



Guide on How to Choose the Right ePRO for Your Clinical Study



Collecting increasing amounts of data in today's clinical trials offers significant benefits, such as better understanding of diseases, more accurate data, and enhanced safety monitoring. However, it can also burden patients responsible for self-reporting.

Choosing the right electronic Patient-Reported Outcomes (ePRO) tool is crucial. An effective ePRO tool not only gathers essential data but also reduces patient burden, ensuring higher compliance and retention.

Selecting an ePRO tool is a critical decision that impacts your clinical trial's success. With many vendors making similar claims, it can be challenging to find the best fit for your specific needs. Making the wrong choice can lead to low patient compliance, dropouts, delays, and increased costs. Given the high stakes and time pressures, making an informed decision quickly is essential.

To help you choose the right ePRO tool, we've developed a guide with five key aspects to consider when evaluating potential ePRO solutions for your clinical study.

1

The ePRO Tool Should Include Features That Promote Patient Engagement

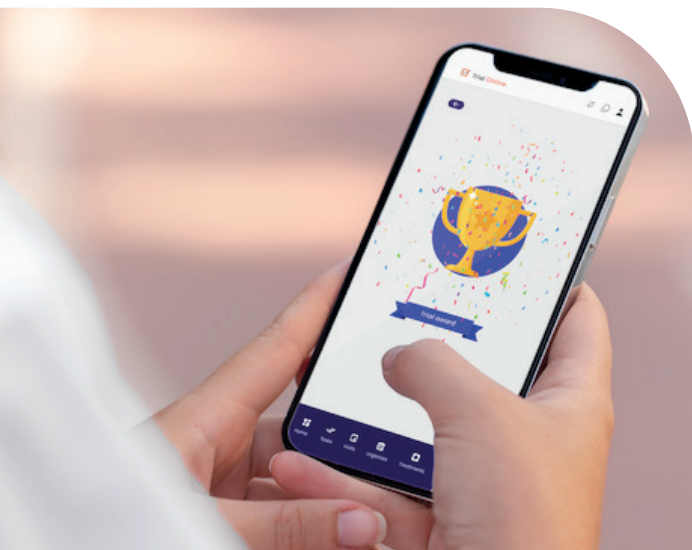
The ePRO is specifically designed for patients in a clinical trial to use and report data. As most clinical trials still struggle with patient engagement (*patient drop-out rates remain at 30%, according to Forte Research*), the ePRO tool should include features targeting patient compliance and engagement. Consider these questions:

The ePRO tool should be designed to enhance patient engagement and compliance. With patient drop-out rates at 30% (Forte Research), features that target engagement are crucial. Consider these questions:

- How does the ePRO tool ensure patient engagement?
- Does the ePRO tool celebrate the patient's activity in the app?
- How is compliance encouraged?
- How is the patient encouraged to log into the app?

Engaging features, such as gamification, significantly improve patient compliance and retention.

We've observed that when ePRO tools include engaging features, such as gamification, patient compliance, and activity in the app significantly improve, leading to better retention rates.



2

The ePRO Tool Should Centralize All Patient Data in One Place

Clinical trials involve collecting a wide range of digital endpoints from patients, including medication intake, temperature, glucose levels, pain levels, heart rate, UV exposure, and blood pressure. Centralizing these diverse data points in one ePRO tool not only reduces the burden on patients but also simplifies data management and enhances trial efficiency.

When evaluating ePRO tools, evaluate whether the tool integrates all necessary data collection into a single, user-friendly platform. Consider these questions:

- Which digital endpoints does the ePRO collect?
- Does the ePRO system centralize all digital endpoints?
- What measures ensure patient compliance and ease of use?

3

Compliance with All Regulations and Continuous Updates Is Essential

The clinical research industry is highly regulated but the difficulty lies not in complying with the regulations but in staying up to date with all the regulatory updates that are continuously released. As of today, ask the potential ePRO provider if the tool complies with the following

- EMA/INS/GCP/112288/2023 Guideline on computerized systems and electronic data in clinical trials, referring to ICH E6 (R3) Guideline on good clinical practice (GCP) - Step 2b.
- FDA Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations Questions and Answers Guidance for Industry.
- EMA equivalent - Part II EudraLex Volume 4 Good Manufacturing Practice Annex II Computerized Systems.

4

The ePRO Should Meet All Patient Needs

Each patient in a clinical trial has unique needs. Some prefer using their own devices, while others may need the vendor to provide one. Additionally, some may prefer larger devices like an iPad or a computer. It's important for the ePRO tool to adapt to these varying needs, ensuring accessibility and ease of use for all participants. Consider these questions:

- Is the ePRO tool intuitive for patients?
- Does the ePRO vendor provide any training if needed?
- Are devices provided if required?
- Which devices support the ePRO tool?

5

The ePRO Provider Should Support a Fast and Efficient Study Build

You want to build a study quickly and efficiently while ensuring high data quality. The ePRO provider should offer comprehensive support during the study build phase, which can significantly impact the overall success of the trial. Consider these questions:

- Can the vendor assist in building the study to align with your specific requirements?
- Does the ePRO system include adaptive study design capabilities for protocol amendments and modifications?
- Does the ePRO vendor provide dedicated customer support services?
- Are there built-in audit trails to ensure transparency and compliance?

Addressing these five aspects and investing the time and effort to choose the best ePRO tool for your study needs will improve the quality and efficiency of your clinical trials. Just as importantly, it will increase patient satisfaction and therefore, retention.

About Replior

With over a decade of experience in supporting clinical trials with advanced software tools, Replior is well-equipped to provide insights that support this guide.

We have applied the principles in this guide to evaluate and enhance our own Trial Online ePRO, which stands out with gamification features like alerts, personalized notifications, and patient progress bars to maximize patient engagement and compliance.

If you're looking for an ePRO provider that combines innovation with a proven track record, consider Replior for your next clinical trial.

Contact us today to learn more about how our solutions can benefit your study.



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