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Updating the status of clinical trials on the EU Clinical Trial Register

Brief for EU National Competent Authorities (NCAs)

Overview

A significant but unknown number of completed clinical trials is currently falsely listed as ‘ongoing’ on EUCTR across all EU Member States, with negative consequences for public agencies, medical researchers and patients.

This brief describes how the UK’s national medicines regulator, the MHRA, is successfully tackling the problem, in order to encourage and inform corresponding efforts by other [National Competent Authorities](#) (national medicines regulators) across Europe.

Background

The European Medicines Agency (EMA) manages the public clinical trials registry EUCTR. Once a trial listed on EUCTR has been completed, it is the responsibility of the national medicines regulator in the EU Member State concerned to update the trial’s status from ‘ongoing’ to ‘completed’ on the registry, following notification by the trial sponsor. (Trial sponsors cannot directly update a trial’s status on the registry.)

The problem

Scale and scope of problem

A [significant but unknown number](#) of completed clinical trials currently remains listed as ‘ongoing’ on EUCTR. While the scale of the problem seems to vary between countries, each EU Member State currently appears to have a significant number of false ‘ongoing’ trials in its national portfolio. For example, TranspariMED recently reviewed a cohort of nearly 1,000 trials sponsored by universities in one Member State and found that less than 3% of those had been marked as ‘completed,’ an implausibly low ratio.

Why this matters

- Health technology assessment agencies, horizon scanners, systematic reviewers and researchers cannot reliably determine whether a trial is still ongoing or has been prematurely ended, terminated, or completed. This [makes it difficult to gain an overview](#) of the complete scientific evidence base on a medicine.
- Clinicians, patient groups and patients cannot reliably determine which trials may currently be recruiting patients, [making enrolment more difficult for patients and recruitment more difficult for sponsors](#). This drives up the cost and slows down the pace of medical research.
- Registry users often have to contact sponsors directly to clarify a trial’s status, which is inefficient and wasteful.
- Compliance with EU reporting rules is undermined. Trial sponsors are unable to upload the summary results for completed trials if at least one of the member states involved has not marked the status as ‘completed’. More broadly, the EMA, national regulators, and trial sponsors themselves cannot reliably determine from EUCTR data (or from the [EU Trials Tracker](#)) which trials are due to post their summary results.

Case study: How the MHRA is systematically updating the status of all trials

Scope of work

The UK National Competent Authority, the MHRA, is currently systematically reviewing and updating the status of all clinical trials listed on EUCTR to ensure the correct trial status is shown to the public. The MHRA’s work covers all clinical trials with at least one trial site located in the UK that are listed on EUCTR.

Two people within the MHRA are working on the updating process, in parallel with performing other responsibilities. Between them, they are spending 2-3 person-days per week on the task.

Prioritisation

The first phase of the work, which began in January 2019 and is ongoing (as of April 2019), covers all applicable trials for which an End of Trial notification was received since 2014, around 4,500 trials total. Once all trials in that cohort have been updated, the MHRA will begin tackling the remainder of trials in its portfolio.

Process

When a trial sponsor completes a trial, [EU Guidance](#) stipulates that the sponsor must send a “Declaration of the End of Trial Form” to the MHRA within 90 days (or 15 days if the trial has to be terminated early).

For the period 2014-2018, the MHRA conducted a search of its internal records to locate trials for which the “Declaration of the End of Trial Form” document had been received. The MHRA then cross referenced their internal record of each individual trial with that in the EUCTR and where the status was wrongly listed as ‘ongoing’ this was corrected to ‘completed’.

In addition, the MHRA responded to requests for updates it received from UK trial sponsors on an ongoing basis. (Following a 2018-2019 parliamentary enquiry into the issue, many non-commercial trial sponsors in the UK are [currently in the process of uploading overdue summary results](#) onto EUCTR.)

Achievements

Between the start of the process in January 2019 and early April 2019, the MHRA successfully reviewed (and if appropriate, updated) the status of over 1,700 clinical trials.

Resources required

Based on the MHRA’s experience, National Competent Authorities seeking to update the status of all trials in their own legacy portfolio should budget around 30 person-days per 1,000 trials in their portfolio.

Fixing the status of legacy trials only requires a one-off allocation of resources. Going forward, the MHRA has already put into place a system that ensures that the status of all trials newly reported by sponsors as “completed” will be routinely updated, on a weekly basis.

Future steps

MHRA expects to complete updating the status of all trials in the initial five year cohort (of trials for which an End of Trial notification was received since 2014) by September 2019. Once MHRA has finished updating the initial cohort of trials, it will start updating the status of the remaining (older) trials in its portfolio.

USEFUL RESOURCES

TranspariMED has compiled a collection of [Transparency Tools](#) to help trial sponsors to comply with WHO primary registry reporting requirements and adopt WHO best practices in trial reporting.

National Competent Authorities and other stakeholders are welcome to use, modify or disseminate these materials without seeking prior permission from TranspariMED.

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