ECCRT
EUROPEAN CENTRE FOR CLINICAL RESEARCH TRAINING

23 NOVEMBER 2023 | GHENT ICC
BCF CAREER EVENT

Make your way into the

Clinical Research or Regulatory Affairs world

Virginie Hamtiaux, Senior Trainer and Business Coach at ECCRT

Testimonial from Andreia Verdade, ECCRT Alumni student

Utrecht, May 2024

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 ?

Senior Trainer
Business Coach
Experience in Pharma Industry
STARs programs

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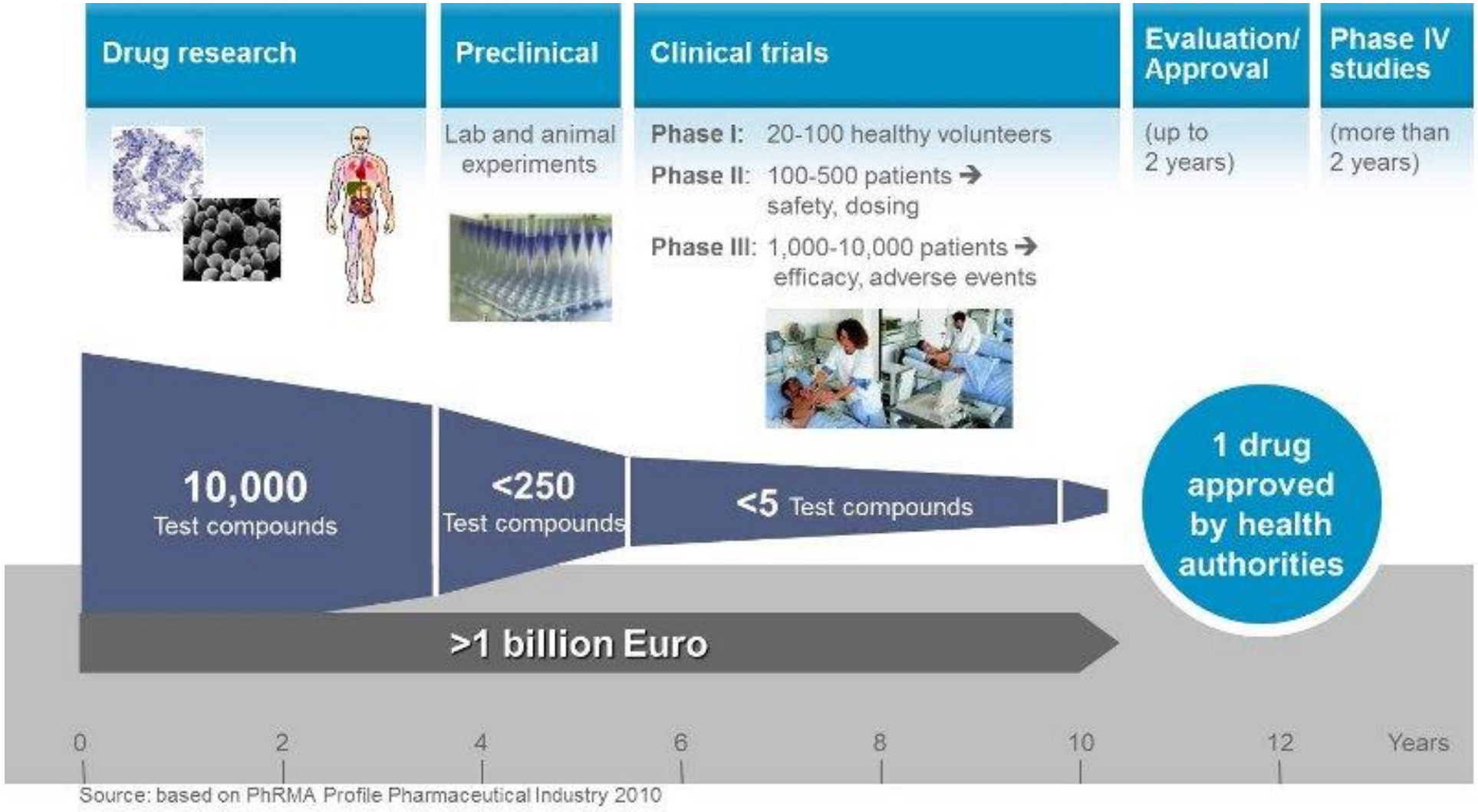
CLINICAL RESEARCH TRAINING

Agenda:

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

Drug Development Overview



Source: based on PhRMA Profile Pharmaceutical Industry 2010

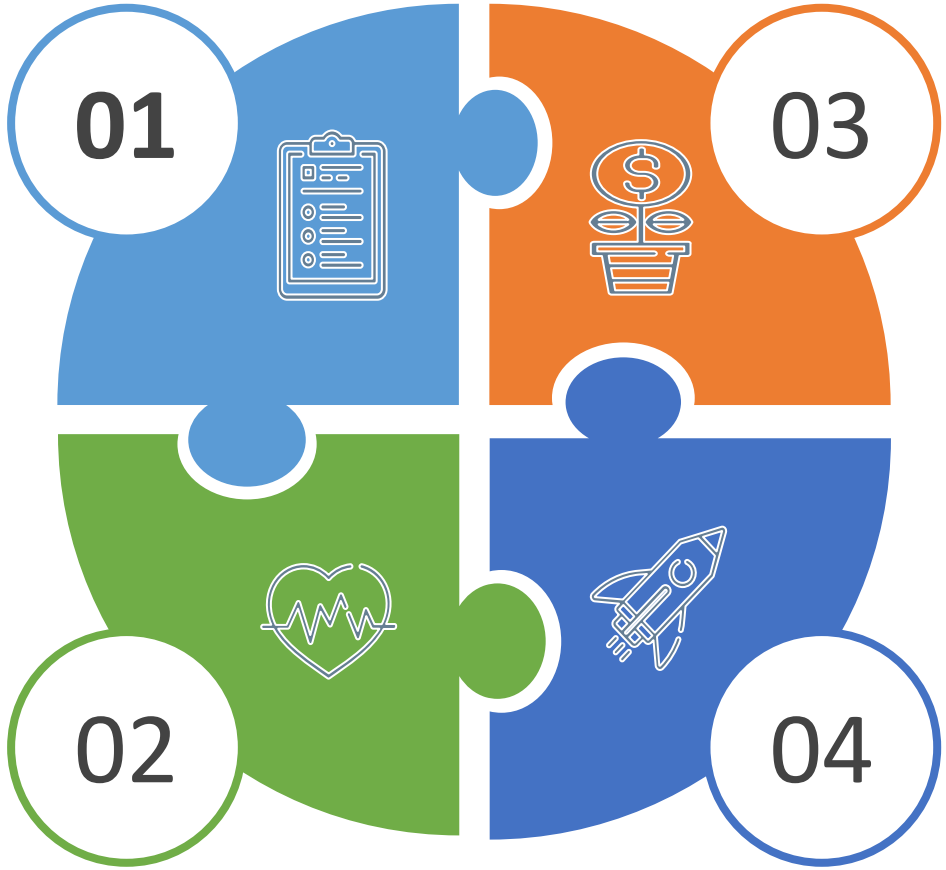
The Pharma Industry: Regulatory Affairs

Regulatory Affairs

Registration
Marketing Authorisation

Clinical

Part of R&D



Market Access

Health Economics
RWE
Reimbursement

Marketing

Sales force
Medical Scientific Liaison

Regulatory Affairs

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).

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

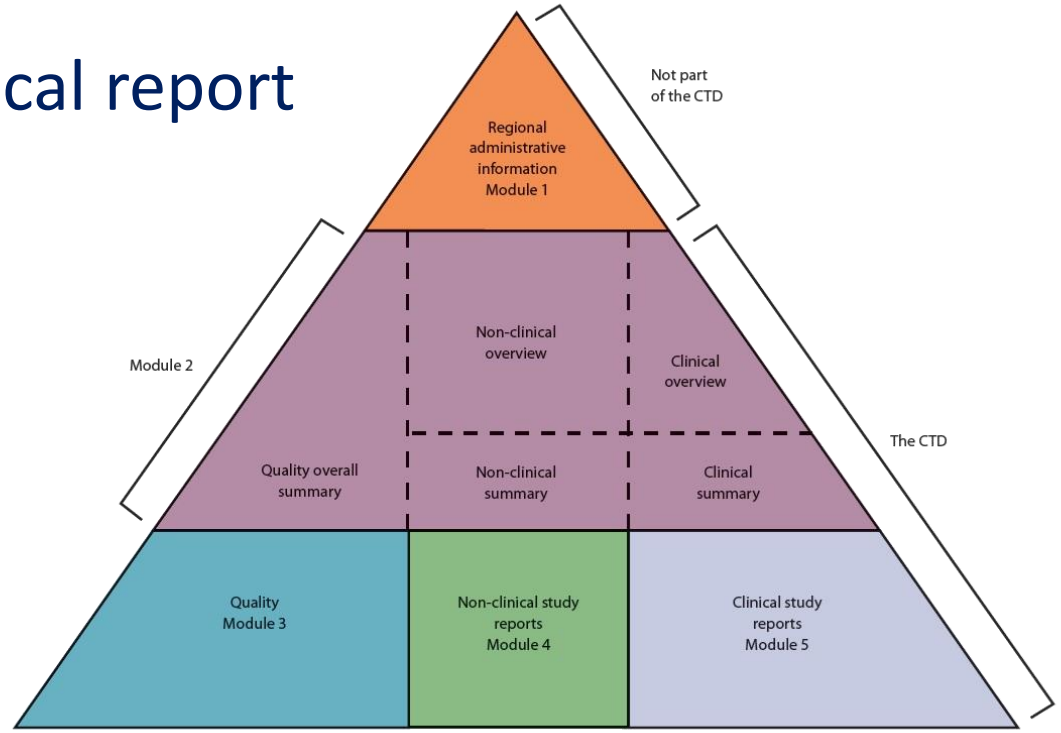
Pharmaceutical legislation

- 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!

Common Technical Document (CTD)

- **Module 1:** Administrative information, incl. proposed labelling
- **Module 2:** Summaries + overviews of the dossier
- **Module 3:** Quality: chemical-pharmaceutical report
- **Module 4:** Non-clinical report
- **Module 5:** Clinical report

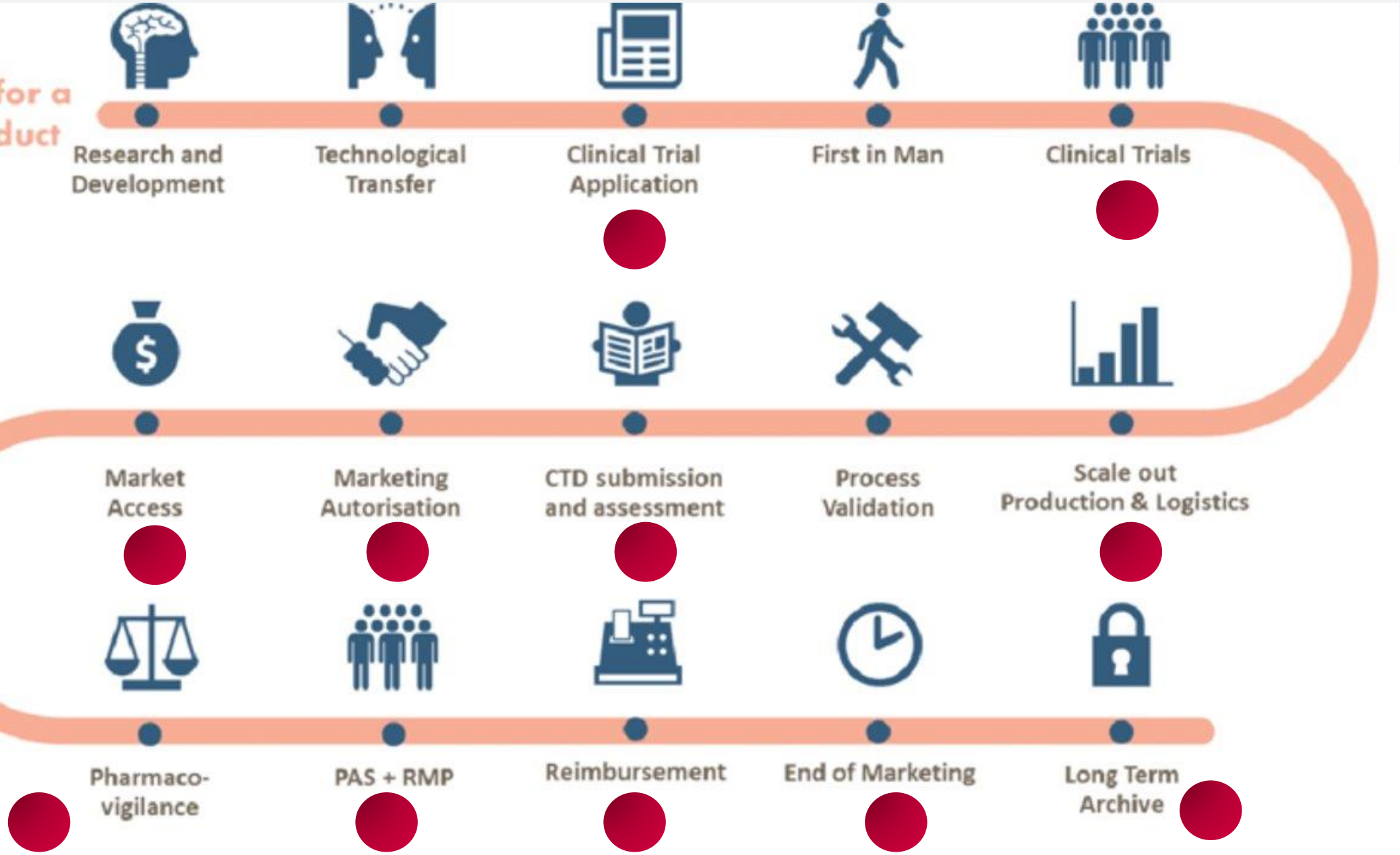
- Module 3-5 together can be >200,000 pages!



Source: www.ich.org/products/ctd.html

Image from: ICH, https://ich.org/page/ctd

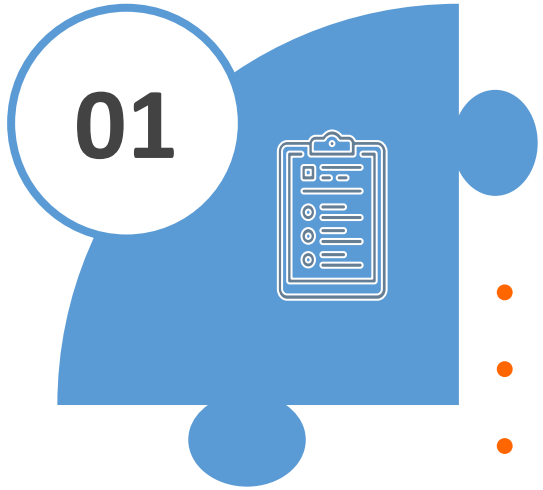
Phases of life for a medicinal product



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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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

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Boost Yourself:
ECCRT Regulatory Affairs STAR Programme

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 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

Develop Yourself:
ECCRT Regulatory Affairs STAR Programme

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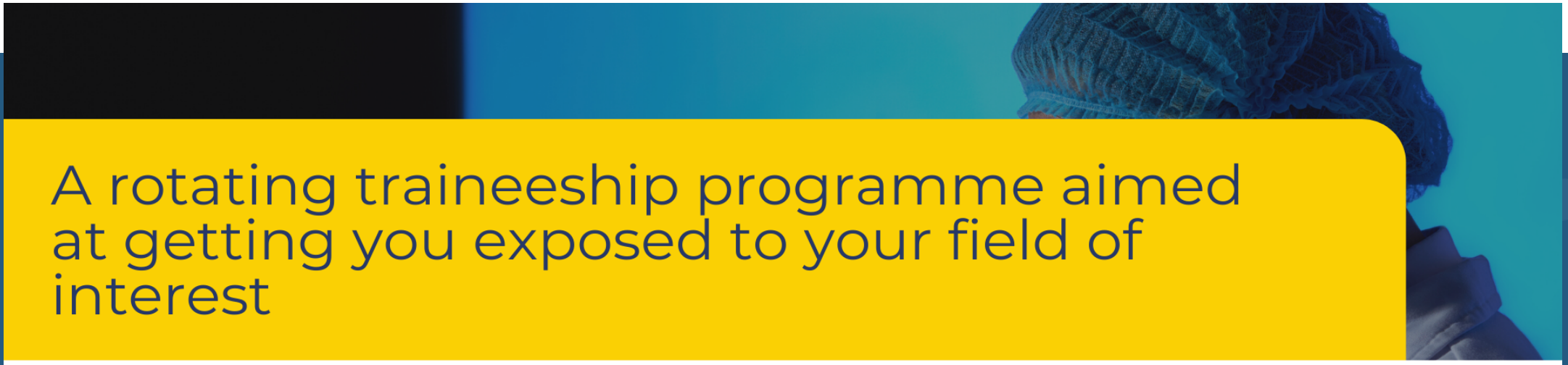
STAR PROGRAMMES



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

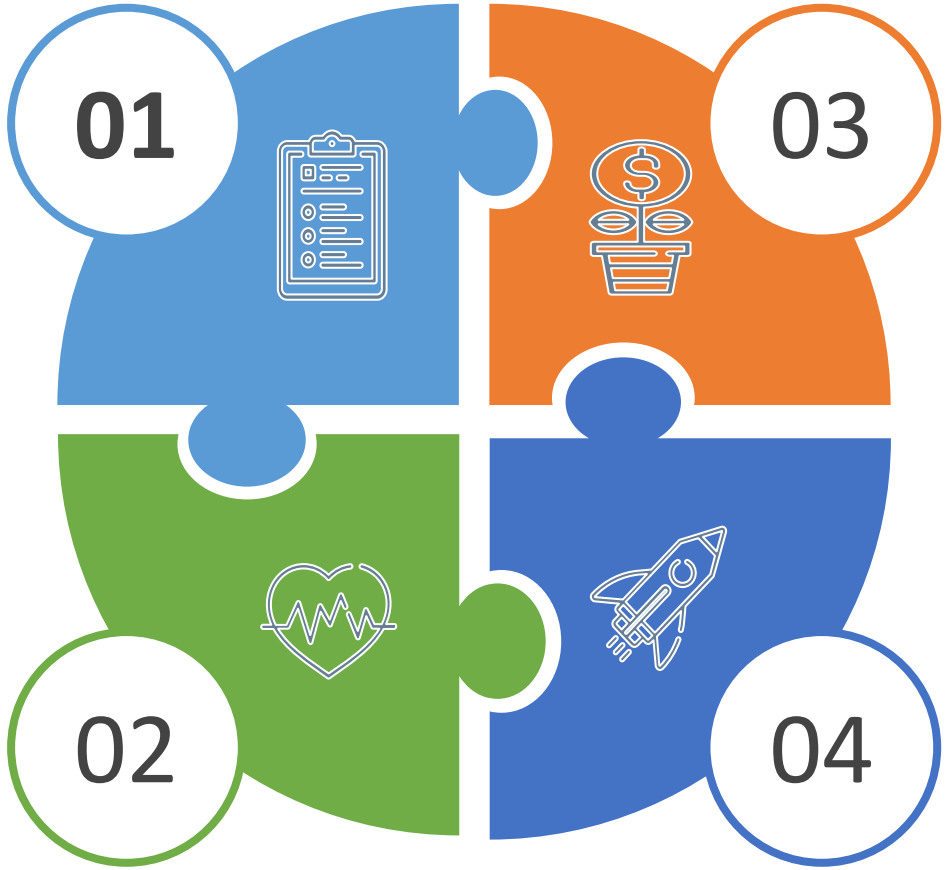
The Pharma Industry: Clinical Research

Regulatory Affairs

Registration, Marketing Authorisation

Clinical

Part of R&D



Market Access

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The Clinical Trial Cycle

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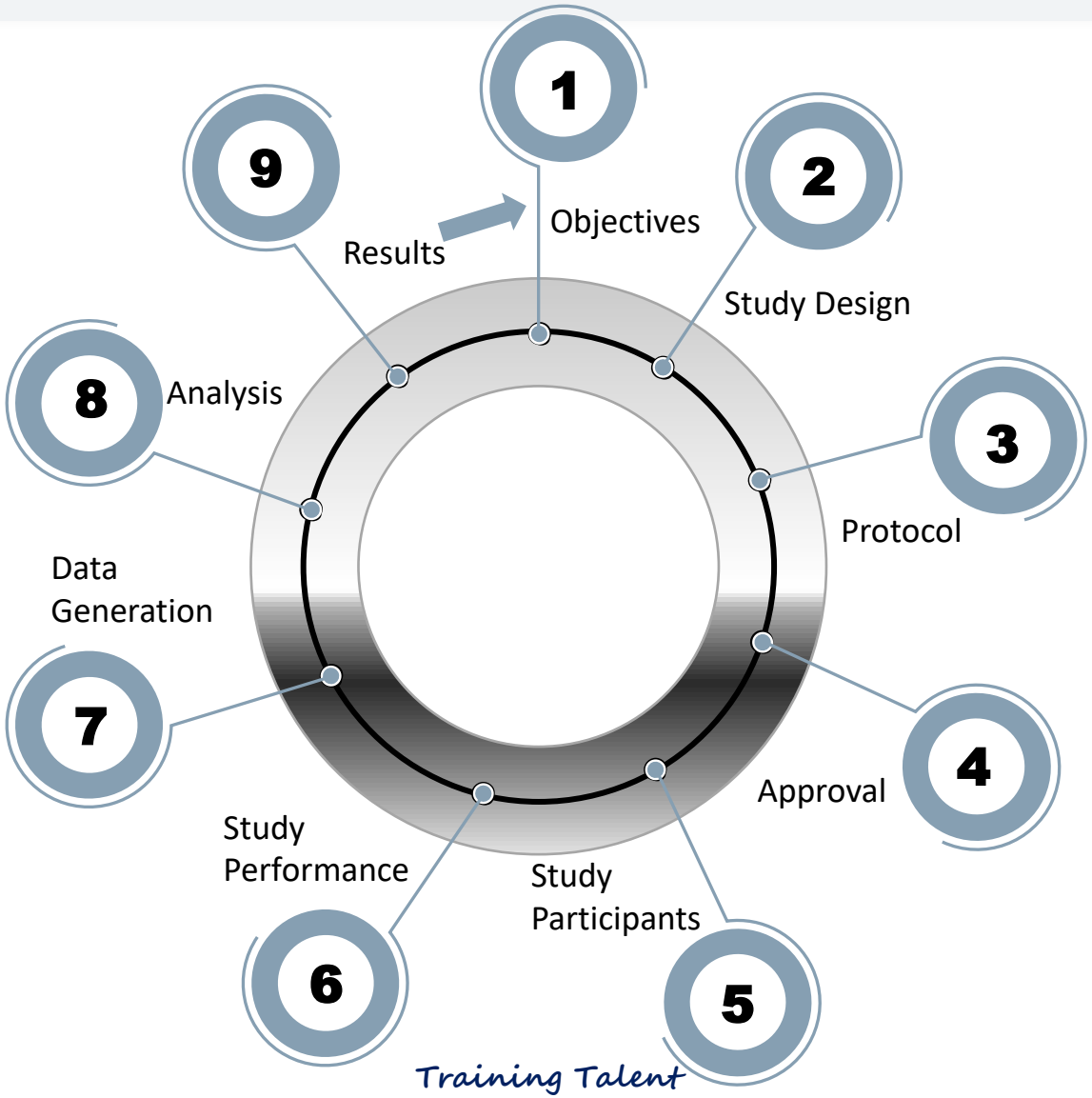
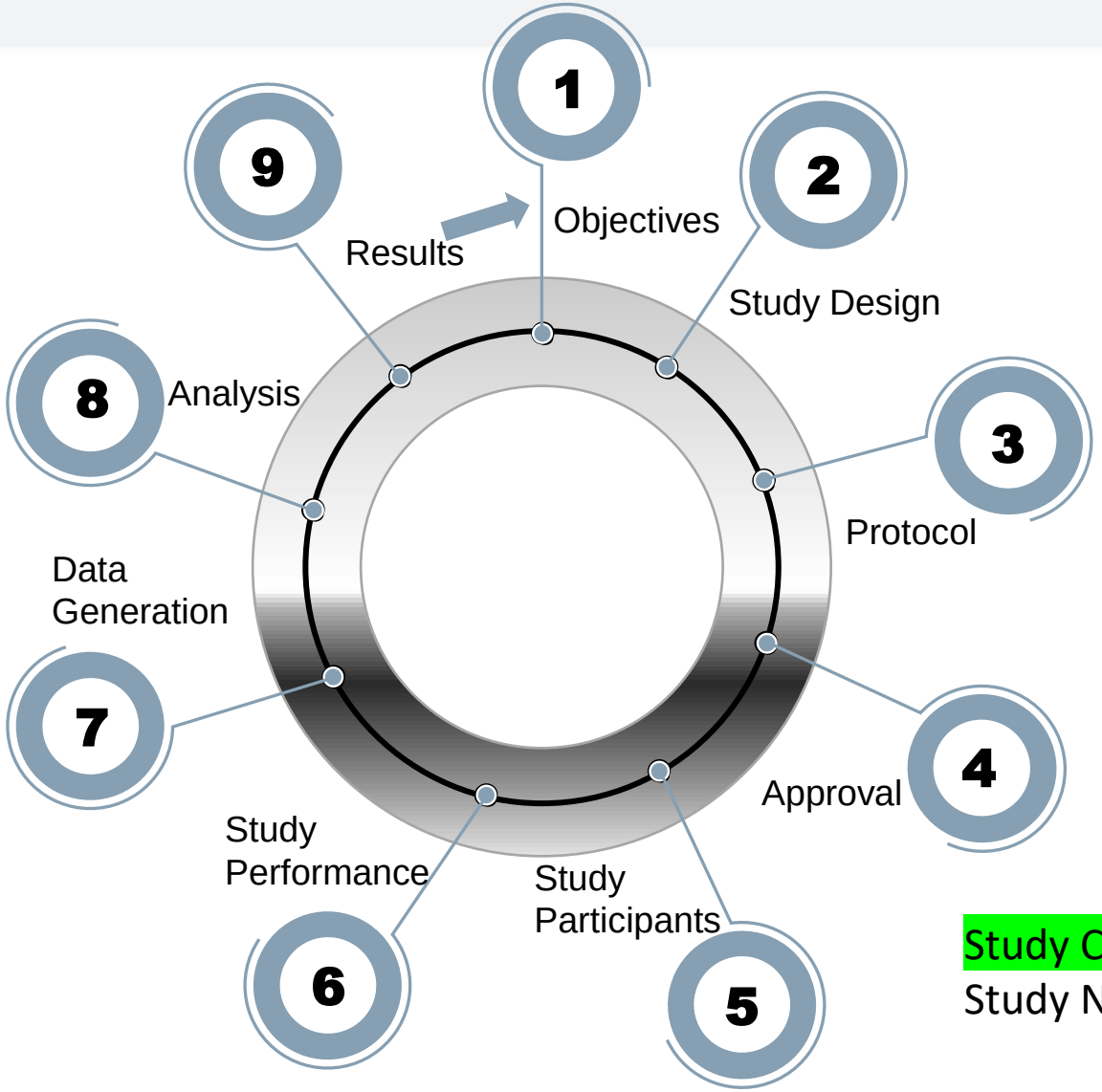


Training Talent

Jobs in Clinical Research

Data Manager



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

Study Coordinator
Study Nurse

Training Talent

Clinical Trial Assistant (CTA)

Role

- **Responsible for study Trial Master File**
- Preparing Investigator & Sponsor binders
- Archiving Trial Master File
- Updating clinical tracking systems
- Administrative tasks to support team
- Other potential tasks
  - Contract
  - Clinical Trial Supplies

Skills

- Scientific background
- Bachelor level
- Document management appetite
- Detailed oriented
- Technical and IT skills
- Good written communication
- English

Clinical Research Associate (CRA) Monitor

Role

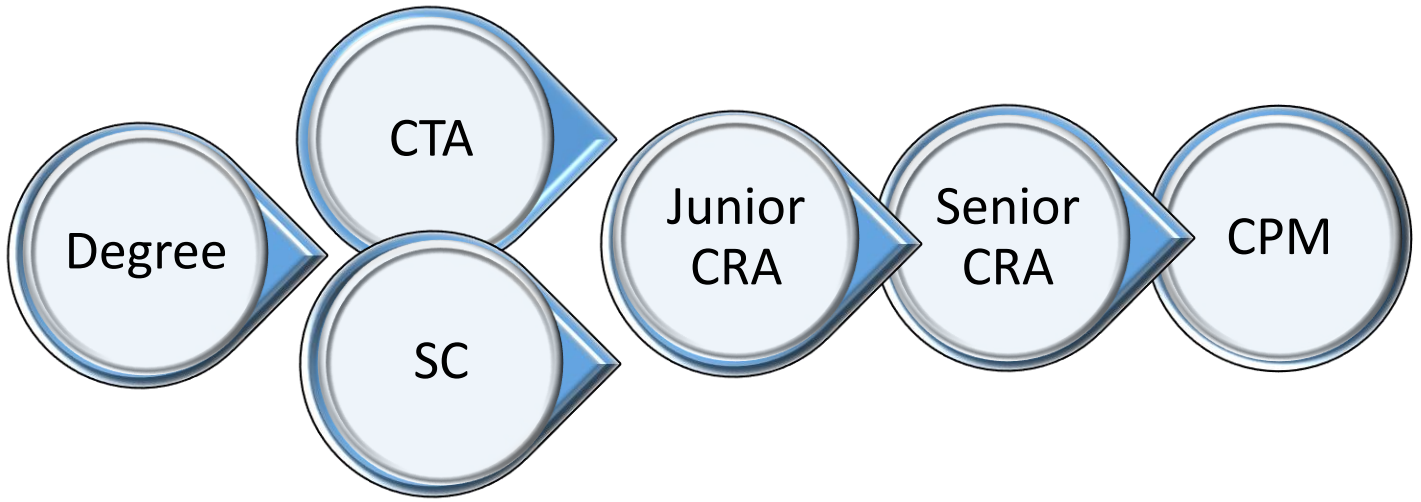
- **Is the contact between Sponsor/CRO and the investigational sites**
- Prepare the sites for the study
- Work with site for recruitment
- Perform sites **Monitoring** visits
- Manage study progress and conduct
- Verify safety events
- Collect key documents
- Quality of study activities and documentation

Skills

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

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

Career path



Training

Evolution of the clinical research professional

From paper to digital and e-environment

What you need to find a job:

Acquire necessary COMPETENCIES

Knowledge

Degree

Trainings

Languages

Experience

On the job

Expertise

Attitude

Soft skills

Communication

Training Talent

ECCRT 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

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

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Develop Yourself: ECCRT Junior Clinical Researcher STAR Programme

STAR PROGRAMMES

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

July 2024
Sept 2024
Dec 2024

EUROPEAN CENTRE FOR CLINICAL RESEARCH TRAINING

Testimonial

Andreia Verdade

Associate Clinical Research Monitor @ Medtronic

Biomedical Engineer, MSc @ University of Coimbra, Portugal

Eindhoven, The Netherlands

My journey in the STAR Programme [2022-2023]:

Hospital	Pharma	Medical Devices
Clinical Research Specialist Trainee **HartCentrum, Catharina Ziekenhuis, Eindhoven**	Clinical Operations Trainee **Trained Therapeutix Discovery, Pivot Park, Oss**	Clinical Research Monitor Trainee **Medtronic, BRC, Maastricht**

EUROPEAN CENTRE FOR CLINICAL RESEARCH TRAINING

Testimonial

Andreia Verdade

Associate Clinical Research Monitor @ Medtronic

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Why the STAR Programme @ ECCRT?

Combination of **theoretical learning & practical experience**

Personal guidance w/ professional coach with focus on *how to surf the industry and your career development*

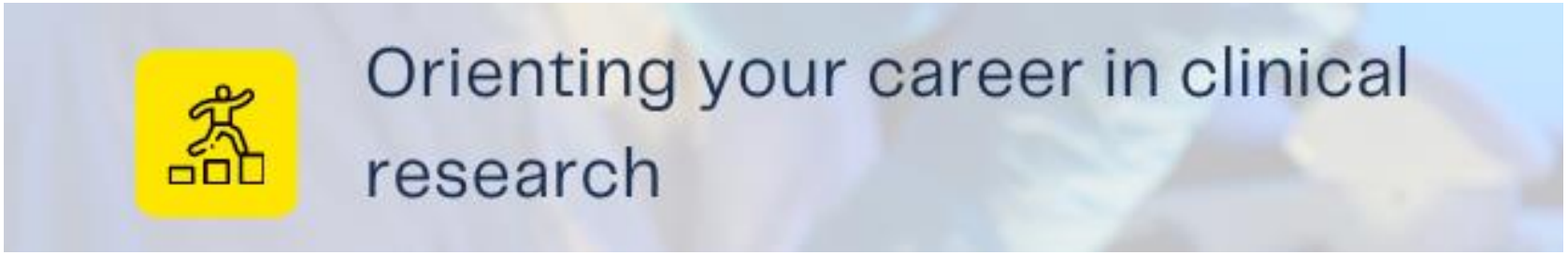
Flexibility to **tailor the program to your goals and ambitions**

Recognized Institution with relevant network in the CR field

1 Year of practical experience → **kick-off of your career in CR**

Supporting network: shared experience with other trainees

Next step?
Orienting your career in Clinical Research



03 July 2024 - Brussels

Contest to win a free course - come and visit our booth

We are at BOOTH 17

Ground floor
Expo room