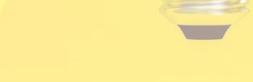


GREAT! You've just found

THE PERFECT CLINICAL RESEARCH LEARNING & DEVELOPMENT SOLUTION



Course Prospectus 2025

eccrt.com

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Embracing a Train ECCRT's offering

Embracing a Transformative Future: ECCRT's Learning and Development Offerings for 2025. ECCRT's offering to help its customers transform the way clinical research is conducted!

Dear esteemed readers,

We are excited to present to you our new Course Prospectus for 2025. At ECCRT, we are on the forefront of innovation in leaning & development with the aim to nurture personal growth and enhance development of clinical research professionals.

What's Inside?

- 1. <u>Public Courses</u>: Our wide range of courses open to the public awaits you. Whether you're looking to enhance your skills, gain new knowledge, or simply stay ahead of the curve, our 2025 course schedule is here to guide you. We've meticulously curated an impressive lineup of training programmes to cater to your diverse needs. We are proud to announce that many new programs will be added in the coming year including the long-awaited ICH GCP E6 (R3).
- 2. <u>Tailored Courses</u>: Your unique requirements are at the core of our training solutions. At ECCRT, we understand that one size does not fit all. Our tailored courses are designed to meet your specific needs, ensuring that you get the most out of your learning experience.
- 3. <u>More about ECCRT</u>: Dive deeper into our organisation, our values, and our commitment to nurturing a culture of continuous development.

What else is New?

- 1. <u>Mentorship for On-The-Job Application of learnings</u>: Learning is truly valuable when it's applied effectively. To ensure that your learnings translate into clinical development excellence, we are thrilled to offer mentorship programs. Dive into the details on page 24 and discover how we're committed to your success, not just in the classroom, but in your professional life.
- 2. We are more than just educators: We are your partners in growth & development. Here's to a year of transformation, growth, and endless possibilities. Together, let's make 2025 a year of unparalleled success.
- 3. <u>Adaptive Design Feature</u>: We now offer Adaptive Design in some of our eLearning courses. Before each section, participants take a quiz to see if they can pass the section or not. This ensures participants can prove their knowledge and focus on areas they need to learn.

Together, let's make 2025 a year of unparalleled success!



Prof. Dr. Benedikt Van NieuwenhoveManaging Director

ECCRT Mission

We are a professional Clinical Research
Training Organisation for the **pharma**, **biotech & medical device industries** as well as for CROs,
investigational and academic groups.

Our mission is to facilitate Clinical Research professionals to **excel in their job** for the benefit of patients.

To achieve this, we have **60+ seasoned experts on our team** covering a wealth of know-how which they enthusiastically share with our course participants in the most interactive, engaging and innovative way.



EFFECTIVE LEARNING

Our goal is to provide a **360 degree approach**combining training, coaching,
and consulting, benefiting
individuals and organisations!



EXPERTISE

We want you to be trained by real and experienced trainers who are keen to share and personalise their trainings according to your needs!



INNOVATION

With our Virtual Campus, you can **learn, share and exchange knowledge** as you have never experienced before!



Why ECCRT?





Testimonials



This week has been intense and very rich in learnings. The richness of this training comes by large from the speakers/teachers who bring their realworld experiences of the field and their vision of the regulatory history and future changes in Europe...

-Juliette Moyersoen (Regulatory Affairs STAR Programme)

Thanks to the Jr Clinical Researcher STAR Programme I understood better who can become a CRA and where to go. Through this knowledge and the interaction I had with the trainer, I know how to start and build my career in clinical research.







I decided to take the ECCRT career coaching. This helped me get a better overview of the roles and functions in the area of clinical development.

Together with my coach – Virginie Hamtiaux – we identified what my own strengths are and how to link them to a possible career in the pharma industry. - Kristien Van Belle (Career Coaching)



This course opened my mind and gave me the opportunities to know different jobs related to clinical research especially regarding my own case as medical doctor i have discovered different positions

-Deppinair Mundabi Nzasi (Orienting your career in Clinical Research)

Since several years, ECCRT provides a yearly refresher GCP course for all our staff members. We are very satisfied... The content is tailored to our needs, and taught by a dynamic and very knowledgeable trainer. This course has become a valuable element in our education and training program.

-Gert Everaet (ICH-GCP (Good Clinical Practice) E6 (R2) Refresher)





It was very helpful to get an overview on all aspects to be considered in regard of pre-clinical to pre-clinical phase, especially the regulations referred to. So it's easier to read through the one or the other part later on when required.

-Michaela Schaden (Bridging Preclinical and Clinical Development)

'Budgeting Clinical Studies' is one of the best courses I had at ECCRT. A well designed interactive course, with practical orientation. The guidelines given by Dr. Baeyens are very useful and enhance our knowledge in budget management.

-Elizabeth Boghossian (Budgeting Clinical Studies)



Insightful lectures, friendly environment and interactive learning experience. I was very welcomed by the ECCRT team who provided a pleasant and well-located place to do the training. Lectures were given by highly experienced professionals who gave a clear understanding of the drug life cycle and the required regulation... - Joana Reis (Regulatory Affairs STAR Programme)



The deep expertise of the presenters, while still being accessible, speaking in a comprehensive matter. No answer was made up. Great answers, exactly on the questions. The whole program «tells a story». Not just a bunch of slides put side by side. The best training session I had in a long, long time.

-Federico Melo Ferrer (Introduction to Oncology for Clinical Researchers)

The Programme was the perfect opportunity for me to gain practical experience in this field. The internships in 3 different organisations gave me a better view of the different job functions and possibilities. I'm ready to dive into the world of clinical research...

-Veronique Shiwa (Junior Clinical Researcher STAR Programme)

Trust



ECCRT has achieved the prestigious Qfor certification. It is a testament to our dedication to providing exceptional services and the highest standards of quality in the industry.



ECCRT has been approved by TransCelerate's GCP Mutual Recognition Program.

Some of our Trusted Customers



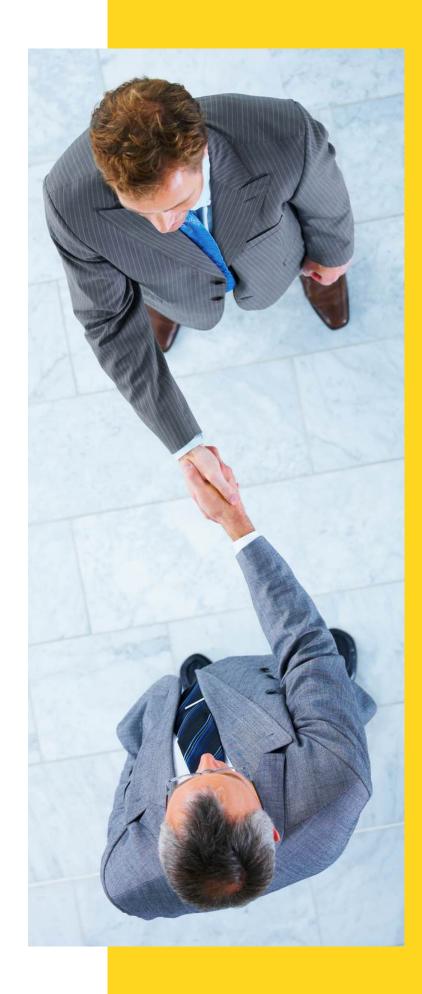












Our solutions

Our ultimate goal is to train talent by providing implementable knowledge in the day-to-day activities of our learners.

Public Courses

Individual & Group Solutions

We offer a range of face-to-face or live webinar training sessions scheduled throughout the year as well as courses in eLearning and microLearning formats.

Choose the training according to your needs and your preferred location and format.



Business Solutions

Our Tailored Solutions are personalised training services that are provided according to your specific needs.

These solutions cover a range of areas, such as tailored courses, coaching, consulting and many other solutions, with the aim of meeting all of your training needs.



Courses categories Hard skills Soft skills COMMUNICATION **TECHNICAL TRAININGS** Training sessions for anyone trying to improve Clinical Operations their communication Regulatory Courses skills. Quality Assurance • Clinical Research **MANAGEMENT** Training sessions for anyone managing a clinical trial and a team. **LEADERSHIP** Training sessions for anyone aspiring to become a leader. Course Prospectus 2025 | Public courses



Course formats

Classroom Face-to-face sessions taking place in a specific location Webinar Live interactive online sessions **eLearning** microLearning Online recorded trainings available in Online short recorded our Virtual Campus training topics that are available anytime Blended A combination of recorded and live sessions

Discount eligibility

NOTE: Discounts are not cumulative



on all our courses for hospital and university staff members, non-profit organisations, students and academia.



of the total course fee in each STAR Programme (package of trainings)



Early bird (3 months before the starting date)



Free of charge, cumulates discount until 5 purchases by the company for 10% discount

MicroLearning

microLearning is a term used for small online learning units and short-term educational activities.

microLearning is a brief, to-the-point and more engaging training format than our regular eLearning courses, covering practical topics such as CAPA, Investigator Site File, drug accountability log and many others, that will help you improve your productivity, avoid double work and bad time management.

At any time and anywhere, you can quickly access our short online educational videos that will provide you with the knowledge to accomplish your daily tasks at work.

microLearning categories:

COMMUNICATION

CLINICAL OPERATIONS

DATA

ETHICS

GCP

HOT TOPICS

LEADERSHIP

REGULATORY

Some of our microLearnings:

- •Serious Breaches in Clinical Trials
- ·How to write an effective CAPA?
- eTMF Reflections
- Linking Essential Docs with GCP
- Difference between ISO 14155 and GCP
- Informed Consent the Right Way
- •What to look for when not doing 100% SDV
- •How To Enhance Oversight of the TMF?
- •What to verify in an Investigator Site File?
- Optimising Site Selection
- Difference between Protocol Violation
- Creating Worksheets for Clinical Source Data
- Using eSource Data in clinical investigations

The full list and more information HERE.



STAR Programmes

STAR Programmes are a mix of both technical and soft skills training sessions, assuring that you will get an all-round curriculum, providing you with all competencies required for a specific function or role.

There are two more advantages to the STAR Programmes:

- We offer you the flexibility to follow the individual courses: when you register for a STAR Programme, you can freely choose the dates of the courses throughout the year, to allow minimal disturbance of your daily activities and to optimise your travel schedules.
- Secondly, the costs of the STAR Programme is 15% lower than the total price of the individual course's fees.

JUNIOR LEVEL

CLINICAL PROJECT MANAGEMENT

The perfect combination of training sessions to start or to advance in your career to become a clinical PM.

CLINICAL REGULATORY

Get a oversight of clinical study regulations with medicinal products, including the latest updates.

AUDITORS

The essential trainings
you need to start a
career as an Auditor in a
GCP environment.

CLINICAL RESEARCHER

A full week training combined with a 1-year internship to find a job in clinical research.

MEDICAL DEVICES

Learn the different products, legislations, concepts and strategies for medical devices.

REGULATORY AFFAIRS

A full week training with a 1-year internship to help you have the expertise required to start a career.

CLINICAL TRIAL ASSISTANT

Learn everything you need to know to become a successful Clinical Trial Assistant.

ADVANCED LEVEL

AUDITORS

Intended for experienced auditors who need the skills and expertise to advanced in their career.

CLINICAL RESEARCHER

Especially for CRAs who are eager to further develop their professional soft and technicall skills.

ADVANCED LEVEL

PROJECT MANAGEMENT

Targeted to Project Managers who wish to advance in their professional career.

Course Schedule

Many training topics are available upon request, even if these aren't scheduled.

You can either request to join our waiting list for the next session or ask for a tailored project for your organisation. For the eLearnings, please go to page 27.



For clients in the Flemish region of Belgium, we proudly accept KMO subsidies, enabling you to enhance your team's skills cost-effectively through employee training and development.



If you're in the Walloon region, we support Cheque Formation, providing financial assistance to make our courses more accessible.



CLINICAL OPERATIONS COURSES



| COURSE | FORMAT | LOCATION | JAN | FEB | MAR | APR | MAY | JUNE | JULY | AUG | SEPT | ОСТ | NOV | DEC |
|--|-----------|-------------------|-----|-----|---------|-----|--------------------|------|-------|-----|---------|-------|-----|-------|
| ADVANCED CLINICAL PROJECT MANAGEMENT | CLASSROOM | BRUSSELS | | | 17 & 18 | | | | | | | 6 & 7 | | |
| ADVANCED CRO MANAGEMENT AND OVERSIGHT | CLASSROOM | BRUSSELS | | | 20 | | | | | | | 9 | | |
| BUDGETING CLINICAL STUDIES | CLASSROOM | BRUSSELS | | | | | | | | | | | 27 | |
| CLINICAL PROJECT MANAGEMENT | BLENDED | BRUSSELS & ONLINE | | 17 | | | | | | | 29 | | 24 | |
| CLINICAL RESEARCH TRAINING FOR CLINICAL TRIAL ASSISTANTS | CLASSROOM | BRUSSELS | | | | | | | | | | 1 | | |
| CLINICAL RESEARCH TRAINING FOR JUNIOR CRAS | CLASSROOM | BRUSSELS | | | 26 & 27 | | | | 2 & 3 | | | 1 & 2 | | |
| CLINICAL RESEARCH TRAINING FOR JUNIOR CRAS | WEBINAR | ONLINE | | | | | 13 & 15 20 & 22 | | | | | | | |
| CLINICAL RESEARCH TRAINING FOR JUNIOR CRAS | CLASSROOM | AMSTERDAM | | | | | | | | | | | | 3 & 4 |
| CLINICAL RESEARCH TRAINING FOR SENIOR CRAS | BLENDED | BRUSSELS & ONLINE | | | | | 12 | | | | | 13 | | |
| COMPUTER SYSTEM VALIDATION FOR CLINICAL OPERATIONS | CLASSROOM | BRUSSELS | | | | | | | | | 22 & 23 | | | |
| DESIGNING CLINICAL RESEARCH PROTOCOLS FOR A BETTER OUTCOME | | BRUSSELS & ONLINE | | | | | | | | | | 1 | | |

CLINICAL OPERATIONS COURSES



| COURSE | FORMAT | LOCATION | JAN | FEB | MAR | APR | MAY | JUNE | JULY | AUG | SEPT | ОСТ | NOV | DEC |
|--|-----------|----------|---------|-----|-----|-----|-----|------|------|-----|---------|-----|-----|-----|
| FOUNDATIONAL ICH-GCP E6 (R3) | CLASSROOM | BRUSSELS | | | 31 | | 21 | | | | | | 12 | |
| FOUNDATIONAL ICH-GCP E6 (R ₃) | WEBINAR | ONLINE | 28 & 30 | | | | | | | | 23 & 25 | | | |
| ICH- GCP E6 (R3) REFRESHER | WEBINAR | ONLINE | | 18 | | | 26 | | | | 30 | | 25 | |
| ICH-GCP E6 (R ₃) REFRESHER <u>US EDITION</u> | WEBINAR | ONLINE | | | 27 | 29 | 27 | 26 | 17 | 26 | 16 | 28 | 20 | 18 |
| FUNDAMENTALS OF EFFECTIVE CRO MANAGEMENT AND OVERSIGHT | CLASSROOM | BRUSSELS | | 19 | | | | | | | | | 26 | |
| GETTING THE RIGHT LEVEL OF SPONSOR OVERSIGHT | CLASSROOM | BRUSSELS | | | 19 | | | | | | | 8 | | |
| KEEPING OVERSIGHT OF DATA MANAGEMENT FOR CLINICAL PROJECT MANAGERS | WEBINAR | ONLINE | | | 24 | | | | | | | 13 | | |
| MAKING INFORMED CRO SELECTION FOR CLINICAL TRIAL SUCCESS | CLASSROOM | BRUSSELS | | | | | | | | | | 10 | | |
| MANAGING THE TMF AND BASICS OF CLINICAL TRIAL SYSTEMS | CLASSROOM | BRUSSELS | | | | | | | | | | 2 | | |
| ORIENTING YOUR CAREER IN CLINICAL RESEARCH | CLASSROOM | BRUSSELS | | | 25 | | | | 1 | | 30 | | | 2 |

ourse Prospectus 2025 | Public courses

CLINICAL OPERATIONS COURSES



| COURSE | FORMAT | LOCATION | JAN | FEB | MAR | APR | MAY | JUNE | JULY | AUG | SEPT | ОСТ | NOV | DEC |
|---|-----------|-------------------|-----|-----|-----|-----|-----|---------|------|-----|------|-----|-------|-----|
| PLANNING FOR A SUCCESSFUL MANAGED OR EARLY ACCESS PROGRAMME | WEBINAR | ONLINE | | | | | | | | | | | 6 | |
| RISK BASED MONITORING | BLENDED | BRUSSELS & ONLINE | | | | | 13 | | | | | 15 | | |
| RISK MANAGEMENT IN CLINICAL RESEARCH | BLENDED | BRUSSELS & ONLINE | | | | | | | | | | | 25 | |
| RUNNING MEDICAL DEVICE STUDIES | CLASSROOM | BRUSSELS | | | | | | 17 & 18 | | | | | 5 & 6 | |
| ADVANCING CLINICAL TRIALS WITH ARTIFICIAL INTELLIGENCE | CLASSROOM | BRUSSELS | | | | | | | | | | 21 | | |

THE FOLLOWING COURSES AREN'T SCHEDULED, BUT CAN BE REQUESTED AS A TAILORED COURSE (CHOOSE THE TOPIC, THE LOCATION, THE TIMING, ETC).

GMP ESSENTIALS FOR CLINICAL OPERATIONS STAFF

REMOTE MONITORING AND OPPORTUNITIES DURING COVID-19 AND BEYOND

THE ECG IN CLINICAL RESEARCH

TRANSFER OF SPONSORSHIP OF ONGOING TRIALS

SAFEGUARDING DATA INTEGRITY IN HIGHLY REGULATED ENVIRONMENTS

STAR PROGRAMMES



A strategic combination of training sessions that will allow you to develop the knowledge and skills required for a specific job function.

| COURSE | FORMAT | LOCATION | JAN | FEB | MAR | APR | MAY | JUNE | JULY | AUG | SEPT | ОСТ | NOV | DEC |
|---|-----------|-------------------|-----|---------|---------|-----|---------|---------|------|-----|------|---------|---------|-----|
| ADVANCED CLINICAL RESEARCHER STAR PROGRAMME | CLASSROOM | BRUSSELS & ONLINE | | | | | 12 - 14 | | | | | 13 - 14 | | |
| ADVANCED PROJECT MANAGEMENT STAR PROGRAMME | WEBINAR | ONLINE | | | 17 - 27 | | | | | | | 6 - 16 | | |
| CLINICAL PROJECT MANAGEMENT STAR PROGRAMME | CLASSROOM | BRUSSELS | | 17 - 20 | | | | | | | | | 24 - 26 | |
| CLINICAL TRIAL ASSISTANT STAR PROGRAMME | CLASSROOM | BRUSSELS | | | | | | | | | | 1 - 3 | | |
| JUNIOR CLINICAL RESEARCHER STAR PROGRAMME | CLASSROOM | BRUSSELS | | | 25 - 27 | | | | | | | 1 - 3 | | |
| MEDICAL DEVICES STAR PROGRAMME | CLASSROOM | BRUSSELS | | | | | | 16 - 18 | | | | | 4 - 6 | |

CLINICAL RESEARCH COURSES



| COURSE | FORMAT | LOCATION | JAN | FEB | MAR | APR | MAY | JUNE | JULY | AUG | SEPT | ОСТ | NOV | DEC |
|---|-----------|----------|-----|-----|-----|-----|---------|-------|------|-----|------|---------|---------|-----|
| BRIDGING PRE-CLINICAL AND CLINICAL DEVELOPMENT | CLASSROOM | LONDON | JAN | ILD | MAK | AFR | 14 & 15 | JOIAL | JOLI | AUG | JLF1 | OCI | NOV | DEC |
| BRIDGING PRE-CLINICAL AND CLINICAL DEVELOPMENT | CLASSROOM | BRUSSELS | | | | | | | | | | | 20 & 21 | |
| DATA MANAGEMENT ESSENTIALS FOR CLINICAL PROJECT MANAGERS | CLASSROOM | BRUSSELS | | | | | | | | | | | 13 | |
| DATA PROTECTION IN CLINICAL RESEARCH AND GDPR IN ACTION | CLASSROOM | BRUSSELS | | | | | | 19 | | | | | | |
| DECENTRALISED CLINICAL TRIALS | CLASSROOM | BRUSSELS | | | | | 22 & 23 | | | | | | | |
| INTRODUCTION TO ONCOLOGY FOR CLINICAL RESEARCHERS | CLASSROOM | BRUSSELS | | | | | | | | | | 21 & 22 | | |
| KEEPING OVERSIGHT OF SAFETY FOR CLINICAL PROJECT MANAGERS | WEBINAR | ONLINE | | | 27 | | | | | | | 16 | | |
| LEGAL BASICS FOR CLINICAL STUDY CONTRACTS | CLASSROOM | BRUSSELS | | 20 | | | | | | | | | 27 | |
| PHARMACOVIGILANCE SYSTEM COMPLIANCE DURING MEDICAL PRODUCT LIFE CYCLE | CLASSROOM | BRUSSELS | | | | | | | | | | | 17 & 18 | |

CLINICAL RESEARCH COURSES



| THE FOLLOWING COURSES AREN'T SCHEDULED, BUT CAN BE REQUESTED AS A TAILORED COURSE (CHOOSE THE TOPIC, THE LOCATION, THE TIMING, ETC). |
|--|
| CLINICAL DEVELOPMENT OF A VACCINE |
| EFFECTIVE MEDICAL WRITING & DATA PRESENTATION |
| HOW TO PREPARE YOUR VACCINE CANDIDATE FOR CLINIC |
| INTRODUCTION TO PAEDIATRIC CLINICAL DEVELOPMENT |
| INTRODUCTION TO STATISTICS |
| LABORATORY TESTING IN CLINICAL RESEARCH |
| WRITING PROCEDURAL DOCUMENTS |

SOFT SKILLS COURSES



| COURSE | FORMAT | LOCATION | JAN | FEB | MAR | APR | MAY | JUNE | JULY | AUG | SEPT | ост | NOV | DEC |
|-------------------------|-----------|----------|-----|-----|-----|-----|-----|------|------|-----|------|-----|-----|-----|
| COMMUNICATION SKILLS | CLASSROOM | BRUSSELS | | | | | | | | | | 3 | | |
| PEOPLE MANAGEMENT | CLASSROOM | BRUSSELS | | 21 | | | | | | | | | 28 | |

| | THE FOLLOWING COURSES AREN'T SCHEDULED, BUT CAN BE REQUESTED AS A TAILORED COURSE (CHOOSE THE TOPIC, THE LOCATION, THE TIMING, ETC). |
|-----------------------|--|
| CHANGE MANAGEMEI | IT FOR CLINICAL RESEARCH |
| COMMUNICATING WIT | H EU REGULATORS/HEALTH AUTORITIES |
| INFLUENCING SKILLS | |
| INTERCULTURAL TEAM | MANAGEMENT: HOW TO SUCCESFULLY LEAD |
| LEADING IN A SOLUTION | ON FOCUSED WAY |
| LINE MANAGEMENT E | SSENTIALS |
| MICROSOFT PROJECT | BASICS FOR CLINICAL PROJECT MANAGERS |
| STRESS PREVENTION | AT WORK |
| TIME MANAGEMENT | |
| TRAIN THE TRAINER | |

REGULATORY COURSES



| COURSE | FORMAT | LOCATION | JAN | FEB | MAR | APR | MAY | JUNE | JULY | AUG | SEPT | ОСТ | NOV | DEC |
|--|-----------|----------|-----|-----|-----|-----|-----|------|------|-----|------|---------|-----|-----|
| INTRODUCTION TO REGULATORY AFFAIRS | WEBINAR | ONLINE | | | | | | | | | 18 | | | |
| MEDICAL DEVICE REGULATIONS | CLASSROOM | BRUSSELS | | | | | | 16 | | | | | 4 | |
| ORIENTING YOUR CAREER IN REGULATORY AFFAIRS | CLASSROOM | BRUSSELS | | | | | | | 8 | | | | | |
| THE BELGIAN CLINICAL TRIALS LAW OF 2017: A CLEAR VIEW ON RULES | WEBINAR | ONLINE | | | | | | | | | | 23 | | |
| THE EUROPEAN CLINICAL TRIAL REGULATION 536/2014 | WEBINAR | ONLINE | | | | | | | | | | | 20 | |
| UNDERSTANDING AND COMPLYING WITH THE EU CTR | CLASSROOM | BRUSSELS | | 11 | | | | | | | | | | |
| UNDERSTANDING AND COMPLYING WITH THE EU CTR | WEBINAR | ONLINE | | | | | | | | | | 15 & 17 | | |

REGULATORY COURSES



| THE FOLLOWING COOKSES AREN'T SCHEDOLED, DOT CAN DE REQUESTED AS A TAILORED COOKSE (CHOOSE THE TOPIC, THE LOCATION, THE HIMING, ETC | SCHEDULED, BUT CAN BE REQUESTED AS A TAILORED COURSE (CHOOSE THE TOPIC, THE LOCATION, THE TIMING, ETC). | C). |
|--|---|-----|
|--|---|-----|

CLINICAL INVESTIGATIONS: IMPLEMENTATION OF MDR 2017/745 IN BELGIUM

EU CTR AND SERIOUS BREACHES

EUROPEAN LEGISLATION FOR CLINICAL RESEARCH - IMPLEMENTATION IN BELGIUM

GOOD CLINICAL LABORATORY PRACTICE

GOOD MANUFACTURING PRACTICE (GMP)

GOOD DISTRIBUTION PRACTICE (GDP)

HOW TO COPE WITH DEVELOPMENT OF DRUG-DEVICE COMBINATIONS?

IMPACT OF THE EU CTR 536/2014 ON OUR ORGANISATION

ISO14155 TRAINING

READY FOR THE IVDR? REGULATORY IMPACT AND MILESTONES FOR CE MARKING

STAR PROGRAMMES

A strategic combination of training sessions that will allow you to develop the knowledge and skills required for a specific job function.

| COURSE | FORMAT | LOCATION | JAN | FEB | MAR | APR | MAY | JUNE | JULY | AUG | SEPT | ОСТ | NOV | DEC |
|---------------------------------------|-----------|----------|-----|-----|-----|-----|-----|------|------|-----|---------|-----|-----|-----|
| CLINICAL REGULATORY STAR PROGRAMME | WEBINAR | ONLINE | | | | | | | | | | | 20 | |
| REGULATORY AFFAIRS STAR PROGRAMME | CLASSROOM | BRUSSELS | | | | | | | | | 18 - 26 | | | |

Course Prospectus 2025 | Public courses

QUALITY ASSURANCE COURSES



| COURSE | FORMAT | LOCATION | JAN | FEB | MAR | APR | MAY | JUNE | JULY | AUG | SEPT | ОСТ | NOV | DEC |
|--|-----------|----------|-----|-----|-----|-----|-----|------|------|-----|-------|-----|-----|-----|
| A RISK-BASED APPROACH TO CLINICAL AUDITS | CLASSROOM | BRUSSELS | | | | | | | | | 17 | | | |
| AUDIT AND INSPECTION READINESS - HOW TO BE PREPARED! | CLASSROOM | BRUSSELS | | | | | 27 | | | | 10 | | | |
| AUDITING CLINICAL DEVELOPMENT DOCUMENTS | WEBINAR | ONLINE | | | | | | | | | 11 | | | |
| CLINICAL SERVICE PROVIDER AUDITS | CLASSROOM | BRUSSELS | | | | | | | | | 18 | | | |
| COMMUNICATION AND APPRECIATIVE AUDITING | WEBINAR | ONLINE | | | | | | | | | 12 | | | |
| INTRODUCTION TO SYSTEM AUDITS FOR CLINICAL AUDITORS | CLASSROOM | BRUSSELS | | | | | | | | | 15 | | | |
| INTRODUCTORY COURSE ON AUDITING INVESTIGATOR SITES | CLASSROOM | BRUSSELS | | | | | | | | | 8 & 9 | | | |
| SPONSOR CO- MONITORING | CLASSROOM | BRUSSELS | | | | | 14 | | | | | 14 | | |
| WRITING AUDIT REPORTS | CLASSROOM | BRUSSELS | | | | | | | | | 16 | | | |
| WRITING CLINICAL STUDY REPORTS | CLASSROOM | BRUSSELS | | | | | | | | | | | 20 | |

QUALITY ASSURANCE COURSES



THE FOLLOWING COURSES AREN'T SCHEDULED, BUT CAN BE REQUESTED AS A TAILORED COURSE (CHOOSE THE TOPIC, THE LOCATION, THE TIMING, ETC).

REMOTE AUDITING

STAR PROGRAMMES

A strategic combination of training sessions that will allow you to develop the knowledge and skills required for a specific job function.

| COURSE | FORMAT | LOCATION | JAN | FEB | MAR | APR | MAY | JUNE | JULY | AUG | SEPT | ОСТ | NOV | DEC |
|-----------------------------------|-----------|----------|-----|-----|-----|-----|-----|------|------|-----|--------|-----|---------|-----|
| JUNIOR AUDITORS STAR PROGRAMME | CLASSROOM | BRUSSELS | | | | | | | | | 8 - 12 | | | |
| ADVANCED AUDITORS STAR PROGRAMME | CLASSROOM | BRUSSELS | | | | | | | | | | | 15 - 18 | |

ELEARNING



| REGULATORY | COURSE CREDIT |
|---|---------------|
| BASICS ON REGULATORY REQUIREMENTS IN CLINICAL RESEARCH | 2H |
| CLINICAL TRIAL REQUIREMENTS: COMPARING EUROPE WITH THE USA | 6H |
| FOUNDATIONAL ICH-GOOD CLINICAL PRACTICE (GCP) E6 (R3) | 5H30 |
| GCP ESSENTIALS IN 90 MINUTES | 1H30 |
| GOOD MANUFACTURING PRACTICE (GMP) IN RELATION TO GCP | 6H |
| ICH E8 R1 GUIDELINE COURSE: CLINICAL RESEARCH BEST PRACTICES | COMING SOON |
| ICH-GCP E6 (R2) REFRESHER + COMPLEMENTARY ICH-GCP REFRESHER FOR BIOMETRICS STAFF | 5.5H |
| ICH-GCP E6 (R2) REFRESHER + COMPLEMENTARY ICH-GCP REFRESHER FOR REGULATORY STAFF | 5H |
| ICH-GOOD CLINICAL PRACTICE (GCP) E6 (R3) REFRESHER | 4H |
| ICH-GOOD CLINICAL PRACTICE (GCP) E6 (R2) FOR INVESTIGATORS | 3H |
| IMPLEMENTING GDPR IN YOUR ORGANISATION | 3H |
| ISO GCP (ISO 14155) REFRESHER TRAINING FOR CLINICAL INVESTIGATIONS WITH MEDICAL DEVICES | 2H |
| ISO 14155 GOOD CLINICAL PRACTICE TRAINING | 4H |
| THE EUROPEAN CLINICAL TRIAL DIRECTIVE FOR MEDICINAL PRODUCTS | 5H |

| CLINICAL OPERATIONS | COURSE CREDIT |
|--|---------------|
| INTRODUCTION TO CLINICAL RESEARCH | 3H |
| INTRODUCTION TO CLINICAL RESEARCH WITH MEDICAL DEVICES | 2H3O |
| WHAT IS THE ROLE OF A CLINICAL RESEARCH ASSOCIATE (CRA) AND HOW CAN A MSL SUPPORT? | 1H |

| CLINICAL RESEARCH | COURSE CREDIT |
|-----------------------------------|------------------|
| CLINICAL DEVELOPMENT OF A VACCINE | 5H |
| DRUG DEVELOPMENT CYCLE | MODULE 1 : 0.45H |



Tailored Solutions

Our 360-degree approach is built on a foundation of diverse services tailored to meet the specific needs of your teams and company.

By utilizing all these services in harmony, ECCRT ensures that your teams are equipped with the knowledge, skills, and resources they need to excel in clinical research.

We believe that excellence in this field is not achieved through a single approach but through a 360-degree perspective that addresses every facet of the journey.

Whether you're seeking to enhance the capabilities of your team, streamline your processes, or adapt to the ever-evolving landscape of clinical research, our 360-degree approach is here to make miracles happen for your teams and your company.



Tailored Courses

Request any training about clinical research related topic for your organisation.

You can decide:

• Topic

(what points to focus on that subject)

Training format

(face-to-face or live webinar and via eLearning sessions. Some trainings are sometimes blended, i.e. carried out combining different formats)

- Location of the training
- Number of participants

Process



We create a training plan We deliver the training We'd love to hear your assessment of the training!

5.Feedback

2.Assessment

4.Training

Competency Framework

Competency Framework is a standard mapping of competencies to roles, used to help organisation assess and manage individual and collective work performance.

Based on the developments of the Joint Task Force for Clinical Trial Competency and on our vast expertise in Clinical Research, ECCRT has taken the Competency Framework concept a step further to fit your specific needs.



The Competency domain includes:

- Scientific Concept and Research Design
- Ethical Participant Safety Consideration
- Clinical Studies Operations (GCPs or ISO 14155)
- Study and Site Management
- Leadership and Professionalism



Team To Go



The Team To Go programme focuses on your team and on the communication between each stakeholder in order to increase efficiency in the day-to-day activities of a team.

Team To Go (TTG) is not only about training a team on specific skills, but it is also about bonding the team for success. Not designed to be a one-time effort, it will provide guidance and coaching to your team throughout the project in order to have a successful outcome.

The main 3 components are:

Core team meeting

- •Define the client team vision and means •Define goals and objective
- •Define KPI

Teaming

•Team building and workshops to enhance team dynamics & performance

Guiding & Coaching

- •Ongoing training via an online forum and Q&A sessions
- •Coaching individuals, including performance management and competency assessment

Link: <u>https://eccrt.com/team-to-g</u>

Coaching

At ECCRT, we aim at guiding you and your team to succeed and to brilliantly face new challenges.

Therefore, we have put different coaching solutions in place that will be beneficial for you: career, personal and team coaching.

Together with our expert coaches you will achieve your goals.

You can choose between:

- Coaching on how to start your career in Clinical Research
- Coaching on how to advance in your career, in Clinical Research

Mentoring

ECCRT is your ideal partner to provide mentoring that empower individuals to thrive in the field of clinical research.

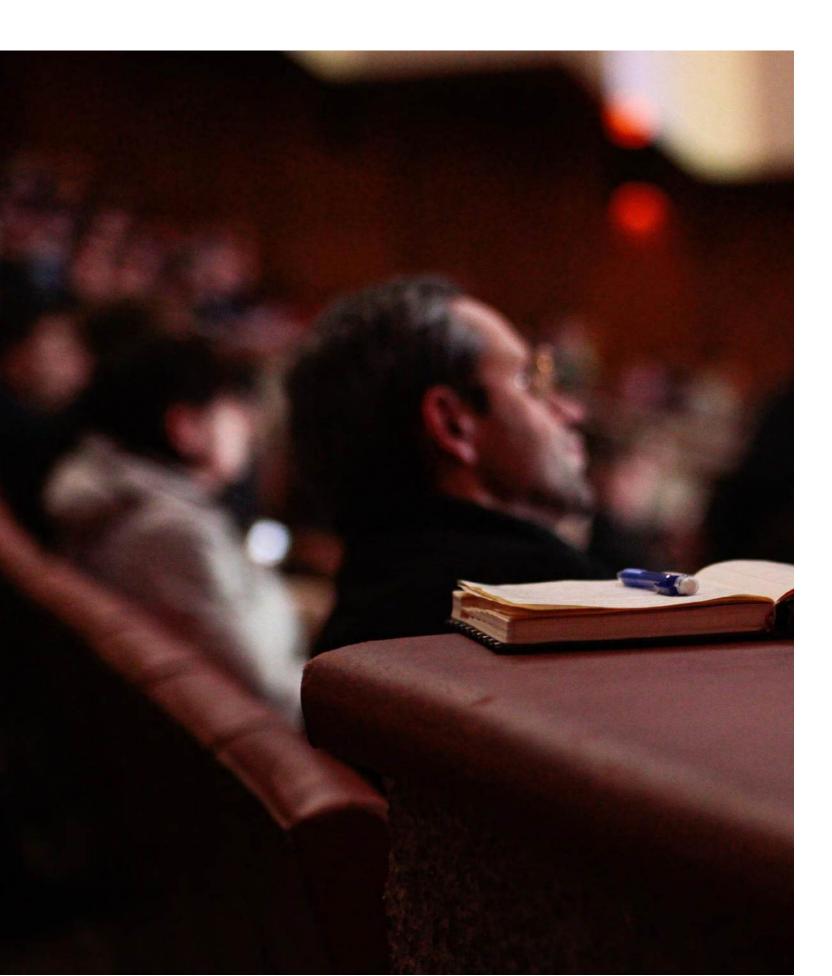
Our mentoring initiatives are designed to bridge the gap between theoretical knowledge and practical application in the complex world of clinical research. They pair seasoned industry experts with eager learners, creating a dynamic and supportive learning environment.

This hands-on approach ensures mentees develop the skills and confidence needed to excel in their jobs.





Behavioural Change



Did you find difficulties in following-up with any training?

Do you struggle with changing the performance and activities of your staff?

ECCRT is providing training and development programmes that combine conventional training tools and approaches with innovative interventions rooted in evidence from behavioural sciences and tailored to the clients circumstances and requirements.

What does it imply?

BEHAVIOURAL DIMENSION

Behavioural dimension to Learning and Development, through galvanising the entrepreneurial potential of employees

EMPIRIC RESULTS

Creation and monitoring of data-driven and evidenceinformed approach based on the principles of design, behavioural and educational sciences principles

INNOVATIVE LEARNING Areas such as stimulating/revitalising innovation, ensuring compliance, strengthening entrepreneurial and intrapreneurial culture, designing robust Learning and Development interventions

Clinical Development Excellence

Journey to Excellence

We commit to lower the risk of failing your clinical development because, as clinical research experts, we help you tackle the challenges you face such as delayed timelines, lack of quality, high costs etc.

Reducing risks

Team development

Our experienced mentors accompany you throughout the clinical development process and assure the streamlined involvement and development of your teams.

More than just expertise, it is all about mentoring

Is your team lacking <u>engagement or facing</u> inefficiencies? Have you ever noticed insufficient conformity or quality? Are you often confronted with uncontrolled financial losses

Our mentors will accompany your teams throughout the

due to the risks faced during clinical development?

journey of the clinical research process with a 360°

development approach.

TECHNICAL EXPERTISE

Thanks to our strong network of experts, we can clearly identify the gaps and propose high-quality training, to build the foundation of the required knowledge.

ON-THE-JOB MENTORING

Our experienced mentors will accompany your staff by providing "learning-on-the-job" tasks in order to consolidate the previously acquired concepts and deepen their clinical development knowledge;

COMPETENCIES DEVELOPMENT

Ultimately, your staff will develop their competencies, become more effective and increase the value of your organisation.

Consulting

Our approach is rooted in our own Competency Framework, which defines the essential domains and cognitive skills needed for conducting high-quality, ethical, and safe clinical trials.

Our ultimate goal is to empower teams to apply the knowledge gained practically. With our expert consultants, trainers, and coaches, who are chosen for their professional expertise, we always encourage interactive learning within the group.

What can we do for you?

Let's say you are recruiting new staff and you need to harmonize and bond the current team with new workers, here is what we can do for you:

- Make an inventory of the current clinical operations group
- Provide on-boarding for the new team members
- Bond the team for success
- Create an inventory of the competencies needed and available
- Advise on training in order to assure all required competencies are available





Our trainers





Christophe De

Vleeschouwer

An Vijverman





Erwin Cayenberghs

Andrea Rossi



Angeles Escarti-Nebot









Bodo Lutz







Evren Henslegers



Fabienne Zeegers

Anicet Tchibozo



Francisco Hernandez

Annemieke Den Boer



Geert Briers

Benedikt Van

Nieuwenhove

Hedwig Beernaert

Hugues Bogaerts

Ingrid Van Klooster

Jean Van Rampelbergh

Joris Vandeputte

Julie Barnett

Karen Gabriels



Katrien Clinckx



Kevin Punie



Kieron Lewis



Koen Nauwelaerts



Kristof Vercruysse



Liesbeth Lemmens



Lieve Vrints

Our trainers



ARE YOU INTERESTED IN BECOMING A TRAINER?

Join us

ECCRT has a broad network of trainers, coaches and subject matter experts, always providing you with the best and most up-to-date insights and hands-on learning. To keep providing valuable content to students, we are constantly looking for new trainers to share their expertise.

Contact us at info@eccrt.com or +32 (0)2 504 07 20 and we'll work together on creating a great learning experience.

Questions & Answers

1.I am new to Clinical Research, which courses can I follow?

Training is the key to clinical research development. The more education and training you follow, the better suited you are for your job. ECCRT can offer you a wide variety of training sessions, to be up to date with the new trends, regulations and topics in clinical research.

- Introduction to Clinical Research
- Junior CRA Training
- Orienting your Career
- Foundational GCP
- Introduction to Regulatory Affairs

Contact us for more information.

2.Do I have to create an account for myself or the person I am booking the course for?

If you have to book a course for someone else, we ask that you create an account for yourself.

When booking the course please mention the name and email address of the participant.

3.Do we receive a certificate at the end of the course?

Everyone who participates in our courses receives a **certificate of attendance**. We also offer a **Certificate of Achievement** for a growing selection of our courses.

The Certificate of achievement can only be given to participants who completed their test with a score of at least 70%. Participants are allowed to consult their course notes and the extensive training material provided.

In the case of an online grading test, you will be offered to download your digital certificate directly from the ECCRT Virtual Campus once you've completed your test.

All certificates are globally recognised.

4. What is ECCRT's cancellation policy?

If you need to cancel your registration, the following cancellation terms are applicable:

- Cancellation by ECCRT: due to unforeseen circumstances, it is possible that the training programme may change and the ECCRT reserves the right to alter the venue or to cancel the event.
- Cancellation by the registrant:
 - More than 30 calendar days prior to the course: no cancellation fee will be charged.
 - Between 21–30 calendar days prior to the course: 50% of the fee will be charged
 - Less than 21 days prior to the course or if no notification is received: the registrant will be liable to pay the full course fee.
- An administration fee of 50 EUR can be charged for each cancellation.
- Alternative delegates may replace a registrant; however all cancellations/replacements must be received in writing.

ECCRT reserves the right to reschedule or cancel classes up to **two weeks prior** to the scheduled date. Registered participants will be informed of any such changes.

Theils Your For choosing ECCRT



Follow us on social media, to keep yourself up to date:









