

Citizen's Summary

EU proposal to improve laws on clinical trials with medicines

WHAT IS THE ISSUE?

Clinical trials test **new medicines** and **medical treatments** on humans.

The data they generate is used by pharmaceutical companies applying for authorisation to sell their products, and by researchers publishing data in medical journals.

Why are clinical trials important?

- They give patients access to **new medicines and treatments** – for example when a trial shows that combining 2 medicines can cut the risk of heart attack.
- They make a significant contribution to pharmaceutical **innovation** and **investment in healthcare** in Europe (over **€20bn** spent every year on healthcare-related R&D).

What's the problem?

- The number of clinical trials in the EU has **fallen by 25%** in recent years, partly as a result of strict EU laws – so we need to streamline the rules.

WHAT EXACTLY WOULD CHANGE?

The proposal would see:

- greater **collaboration on approval** – authorities in EU countries would work together and be held to the same timeframe when approving clinical trials, ensuring they are thoroughly and expertly assessed.
- rules for clinical trials based on the **actual risk** posed to the safety of participants.
- greater **openness** in clinical trials both within and outside the EU, including more public access to the results, whether positive or negative.

The rules for clinical trials would continue to protect **patients' rights and safety** and ensure data is **reliable**.

WHO WOULD BENEFIT AND HOW?

- **All of us** – more innovative treatments would be available, using new or existing medicines.
- **Academic research institutions** and the **pharmaceutical industry** would have clearer rules governing their research into new drugs.

WHY DOES ACTION HAVE TO BE TAKEN BY THE EU?

- Results of clinical trials are **recognised throughout the EU**, so it's important rules are applied consistently EU-wide.
- Practically all large clinical trials are carried out in **more than one EU country**.

WHEN IS THE PROPOSAL LIKELY TO COME INTO EFFECT?

Towards the end of **2016**.

Title tag	EU proposal – better rules for clinical trials with medicines - summary
Description	Explained – European Commission proposal to streamline rules for clinical trials, to guarantee innovation and investment in European healthcare.
Link name	Summary - EU clinical trials proposal