PD233: Design of Biomedical Devices and Systems

(Lecture-15 Clinical Trials)

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Course Website:
http://cpdm.iisc.ac.in/utsaah/courses/

Clinical Trials

Why?

- Regulatory approval
- Market acceptance
- Reimbursement

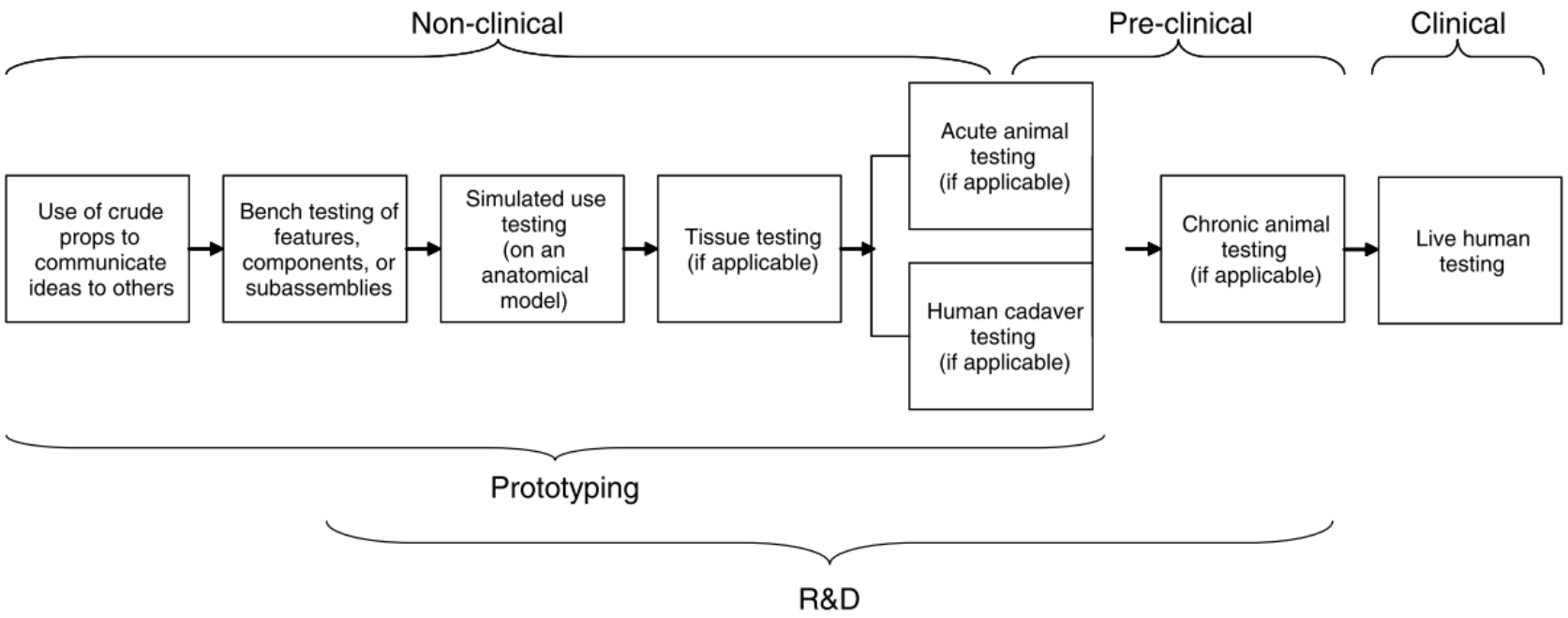
The main objective of clinical trials is to demonstrate that new device offers ***measurable, clinically important*** benefits to patients in terms of its ***effectiveness and safety***

Clinical Study Gaols

- Regulatory Approval:
  - What results are needed to support regulatory approval?
- Reimbursement:
  - Are economic outcomes important to support reimbursement decisions?
- Market Adoption:
  - What results would KOLs need to making there recommendations?
  - Will data be necessary to help market the device to physicians and/or patients?

Clinical study may be carried out to address one or more of the above

Non-clinical, preclinical, clinical testing



Chapter 5, Zenios et al. , Biodesign,

FDA regulatory pathway

Pathway	Description
Device exemption	These are devices for which the risk is so low that they are exempt from regulatory clearance. Most class I devices take this pathway.
510(k)	This is the largest category of medical device applications, in which clearance is based on a device being similar to existing devices in clinical use. Some class I devices and most class II devices take this pathway.
Premarket approval (PMA)	This is the most stringent pathway, used for devices that are significantly different from existing technologies and/or represent the highest risk to patients. The vast majority of class III devices take the PMA pathway, although a few remain eligible for 510(k) clearance.

Pilot Clinical Investigation

- **First-in-human studies**
- Small scale, preliminary human studies
- Primary objective is establishing safety
  - Though investigators are observe if the device performs as indented
- 10-100 cases performed in real world setting as **Registry of cases or Observational studies**
- Learn enough about device to design a definitive trial of the device
- **Case Controlled studies** allow statistical comparison of group of patient treated with new device or procedure to a matched group with no treatment or standard treatment.

Prospective, randomized controlled (blinded) trials

- Gold Standard of medical device testing
- Have statistical ‘power’ to discriminate whether or not the outcome and safety profile of the new device indeed superior to the control group.
- In ‘double blind’ trials both the patients and the physician are blind to the treatment
- Also know as **pivotal trial**

Post-market studies

- After commercial approval of the device
- Maybe required as part of Pre-market approval (PMA)
- But also useful as part of overall strategy e.g. for getting reimbursement etc.