

Norman Lamb MP
Science and Technology Committee
House of Commons
London
SW1A 0AA

Bristol, London and Berlin, 20 August 2019

Please act now to ensure that all clinical trials conducted in the UK are registered and reported

Dear Mr Lamb,

Every year, 870,000 UK patients volunteer to participate in clinical trials¹ in the hope of making a contribution to medical progress. However, these hopes are betrayed when the institutions sponsoring clinical trials fail to ensure that research results are made publicly available.

In recent months, many UK universities and NHS Trusts in particular have significantly strengthened their clinical trial registration and reporting policies and performance. However, while the progress of the non-commercial research sector as a whole is impressive, it is also uneven.² Meanwhile, the reporting performance of smaller commercial trial sponsors also remains a concern.

The Science and Technology Committee's 2018 report on Clinical Trial Transparency identified the need to review and strengthen the current framework to ensure that in future, all clinical trials are registered and their results reported.³ In response, the HRA set up a Research Transparency Strategy Group to explore possible options. A key question is whether or not the revised framework should include sanctions.

Minutes from a recent meeting of the HRA's Research Transparency Strategy Group state that:

*"The Group agreed that we need to tighten up the requirement here as it is crucial that registered studies report their results. However, **the Group felt that discussing firmer [sic] sanctions was premature** and that before that it explored we should do much more to facilitate compliance through better systems, collaboration with funders, data sharing and making information public."⁴ [emphasis added]*

We do not share the HRA Group's perspective that discussing sanctions is "premature". The HRA itself has held a mandate to promote transparency in health research since 2011,⁵ and reporting clinical trial results has been a global medical research ethics requirement since 2013.⁶

¹ NIHR. 2019. "Record number of patients take part in clinical research"
<https://www.nihr.ac.uk/news/record-number-of-patients-take-part-in-clinical-research/11460> (accessed 09 July 2019)

² TranspariMED. 2019. Clinical Trial Reporting by UK Universities: Progress Report June 2019
https://docs.wixstatic.com/ugd/01f35d_915fb4e5aab048afb5cf89f2a369d8f0.pdf?index=true (accessed 09 July 2019)

³ UK House of Commons Science and Technology Committee. 2018. "Research integrity: clinical trials transparency"
<https://publications.parliament.uk/pa/cm201719/cmselect/cmsctech/1480/148002.htm> (accessed 09 July 2019)

⁴ Minutes of the second meeting of the Research Transparency Strategy Group, London, 08 May 2019. HRA website.
<https://www.hra.nhs.uk/about-us/what-we-do/our-transparency-agenda/research-transparency-strategy-group/research-transparency-strategy-group-minutes/> (accessed 09 July 2019)

⁵ HRA website. <https://www.hra.nhs.uk/about-us/> (accessed 09 July 2019)

⁶ World Medical Association. 2013. Declaration of Helsinki (2013 amended version)

Also in 2013, a Science and Technology Committee report stated that:

*“We recommend that the HRA... ensures that all trials have been registered and published according to an agreed timeline... In addition, **there must be penalties for non-compliance.**”⁷ (Paragraph 110) [emphasis added]*

Subsequently, the HRA did not adopt the Parliamentary recommendation to impose penalties. It continued to promote compliance on a purely voluntary basis.

This approach failed to bring about an acceptable level of trial registration and reporting. When the Science and Technology Committee revisited the issue five years later, it stated that:

*“Echoing our predecessor Committee’s conclusions from 2013, **we recommend that the HRA introduce a system of sanctions** to drive improvements in clinical trials transparency, such as withdrawing favourable ethical opinion or preventing further trials from taking place. The Government should consult specifically on whether to provide the HRA with the statutory power to **fine sponsors for non-compliance.**”⁸ (Paragraph 41) [emphasis added]*

Based on the groundwork laid by its Research Transparency Strategy Group, the HRA is currently holding a public consultation on its future transparency strategy, which will close on September 6th, 2019.⁹

Noting your strong past engagement for greater clinical trial transparency, we ask you to seize this opportunity to write a public letter to the HRA to remind it of Parliament’s expectations, and encourage it to set out a clear timetable for the phasing in of sanctions.

Thank you for your time, best wishes,

/signed/

Action against Medical Accidents	(Peter Walsh, Chief Executive)
Cochrane	(Mark Wilson, CEO)
HealthWatch	(Susan Bewley, Chair)
International Alliance of Patients’ Organizations	(Kawaldip Sehmi, Chief Executive Officer)
JustTreatment	(Diarmaid McDonald, Lead Organiser)
Sling the Mesh	(Kath Samson, Coordinator)
STOPAIDS	(James Cole, Advocacy Officer)
T1International	(Fiona Conner, Trustee)
Transparency International Health Initiative	(Rachel Cooper, Director)
TranspariMED	(Till Bruckner, Founder)
Universities Allied for Essential Medicines UK	(Sarai Keestra, National Coordinator)
Universities Allied for Essential Medicines Europe	(Priscilla Li Ying, Executive Director)

<https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/> (accessed 09 July 2019)

⁷ UK House of Commons Science and Technology Committee. 2013. “Clinical trials”

<https://publications.parliament.uk/pa/cm201314/cmselect/cmsctech/104/104.pdf> (accessed 09 July 2019)

⁸ UK House of Commons Science and Technology Committee. 2018. “Research integrity: clinical trials transparency”

<https://publications.parliament.uk/pa/cm201719/cmselect/cmsctech/1480/148002.htm> (accessed 09 July 2019)

⁹ HRA. 2019. “Make it Public” <https://www.hra.nhs.uk/about-us/consultations/make-it-public/> (accessed 09 July 2019)