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New UK System Will Check Trial Sponsors Report Study Results

HRA Makes Changes To End-Of-Study Reporting Requirements

by Vibha Sharma

The UK has started monitoring whether clinical trial sponsors are fulfilling responsibilities to make their research open and transparent.

The UK's Health Research Authority (HRA) has introduced a new system to measure how clinical trial sponsors are complying with their obligation to make all study results public.

The new monitoring system came into effect on 15 September and requires researchers to submit information to the HRA at the end of their study, explaining how they have fulfilled various transparency responsibilities.

Also, researchers are expected to submit a lay summary of their trial results, which the HRA will publish on its website, ensuring research participants and the public can easily find and understand the outcome of the studies.

"These aren't new responsibilities but we are now going to be asking and checking," HRA chief executive Matthew Westmore said in a Tweet last week.

The new system is also expected to help sponsors publicly demonstrate compliance with their transparency obligations. "We know that most researchers want to be transparent and just need help to do that. Our published guidance on writing a lay summary of their results can support them in doing this," said Juliet Tizzard, director of policy and partnerships at the HRA.

The new monitoring system is a "world first" and covers every interventional clinical trial involving UK patients, including trials of drugs, medical devices and non-drug interventions, and international trials with study arms in the UK, said Till Bruckner, founder of advocacy group

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TranspariMED.

It represents a “huge step forward” in promoting clinical trial transparency without creating any additional bureaucracy on researchers, said Bruckner. The transparency proponent hopes that “patients in other countries will soon demand that their governments put similar systems in place.”

The new monitoring system is part of several changes the HRA is introducing to implement its “Make it Public” strategy that was unveiled last year and which seeks to make clinical trial transparency 'second nature' for sponsors. (Also see "*Clinical Trial Transparency To Move Up A Notch In UK*" - Pink Sheet, 30 Jul, 2020.)

The strategy was drawn up in response to a scathing report by a parliamentary committee in 2018, which criticized the HRA for not doing enough to resolve the problem of un-registered, non-reported and mis-reported clinical trials, even though research transparency was one of its statutory objectives. (Also see "*UK Explores Feasibility Of 100% Trial Registration Rates In Major Transparency Push*" - Pink Sheet, 11 Jun, 2019.)

Asking And Checking

While drawing up the “Make it Public” strategy, Tizzard said the authority received feedback from several trial participants that they “felt undervalued and frustrated” as they never heard about the results of the studies in which they had participated. The new monitoring system aims to address this frustration.

Tizzard explained that researchers are already expected to plan at the outset of their study about how they would communicate the trial results to participants once the study has ended. “The new reporting requirement will help the HRA check that this has been done,” she added.

To support the monitoring process, the HRA has made changes to the *online form* that sponsors currently have to fill up one year after their trial is completed. Standardized datasets on research transparency have been added to the end-of-study form to confirm, for example, whether the sponsor has:

- Followed the “dissemination plan” (submitted at the time of seeking the study’s approval) to provide research participants and other interested groups or communities information about study results.
- Published lay summary of study results.
- Updated the clinical trial registry to include summary results.

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- Informed trial participants of the study results.

- Enabled sharing of study data and tissue sample (where applicable) with others.

The new end-of-study reporting requirements will apply to all studies across England, Scotland, Wales and Northern Ireland for which a final report was yet to be submitted as of the September date.

Sanctions For Non-Compliance?

Under its transparency strategy, the HRA had earlier promised that it would launch a new system in 2021-22 under which it would consider a trial sponsor's past "transparency performance" when reviewing applications to conduct new studies.

Bruckner noted that the HRA had not set a date for introducing this sanction yet. The TranspariMED founder, along with other transparency advocates, has been calling for a clear timetable for the phasing in of sanctions.

He hopes that the issue of sanctions will be revisited by the UK parliament's Science and Technology Committee as part of its ongoing inquiry into the "reproducibility of research" on which evidence is being accepted until 30 September.

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