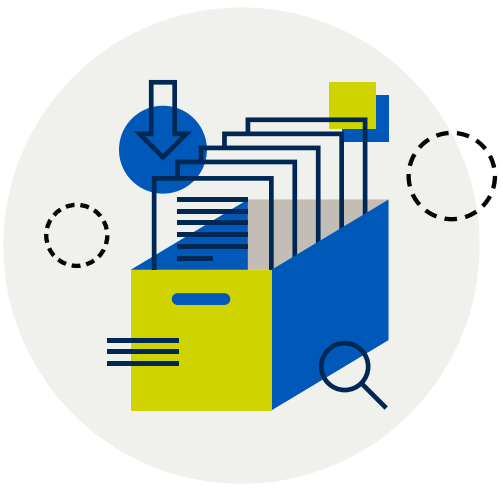
Are You Putting Your Trial at Risk Due to Informed Consent Errors?

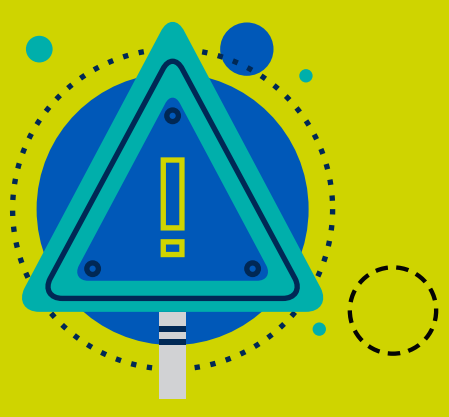
Traditional Informed Consent Process

Today's research context is characterized by rising complex protocols, additional processes and increased administrative burden. Informed Consent which is the cornerstone of clinical development has also become increasingly more onerous, with long, complicated forms that may be confusing to participants. To date, despite new technologic advances, informed consent is still primarily captured using a paper-based process. Whether a signed copy of the informed consent is missing, a patient completes the form incorrectly, or a participant was provided an outdated version of the consent form, the potential for human error is amplified.



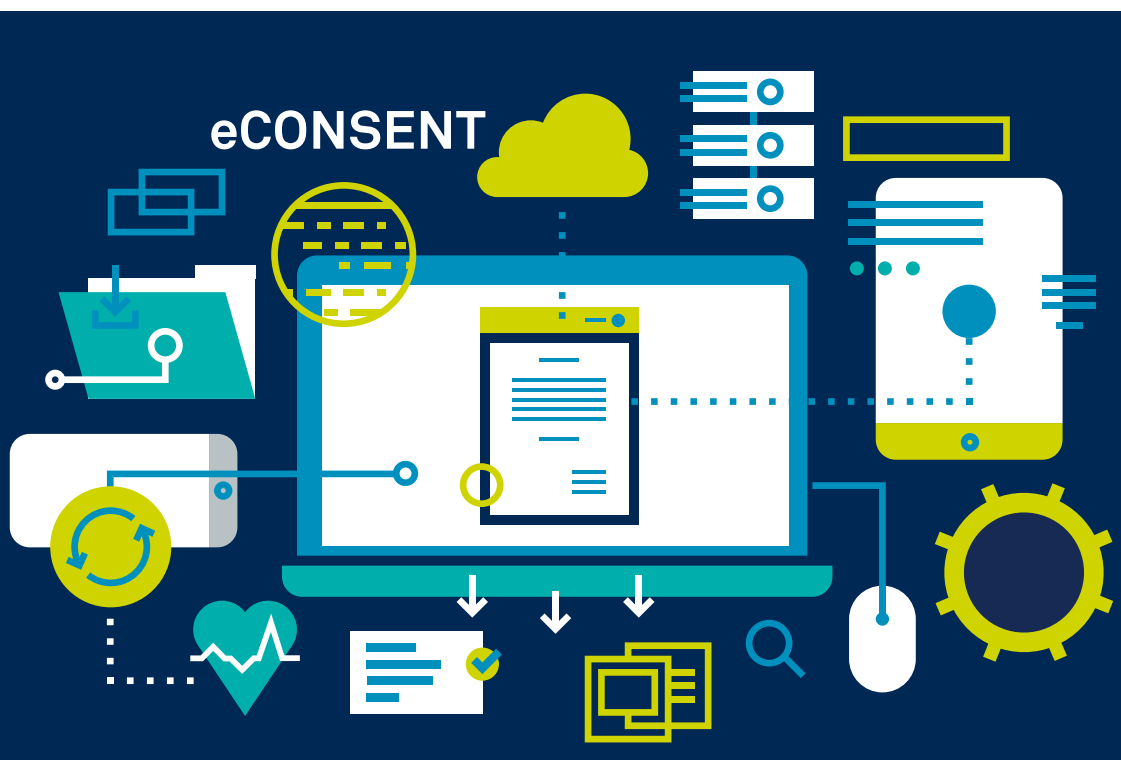
Missteps Occur

Based on the U.S. Food and Drug Administration's Inspectional Observations (FDA-483), failure to properly obtain informed consent is one of the most commonly cited violations at research sites. From 2013-2017, there were over 140 FDA-483 observations cited due to improper consent. Dependent upon the findings, consent violations can potentially lead to a warning letter from the FDA which could delay or prevent approval of a sponsor's marketing application.



eConsent

On December 15, 2016, the Office for Human Research Protections (OHRP) of the U.S. Department of Health and Human Services (HHS) and the FDA published final guidance aimed about the use eConsent in clinical trials. eConsent may be used to provide information usually contained within the written informed consent document, evaluate the participant's comprehension of the information presented, and document the consent.



eConsent delivers study information in an interactive, electronic, multi-media format enabling improved participant understanding and accurate data capture.

Rave Enroll eConsent Reduces Study Risk

- Enhance the ability to track individual consent—Ensure the correct version of the consent form is signed and dated by patients across all sites.
- Reduce the risk of regulatory audits and findings—Reduce the cost of addressing audit and inspection findings associated with Form 483.
- Reduce the risk of data retraction for patients where consent does not meet regulatory requirements—Reduce the risk of insufficient data and the costs of finding new patients.