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CLINICAL TRIAL BASICS

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CLINICAL TRIAL BASICS

This resource is designed to give a brief overview to what clinical trials are, how they apply to the medtech sector, and introduces you to key requirements such as ethical reviews.

CONTENTS

WHAT ARE CLINICAL TRIALS?

What are Clinical Trials?

A type of research **involving people**

A way to test **health-related interventions** and outcomes

A method of **answering questions** like:

- Is the intervention safe?
- Does the intervention cure a disease or extend the lives of people with the disease?
- Does the intervention improve the lives of the people it is for?

Why are Clinical Trials done?

To provide **research data** (evidence) about the intervention(s) being tested

To help decide **what therapies or other interventions might work best** for people

A clinical trial is **a research project that studies biomedical or behavioural aspects of human health**, and often includes comparisons of health-related medicines, technologies, and interventions such as new treatments vs existing treatments.

Clinical trials can involve hospital patients, healthy members of the public, members of the public with a specific health condition, or a combination. Clinical trials often have at least one group of people with a condition, and one groups of healthy volunteers (the control group) for comparison.

Clinical trials aim to generate high quality evidence about the focus of the study, such as effective medical treatments, the efficacy of medical technologies, and comparisons that include existing treatments and therapeutic interventions.

Clinical trials use scientific methodologies to adhere to the high standards of evidence-based care.

TYPES OF CLINICAL TRIAL

Clinical Trial of an Investigational Medicinal Product (CTIMP)

A clinical trial within the scope of the UK Medicines for Human Use (Clinical Trials) Regulations 2004.
An investigation in human subjects intended: a) to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more medicinal products, b) to identify any adverse reactions, and/or c) to study absorption, distribution, metabolism and excretion, with the object of ascertaining the safety and/or efficacy of those products.

Non-CTIMP Studies

Trials that do not involve an investigational medicinal product and therefore do not fall under the UK Medicines for Human Use (Clinical Trials) Regulations 2004.

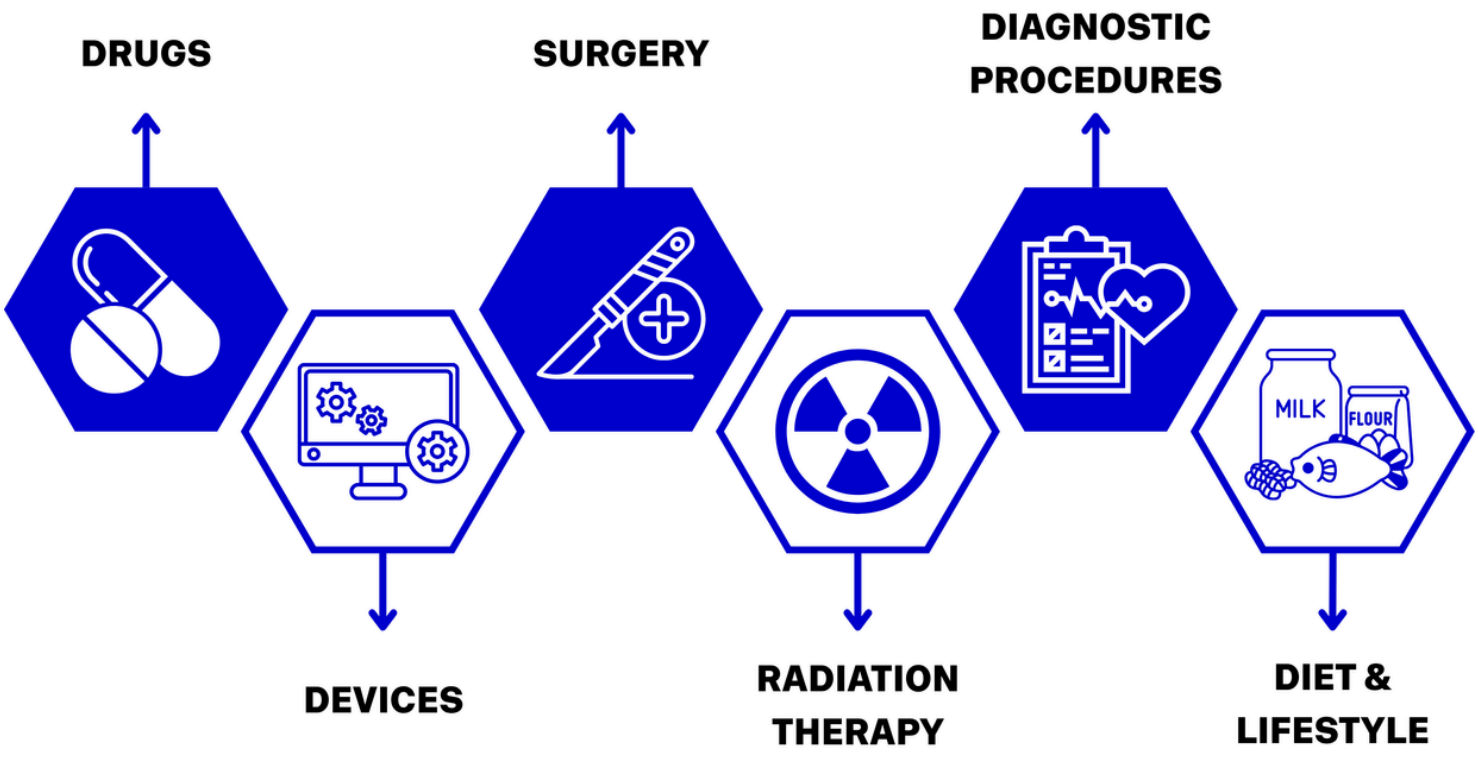
Advanced Therapy Medicinal Trial (ATMP) or Advanced Therapy Investigational Medicinal Trial (ATIMP)

ATMP - As defined by Article 2 (1) of Regulation 1394/2007, a medicinal product for human use that is either a gene therapy medicinal product, a somatic cell therapy medicinal product, or a tissue engineered product.
ATIMP - An ATMP as defined above that is used within a clinical trial in accordance with Article 2(d) of Directive 2001/20/EC.

Medical Device Clinical Trial (MDCT)

Investigations undertaken to assess or test the safety and efficacy of a given medical device or innovation. These projects usually test the devices' performance in preventing, diagnosing, or treating a particular condition.

HEALTH INTERVENTIONS STUDIED IN CLINICAL TRIALS



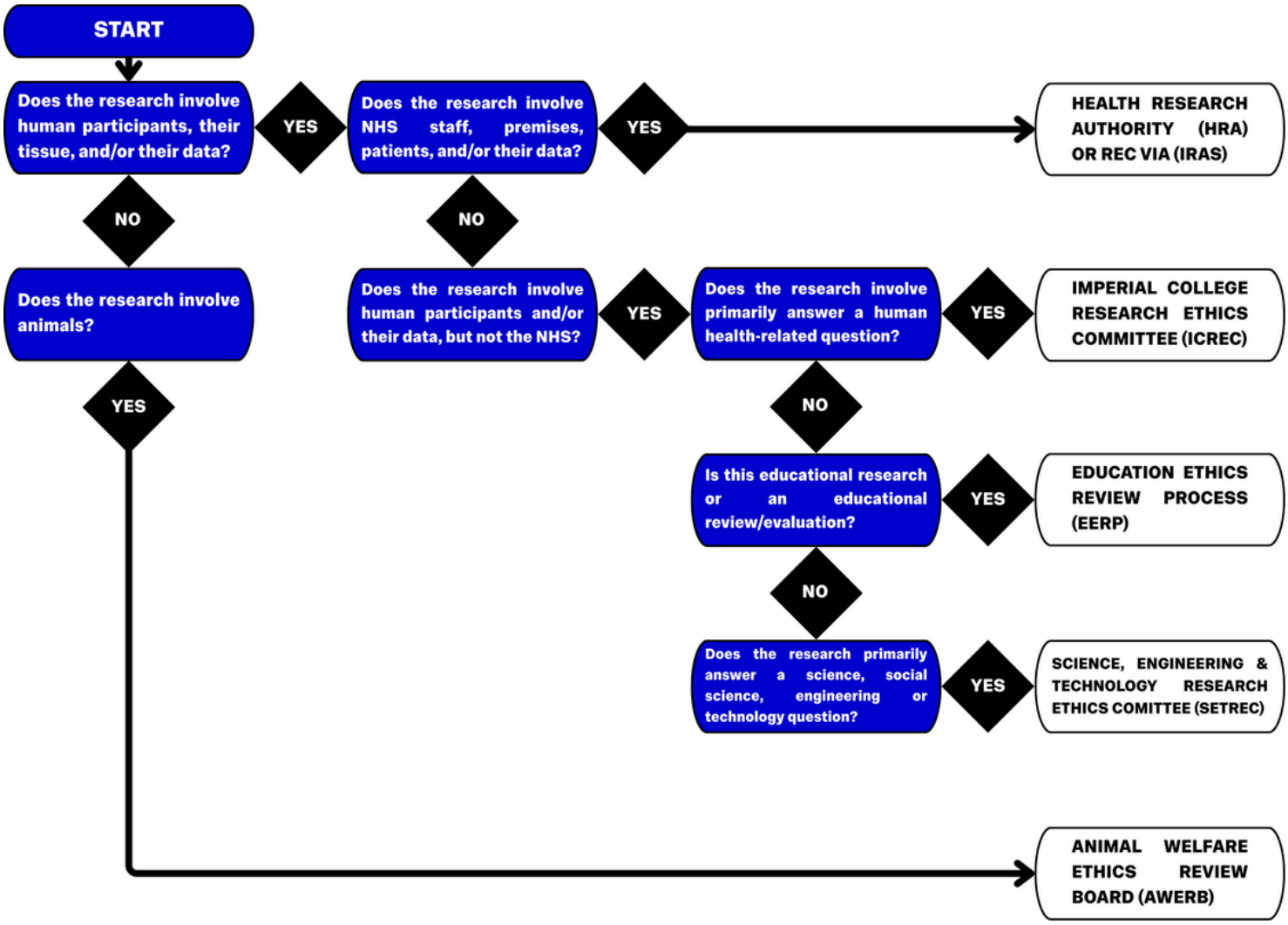
HOW CAN THIS BE APPLIED TO MEDICAL TECHNOLOGIES?

Clinical trials can:

- Test the efficacy and functioning in practice of novel medical technologies
- Test novel medical technologies against the benchmark of existing technologies within the field
- Demonstrate the benefits of novel technologies, or redesigns of existing technologies when compared to existing and adopted technologies
- Give scientific backing to novel technologies and begin an evidence-base that could lead to adoption within the wider field

Novel interventions must go through clinical trials to be proven safe and effective.

ETHICS: WHICH COMMITTEE DO I NEED TO APPLY TO?



CLINICAL TRIAL REQUIREMENTS

To be considered a clinical trial, a study must:

- **Be conducted on human subjects** – no study in non-human animals is considered a clinical trial.

- **Investigate an intervention** – the study treats or diagnoses its subjects with a drug, medical device, gene-therapy or other medical intervention. If your study is not an interventional trial, then it is likely an observational study (E.G.: a case-control, cross-sectional, or cohort study).

- **Look for an effect** – the study must collect data on measures chosen during trial design.

- **Compare the intervention to a control** – a portion of subjects are given no treatment, a placebo, or the best available treatment other than the intervention. The effects for both the intervention and control group are compared.

- **Be prospective** – subjects must be studied forward in time, which means retrospective studies are not classed as clinical trials.

- The MHRA has designed an algorithm to help researchers check if their project is classed as a clinical trial. You can access it here: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/949145/Algorithm_Clean__1_.pdf

TRIALS AT IMPERIAL

At Imperial there are a number of resources designed to help support your research, and to support with clinical trials.

In the first instance you should contact an appropriate person from the contact list available on the Imperial Research Office webpage.

FURTHER READING & RESOURCES

INTERNAL

- **The Joint Research Office**
  - Grants
  - Contracts
  - Accessing the Imperial NHS Trust
  - Healthcare Research studies

https://www.imperial.ac.uk/research-and-innovation/support-for-staff/joint-research-office/

- **Imperial Research Ethics Committee**

https://www.imperial.ac.uk/research-ethics-committee/

- **Research Impact Management Office (RIMO)**

https://www.imperial.ac.uk/enterprise/about/meet-the-enterprise-team/research-impact-management-office/

- **Research Office (RO)**

https://www.imperial.ac.uk/research-and-innovation/research-office/

- **Statistical Advisory Service (SAS)**

https://www.imperial.ac.uk/research-and-innovation/support-for-staff/stats-advice-service/

- **Imperial Funding Opportunities**

https://www.imperial.ac.uk/research-and-innovation/research-office/funder-information/funding-opportunities/

EXTERNAL

- **Funding opportunities:**
  - NIHR https://fundingawards.nihr.ac.uk/
  - UKRI https://www.ukri.org/opportunity/

- **Health Research Authority (HRA) Research Ethics Committees**

https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/research-ethics-committee-review/

- **Confidentiality Advisory Group (CAG)**

https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/

- **Human Tissue Authority / Human Tissue Act**

https://www.hta.gov.uk/

- **Good Clinical Practice (GCP)**

https://www.nihr.ac.uk/health-and-care-professionals/training/good-clinical-practice.htm

- **Medicines & Healthcare Products Regulatory Agency (MHRA)**

https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

- **The Concordat to Support Research Integrity**

https://www.universitiesuk.ac.uk/topics/research-and-innovation/concordat-support-research-integrity

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