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.
<table>
<thead>
<tr>
<th>Title tag</th>
<th>EU proposal – better rules for clinical trials with medicines - summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
<td>Explained – European Commission proposal to streamline rules for clinical trials, to guarantee innovation and investment in European healthcare.</td>
</tr>
<tr>
<td>Link name</td>
<td>Summary - EU clinical trials proposal</td>
</tr>
</tbody>
</table>