

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 | | | | | | | | | | | |

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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

| 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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Course Schedule 2022

Regulatory courses

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|---|------------------|-----------------|-----|-----|-----|--------|-------|-------|-----|--------|--------|-----|-----|
| 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

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| 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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