

Course Schedule 2023

Clinical Operations courses

| COURSE NAME | FORMAT | LOCATION | JAN | FEB | MAR | APR | MAY | JUN | JUL | AUG | SEP | OCT | NOV | DEC |
|---|-----------------------|-------------------|-----|-----|---------------|--------|------------------------|----------------|--------|-----|--------|--------|--------|-----|
| Advanced Clinical Project Management ⁸ | Classroom | Brussels | | | 23, 24 | | | | | | | 16, 17 | | |
| | Webinar | Online | | | | | 22, 24, 26, 30, 01, 02 | | | | | | | |
| Clinical Project Management ⁹ | Webinar | Online | | | 8, 10, 15, 17 | | | | | | | | | |
| | eLearning + Classroom | Online + Brussels | | | | | | | | | | | 7 | |
| Online + Zurich | | | | | | | 12 | | | | | | | |
| Clinical Research Training for Junior Clinical Research Associates ² | Webinar | Online | | | | | 02, 04, 09, 11 | | | | | | | |
| | Classroom | Brussels | | | | | | | 06, 07 | | 27, 28 | | | |
| Leiden | | | | | | | | | | | | | 14, 15 | |
| Clinical Research Training for Senior Clinical Research Associates ¹ | Webinar | Online | | | | 24, 26 | | | | | | | | |
| | eLearning + Classroom | Online + Brussels | | | | | | | | | | 9 | | |
| Computer System Validation for Clinical Operations | Webinar | Online | | | 20, 22 | | | | | | | | | |
| | Classroom | Brussels | | | | | | | | | | 23, 24 | | |
| CRO Management and Oversight ⁸ | Webinar | Online | | | | | | 06, 08, 13, 15 | | | | | | |
| | Classroom | Brussels | | | | | | | | | | 18, 19 | | |
| Designing clinical research protocols for a better outcome | eLearning + Classroom | Online + Brussels | | | 30 | | | | | | | | | |
| Importance of the Involvement of Clinical Operations in Clinical Study Protocol Review ⁸ | Webinar | Online | | | | | | 19 | | | | 20 | | |
| Risk-Based Monitoring ² | eLearning + Classroom | Online + Brussels | | | | | | | | | | 11 | | |
| | Webinar | Online | | | | | 03, 05 | | | | | | | |
| Risk Management in Clinical Research ¹ | eLearning + Classroom | Online + Brussels | | | | | | | | | | | 8 | |
| | Webinar | Online | | | 15, 17 | | | | | | | | | |

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|---|--------------|----------|-----|-----|----------------------------|-----|--------|----------------|----------------------------|-----|-----|-----------|--------|-------|
| Introduction to Clinical Research ² | eLearning | Online | | | | | | | | | | | | |
| Introduction to Clinical Research with Medical Devices ³ | eLearning | Online | | | | | | | | | | | | |
| People Management | Classroom | Brussels | | | | | | | | | | | 9 | |
| | Webinar | Online | | | 29, 31 | | | | | | | | | |
| Running Medical Device Studies ³ | Classroom | Brussels | | | | | | 27, 28 | | | | | 21, 22 | |
| Sponsor Co-Monitoring ¹ | Webinar | Online | | | | | 08, 10 | | | | | | | |
| | Classroom | Brussels | | | | | | | | | | 10 | | |
| Advanced Clinical Researcher STAR Programme ¹ | Classroom | Brussels | | | | | | | | | | 9, 10, 11 | | |
| | Webinar | Online | | | | | 24, 26 | 03, 05, 08, 10 | | | | | | |
| Advanced Project Management STAR Programme ⁸ | Classroom | Brussels | | | | | | | | | | 16-20 | | |
| | Webinar | Online | | | | | | 22, 24, 26, 30 | 01, 02, 06, 08, 13, 15, 19 | | | | | |
| Clinical Project Management STAR Programme ⁹ | Classroom | Brussels | | | | | | | | | | | 6-9 | |
| | Webinar | Online | | | 8,9,15, 17, 22, 24, 29, 31 | | | | | | | | | |
| Junior Clinical Researcher STAR Programme ² | Classroom | Brussels | | | | | | | | 5-7 | | 26-29 | | |
| | | Leiden | | | | | | | | | | | | 12-14 |
| Medical Devices STAR Programme ³ | Classroom | Brussels | | | | | | | 26-28 | | | | 20-22 | |
| 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 | | | | | | | | | | | | | |
| Safeguarding Data Integrity in Highly Regulated Environments | Upon Request | | | | | | | | | | | | | |
| What's new with ISO 14155:2020 GCP | Upon Request | | | | | | | | | | | | | |
| Introduction to Statistics | Upon Request | | | | | | | | | | | | | |

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Course Schedule 2023

Clinical Research courses



| COURSE NAME | FORMAT | LOCATION | JAN | FEB | MAR | APR | MAY | JUN | JUL | AUG | SEP | OCT | NOV | DEC |
|---|--------------|----------|-----|-----|--------|-----|----------------|-----|-----|-----|-----|--------|--------|-----|
| Bridging preclinical and clinical development | Classroom | Brussels | | | | | | | | | | | 27, 28 | |
| | Webinar | Online | | | | | 02,04 09,11 | | | | | | | |
| Data Protection in Clinical Research and GDPR in action | Classroom | Brussels | | | | | | 20 | | | | | | |
| Introduction to Oncology for Clinical Researchers | Classroom | Brussels | | | | | | | | | | 26, 27 | | |
| Legal Basics for Clinical Study Contracts ⁹ | Classroom | Brussels | | | | | | | | | | | 6 | |
| | Webinar | Online | | | 22, 24 | | | | | | | | | |
| Orienting your Career in Clinical Research ² | Classroom | Brussels | | | | | | | 5 | | 26 | | | |
| | Classroom | Leiden | | | | | | | | | | | | 12 |
| How to prepare your vaccine candidate for clinic | Classroom | Brussels | | | 28 | | | | | | | | | |
| Pharmacovigilance System Compliance - Medical Product Life Cycle | Classroom | Brussels | | | 20, 21 | | | | | | | | | |
| The following courses aren't scheduled but can be requested as a tailored course (choose topic, location, number of participants and format) | | | | | | | | | | | | | | |
| Clinical Development of a Vaccine | Upon request | | | | | | | | | | | | | |
| Data Management Essentials for Clinical Project Managers | Upon request | | | | | | | | | | | | | |
| Implementing GDPR in your organisation | Upon request | | | | | | | | | | | | | |
| ISO14155 Training ³ | Upon request | | | | | | | | | | | | | |
| 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 2023

Quality Assurance courses

| COURSE NAME | FORMAT | LOCATION | JAN | FEB | MAR | APR | MAY | JUN | JUL | AUG | SEP | OCT | NOV | DEC |
|---|------------------|-----------------|-----|-----|-----|-----|-----|------------|-----|-----|-----|-----|-----|-----|
| A Risk-Based Approach to Clinical Audits | Classroom | Brussels | | | | | | 21 | | | | | | |
| Audit and System Inspection Readiness - How to be prepared ^{1 5 8} | Classroom | Brussels | | | | | | 14 | | | | | | |
| Auditing Clinical Development Documents ⁵ | Webinar | Online | | | | | | 15 | | | | | | |
| Clinical Service Provider Audits ⁴ | Classroom | Brussels | | | | | | 22 | | | | | | |
| Communication and Appreciative Auditing ⁵ | Webinar | Online | | | | | | 16 | | | | | | |
| Introduction to System Audits for Clinical Auditors ⁴ | Classroom | Brussels | | | | | | 19 | | | | | | |
| Introductory Course on Auditing Investigator Sites ⁵ | Classroom | Brussels | | | | | | 12, 13 | | | | | | |
| Writing Audit Reports ⁴ | Classroom | Brussels | | | | | | 20 | | | | | | |
| Advanced Auditors STAR Programme⁴ | Classroom | Brussels | | | | | | 19-22 | | | | | | |
| Junior Auditors STAR Programme⁵ | Classroom | Brussels | | | | | | 12, 13, 14 | | | | | | |
| | Webinar | Online | | | | | | 15, 16 | | | | | | |
| The following courses aren't scheduled but can be requested as a tailored course (choose topic, location, number of participants and format) | | | | | | | | | | | | | | |
| Remote Auditing | Upon request | | | | | | | | | | | | | |

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Course Schedule 2023

Regulatory courses

| COURSE NAME | FORMAT | LOCATION | JAN | FEB | MAR | APR | MAY | JUN | JUL | AUG | SEP | OCT | NOV | DEC |
|---|------------------|-----------------|-----|-----|-----|-----|--------|-----|-----|-----|-------|-----|-----|--------|
| Basics on Regulatory Requirements in Clinical Research ² | eLearning | Online | | | | | | | | | | | | |
| Clinical Research Training for Clinical Trial Assistants (CTAs) | Classroom | Brussels | | | | | | | | | | | 13 | |
| Foundational ICH-Good Clinical Practice (GCP) E6 (R2) Training ² | 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-Good Clinical Practice (GCP) E6 (R2) for Investigators | eLearning | Online | | | | | | | | | | | | |
| Implementation of MDR 2017/745 in Belgium | eLearning | Online | | | | | | | | | | | | |
| Clinical Investigations: Implementation of MDR 2017/745 in Belgium | Webinar | Online | | | | 20 | | | | | | | | |
| How to cope with the development of drug-device combinations? | eLearning | Online | | | | | | | | | | | | |
| ICH-GCP E6 (R2) Refresher + Complementary ICH-GCP Refresher for Regulatory Staff ⁶ | eLearning | Online | | | | | | | | | | | | |
| Local Clinical Trial Legislation in the USA ⁶ | eLearning | Online | | | | | | | | | | | | |
| Medical Device Regulations ³ | Classroom | Brussels | | | | | | 26 | | | | | 20 | |
| The Belgian Clinical Trials Law of 2017: A Clear View on Rules | Webinar | Online | | | 27 | | | | | | | 12 | | |
| The European Clinical Trial Directive for Medicinal Products ⁶ | eLearning | Online | | | | | | | | | | | | |
| The European Clinical Trial Regulation (CTR) 536/2014 ⁶ | Webinar | Online | | | | | | 20 | | | | | 16 | |
| Understanding and complying with the EU CTR | Webinar | Online | | | | | 23, 25 | | | | | | | 12, 14 |
| | Classroom | Brussels | | 28 | | | | | | | | 5 | | |
| Clinical Regulatory STAR Programme⁶ | Webinar | Online | | | | | | 20 | | | | | 16 | |
| Regulatory Affairs STAR Programme⁷ | Classroom | Brussels | | | | | | | | | 18-22 | | | |
| 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 | | | | | | | | | | | | | |
| How to cope with the development of drug-device combinations? | 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 ² | Classroom | Brussels | | | | | | | | | 29 | | | |
| Line Management Essentials | Classroom | Brussels | | | | | | | | | | 26, 27 | | |
| People Management ³ | Webinar | Online | | | 29, 31 | | | | | | | | | |
| | Classroom | Brussels | | | | | | | | | | | 9 | |
| 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 | | | | | | | | | | | | | |
| Leading in a Solution Focused Way | Upon request | | | | | | | | | | | | | |
| Stress Prevention at Work | Upon request | | | | | | | | | | | | | |
| Time Management | Upon request | | | | | | | | | | | | | |
| Microsoft Project Basics for Clinical Project Managers | Upon request | | | | | | | | | | | | | |
| Intercultural Communication Skills | Upon request | | | | | | | | | | | | | |
| Remote Team Management : How to successfully lead | Upon request | | | | | | | | | | | | | |
| Train the Trainer | Upon request | | | | | | | | | | | | | |
| Female Leadership in Clinical Research | Upon request | | | | | | | | | | | | | |

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