

# Risk-Based Monitoring of Clinical Trials 2017

New Trends and Best Practices

## Table of Contents

### Introduction

- Moving to a System of Centralized, Risk-Based Monitoring..... 4**
  - Advantages to a Centralized, Risk-Based Approach..... 4
  - FDA Expectations..... 5
- Creating/Documenting a Centralized, Risk-Based Monitoring Plan ..... 7**
  - Risk Assessment..... 7
  - Documenting the Monitoring Plan..... 10
  - The Role of Site Visits ..... 12
  - Training Clinical Investigators ..... 12
  - Training Monitors ..... 13
  - Transmitting Data ..... 13
- Strategies for Effective Monitoring..... 15**
  - Lessons Learned from FDA Warning Letters ..... 15
  - Making the Most of Site Visits ..... 19
  - Tools for On-site Monitoring ..... 19
  - Tools for Remote Monitoring..... 20
  - Communication Between Monitor and Principal Investigator ..... 21
- Creating a Clinical Data/Document Management Plan ..... 22**
  - Developing a Data Management Plan..... 22
  - Developing Analysis Datasets ..... 29
- Preparing for an FDA Inspection ..... 32**
  - Study Sites ..... 33
  - Sponsors ..... 34
  - Independent Review Board ..... 35

Inspection Closure.....	36
<b>Industry Response to Risk-Based Monitoring.....</b>	<b>38</b>
Gradual Introduction.....	38
Faster and More Frequent Results.....	40
<b>Appendices.....</b>	<b>41</b>
A. Oversight of Clinical Investigators – A Risk-Based Approach to Monitoring (FDA guidance)	
B. ICH Q9: Quality Risk Management	
C. ICH E6: Good Clinical Practice	
D. FDA Compliance Program Guidance Manual 7348.810, Bioresearch Monitoring: Sponsors, Contract Research Organizations and Monitors	
E. FDA Compliance Program Guidance Manual 7348.811, Bioresearch Monitoring: Clinical Investigators and Sponsor-Investigators	
F. Informed Consent Information Sheet: Guidance for IRBs, Clinical Investigators, and Sponsors (FDA draft guidance)	