Are you Prepared for the new ICH GCP Addendum?

20 Oct 2015

Introductions / Agenda

Implications of the ICH E6 Amendment on Managing Clinical Trials

Dr. Peter Schiemann

Risk Based Study Oversight supported by the Quality Risk Radar

(Including Demo)

Randy Ramin-Wright

- Questions and Answers
- Getting Started with the Quality Risk Radar
- Outlook

ICH E6 Addendum

Its Implications on Clinical Development

What is new?

- Increased emphasis on **Investigator Responsibilities**
- Complete Chapter on **Risk-based Quality Management System**
- **Outsourcing and Oversight**
- Strong emphasis on **Risk-based Monitoring**
- **Root Cause Analysis**
- Further clarification on **e-Records** and **essential Documents**

Why the Addendum?

"Since the development of the ICH GCP Guideline, the scale, complexity, and cost of clinical trials have increased. Evolutions in **technology** and **risk management processes** offer new opportunities to **increase efficiency and focus** on relevant activities.

This guideline has been amended to encourage implementation of improved and more **efficient approaches to clinical trial design, conduct, oversight, recording and reporting** while continuing to ensure human subject protection and data integrity. **Standards** regarding **electronic records** and **essential documents** intended to increase clinical trial quality and efficiency have also been updated."

What are the Implications?

Investigator Responsibilities:

"The investigator is responsible for supervising **any individual or party to whom the investigator delegates study tasks** conducted at the trial site"

"If the investigator/institution **retains** the **services** of any party to perform study tasks they should ensure this **party is qualified** to perform those study tasks and should implement **procedures to ensure the integrity of the study tasks** performed and any data generated."

What are the Implications?

Risk-based QMS:

"The sponsor should implement a **system to manage quality** throughout the **design, conduct, recording, evaluation, reporting and archiving** of clinical trials."

- Critical Process and Data Identification
- Risk Identification
- Risk Evaluation
- Risk Control
- Risk Communication
- Risk Review
- Risk Reporting

Nothing else than what ISO 31000 requires

What are the Implications?

CRO and Oversight:

"The sponsor should **ensure oversight of any trial-related duties** and functions carried out on its behalf."

"The sponsor should **document approval of any subcontracting** of trial-related duties and functions by a CRO."

Risk-based Monitoring

"The sponsor should develop a systematic, prioritized, risk-based approach to monitoring clinical trials…"

"A combination of on-site and centralized monitoring activities may be appropriate."

CLINERION
Data › Context › Value

Risk-based Monitoring

"**Routine review** of submitted data."

Data Quality: "Identification of missing data, inconsistent data, data outliers or unexpected lack of variability and protocol deviations that may be indicative of systematic or significant errors in data collection and reporting at a site or across sites, or may be indicative of potential data manipulation or data integrity problems."

"Using **statistical analyses** to identify data trends such as the range and consistency of data within and across sites."

"Analyzing site characteristics and performance **metrics**."

"Selection of sites and/or processes for **targeted on-site monitoring**."

Risk Based Monitoring – Monitoring Plan

"The sponsor should develop a **monitoring plan** that is tailored to the specific human subject protection and data integrity risks of the trial.

The plan should describe the monitoring **strategy**, the monitoring **responsibilities of all the parties involved**, the various monitoring **methods** to be used and the **rationale** for their use.

The plan should also emphasize the monitoring of **critical data and processes**.

Particular **attention** should be given to those aspects that are **not routine clinical practice** and that require additional training.

The monitoring plan should **reference the applicable policies and procedures**."

What are the implications?

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Documentation

"The investigator should **maintain adequate and accurate source documents** and trial records…"

"Changes to source data should be **traceable**…"

e-Records

Detailed description of what a system for electronic data handling should consist of

"**Ensure the integrity of the data** including any data that describe the context, content and structure of the data. This is particularly important when making **changes to the computerized systems**, such as software upgrades or migration of data."

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How does the Quality Risk Radar contribute to complying with the addendum's requirements?

- Clinical trial design
- Conduct
- Oversight
- Recording
- Reporting

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Risk Based Study Oversight

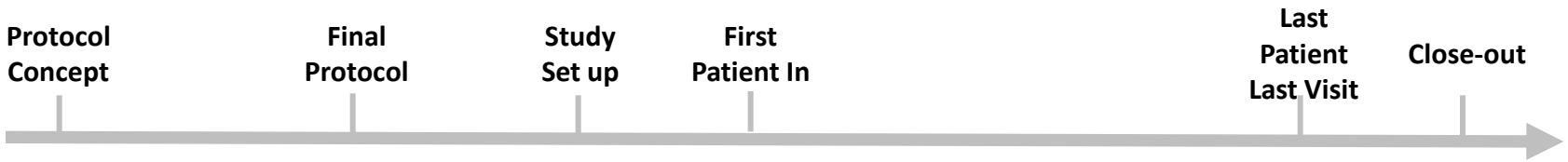
Quality Risk Radar

- Complete risk based quality management system for clinical trials
- Covering planning phase and trial conduct phase

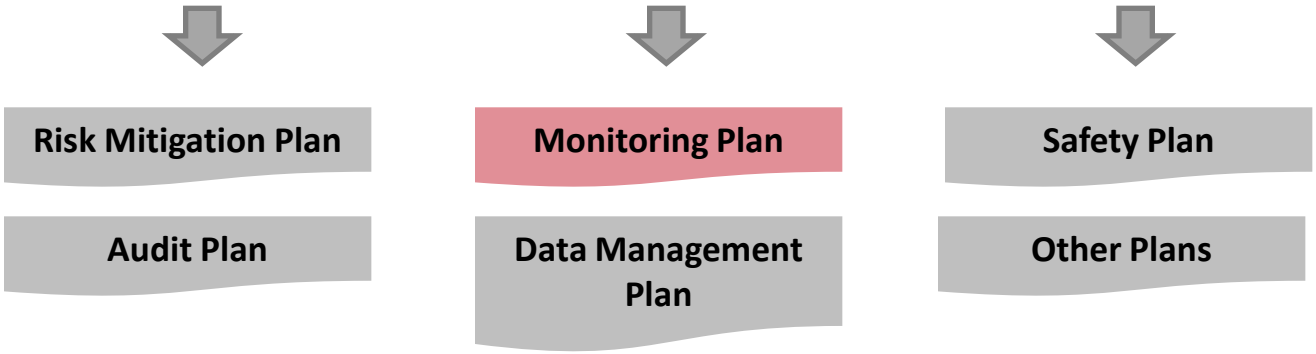
Demo of Risk Based Study Oversight

- Example: Study Manager's oversight, automated risk mitigation
- Trial Sites Overview > Site Risk per Study > Site Risk per Site > Mitigation Actions

Risk Based Study Oversight

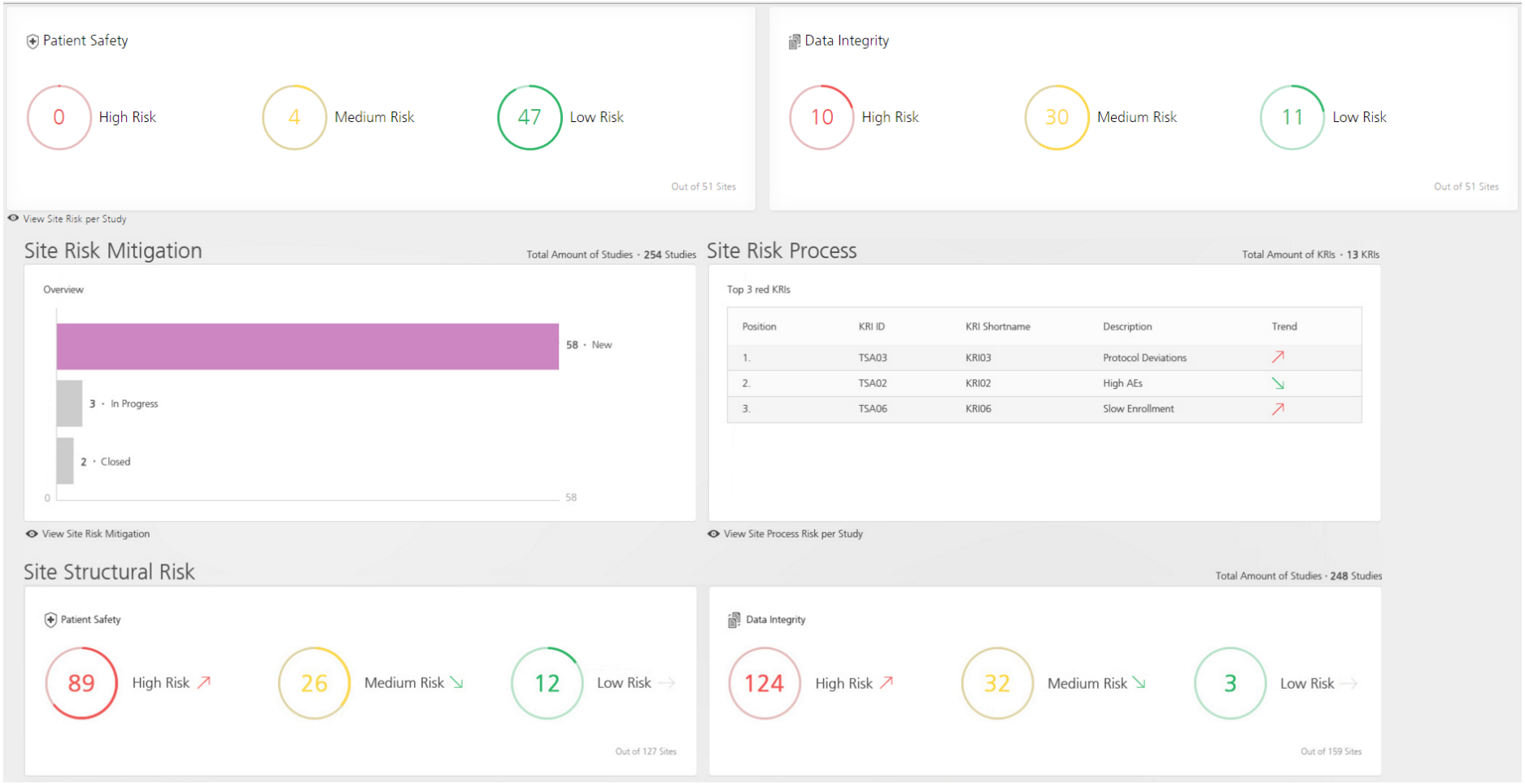


- Study Quality Assessment (SQA)
  - Impact on protocol
  - Plan critical monitoring & mitigation tasks
  - Define monitoring intensity
- Trial Site Assessment (TSA)
  - Impact on site selection
- Targeted Monitoring
  - Focus on critical areas
  - Ongoing risk analysis
- Adapt Functional Plans



Integrated Quality Risk Management Plan

Demo: Risk Based Monitoring



http://qrr.clinerion.com

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Getting Started

Get started with Risk Based Monitoring for Clinical Trials in the Cloud.

Try Me

Access the Free Sandbox of the Quality Risk Radar and try it out yourself!

- Find out how to improve study quality and identify high risk sites
- Let yourself be guided to industry tested risk mitigation actions

Access the Try Me System

Request a Demo

Contact us for a the demo of the Quality Risk Radar!

- Have a close look at the Quality Risk Radar functionality
- Find out how the Quality Risk Radar can facilitate your Study Quality Oversight

Request For A Demo

Start a Pilot Project

Considering Risk Based Monitoring (RBM) or Study Quality Management? Then our Pilot Projects are for you!

- Orientation and Planning Workshops
- Setup and configure System
- Train Pilot Project Team
- Pilot Risk-based Approach and Technology
- Gain experience and Review Results
- Make an informed decision about Risk Based Monitoring
- We also offer a Study Quality Management Pilot Project

Pilot the Quality Risk Radar

Order Core

The QRR Core Subscription contains a feature-rich production-ready set of application and support services for FREE.

Order Quality Risk Radar

Outlook

Next Webinar:

Spirometry Key Risk Indicators (December 2015)

Next QRR Release:

New Risk Analytics User Interface (November 2015)

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Thank you for attending our Webinar!