EUROPEAN CENTRE FOR CLINICAL RESEARCH TRAINING

We facilitate Clinical Research professionals to excel in their job for the benefit of patients.

RISK BASED MONITORING

Trainers: Ms. Nelle Stocquart
Steven Thys

Blended learning

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How to enter the Virtual Campus:

Refer to the instructions and credentials received by email. Should you have questions during or after the course, contact your dedicated helpline at campus@eccrt.com.

Important Note:

Your access to the Virtual Campus will expire 3 months after your enrolment date.

Contact details

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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 **PART I – eLearning**	**Duration**
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)

- Concise review of the theory with Q&A sessions*
  - Workshops
    - Risk identification and analysis
    - RACT
    - Critical data and Risk indicator identification
    - Threshold Definition
    - Risk based monitoring actions identification

- Integrated Quality Risk Management Plan (IQRMP)

- RBM roles and responsibilities workshops

- RBM implementation
  - Study cases**
    - Steven Thys, Director Clinical Operations at Servier, France
  - RBM tool demonstration**

- Status on RBM implementation
  - CRO lessons learned
  - Sites Point of view

* = 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 & II 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 reumatology. 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.

In his free time he is playing soccer, biking and playing guitar.