July 27, 2021
Regulatory Trends and Audit Preparedness
Summary of Key Points

- Benefits to using mobile technology in clinical research include patient-centricity, efficacy, and efficiency.
- What participants need to know about mobile technology: A tiered consent approach may help convey information clearly to answer questions surrounding data privacy, confidentiality, who has access to data, technical support, etc.
- Patients are concerned about data privacy and confidentiality. Sites need to know how data is being collected and how it will be used in order to share that with patients.
- Only 3% of survey respondents said it was not important that they be shown the data being collected about them by mobile tech.
- Staff should be trained to be able to understand and explain the platform to patients when asked. This may need to be handled by dedicated technical staff such as IT.
- Sponsors are concerned about GDPR (based in EU/EEA) which covers research data. GDPR data protection includes consumers' right to be forgotten, erased, and know what data a company may have about them.
- Sponsors might ask sites to start committing to GDPR data protections in contracts. There are additional things sites have to do to comply with GDPR and these requirements are now being seen in contracts with U.S.-based sites with U.S.-based sponsors.
- California Consumer Privacy Act protects any California resident and applies to businesses that do any business in California.
- FDA regulation 21 CFR Part 11 requires additional technology and systems validation. Validation includes evidence that will satisfy FDA and EMA records that can be accepted as equivalent to paper records.
- Technology providers should implement a basic set of part 11 related SOPs. Need records of all validation, plans, summaries, testing results, deployment histories, and training for each system stored in a binder and ready to hand to the FDA inspector.
- Sites that have standardized processes can reduce time in data management. The more control sites have over their data, the more reduction in errors and queries and less friction in working with data.
- Sponsors expect a quick turnaround and response. One way to achieve that is leveraging more systems or hiring more staff which means sites are able to respond faster to queries and have faster study start-up.
- Reducing clerical work and repetitive tasks can reduce staff burnout and turnover. Leverage systems to help staff to improve efficiencies and key performance indicators (KPIs) such as profitability, revenue per study coordinator, etc.
- Technology and systems help with audit preparedness. FDA may come on-site prior to study completion to review documents and sites that were using systems were more prepared for audits.
- Well-defined and automatic data maintenance procedures reduce regulatory risk and improve staff performance and satisfaction.
- Sites should let sponsors know what technologies and systems they have already adopted. There may be an opportunity to hire programmers to create APIs to connect different applications.
- Require new site staff to validate systems so they are reviewed more thoroughly.
- Sites need well-defined and automated data maintenance SOPs. Technology providers should be providing template SOPs and validation of data protection protocols. Sites can ask vendors for adoption advice and SOP support.
- Audits can be used to improve processes. Learn to make improvements and not be afraid to make mistakes. We need to move research forward and that means trying new systems and technologies.
- Document appropriately but should focus on key points. It's more important to not have inconsistencies in reporting.