Career Opportunities in Nonclinical Development

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Outline

- Introduction
- Management structures in nonclinical drug development
- Career paths in nonclinical drug development
- Tips for a successful career in the pharmaceutical industry

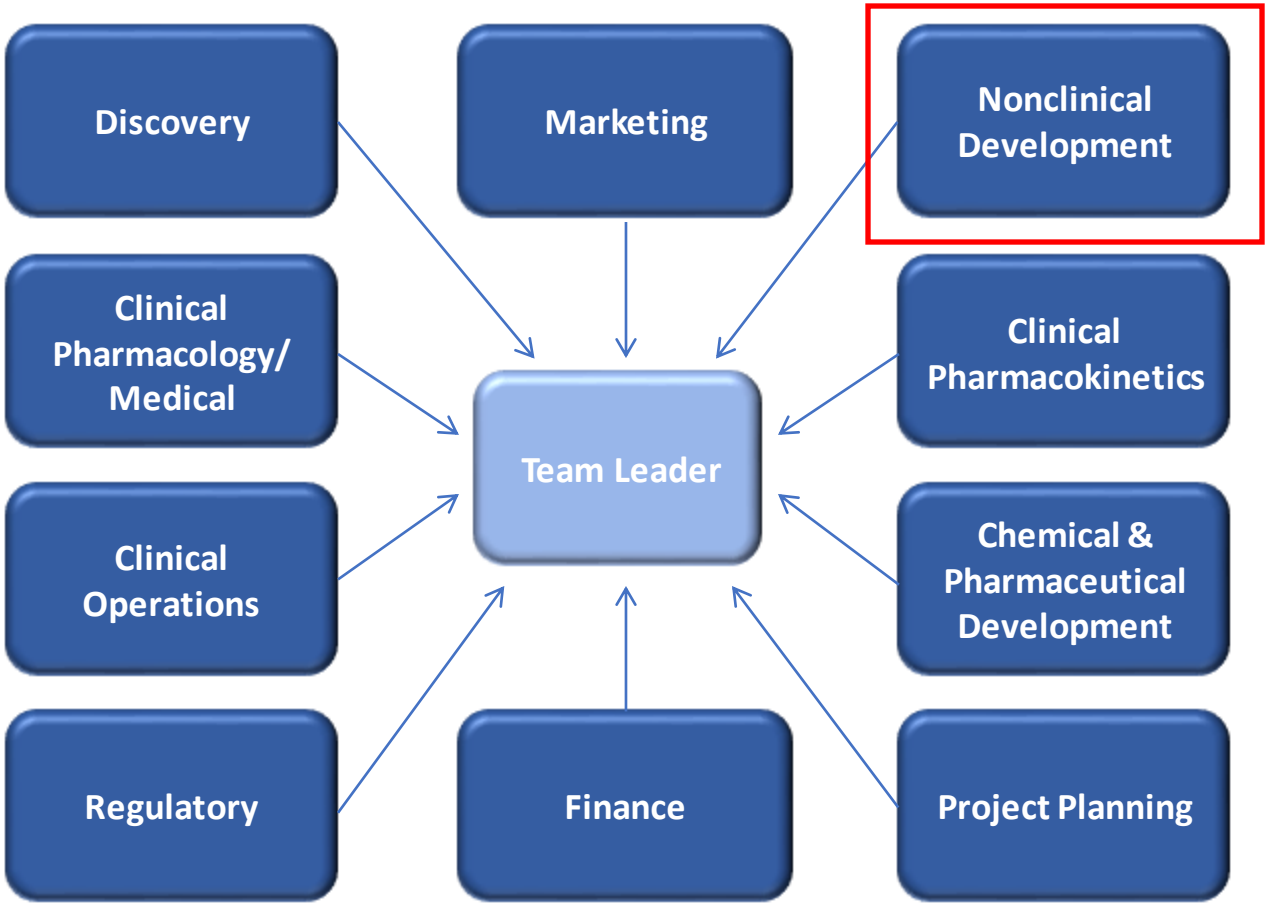
Overview of Drug R&D

3 -5 years	2 -4 years	3 -5 years	0.5 -1 year	3 -10 years
Drug Discovery and Design	Early Development	Pre-approval Late Development	Registration and Market Authorisation	Market and Post-approval Late Development

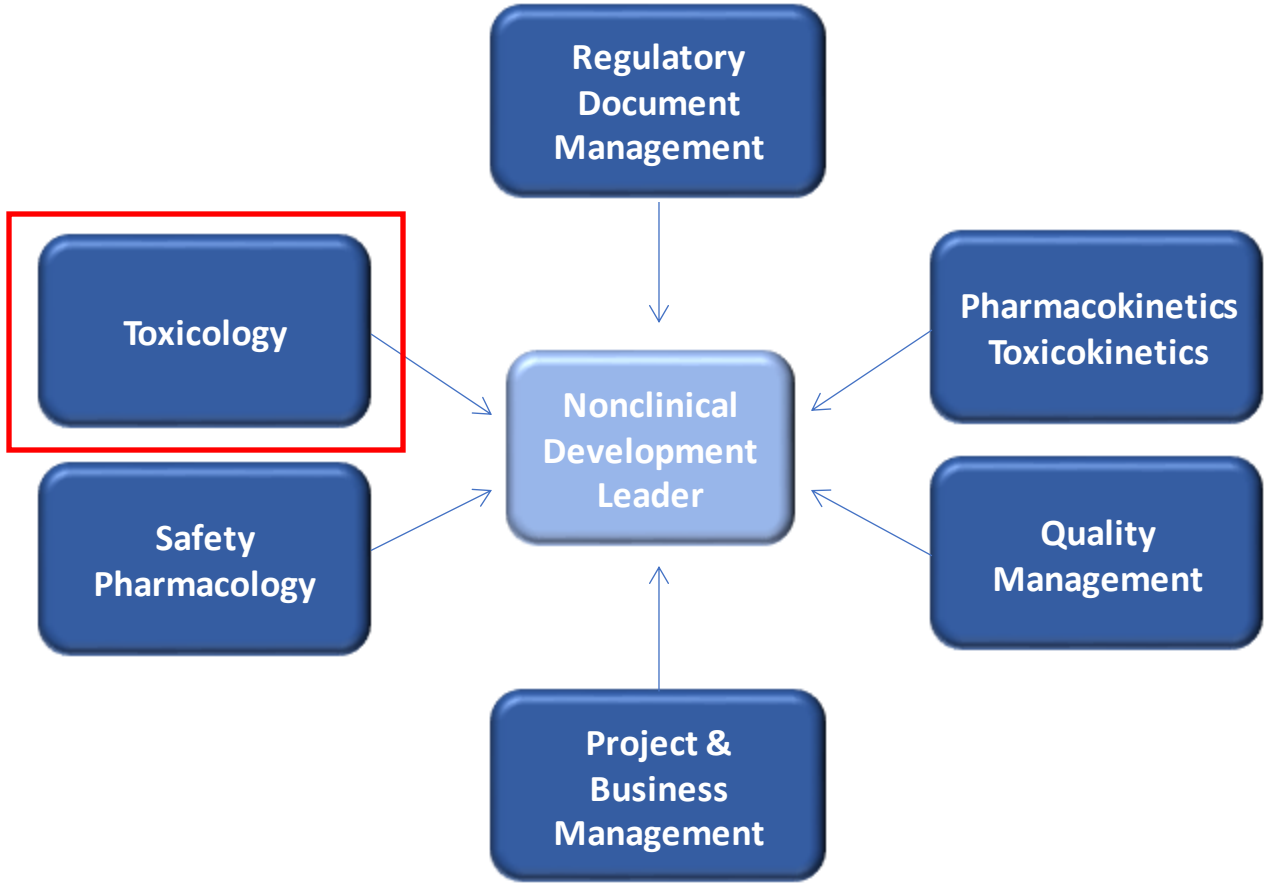
Involvement of Nonclinical Development in the R&D process

Management Structures in Nonclinical Drug Development

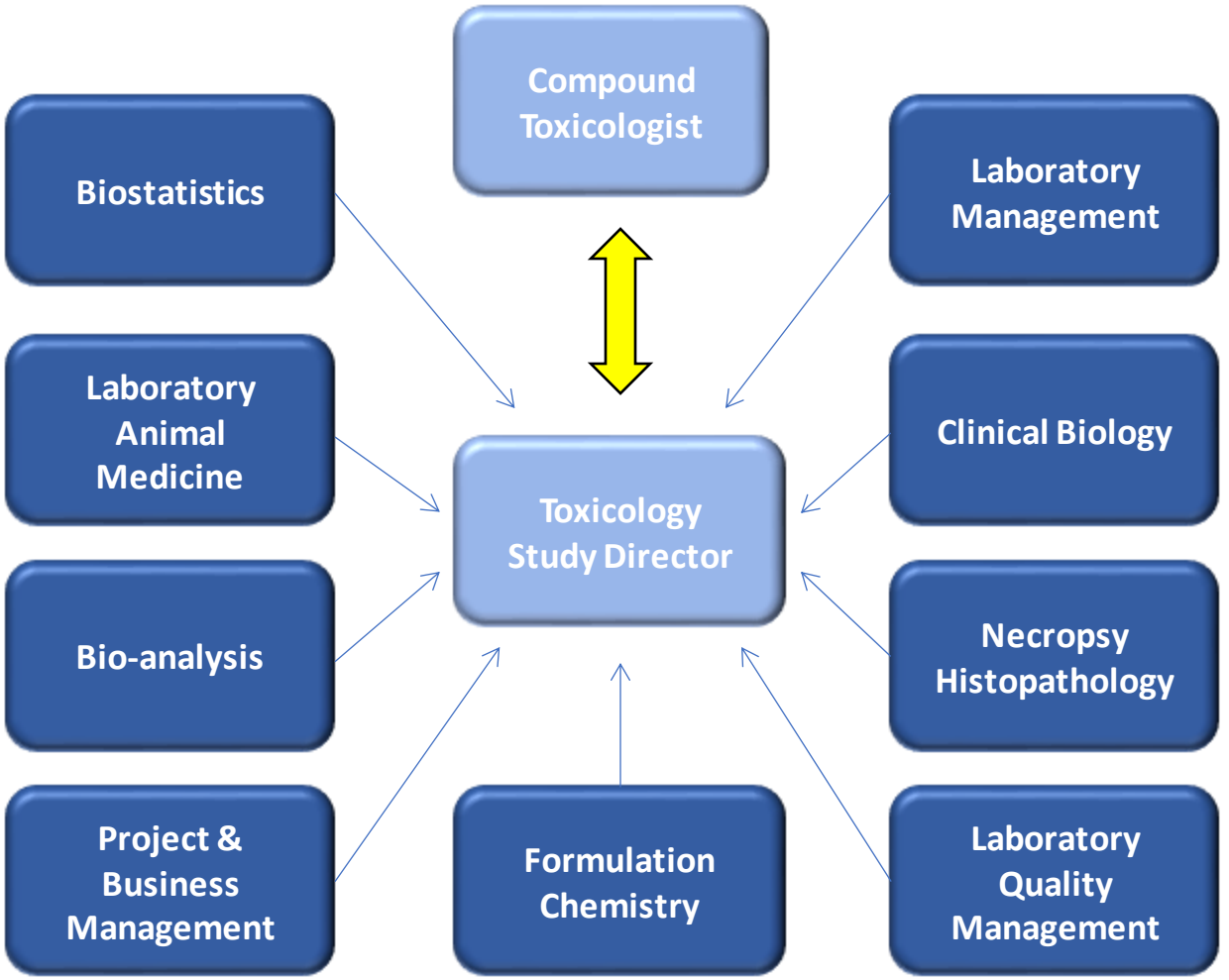
The Drug Development Team (one drug candidate)



The Nonclinical Drug Development Team (one drug candidate)



The Toxicology Team (laboratory level for 1 study)

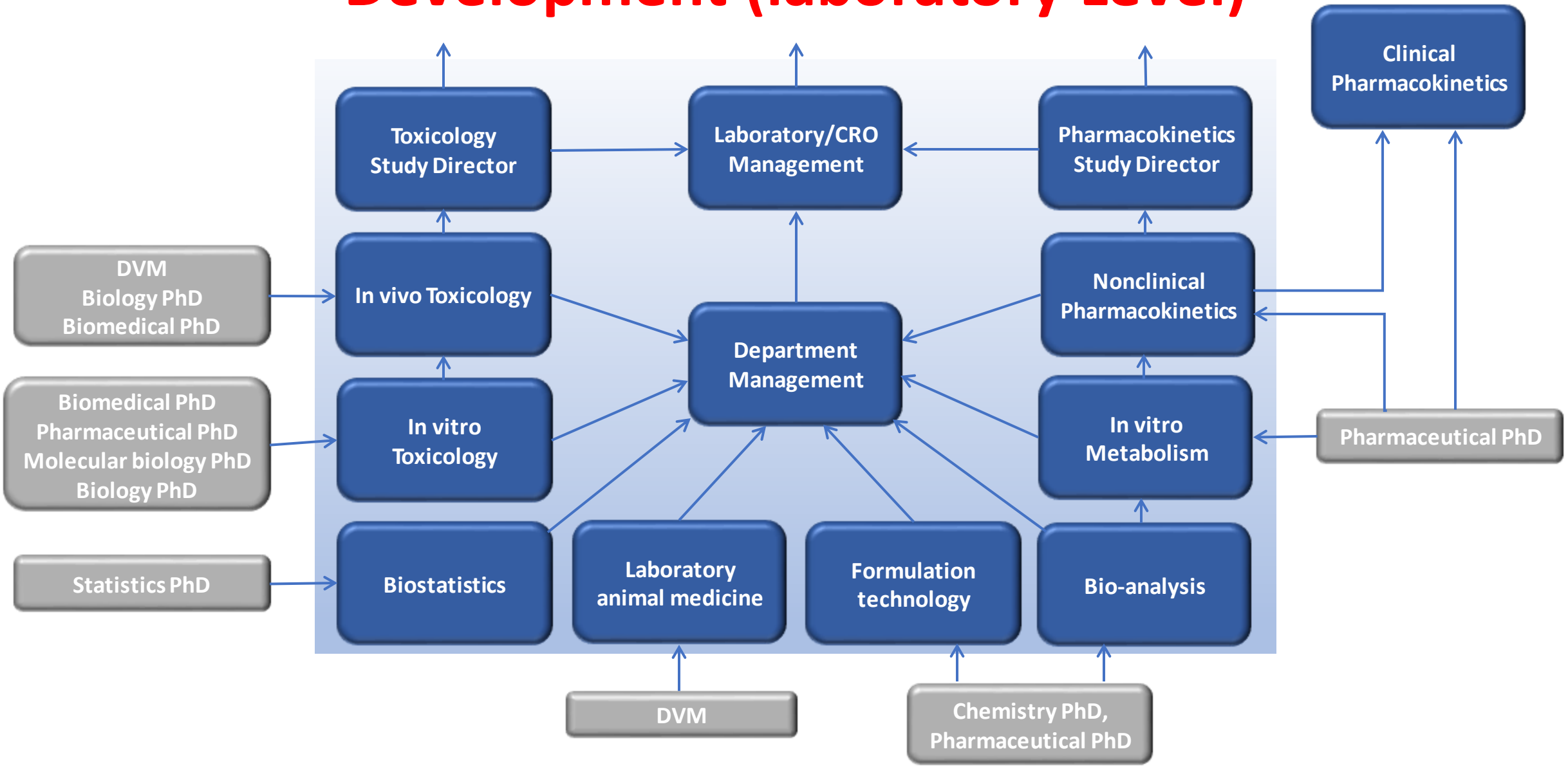


Career Paths in Nonclinical Drug Development

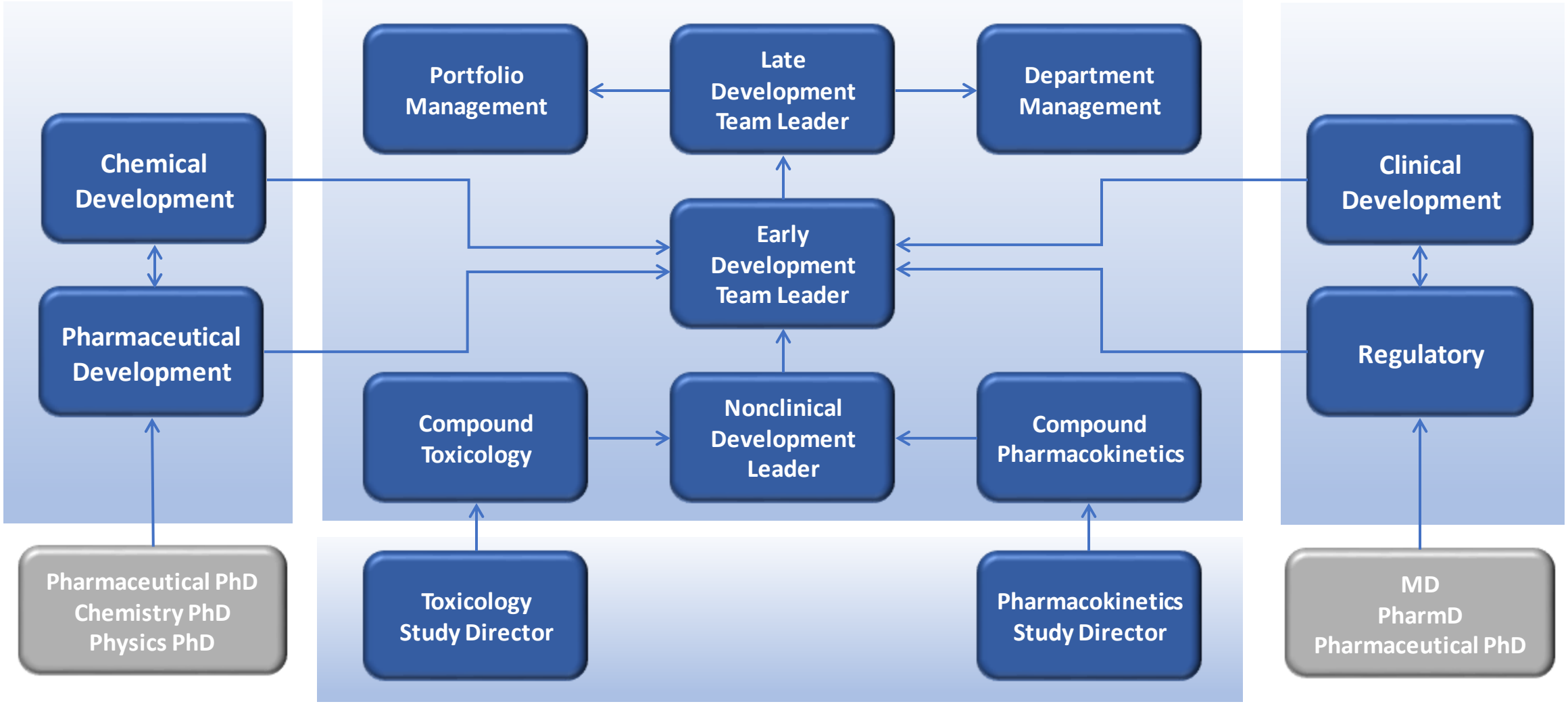
University Degrees needed in Nonclinical Drug Development

- Biomedical sciences
- Biology
- Molecular biology
- Biotechnology
- Pharmacy
- Veterinary medicine
- Chemistry
- Bio-engineering
- Physics (physical chemistry)
- Statistics

Examples of Career Paths in Nonclinical Development (laboratory Level)



Examples of Career Paths in Nonclinical Development (Compound Management Level)



Career Ladders in the Pharmaceutical Industry

Managerial ladder

Supervisor

↓

Manager

↓

Senior manager

↓

Director

↓

Senior Director

↓

Vice-president

Scientific ladder

Scientist

↓

Principal scientist

↓

Fellow

↓

Senior fellow

↓

Distinguished fellow

Some Tips for a Successful Career in the Pharmaceutical Industry

- Team spirit
- Leadership
- Open mind for other ideas
- Think “out of the box”
- Good communication skills
- Always be critical for yourself
- Get interested in other disciplines in drug R&D
- Flexibility is key
- Continuous learning
- Open for change, migrate to other disciplines
- Learn from mistakes
- Take on new challenges
- Change jobs from time to time
- Spend time abroad
- Take international positions

Some Golden Rules

It is better to stay employable than to stay employed

Be ambitious in doing a good job, the rest will follow

Don’t try climbing the career ladder too fast

You spend 1/3 of your life on the job, so enjoy yourself

Global New Drug Development

An Introduction

Jan A. Rosier, Mark A. Martens
and Josse R. Thomas

UIA POSTGRADUATE PHARMACY SERIES

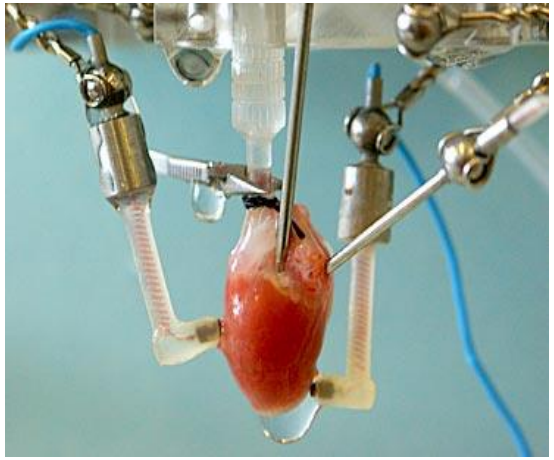
WILEY Blackwell

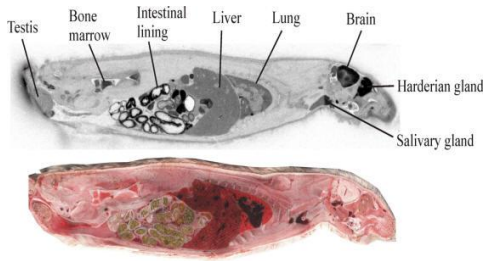
Thank you

Questions?

Back-up slides
Nonclinical Drug Development

Scientific Disciplines in Nonclinical Development





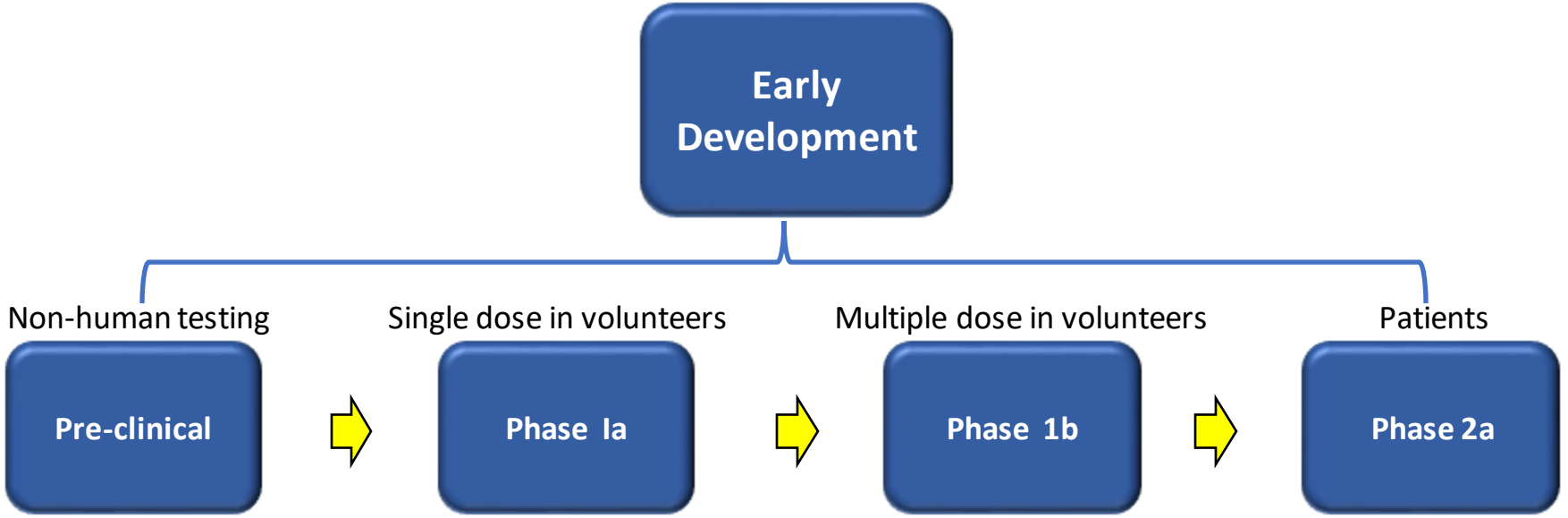
Safety Pharmacology:
- Cardiovascular function*
- Respiratory function
- Nervous system function
- GIT function

Toxicology:
- Acute and chronic systemic toxicity
- Local toxicity*
- Genotoxicity*
- Developmental toxicity
- Reproduction toxicity
- Cancer
- Mechanistic toxicology*

Pharmacokinetics:
- Bio-analysis
- Absorption
- Drug metabolism*
- Tissue distribution
- Excretion
- Drug-drug interaction*
- PK modelling

*: *In vitro* and *in vivo*

Contribution of Toxicology to Drug Development (1)



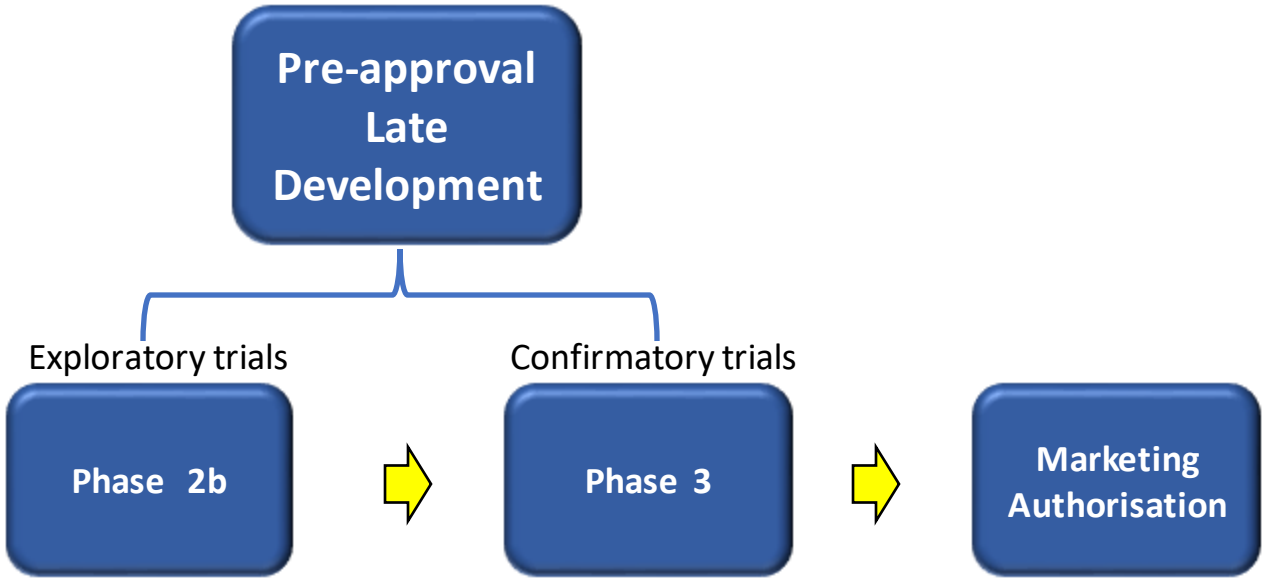
- PK, **toxicology** and safety pharmacology *in vitro* and *in vivo* to assess bioavailability and **safety in man after single and repeated exposure**,
- Preparation of the IMPD, the investigator's brochure (IB) and IND/CTA dossier.

- **Repeated dose toxicology studies,**
- Further PK studies,
- **Studies to address specific toxicological endpoints of concern identified in nonclinical studies,**
- Update of IMPD and IB.

- **Fertility and embryo-fetal toxicology studies,**
- **Extended repeated dose toxicology studies and resolution of safety issues identified in non-clinical and clinical studies,**
- More advanced PK studies,
- Update of IMPD and IB.

- **Extended repeated dose toxicology studies in rat and dog, pre-and post natal development study in rat,**
- Preparation of non-clinical part of risk assessment transfer to late development,
- Update of IMPD and IB.

Contribution of Toxicology to Drug Development (2)



- **Repeated dose toxicity studies,**
- **Carcinogenicity studies,**
- **Pre-natal and post-natal development toxicity study,**
- Advanced PK studies,
- **Mechanistic toxicology studies *in vitro* and *in vivo***; preparation of the end-of-phase 2 (EoPh2) dossier,
- Update of IMPD and IB.

- **Carcinogenicity studies**,
- **Juvenile toxicology studies if pediatric indication,**
- Advanced PK studies,
- **Ad hoc mechanistic toxicology studies,**
- Preparation of non-clinical part of NDA and MAA dossiers.

Contribution of Toxicology to Drug Development (3)

- Bio-equivalence studies *in vivo,*
- ***M*echanistic toxicology and safety pharmacology studies *in vitro* and *in vivo* to respond to questions from translational medicine,**
- PK when new routes of administration or fixed dose combinations are explored,
- **Ad hoc juvenile toxicology studies to support pediatric development.**