



LOCAL CLINICAL TRIAL LEGISLATION IN NORWAY

Trainer: Ms. Nelle Stocquart

eLearning



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Important Note:

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

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1. Agenda

Course Credit: **1.5 hours**
 Cumulated Videos Duration: **40min** (excl. quizzes and workshops)
 Final Grading Test: 60 minutes (10 questions).

Local Clinical Trial Legislation in Norway	Duration
Norwegian Legal Framework	03:00 min + 1 quiz
Scope of the Norwegian CT legislation	02:00 min
Norwegian Submission Process, Timelines, Fees	06:00 min + 1 quiz
Clinical Trial Application to Ethics Committee	09:00min + 2 quizzes
Clinical Trial Application to National Competent Authority	09:00 min + 1 quiz
Amendments & End of Trial Notification	06:00 min
Safety Reporting	03:00 min + 1 quiz
Other	01:00 min + 2 quizzes



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 I & 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.