Dear Mr Lamb

Contact with NHS research sponsors regarding research transparency

In the Health Research Authority’s response to the Committee’s report, ‘Research Integrity: Clinical Trials Transparency’, we reported that we had written to NHS sponsors which had not reported results of their clinical trials of medicines to the relevant EU registry. I am writing to you today to update the Committee about progress with NHS sponsors and how we are working with the Medicines and Healthcare products Regulatory Agency (MHRA) to improve compliance with transparency requirements around medicines trials.

I wrote to English NHS sponsors in February this year and our equivalent organisations in the devolved administrations wrote to sponsors across the rest of the UK. We wrote to 71 sponsors in total. Using data from the EU Trials Tracker tool, we highlighted to each sponsor their own performance on reporting results of clinical trials of medicines and requested that they take steps to address their performance. We also asked for feedback about practical difficulties in complying with the requirements.

In their replies to my letter, sponsors voiced their strong support for our work to improve research transparency and many reported local improvements to how they monitor trials and ensure investigators are clear about their responsibilities.

Many hospitals have however cited significant difficulties with the system administered by the European Medicines Agency (EMA). We have reported these difficulties to the MHRA as the competent authority under the clinical trials directive. MHRA along with the other EU competent authorities has engaged with the European Commission and EMA to remind sponsors of their responsibility to ensure that the protocol information and results of all clinical
trials are submitted to the EU Clinical Trials Database. A letter, co-signed by the European Commission, the EMA and the Heads of Medicines Agencies (HMA) was published on 3 July to this effect. The letter also includes links to materials and tools that are available for stakeholders in order to provide them with information and guidance on reporting trial results to EudraCT. MHRA has been working to ensure that the status of UK clinical trials is accurately reflected in the EudraCT database and has been providing assistance to sponsors via its Helpline. MHRA has allocated staff specifically to address the concerns raised around trial status and has completed upload of all outstanding end of trial notifications for 2014-2019 into the EudraCT database. The status of 80% of those received from 2004-2013 has also been confirmed as correct. The EMA are also addressing the issue of how to reflect the status of trials where there are no results to upload, for example due to the trial never starting.

I’m pleased to say that the performance of NHS sponsors regarding transparency around clinical trials of medicines has started to improve. In February this year, when we wrote to NHS sponsors which had not reported results of their clinical trials of medicines to the EU Clinical Trials Database, the proportion of studies reported on time across all those NHS sponsors was 23% (note that this does not represent all NHS sponsors, as we only contacted those which had at least one unreported study). When we analysed the data again in July, we saw that the proportion of studies across these same sponsors which were reported on time had risen to 39%. This shows that follow-up with sponsors and the wider attention that research transparency has received over recent months is having a positive effect on performance, although there is still some way to go. We are now turning our attention to other non-compliant sponsors.

However, we clearly need to find a more sustainable and efficient way of increasing performance, not just on clinical trials of medicines, but across all health and care research. Our new research transparency strategy, as recommended by the Committee, will articulate that sustainable and efficient approach that we intend to implement.

A draft version of the strategy, which is called Make it Public, is currently out to public consultation, closing on 6 September. Through the consultation, which consists of open workshops across the UK and an online survey, we are asking for feedback about steps we either plan to or could take to address poor transparency performance, including taking action or using sanctions against non-compliant sponsors. We are hearing a range of views from many different audiences, which will be very useful in finalising the strategy later this year.

I understand that the committee will revisit clinical trials transparency this autumn. We will of course be happy to provide further evidence to the committee if requested.

Yours sincerely

Teresa Allen
Chief Executive