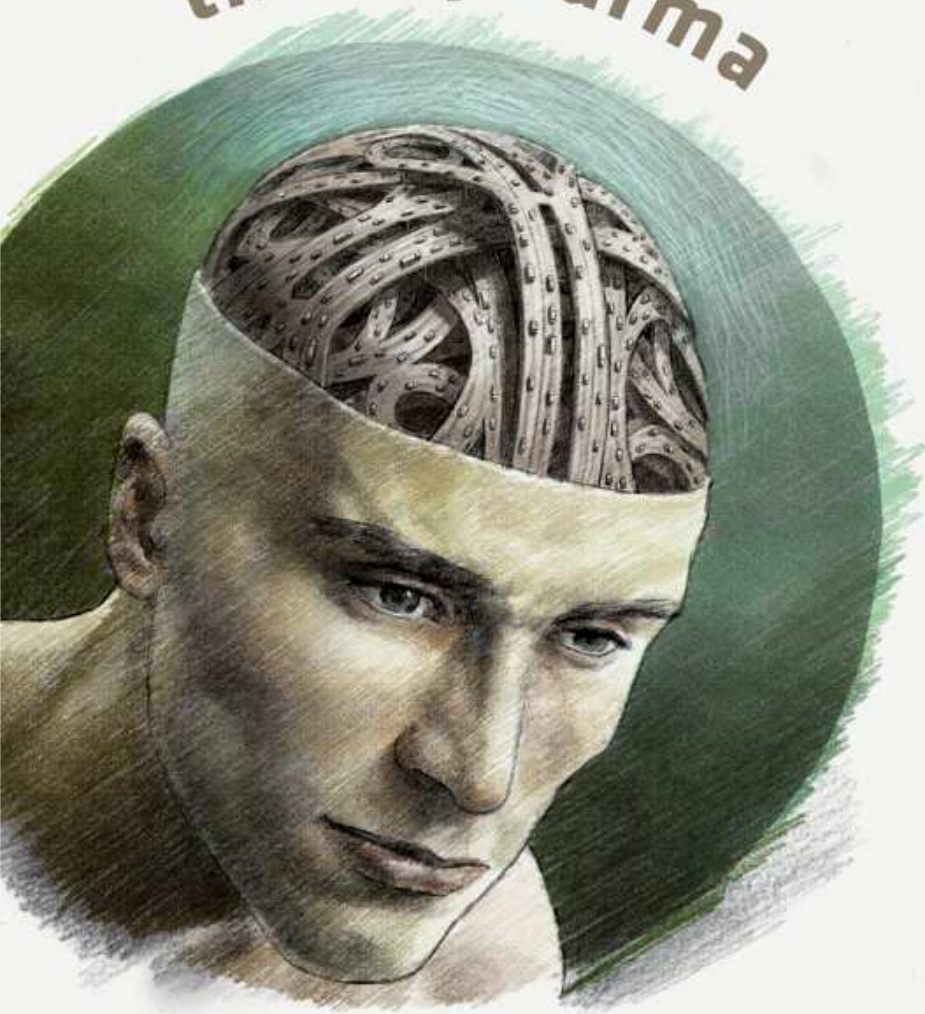


Think forward,
think pharma



CLINICAL & PHARMACOVIGILANCE DEPARTMENT

MARTA FORCADELL FERRÉ

BARCELONA - 13th MARCH 2019

■ believe in life
Galenicum
PHARMACEUTICAL COMPANY

Goal

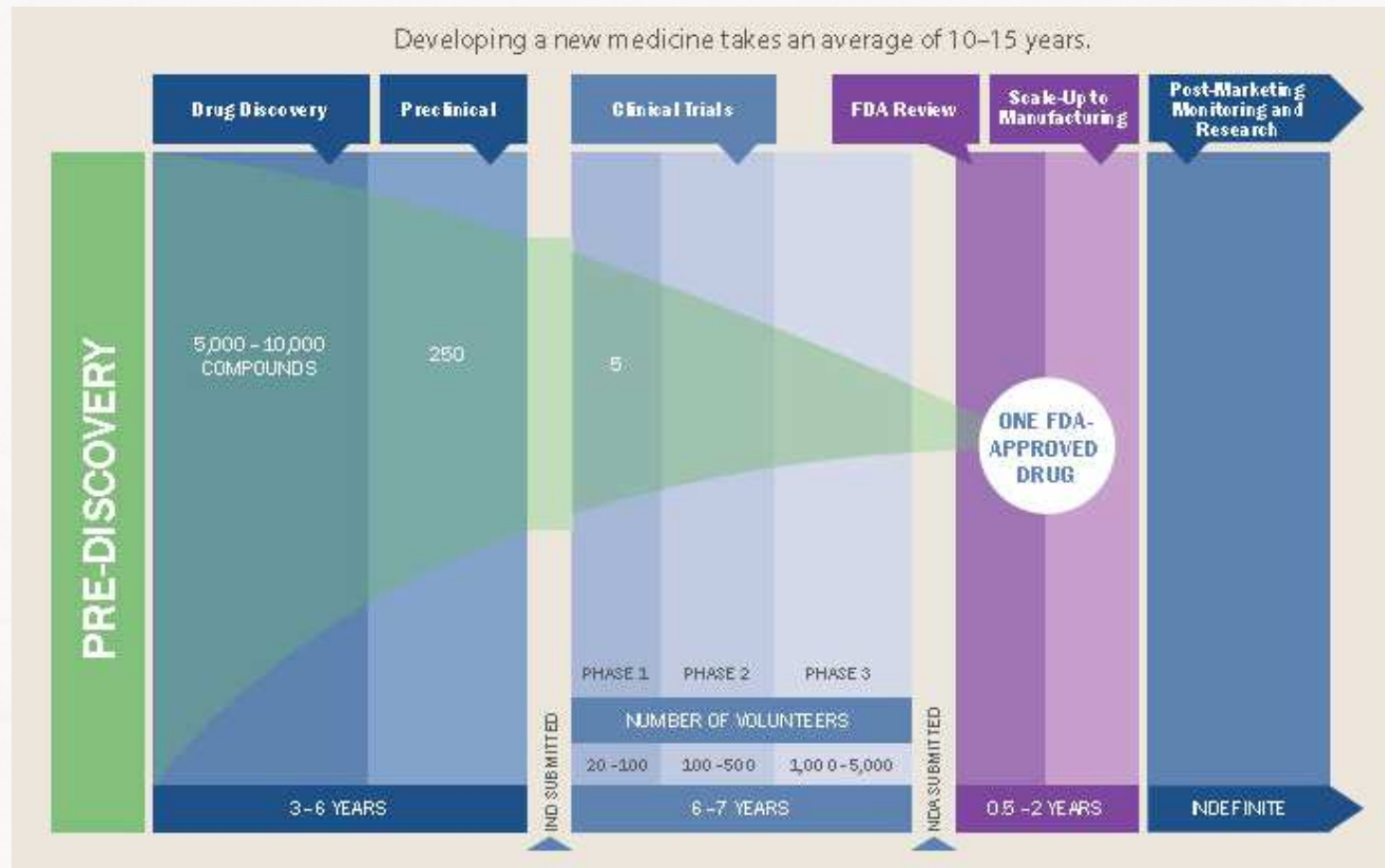
CLINICAL & PHARMACOVIGILANCE DEPARTMENT

1. Role of your area within the pharmaceutical industry
2. One day in the office
3. What is the marked looking for?
4. Are you the right profile?
5. Career development



1. Role of your area within the pharmaceutical industry

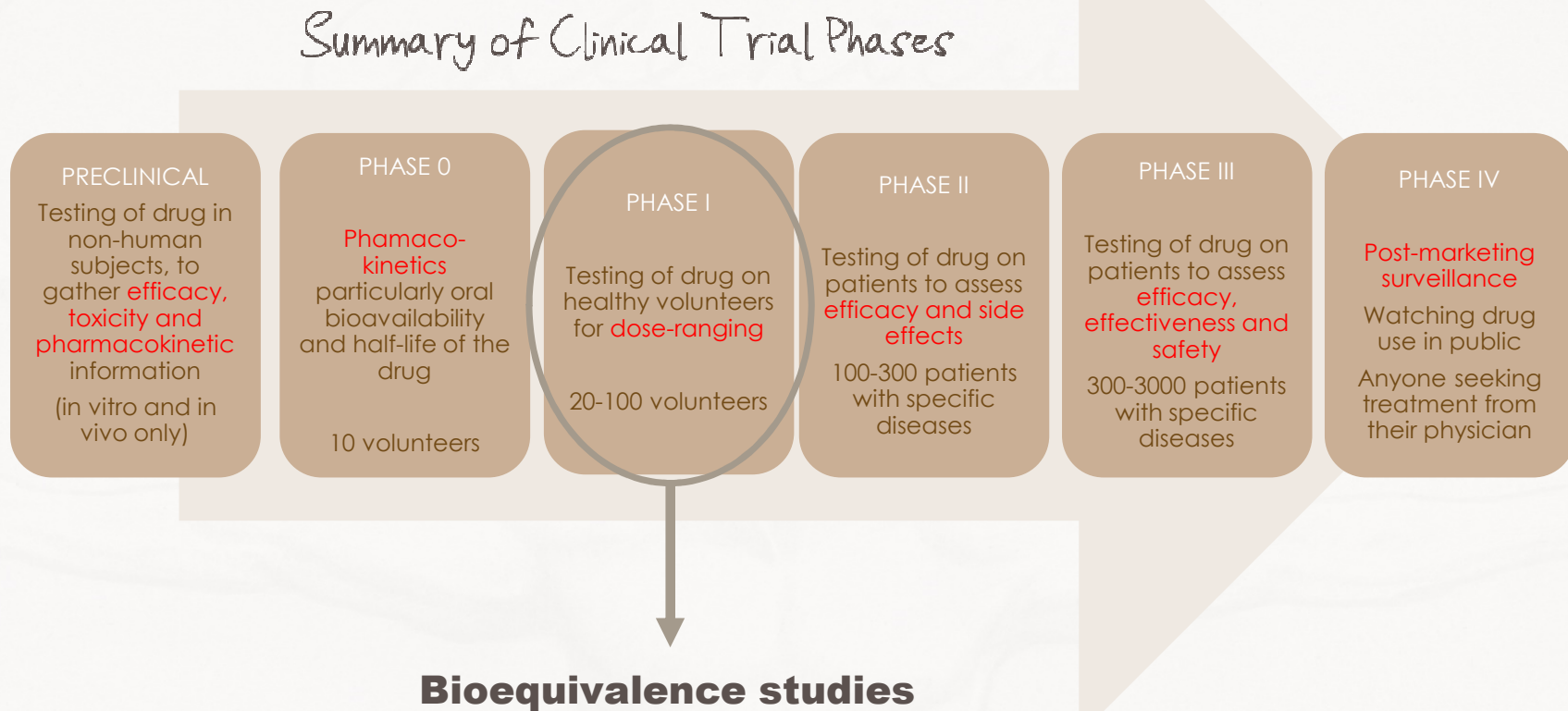
- Development of a new medicine



SOURCE: Pharmaceutical Research and Manufacturers of America, Drug Discovery and Development (www.innovation.org)

1. Role of your area within the pharmaceutical industry

- Clinical trials



1. Role of your area within the pharmaceutical industry

- **Generic – Bioequivalence studies**



Ley Garantías 29/2006 Dir. 2001/83/EC (1990 Ley del Medicamento)

- La misma composición cualitativa y cuantitativa en principios activos
- La misma forma farmacéutica
- Bioequivalencia con el medicamento de referencia

Diferencias con los productos de referencia:

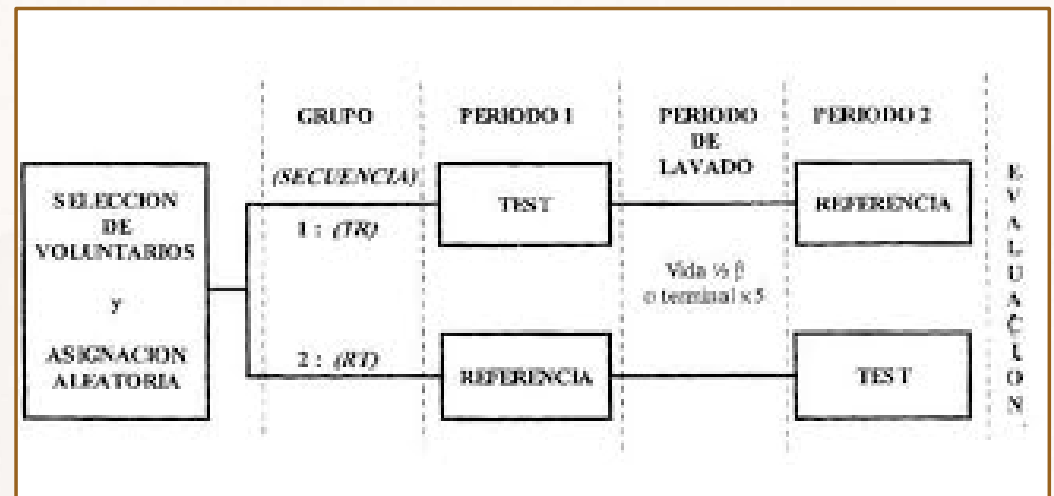
- ✓ Excipientes (condicionan la prescripción en casos muy concretos)
- ✓ Apariencia (color, tamaño, forma, sabor, embalaje)
- ✓ Laboratorio fabricante (puede ser el mismo)

1. Role of your area within the pharmaceutical industry

- Generic – Bioequivalence studies

Design of the study

- ▶ Clinical trials Phase I:
 - Pilot study
 - Pivotal study
 - Simple or replicative
- ▶ Principal parameters:
 - C_{max}
 - AUC
 - t_{max}



Principal parameters should show 90% confidence interval

Interval for AUC and C_{max} of 80-125%

T_{max} is a secondary parameter

1. Role of your area within the pharmaceutical industry

- **Pharmacovigilance**

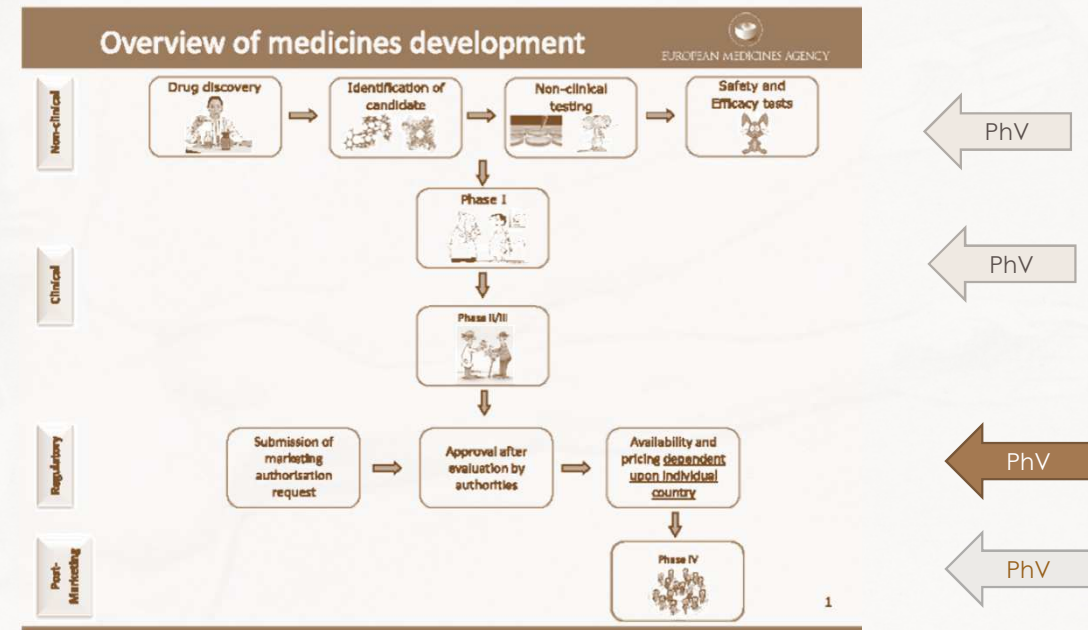
1960-62 “The talidomide disaster” cases of focomelia (congenital malformation). The first case was published in Lancet (WG McBridel) suggesting a relationship with the thalidomide ingestion.

Thalidomide was withdrawn in 1962 after more than 4.000 cases were registered worldwide.

1962 WHO initiates an international program to collect and monitor adverse drug reactions.



- **Pharmacovigilance:**
Detection, assessment and prevention of adverse drug reactions.
- **Objective:** optimise the benefit-risk balance of medicinal products.



1

2. One day in the office

- **Department tasks and responsibilities of the SPONSOR of Bioequivalence Studies**

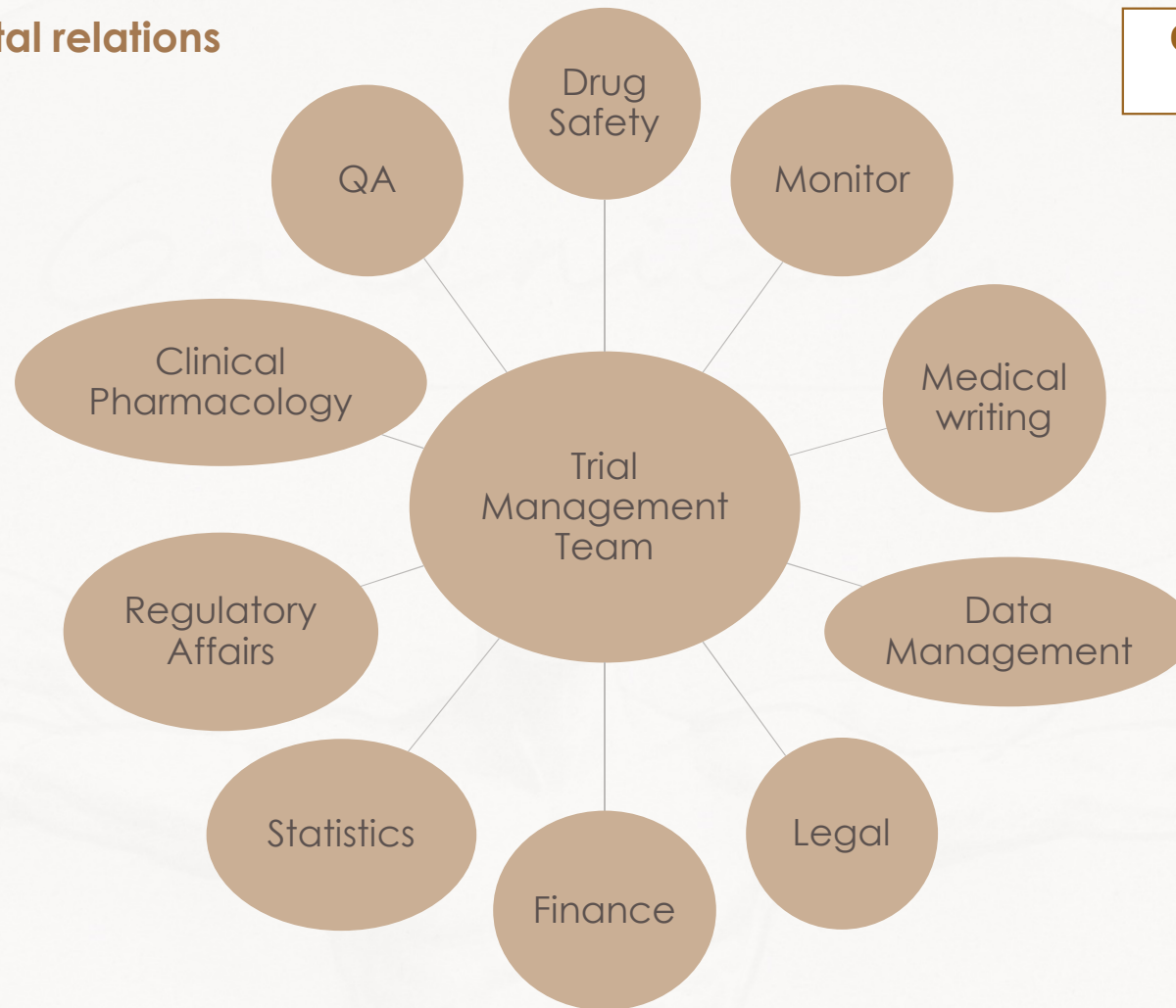


- ▶ Investigator/monitor selection
- ▶ Revision of Protocol/ Informed consent/ Case Report form/ Investigator brochure (IB)
- ▶ Ethics Committee and Health Authorities approval
- ▶ Provide drug study medication
- ▶ Submit any serious adverse event occurred during study
- ▶ Provide insurance to patients participants
- ▶ Collection and Analysis of patient data
- ▶ Revision of Clinical & Analytical Final Reports
- ▶ Complilation of Module 5 of the Dossier
- ▶ Responses to Letters of Defficiency from Regulatory Authorities
- ▶ Feasibilities for new projects and clinical justifications

- Email
- Inter/Intra- Departmental meetings
 - New projects
 - Follow-up projects
- Trainings
- Be updated of the clinical and pharmacovigilance requirements (legislation and guidelines)

2. One day in the office

- Interdepartmental relations



Clinical Trial Team - Internal

2. One day in the office

- Interdepartmental relations

**Clinical Trial Team -
Internal**



2. One day in the office

- **Best/worse of the job position**
- **What you have to lead with?**
- Generics company – High pressure to be the first in the market
- Strict timelines and deadlines – Planification and Project Management
- Supervise the CRO's tasks
- Be in contact with health authorities
- Detailed revision of protocols and informed consent



3. What is the marked looking for?

Personal skills for the job position

- 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



4. Are you the right profile?

Dynamic job description

- To perform routine pharmacovigilance activities such as literature searches focus on identify adverse drug reactions or safety information or management of spontaneous adverse drug reactions
- Support in review and assessment of new research products
- Scientific and clinical support during development
- Support in management of clinical & analytical CROs
- Support in the management and monitoring of clinical trials, mainly bioequivalence studies. Coordinating and following ethical, regulatory and contractual topics of the trials. Following the design and phases of all clinical trials
- Evaluate the comparative dissolution profiles in order to potentially select the most successful candidates for the biobatches of the clinical trial
- Contribute to regulatory documents preparation, such as written expert reports

Previous Knowledge

- Graduate in Health Science, preferably Pharmacy (Medicine, biology, biomedicine, biochemistry, etc)
- Normally, post-graduate focused in Pharmaceutical Industry is required, including internship.
- For example, CESIF, UB, ESAME, etc.
- Excellent level of business English, spoken and written.
- Excellent computer skills, specifically Excel, Word, Outlook and Power Point

Knowledge

- Specialised mainly in Regulatory Affairs, Clinical Trials and Pharmacovigilance

5. Career development

High quality future opportunities

- Clinical, Pharmacovigilance and Regulatory affairs
- Technical and high specialization in Generics valued by the company

Knowledge development

- In vivo studies – Bioequivalence studies – Phase I
- In vitro studies – Dissolution Profiles
- Pharmacokinetics & Pharmacodynamics
- Scientific Bibliographical search – Medical writing
- Pharmacovigilance

Expected salary for junior/senior positions

- 25.000 – 50.000 euros

Thank you



Clinical &
Pharmacovigilance
Department



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