

# PHARMA INNOVATION ACCELERATOR

## TURNING IDEAS INTO THERAPIES

Day 1

Day 2

1

### Global Development Strategy

- Elements and considerations for a successful development strategy
- Product classification and regulatory frameworks

2

### Clinical Development

- Clinical development phases and clinical study design
- Regulatory procedures for clinical trial applications/ INDs
- Acceleration strategies

3

### Nonclinical Development

- Concepts of nonclinical studies
- Pharmacology
- Pharmacokinetics/ pharmacodynamics
- Toxicology
- Immunogenicity

4

### CMC

- Overview of CMC development and data requirements
- Pharmaceutical manufacturing and process development
- Analytical methods

5

### Regulatory Affairs

- Scientific advice and regulatory interactions
- Integrated development plans and platform technologies
- Marketing authorization application in the EU and US



Case Studies, Tools & Group Exercises

FOCUS