and data storage tasks which can simplify and shorten busy site visits.



04 INCREASED STATISTICAL POWER

Improved data quality, timeliness, and completeness lead to more precise estimates of treatment effects, reducing variability and increasing the ability to detect statistically significant differences.



05 SATISFY REGULATORY REQUIREMENTS

FDA's 2009 PRO guidance emphasizes the need for accurate, complete, and accessible source data that can be verified by FDA inspectors. It also indicates that FDA will assess how the timeliness of PRO data collection is achieved, when it is collected unsupervised from home.

In line with GCP (Good Clinical Practice), ePRO helps ensure that source data meets ALCOA++ requirements: attributable, legible, contemporaneous, original (true copy), and accurate, as well as complete, consistent, enduring, available, and traceable.



06 ELIMINATE HIDDEN COSTS OF PAPER

ePRO solutions help sponsors avoid hidden costs associated with paper-based data collection including eliminating printing and shipping costs, eliminating data transcription activity and associated errors, reducing the volume of data queries to resolve, reducing Source Data Verification (SDV) activities and monitoring, and reducing paper archiving.



07 IMPROVED PATIENT EXPERIENCE

ePRO solutions empower patients by giving them a convenient and user-friendly method for reporting outcomes data. Intuitive interfaces, clear instructions, alarms and reminders, enhance usability and engagement. By aligning with consumer expectations for convenience, accessibility, and active participation, ePRO solutions contribute to a more positive and patient-centric experience in clinical research.

ALCOA PRINCIPLES IN DATA INTEGRITY

ATTRIBUTABLE

Data should be linked to the individual who created or changed it

LEGIBLE

Data should be readable and understandable

CONTEMPORANEOUS

Data should be recorded at the time the event occurred

ORIGINAL OR TRUE COPY

Original data should be preserved

ACCURATE

Data should be correct, complete, and truthful

Learn more in our white paper, "Why Choose Electronic PROs Instead of Pen and Paper"

[READ & DOWNLOAD](#)

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