How to start a career in

Clinical Research or Regulatory Affairs

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Utrecht, May 2026

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

- ✓ Drug Development Overview
- ✓ Clinical Research and Regulatory Affairs
- ✓ Boost your competencies
- ✓ ECCRT STAR programs

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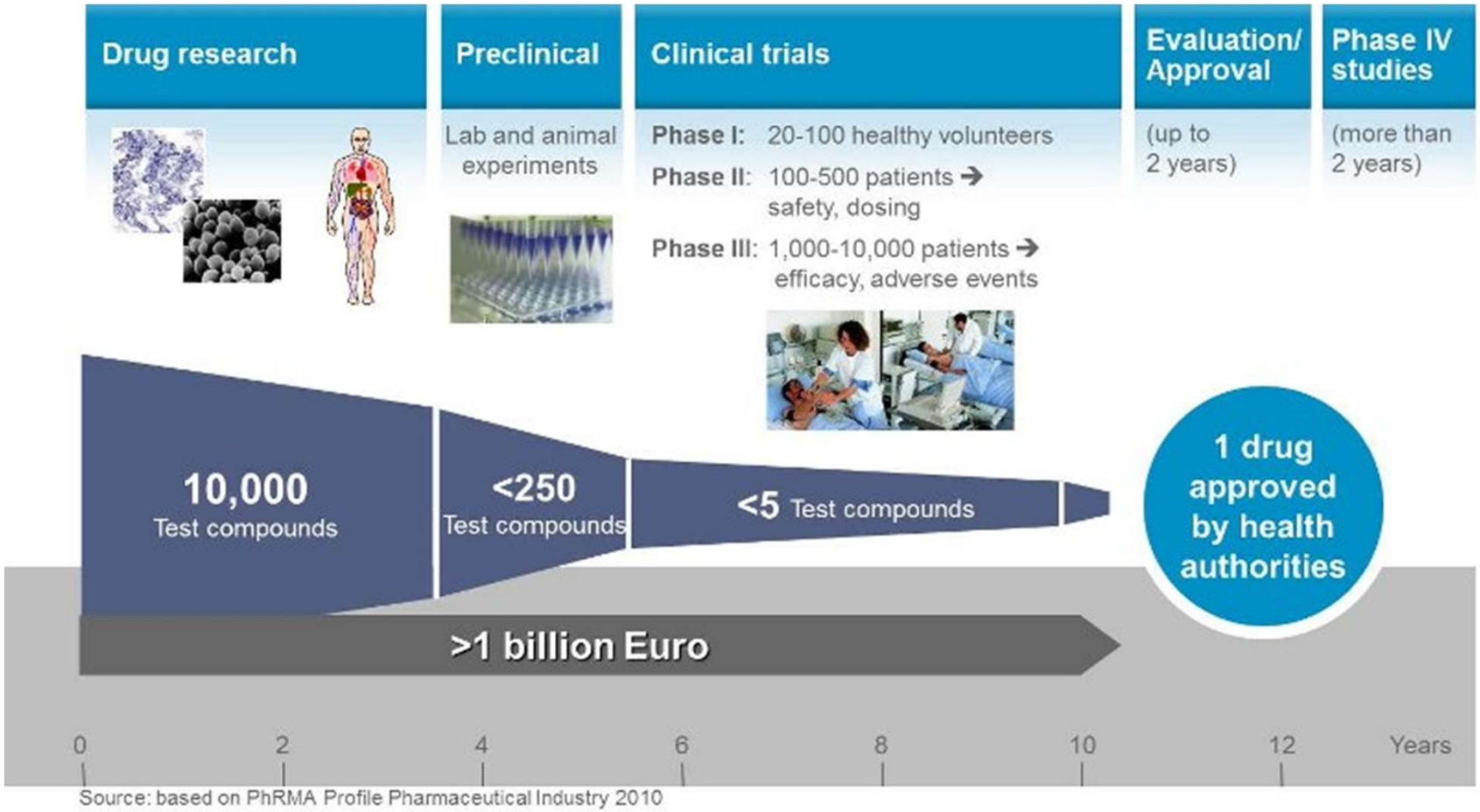
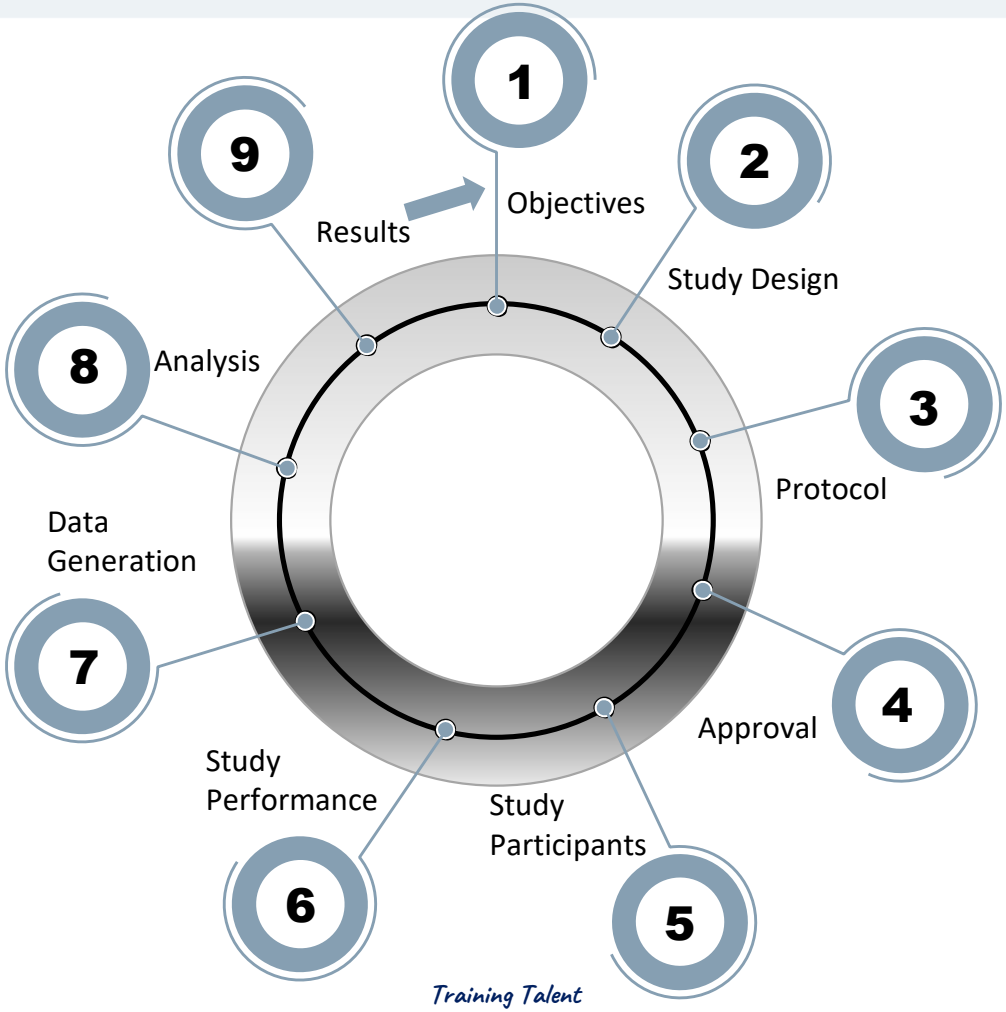
Drug Development Overview



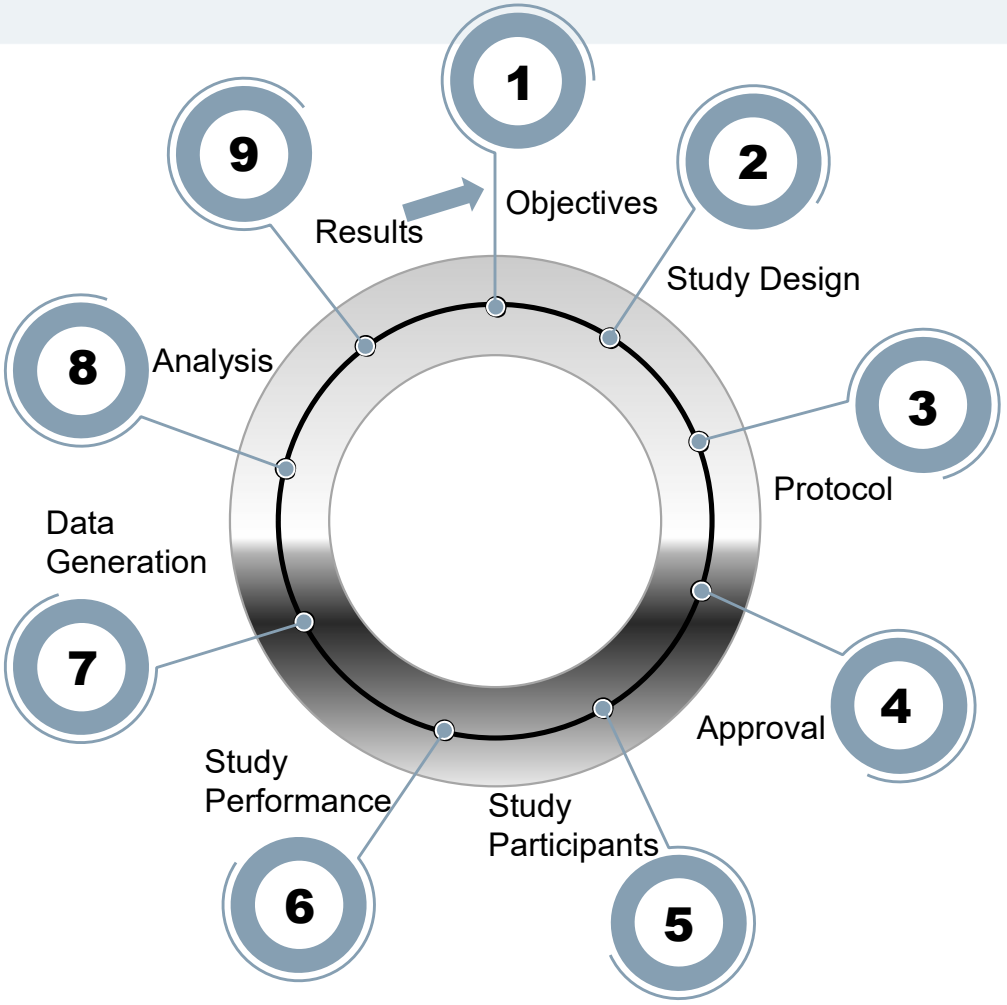
Source: based on PhRMA Profile Pharmaceutical Industry 2010

The Clinical Trial Cycle



Training Talent

Clinical Research Associate (CRA)



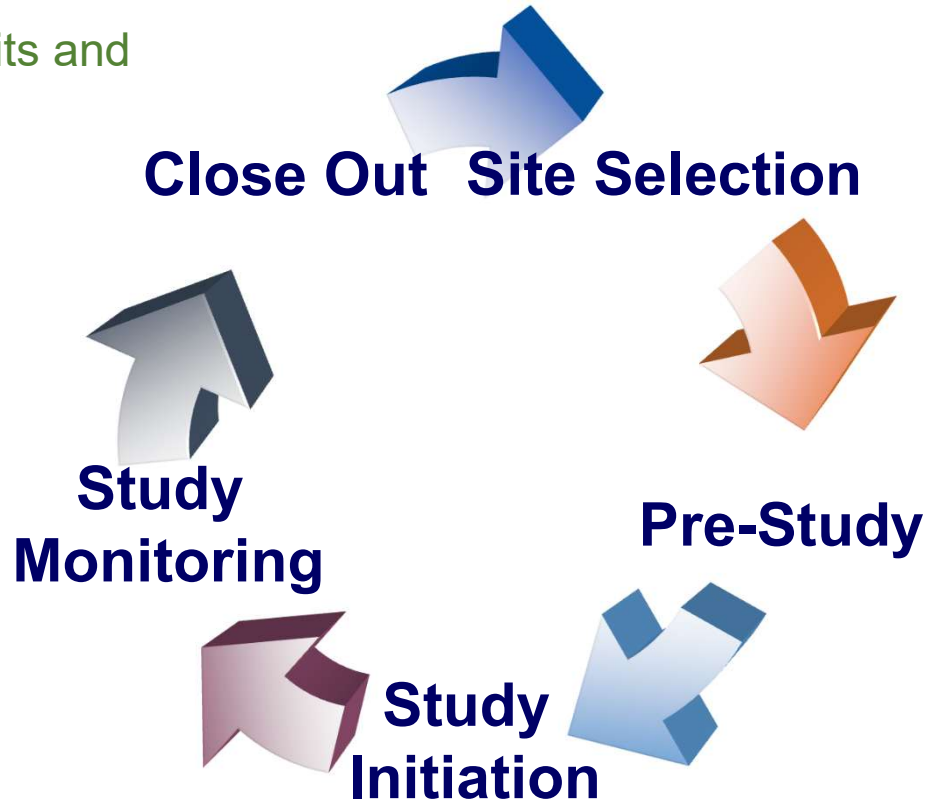
Clinical Research Associate (CRA or Monitor)

The Sponsor: Monitoring ICH-GCP

Monitoring in theory:

- Verify if rights & wellbeing of each trial subject is respected
- Verify that reported data is accurate, complete & verifiable from source documents
- Verify that the conduct of the trial is in compliance with protocol, GCP, regulatory requirements

CRA tasks during Project life cycle



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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

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Clinical Research Associate (CRA)

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

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

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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

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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!

Roles 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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Testimonial
Regulatory Affairs STAR programme

Natalia Peñaranda, PhD

Microbiology, Biomedical Sciences
In vitro diagnostic devices Regulatory affairs

STAR Programme – Traineeships – Place, scope , activities :

Johnson & Johnson, Oncology, Solid tumors team.
RA post-marketing maintenance activities: variations, line extensions, PSURs
CTAs early developments and new indications

Why we would recommend this programme

This is a hands-on learning program taught by senior experts in the field, enriched with real-life examples. The community is highly engaged and fosters active discussion and knowledge sharing. Given the wide scope of Regulatory as a discipline, the program offers a valuable opportunity to explore its many aspects and identify the areas that best align with your interests. The internship further enables you to translate theory into practice by seeing regulatory strategy in action.

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Boost your competencies

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Know yourself !

Short-Term Goals
(1-2 years)

Mid-Term Goals
(3-5 years)

Long-Term Goals
(6 years +)

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Acquire necessary COMPETENCIES

Knowledge	Degree Trainings
Skills	Communication Experience
How	Behaviour

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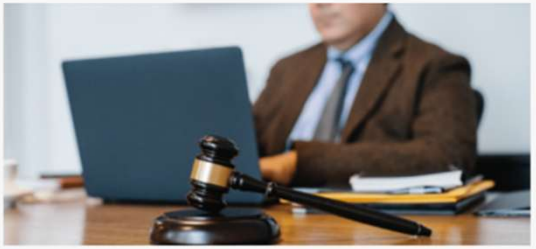
ECCRT STAR Programs

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



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

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Junior Clinical Researcher STAR Programme

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:

June 2026
Sept 2026
Dec 2026
March 2027

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Regulatory Affairs STAR Programme – Sept 2026

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

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EUROPEAN CENTRE FOR CLINICAL RESEARCH TRAINING

Connect to receive manual and free courses

½ day Orienting Training in Clinical Research

½ day Orienting Training in Regulatory Affairs

In Brussels
Face to face
23rd June

Training Talent

Any Questions ?

Visit our booth #19

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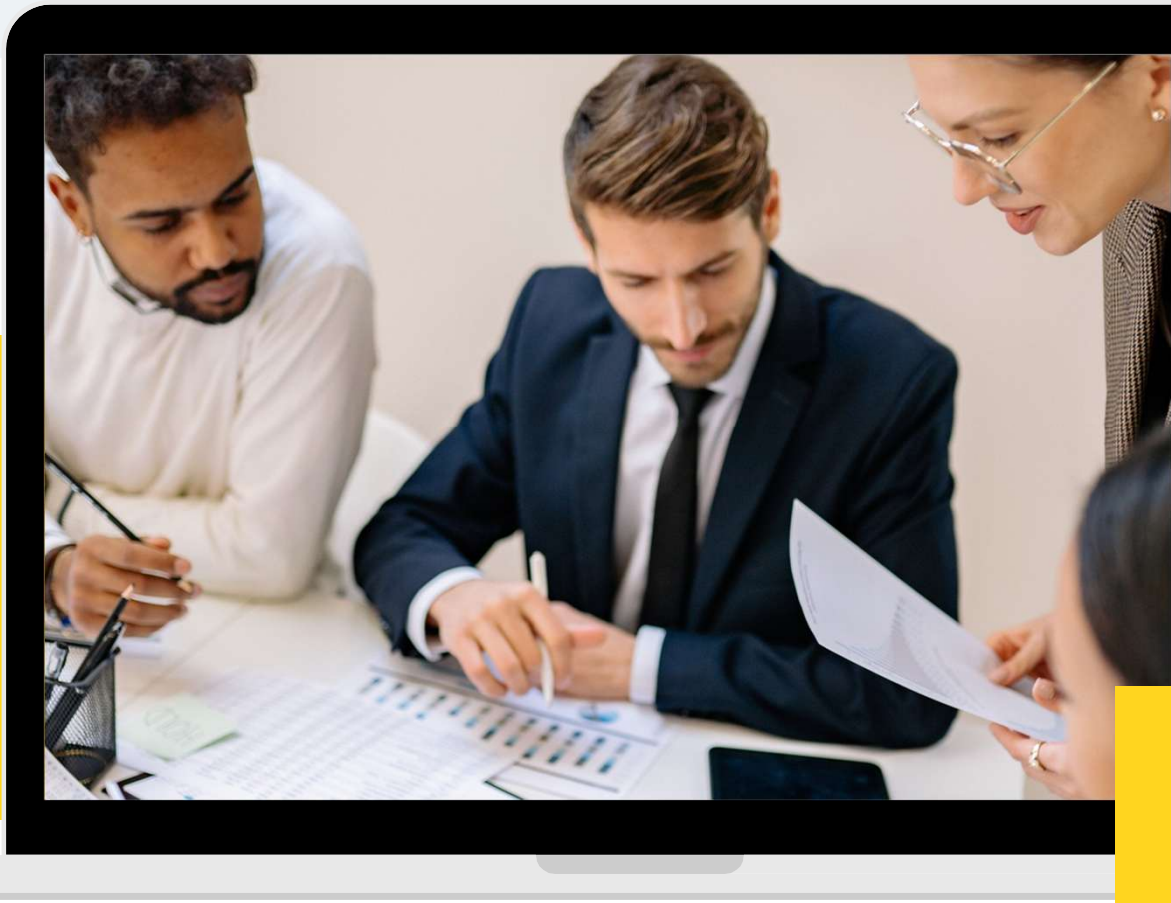
Questions? Contact us !



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Thank you