DARE TO **FLY**

CLINICAL TRIALS

EUGENIA ROM
CLINICAL DEVELOPMENT LEADER
INSUD PHARMA

Barcelona - March 15th 2023

Galenicum 20 YEARS

INSUD PHARMA

Health to everyone

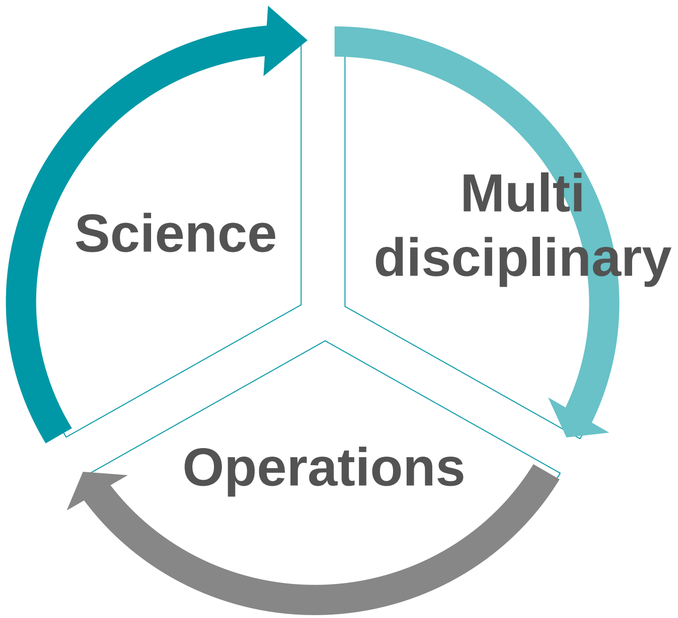
Barcelona - March, 2023

Clinical Department Presentation

Eugenia Rom Mas
Clinical Development Leader

Today’s agenda

Clinical Department DNA



1. Role of the Clinical Department within Pharmaceutical Industry
2. One day in the office
3. What is the market looking for?
4. Are you the right profile?
5. Career development

INSUDPHARMA

Role of the Clinical Department within Pharmaceutical Industry

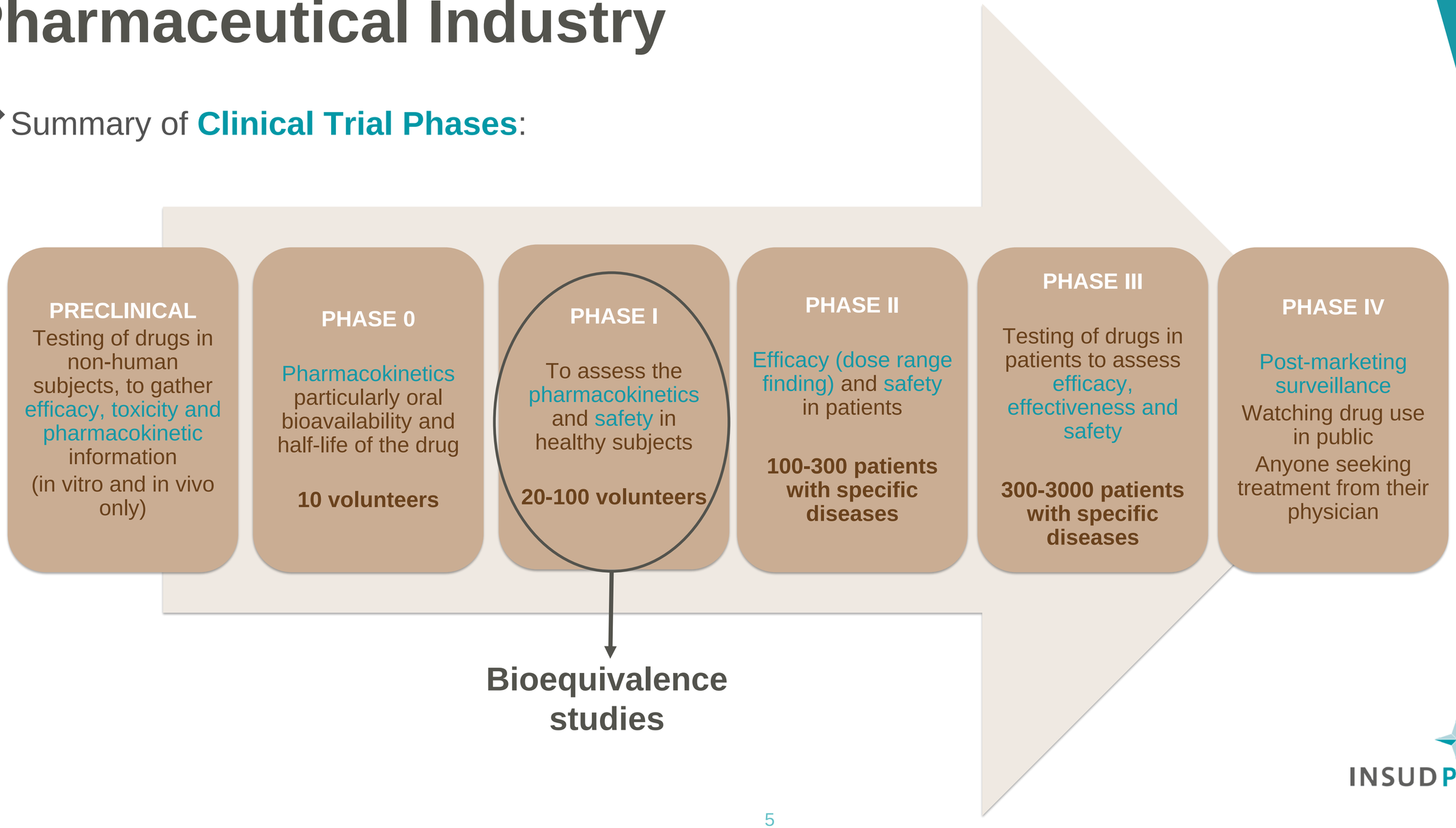
✔ **Clinical Department** is involved since the beginning of the drug development until the approval of the medicinal product in all targeted markets. It can also be involved in post-marketing activities and variations.

It is crucial to define the clinical strategy and the design of all clinical studies in order to obtain the medicinal product approval around the world.

INSUDPHARMA

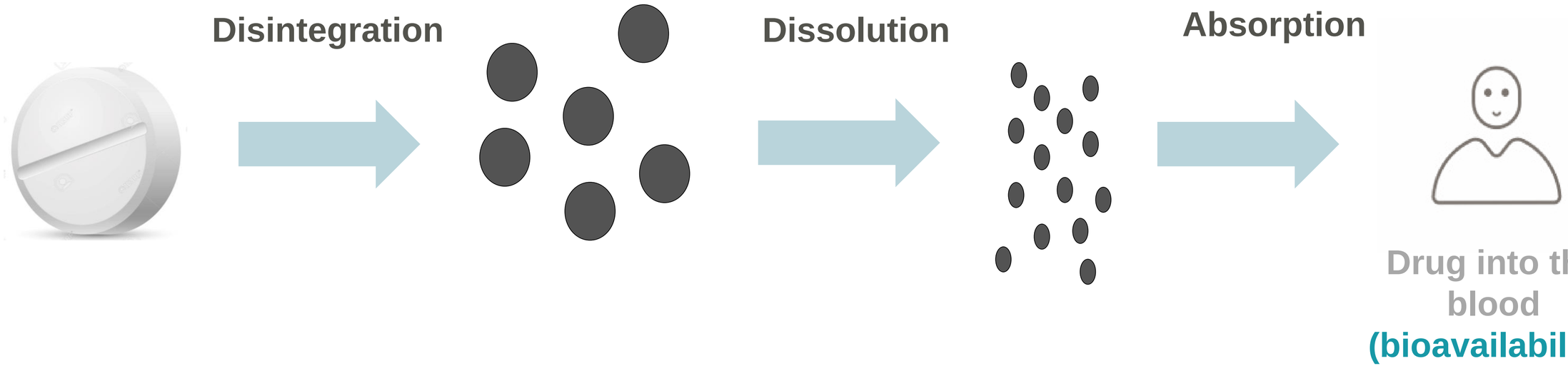
Role of the Clinical Department within Pharmaceutical Industry

✔ Summary of **Clinical Trial Phases**:



Role of the Clinical Department within Pharmaceutical Industry

✔ **Bioequivalence** studies:



Two medicinal products containing the same API are considered **bioequivalent** if **their bioavailabilities (rate and extent) after administration in the same molar dose lie within acceptable predefined limits**. These limits are set to ensure comparable *in vivo* performance, i.e. similarity in terms of safety and efficacy.

EMA (2010). Guideline on the investigation of bioequivalence. CPMP/EWP/QWP/1401/98 Rev. 1/ Corr **

INSUDPHARMA

A day in the office

Characteristics

Dynamism
Flexibility
No suitable for routine lovers
High pressure: TIME IS MONEY

Tasks

- Email correspondence
- Inter/Intra departmental meetings (new and follow-up projects)
- External meetings (CROs, partners, clients)
- Bibliographical research
  - Scientific background
  - Legislation
  - Regulatory Guidelines
  - Quality Assurance Guidelines (GMP, GCP, GLP)
- Clinical study design/strategy preparation
- New projects feasibility preparation
- Preparation of clinical queries (from clients or Authorities) responses

INSUDPHARMA

A day in the office

Design

Activities:

Literature review

Feasibilities for new projects

Draft Study Design/Strategy

Time/Cost assessment and planification

Quotation & CRO Selection

Activities:

Identification of possible CROs

Quotations

Final study design

Final CRO Selection

Send to negotiation process

Budget preparation

Preparation & Initiation

Activities:

Project contract preparation

Monitoring agreement

Insurance

Protocol review & approval

Clinical Trial Application for approval

Medicinal products shipment

Conduct & Closure

Activities:

Monitoring reports review and approval

Preliminary results

Draft report review

Final report approval

Clinical dossier modules preparation

Archiving clinical documentation

Approval process

Activities:

Clinical queries (from clients or Authorities) responses preparation

Post-marketing

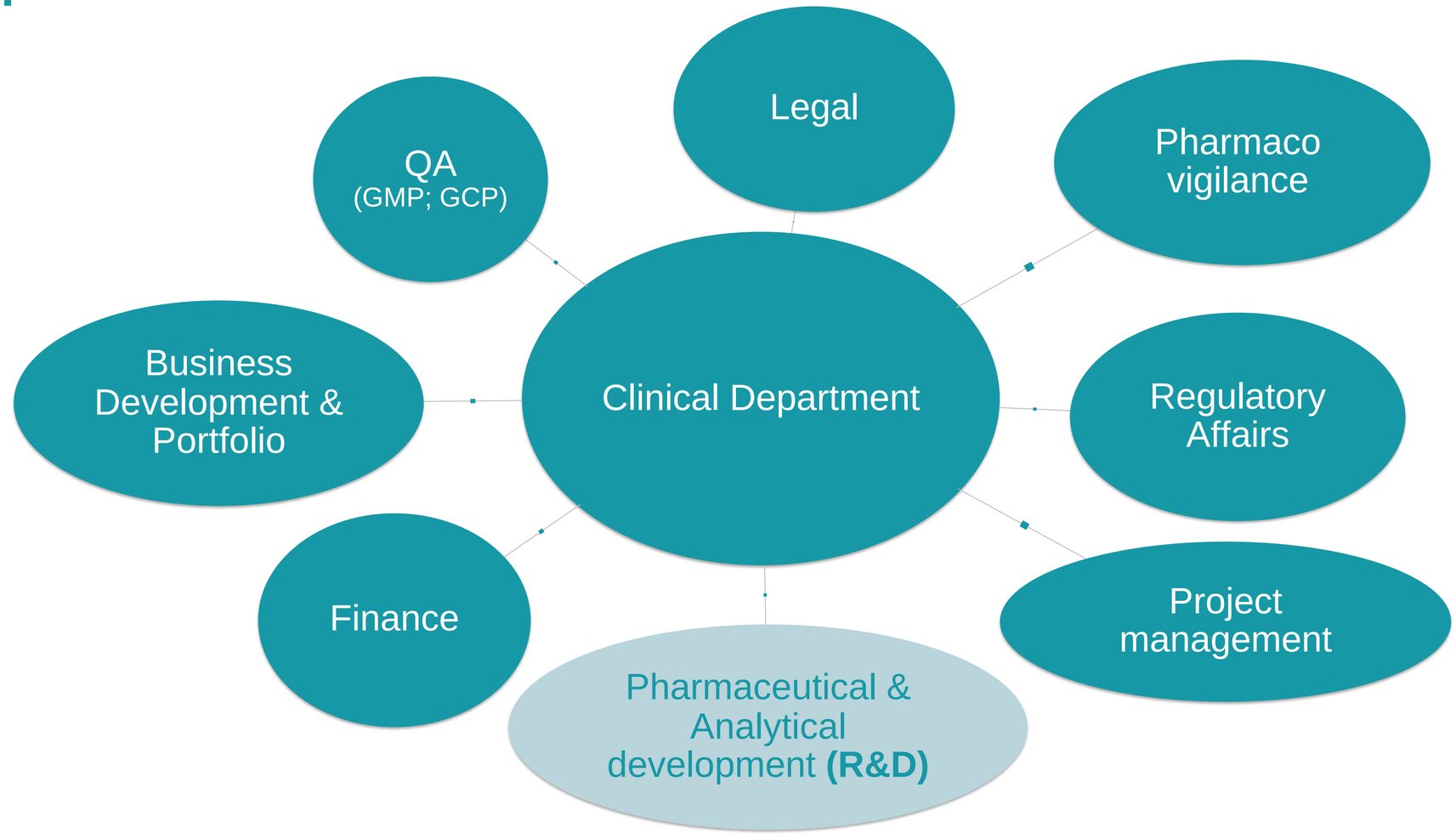
Activities:

Regulatory variations support

INSUDPHARMA

A day in the office

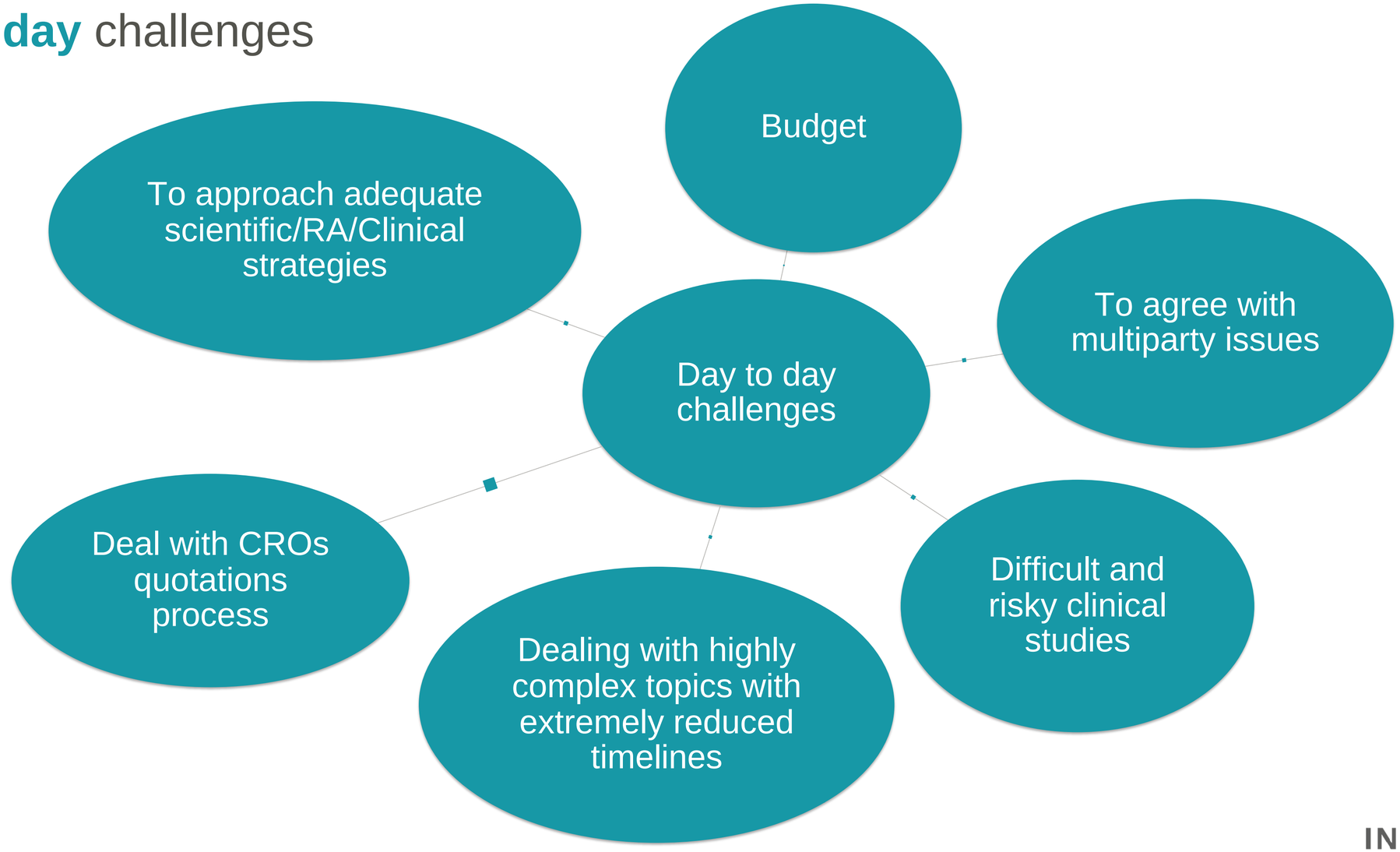
✔ **Interdepartmental** connections



INSUD PHARMA

A day in the office

✔ **Day to day** challenges



INSUDPHARMA

What is the market looking for?

- ✔ Highly responsible, proactive, dynamic, methodical, decisive and organized individual.
- ✔ Excellent oral and written communication and interpersonal skills.
- ✔ Strong analytical frame of mind and problem solving.
- ✔ Capable to work under pressure.
- ✔ Strong organizational and time management skills.
- ✔ Teamwork skills to collaborate with internal and external stakeholders.

INSUDPHARMA

Are you the right profile?

DEGREE:

- Health Sciences, preferably Pharmacy, but also: Chemistry, Biochemistry, Biotechnology, Medicine, etc
- Desirable post-graduate focused in Pharmaceutical Industry, including internship. E.g.: CESIF, UB, ESAME etc.
- High level of English (both oral and written communication)

PROFESSIONAL EXPERIENCE:

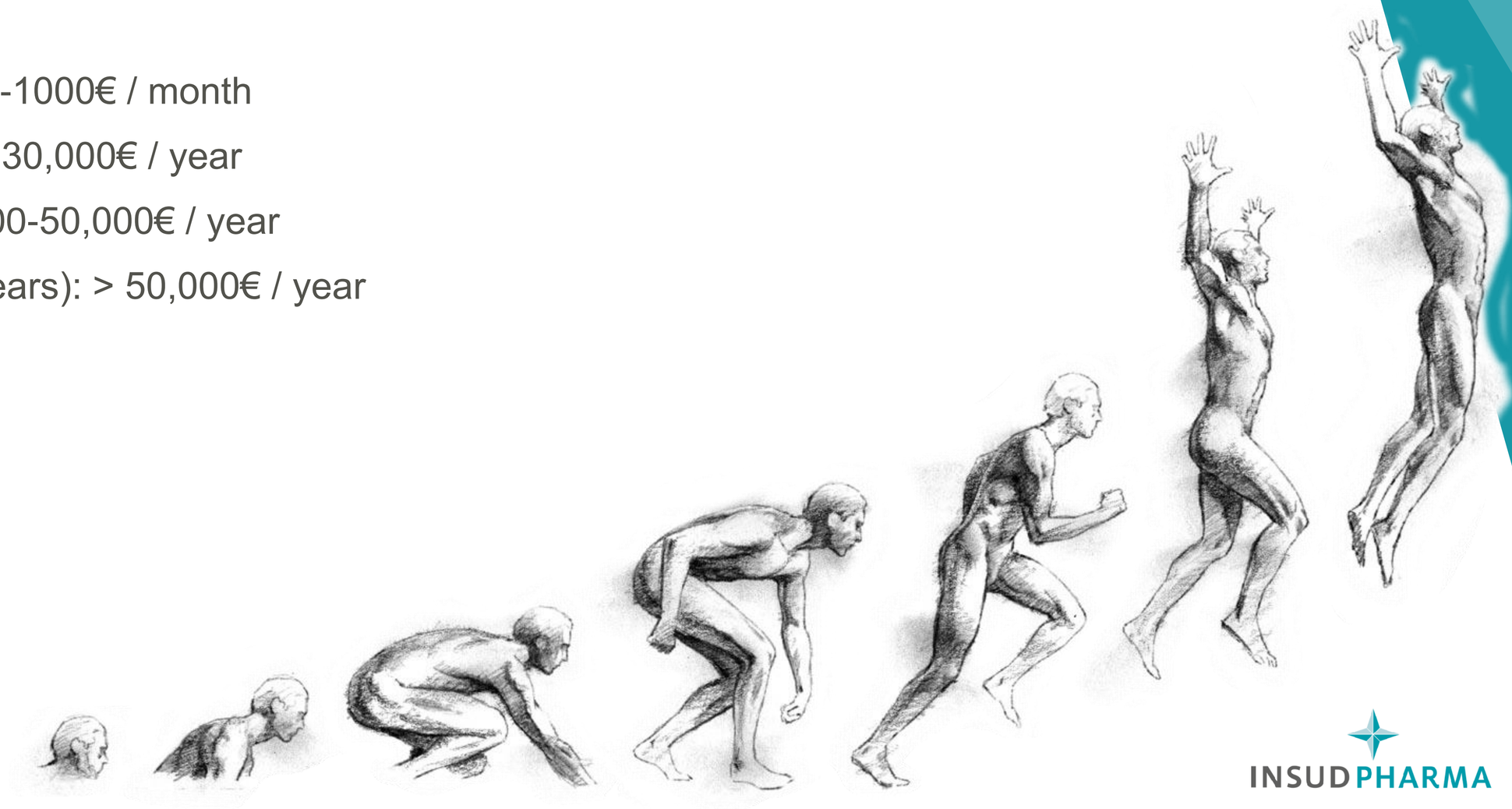
- Clinical affairs
- Biopharmaceutics
- Clinical and non-clinical development
- Monitoring (CRA)
- Clinical operations
- Bioanalytical
- Statistical databases management
- Medical Affairs / Advisor

INSUDPHARMA

Career Development

Clinical Department:

- Internship: 600-1000€ / month
- Junior: 20,000-30,000€ / year
- Senior 1: 30,000-50,000€ / year
- Senior 2 (>8 years): > 50,000€ / year



INSUDPHARMA

INSUD PHARMA

Barcelona - March, 2023

@InsudPharma

insudpharma.com

This is who we are.
Nice to meet you.

Kahoot! questions

What kind of clinical trial is a bioequivalence study?

1. Phase I in healthy volunteers
2. Phase III in patients
3. Phase II in healthy volunteers
4. Phase II in patients

When are clinical trial monitoring reports reviewed and approved?

1. During clinical trial design preparation
2. During CRO selection process
3. During clinical trial initiation activities
4. During clinical trial conduct

INSUDPHARMA