Make your way into the

Clinical Research or Regulatory Affairs worlds

Virginie Hamtiaux, Senior Trainer and Business Coach at ECCRT
Testimonial Zhanar Mustapova ECCRT Intern

Gent, November 2025

EUROPEAN CENTRE FOR
CLINICAL RESEARCH TRAINING

MISSION

Upholding professional excellence

Our mission is to facilitate Clinical Research professionals to excel in their job for the benefit of patients. We aim to achieve this by providing clinical research professionals with competencies to develop new therapies for patients quicker & more efficient, without jeopardizing quality.

Effective Learning Approach

Innovation

Human Centred Approach

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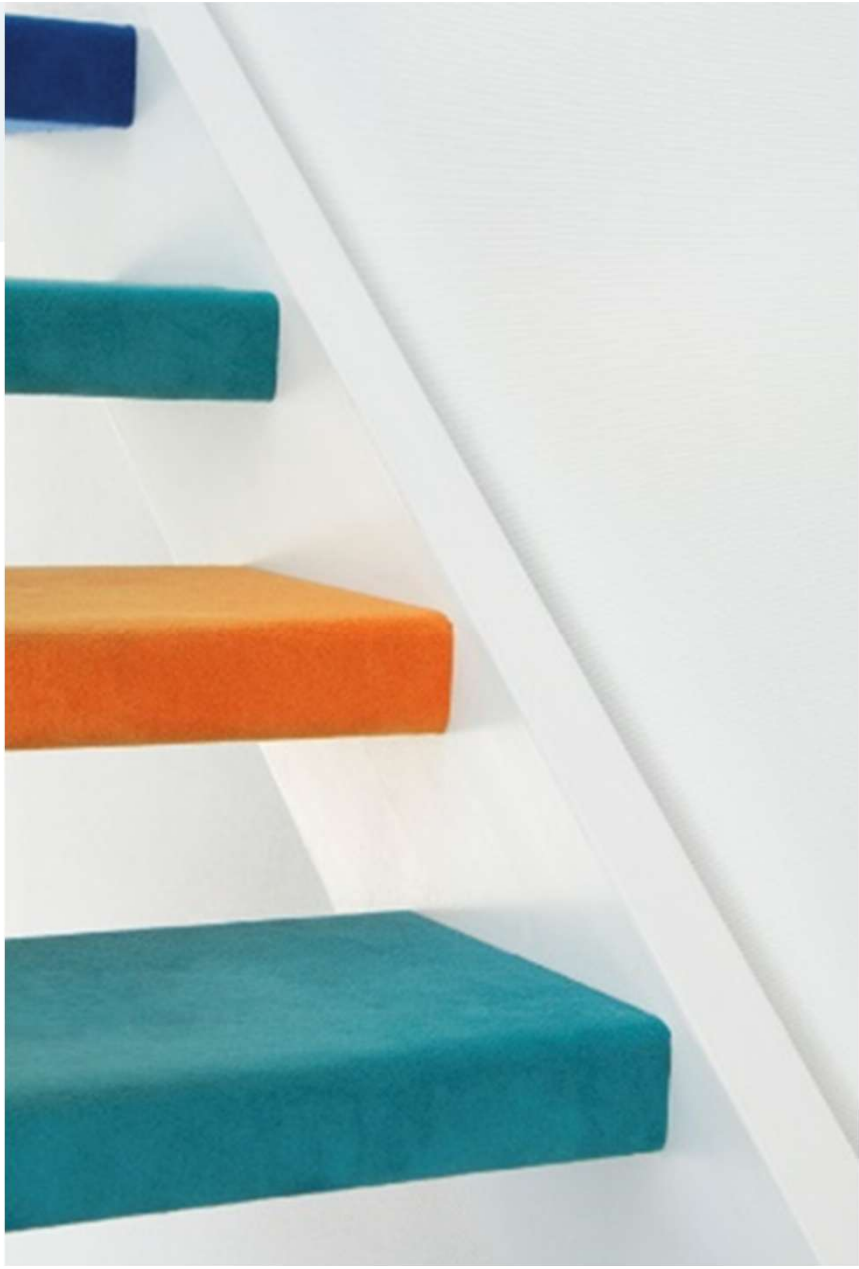
Agenda:

1. Drug Development Overview
2. Regulatory Affairs and Clinical Research
3. Boost your competencies to find a job
4. ECCRT STAR programs



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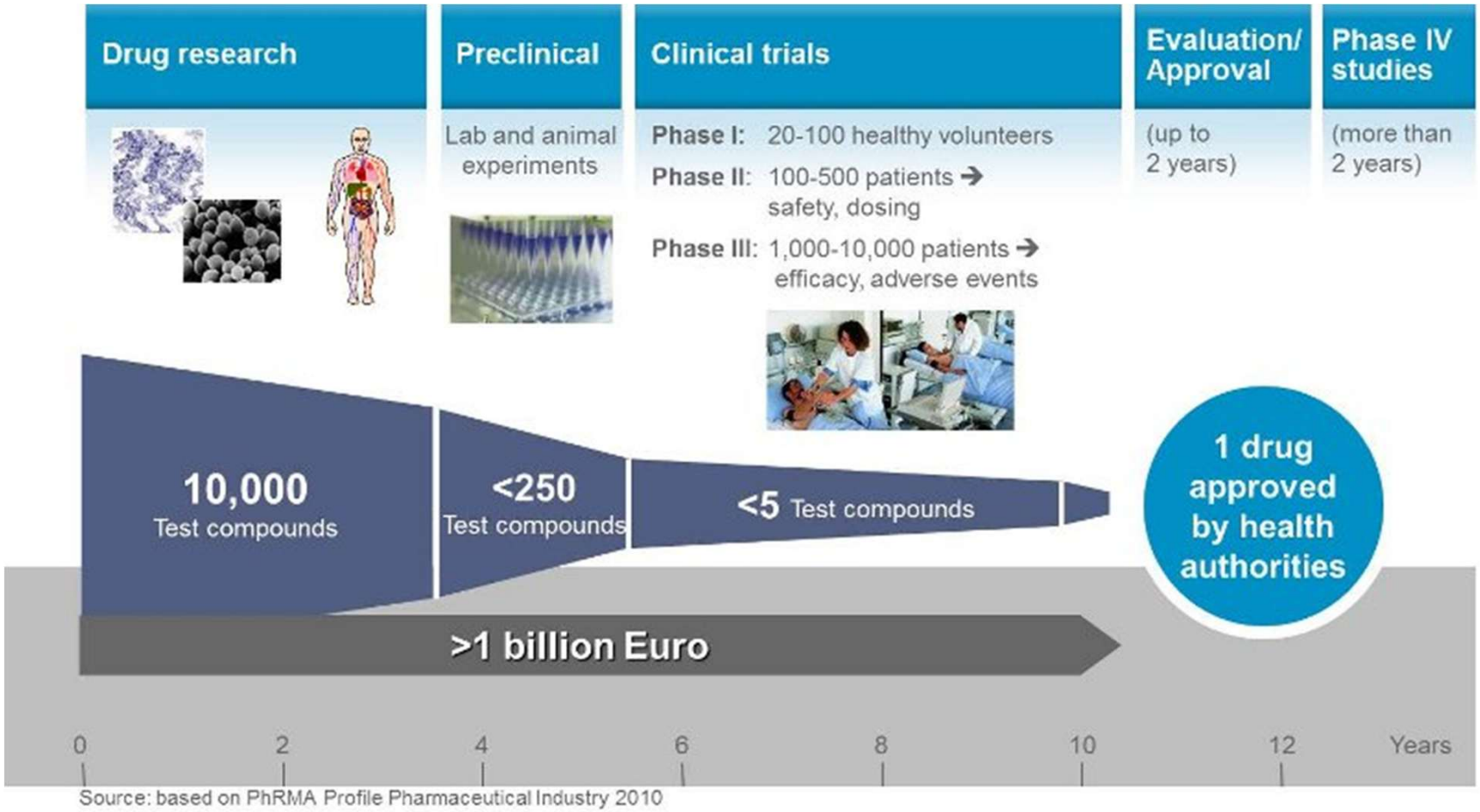
Drug Development Overview



Source: based on PhRMA Profile Pharmaceutical Industry 2010

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The Pharma Industry: Regulatory Affairs

Regulatory Affairs

Registration
Marketing Authorisation

Clinical

Part of R&D

Market Access

Health Economics
RWE
Reimbursement

Marketing

Sales force
Medical Scientific Liaison

Training Talent

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Regulatory Affairs

Regulatory affairs (RA), is a profession within regulated industries, such as pharmaceuticals, medical devices, energy, banking, telecom etc. Regulatory affairs also has a very specific meaning within the healthcare industries (pharmaceuticals, medical devices, biologics and functional foods).

Mission of RA in drug development

- Ensure products can be:

➢ Developed
➢ Authorized
➢ Maintained on the market

- in line with all applicable legislations & regulations
- through continuous collaboration with partner functions

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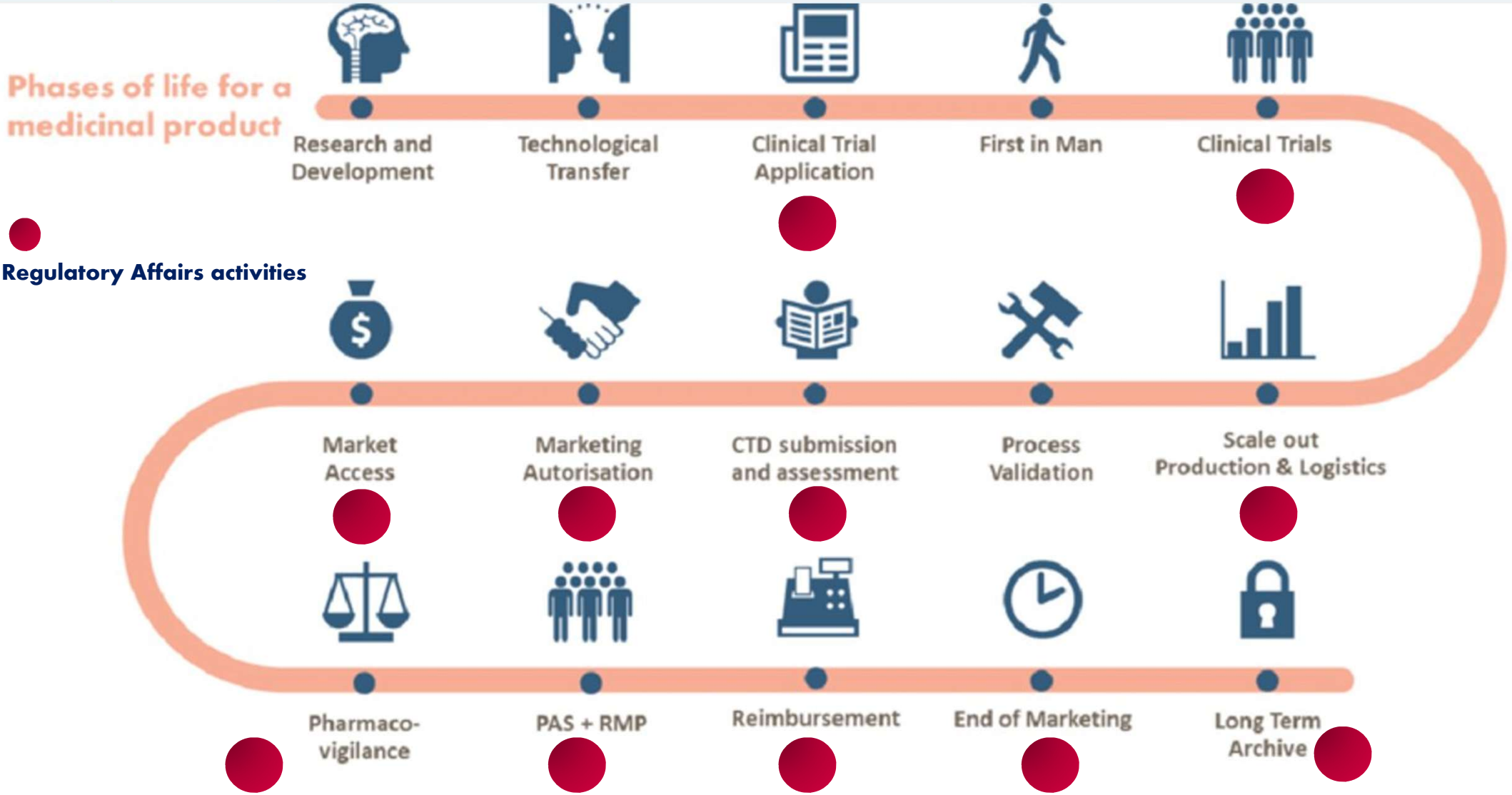
Pharmaceutical legislation

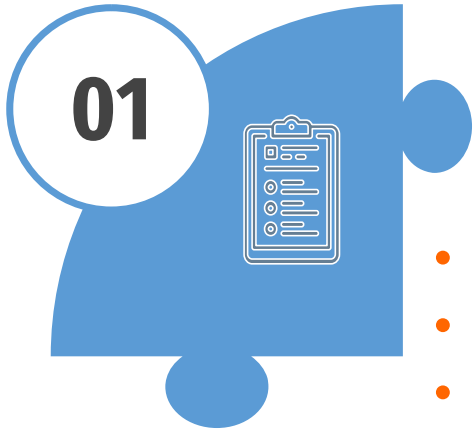
- A **Marketing Authorisation (MA)** can only be obtained if a company provides sufficient data that show that the medicine:
  - Has the effect that is claimed (**efficacy**)
  - Is (relatively) harmless (**safety**)
  - Is of acceptable and constant quality (**quality**)
- Post-authorisation, the **benefit-risk balance (B/R)** should remain to be favourable!



Jobs in Regulatory Affairs

Regulatory Affairs

Registration
Marketing Authorisation (MA)



- Submission for Marketing Authorisation (MA)
- Chemistry Manufacturing Control (CMC)
- Labelling
- Good Distribution Practice (GDP)
- Pharmacovigilance (PV)
- Regulatory Policy and Intelligence
- Information and Publicity

Examples of job title:
Associated Regulatory Affairs
Regulatory Affairs Manager
Regulatory Officer
Regulatory Affairs Specialist
Labelling Operation Manager
Pharmacovigilance associated
Regulatory CMC consultant
Ect ….

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Regulatory Affairs STAR Programme – 24 Sept 2026

Comprehensive Course Programme

- Introduction to Regulatory Affairs
- Life Cycle of a pharmaceutical product
- Submission for Marketing Authorisation
- Chemistry, Manufacturing and Controls
- Labelling, GMP
- Good Distribution Practice
- Regulatory Information
- Pharmacovigilance
- Information and publicity

Practical Traineeship

Optional

Pharmaceutical or Consultancy Company

Duration: 6 months

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The Pharma Industry: Clinical Research

Regulatory Affairs

Registration, Marketing Authorisation

Clinical

Part of R&D

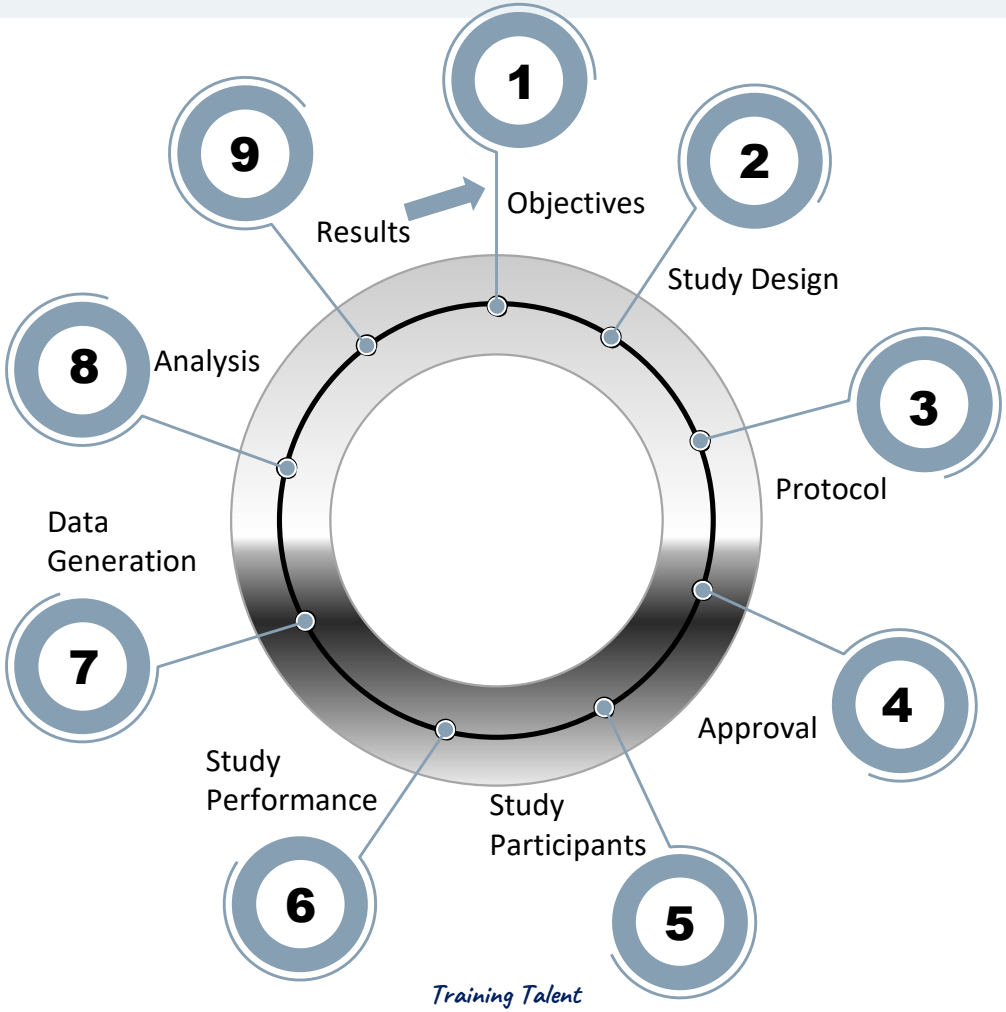
Market Access

Health Economics
RWE
Reimbursement

Marketing

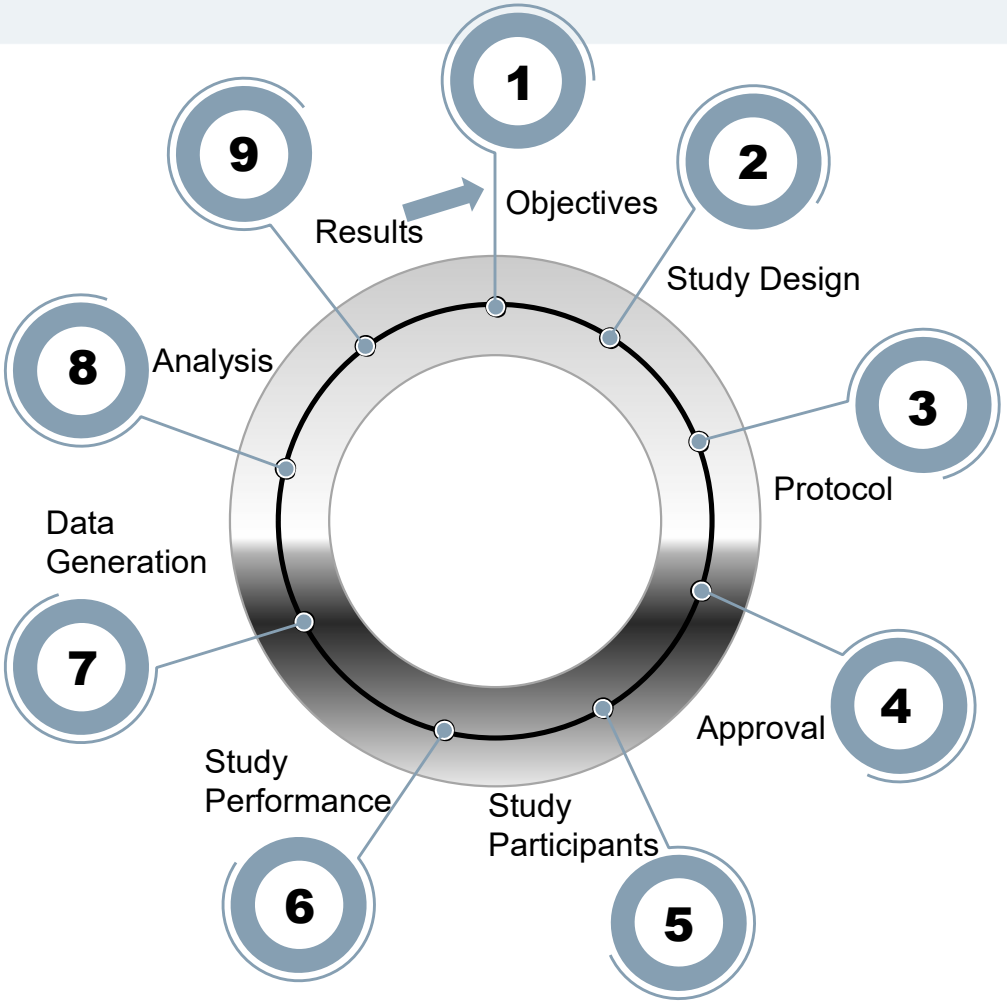
Sales force
Medical Scientific Liaison

The Clinical Trial Cycle



Training Talent

Clinical Research Associate (CRA)



Clinical Research Associate (CRA or Monitor)

Junior Clinical Researcher STAR Programme

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STAR PROGRAMMES

This programme aims to bridge the GAP by providing...

Comprehensive Course Programme

- Introduction to Clinical Research
- Basics on regulatory requirements in clinical research
- Orienting your career in clinical research
- ICH-GCP
- Clinical Research training for CRAs
- Communication Skills

3 Internships: learn by doing

Hospital
Duration: 2 months

Pharmaceutical Company
Duration: 6 months

Contract Research Organisation
Duration: 4 months

Next sessions:

13 April 2026
23 June 2026
22 Sept 2026
In Brussels

NEW

Available WITH or WITHOUT Internships

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Testimonial

Junior Clinical Researcher STAR programme

Zhanar Mustapova

MSc Biomedical sciences

- Junior Researcher in Oncology Center for preclinical studies
- Laboratory Manager of clinical laboratory

STAR Programme – Traineeships – Place, scope , activities :

1. CUSL - Cliniques Universitaires Saint Luc - Clinical Trial Centre in the Emergency Department, 2 months
2. Eli Lilly and Company - **Investigator Engagement Team**, 2 months
3. Eli Lilly and Company - **Trial Capabilities Center**, 4 months

Why we would recommend this programme

- **Comprehensive theoretical instruction complemented by practical application**
- **Proactive engagement and networking within the industry**
- **Flexibility to pursue opportunities aligned with your strengths and interests**

Monitor/CRA

- Monitoring in practice = monitor **checks** if:
  - INV supervises the team on site, i.e., team is adequately informed, performs trial specific functions
  - INV did not delegate functions to unauthorised individuals
  - INV enrols only eligible subjects
  - INV follows the study protocol
  - INV completes/updates/maintains source and trial records accurately, completely, legibly, timely and dated
  - INV follows up on action items
  - ……

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Site Management

- Keep team informed & be informed
  - Keep track of recruitment, of problems
  - Inform study team about any problem, indicate actions and follow-up until solutions
  - Follow-up outstanding matters asap
  - Inform, motivate & support the investigator and his/her study team
  - Escalate to manager poor performing / persistent non-compliant sites

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Clinical Research Associate (CRA) Monitor

Role

- **Is the contact between Sponsor/CRO and the investigational sites**
- Prepare the sites for the study
- Work with site for recruitment
- Perform sites **Monitoring** visits
- Manage study progress and conduct
- Verify safety events
- Collect key documents
- Quality of study activities and documentation

Skills

- Scientific background, Life Science Degree
- Master level
- Good written and verbal communication
- Good organizational skills
- English + Local languages
- Mobile (driving licence) and willing to travel

- 1-2 years' experience for Junior CRA
- More experience for Senior CRA

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Know yourself !

Short-Term Goals
(1-2 years)

Mid-Term Goals
(3-5 years)

Long-Term Goals
(6 years +)

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Develop your competencies !

[Competencies] = [Training + Hands-on experience + How to do it]

ECCRT STAR Programmes:

Junior Clinical Researcher STAR

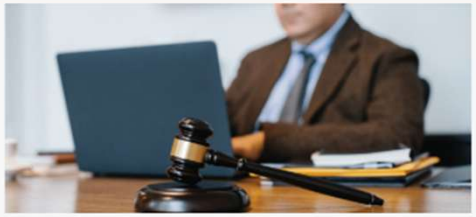
Regulatory Affairs STAR

All info on our website:

- www.eccrt.com

- Public Courses / STAR Programmes

Apply Online



Regulatory Affairs

This STAR Programme is different from most of the others because it includes practical traineeships throughout the year. This will give you the possibility to acquire practical experience in the field and thus a kick-start of a brand-new career in Regulatory Affairs

Read more

Junior Clinical Researcher

This STAR Programme will provide the capabilities you need to become a Junior Clinical Researcher. Most employers will require practical experience on the job before considering your application. At ECCRT, we are aware of this and combine trainings with real-life experience in several organisations.

Read more

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Next opportunity to learn more, join us !

½ day Orienting Training in Clinical Research
13 April 2026 – in Brussels

½ day Orienting Training in Regulatory Affairs
23 June 2026 – in Brussels

=> Connect to register for free course

Any Questions ?

Visit our booth # 16

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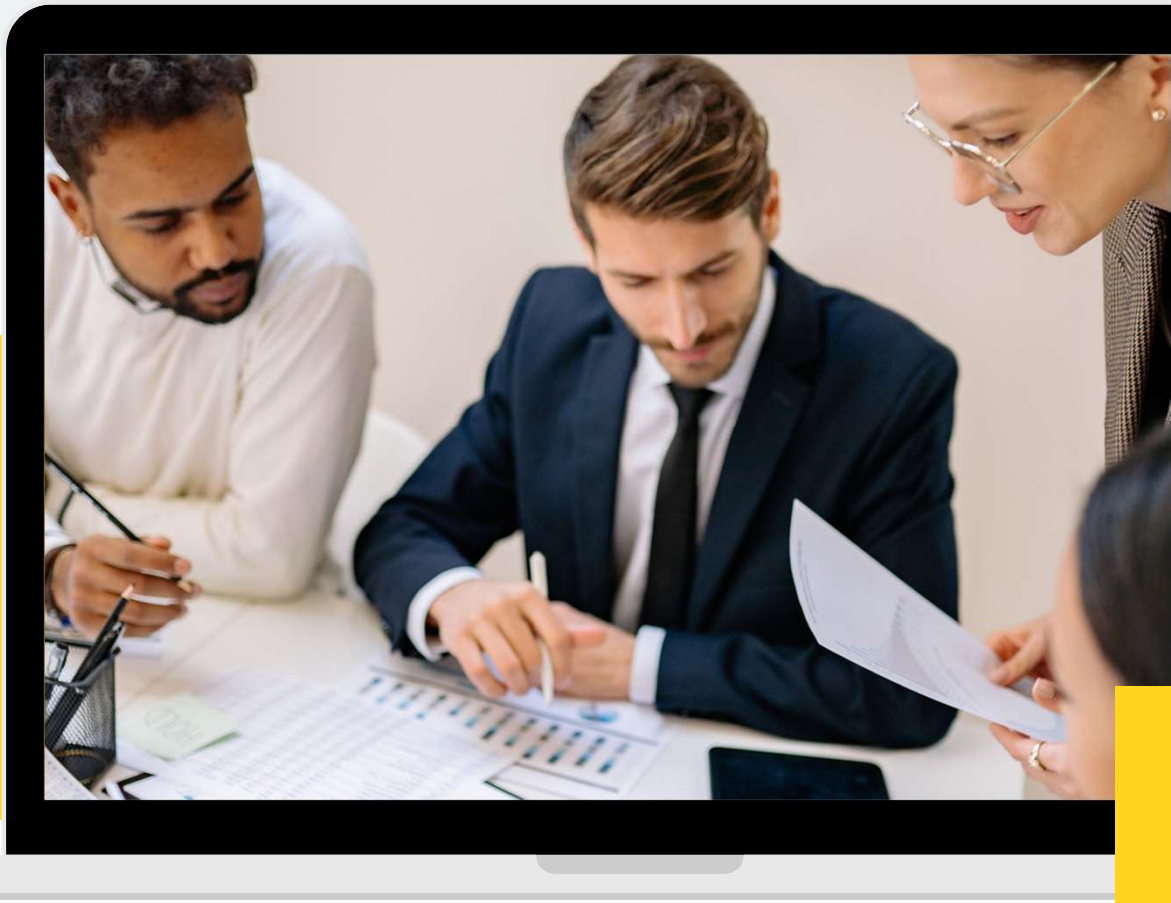
Questions? Contact us !



European Centre for Clinical Research Training (ECCRT)

Phone : +32-2-504-07-20
Website : www.eccrt.com
Email : info@eccrt.com
Address : Cantersteen 47, 1000 Brussels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Thank you