

Clinical Trials

This learning journey is designed to introduce the various phases of clinical trials, their ethical framework, human consent, study design, and trial endpoints. Selection bias and statistical aspects are also discussed in this journey.

Phase 1 clinical trials



Extract from:

'Drug development: from discovery to manufacture'

Prof. Michael Kinch – Washington University in St. Louis, USA

6 mins

Ethical framework of clinical research



Extract from:

'Historical and ethical issues in trial design'

Dr. J. Rosser Matthews – University of Maryland, USA

3 min

Elements of consent



Extract from:

'The history and foundations of medical research ethics'

Prof. Dr. Christian Lenk – Ulm University, Germany

4 mins

Protection of human subjects



Extract from:

'Development and regulation of cellular and gene therapy products: FDA perspective'

Dr. Larissa Lapteva – Center for Biologics Evaluation and Research, FDA, USA

2 mins

First in human trials



Extract from:

'Development of a cancer drug'

Prof. Martin Edelman – Fox Chase Cancer Center, USA

3 mins

Phase 2 clinical trials



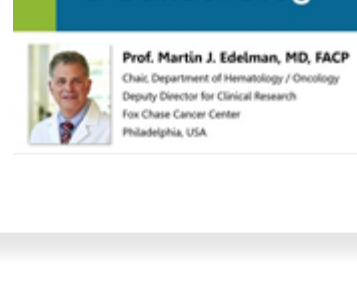
Extract from:

'Drug development: from discovery to manufacture'

Prof. Michael Kinch – Washington University in St. Louis, USA

3 mins

What is an adequate and well-controlled study?



Extract from:

'Development of a cancer drug'

Prof. Martin Edelman – Fox Chase Cancer Center, USA

6 mins

Ethics and research design: preconditions for placebo



Extract from:

'Ethics and drug development'

Prof. Dr. Christian Lenk – Ulm University, Germany

5 mins

Historical controls and trial design for rare diseases



Extract from:

'Clinical trial designs for rare diseases 1: trial designs'

Dr. Anne Pariser – National Institutes of Health, USA

3 mins

Selection bias and randomization



Extract from:

'Detection of and adjustment for selection bias in randomized controlled clinical trials'

Prof. Lieven Nils Kennes – University of Applied Sciences, Germany

4 mins

Trial statistical aspects



Extract from:

'Development of a cancer drug'

Prof. Martin Edelman – Fox Chase Cancer Center, USA

4 mins

Endpoints in phase II trial design: response rate



Extract from:

'Phase II trials'

Dr. Patricia Tang – University of Calgary, Canada

4 mins

Surrogate endpoint



Extract from:

'Surrogate endpoints: from definition to meta-analytic framework 1'

Prof. Geert Molenberghs – Universiteit Hasselt & KU Leuven, Belgium

2 mins

Oncology trial endpoints



Extract from:

'Development of a cancer drug'

Prof. Martin Edelman – Fox Chase Cancer Center, USA

6 mins

Phases 3 and 4 clinical trials



Extract from:

'Drug discovery: from discovery to manufacture'

Prof. Michael Kinch – Washington University in St. Louis, USA

4 mins