Regulatory Trends and Audit Preparedness

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How New Regulatory Trends and Electronic Data Management Affect Research Sites Around the World

Patient-facing and site management software enable research sites to reach more patients and improve operational efficiency. However, both technologies come with challenges that clinical research sites should consider before adoption.

Sites are continuing to leverage technology to drive efficiency, scale their operations and improve compliance. Having control of systems provides an operational advantage but also raises new considerations. If a site uses electronic systems, then they are required to comply with FDA 21 CFR Part 11. This compliance involves validating electronic system(s) and amending SOPs to include language describing how the system is employed in research. It's important to note that the technology vendor should be providing validation scripts, sample SOPs, guidance, and support system adoption so it doesn't fall on the sites. Because validation involves performing a set of tasks in the system, the validation process may also be used to train employees on features and functionality while fulfilling regulatory requirements. SOPs should be sufficiently detailed, however making them too verbose may lead to additional maintenance without providing any benefits.

During COVID-19, sponsors expected faster study startup and query turnaround due to the urgent need for a vaccine. This expectation persisted post-COVID and spread to non-COVID studies. Some sites are handling the additional demand on their time by leveraging electronic systems such as eReg and eSource. Some sponsors may help sites by providing access to systems to use for the trial. However, this results in sites using multiple systems and creates more work in the long run. Using many systems across trials duplicates data maintenance tasks and leads to errors. Another issue to keep in mind is the site may lose access to a system after the trial ends or may be asked to pay for continued access.

Some sponsors also require the use of electronic systems. If a site has a system, it could meet the sponsor's request by providing the sponsor with restricted access to their systems. Additionally, sites that own their systems and have agency over their data tend to perform better as measured by staff to study ratio, study startup time, number of queries, query resolution time, and other key measurements. An emerging best practice is delegating the responsibility of data maintenance to a small subset of staff. Doing so centralizes data maintenance while reducing duplicative work and mistakes.

As the trend of employing mobile technology in clinical research opens the door to new regulatory considerations, patients may voice concerns about their data privacy, and sites must be prepared to address those questions. This is becoming increasingly important as the industry is starting to see additional language in the Informed Consent that pertains to the use of mobile technology in trials. Additional training may be required for clinical staff to be familiar with the technology distributed to patients and be able to address patient concerns regarding these technologies.

Patient privacy language is also appearing more frequently in contracts. Sponsors are voicing concerns about General Data Protection Regulation (GDPR) and are starting to include contracts requesting U.S. sites comply with GDPR rules. This language is even appearing in contracts with U.S. sites that only see U.S. patients. Sites should be aware of the additional privacy and regulatory requirements in GDPR language and make sure they can accommodate it. Also, California recently passed a new consumer privacy act that carries hefty fines for violations and is applicable to businesses that conduct business in CA or with CA residents, irrespective of the site's physical location.

Patient privacy is a prominent trend that is expected to continue as technology and globalization become a more significant part of clinical trials. Although technology brings with it a new set of challenges, sites can differentiate themselves by adopting technology, taking ownership of their systems, and leveraging their own data.

See July's Sites NOW presentation slides and meeting minutes at myscrs.org/scrs-sites-now.

July's Sites NOW Presenters:

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SCRS Sites NOW is a virtual discussion and content project created in response to the COVID-19 pandemic and focused on the changing landscape clinical research sites and industry partners now face. Each session is centered around a singular topic; in January, the topic was the Evolution of Patient Engagement. Attendees benefit from an opening presentation hosted by an industry leader who provides a unique perspective and meaningful metrics on the topic at hand, then break out into groups for a dynamic discussion guided by relevant queries designed to identify areas of opportunity for participants in the clinical research pipeline.

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