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

Kunika van der Meer – Wakamatsu, RA Professional , J&J

Utrecht, May 2025

EUROPEAN CENTRE FOR
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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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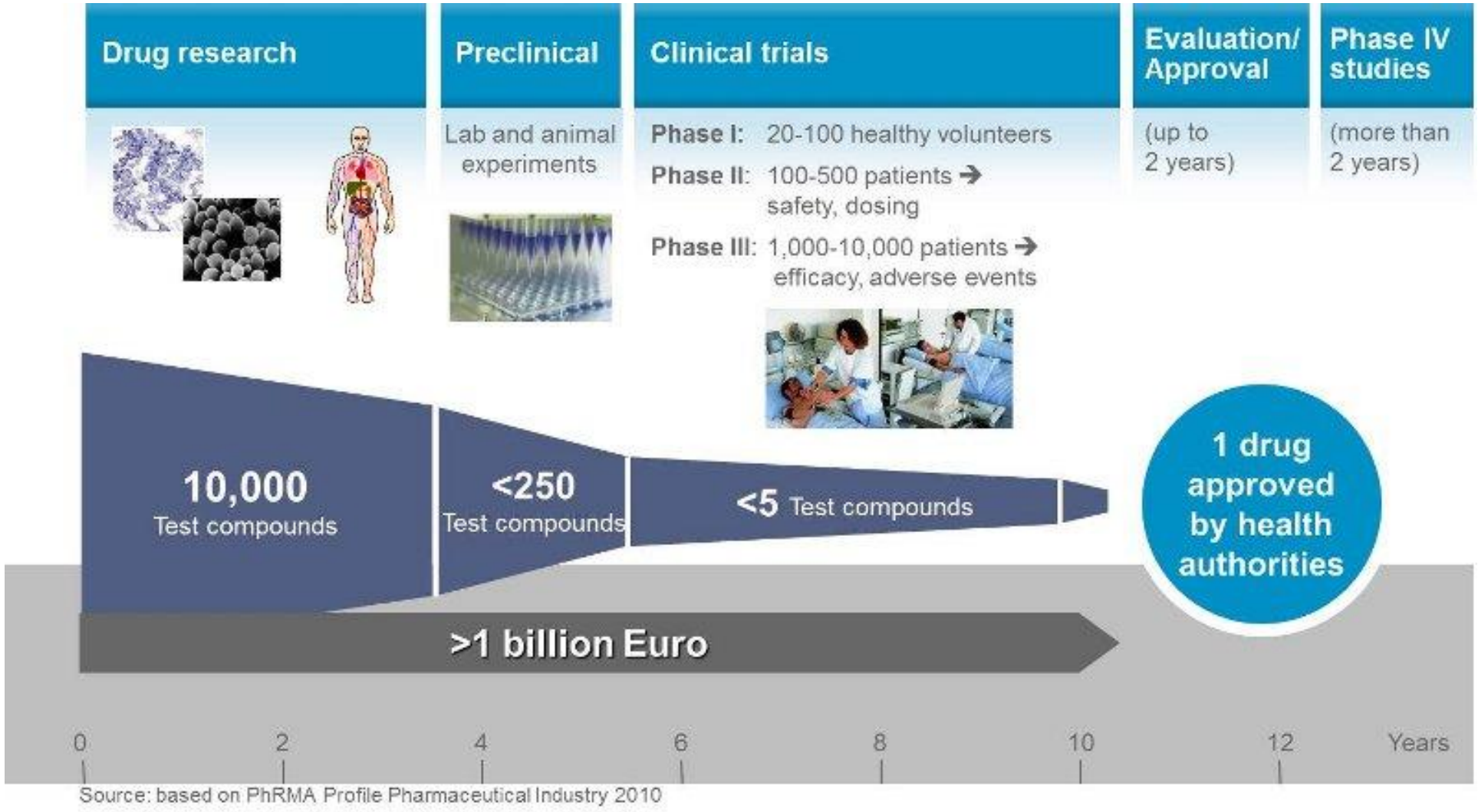
Agenda:

1. Drug Development Overview
2. 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

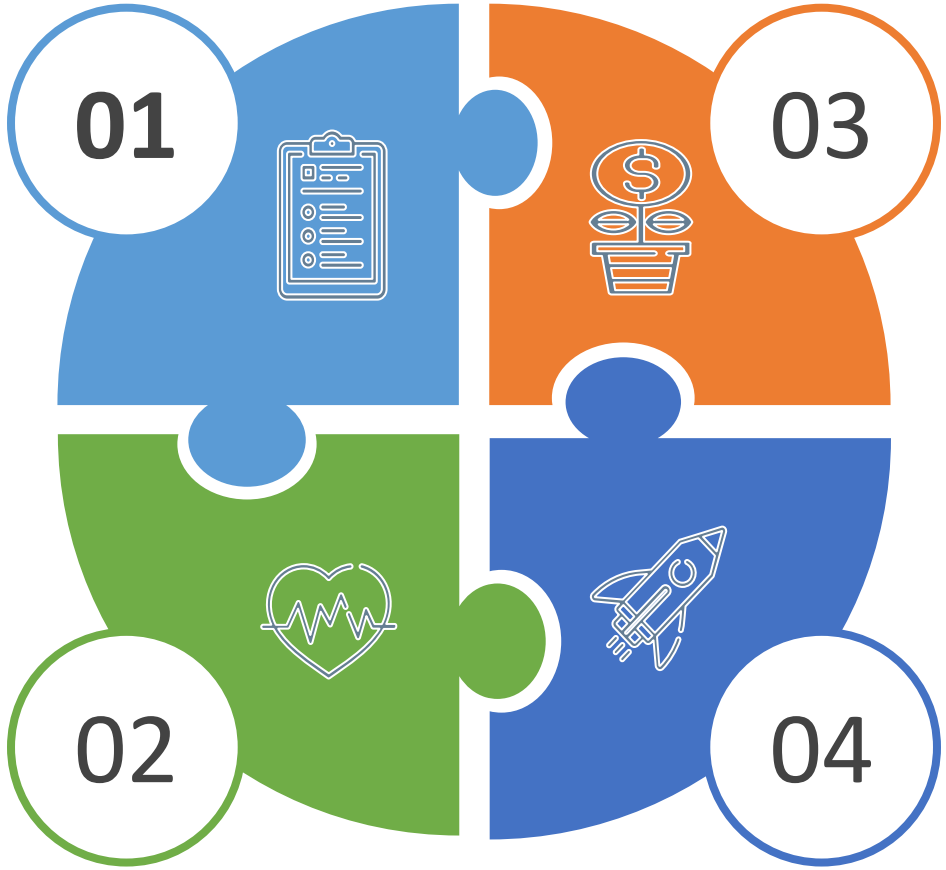
The Pharma Industry: Clinical Research

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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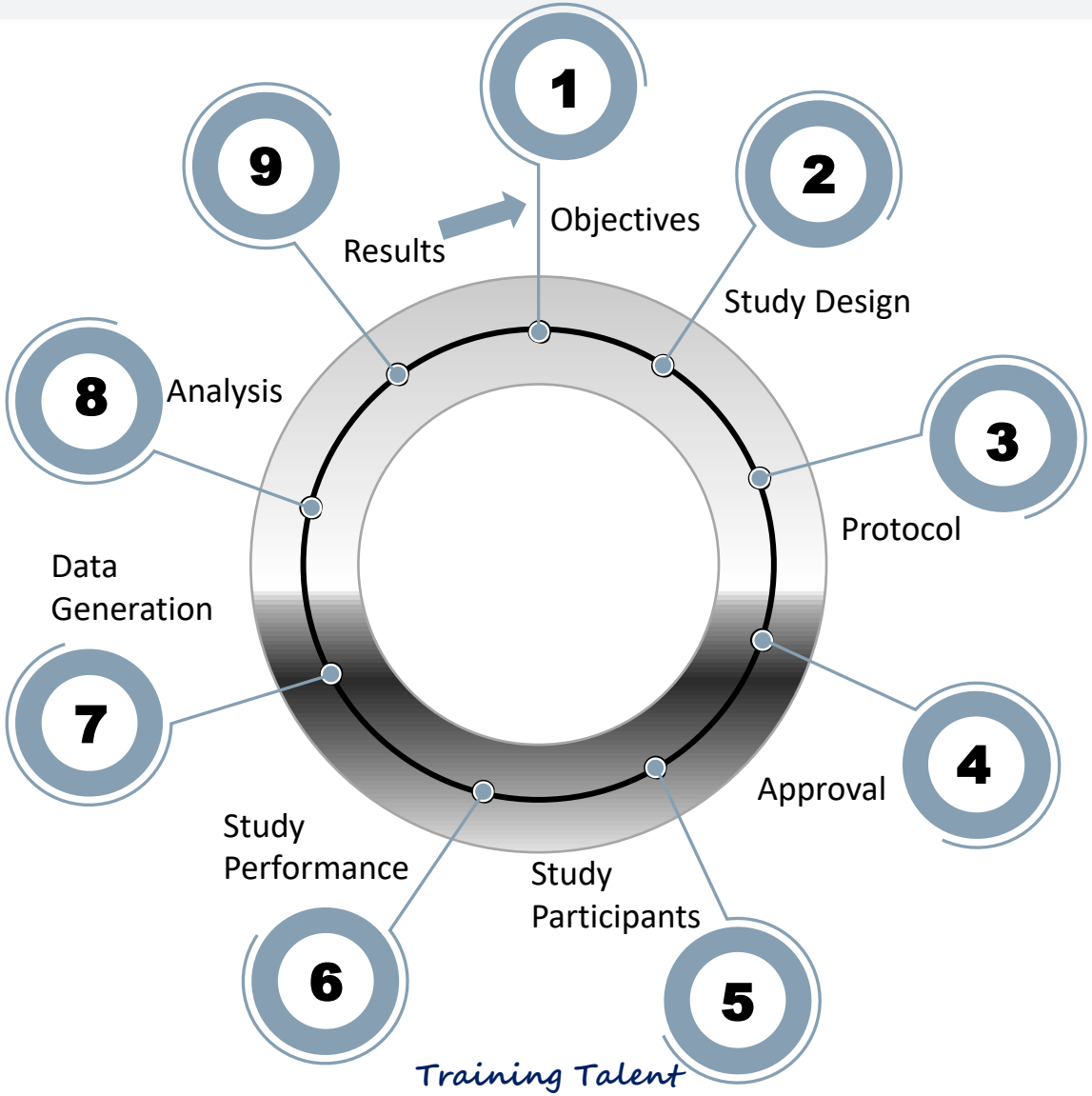
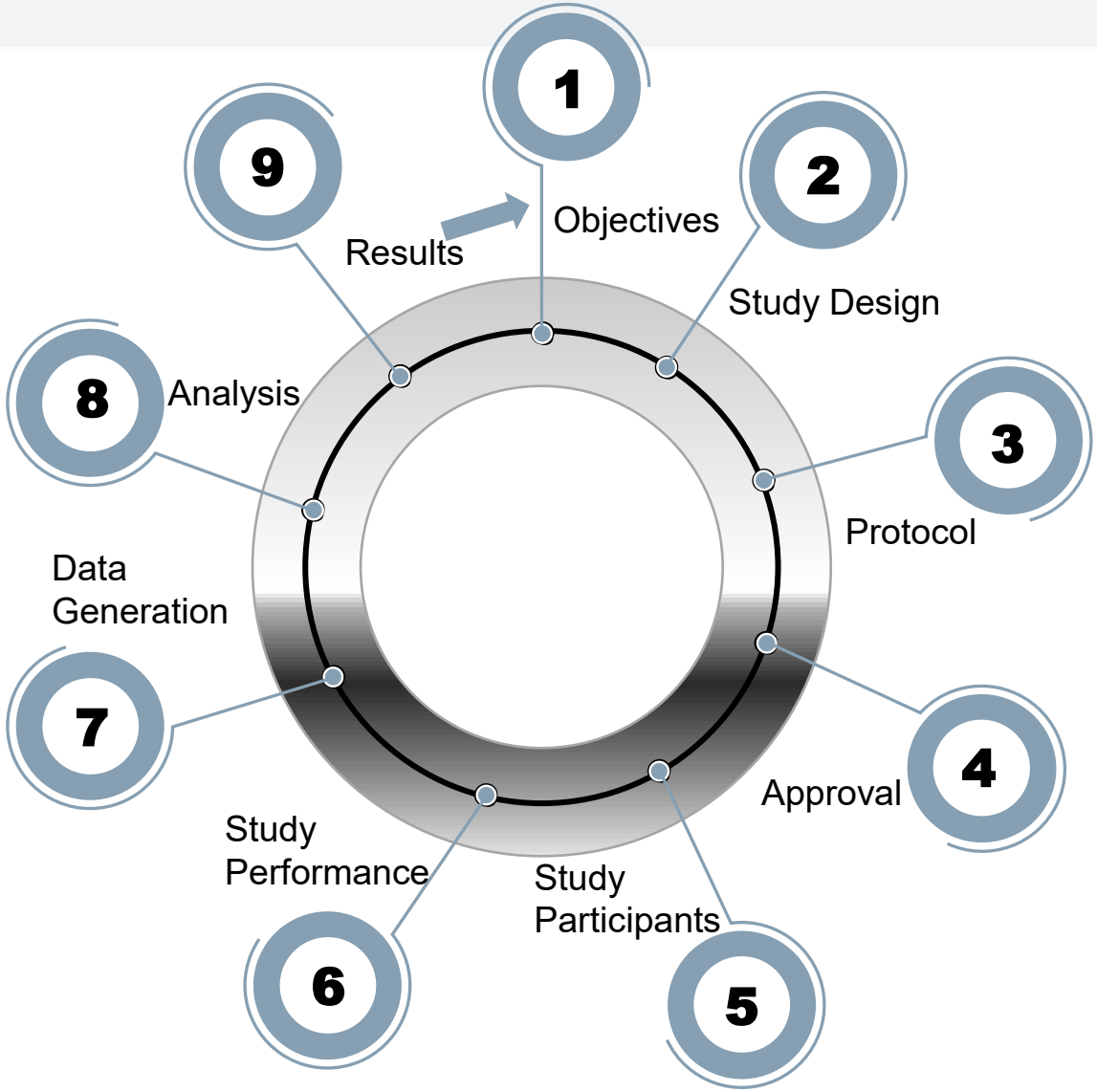


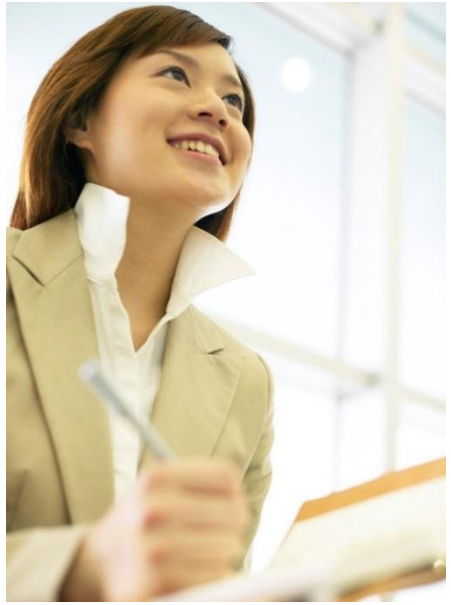
Training Talent

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:

July 2025
Sept 2025
Dec 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)

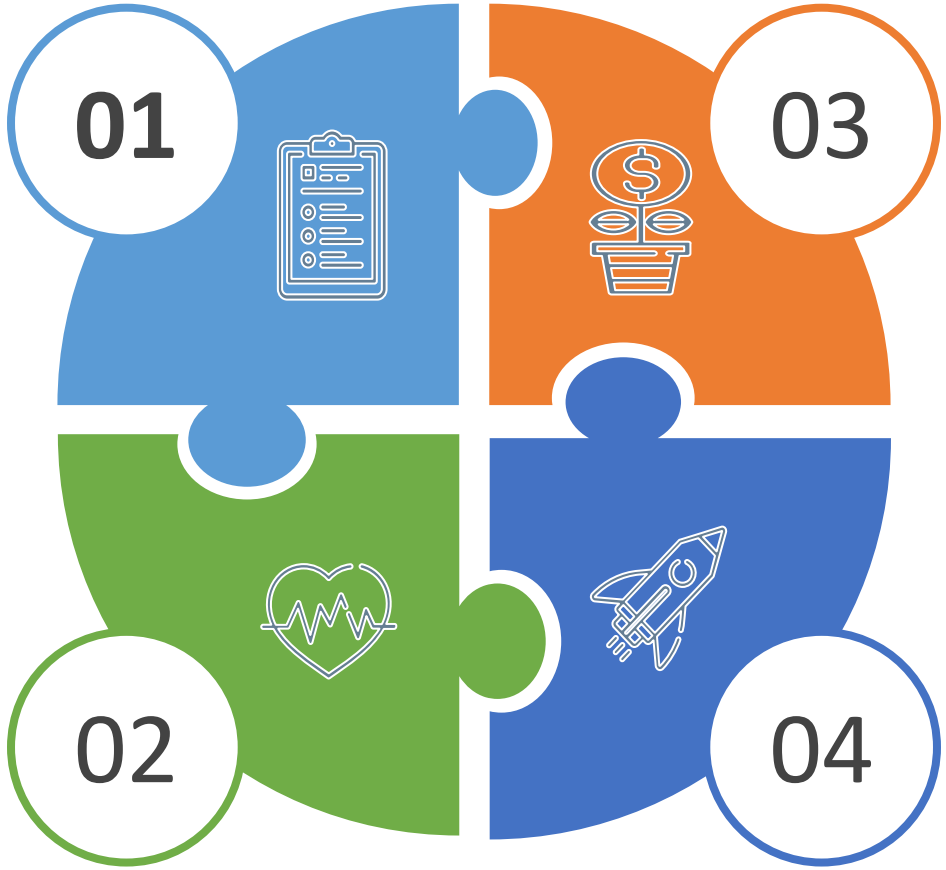
The Pharma Industry: Regulatory Affairs

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

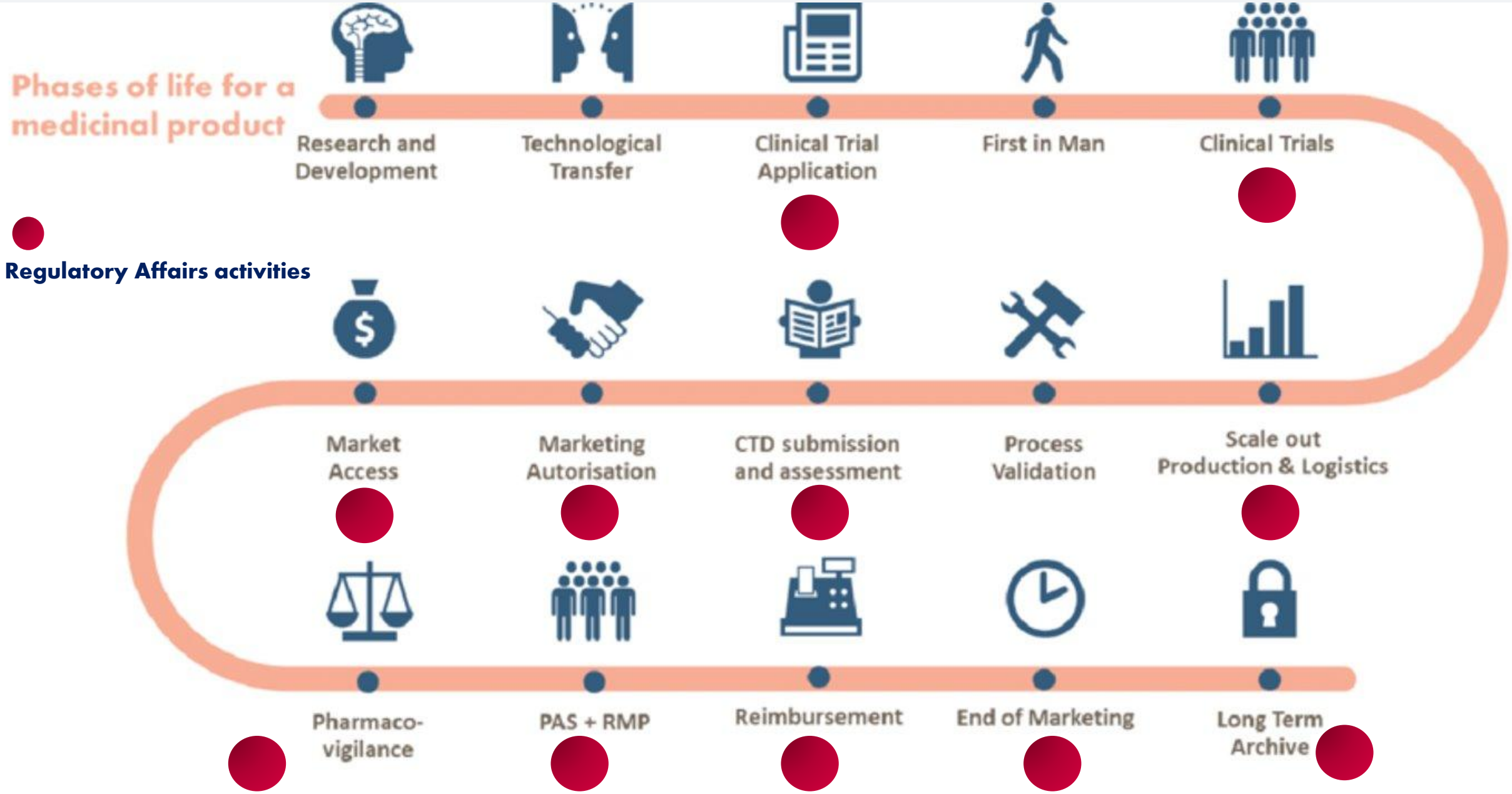
➢ Authorized

➢ Maintained on the market

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

Pharmaceutical legislation

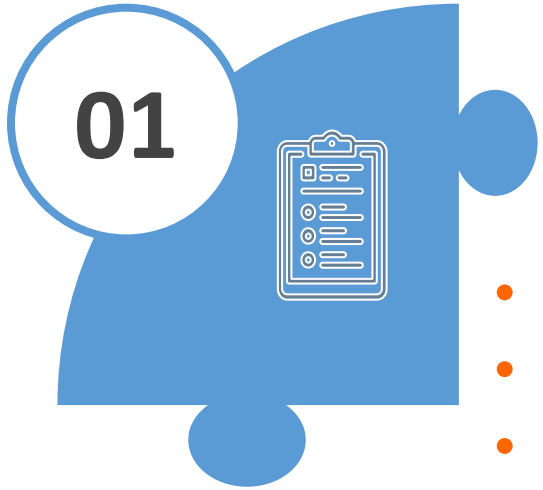
- A **Marketing Authorisation (MA)** can only be obtained if a company provides sufficient data that show that the medicine:
  - Has the effect that is claimed (**efficacy**)
  - Is (relatively) harmless (**safety**)
  - Is of acceptable and constant quality (**quality**)
- Post-authorisation, the **benefit-risk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



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 ….

Know yourself!

Short-Term Goals
(1-2 years)

Mid-Term Goals
(3-5 years)

Long-Term Goals
(6 years +)

Testimonial

Regulatory Affairs STAR programme

Kunika van der Meer - Wakamatsu
MD, MSc. International Health
Clinical development in Pharma&CRO (5yrs), PM in health sector (8yrs)

STAR Programme – Traineeships – Place, scope , activities :

1. Johnson and Johnson Innovative Medicine: Leiden, Dec 23- Dec 24, Clinical Trial application (CTA) submission manager trainee

Why we would recommend this programme

- **Comprehensive learning** through a combination of theoretical courses and practical internships
- **Hands-on experience** as a trainee, you learn day-to-day operations as a regulatory affairs professional
- **Mentorship** Regular follow-up with ECCRT stuff throughout internship
- **Continuous learning opportunities** ECCRT offers short courses to catch up recent clinical development regulations

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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

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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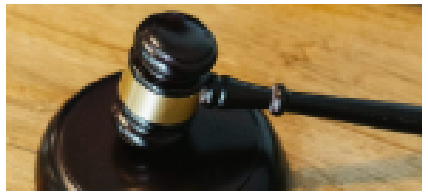
Next opportunity to learn more , join us !



½ day Orienting Training in Clinical Research
01 July 2025 – in Brussels

½ day Orienting Training in Regulatory Affairs
08 July 2025 – in Brussels

=> Connect to register for free course

Any Questions ?

Visit our booth 19

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Questions? Contact us !

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Thank you