FACTSHEET Clinical Trial

What is a clinical trial?

Before any medicine is prescribed by your doctor, sold over the counter or used in hospital, it undergoes a series of tests ensuring it is safe and effective. These tests are called clinical trials[1]. They are investigations conducted with healthy volunteers or patients affected by a disease. Before they undertake the trial, participants must give their informed consent.

Trials can be performed by pharmaceutical companies, independent research laboratories or healthcare organisations. Studies vary in scope and duration, some lasting several years.

When research finds positive results, pharmaceutical companies usually request marketing authorisation from the relevant national regulatory agency or The European Medicines Agency (EMA). Every year approximately 4,000 clinical trials are authorised in the EU.

Can consumers access trial results?

As set out in the Helsinki Declaration[2] by the World Medical Association, all authors have a duty to ensure the results of their research on human subjects are available to the public. Authors are also held accountable for the completeness and accuracy of their reports. At present, only half of clinical study reports (CSRs) are published and some trials are not even registered.

The EU pharmaceutical legislation requires the EMA to provide information held in the confidential EudraCT database to the public[3]. Since 2011, clinical trials have been available on request via the EU Clinical Trials Register, which is administered by EMA. Other reports are also available on the American-run website: www.clinicaltrials.gov.

What is the current situation in the EU?

As it is not mandatory to disclose clinical study reports, only a fraction of those carried out are available. Significantly, trials with positive results are twice as likely to be published as others.

In 2012, the European Commission proposed a revision of the legislation on clinical trials. In April 2014, the European Parliament voted with a massive majority to make trial information available on an EU database, in an effort to boost drug trial transparency. The Regulation entered into force in June 2014, but will apply no earlier than May 2016.

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[1] This factsheet refers to clinical trials for medicinal products only.
[2] Article 30 and 33 of the World Medical Association's Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects
[3] Article 57 of Regulation (EC) No 726/2004 and article 41 of the Paediatric Regulation (EC) No 1901/2006

BEUC The European Consumer Organisation
Rue d'Arlon 80
B-1040 Brussels
Tel +32 (0)2 743 15 90
www.beuc.eu
@beuc

In the meantime, the European Medicines Agency is developing a new policy regarding the publication of and access to clinical trial data. It complements the existing EU legislation.

In early 2013, two pharmaceutical companies brought a case against EMA at the European Court of Justice on the release of clinical trial data on their products. BEUC has backed the European Medicines Agency from the outset and has been officially participating in the case since September 2013. One of the litigating companies, AbbVie dropped its allegations in April 2014, while the other Intermune, scrapped part of its submissions.

Why should clinical trials be public?

The volunteers who take part in drug trials risk their own life and unexpected adverse drug reactions. They do so in a spirit of altruism to contribute to scientific progress for the benefit of wider society. Therefore, the results of the trials belong to the public sphere and should not be considered as trade secrets.

Information on the procedures involved and results of these trials could be lost to doctors and researchers forever, thereby leading to bad treatment decisions or missed opportunities for evidence-based medicine.
Being transparent is also a way to avoid the unnecessary duplication of clinical trials.

BEUC is convinced that disclosing trial data empowers patients and promotes better quality healthcare. It also contributes to the restoration of public confidence in regulators, something which is much-needed after the scandals which recently affected the medical sector e.g. the faulty PIP breast implants.

BEUC contends that the new EMA proactive policy on clinical trial transparency should be upheld and reinforced. Such a bold stance should not be diluted in any way by commercial considerations.

People who take part in drug trials risk their own life.
Therefore the results belong to them and society at large.

Co-funded by the European Union