

Course Schedule 2022

Clinical Operations courses

COURSE NAME	FORMAT	LOCATION	JAN	FEB	MAR	APR	MAY	JUN	JUL	SEP	OCT	NOV	DEC
Advanced Clinical Project Management ²	Classroom	Brussels		21-22							10-11		
	Webinar	Online				25, 26, 29, 02, 04, 06							
Clinical Project Management ³	Webinar	Online			08, 15, 22, 29								
	eLearning + Classroom	Online + Brussels										22	
		Online + Leiden							20				
		Online + Zurich									12		
Clinical Research Training for Junior Clinical Research Associates ⁴	Webinar	Online	24, 26, 31, 02				05, 06, 09, 13						
	Classroom	Brussels							07-08	28-29			
Leiden													14-15
Clinical Research Training for Senior Clinical Research Associates ¹	eLearning + Webinar	Online				26, 28		01			03		
	eLearning + Classroom	Online + Brussels							07-08	28-29			
Computer System Validation for Clinical Operations	Webinar	Online			14, 15								
	Classroom	Brussels			08							08	
CRO Management and Oversight ²	Webinar	Online					09, 11, 16, 18						
	Classroom	Brussels									12-13		
NEW Decentralised Patient-Centric Trials: From Theory to Practice	Webinar	Online									06, 13, 20, 27, 03, 06		
NEW Designing clinical research protocols for a better outcome	Classroom	Brussels				19-20							
Importance of the Involvement of Clinical Operations in Clinical Study Protocol Review ²	Webinar	Online										09	
Introduction to Clinical Research ⁴	eLearning	Online											
Introduction to Clinical Research with Medical Devices ⁵	eLearning	Online											
Introduction to Statistics	Classroom	Brussels				19-20							
Investigator Initiated Studies	Webinar	Online									TBC		

* Courses followed by numbers in upper script are the training sessions included in a specific **STAR Programme**.

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Risk-Based Monitoring ¹	eLearning + Webinar	Online						28-29					
	eLearning + Classroom	Online + Brussels								05			
Risk Management in Clinical Research ³	eLearning + Classroom	Online + Brussels										23	
Running Medical Device Studies ⁵	Classroom	Brussels						28-29					
	Webinar	Online										14, 16, 21, 23	
Safeguarding Data Integrity in Highly Regulated Environments	Classroom	Brussels						02-03					
Sponsor co-monitoring ¹	Webinar	Online					10, 12						
	Classroom	Brussels									04		
What's new with ISO 14155:2020 GCP?	Webinar	Online		30									
Advanced Clinical Researcher STAR Programme¹	Classroom	Brussels									03-07		
Advanced Project Management STAR Programme²	Classroom	Brussels					09-13				10-14		
Clinical Project Management STAR Programme³	Classroom	Brussels			21-25							21-25	
Junior Clinical Researcher STAR Programme⁴	Classroom	Brussels							04-08	26-30			
		Leiden											12-16
Medical Devices STAR Programme⁵	Classroom	Brussels						27-01					
	Webinar	Online										14-18	
The following courses aren't scheduled but can be requested as a tailored course (choose topic, location, number of participants and format)													
Budgeting Clinical Trials	Upon request												
Monitoring and Protocol Deviation	Upon request												
GMP Essentials for Clinical Operations Staff	Upon request												
Remote Monitoring and Opportunities during COVID-19 and Beyond	Upon request												
The ECG in Clinical Research	Upon request												
Transfer of Sponsorship of ongoing trials	Upon request												

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Course Schedule 2022

Clinical Research courses



EUROPEAN CENTRE FOR
CLINICAL RESEARCH TRAINING

COURSE NAME	FORMAT	LOCATION	JAN	FEB	MAR	APR	MAY	JUN	JUL	SEP	OCT	NOV	DEC
Bridging preclinical and clinical development	Webinar	Online					10, 12, 16, 17						
	Classroom	Brussels							07-08	28-29			
Clinical Development of a Vaccine	Webinar	Online			03, 07, 09, 14, 16, 17								
NEW Data Management Essentials for Clinical Project Managers	Webinar	Online		28, 02, 07									
Data Protection in Clinical Research and GDPR in action	Classroom	Brussels				19-20							
Implementing GDPR in your organisation	eLearning	Online											
Introduction to Oncology for Clinical Researchers	Classroom	Brussels			29-30								
ISO14155 Training ⁵	Classroom	Brussels							04				
	Webinar	Online									07-10		
Legal Basics for Clinical Study Contracts ³	Webinar	Online		28, 29									
	Classroom	Brussels									24		
Orienting your Career in Clinical Research ⁴	Classroom	Brussels						6	27				
		Leiden											13
Pharmacovigilance System Compliance - Medical Product Life Cycle	Classroom	Brussels			22-23								
The following courses aren't scheduled but can be requested as a tailored course (choose topic, location, number of participants and format)													
Critical Literature Review	Upon request												
Data Management Essentials for Clinical Project Managers	Upon request												
Effective Medical Writing & Data Presentation	Upon request												
Introduction to Statistics	Upon request												
Laboratory Testing in Clinical Research	Upon request												
Learning Journey on Drug Development	Upon request												
Recist Training	Upon request												
Writing Procedural Documents	Upon request												

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Course Schedule 2022

Quality Assurance courses



EUROPEAN CENTRE FOR
CLINICAL RESEARCH TRAINING

COURSE NAME	FORMAT	LOCATION	JAN	FEB	MAR	APR	MAY	JUN	JUL	SEP	OCT	NOV	DEC
A risk-based approach to Clinical Audits ⁶	Webinar	Online					09-10						
Audit and Inspection Readiness - How to be prepared! ^{1, 2, 7}	Webinar	Online					09-10						
Auditing Clinical Development Documents ⁷	Webinar	Online					11						
Clinical Service Provider Audits ⁶	Webinar	Online					11-12						
Communication and Appreciative Auditing ⁷	Classroom	Brussels					12						
Introduction to System Audits for Clinical Auditors ⁶	Webinar	Online					02-03						
Introductory Course on Auditing Investigator Sites ⁷	Webinar	Online					02, 03, 04, 05						
NEW Remote Auditing	Webinar	Online											
Writing Audit Reports ⁶	Webinar	Online					04-05						
Advanced Auditors STAR Programme⁶	Webinar	Online					02-06						
Junior Auditors STAR Programme⁷	Webinar	Online					02-06						

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Regulatory courses

COURSE NAME	FORMAT	LOCATION	JAN	FEB	MAR	APR	MAY	JUN	JUL	SEP	OCT	NOV	DEC
NEW Basics on Regulatory Requirements in Clinical Research ⁴	eLearning	Online											
Clinical Research Training for Clinical Trial Assistants (CTAs)	Classroom	Brussels									17-18		
Foundational ICH-Good Clinical Practice (GCP) E6 (R2) Training ⁴	eLearning	Online											
GCP Essentials in 90 Minutes	eLearning	Online											
Good Manufacturing Practice (GMP) in relation to GCP	eLearning	Online											
ICH-GCP E6 (R2) Refresher	eLearning	Online											
ICH-GCP E6 (R2) Refresher + Complementary ICH-GCP Refresher for Biometrics Staff	eLearning	Online											
ICH-GCP E6 (R2) Refresher + Complementary ICH-GCP Refresher for Clinical Operations Staff	eLearning	Online											
ICH-GCP E6 (R2) Refresher + Complementary ICH-GCP Refresher for Regulatory Staff ⁸	eLearning	Online											
ICH-Good Clinical Practice (GCP) E6 (R2) for Investigators	eLearning	Online											
NEW Implementation of MDR 2017/745 in Belgium	Webinar	Online				25							
NEW How to cope with the development of drug-device combinations?	Webinar	Online						28-29					
NEW Local Clinical Trial Legislation in the USA ⁸	eLearning	Online											
Medical Device Regulations ⁵	Classroom	Brussels		18									
	Webinar	Online					11				28, 05		
The Belgian Clinical Trials Law of 2017: A Clear View on Rules	Webinar	Online								12			
The European Clinical Trial Directive for Medicinal Products ⁸	eLearning	Online											
The European Clinical Trial Regulation (CTR) 536/2014 ⁸	Webinar	Online						09				07	
NEW Understanding and complying with the EU CTR	Classroom	Brussels		24				21				24	
	Webinar	Online				26, 28				20, 22			
Clinical Regulatory STAR Programme⁸	eLearning	Online											
NEW Regulatory Affairs STAR Programme	Classroom	Brussels					16-20						
The following courses aren't scheduled but can be requested as a tailored course (choose topic, location, number of participants and format)													
Ready for the IVDR? Regulatory impact and milestones for CE marking	Upon request												
Clinical Investigations: Implementation of MDR 2017/745 in Belgium	Upon request												
European Legislation for Clinical Research – Implementation in Belgium	Upon request												
Good Clinical Laboratory Practice	Upon request												
Good Manufacturing Practice (GMP)	Upon request												
Good Distribution Practice (GDP)	Upon request												

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Soft Skills courses

COURSE NAME	FORMAT	LOCATION	JAN	FEB	MAR	APR	MAY	JUN	JUL	SEP	OCT	NOV	DEC
Communication Skills ⁴	Classroom	Brussels								30			
Line Management Essentials	Classroom	Brussels						23-24					
People Management ³	Webinar	Online			31, 01								
	Classroom	Brussels										25	
NEW Remote Team Management: How to successfully lead	Webinar	Online						07, 16					
Train the Trainer	Classroom	Brussels										25	
Career Launch Coaching (flexible schedule)	Webinar	Online	Upon your agenda										
Clinical Career Coaching (flexible schedule)	Webinar	Online	Upon your agenda										
The following courses aren't scheduled but can be requested as a tailored course (choose topic, location, number of participants and format)													
Change Management for Clinical Research	Upon request												
Communicating with EU Regulators/Health Authorities	Upon request												
Enhancing your Communication and Presentation Skills in the changing Clinical Trial world	Upon request												
Influencing skills	Upon request												
Intercultural Communication Skills	Upon request												
Female Leadership in Clinical Research	Upon request												
Leading in a Solution Focused Way	Upon request												
Microsoft Project Basics for Clinical Project Managers	Upon request												
Stress Prevention at Work	Upon request												
Time Management	Upon request												

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microLearning is a short and straightforward way of learning, available in a library of content. You can follow any microLearning at any time from anywhere!

Find below some microLearning topics available
(a new microLearning is released every month)

1. COMMUNICATIONS

- Stakeholder's Analysis for project Communication Plan

2. CLINICAL OPERATIONS

- eTMF Reflections
- Informed Consent the Right Way
- What to look for when no 100% SDV
- How to Enhance Oversight TMF
- What to Verify in an Investigator Site File
- Optimising Site Selection
- Creating worksheets for Clinical Source Data
- Informed Consent in a Nutshell
- What is drug accountability verification?
- Situational Management of your Contracts
- Patient Centricity
- ISO GCP Version 3! What's new?

3. DATA

- How to deal with incomplete data?

4. ETHICS

- Applying Ethical Principles in Clinical Research

5. GCP

- How to write an effective CAPA?
- How to prove oversight by the investigator?
- ICH-GCP E6 (R2) Oversight
- Differences between TMF and ISF

6. HOT TOPICS

- COVID-19 and ongoing Clinical Trials

7. LEADERSHIP

- Resolving Issues at Work
- Impact and Influence

8. REGULATORY

- A Safety Monitoring Approach during Clinical Trials
- Difference between ISO 14155 and GCP
- Difference between Protocol Violation and Deviation
- Linking Essential Docs with GCP
- Serious Breaches
- Using eSource Data in clinical investigations

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