CLINICAL
TRIAL DAY

International Clinical Trials' Day

MILAN
20 MAY 2025

www.clinicaltrialdayitalia.com

Associazione Farmaceutici Industria Società Scientifica

Cluster lombardo scienze della vita

FADOI

GIDM Coordinatori di Ricerca Clinica
Gruppo Italiano Data Manager

SIMeF
Società Italiana di Medicina Farmaceutica
Italian Society of Pharmaceutical Medicine

Aims

As every year, 20 May is the **International Clinical Trials Day**, commemorating the day in 1747 when James Lind started the first randomized trial comparing different treatments for scurvy in sailors of the *British Royal Navy*. The aim of the International Clinical Trials Day is to **raise awareness of the importance of clinical research** as a prerequisite for advancing scientific knowledge and improving treatments.

This year, a number of national scientific associations (AFI, FADOI, GIDM, SIMeF) with the support of Lombardy Life Sciences Cluster wish to celebrate this day together in public. **The goals of this initiative are to help people understand better what Clinical Research means**, to highlight how extensive and complex it is, and to raise awareness of the added value of high-quality research that complies with regulations and is profitable, dynamic, and always patient-centric. In order to raise public awareness on these important issues, a corner will be set up in the center of Milan from 12:00 PM to 7:00 PM. Volunteers from various associations will be available to provide accurate information on the subject, aiming to properly inform citizens and debunk myths and misconceptions about Clinical Research. Additionally, some local Research Centers will be involved to make the event more widespread.

Under the auspices of

THE VALUE OF CLINICAL RESEARCH

Clinical trials are essential to transform potential new medicines into new effective therapies that can improve treatments and disease outcomes.

As a whole, clinical research brings value to:

The National Health Service:

- Clinical research means innovation dedicated to promoting health. Indeed, new treatment options resulting from clinical trials can improve the health, well-being, and quality of life of patients and carers. Likewise, it can reduce the impact of diseases and their related disabilities.
- The availability of new treatment options offering a better efficacy and safety profile may result in a more efficient use of NHS resources.
- Funds from sponsored research can be reinvested in research and innovation, thus triggering a virtuous circle for the healthcare facilities involved.

Healthcare Providers:

- New medicines can improve clinical practice, since they are new therapeutic tools that can enable healthcare providers to respond to unmet clinical needs;
- Healthcare providers involved in clinical research have the opportunity to use innovative technologies and treatments at an early stage. This can promote their professional development, and their recognition within the scientific community and allows them to play a role in the evolution and advancement of medicine.

Society:

- The outcome of clinical research can lead to a deeper understanding of any disease being studied, thus improving its treatment and promoting individual and/or public health.
- Patients participating in clinical trials may have earlier access to potential treatments and advanced technologies that are more effective than those already available;
- It has a positive impact on healthcare providers, their competence and knowledge of new therapeutic technologies, and their relevance within the national and international scientific community;
- Clinical research, fuelled by its related investments, creates a favourable context that can nurture new skills and create new jobs.

Patients:

- They can benefit from access to a medicine in the pipeline, which is not yet available on the market and can potentially be more innovative and effective than standard therapy;
- They can have access to centres qualified to conduct clinical trials, where they can benefit from more examinations and tests than in standard clinical practice;
- They can participate in clinical trials, thus contributing directly to the development of a potential new medicine that could benefit many patients with the same disease;
- Through appropriate training and understanding of the drug development process, expert patients can work with regulatory authorities, healthcare professionals, and health promoters to have a say and express the needs of patients in the development of new medicines.

CLINICAL RESEARCH PHASES

Pre-clinical research

In vitro

In vivo

Clinical research

PHASE I
20-100
patients

PHASE II
100-300
patients

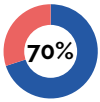
PHASE III
300-3000
patients

5-6 years

Target molecule identification
Only if no reliable in-vitro tests are available, animal tests are used to test the molecule activity

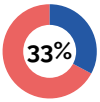
6-7 years

Assessment of action and safety



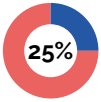
70% of medicines move to phase 2

Assessment of efficacy and adverse events in the short term



33% of medicines move to phase 3

Assessment of adverse events and risk-to-benefit ratio



25-30% of medicines move to phase 4

Approval by Regulatory Agencies (EMA / AIFA)

Medicine on the market

PHASE IV
Thousands of patients

Variable timeframe

Monitoring, finetuning of usage and other applications

Pharmacovigilance to keep protecting public health

CLICHES AND FALSE MYTHS

Patients are enrolled in clinical trials without receiving information → FALSE

- Every patient must receive detailed information about the trial approved by an ethics committee and be free to express one's consent by signing a specific form.

Healthcare professionals only conduct trials after obtaining all required authorisations → TRUE

- Every trial must be approved by the Italian Medicines Agency (AIFA) and an Ethics Committee, i.e. an independent body that evaluates the ethical and scientific aspects of clinical trials to protect the rights, safety and well-being of the patients involved.

Patients are not paid to participate in clinical trials → TRUE

- Patients cannot be paid; at most, in special situations, they may receive reimbursement for travel expenses.

Clinical trials on paid (reimbursed) healthy volunteers are only conducted in Switzerland → FALSE

- Only 1% (or less) of all trials are conducted with healthy volunteers. They get reimbursed for the days spent at the hospital. Switzerland is one of the countries where this kind of trials are carried out, but other countries, including Italy, also conduct studies with healthy volunteers.

Clinical trials are not only carried out by pharmaceutical companies → TRUE

- Pharmaceutical companies perform numerous clinical studies on their proprietary molecules; but many studies are also conducted by universities, research centres and scientific societies on non-proprietary medicines in order to gain a better understanding of their characteristics and use.

Results of clinical trials are kept secret → FALSE

- All results must be published in scientific journals; the European Regulation even requires that these results must be made public and presented in 'plain' language for the benefit of all citizens.

CLICHES AND FALSE MYTHS

Anyone can test a medicine → FALSE

- Only physicians in selected facilities can act as investigators, and only if they underwent adequate and specialised training, which is assessed by the institutions and sponsors.

Participating in a clinical trial does not necessarily guarantee a real benefit for the patient's health → TRUE

- Every trial has potential benefits and potential risks; these must be presented in a clear and comprehensible manner to all stakeholders. It is important, however, that even in the case of negative results of a trial, patients are aware that their participation and data will be valuable in the future for patients and healthcare professionals.

No clinical trials are carried out on vaccines → FALSE

- Vaccines are tested in the same way as all medicines (being medicines themselves).

Clinical trials are always controlled → TRUE

- Pharmaceutical companies and hospitals are thoroughly inspected by regulatory bodies such as the Italian Medicine Agency. Therefore, the pharmaceutical companies themselves put in place a series of internal and external controls with frequent inspection in clinical centres to verify that the trials are managed appropriately.

The data and privacy of patients enrolled in trials are strictly protected → TRUE

- The data of patients enrolled in clinical trials are always kept confidential. Only selected and trained staff can have access to such data. The databases and computer systems used are validated and access to them is duly authorized. Medical records and patients' names are never disclosed.

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Organizing Secretariat
NEW AURAMEETING S.r.l.
Via Rocca D'Anfo, 7 - 20161 MILAN (Italy)
Ph. +39 02 66203390
Fax +39 02 45486457
eventi@newaurameeting.it
www.newaurameeting.it

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