J Clin Trials 2018, Volume 8
DOI: 10.4172/2167-0870-C3-029

Implementing an eConsent solution: Lessons learned

Eric Delente
Drug Dev, United States

Learning Objectives:

- Recognize the challenges of paper-based consent in a clinical trial
- Understand the benefits of eConsent in regulatory compliance and patient engagement
- Discuss potential approaches and solutions

In recent years support from patient advocacy groups and draft guidance from the FDA have served as catalysts for adoption of eConsent. Considering 10-15% of audit findings are related to consent, there is the significant risk for sponsors to rely on antiquated paper methods which lack control over the process to ensure patients sign the right documents, use correct dates, and acknowledge protocol changes. Deploying an eConsent solution using familiar and efficient tools such as tablets or the patients' own device can optimize the site and patient convenience while delivering easily consumed informational content. The impact an eConsent solution can have on monitoring costs and quality oversight is difficult to quantify but cannot be overstated. The presentation will discuss the potential benefits of adopting an eConsent strategy for clinical trials including increasing patient comprehension, facilitating oversight, improving integration with other eSystems, and version control and consistency. The speaker, an international expert on eConsent for clinical trials, will offer real-world experiences of several experts within pharma companies. The discussion will start with using eICF in initial studies, move into regulatory and quality considerations, perspectives from the IRB, and then discuss the challenges of broader, global implementations. The presenter will discuss the elements of a viable first study to implement eConsent, and how to evaluate the pilot for future studies. Regulatory considerations including the USA vs RoW also will be covered. The presentation also will discuss data from a recent global survey on eConsent adoption that reveals some of the reasons why the use of eConsent is not yet ubiquitous across the pharma industry. A look at how eConsent supports patient engagement and future models of eConsent will illuminate the path beyond pilot implementations, and attendees' understanding of how an eConsent program can improve patient engagement.