ECCRT
EUROPEAN CENTRE FOR
CLINICAL RESEARCH TRAINING

BCF CAREER
MOVING CAREERS FORWARD IN LIFE SCIENCES

Make your way into the Clinical Research, Data Management or Regulatory Affairs worlds

Virginie Hamtiaux, Senior Trainer and Business Coach at ECCRT

Aline Bracke, ECCRT Alumni student now Clinical Research Associate I at IQVIA

Gent, November 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 ?

Virginie Hamtiaux
Senior Trainer
Business Coach
Experience in Pharma Industry
STARs programs

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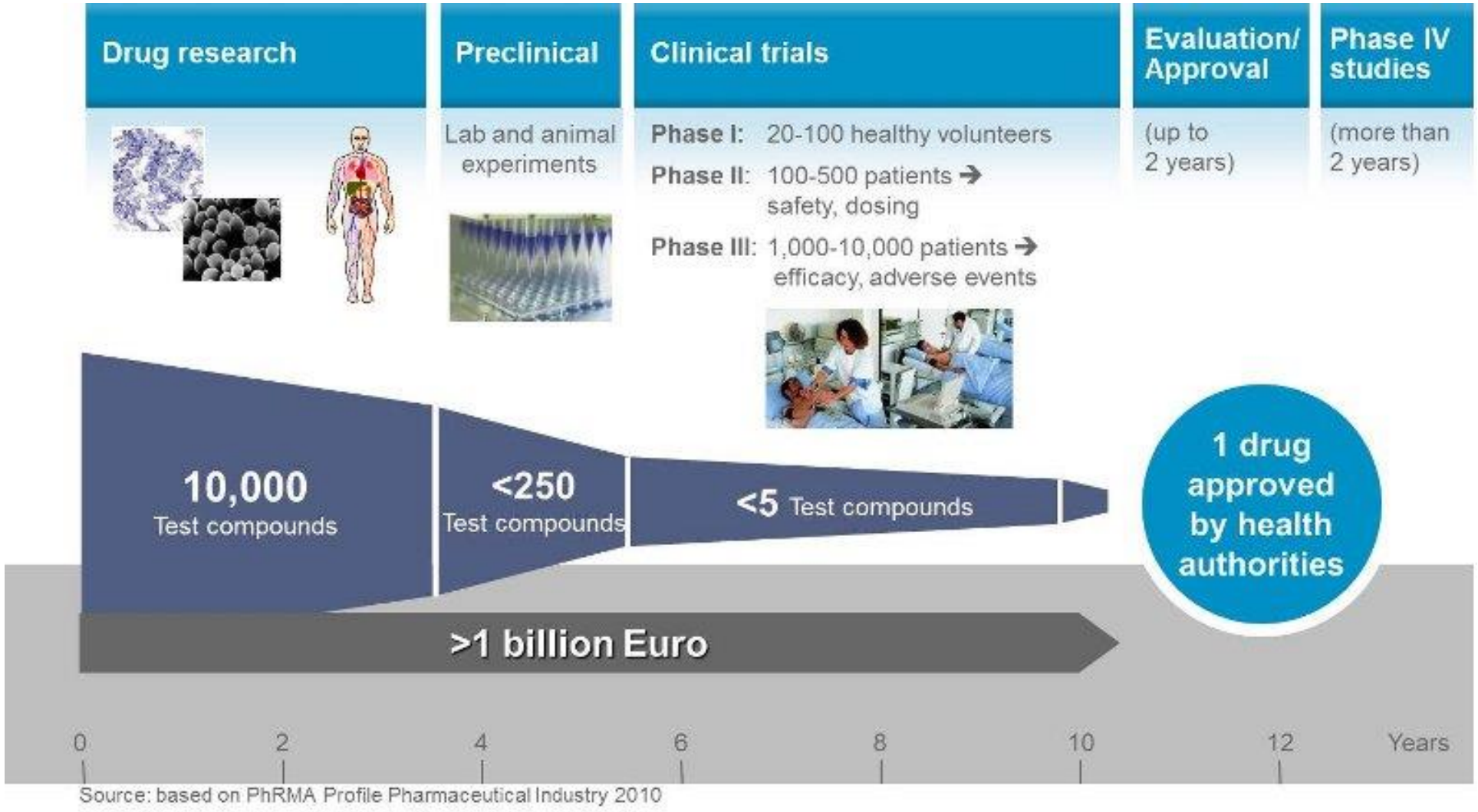
Agenda:

1. Drug Development Overview
2. Clinical Research and Regulatory Affairs
3. What you need to find a job
4. Boost yourself: ECCRT STAR programs

Drug Development Overview



Source: based on PhRMA Profile Pharmaceutical Industry 2010

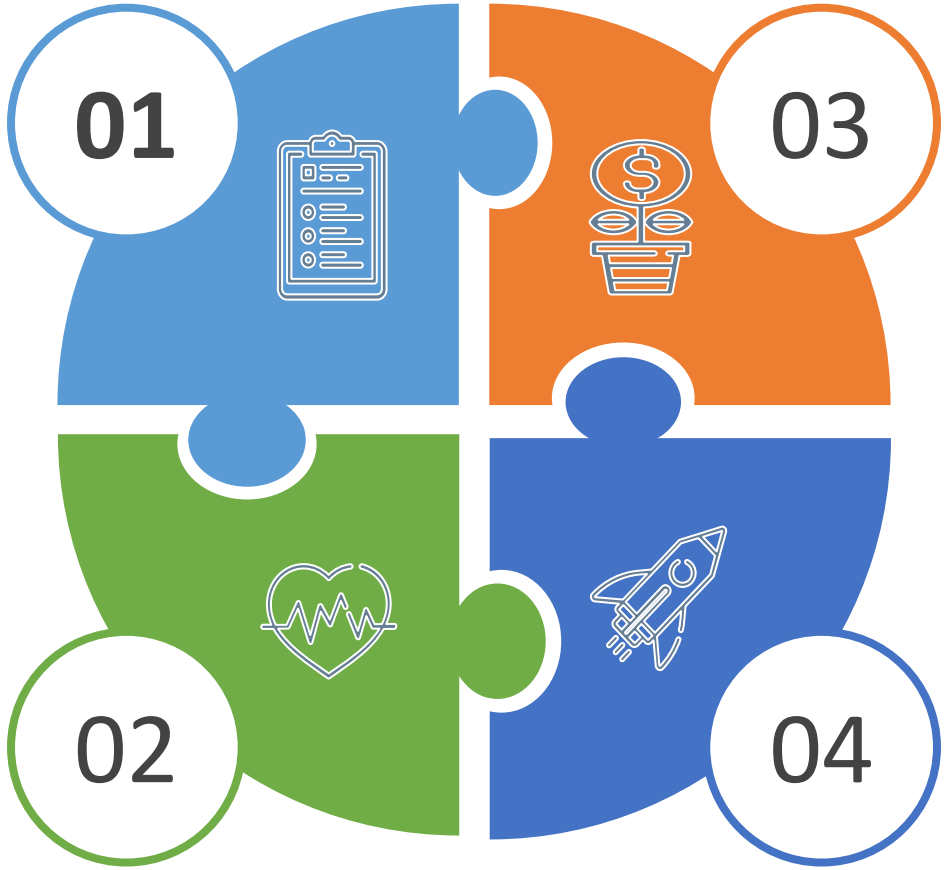
The Pharma Industry: Clinical Research

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

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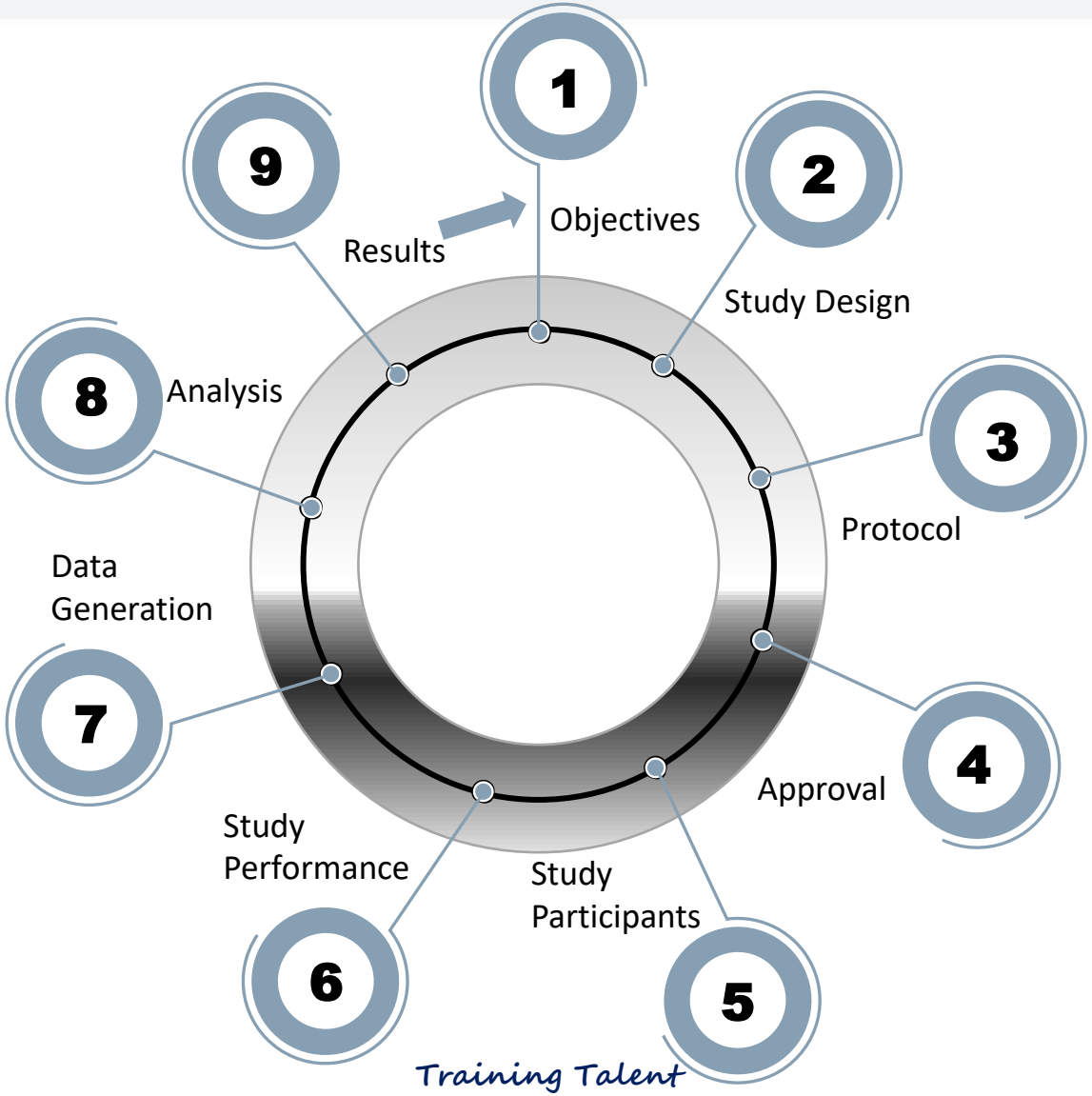


Training Talent

Junior Clinical Researcher STAR Alumni Now CRA I at IQVIA

Aline Bracke
Master in Biomedical Sciences
Graduated in June 2023

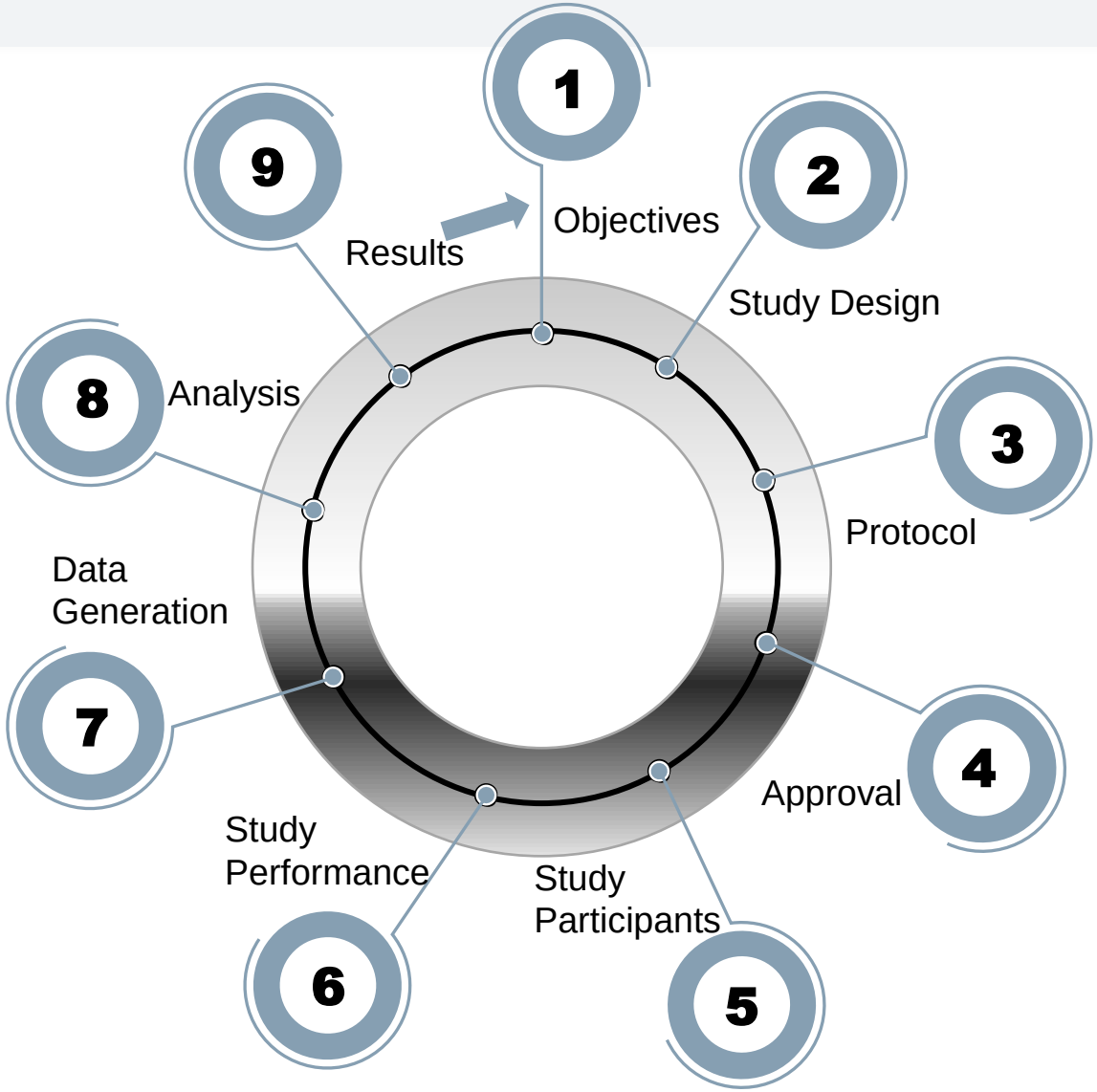
STAR Programme - Traineeships:

1. Hospital (2-months): **Study Coordinator** at **UZ Ghent**, Department of Cardiology
2. Pharmaceutical Company (6-months): **Site Manager / Clinical Research Associate (CRA)** at **J&J**, Global Clinical Operations BeNe
3. Contract Research Organisation (CRO) (4-months): not needed – found a job thanks to acquired competencies during internship 1 and 2

Why we would recommend this programme

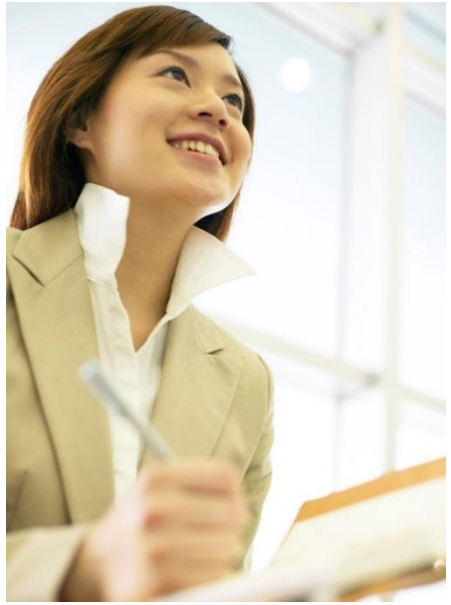
- **Comprehensive learning** through a combination of theoretical courses and practical internships
- **Hands-on experience** by working in a real-world clinical research setting
- Enhancing your **career orientation** by gaining insights into all the different opportunities within the industry
- An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

Clinical Research Associate (CRA)



Clinical Research Associate (CRA or Monitor)

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
  - ……

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

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

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:

Dec 2024
Mar 2025
July 2025
Sept 2025

Data Management (DM)

Data Manager

Data Management Positions
Clinical Data Manager

- What does a clinical data manager do?

Clinical trial protocol

Development of the Data Management sections of the clinical trial protocol
Assisting in final review of the clinical trial protocol for consistency
Definition & creation of the study protocol in the database

Case Report Forms

Development of the Case Report Forms in accordance with the protocol and the database
Development of the guidelines for Case Report Forms completion

Data handling

Coordination and control of data collection, data cleaning and data reporting activities
Application of QC to each stage in the data handling to ensure the data are reliable and processed in compliance with ICH-GCP requirements
Communication with the participating investigators in order to resolve queries and collect missing data
Conduct of the reconciliation of SAEs

Data Management Positions
Clinical Data Manager

- Profile of a clinical data manager?

University Degree in life sciences (biomedical, pharmacy, veterinarian…)
Good organizational & administrative skills
Experience in data monitoring and/or reviewing is an asset
Excellent analytical skills + Computer skills
Team spirit
English very good (written & spoken)

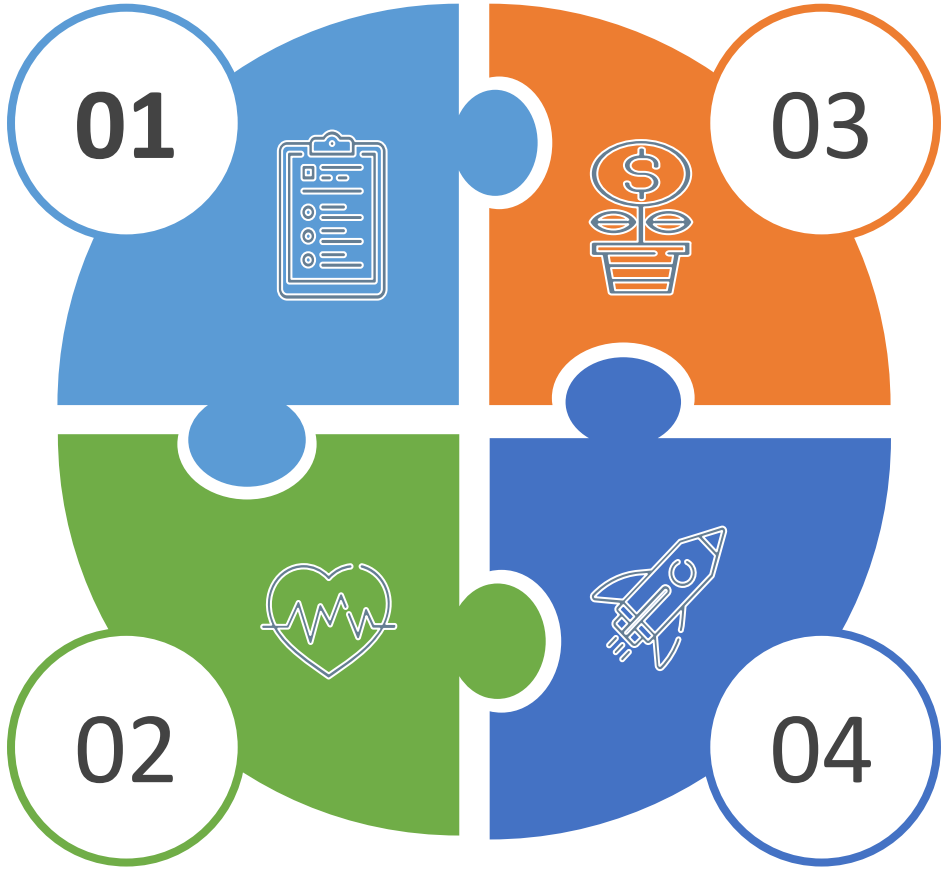
The Pharma Industry: Regulatory Affairs

Regulatory Affairs

Registration
Marketing Authorisation

Clinical

Part of R&D



Market Access

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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

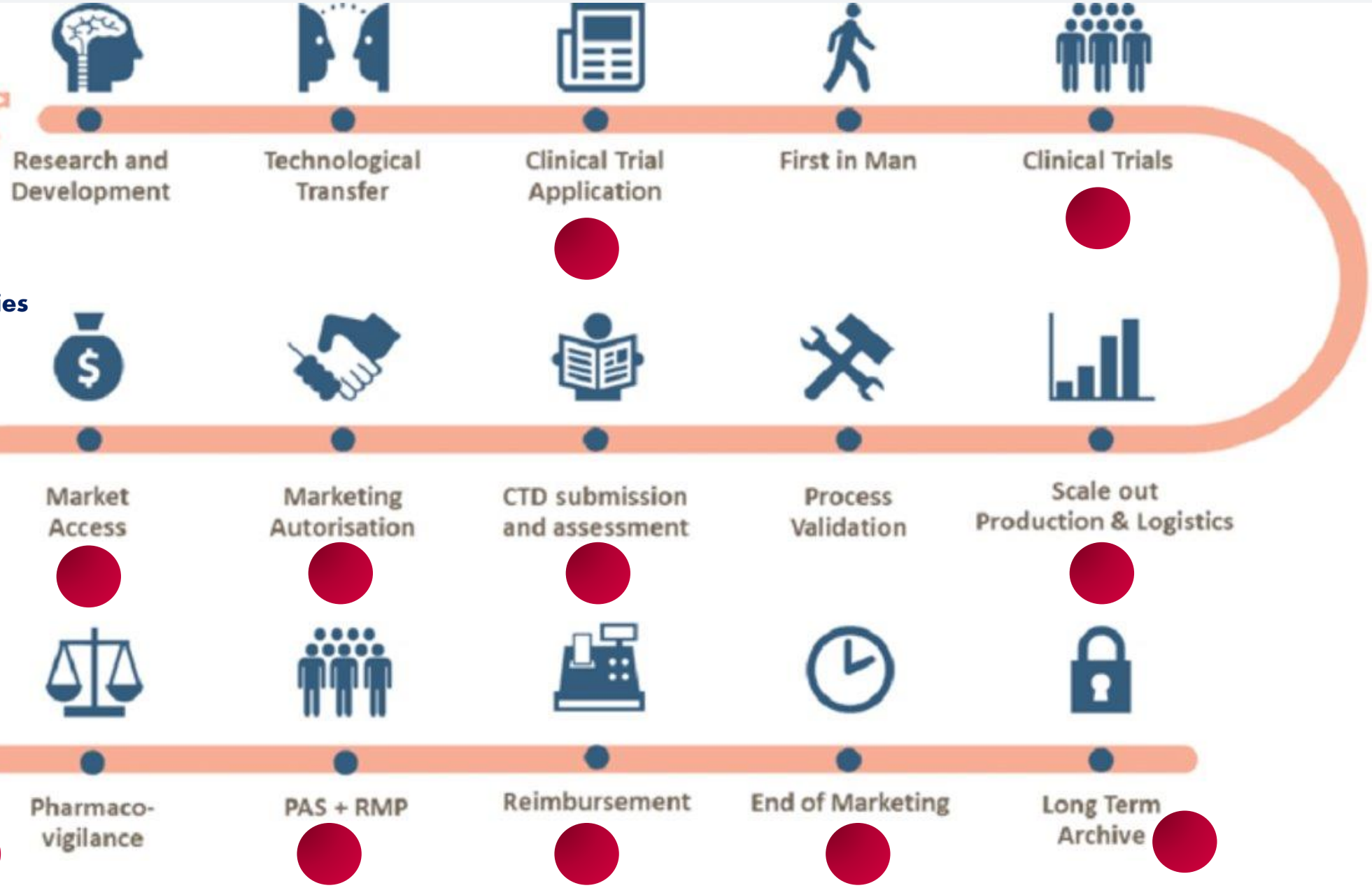
➢ Maintained on the market

- 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!

Phases of life for a medicinal product

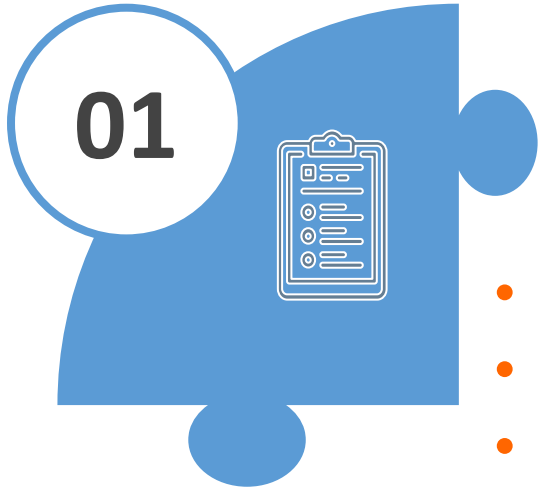


Regulatory Affairs activities

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 – Sept 2025

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

Pharmaceutical or Consultancy Company

Duration: 6 months

Know yourself!

Short-Term Goals
(1-2 years)

Mid-Term Goals
(3-5 years)

Long-Term Goals
(6 years +)

Acquire necessary COMPETENCIES

Knowledge	Degree Trainings
Skills	Communication Experience Expertise
Competency	Behaviour

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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

ECCRT STAR Programs

Junior Clinical Researcher STAR

Regulatory Affairs STAR

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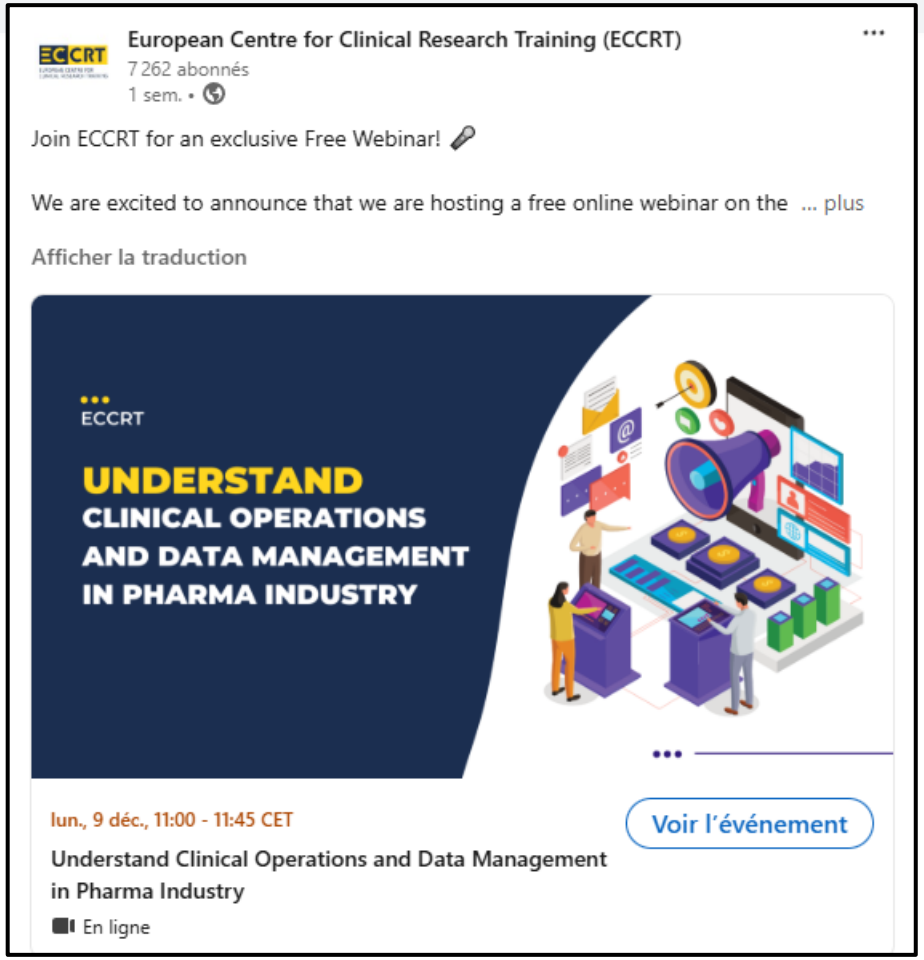
Next opportunity to learn more about CR and DM

Free Webinar

Understand Clinical Operations and Data Management in Pharma Industry
Deliver by expert in the field working at J&J



09 December 2024 at 11 am - Online
Info to Register via LinkedIn
(24) Understand Clinical Operations and Data Management in Pharma Industry | LinkedIn

Any Questions ?
Visit our booth # 2