

REGISTRATION

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DATE & TIME

Date: Thursday, 17th of March 2015
 Time: 16:00-17:00 (CEST, UTC+2)



EVENT'S QUOTE

“Few practice is worth of much theory.”

TOPICS

- **Welcome & Agenda**
 (Presenter: A. Andrianov , 5 mins)
- **Introduction into Clinical Risk Management - Controlled risks are manageable risks**
 (Presenter: S. Engel, 10 mins)
- **10 Practical Questions of Risk-based Monitoring**
 (Presenter: A. Andrianov & S. Engel, 35 mins)
- **Q&A**

SPEAKER'S PROFILE

Artem Andrianov, PhD, MBA

- Professional with vast experience in development of software for pharmaceutical industry.
- Originally comes from programming and mathematical statistics, obtained rich experience in clinical data quality, managed a team of ERT for a long period. The team was responsible for clinical data quality software and data cleaning.
- Proven track record in medical projects with international teams: US, Germany, China, India etc.



ABOUT WEBINAR

LEARNING OBJECTIVES:

- Review the definition of Risk-based Monitoring (RbM) in clinical research and statistical surveillance. Difference of views between FDA and EMA
- Answer “What it’s in it for me?” question. - Share real-life examples of the RbM application and its pitfalls.
- Identify the difficulties & potential pitfalls of RbM application

Is RbM 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.

In our webinar, we will devote our attention to practical insights of implementation risk-based monitoring strategy and application of innovative software projects in this domain - *controlled risks are manageable risks.*

SPEAKER'S PROFILE

Sven Engel

- Biotechnician with proficiency in molecular biology and genetic engineering, currently CEO at SynapCon
- Professional in clinical project management and clinical monitoring, combined with IT services, consultancy and compliance services.
- 30+ years of experiences in the pharmaceutical industry, biotech and CRO business. Since 1999 - an independent entrepreneur.

