14th Annual PCT PARTNERSHIPS IN CLINICAL TRIALS

SPECIAL FOCUS DAY: Tuesday 17 November 2015

Workshop Z – The Fundamentals of RBM

Quality Risk Management (QRM), Quality by Design (QbD), Risk-based Monitoring (RbM), data driven monitoring or centralised monitoring have become interrelated terms of a hot topic. There is hardly an organisation that does not claim to already apply or considers to implement such an approach for clinical development and pharmacovigilance. This begs the question: is it just hype or a shift in paradigm? We are convinced that this is more than just hype. However, the shift in paradigm has not yet happened either. We observe many approaches to a risk-based study management but came to the conclusion that it is too early to celebrate an advent of a new era in clinical trials and development. We notice that the majority of approaches proposed lack fundamental elements of Quality by Design and Quality Risk Management strategies.

This day will be divided up into interactive sessions and case studies. It will be highly interactive and is designed to complement the main conference days at PCT.

09:45 **Registration**

10:20 **Opening remarks from the hosts**

10:30 **Introduction to risk management and risk-based monitoring**

11:00 **Session A: Interactive discussion addressing:**

- Is it true that only larger pharma or device companies can apply a risk-based approach?
- Do I need sophisticated IT tools to implement a risk-based approach?
- Is it true that we need to change the way we write protocols and set up trials to implement successfully a risk-based approach?

11.45 **Morning networking break**

12:15 **Session B: Interactive discussion addressing:**

- What are KRIs and KPIs, and how can they support a risk-based approach?
- Will a risk-based approach make site selection/qualification and patient recruitment into my trials any easier, and will it help to get better data faster and cheaper?

12:45 **Session C: Case Study from Mitsubishi Tanabe Pharma**

Aldir Medeiros Filho, *Senior Data Quality Reviewer- Data Sciences Department,* **Mitsubishi Tanabe Pharma Europe, UK**

13:15 **Networking lunch**

14:15 **Session D: Case Study: RBM retrofit, transforming risks into returns**

- Letting regulators, data and systems drive change
- Incorporating data driven reporting retroactively
- Driving awareness & control of site risk
- Reducing manual effort

Adam Baumgart, B.Sc., CPM, *Director, Process Excellence, Business Lead, Risk-Based Monitoring,* **Covance, UK**

> Very impressed by the enthusiasm of industry wanting to hear more about how we engage with patients post talks and on stands wanting to discuss this- great opportunities for collaborations
>
> Past speaker PCT 2014

14:45 **Session E: Interactive discussion addressing:**

- Will a risk-based approach allow me to stop SDV (Source Document Verification) and reduce the burden of on-site monitoring?
- How much money do I save by implementing a risk-based approach?
- How will Health Authorities react if they discover a major or critical finding that was not detected or not addressed through your risk management approach?

15:45 **Networking break**

16:15 **Session F: Interactive discussion addressing:**

- How does a risk-based approach impact on my organisation, i.e., study site, quality assurance, data management, clinical operations, drug safety, biometrics, etc.?
- What is the best implementation strategy for a risk-based approach?

16:45 **Summary remarks and end of special focus day Z**

Facilitators:
Dr Beat Widler,
Managing Partner,
Widler & Schiemann AG, Switzerland

Dr Peter Schiemann,
Managing Partner,
Widler & Schiemann AG, Switzerland

PCT Welcome Reception

17:30 - 19:00, Congress Centre

Kicking off the main two days of PCT, the Welcome Reception provides a great opportunity to catch-up with friends and peers. We look forward to seeing you there.

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