**Discovery & Development:** Research is conducted in laboratories with the purpose of discovering promising compounds.

**Preclinical Research:** Basic safety questions for compounds are answered via laboratory and animal testing.

**Clinical Research:** Compound is tested on humans in clinical trials to ensure its safety and effectiveness.

**Government Review:** Compound is submitted for government review / approval. A thorough examination of data is conducted.

**Post-Market Safety Monitoring:** Safety and efficacy of the drug is closely monitored once made available for use by the public.

### Clinical Pharmacology in Drug Development
- Discovery of a Drug candidate: Safety, Efficacy, and Manufacturability
- Pharmacokinetics (PK) and Pharmacodynamics (PD) models & simulations
- Biomarkers and Endpoints
- Toxicology Studies
- Evaluation of Drug Candidate: DMPK (Drug Metabolism & Pharmacokinetics), PD (Pharmacodynamic Studies)
- Regulatory Compliance Statements
- Assessment of Risk/Benefits: Regulatory decision-making, Real-World Data

### Design Thinking for Entrepreneurs
- Introduction to the Healthcare and Pharmaceutical Industry
- Finding Opportunities and Market Segments in Healthcare
- Concept Development, Implementation and Planning
- Understanding types of companies / partnerships
- Analyzing Financials
- Key business decisions during clinical trials
- Filing an Investigational New Drug (IND), Investigational Device Exemption (IDE), New Drug Application (NDA)
- Maneuvering Regulatory Landscape
- Building social capital
- Patenting Life Science Inventions and Intellectual Property due Diligence
- Commercial Activity in each stage of the drug development process
- Mergers, Acquisitions and IPO process

### Regulatory Science for Drug Development Scientists
- The role of a regulatory professional
- Differences between US and EU regulatory agencies and impact on companies
- Drug Substance Process Dev.: understand and differentiate the drug substance and drug product, and the regulations for each
- Describe and differentiate the regulatory guidance on setting specifications for Immediate Release and Modified Release Drug Products
- Formulation & Process Development: understand the guidance for formulation, process, scale-up, and post approval changes
- Life cycle management: understand the regulatory considerations related to life cycle management of a drug product

### Market Principles and Applications for Pharma Entrepreneurs
- The Marketing Research Process: from defining problems and research objectives to decision making
- Technology Assessment: Evaluation of early-stage technology and value assessment during the product development process
- Forecast and Modeling with case studies and exercises
- Cost analysis and Budget
- How to build marketing into product development process
- Conducting market research and simple techniques for gathering information and understanding pharmaceutical data sources (audits)
- Assessing the market-size of patient population Competitors, analysis of their strengths and weaknesses