HSTalks
The Biomedical &
Life Sciences Collection

Drug Development: From Molecule to Market

A learning journey on the process of developing a novel medicine

This learning journey is designed to provide a general introduction to the drug development process. It covers several key stages within the classical process, including drug discovery, non-clinical studies, clinical trials, regulatory frameworks, safety assessments, patents, and pharmaceutical marketing. The final section covers novel approaches to methods used within drug development.

A visual outline of the drug research and development process
This flowchart was adapted from a lecture on 'Drug discovery: from discovery to manufacture' by Prof. Michael Kinch.

Research: Identifying the Drug Product

Target Discovery → Target Validation → Assay Development → Screening → Lead Optimization

Development: Obtaining Regulatory Approval

Preclinical Development → Phase I → Phase II → Phase III → Phase IV

Clinical Trial Phases
- Phase I: evaluating safety, maximum tolerable dosage, and route of administration (usually in a small cohort of healthy volunteers).
- Phase II: first evaluation of efficacy and side effects (in small cohort of patients).
- Phase III: evaluation of efficacy (vs standard of care), monitor safety and side effects (in large cohort of patients).
- Phase IV: post-approval evaluation of risks, benefits and use in the wider population.

01 An Introduction to Drug Discovery

Extract from:
'Where did drugs come from?'
Dr. David Swinney – Institute for Rare and Neglected Diseases Drug Discovery, USA
7 mins (00:30 - 36:32)

02 Main Considerations for Promising Novel Drugs

Extract from:
'Drug discovery: from discovery to manufacture'
Prof. Michael Kinch – Washington University in St. Louis, USA
9 mins (00:26 - 09:27)

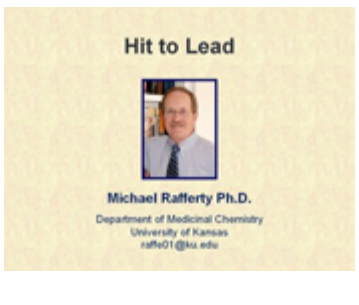
03 The Sustainability of Drug Development

Extract from:
'Biomarkers in drug development: potential use and challenges'
Dr. Abdel-Bassett Halim - Daiichi-Sankyo, Inc.
2 mins (01:18 - 03:36)

04 Identifying a Drug Target through Research

Extract from:
'Drug discovery: from discovery to manufacture'
Prof. Michael Kinch – Washington University in St. Louis, USA
4 mins (11:00 - 17:30)

05 A Summary of Hit to Lead in Drug Discovery

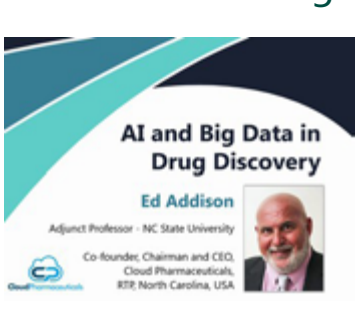


Extract from:
'Hit to lead'
Dr. Michael Rafferty – University of Kansas, USA
5 mins (01:25 - 07:39)

06 Pharmacophores and Lead Optimisation

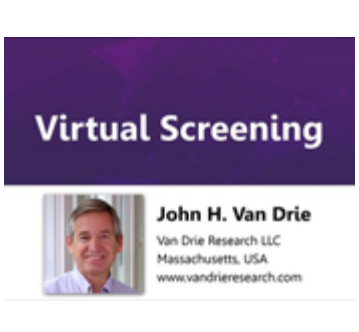
Extract from:
'Pharmacophore methods in drug discovery'
Dr. John H. Van Drie – Van Drie Research LLC, USA
14 mins (01:14 - 16:07)

07 The Modern Drug Discovery Process and Machine



Extract from:
'AI and big data in drug discovery'
Mr. Ed Addison – Cloud Pharmaceuticals, USA
8 mins (01:08 - 09:21)

08 An Introduction to Virtual Screening

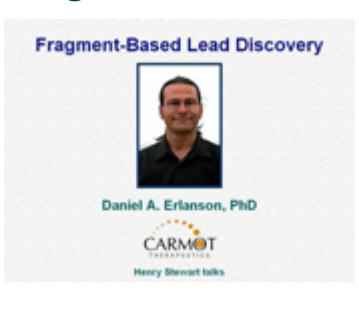


Extract from:
'Virtual screening'
Dr. John H. Van Drie – Van Drie Research LLC, USA
16 mins (01:32 - 18:30)

09 Traditional High Throughput Screening Versus Virtual Screening

Extract from:
'The utility of consensus approaches in virtual drug discovery'
Dr. Douglas Houston – University of Edinburgh, UK
10 mins (00:40 - 11:30)

10 High Throughput Screening Versus Fragment-Based Screening



Extract from:
'Fragment-based lead discovery'
Dr. Daniel A. Erlanson – Carmot Therapeutics, Inc., USA
4 mins (01:25 - 05:30)

11 Biologics and Biosimilars

Extract from:
'Modern management of rheumatoid arthritis - with a focus on biologic therapies'
Prof. John Isaacs – Newcastle University, UK
3 mins (28:52 - 34:20)

12 Non-Clinical Safety Assessment and ICH Guidelines

Extract from:
'Overview of nonclinical safety assessment'
Dr. Claudette L. Fuller – Merck Research Laboratories, USA
5 mins (00:58 - 05:53)

13 Non-Clinical and Toxicology Studies

Extract from:
'Overview of nonclinical safety assessment'
Dr. Claudette L. Fuller – Merck Research Laboratories, USA
4 mins (05:55 - 10:22)

14 Clinical Trials Overview

Extract from:
'Medical communications: principles and best practice'
Dr. Hannah Polson – Nucleus Global, UK
4 mins (14:22 - 18:50)

15 The Phases of Clinical Trials

Extract from:
'Drug discovery: from discovery to manufacture'
Prof. Michael Kinch – Washington University in St. Louis, USA
14 mins (28:46 - 43:41)

16 An Introduction to Clinical Trials and Randomization

Extract from:
'An introduction to randomization for clinical trials 1'
Prof. William Rosenberger – George Mason University, USA
5 mins (00:55 - 06:30)

17 Adaptive Clinical Trials

Extract from:
'Adaptive clinical trials: conclusion and future directions'
Prof. Yu Shyr – Vanderbilt University Medical Center, USA
17 mins (02:09 - 19:56)

18 Pre-Marketing Safety Surveillance

Extract from:
'A structured approach for pharmaceutical pre-marketing safety surveillance'
Dr. Lothar Tremmel – CSL Behring, USA
4 mins (01:40 - 05:18)

19 Patents in the pharmaceutical industry

Extract from:
'Introduction to patents in the pharmaceutical industry'
Dr. Jonathan D.M. Atkinson – Atkinson IP Consulting Limited, UK
8 mins (05:39 - 14:11)

20 Modern Medical Communication Channels

Extract from:
'Medical communications: principles and best practice'
Dr. Hannah Polson – Nucleus Global, UK
13 mins (19:10 - 33:57)

Novel Approaches to Drug Development

21 Humanized Antibodies and Phage Display

Extract from:
'Phage display for generating monoclonal antibodies'
Dr. Andre Frenzel – YUMAB GMBH, Germany
11 mins (02:00 - 13:43)

22 An introduction to Antibody Engineering

Extract from:
'Antibody engineering: beginnings to bispecifics and beyond'
Dr. Ian Wilkinson – Absolute Antibody, UK
3 mins (06:12 - 10:10)

23 CRISPR-Engineered T Cells and CAR-T Therapy

Extract from:
'Latest advances in the development of CAR & TCR T-cell treatments for solid tumours'
Dr. Else Marit Inderberg – The Norwegian Radium Hospital, Norway
Prof. John Isaacs – Newcastle University, UK
4 mins (16:37 - 21:28)

Additional upcoming talks include:
- Updates to the pharmaceutical marketing talks
- Gene therapy development
- EMA-Related regulatory challenges
- In-Vivo antibody discovery and hybridoma technology
- Therapeutic antibody development