Dear Sir Norman

Clinical trials transparency

Thank you for your letter of 9 September referring to a letter you had received from patient and integrity groups about the use of sanctions to improve research transparency.

As you rightly say in your letter, the Research Transparency Strategy Group, established to support the development of a robust strategy to improve transparency, discussed the potential use of sanctions at its meeting in May 2019. No decision was made at this point. Instead, the Group recommended that the HRA should seek views about three different sanctions as part of the public consultation which was launched in mid-June. I’m pleased to say that we had a very good response to the consultation, with more than 700 individuals and organisations taking part - around a quarter of which were patients, carers, patient advocates and research participants.

We are still analysing the responses to the consultation and the Strategy Group has yet to finalise its recommendations to the HRA, so I would not want to prejudge that. I would say though that when discussing the potential use of punitive steps to drive better transparency performance, we are mindful of the need to weigh up the impact of such steps on patients. Sanctions present the potential to improve reporting to avoid research waste and enhance open science, but we must be alert to unintended consequences. Our biggest concern with sanctions is that they could also drive clinical research out of the UK which would have a detrimental impact on thousands of UK patients who benefit from participating in research every year.

At this critical time for the UK we must ensure that it remains an attractive place for domestic and overseas research sponsors to place clinical trials of medicines and medical devices. If the introduction of sanctions results in a decline in research activity in the UK, this would ultimately be to the detriment of patients.
I must stress that we have not yet made a decision about sanctions. The HRA is focussed on bringing about a step-change in transparency and openness in health and social care research in the UK and has already committed, in the draft Make it Public strategy, to a series of steps to achieve that. We are already working in partnership with funders, registries and publishers to ensure that incentives are aligned across the system and we are setting consistent expectations of researchers and sponsors.

The HRA Board will be receiving recommendations from the Research Transparency Strategy Group at our meeting on 10 December and finalising our strategy at that point. I would be very pleased to provide an update to you after that date.

Yours sincerely

Teresa Allen
Chief Executive