HSTalks
The Biomedical &
Life Sciences Collection

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.

01

Phase 1 clinical trials

Extract from:
'Drug development: from discovery to manufacture'
Prof. Michael Kinch – Washington University in St. Louis, USA
6 mins

02

Ethical framework of clinical research

Extract from:
'Historical and ethical issues in trial design'
Dr. J. Rosser Matthews – University of Maryland, USA
3 min

03

Elements of consent

Extract from:
'The history and foundations of medical research ethics'
Prof. Dr. Christian Lenk – Ulm University, Germany
4 mins

04

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

05

First in human trials

Extract from:
'Development of a cancer drug'
Prof. Martin Edelman – Fox Chase Cancer Center, USA
3 mins

06

Phase 2 clinical trials

Extract from:
'Drug development: from discovery to manufacture'
Prof. Michael Kinch – Washington University in St. Louis, USA
3 mins

07

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

08

Ethics and research design: preconditions for placebo

Extract from:
'Ethics and drug development'
Prof. Dr. Christian Lenk – Ulm University, Germany
5 mins

09

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

10

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

11

Trial statistical aspects

Extract from:
'Development of a cancer drug'
Prof. Martin Edelman – Fox Chase Cancer Center, USA
4 mins

12

Endpoints in phase II trial design: response rate

Extract from:
'Phase II trials'
Dr. Patricia Tang – University of Calgary, Canada
4 mins

13

Surrogate endpoint

Extract from:
'Surrogate endpoints: from definition to meta-analytic framework 1'
Prof. Geert Molenberghs – Universiteit Hasselt & KU Leuven, Belgium
2 mins

14

Oncology trial endpoints

Extract from:
'Development of a cancer drug'
Prof. Martin Edelman – Fox Chase Cancer Center, USA
6 mins

15

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