

Make your way into Clinical Research or Regulatory Affairs world

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24 MAY 2023 | BEATRIX BUILDING - JAARBEURS UTRECHT

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ENERGIZE
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LIFE SCIENCES

1. What we do?

Facilitating Clinical Research professionals to excel in their job for the benefit of patients.

2. How we achieve our goal?

**Open
Courses**

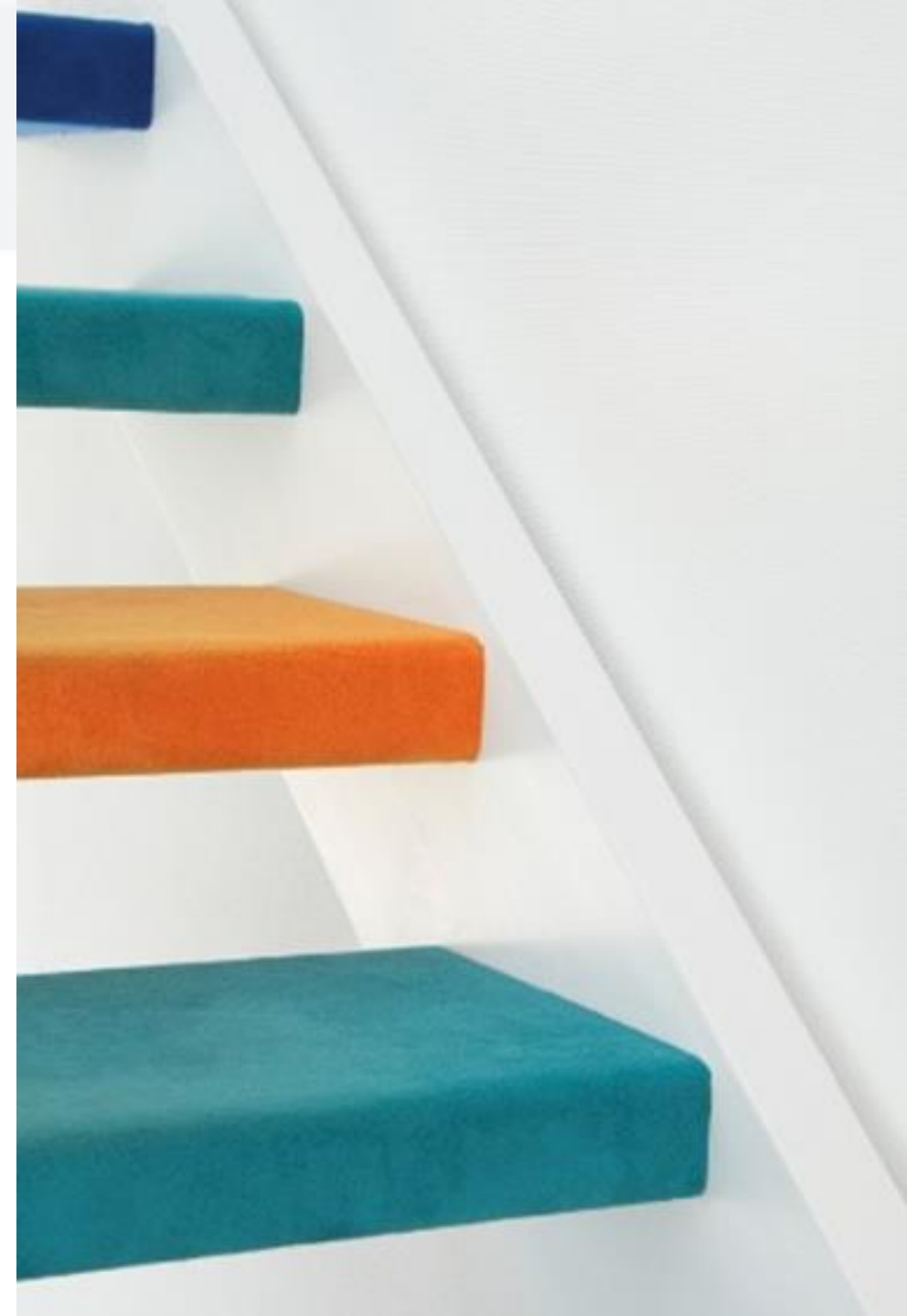
**Tailored
Courses**

**SMART
Solutions**

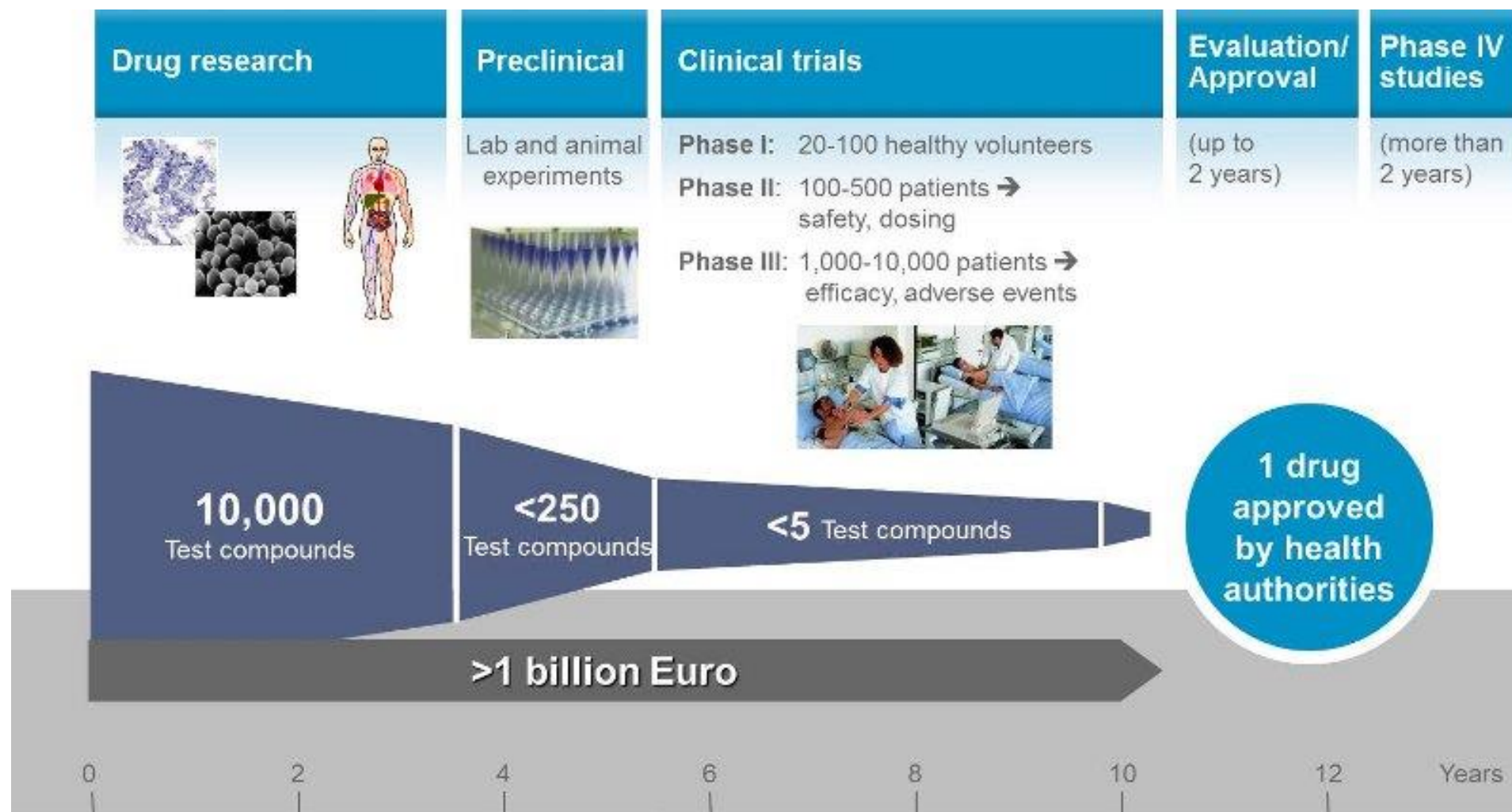
**micro
Learning**

Agenda:

1. What are job the in Clinical Research and Regulatory Affairs
2. What you need to find a job
3. Boost Yourself: ECCRT programs



Drug Development Overview



Source: based on PhRMA Profile Pharmaceutical Industry 2010

The Pharma Industry

Regulatory Affairs

Registration, Marketing
Authorisation

Clinical

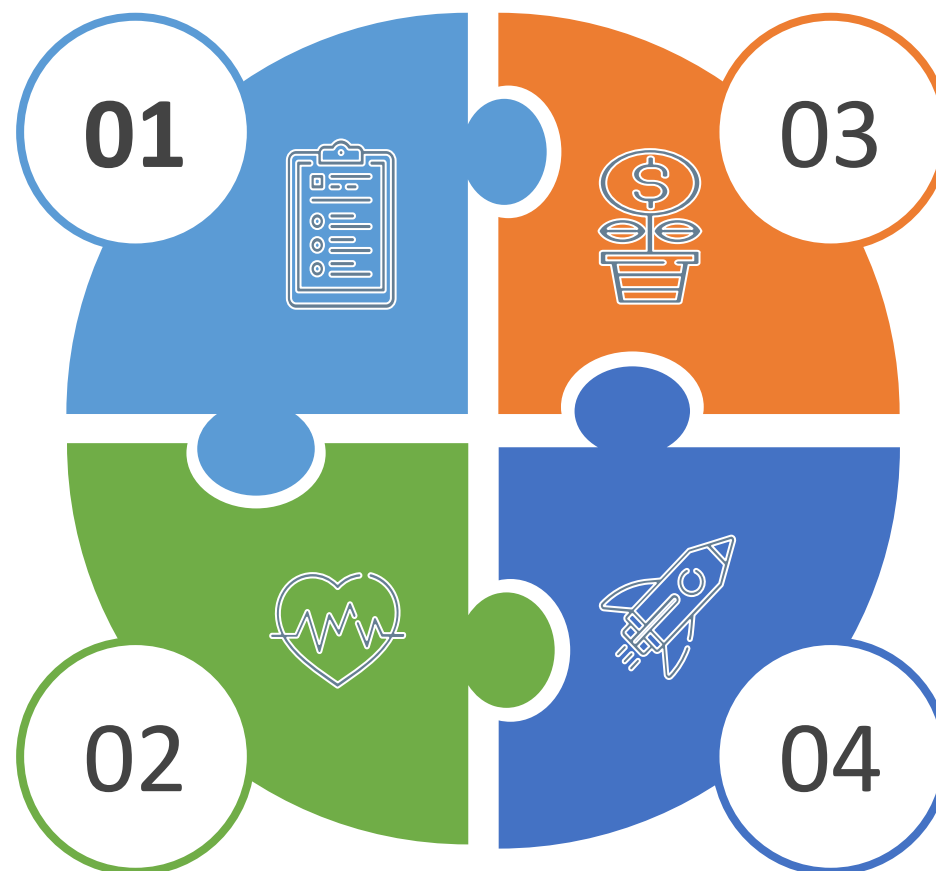
Part of R&D

Market Access

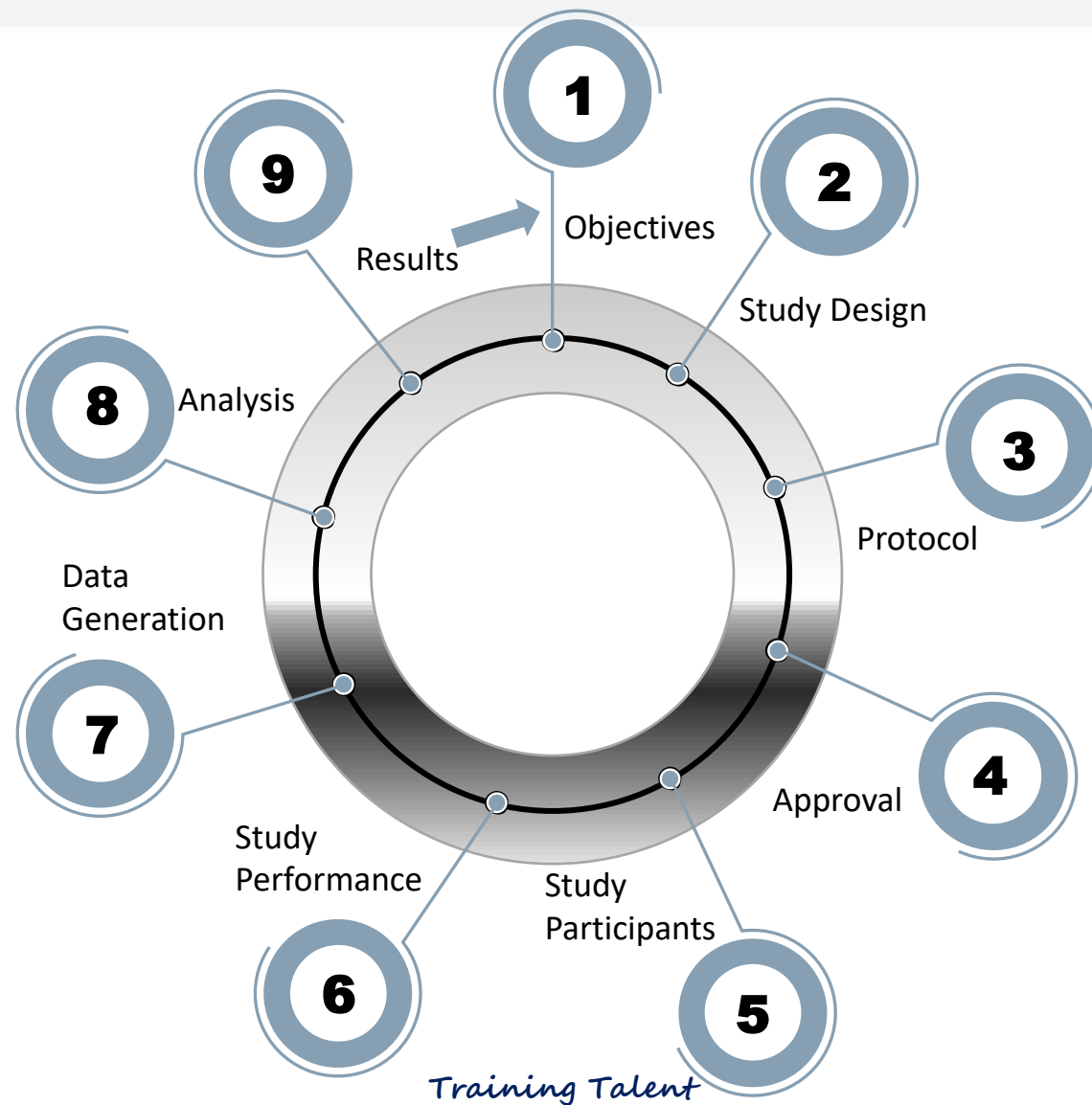
Health Economics
RWE
Reimbursement

Marketing

Sales force
Medical Scientific
Liaison



The Clinical Trial Cycle



Jobs in Clinical Research

Clinical

Part of
R&D

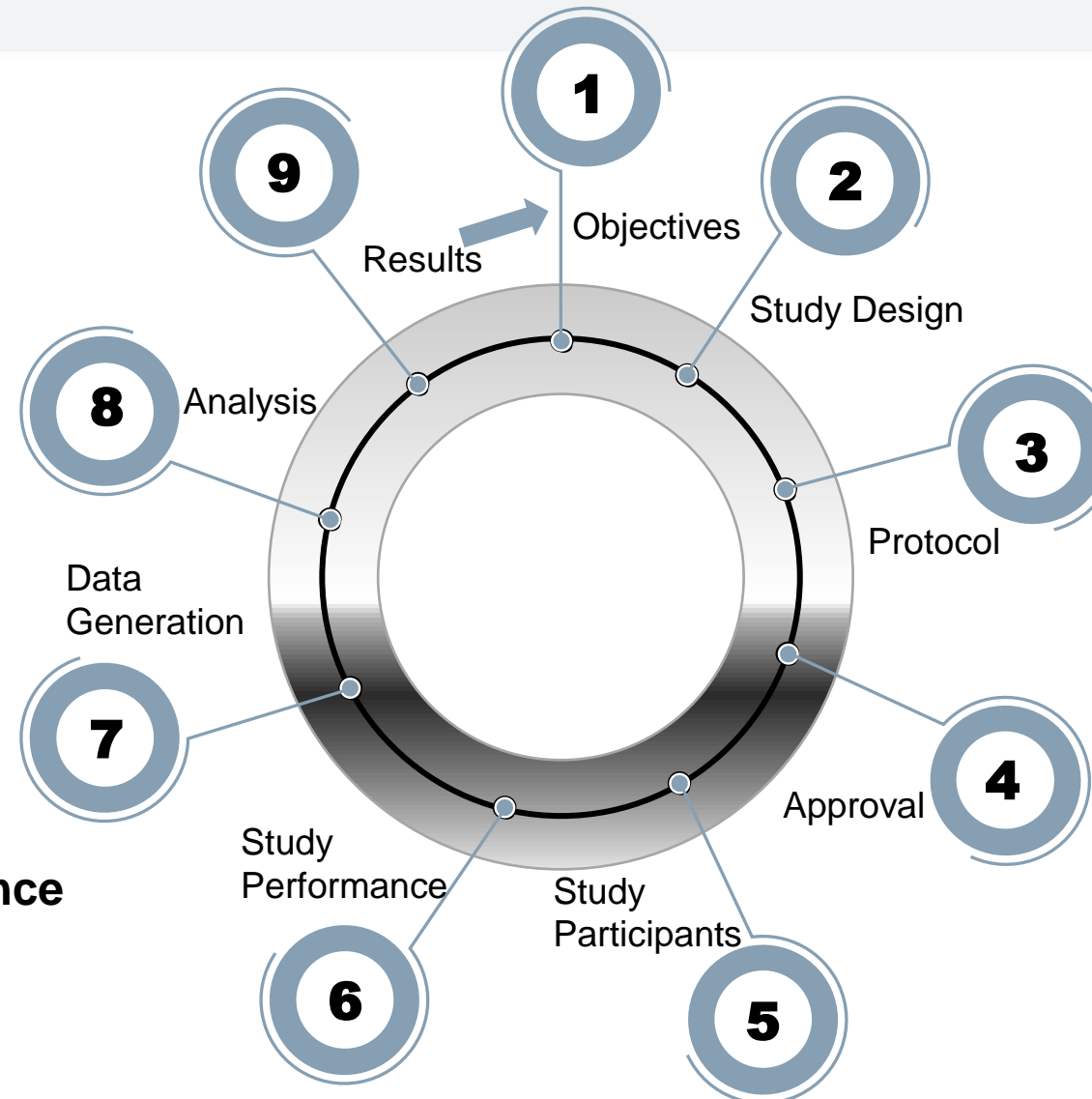
02



Statistician
Data Manager
Medical Writer

Drug Safety/Pharmacovigilance

- Drug Safety Officer
- PV Associate
- PV Manager



Training Talent

Study Physician
Medical Writer
Scientific Writer
Clinical Research Associate
Clinical Trial Assistant
Project Manager

Study Startup
Clinical Regulatory affairs

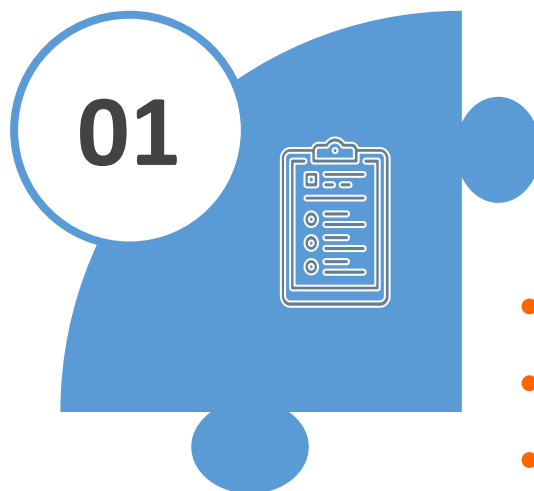
Site Investigator
Study Coordinator
Study Nurse

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



- Submission for MA in EU
- Submission for MA in a non-EU country / US
- CMC
- Labelling, GMP
- GDP
- Regulatory Information
- PV
- Information and publicity

Evolution of the clinical research professional

From paper to digital



Acquire necessary COMPETENCIES



Knowledge

Degree
Trainings




Skills

Language, Communication
Experience
Expertise



Attitude

Behaviour

The background of the slide is a blue-tinted photograph of a man in a white lab coat and glasses, looking down at a tablet or clipboard. The image is slightly blurred and has a soft, ethereal quality.

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

Develop Yourself: ECCRT Regulatory Affairs STAR Programme

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



Pharmaceutical or Consultancy Company

Duration: 2 x 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 2023**

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

July 2023

Sept. 2023

Dec 2023

Sonja Boes, graduated
in Nutrition & Dietetics
in 1996



STAR Programme - Traineeships:

- Traineeship 1: Amsterdam University Hospital – SC Oncology (AUMC) – (Hospital)
- Traineeship 2: Janssen Pharmaceuticals Johnson & Johnson – CRA Oncology Studies – (Pharma)
- Traineeship 3: European Organization for Research Treatment of cancer (EORTC) – remote CRA - (CRO)

Why I would recommend this programme

- Learning theory and practically within clinical research environment
- With personal guidance by professional coach during all internships
- Connecting with different research professionals
- Sharing learning curve and experiences with other students

Find us at the booth!

