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Opportunities & Challenges in Transitioning to Risk-Based Monitoring in Clinical Trials

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Given our current environment, it is no surprise that pharma and device companies are doing everything possible to boost efficiencies. Increasing drug development and production in safe and effective ways, while limiting resources used and dollars spent can be a balancing act. This also applies to clinical trials. Adoption of a risk-based monitoring (RBM) approach may be the best method to support clinical studies while keeping an eye on compliance. In this episode we talk about the opportunities and challenges of implementing automated clinical trial management solutions using RBM with our guest Amanda Coogan.

Resources for this episode:

- Oversight of Clinical Investigations — A Risk-Based Approach to Monitoring - Guidance for Industry (2013)
- A Risk-Based Approach to Monitoring of Clinical Investigations Questions and Answers - Draft Guidance for Industry (2019)
- Tackling the Challenges of Transitioning to Risk-Based Monitoring