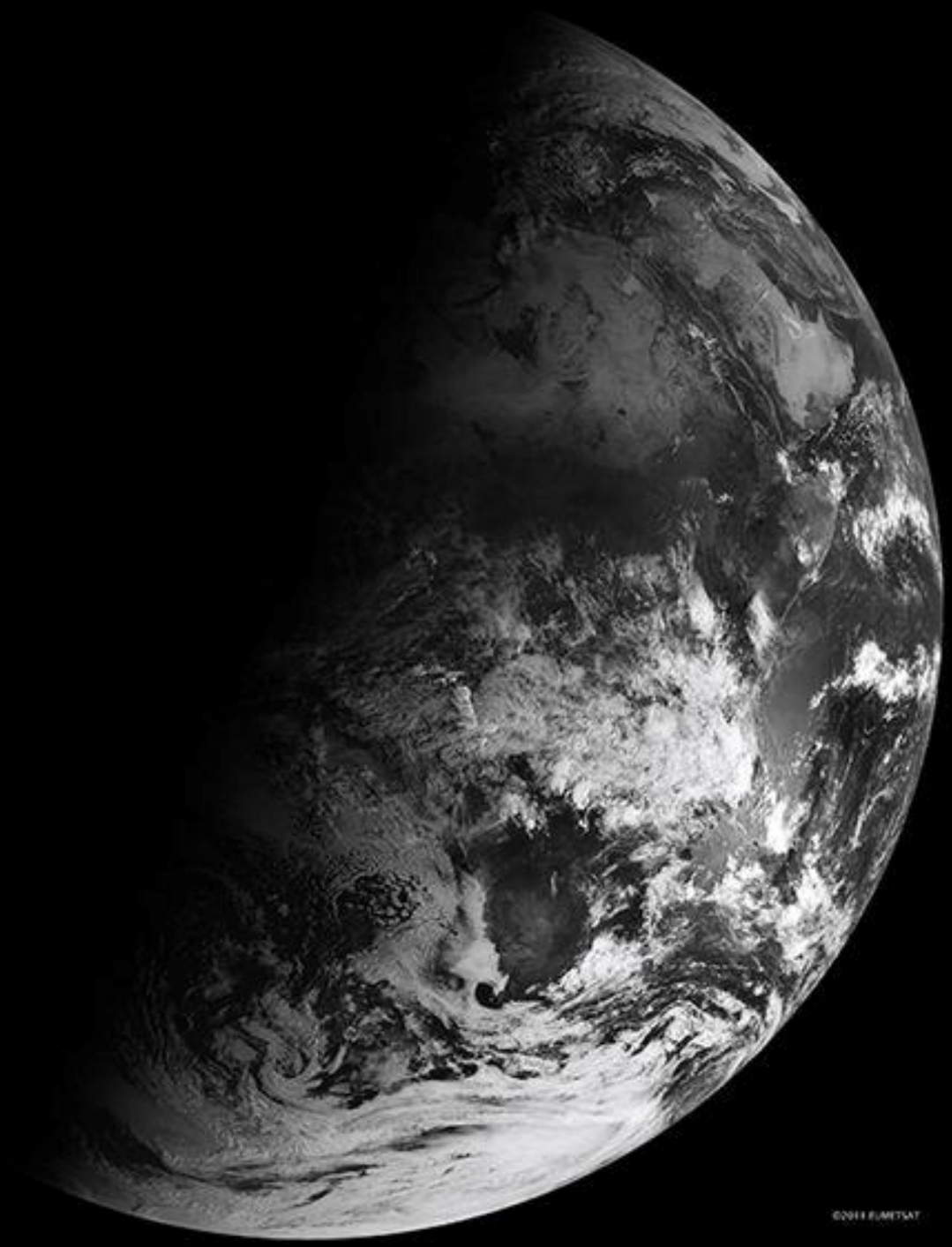
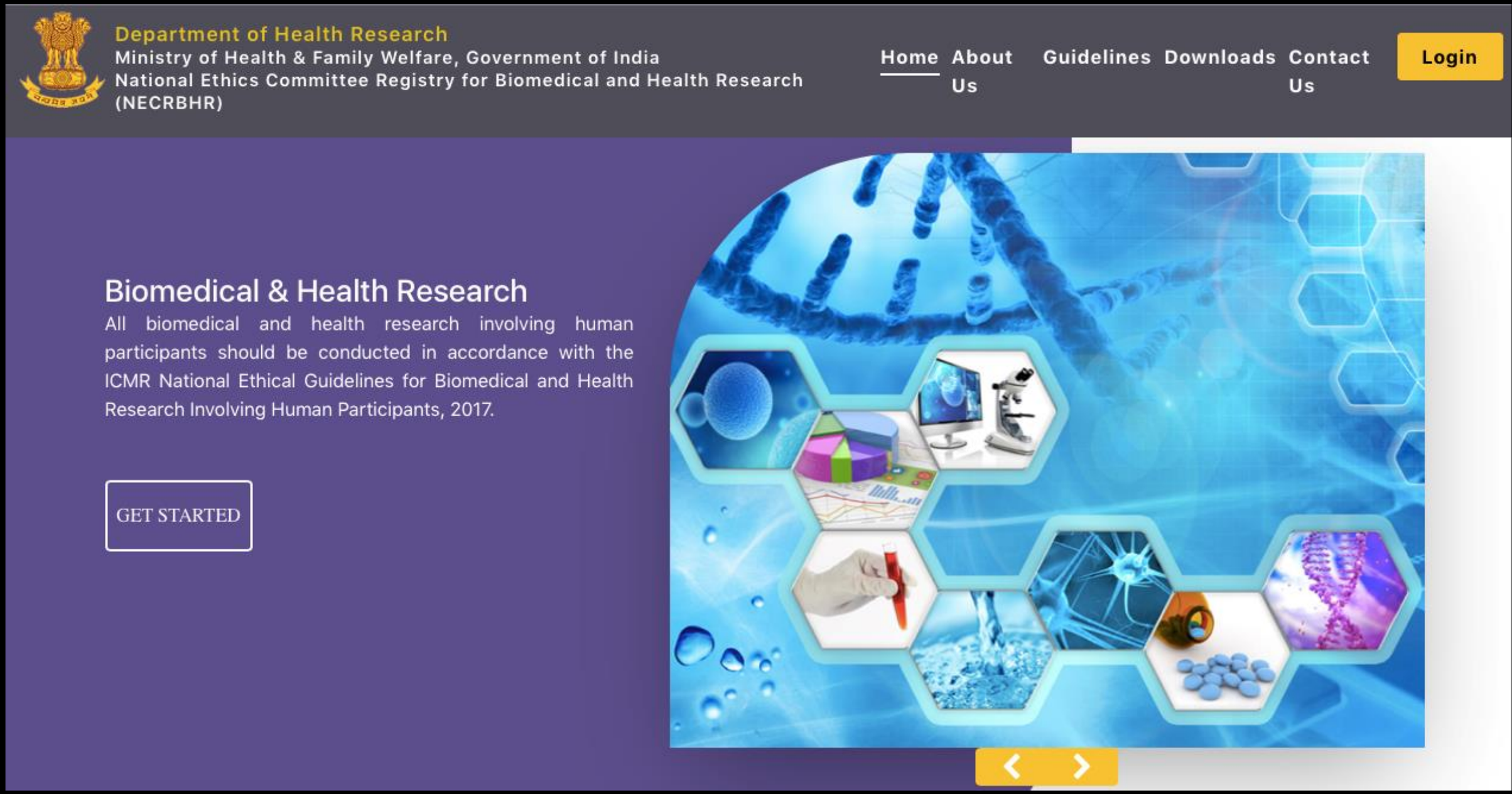

DECEMBER
21
MEDICAL ETHICS
LEARN,
IMPLEMENT, TEACH





https://naitik.gov.in/DHR/Homepage#

Biomedical and health research

A large number of biomedical and health research studies are being conducted across the country at various research centres/medical institutions/ universities etc. Ethics Committees (EC) are entrusted with the responsibility to undertake the ethical review of research proposals prior to initiation, and also have a continuing responsibility to regularly monitor the approved research to ensure ethical compliance during the conduct of research and to ensure that the rights, safety and well-being of research participants is protected. These Ethics committee reviewing biomedical and health research shall be constituted and are required to function in accordance with the ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017.

Department of Health Research
Ministry of Health & Family Welfare, Government of India
National Ethics Committee Registry for Biomedical and Health Research (NECRBHR)

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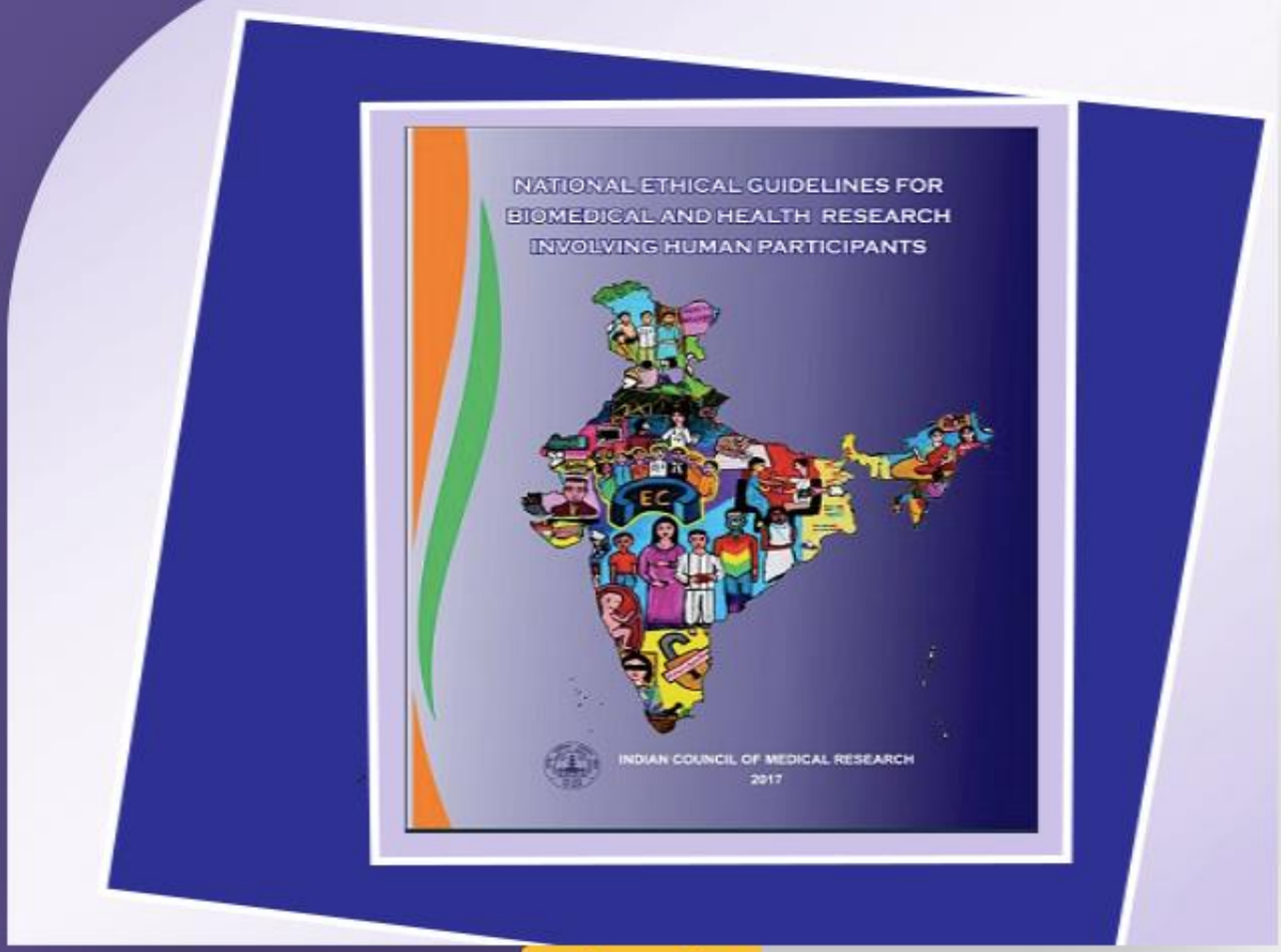
Ethics Committees

The Ethics Committee (EC) is responsible for scientific and ethical review of research proposals. Although ECs may obtain documentation from a prior scientific review, they must determine that the research methods are scientifically sound, and should examine the ethical implications of the chosen research design or strategy.

GET STARTED



Department of Health Research
Ministry of Health & Family Welfare, Government of India
National Ethics Committee Registry for Biomedical and Health Research (NECRBHR)

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Ethics Committee's Members

The composition, affiliations, qualifications, member specific roles and responsibilities of an Ethics committee should be in accordance with ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants.

GET STARTED

Downloads

S.No	Name	File
1.	Handbook on National Ethical Guidelines for Biomedical and Health Research Involving Human Participants	PDF
2.	Extracts of New Drugs and Clinical Trials Rules 2019 relevant to biomedical and health research	PDF
3.	Common forms for EC review	PDF
4.	Checklist for EC Registraion for Biomedical and Health Research	PDF
5.	The New Drugs and Clinical Trials Rules, 2019	PDF
6.	Undertaking for Ethics Training	PDF

https://ethics.ncdirindia.org

Propaganda for Nazi Germany's T-4 Euthanasia Program: "This person suffering from hereditary defects costs the community 60,000 Reichsmark during his lifetime. Fellow German, that is your money, too." from the Office of Racial Policy's Neues Volk.

- Indian GCP guidelines
- Declaration of Helsinki
- National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017)
- Amendments to the Drugs & Cosmetics Act (1940), and Rules (1945)

- Drugs
- Vaccines
- Biosimilars, biologics
- Phytopharmaceuticals
- Public health or socio-behavioural interventions
- Devices
- Surgical techniques
- Traditional systems of medicine, etc

PRE-REQUISITES FOR THE STUDY

- Investigational Pharmaceutical Product
- Pre-clinical supporting data
- Well defined research protocol
- Ethical and Safety Considerations
  - Submission
  - Decision

- Students - thesis, guides/and institutions should take the responsibilities of sponsor.
- Registration with CTRI - mandatory for clinical trials under the purview of CDSCO.
- Patients should not be charged
- Ancillary care
- Adverse effects of drugs should be reported in a timely manner.
- Clinical trials should be scientifically and ethically sound and preclinical studies should precede trials on humans.

(Annexure 8)

Application Form for Clinical Trials

Logo of the Institute

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(Name of the Institution) **EC Ref. No.** *(For office use):*

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. **Type of clinical trial** **Regulatory trial** ☐ **Academic trial** ☐

CTRI registration number: ..... **NABH accreditation number:**..... **EC registration number:**.....

Clinical Trials

Nature of trials

Permission for trials

- **Regulatory trials** - clinical evaluation of new drugs and medical devices

- **Academic clinical trial** - not funded by pharmaceutical or biotechnology company for commercial ends but by public-good agencies (usually universities or medical trusts) to advance medicine.

http://ctri.nic.in/Clinicaltrials/login.php

http://ctri.nic.in/Clinicaltrials/faq.php#1a

CLINICAL TRIALS REGISTRY - INDIA

ICMR - National Institute of Medical Statistics

Home Page | Trial Search | Advanced Search | FAQs | Publications | Secretariat | Feedback | Disclaimer | Sitemap

Font Size: A | A | A | A

SIGN IN TO CTRI

Username

Password

6xd6g

Login

Forgot Password | New Applicant

Trial Registration Data Set Download:[Pdf]

Keyword Search

wpwyj

News / Highlights

PG Thesis Registration

Trials being conducted as part of PG thesis should mention both student's as well as Guide's name and full official address, including department. Co-guide name may also be included, if desired). Names should be included in Contact Person details after mutual agreement on division of responsibilities. Verification is sought by email from all trial Contact Persons, except the trial Registrant.

2. If regulatory trial, provide status of CDSCO permission letter

Approved and letter attached ☐ Applied, under process ☐

Not applied (State reason) ☐.....

https://cdsco.gov.in/opencms/opencms/en/Home/


CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
CDSCO CDSCO
सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA
WHO declares CDSCO
as Functional
NRA (National Regulatory Authority)

3. Tick all categories that apply to your trial

Phase - I	☐	Phase II	☐
Phase III	☐	Phase IV or Post Marketing Surveillance	☐
Investigational medicinal products	☐	Investigational New drug	☐
Medical devices	☐	New innovative procedure	☐
Drug/device combination	☐	Bioavailability/Bioequivalence studies	☐
Non-drug intervention	☐	Repurposing an existing intervention	☐
Indian system of medicine (AYUSH)	☐	Stem cells	☐
Phytopharmaceutical drug	☐	Approved drug for any new indication	
Others (specify)	☐	or new route of administration	☐

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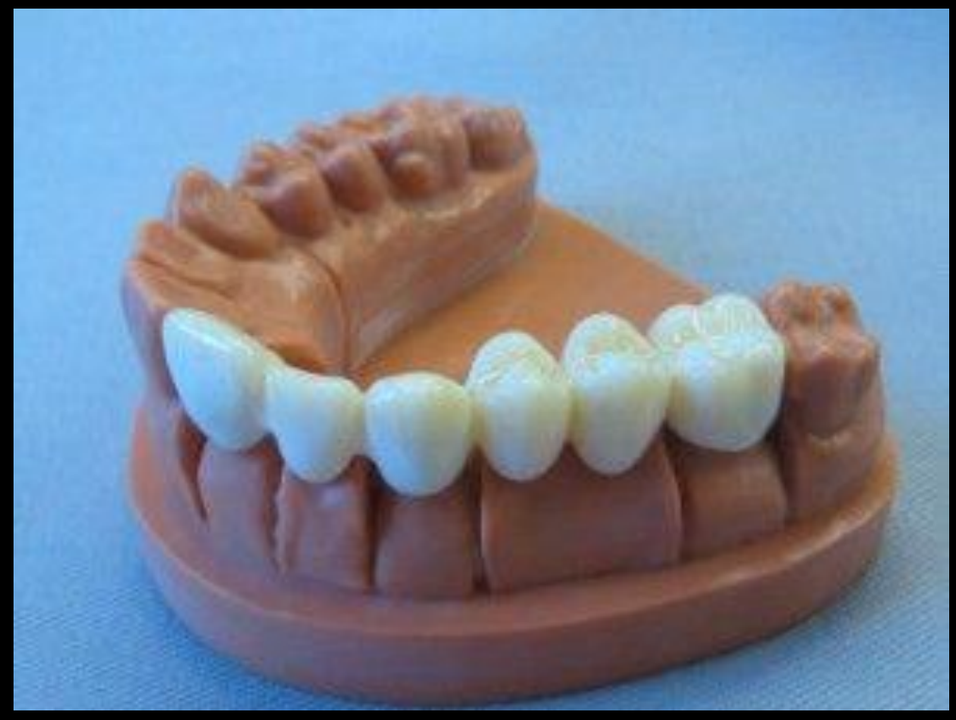
Summary of clinical trial phases

Phase	Primary goal	Dose	Patient monitor	Typical number of participants	Success rate[2]	Notes
Preclinical	Testing of drug in non-human subjects to gather efficacy, toxicity and pharmacokinetic information	Unrestricted	Scientific researcher	No human subjects, *in vitro* and *in vivo* only		Includes testing in model organisms. Human immortalized cell lines and other human tissues may also be used.
Phase 0	Pharmacokinetics; particularly oral bioavailability and half-life of the drug	Small, subtherapeutic	Clinical researcher	10 people		Often skipped for Phase I.
Phase I	Dose-ranging on healthy volunteers for safety	Often subtherapeutic, but with ascending doses	Clinical researcher	20–100 normal healthy volunteers (or cancer patients for cancer drugs)	Approx. 70%	Determines whether drug is safe to check for efficacy.
Phase II	Testing of drug on participants to assess efficacy and side effects	Therapeutic dose	Clinical researcher	100–300 participants with a specific disease	Approx. 33%	Determines whether drug can have any efficacy; at this point, the drug is not presumed to have any therapeutic effect
Phase III	Testing of drug on participants to assess efficacy, effectiveness and safety	Therapeutic dose	Clinical researcher and personal physician	300–3,000 people with a specific disease	25–30%	Determines a drug's therapeutic effect; at this point, the drug is presumed to have some effect
Phase IV	Post marketing surveillance in public	Therapeutic dose	Personal physician	Anyone seeking treatment from a physician	N/A	Monitor long-term effects

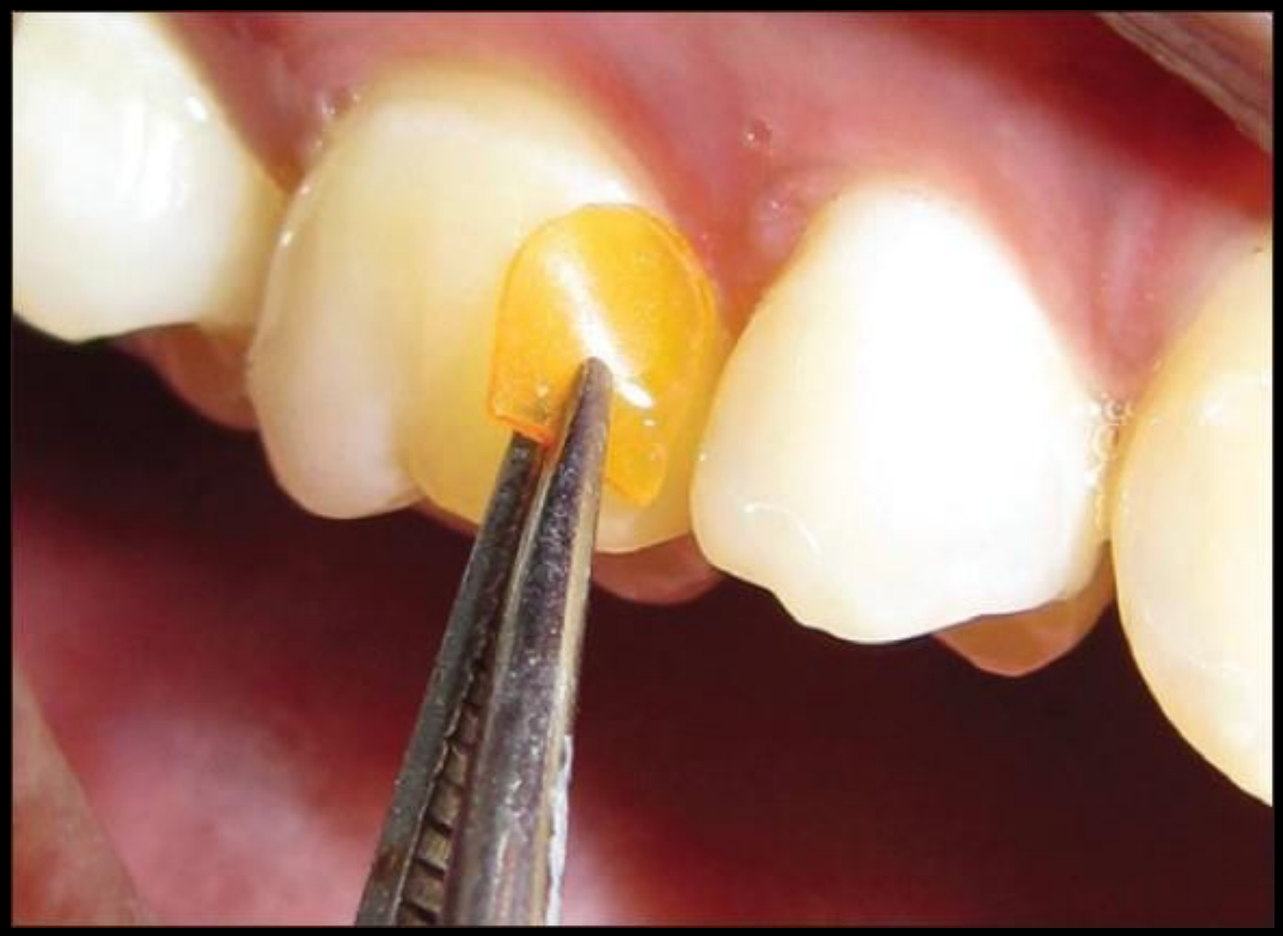
Medical device

- Inert , does not achieve any of its principal intended purposes through chemical action
  - Prosthodontic appliances (dentures, obturators, crowns and bridges)
  - Orthodontic appliances
  - Appliances that facilitate surgical procedures such as arch bars and wafers for orthognathic surgery



Drug /device combination

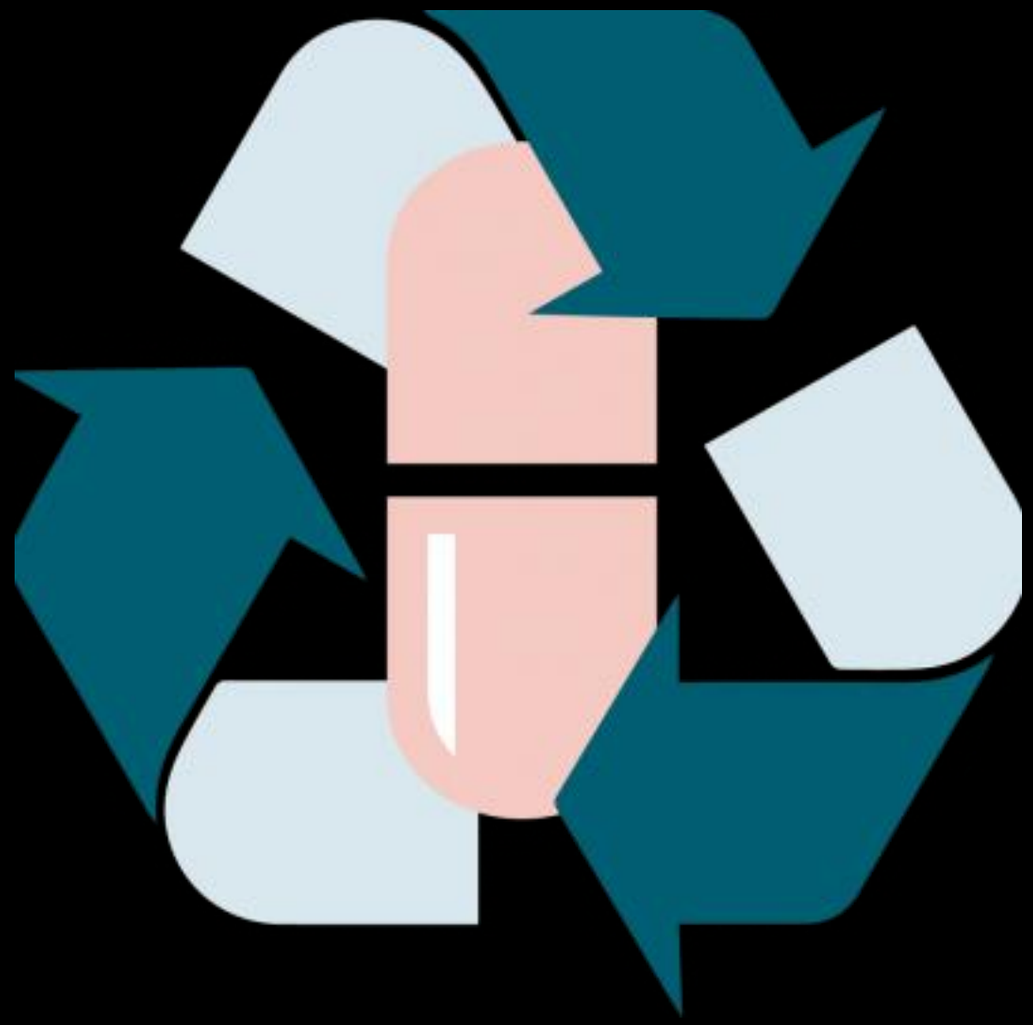
- Where the components are physically, chemically or otherwise combined
  - Eg - Photosensitizing drug and activating laser/light source
  - Local drug delivery - scaffold + drug Eg - CHX chip



Bioavailability / Bioequivalence

- Measuring active drug ingredient available at site of action
- Healthy volunteers
- Safety and efficacy of drug dose

- **Non-drug intervention**
  - Supportive Therapies
  - Physical and occupational therapy
- **Repurposing an existing intervention**
  - New therapeutic use(s) for old/existing/available drugs

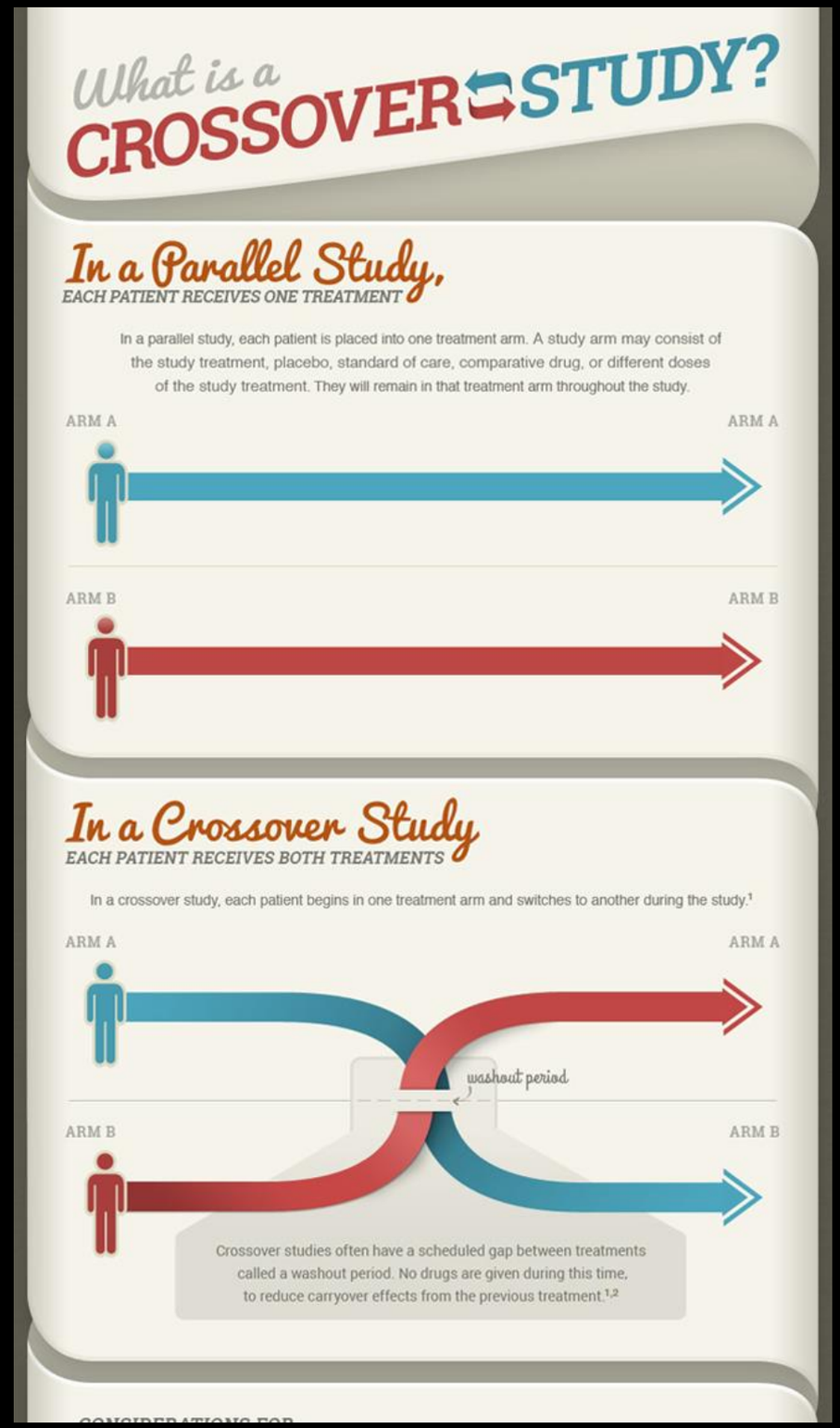


- Indian system of medicine (AYUSH) - Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy

- Phytopharmaceutical drug - extract of a medicinal plant or its part

Trial design

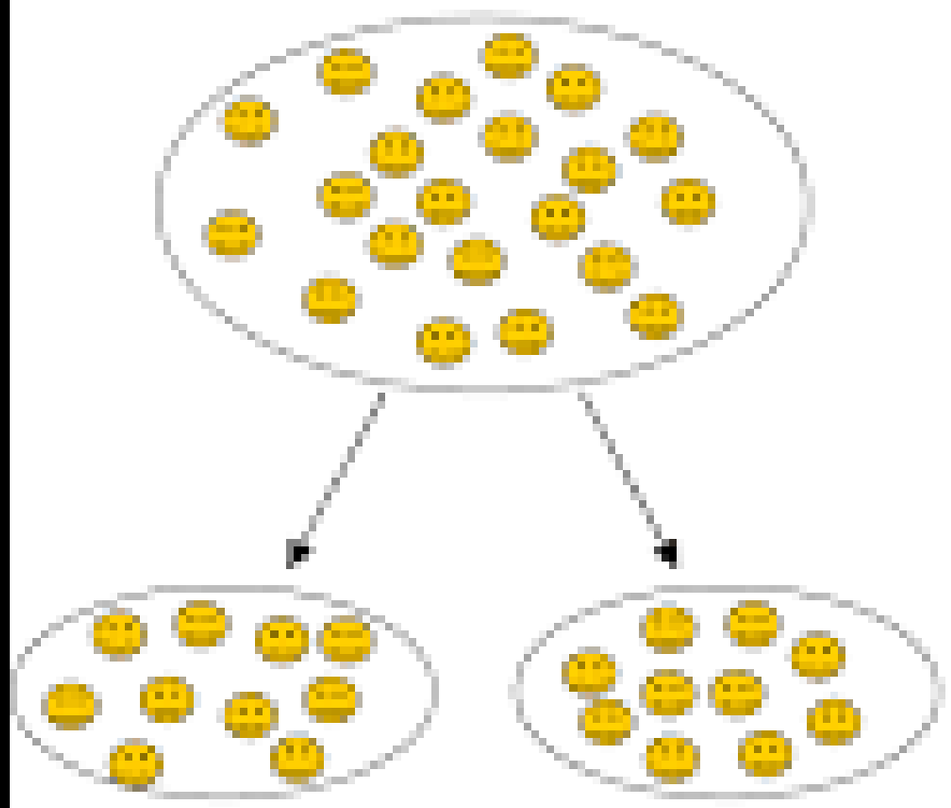
- Randomized clinical trial
- Non Randomised Clinical trial
- Parallel clinical trial
- Crossover



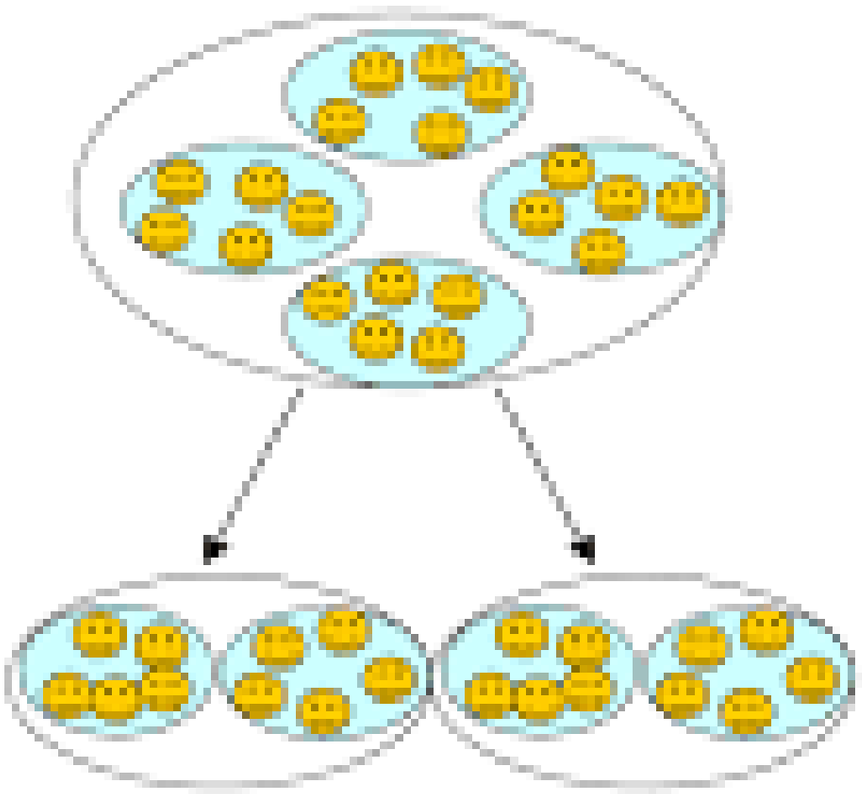
Cluster Randomized Trials

… are clinical trials (experiments) in which **social units** or **clusters of individuals** rather than independent individuals **are randomly allocated** to intervention groups.

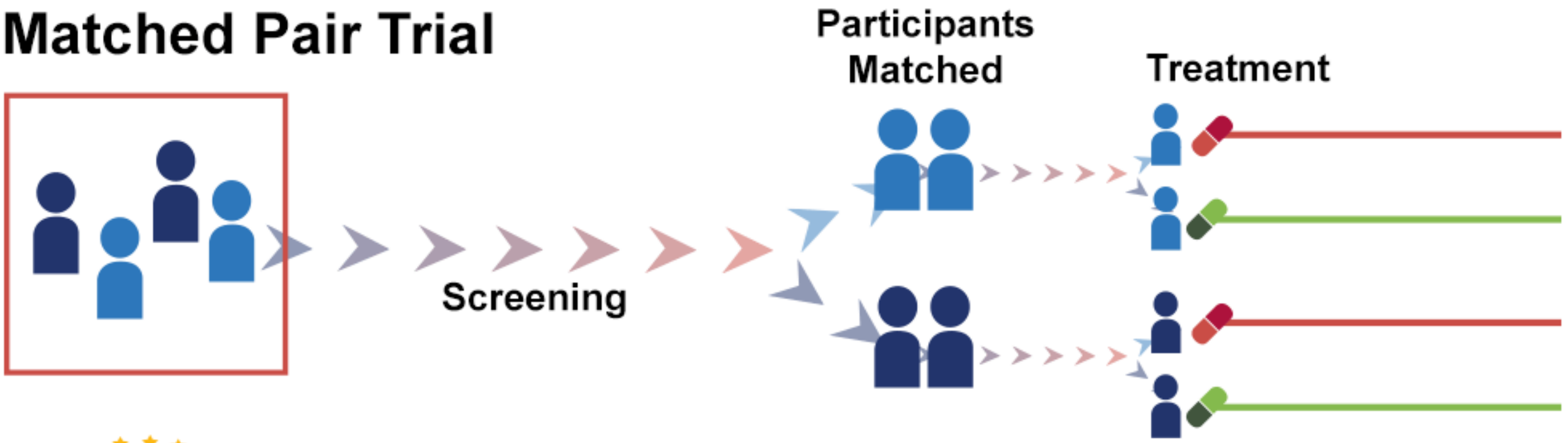
Individual randomization



Cluster randomization



Matched Pair Trial

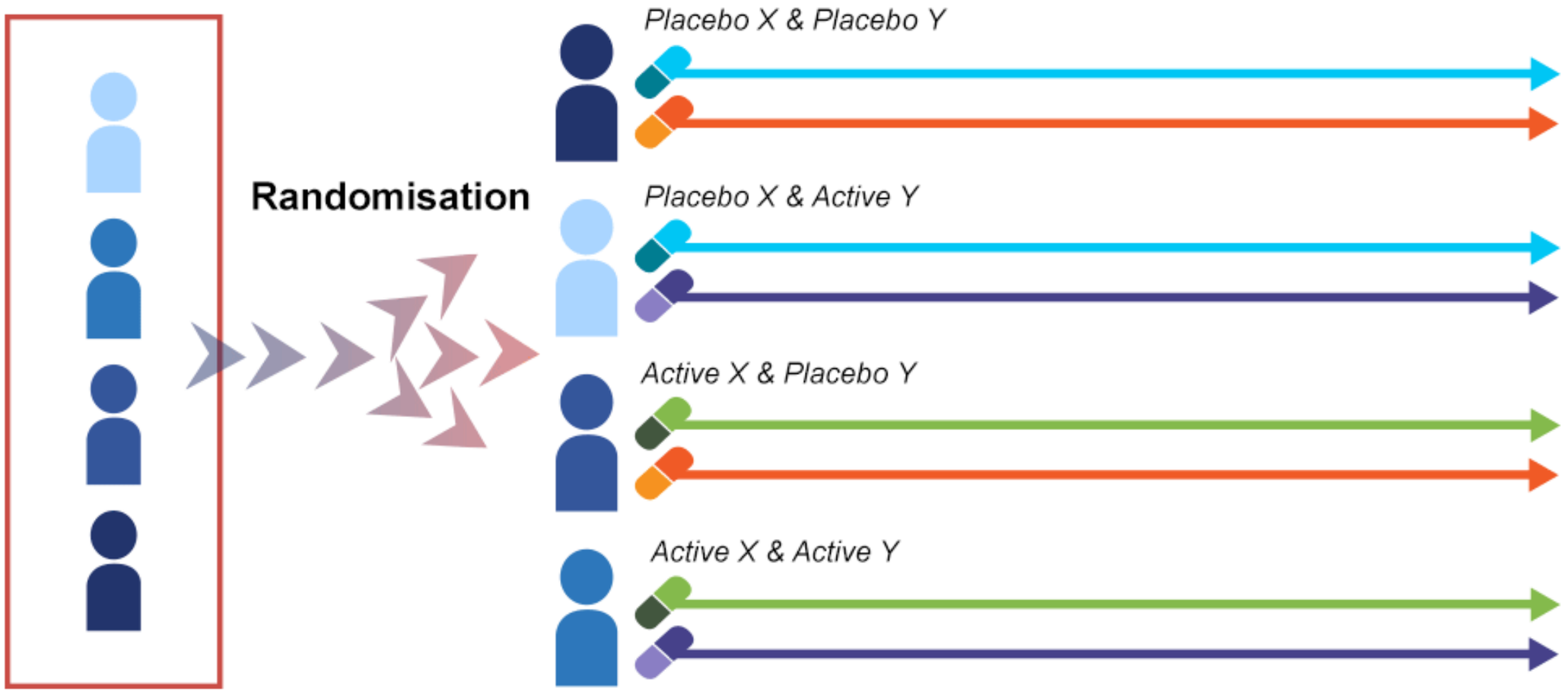


EUPATI
European Patients' Academy
on Therapeutic Innovation
www.eupati.eu

Treatment A

Treatment B

2x2 Factorial design



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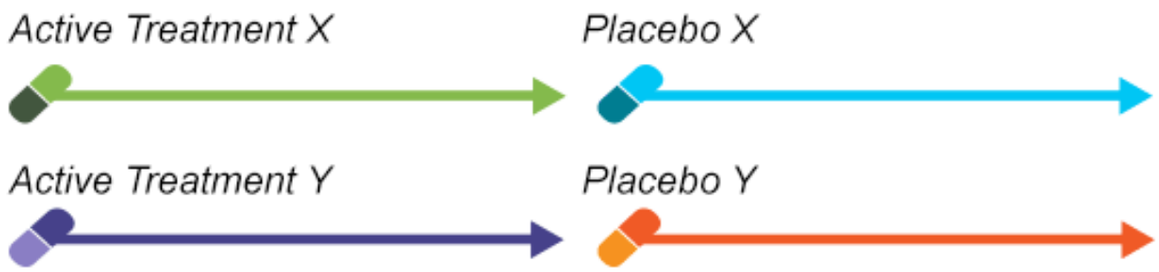
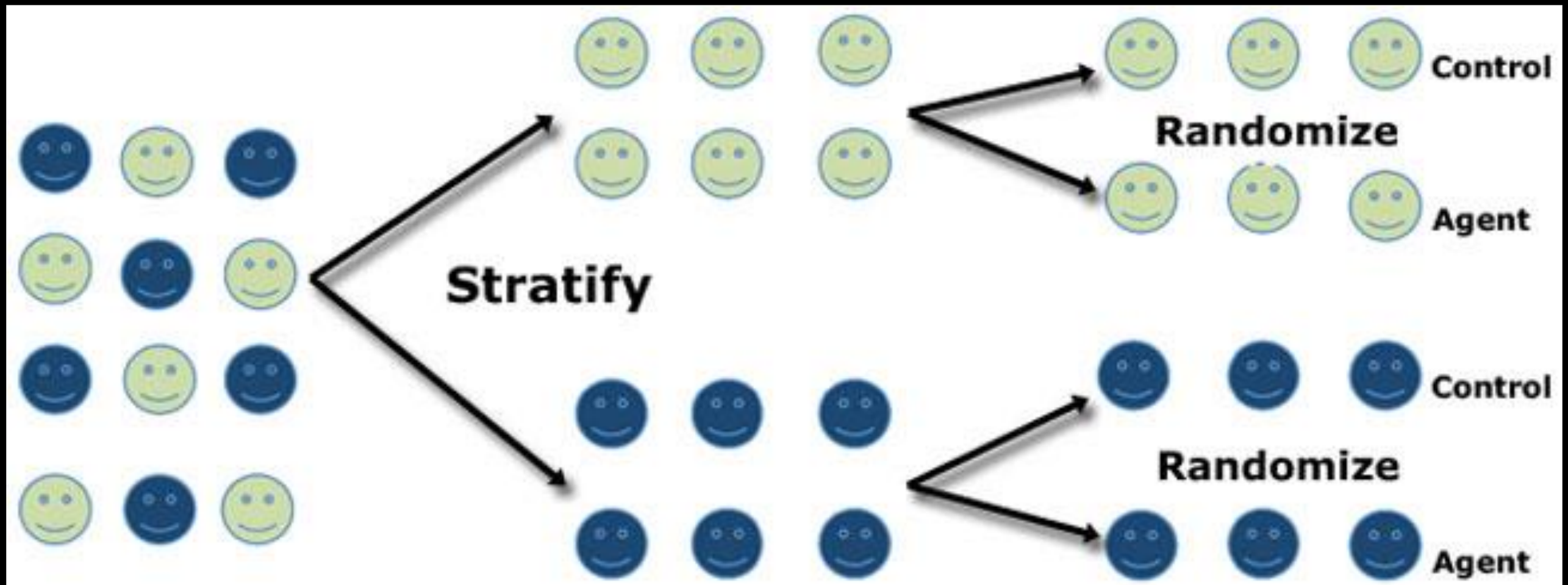
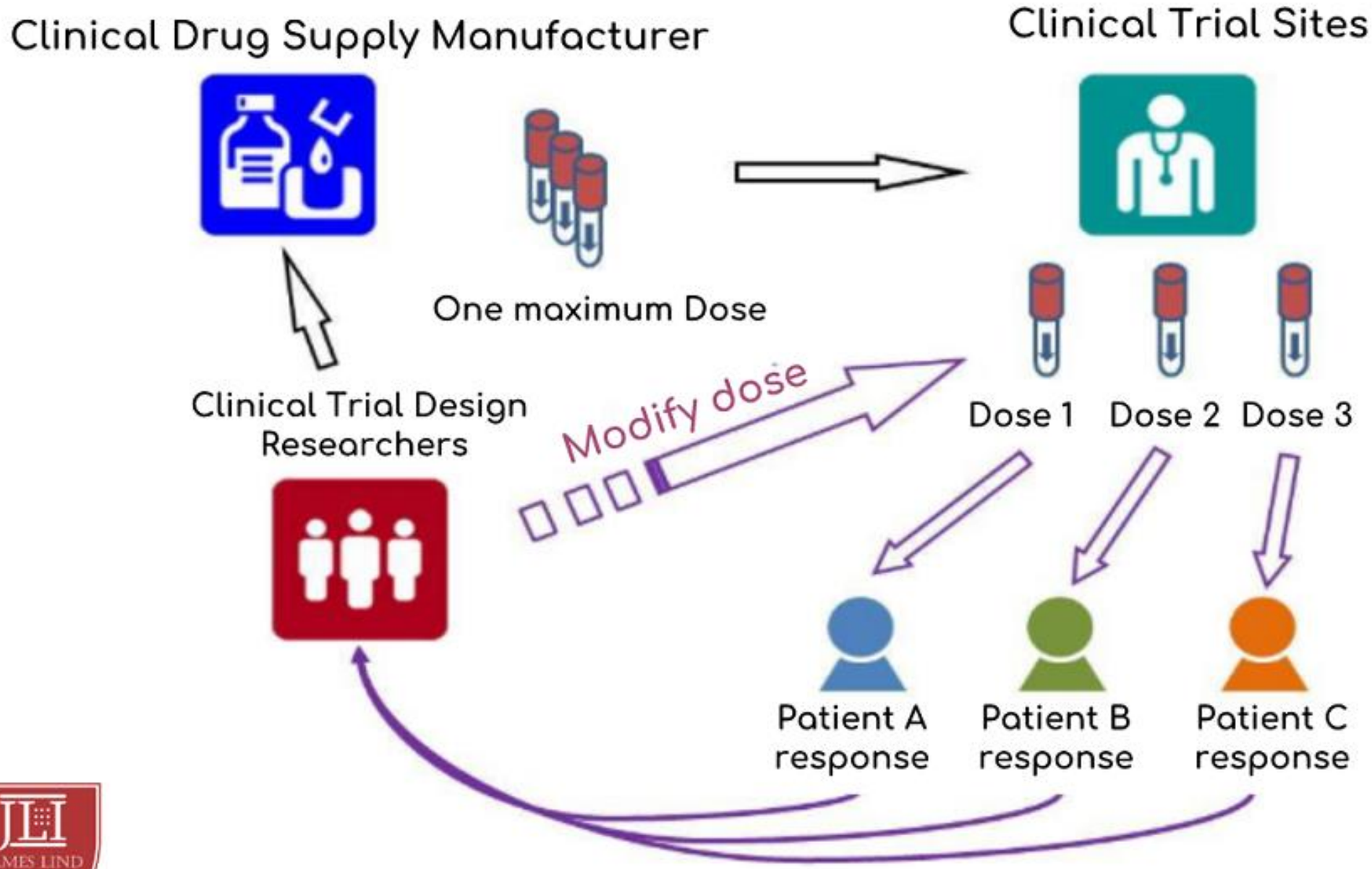
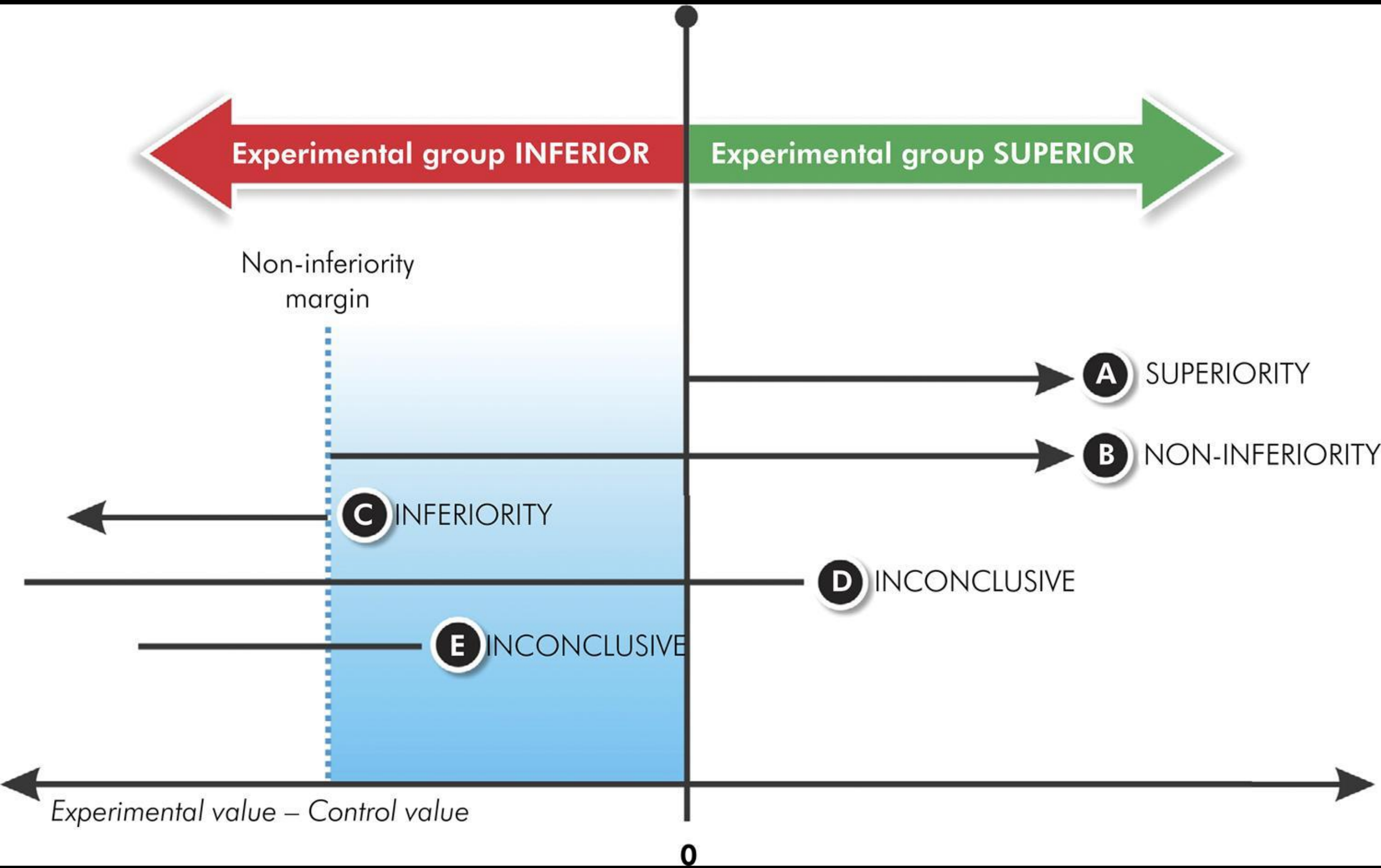


Stratified Clinical Trials

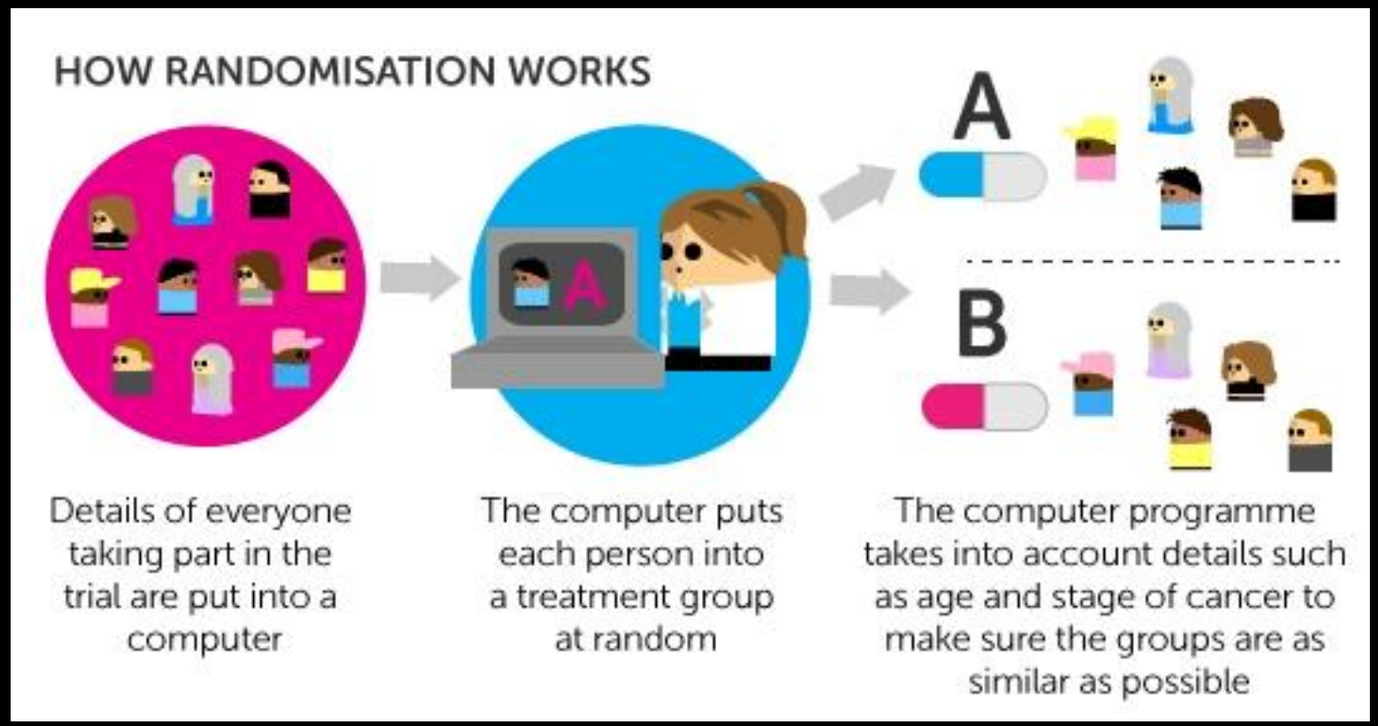


Adaptive Design

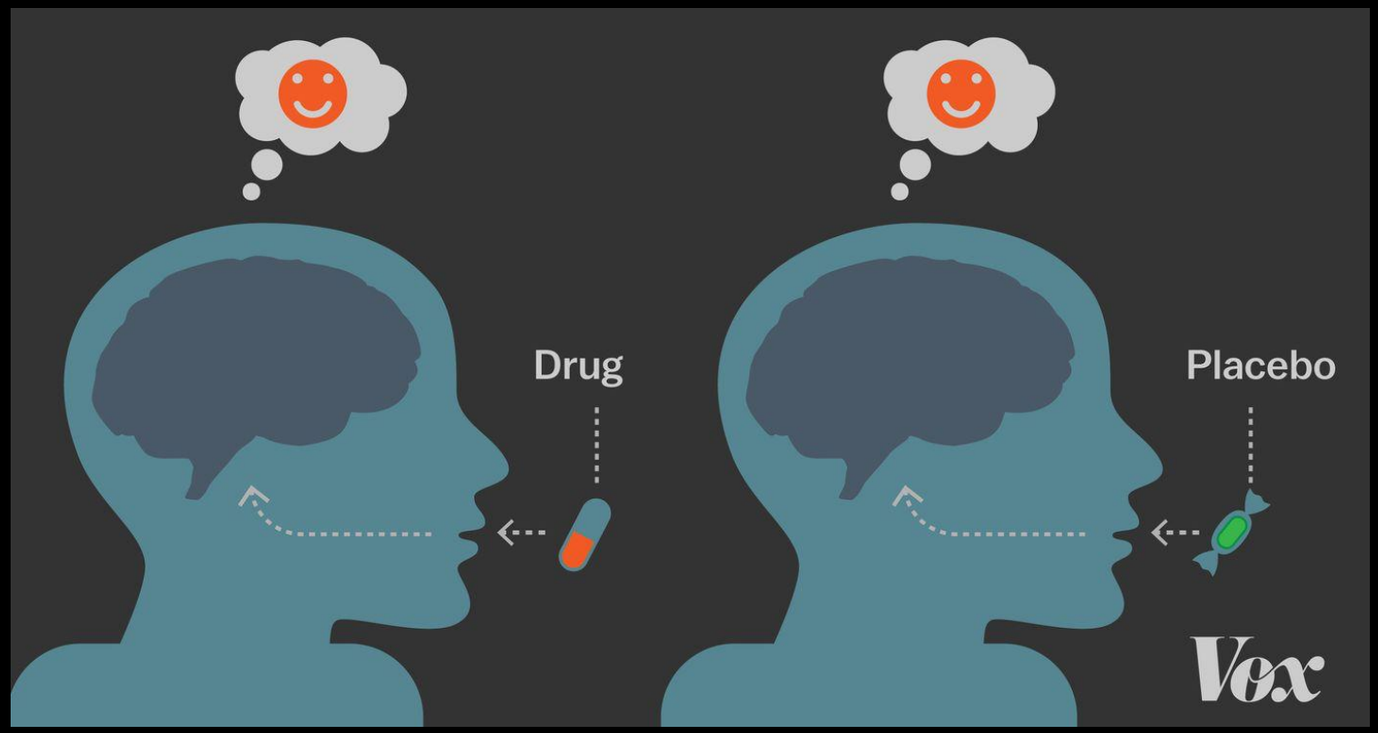



Experimental group INFERIOR
Experimental group SUPERIOR
Non-inferiority margin
A SUPERIORITY
B NON-INFERIORITY
C INFERIORITY
D INCONCLUSIVE
E INCONCLUSIVE
Experimental value – Control value
0

- Randomisation
- Allocation concealment
- Adverse events



- Serious adverse events
- Use of placebo



Logo of the Institute

(Annexure 9)

Serious Adverse Event Reporting Format (Clinical trials)

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(Name of the Institution) **EC Ref. No.** *(For office use):*

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12. Seriousness of the SAE:

Death	☐	Congenitial anomaly	☐
Life threatening	☐	Required intervention to prevent	
Hospitalization-initial or prolonged	☐	permanent impairment / damage	☐
Disability	☐	Others *(specify)*	☐

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.....

14. Outcome of SAE:

Fatal	☐	Recovered	☐
Continuing	☐	Unknown	☐
Recovering	☐	Other *(specify)*	☐

.....

Project Submission / Research Protocol Overview

	A	B
1	**Name/Names of all Investigator / Investigator (Candidate/student)** (underline principle investigator)	
2	**Name of Institution and Address**	
3	**Course of the study and subject:**	
4	**Date of admission of the course**	
5	**Title**	
6	**Need for the study /Introduction / background** Give the background, including human or animal research relevant to the design of the proposed study. When new techniques or procedure are to be used, provide a description of preliminary work. When an investigation drug is to be used, animal data and phase I or II data on the drug should be included. A summary of how the study may help in the future should be included in the protocol.	

How is it intended the results of the study will be reported and disseminated?	- Peer reviewed scientific journals - Other publication - Conference presentation - Internal report - Submission to regulatory authorities - Access to raw data and right to publish freely by all the investigators in study or by independent steering committee on behalf of all investigators - Other .....
REFERENCES	

JANUARY 8TH 2021 - LAST DATE TO RECEIVE DOCUMENTS

SCIENTIFIC REVIEW

JANUARY 13TH 2021 - INSTITUTIONAL REVIEW BOARD MEETING

JANUARY 20TH (tentative) 2021 - ETHICAL MEETING / APPROVAL

JANUARY 31ST 2021 - SYNOPSIS SUBMISSION TO RGUHS

Thank you

For details - Contact

ethicalcommittee@kcdsh.org