

Half of European clinical trials have not complied with EU rules on reporting results

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Half of clinical trials on the EU register have not reported results, despite rules requiring results to be posted within 12 months of completion, finds a study published by *The BMJ* today.

The findings show that, although compliance with EU rules has been poor overall, trials with commercial sponsors are substantially more likely to have posted results than trials with non-commercial sponsors, such as universities, hospitals, governments and charities. They also show that EU registry data commonly contain inconsistencies that might prevent even regulators assessing compliance.

The results of [clinical trials](#) are used by clinicians, patients, and policy makers to make informed choices about which treatments work best.

The European Commission therefore requires all trials conducted in Europe on medicinal products to report results directly on to the EU Clinical Trials Register (EUCTR) within 12 months of trial completion; but compliance has never been assessed.

So a team of researchers, led by Dr. Ben Goldacre at the University of Oxford, set out to assess compliance with these rules, explore factors associated with non-compliance, rank sponsors by compliance, and create a website for live ongoing audit of compliance.

Of 7,274 trials where results were due, they found that 49.5% reported results.

Trials with a commercial sponsor were substantially more likely to post results than those with a non-commercial sponsor (68% v 11%), as were trials by a sponsor who conducted a large number of trials (78% v 18%). More recent trials were also more likely to report results.

Unexpectedly, the researchers also found extensive evidence of errors, omissions, and contradictory data in EUCTR—notably, that 29.4% of trials marked as "completed" gave no completion date, which prevents ascertainment of compliance with reporting requirements.

The paper also describes the development of the EU TrialsTracker website, available online at EU.trialstracker.net. This website gives detailed information on the trial reporting performance of every individual drug company, university and hospital conducting clinical trials in Europe.

It shows which sponsors are the best or worst at complying with the law, and gives detailed information on the individual trials that have failed to report results onto the trials register. The information on EU.trialstracker.net updates every month, so sponsors who report more trials will find their improved performance reflected on the website.

"To our knowledge this is the first study of compliance with European Commission requirements on trial reporting," say the researchers.

"We have found strong evidence that the European Commission guideline, requiring all trials' results to be reported on EUCTR within 12 months of completion, is commonly being breached. Sponsors doing fewer [trials](#), and non-commercial sponsors such as universities, have particularly low reporting rates."

They conclude: "We hope that the accessible and timely information on the [compliance](#) status of each individual trial and sponsor provided by

our EU.trialstracker.net will help to improve reporting rates".

More information: Compliance with requirement to report results on the EU Clinical Trials Register: cohort study and web resource, *BMJ* (2018). www.bmj.com/content/362/bmj.k3218

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