



ePRO MUST HAVE CHECKLIST

Top 5 Considerations for
Choosing the Right ePRO
for Your Clinical Study



Today's clinical trials depend on accurate, reliable data—but patients tasked with self-reporting often feel overwhelmed, leading to compliance issues and dropouts. Choosing the right electronic Patient-Reported Outcomes (ePRO) tool is critical to capturing essential data while reducing patient burden and ensuring trial success.

Selecting the right ePRO tool is critical to your trial's success, but navigating the range of options can be challenging. The wrong choice can lead to low patient compliance, dropouts, costly delays, and increased trial costs. With high stakes and tight timelines, 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

With patient drop-out rates averaging 30% (Forte Research), poor engagement can threaten trial success, driving up costs and delaying outcomes. The right ePRO tool actively sustains compliance and motivates patients to stay involved.

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

Consider these questions:

- What specific features of the ePRO tool sustain patient engagement?
- Does the tool recognize or reward patient activity to encourage continued participation?
- How does it maintain compliance and daily engagement?

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 collect diverse digital endpoints—medication intake, glucose levels, and heart rate, to name a few. Centralizing this data in one platform minimizes data silos, reduces errors, and improves trial efficiency.



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?

When assessing ePRO tools, evaluate whether the tool integrates all necessary data collection into a single, user-friendly platform.

3

Compliance With All Regulations and Continuous Updates Are Essential



In clinical research, staying up to date with evolving regulations is critical for compliance and trial integrity. An effective ePRO tool must ensure both.

Ask your potential ePRO provider whether 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 11 EudraLex Volume 4 Good Manufacturing Practice Annex 11 Computerized Systems.

4 The ePRO Tool 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.



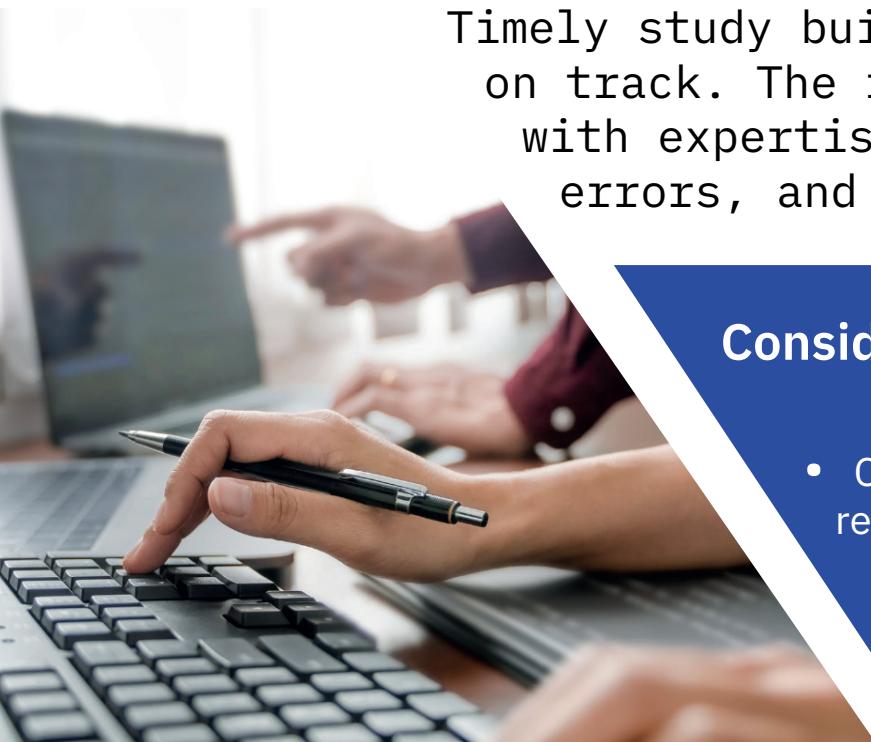
Consider these questions:

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

It's important for the ePRO tool to adapt to varying needs, ensuring accessibility and ease of use for all participants.

5

The ePRO Provider Should Support a Fast and Efficient Study Build



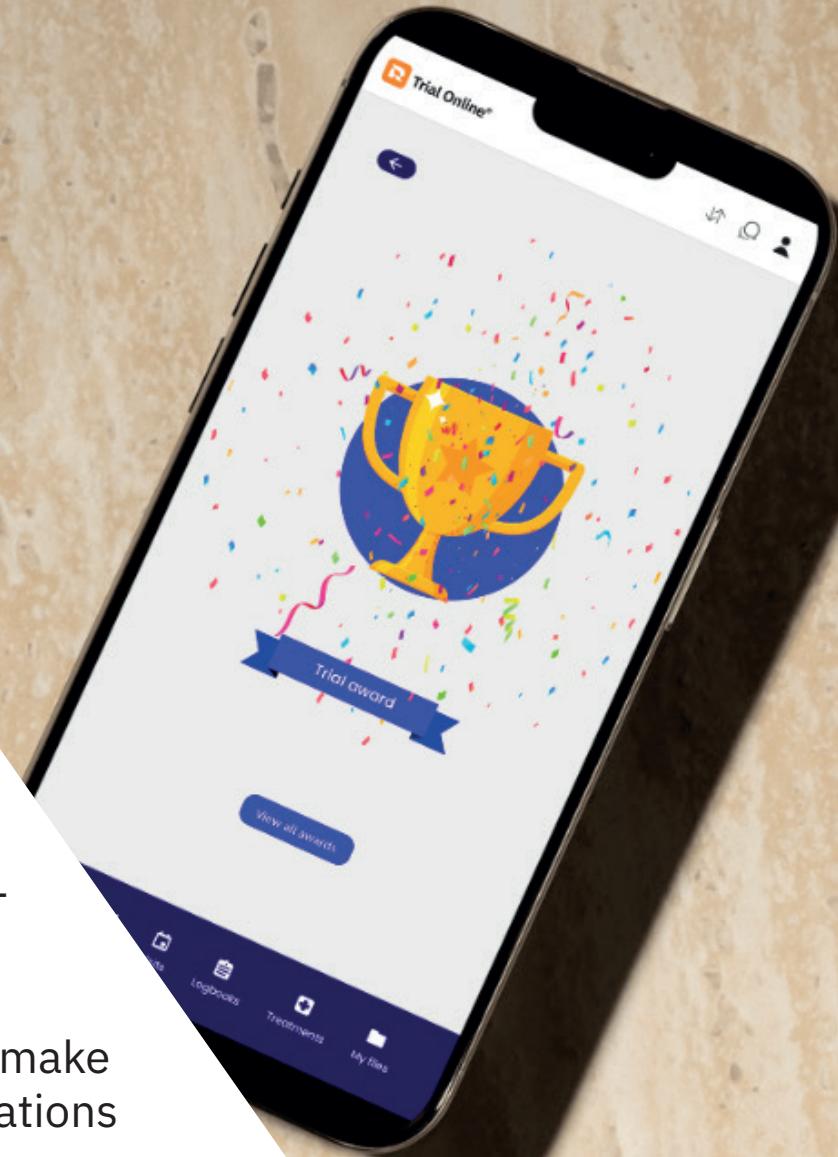
Timely study builds are critical to keeping clinical trials on track. The right ePRO provider supports this phase with expertise in adaptive study designs, reducing setup errors, and helping you avoid costly delays.

Consider these questions:

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

With over 20 years of experience in clinical research, Replior supports interventional and observational trials across cardiology, oncology, endocrinology, and other therapeutic areas.

Our advanced data collection technologies—including gamification and sensors for hard-to-measure endpoints—help improve patient engagement, increase data quality, and drive trial efficiency. Trusted by sponsors, CROs, and MedTech companies, Replior delivers reliable results that make clinical trials more human and impactful for diverse populations worldwide.





Looking to reduce patient dropouts
and improve trial outcomes?

Contact Replior today to discover
how our ePRO solutions drive
patient engagement and deliver
high-quality data for your study.

