

# *Nonclinical Biostatistics Conference*

Theme:

***Nonclinical Statistics  
in the Age of Data  
Science***

Poster abstract submission deadline

– **June 4**

Student poster competition

First-place **\$250**; Second-place **\$150**

The History

The First Conference

The Student Outreach

Opportunities for 2021





# The Non-Clinical Statisticians

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Oluyemi Oyeniran, Ph.D.  
*NCB Student Outreach Committee*

# Outline

Overview of Drug Discovery and Drug Development

Overview of Non-Clinical Statistics

Non-Clinical Statisticians in the Industry

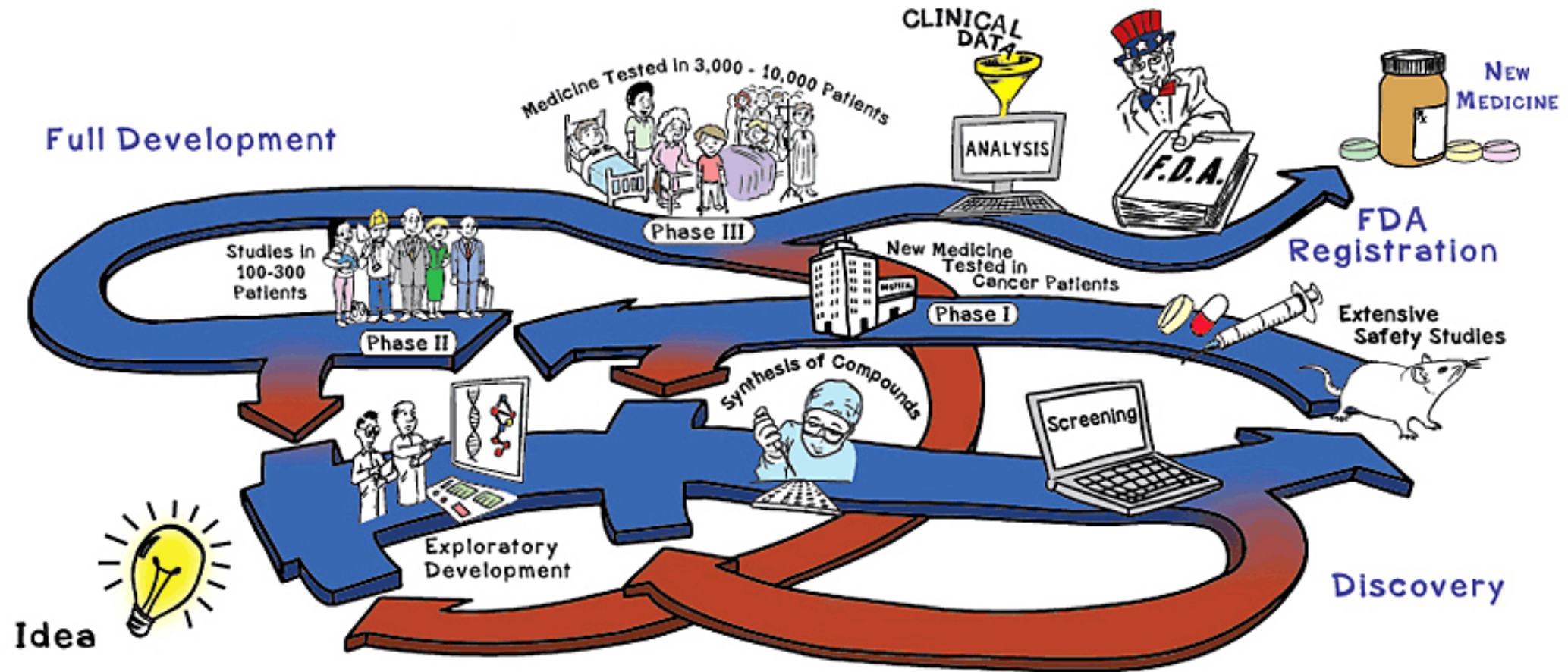
# Outline

## ***Overview of Drug Discovery and Drug Development***

Overview of Non-Clinical Statistics

Non-Clinical Statisticians in the Industry

# The Road to New Medicines



# What's a DRUG?



## FDA

- Substance that facilitates diagnosis, cure, mitigation, treatment, or prevention of disease

## Cosmeceuticals

- Some products that you might not think of as drugs are considered both cosmetics and pharmaceuticals and must comply with FDA regulations for both categories

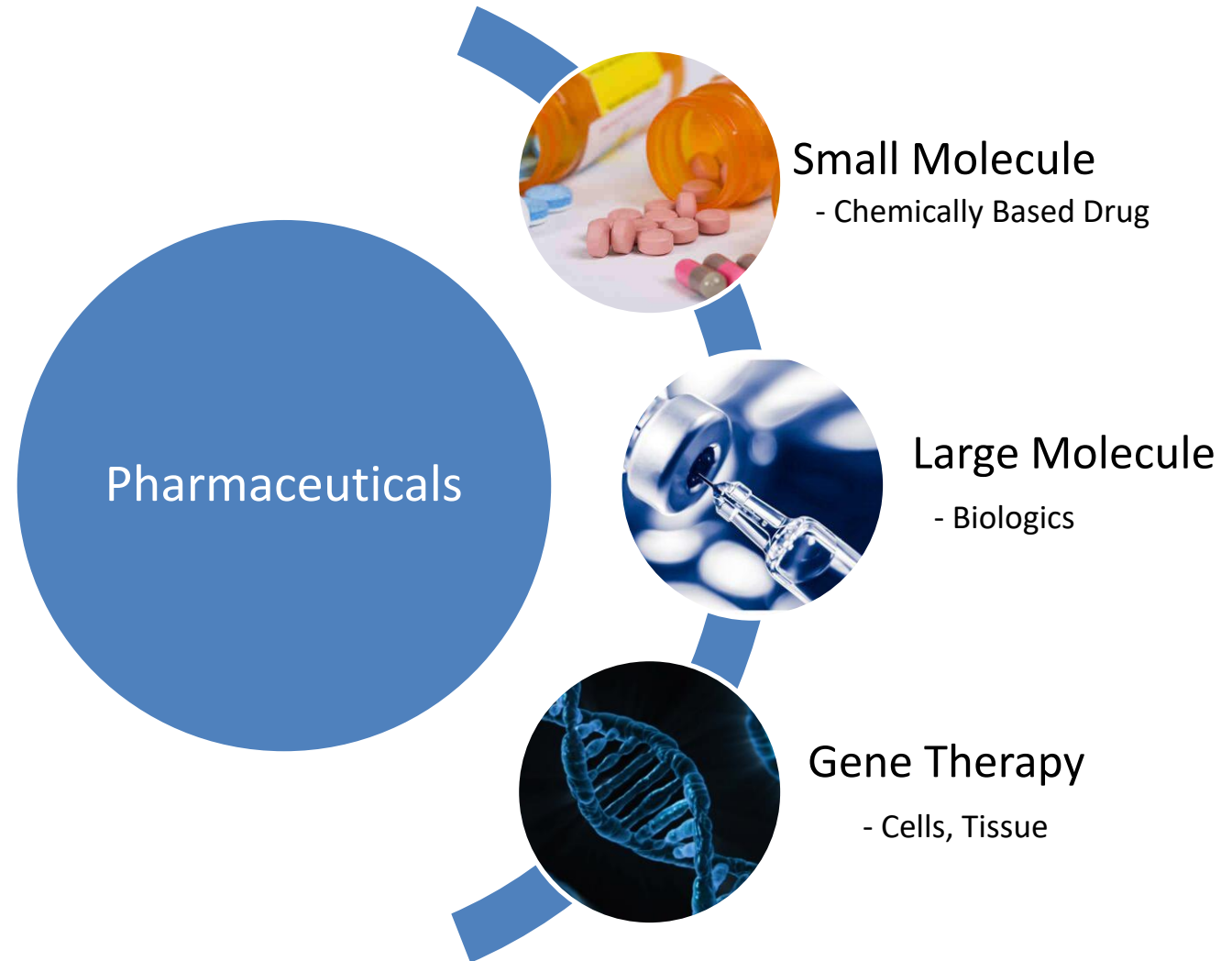
## Medical Devices

- FDA also regulate medical devices as a means of introducing a drug to the body



# Drug Biologics Cells

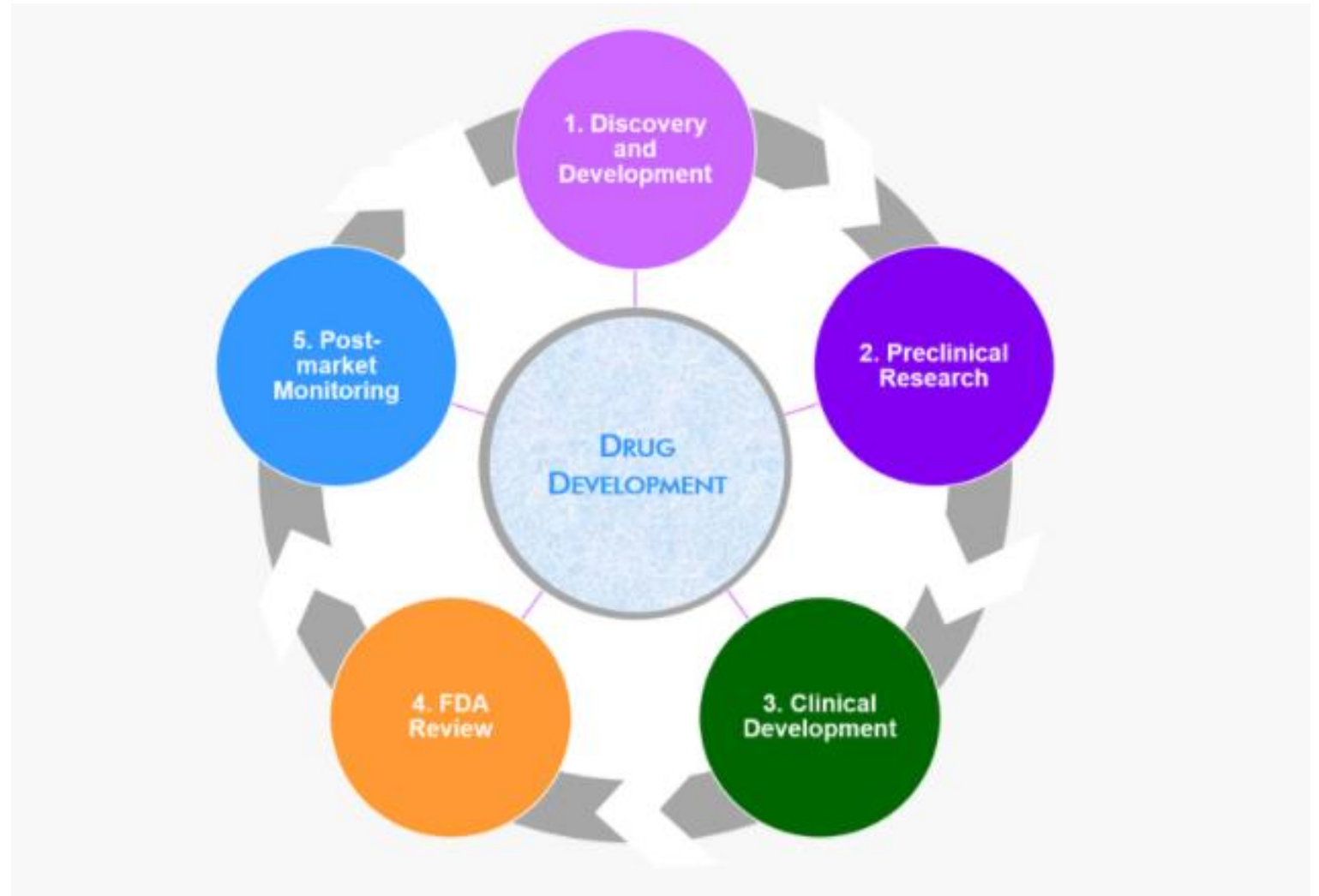
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**What's the classification of COVID-19 Vaccine?**

# Drug Discovery and Development Process

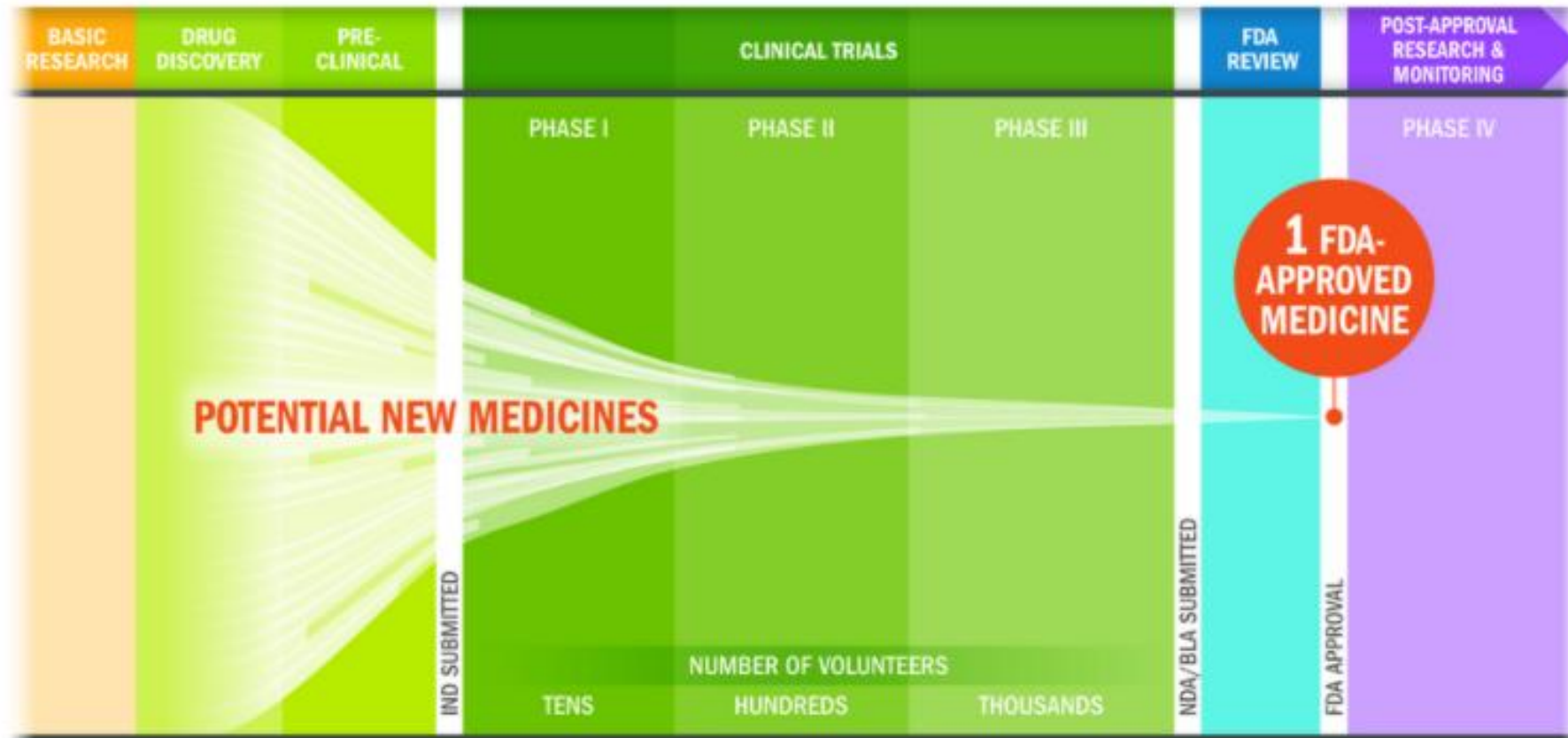
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# Drug Discovery and Development Process

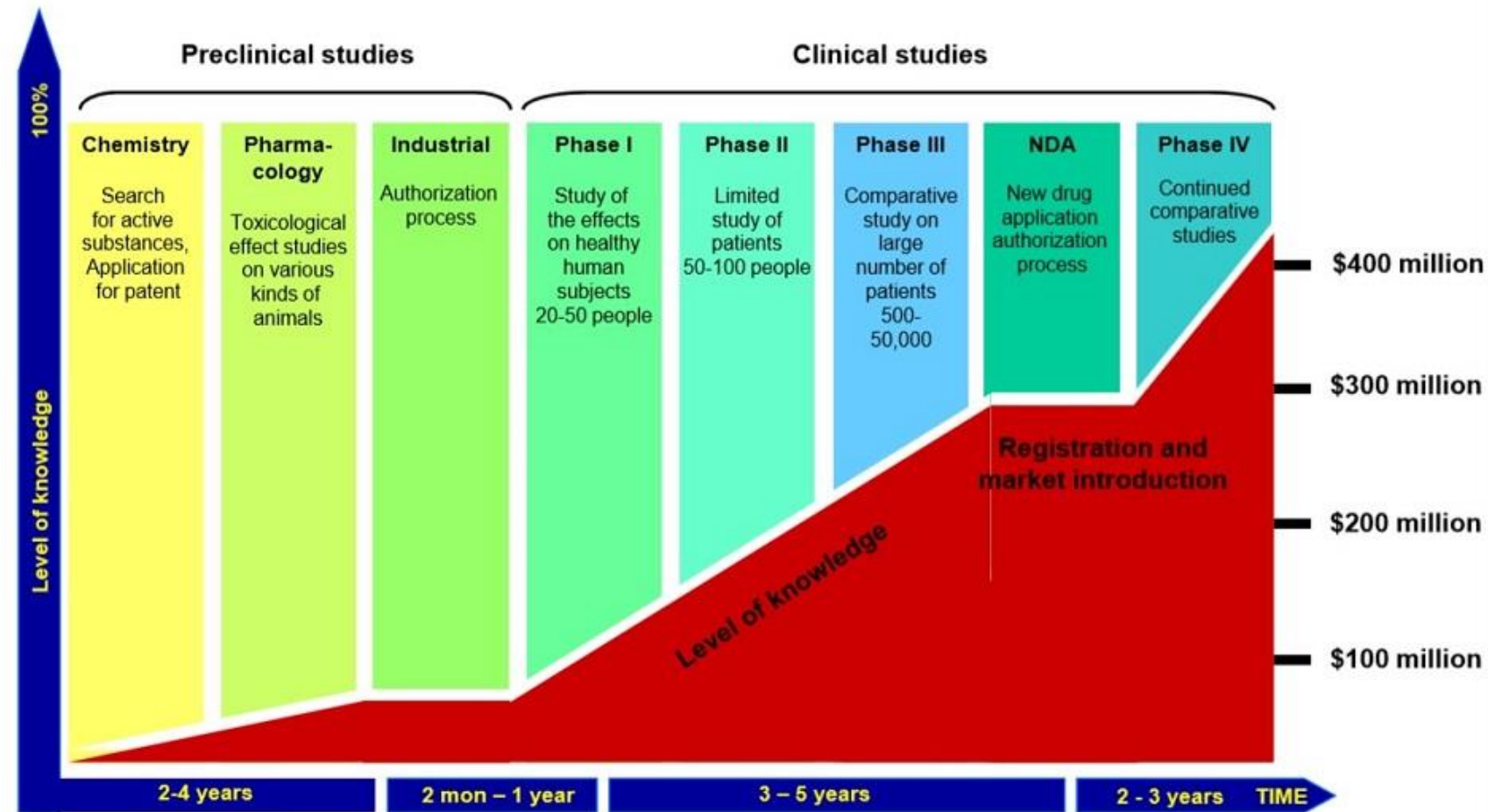
## – Potential New Medicines



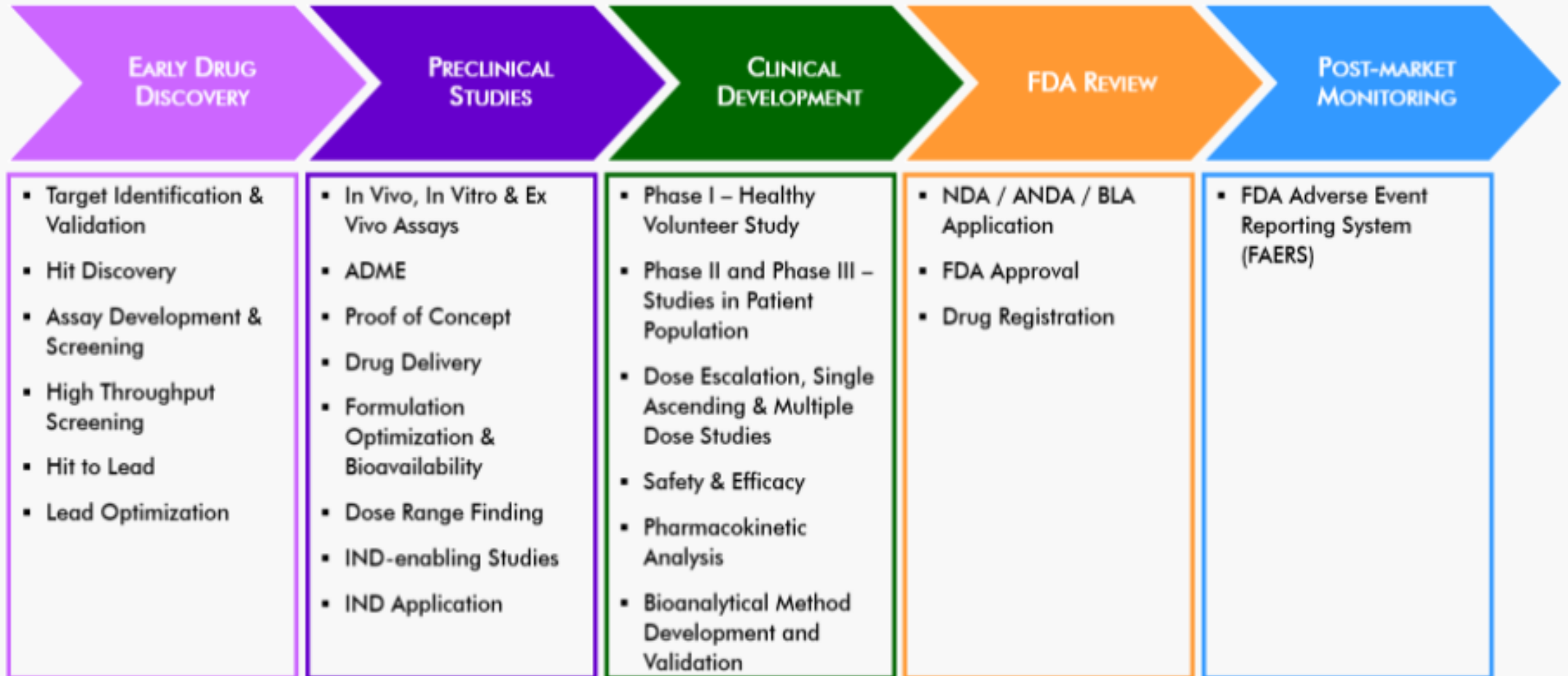
**IND: Investigational New Drug Application, NDA: New Drug Application, BLA: Biologics License Application**

# Drug Discovery and Development Process

## – Estimated Cost and Timeline



# Breakdown of Drug Discovery and Development Process



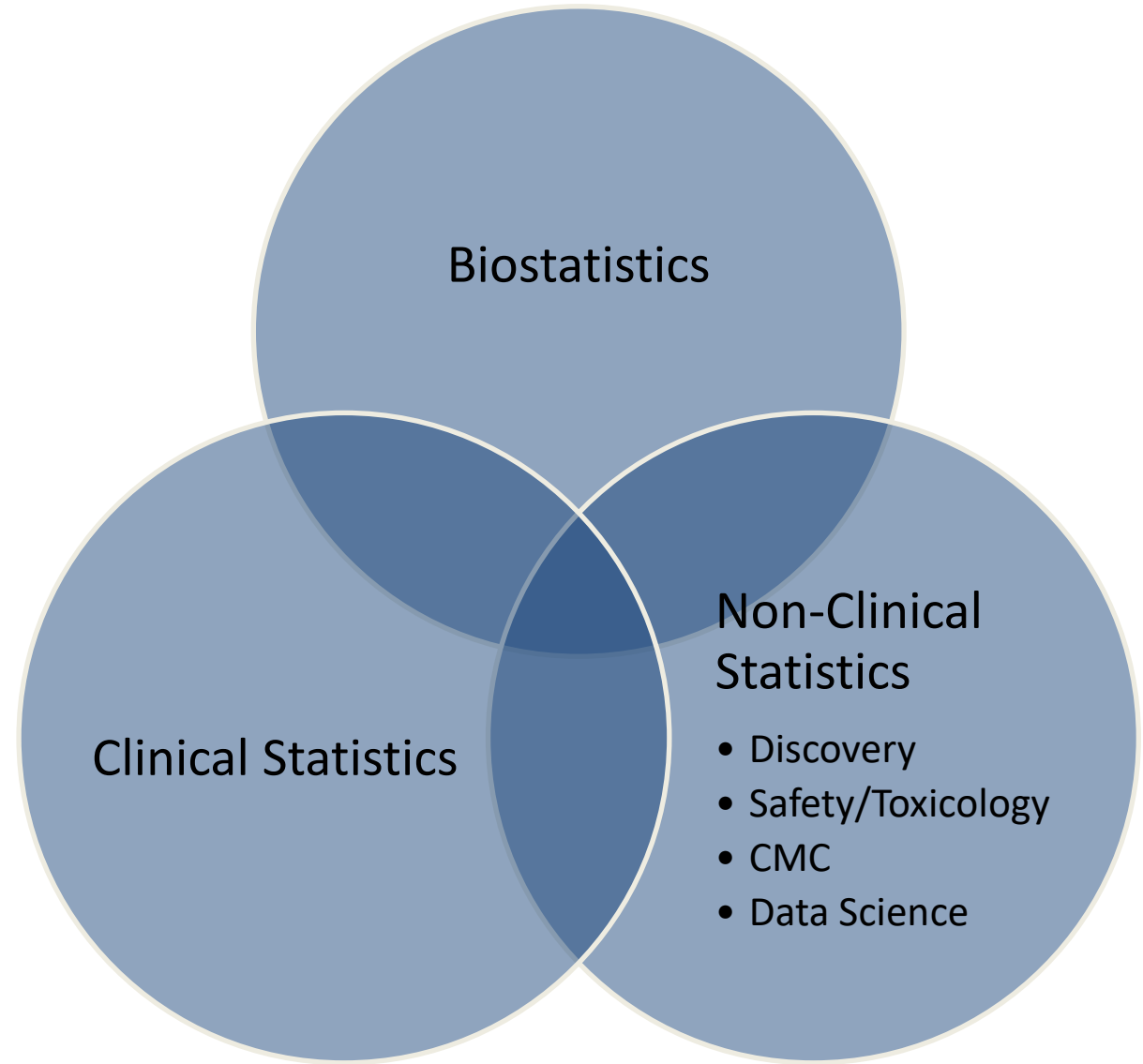
# Outline

Overview of Drug Discovery and Drug Development

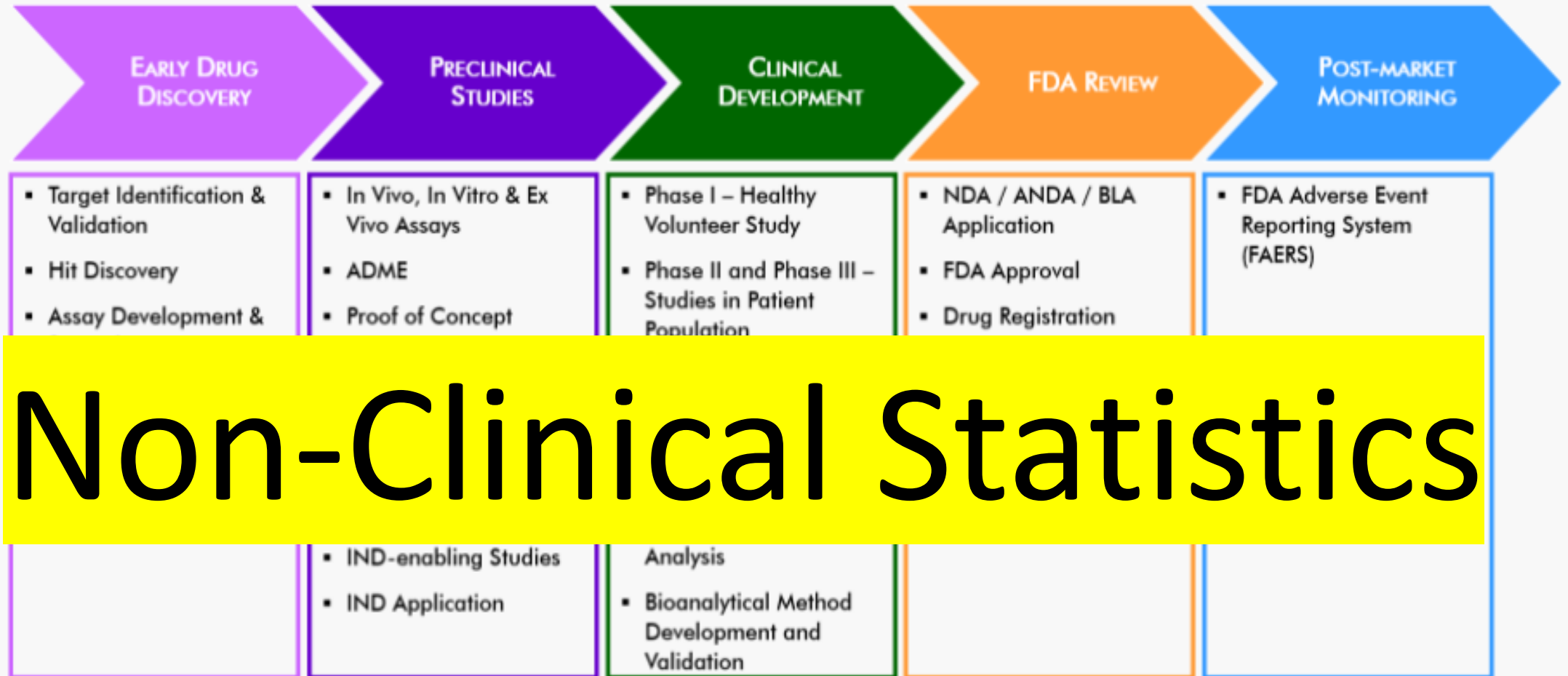
## ***Overview of Non-Clinical Statistics***

Non-Clinical Statisticians in the Industry

# Biostatistics

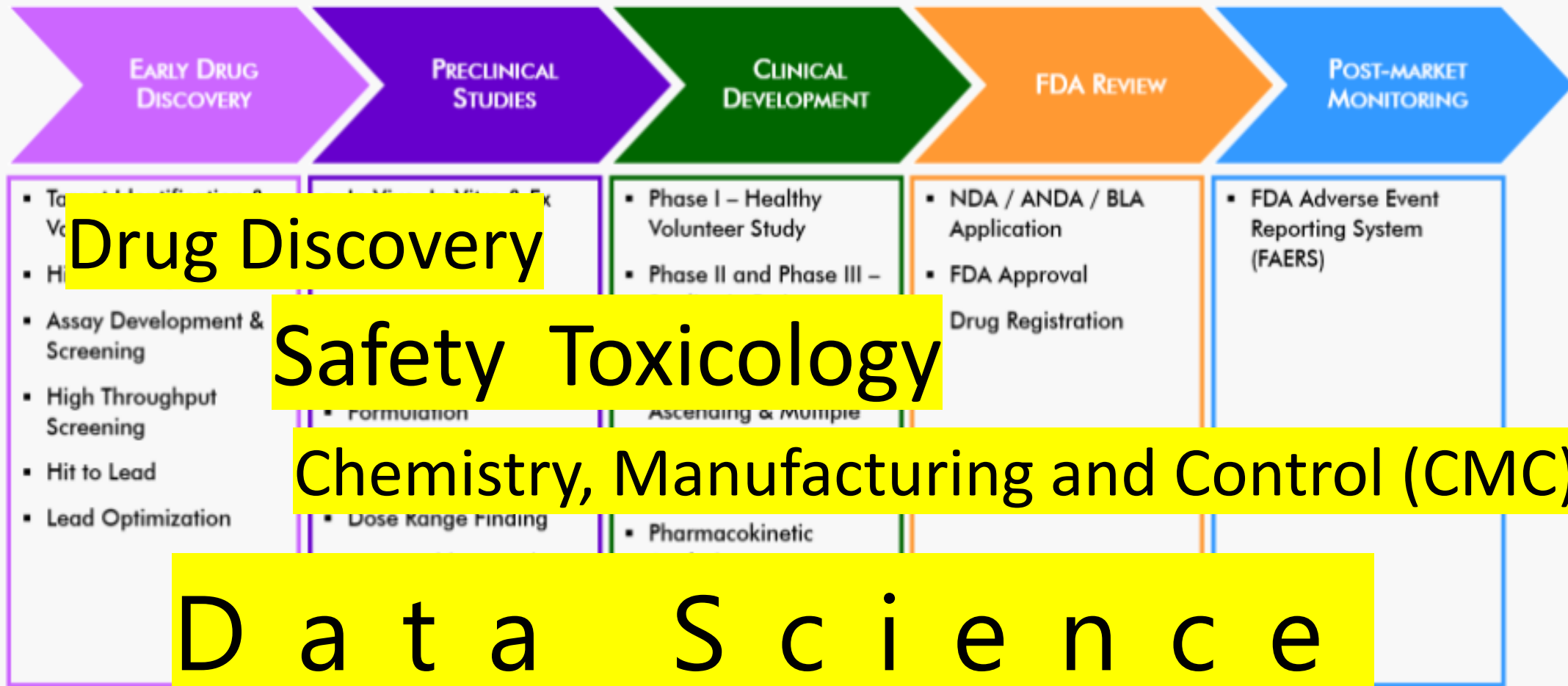


# Non-Clinical Statistics in the Drug Discovery and Development Process





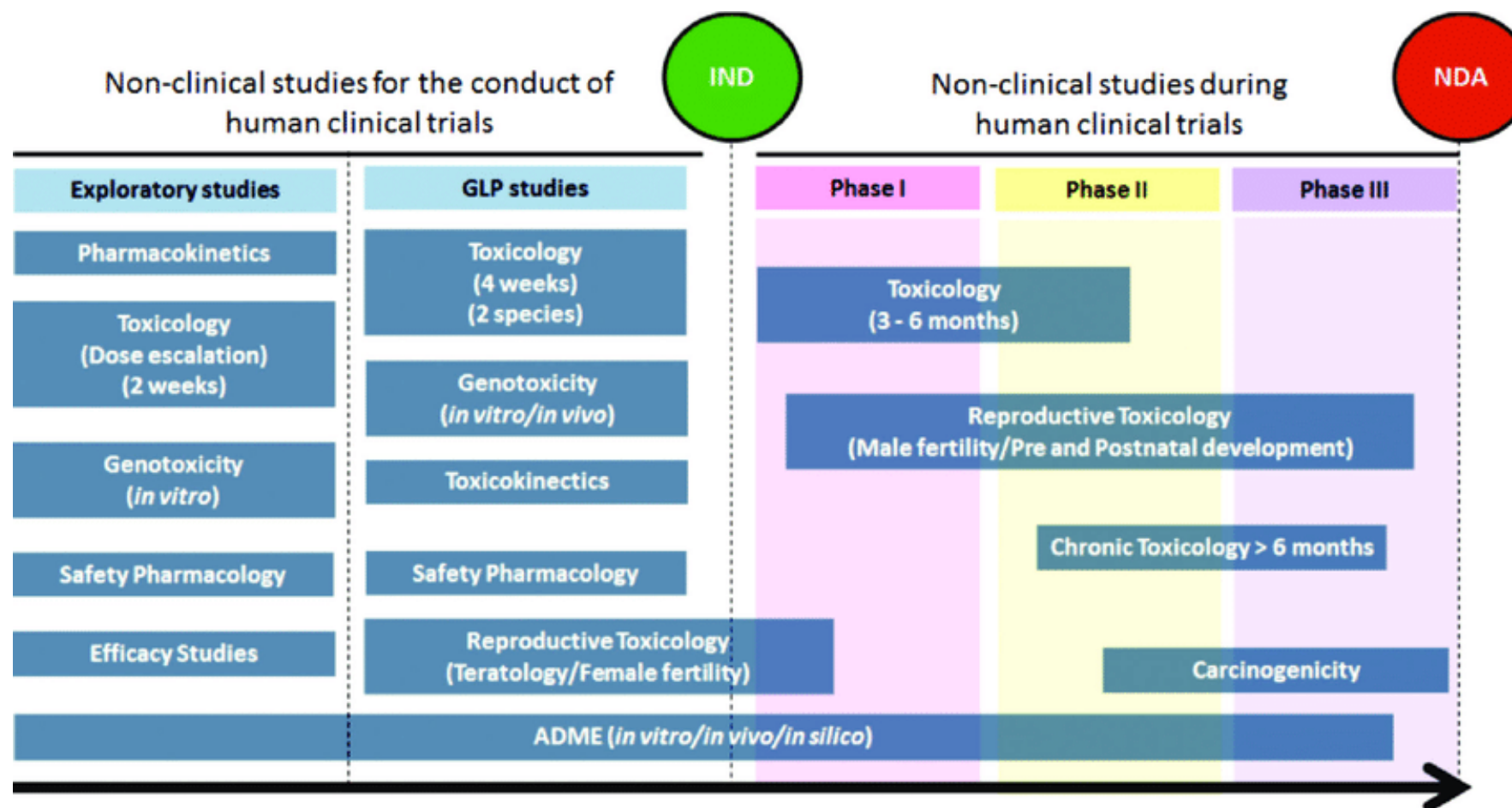
# Non-Clinical Statistics in the Drug Discovery and Development Process



# Drug Discovery

Phase	Target Discovery	Target Validation	Lead Generation & Refinement	Preclinical Development	
Goal	Find All Targets 	Eliminate Wrong Targets 	Generate Molecules 	Eliminate Molecules 	Advance Molecules 

# Safety/Toxicology

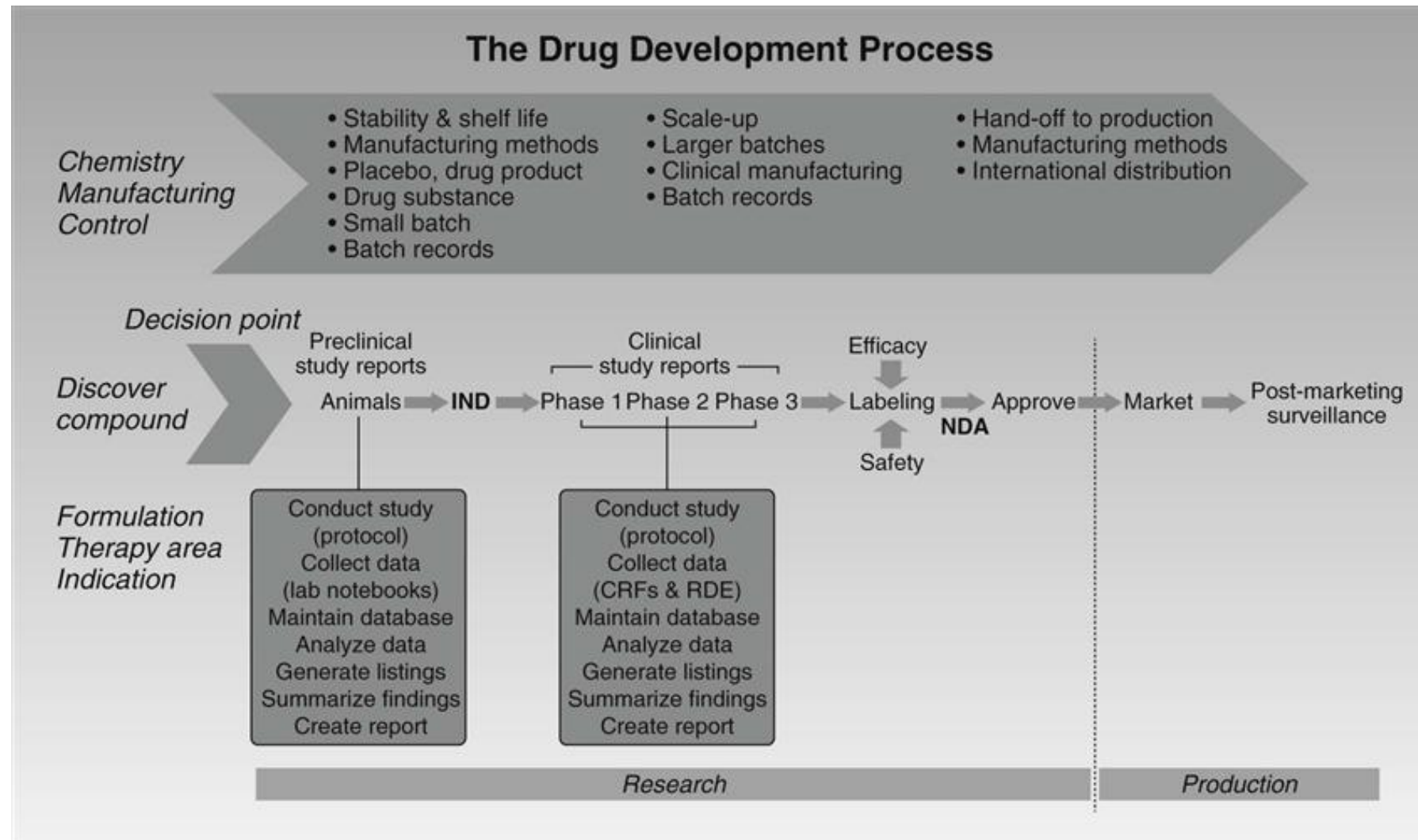


Safety spans the discovery and development process

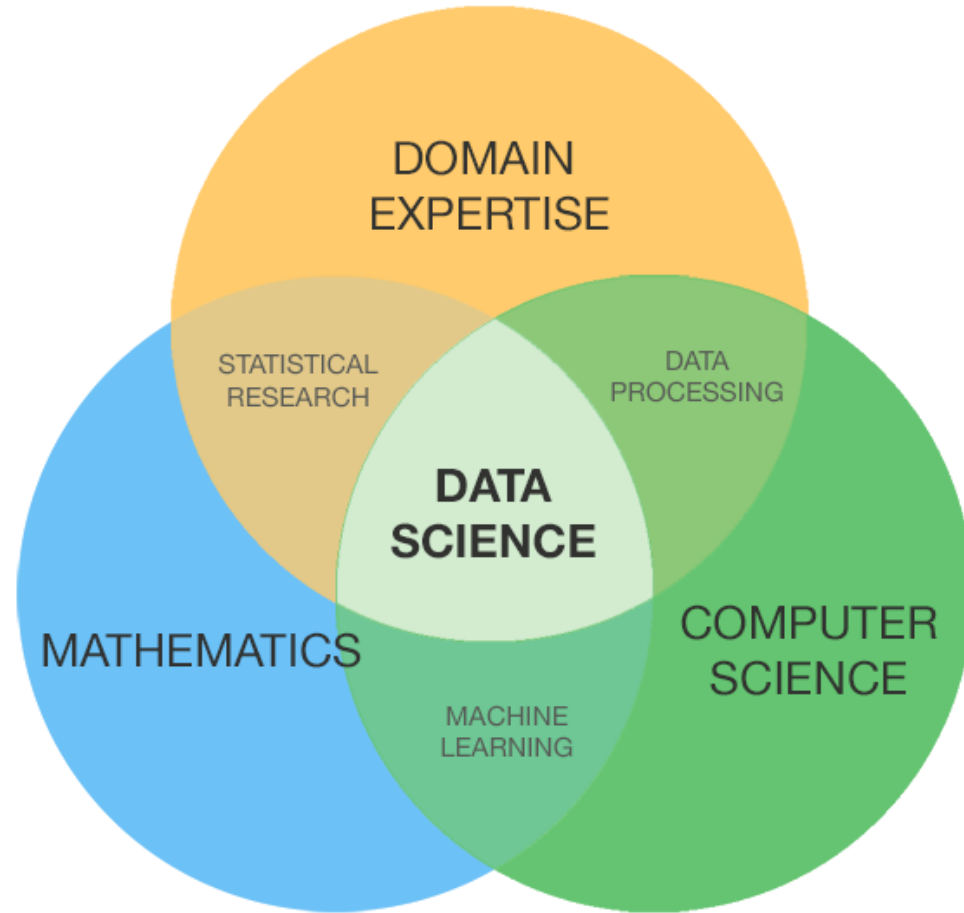
Includes:

- In vitro assays
- In vivo assays
- Ex Vivo assays
- In Silico assays

# Chemistry, Manufacturing and Controls (CMC)



# Data Science



*Source: Palmer, Shelly. Data Science for the C-Suite.  
New York: Digital Living Press, 2015. Print.*

# Outline

Overview of Drug Discovery and Drug Development

Overview of Non-Clinical Statistics

***Non-Clinical Statisticians in the Industry***



## Non-Clinical Statisticians in Pharma Industry

- ❑ Most nonclinical statisticians in the pharmaceutical or biotech industry have a Masters or PhD degree in statistics (or related field)
- ❑ Nonclinical groups are typically small (1-5 statisticians) to medium size (6-30 statisticians)
- ❑ Some nonclinical groups focus either on early drug discovery or on development (*ex.* GSK), other groups support both (*ex.* JNJ)
- ❑ Compared to clinical roles, there may be little or no direct involvement with regulatory agencies (FDA, EMA)
- ❑ There are contract research organizations CROs that support pharma

# The Non-Clinical Statisticians

what do we do?

***use statistical tools to make informed business decisions,  
guide scientific decisions, and ultimately help provide  
quality products and services to patients, nurses, doctors,  
fathers and mothers***

Tools include -

- Linear models & repeated measures
- Statistical Process Control
- Multivariate analysis
- Variance component analysis
- Bayesian analysis
- Power calculations
- Designed experiments
- Data science



*Don't be 'just a statistician.' Aspire to be a Drug Developer!*

*Statisticians are decision scientists*

## The Non-Clinical Statisticians

*who do we work with?*

a wide **variety of scientists** from many different disciplines

- Biologists, Chemists
- Computational Biologists and Chemists
- Pharmaceutical Scientists, Clinicians (MD's)
- Pharmacologists, Biophysicists
- Engineers, Computer Scientists
- Material Scientists and Veterinarians

## The Non-Clinical Statisticians

### *Communication is Key*

We help solve problems. Matching statistical methods to subject-matter problems is a translation exercise. Interacting effectively with non-statisticians is a critical non-technical skill.

- Technical competence is a prerequisite.

**The  
Non-Clinical  
Statisticians**  
*how to prepare*

Core Courses – refer to “what we do” slide

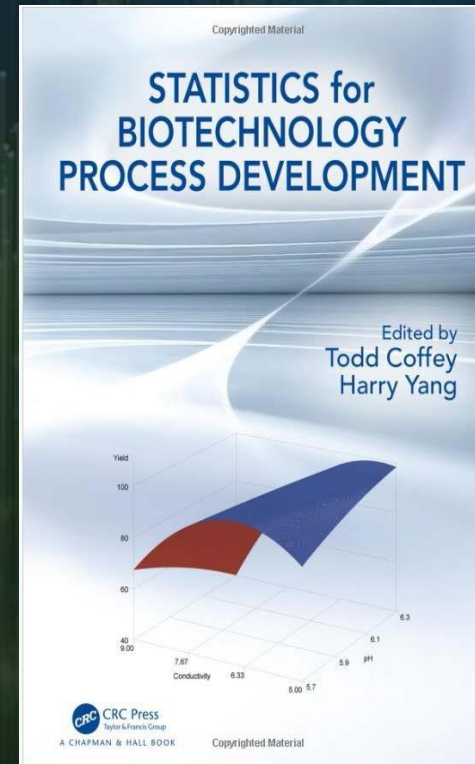
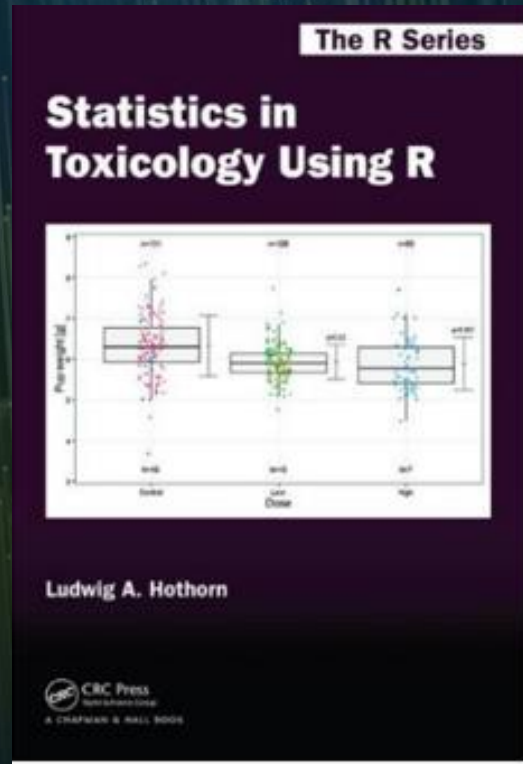
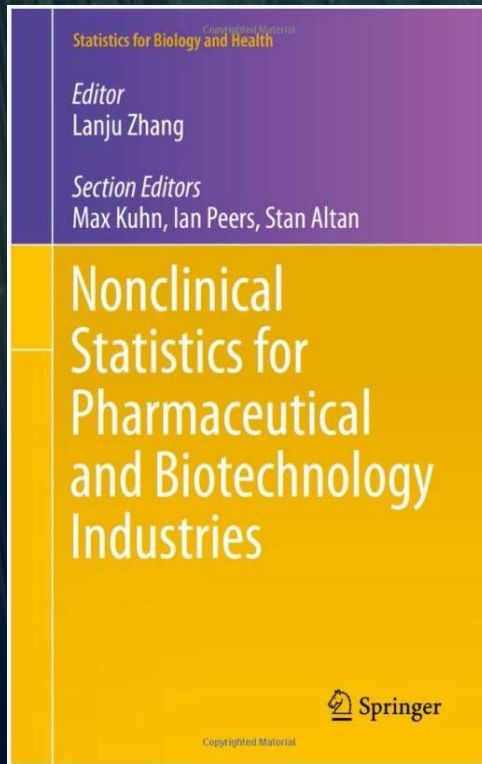
Special Topics – Machine Learning, Image Processing,  
Pharmaceutical Sciences

Seek out Industry Veterans – Networking

Internships – ASA, Company Web Sites/Job Boards

Proximity to Pharma/Biotech R&D or Manufacturing Sites

# Resources





# Conferences and Journal

## Conferences

- **ASA Biopharmaceutical Section Nonclinical Biostatistics Conference (NCB)**
- Midwest Biopharmaceutical Statistics Workshop (MBSW)
- Scientific: e.g., American Association of Pharmaceutical Scientists (AAPS)

## Journals

- *Statistics in Biopharmaceutical Research*
- *Pharmaceutical Statistics*
- *Journal of Biopharmaceutical Statistics*
- Specialty Areas
  - *SLAS Discovery, Journal of Pharmacokinetics and Pharmacodynamics, Bioinformatics, Journal of Pharmaceutical Sciences, Nature Reviews Drug Discovery, Nature Biotechnology, etc.*



“Without **data** you’re  
just another person  
with an opinion.”

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- W. Edwards Deming

# The Panelists



Thomas Bradsteet PhD  
Bristol-Myers Squibb



Jyh-Ming Shoung PhD  
Janssen LLC



Fanni Zhang PhD  
AstraZeneca



Wei Zhao PhD  
Fate Therapeutics



Oluyemi Oyeniran PhD  
JNJ