ECCRTraining

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European Centre for Clinical Research Training

ECCRT Online Training

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EUROPEAN CENTRE FOR CLINICAL RESEARCH TRAINING

How to implement mandatory clinical trials rules as a sponsor?

Training Series for Investigator Initiated Studies

Investigator Initiated Studies (IIS) are crucial for innovation in healthcare. Together with these trials there are responsibilities for the investigators and their teams, which they are not acquainted with.
Indeed, managing a Clinical Trial as sponsor is outside of their day-to-day work. Moreover, the increased need for sponsor oversight has even enlarged this gap.

Who should attend?

Physicians, acting as Investigators in (academic) hospitals and universities and who want to be involved in setting up Investigator Initiated Studies within their organisation. Principal investigators, sub-investigators, graduated doctors, fellowship, general practitioners will benefit attending this training.

Programme Description

The programme consists of a series of 14 webinars of 1-2 hours each. The webinars will be live, to encourage interaction between the subject matter experts and the audience. All sessions will be recorded and available on the ECCRT Virtual Campus, in case you have missed one.

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Webinar series

This training series is developed to help investigators understand how to implement mandatory Clinical Studies rules for sponsor in practice to ensure compliance from protocol development to final study report.
ECCRT developed this series of webinars to help sites to maximise their valuable contribution as non-commercial sponsors without compromising the quality of clinical trials.
See below our training series and the experts for each session:

1. 
What is the role and responsibility of an Investigator acting as Sponsor?
Paula Hemdal - 2h

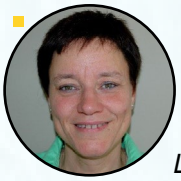
2. 
How to write a Protocol and an Informed Consent?
Paula Hemdal - 2h

3. 
Why do we need Statistics in Clinical Studies?
Eric Rozet - 1.5h

4. 
What type of contract do I need to put in place?
Olivier Van Obberghen - 2h

5. 
How to obtain study approval following Ethical and Scientific Review?
Marleen Verbeeck - 1.5h

6. 
What is the role of the Investigator acting as a Sponsor in data collection?
Roman Bobrovsky - 1.5h

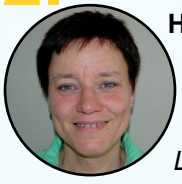
7. 
How to set up and maintain the Trial Master File (TMF)?
Liesbeth Lemmens - 1.5h

8. 
Why is it important to think of Quality Management?
Paula Hemdal - 1.5h

9. 
How to manage an Investigator Initiated Study?
Jolanda Schavemaker - 2h

10. 
What are the challenges in budget management for Investigator Initiated Studies?
Nelle Stocquart - 2h

11. 
What needs to be monitored and reported regarding patient's safety?
Liesbeth Lemmens - 1.5h

12. 
How do I fulfil the ICH-GCP requirements regarding monitoring?
Liesbeth Lemmens - 2h

13. 
How to write a Clinical Study Report (CSR)?
Gertrud Schuster - 1.5h

14. 
What's next?
Benedikt Van Nieuwenhove - 1.5h

Apply now!

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