



RISK BASED MONITORING

Trainers: Ms. Nelle Stocquart
Steven Thys
François Torche

Blended learning



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Trainer(s)

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1. Agenda

Course Credit: **12 hours**
 eLearning - Videos Duration: **1h28** (excl. quizzes and workshops)
 Classroom duration: **7 hours** (1-day face to face)
 Final Grading Test: **60 minutes** (20 questions)

RISK MANAGEMENT IN CLINICAL RESEARCH	Duration
<u>PART I – eLearning</u>	
Introduction	1 quiz + 1 workshop
Rationale for RBM	09:00 min
Risk Based Monitoring Methodology	05:30 min + 2 quizzes + 1 workshop
Risk Assessment	16:00 min + 1 quiz + 1 workshop
Critical Data and Risk Indicator	08:00min + 1 workshop
Risk Plan	20:30 min + 1 quiz
Monitoring Execution	20:30 min + 1 quiz + 2 workshops



RISK MANAGEMENT IN CLINICAL RESEARCH

PART II – Classroom (1 day)

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- Concise review of the theory with Q&A sessions*
 - Workshops
 - Risk identification and analysis
 - RACT
 - Critical data and Risk indicator identification
 - Threshold Definition
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- Integrated Quality Risk Management Plan (IQRMP)
-
- RBM roles and responsibilities
-
- RBM implementation
 - Study cases**
 - Steven Thys, Director Clinical Operations at Servier, France
 - RBM tool demonstration**
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- Status on RBM implementation

* = interactive session

**= Testimony from the Industry

Note: The classroom training includes a lunchbreak of 45 minutes and two coffee breaks of 15 minutes



2. Trainer



Ms. Nelle Stocquart

Nelle obtained a master in Chemistry in 1997 at ULB. She then worked in variety of companies and institutions as researcher until 2002.

Her first experience in clinical trials was in 2003 when she became an IVRS project manager at S-Clinica, a Belgian CRO. Her wish was finally to be on the field and she became CRA at PAREXEL where she got involved in many international phases II & III from early study stage till closure. She then evolved as project manager in pharmaceutical companies and CRO where she managed local and international studies from phase I to phase IV.

Nelle has experience in managing international phase I, II and III studies in oncology but also rare diseases, cardiology and immunology. Training, coaching, education and continuous professional development have always been the common pillars in her educational path and professional career.



Steven Thys

Steven is a seasoned Clinical Research professional with a PASSION for innovative drug research.

He graduated as pharmacist at the KU leuven and holds a master in medical & pharmaceutical research at the vub. after a short career in preclinical development, he oriented his career towards clinical drug development.

In 2002 he started at servier R&D benelux where he held various positions in clinical operations and worked in cardiology, oncology and rheumatology. from 2010 onwards Steven has been leading clinOPS teams in south east asia and in western europe. today he is director global study management at servier's headquarter in Paris, overseeing trials worldwide and managing teams in 6 countries.

In 2014 steven was appointed as global pilot for developing and implementing a risk based approach for servier. Today rbm has been successfully implemented and has become the new standard within servier r&d for managing and monitoring clinical studies.



François Torche

François holds a Master in Business Administration from the ICHEC School of Management, Brussels, Belgium. Over the past 20 years in the pharmaceutical industry, he has held positions as statistical programmer, SAS and JAVA developer and IT project leader for companies such as GSK, UCB and IDDI. During his ten year tenure with IDDI as an IT Specialist, Mr. Torche assisted in the development of the SMART™ engine, a patented software solution and the underpinning of CluePoints. Francois has served as CluePoints' Chief Executive Officer since the company's inception in 2012.