Introduction

As clinical trials have continued to become more complex, sponsors have turned to technology to increase efficiency. But with increased reliance on electronic systems comes more opportunity for risk if the technology is not managed appropriately. The 2016 update to the International Council on Harmonisation's good clinical practices guideline, ICH E6, is intended to address the shift from paper to electronic records, while building in more flexibility for clinical trials. The revised guideline focuses on electronic data, its maintenance and integrity, as well as on quality risk management targeting human subject protection and data integrity.

The most revised segment of the guideline, Section 5 – Sponsors, emphasizes the importance of risk-based thinking in all stages of a clinical trial. Under ICH E6(R2), the quality management system should take a risk-based approach to the following processes:

- Centralized monitoring;
- Clinical monitoring; and
- Software validation.

This report examines the key changes in Section 5, explains why they were made and reviews steps sponsors and other organizations must take to adjust to the requirements.

About the Authors

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