FDA Initiative: Integrated Data Capture for EHR & EDC Systems

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FDA recently announced that it is seeking technology solutions that would integrate the capture of data for electronic health records (EHRs) and electronic data capture (EDC) systems. Specifically, FDA is looking for demonstration projects to test end-to-end EHR to EDC single-point data capture. For example, the system could collect data and simultaneously input it into an electronic health record and a clinical trial system. While the request came from The Center for Drug Evaluation and Research (CDER), the technology standardization would translate to device and biologics studies as well. Further, the 2013 guidance on Electronic Source Data in Clinical Investigators promotes capturing source data in electronic form.

Can you imagine the time savings and other advantages of a single-point data capture system? FDA says the benefits could include the following: eliminate the duplication of data, enable study form auto-population, facilitate remote data monitoring, reduce the opportunity for human error, and facilitate FDA inspection and reconstruction of the study. This could speed up FDA approval/clearance.

As with all new systems in a regulated industry, policy matters can slow things down. These include addressing patient privacy, access control, confidentiality, HIPAA, source data verification, remote monitoring and Part 11. Further, as with all new technology, the process of integrating legacy systems can be a headache. Plus, there are your existing service provider contracts to consider.

At least initially, CROs and other EDC system providers may not be thrilled, as a single-point data capture system will reduce the need for site monitoring visits and related services. Further, these service providers will need to adapt to this new technology.

While technology standards adoption takes time, clinical trial sponsors should consider whether their technology vendor agreements – not just EDC systems, but all cloud computing, software as a service (SaaS) and other technology service provider agreements – are nimble enough to respond to technology changes and business challenges. And if they are not, then how locked into the agreements and providers is your company? For example, does your company follow these EDC/cloud computing/SaaS best practices:

1. Data Portability: How easily can you jump ship to a new service provider?
    - Do you regularly receive an electronic copy of all data in your EDC or cloud-based system? In other words, do you always have a full backup of accessible, readable and manipulable data? In an EDC license agreement I recently negotiated, the CRO agreed to provide the sponsor with a weekly, full copy of its clinical database in a specific format.
    - Is your database copy in a standardized format that is usable outside of your current EDC system? This can help you avoid having to wade through what is often layers of software ownership (original licensor to CRO to consultant who then modifies the database software for your company).
    - Portable data helps with other problems, like CRO/EDC provider bankruptcy, transition assistance challenges, business interruption and data loss.
2. Service Level Agreements: Does your contract carefully address downtime, service credits, audits, business interruption, backups and disaster recovery? Do the terms reflect unified input by your technical and clinical teams?

3. System Interoperability: How robust are the systems integration and testing requirements in the contract? What kinds of cost overruns can you anticipate?
4. Security: Do you have appropriate user controls in place, like identity and credential access management and strong authentication? Who bears the financial burden of data breach and notifications?
5. Data Integrity: What kinds of assurances does the contract provide regarding data corruption, accuracy, delay or loss? Again, do you always have a full backup on hand?
6. Compliance: Do your service providers follow the laws and regulations that apply to your company? How closely do they follow the NIST roadmap (have they heard of NIST?)?
7. Technology Upgrades: This is a tricky road to navigate. On one hand, you want the provider to remain current; on the other, constant upgrades can wreak havoc on interoperability with your legacy systems. Are your contracts nimble enough to handle a single-point data capture system for your clinical trials without having to pay significant amounts to upgrade (see above suggestions regarding data portability)?
8. Termination Penalties: If you do want to jump ship to a new service provider, is there an early termination fee?

CROs, EDC providers and other technology service providers in the clinical trials space have historically been able to offer non-robust (or non-existent) "technology law" provisions in their agreements because the agreements were reviewed by clinical/regulatory personnel but not by technology/IT. Good, usable data is the reason that companies sponsor clinical trials. For sponsors to rest assured in their data usability, sponsors should coordinate input by clinical/regulatory and technology personnel on these agreements. FDA's solicitation of an end-to-end EHR to EDC single-point data capture may help facilitate this convergence.

This FDA technology initiative bears watching. I am curious to see how it plays out in CRO and EDC provider agreements, as it will impact everything from warranties to licensing to limitations of liability and indemnification, not to mention the description of services. If effectively implemented, the FDA's effort will lead to substantial benefits for clinical trial sponsors and others in the industry.

If you have any questions or would like more information about these developing issues, please contact the following:

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