



***Make your way into
Clinical Research or Regulatory Affairs world***

Virginie Hamtiaux, Career Transition Coach and Senior Trainer at ECCRT

Testimonials from Aline Bracke and Emilie De Baene, ECCRT students

Ghent, November 2023

About ECCRT

What we do and what we offer

1. What we do?

**Facilitating Clinical
Research and Regulatory
Affairs professionals to
excel in their job for the
benefit of patients.**

2. How we achieve our goal?

Open
Courses

Tailored
Courses

SMART
Solutions

micro
Learning

3. Who am I ?



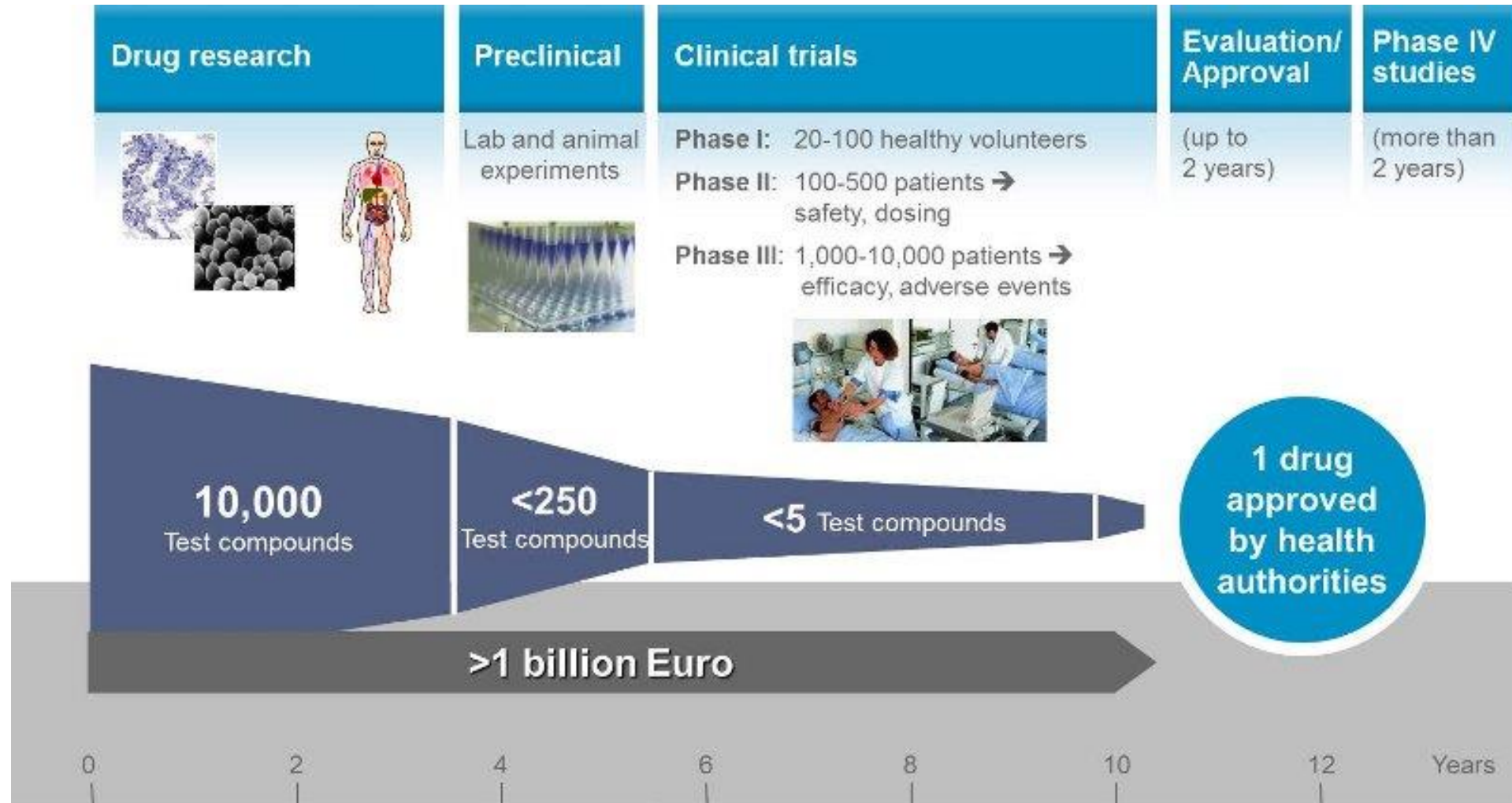
**Career Transition Coach
Senior Trainer
Experience in Pharma Industry
STARs programs**

Agenda:

1. What are the jobs in Regulatory Affairs and Clinical Research
2. What you need to find a job
3. Boost yourself: ECCRT STARs programs
4. Testimonials



Drug Development Overview



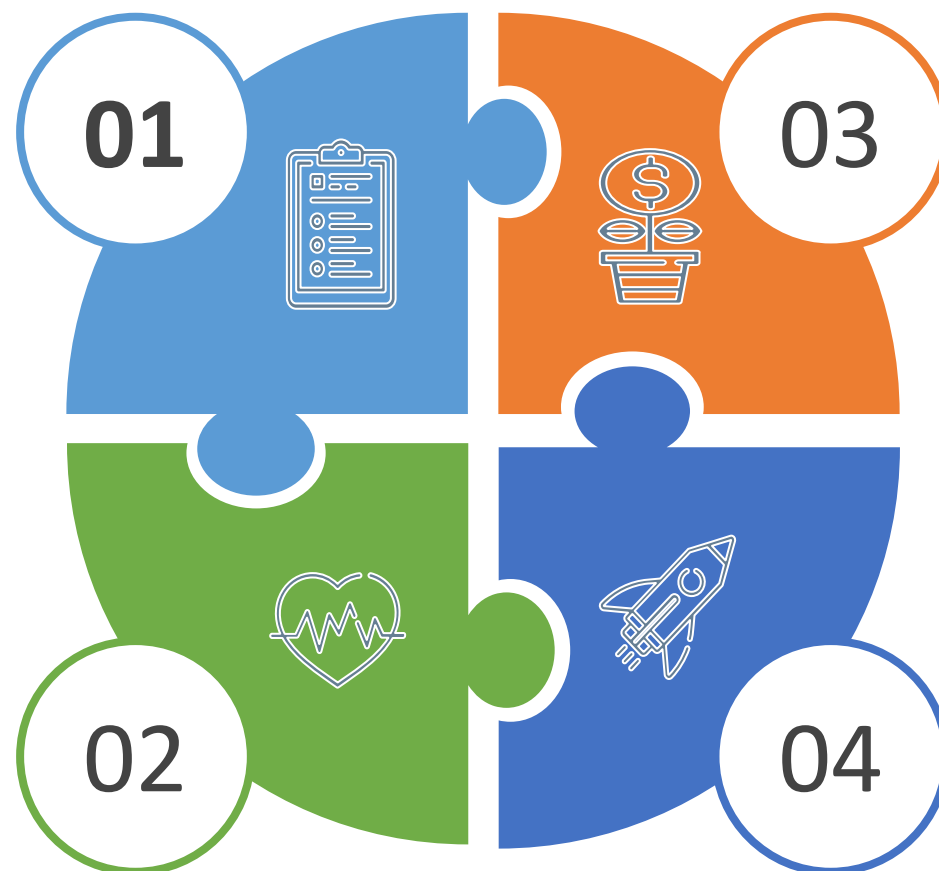
Source: based on PhRMA Profile Pharmaceutical Industry 2010

The Pharma Industry: Regulatory Affairs

Regulatory Affairs

Registration
Marketing Authorisation

Clinical
Part of R&D



Market Access

Health Economics
RWE
Reimbursement

Marketing

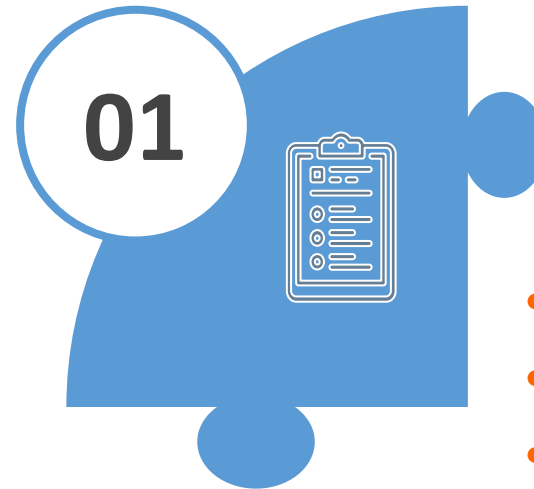
Sales force
Medical Scientific
Liaison

Regulatory affairs (RA), also called **government affairs**, 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](#)).


Jobs in Regulatory Affairs

Regulatory Affairs

Registration
Marketing Authorisation (MA)



- Submission for Marketing Authorisation
- Chemistry Manufacturing Control
- Labelling
- Good Distribution Practice
- Pharmacovigilance
- Regulatory Policy and Intelligence
- Information and Publicity

A background image of a man in a white lab coat and glasses, looking down at a tablet or clipboard. The image is overlaid with a large, dark blue, semi-transparent geometric shape that contains the main text.

There is a GAP between
young graduates trying to find an
entry in the clinical research and
regulatory affairs
and
companies are desperately
looking for experienced people in
these fields

**Comprehensive Course
Programme**

Introduction to Regulatory Affairs

Good Distribution
PracticeLife Cycle of a pharmaceutical
product

Regulatory Information

Submission for Marketing
Authorisation

Pharmacovigilance

Chemistry, Manufacturing
and Controls

Information and publicity



Labelling, GMP

Practical Traineeship Goals



Acquire competencies on the job



Get experience from all angles



Individual programme for every student

Mentor the students to assure all
required competencies are acquired

A rotating traineeship programme aimed at getting you exposed to your field of interest



**Pharmaceutical or
Consultancy Company**

Duration: 6 months

What is the lifecycle of a medicinal product? Which activities are done in the Regulatory Affairs Department and how do they link with other departments?



Certificate

**Next session
September 2024**

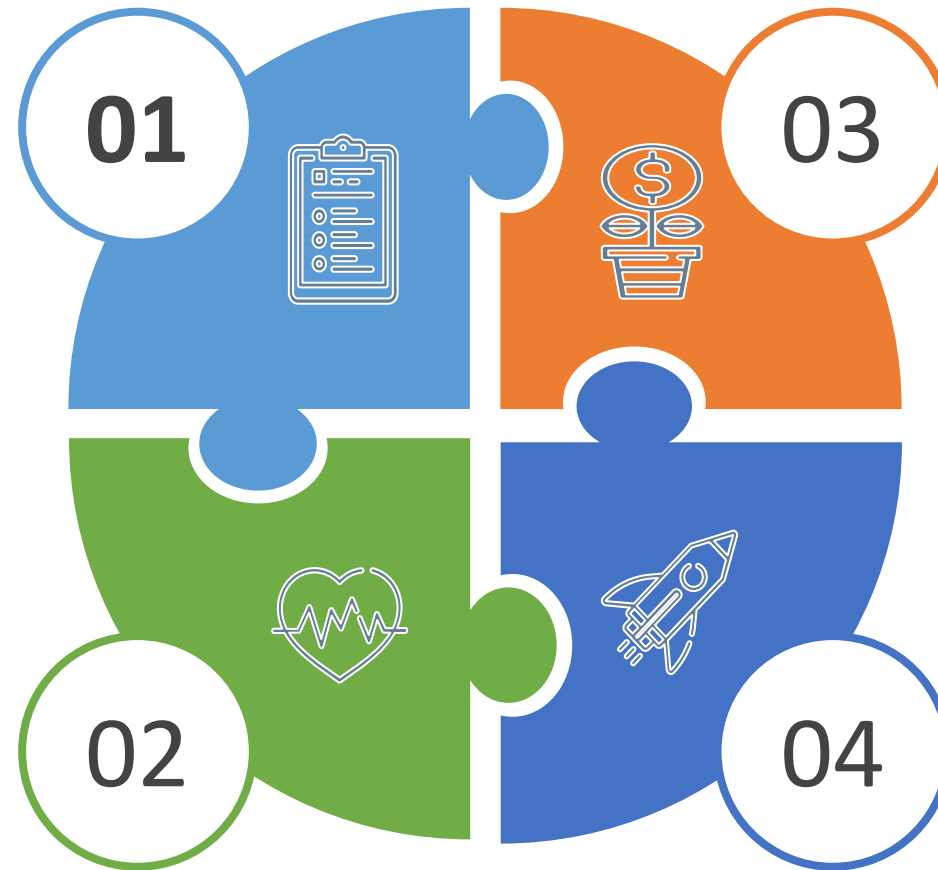
The Pharma Industry: Clinical Research

Regulatory Affairs

Registration, Marketing
Authorisation

Clinical

Part of R&D



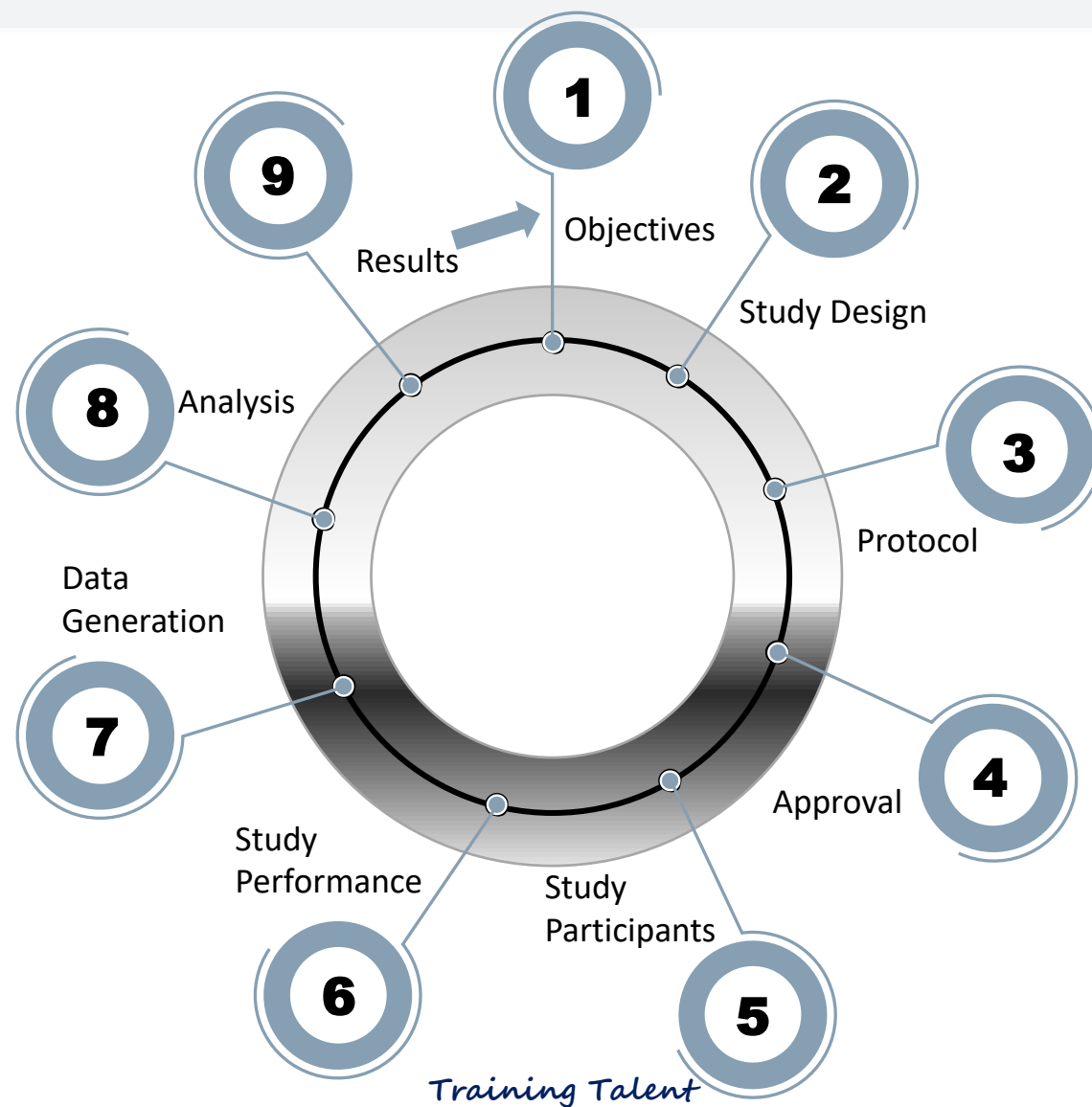
Market Access

Health Economics
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Reimbursement

Marketing

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The Clinical Trial Cycle



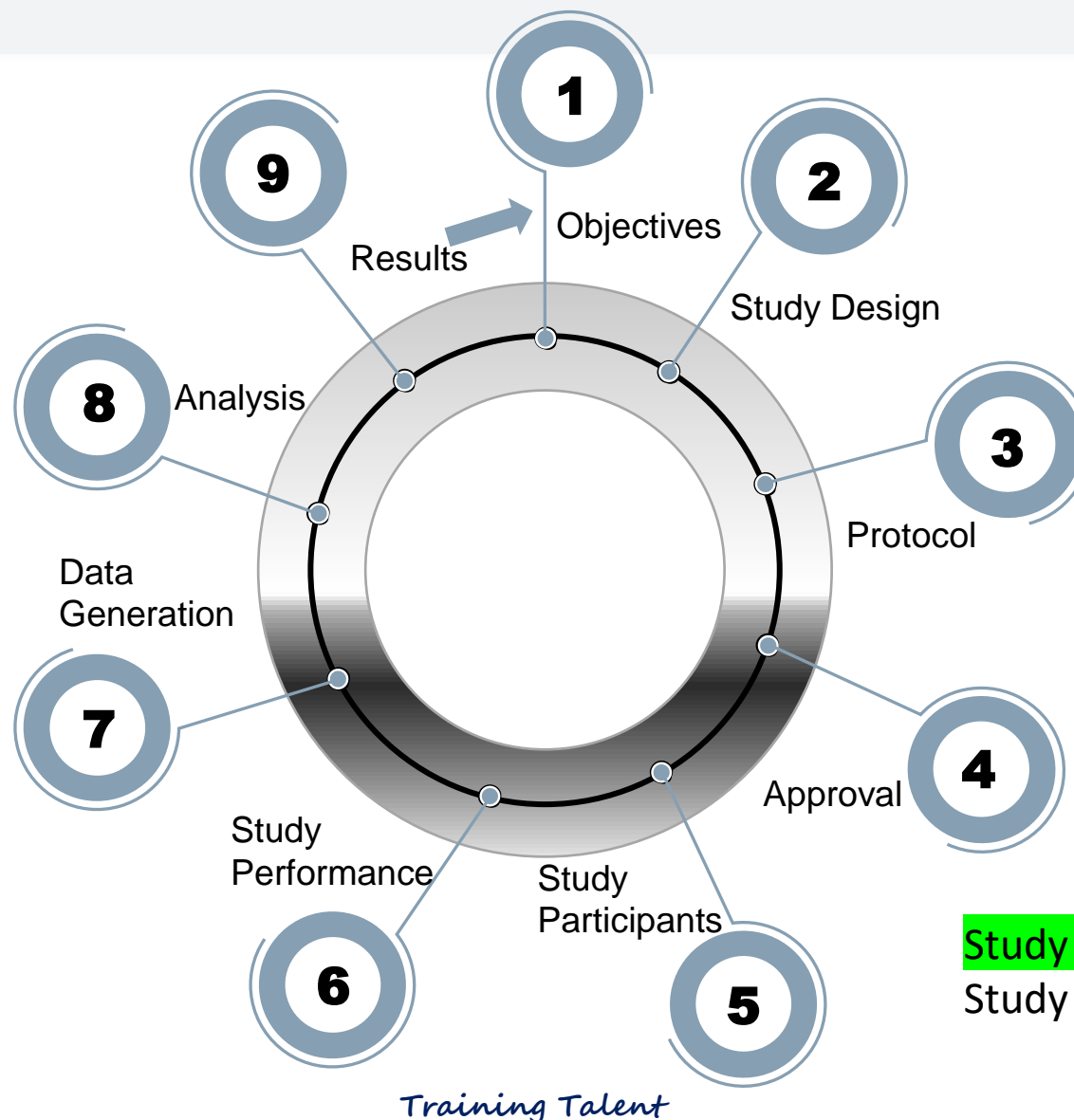
Jobs in Clinical Research

Clinical

Part of
R&D



Statistician
Data Manager
Medical Writer



Scientific Writer
Clinical Trial Assistant
Clinical Research Associate
(CRA or Monitor)
Project Manager

Study Coordinator
Study Nurse

What you need to find a job:

Acquire necessary COMPETENCIES



Knowledge

Degree
Trainings
Languages



Experience

On the job
Expertise



Attitude

Soft skills
Communication

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

Practical Traineeship Goals

- ✓ Acquire competencies on the job
- ✓ Get experience from all angles
- ✓ Individual programme for every student
- ✓ Mentor the students to assure all required competencies are acquired

A rotating traineeship programme aimed at getting you exposed to your field of interest



Hospital

Duration: 2 months

How is clinical research conducted in real life? How does it affect a patient? What is the difference with the regular clinical practice?



Pharmaceutical Company

Duration: 6 months

How are medicines developed? Where does Clinical Research fit in the complete development? Why is clinical research done differently from normal clinical practice?



Contract Research Organisation

Duration: 4 months

What activities need to be done in order to safeguard patients' rights and well-being and at the same time make sure that quality of data obtained in a clinical study is guaranteed?



Certificate

Next sessions

Dec 2023

July 2024

Sept 2024

Testimonial

Junior Clinical Researcher STAR programme



Aline Bracke
Master in Biomedical Sciences
Graduated in June 2023



Emilie De Baene
Master in Pharmaceutical Care
Graduated in June 2023

STAR Programme - Traineeships:

- | | |
|---|--|
| 1 Study Coordinator at UZ Ghent, Department of Cardiology | 1 Study Coordinator at UZ Ghent, Department of Dermatology |
| 2 Pharma internship | 2 Site monitor at Bayer pharmaceuticals |
| 3 CRO internship | 3 CRO internship |

Why we would recommend this programme

- **Comprehensive learning** through a combination of theoretical courses and practical internships
- **Hands-on experience** by working in a real-world clinical research setting
- Enhancing your **career orientation** by gaining insights into all the different opportunities within the industry
- An excellent **launchpad for your career**, providing the knowledge, networks, and practical experience needed to excel in the field



*We are at
BOOTH 16*

*In front of
Photo Booth*



Clinical Research **01**
This STAR Programme will provide the capabilities you need to become a Junior Clinical Researcher, with real-life experience in several organisations.
Internship available

Regulatory Affairs **02**
The Regulatory Affairs STAR Programme will help you acquire practical experience in the field and kick-start of your career in Regulatory Affairs.
Internship available

Clinical Project Management **03**
This programme was designed to get you started as a clinical project manager or to progress your career from a CRA to a PM position.

Medical Devices **04**
This field is fundamentally different from the Pharmaceutical Industry: different products and legislations, different concepts, different strategies.

Auditing **05**
This programme is designed to launch your career as an auditor, mixing technical and soft skills.

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