EUROPEAN CENTRE FOR CLINICAL RESEARCH TRAINING

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

LOCAL CLINICAL TRIAL LEGISLATION IN CZECH REPUBLIC

Trainer: Dr. Marleen Verbeeck

eLearning

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Trainer(s)

ECCRT Virtual Campus

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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

European Centre for Clinical Research Training (ECCRT)

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1. Agenda

Course Credit: **1.5 hours**
Cumulated Videos Duration: **45min** (excl. quizzes and workshops)
Final Grading Test: 60 minutes (10 questions).

Local Clinical Trial Legislation in Czech Republic	**Duration**
Legal Framework in the Czech Republic	07:00 min
Scope of the CT legislation in the Czech Republic	01:00 min
Submission Process, Timelines, Fees in the Czech Republic	06:00 min
Clinical Trial Application to Ethics Committee in the Czech Republic	05:00 min + 1 quiz
Clinical Trial Application to National Competent Authority	10:00min
Amendments & End of Trial Notification	07:00 min
Safety Reporting	03:00 min
Other	06:00 min

2. Trainer

Dr. Marleen Verbeeck

Dr. Marleen Verbeeck is a clinical research professional since 1995. After her academic career in scientific research she gained solid grounding in clinical research, first as a clinical research associate, later as a medical writer and trainer. Since 2004 she works at the European Centre for Clinical Research Training (ECCRT) and trains staff from multinationals and small businesses of the pharmaceutical and medical device industry, of universities, as well as non-profit research organisations across Europe, the United States of America and the Middle East. She is author of scientific papers, clinical trial study protocols and final study reports (Phase I to IV). Her experience in medical areas include gastroenterology, central nervous system, rheumatology, oncology and immunotherapy.

Marleen enjoys developing, lecturing, evaluating and testing comprehension of courses and expands her vast educational classroom expertise by exploring new learning techniques.

As a trainer her expertise is “trial legislation and clinical operations”, such as:

- Good Clinical Practice (Refresher)
- Legal Requirements in Clinical Research in Pharmaceutical and Medical Devices industry in Belgium/ in Europe/ and in the USA
- Preparing for Audits/ Inspections
- Standard Operating Procedures and Operational Challenges
- Clinical Research Trainings for Administrators/Assistants
- Clinical Research Trainings for Clinical Trial Monitors (juniors and seniors)
- Clinical Research Trainings for Investigational Site Team
- Clinical Research Trainings for Investigators

She is providing classroom and virtual teaching of academics and company staff, located globally, but also tailor-made sessions adapted to the specific needs of client and/or company.