UKCORI
UK Committee on Research Integrity

'Make It Public' Strategy

The Health Research Authority

Increasing Transparency in Clinical Trials

The Health Research Authority (HRA) leads a 'Make it Public' strategy to improve transparency in health and social care research.

The HRA recognised that without people, there is no health and social care research, and that those people deserve to know about ongoing research and its findings. Standards and policies to ensure a level of transparency already exist for most organisations and research groups. The HRA identified areas across research processes where it could improve on this, and established ways to develop support for this. Their 'Make it Public' strategy delivers on this vision for improvement.

Why make research public?

The HRA understand the importance of making research public. Research relies on patients, service users and the public who all value visibility of the research being conducted and its findings. It builds trust and accountability, acknowledges their contribution and encourages participation. In turn, research and care professionals can then benefit from improvements in the quality of the research and the avoidance of duplication of research efforts. The public benefit from new and better treatments enabled by the shared findings and a greater wealth of knowledge regarding ways to stay healthy and well.

The HRA Research Transparency Strategy Group ran a public consultation in 2019 bringing together a diverse set of views and experiences from across the UK to discuss transparency in health and social care research. The consultation highlighted the demand for "better support and encouragement for researchers and research sponsors, greater visibility for patients and the public and fair consequences for those who don't take transparency seriously."

"What really rang out were the voices of people who had taken part in research studies but never heard about what the study had found. They were frustrated and felt that things really need to change." - *Matt Westmore, Chief Executive HRA*

These same concerns were also apparent from the following statistics the HRA reported in their Make it Public strategy (July 2020):

30% of clinical trials are not registered

25% of clinical trials of medicines are not reported

90% of clinical trials have not told participants about findings

The HRA knew that in order to create a positive and impactful response to these concerns, they would need to develop a strategy that had been shaped and driven by the people and organisations it affects. They launched the 'Make it Public' strategy which directly answers to the feedback and frustrations they had received from the key players across the research system, patients and the public.

What does the strategy involve?

The vision for the 'Make it Public' strategy is for trusted information from health and social care research studies taking place in the UK (which involve people, their tissue or their personal data, and which require review by an NHS Research Ethics Committee) to be publicly available for the benefit of all. The strategy aims to simplify the process of making information public, make transparency easy and make it the norm.

In many cases there are longstanding transparency requirements in place, however the HRA acknowledged that they could add value and support stakeholders by focusing on making processes easier to follow and research more accessible.

01 - Registering research studies: making it public when a study has started.
The HRA can now register clinical trials of medicines on behalf of the sponsor, using data that applicants submit for their study to be approved, unless a sponsor has been granted permission to defer registration. This makes it easier for professionals to make their research public from the outset, and thus increases the number of studies available to the public.

02 - Reporting results: making the results of a study public.
The HRA has improved communication with applicants to make the reporting expectations clearer at the time of study approval and has taken a more proactive approach in prompting sponsors and researchers of clinical trials to keep study information up to date in registries. This makes it more likely that researchers will factor in time for reporting such results in a timely manner.

03 - Informing participants: letting those who took part know what the study has found. The HRA has made it easier for researchers to share study findings with participants by introducing a new method for submitting a lay person's summary of results and sharing how they have fed back to participants, and providing guidance. Making it easier to acknowledge the contribution from patients in this way should encourage further participation.

Expected improvements

Given that the HRA only launched their commitment to register clinical trials on behalf of the sponsor in January 2022, the full impact of this initiative is not yet measurable. However, with regards to the sharing of findings, the HRA analysed data from 709 final reports received between September 2021 and September 2022*, published in their Research Transparency Annual Report for 2022/23, and found that 44% of clinical trials who submitted a final report to the HRA updated the registry to include a summary of results and 29% of studies who submitted a final report to the HRA informed participants of study results. Although this shows a positive step forward, there is still room for improvement and the HRA will measure these expected improvements over the coming years.

**This number is not indicative of the final reports that should have been submitted in this period and will include final reports which were submitted outside the 12 months from end of study timeframe.*