Responding to Increased
FDA Focus on Data Integrity

As clinical trials grow in complexity and new technologies emerge for capturing clinical data, the need to improve sustainability of data integrity throughout study conduct has heightened.

Over the past five years, the volume of data integrity-related CGMP violations have grown in prevalence. In fact, the number of issued warning letters has more than tripled since 2013, from approximately 25% of all warning letters to nearly 80% citing data integrity in 2016.[1] This rapid increase signals that a growing proportion of organizations in the drug development industry are operating under quality systems that have not adapted to changes in technology and recent regulatory requirements, and therefore do not adequately ensure accurate and safe electronic data and records.

Addressing Safety Requirement Gaps

To address this trend, the FDA issued draft guidance in July of 2016 in order to identify problems and correlate problems to existing requirements. The draft guidance also provides clarifications on data integrity-related concepts including metadata, audit trails, static versus dynamic records, backups, and computerized systems.

With a clear need for improved GxP quality systems and regulatory guidance specifically referencing data integrity, the clinical research industry has started responding by adopting risk-based approaches to data and record governance. Strong improvements are being made in the way clinical research organizations are addressing data integrity in quality management systems. Key areas include:

Changes in practices for handling raw data

Data integrity relies on the concept of chain of custody. Primary and secondary data holders and/or controllers must be able to provide safeguards and traceability for all critical study data that supports clinical trials and manufacturing operations. Raw data is considered primary data generated by someone or a system. The chain of custody and accounting for the accuracy must start at data creation and maintain its history of "who, what, when, where, and why" until its lifecycle has expired and the data is retired.

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Improved measures for access security

Access security measures to maintain data integrity now involve both physical and logical security. Maintaining a business's access security measures successfully cannot be a static activity because physical and logical attempts to intrude and adulterate company data, including clinical data, are a constant. Physical security of facilities, data centers, mobile devices, laptops, and desktops are a first line of defense against compromising data integrity. Access controls around hardware, systems, databases, and mobile devices used in clinical trials must be more clearly planned for, implemented, and maintained.

Enhanced data controls

Data integrity is only as strong as your weakest link. Providing systematic controls over who has access to your data and how it is accessed should be clearly defined in both procedures and technologies. Tools such as active directory, dynamic audit trails, least privilege accounts, and continuous encryption of data both when active and at rest.

Improved approaches for building audit trails

While over 20 years old, FDA 21 CFR Part 11 and its audit trail requirements provide bedrock foundation expectations as to what an audit trail should contain. The challenge

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in today's clinical research environment is maintaining audit trails for electronic data in disparate areas, including cloud environments. Businesses are challenged with designing and implementing fully functional, dynamic audit trail functions to account for the entire data chain of custody.

Solutions are being innovated for research teams that allow for efficient, more reliable collection of audit trail information for all stakeholders of a clinical program. Applying a risk-based approach in conjunction with emerging technologies that enhance audit trail visibility, clinical researchers are able to maintain data integrity by ensuring complete, consistent and accurate data. **PV**

Editor's Note:
[1] *Unger Consulting, Inc. . (2017, January 16). An Analysis Of FDA FY2016 Drug GMP Warning Letters. Retrieved May 2017, from Pharmaceuticals Online.*

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