EUROPEAN CENTRE FOR CLINICAL RESEARCH TRAINING

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

RISK MANAGEMENT IN CLINICAL RESEARCH

Trainers: Ms. Nelle Stocquart

Blended learning

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Enter the ECCRT Virtual Campus and get more about your course!

- Read general news from your trainer
- Post in forums to discuss course-related topics
- Find additional documentation on the course topic
- Download your training certificate

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: **1h15** (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**
Definitions	02:00 min + 1 workshop
Rationale	13:30 min + 1 quiz
Why?	03:30 min
Risk Identification	19:30 min + 1 workshop
Risk Analysis	05:00 min + 1 quiz
Risk Response	13:00 min + 1 quiz
Risk Monitoring and Control	06:30 min + 1 workshop
Risk Management plan	07:00 min + 1 real case situation
Conclusion	00:30 min

RISK MANAGEMENT IN CLINICAL RESEARCH

PART II – Classroom (1 day)

Introduction
Q&A from online course
Workshop 1: risk identification, analysis and response
Risk monitoring and control
Risk Management plan workshop • Prepare a risk management plan • Analyse a risk management plan
Difference between issues, CAPA and risks
The documentation Q&A
Risk communication
Link and difference with the Risk-Based Monitoring
Conclusion

Note: The classroom training includes a lunchbreak of 45 minutes and two coffee breaks of 10 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.