Opportunity to fully deliver on UK clinical trial transparency

Dear Mr Barclay,

We welcome the government’s intention to make the UK a global leader in clinical trials, and the recently announced plan to invest £81 million over 3 years, provided by the NIHR, to “ensure that transparency and accessibility for patients, clinicians and research funders is enhanced”.

We ask you to ensure that the government uses this opportunity to:

1. Fully deliver on the Health Research Authority’s #MakeItPublic strategy
2. Align the transparency requirements for medicinal product and medical device trials

There are compelling reasons to seize this opportunity:

- **Positioning the UK as a global leader in clinical trials.** Taking these actions would make the UK the undisputed global leader in clinical trial transparency, would cement the UK’s reputation for regulatory excellence, and would make the UK a more attractive location to conduct clinical trials because more UK patients will be more willing to enrol in trials if they have assurance that their contributions will advance medical science and inform clinical practice.

- **Safeguarding public health.** There is unanimous consensus among experts that failures to register and report the outcomes of clinical trials distort the medical evidence base, impede scientific progress, harm patients, and undermine public health. Both UK Parliament and the World Health Organisation have repeatedly highlighted the importance of ensuring that all trials are registered and their results are reported.

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2. Transparency International et al. Clinical Trial Transparency: A guide for policy makers. 2017. [https://docs.wixstatic.com/ugd/01f35d_def0082121a648529220be1d56df4b50a.pdf](https://docs.wixstatic.com/ugd/01f35d_def0082121a648529220be1d56df4b50a.pdf)
• **Reducing red tape.** Direct registration of all clinical trials by the HRA would reduce the compliance burden both for industry and for non-commercial trial sponsors. Effective HRA compliance monitoring for trial reporting and giving legal force to long-standing regulatory requirements will not create any additional reporting requirements or red tape for sponsors, as the HRA already requires all clinical trial results to be made public, and HRA monitoring can be performed using existing data sources.

• **Strong support by all UK stakeholders.** The proposals to introduce a legal requirement to register and make public the results of clinical trials involving medicinal products were supported by 97% and 94% of respondents to the relevant government consultation. The ABPI has explicitly called for the MHRA and HRA to “be appropriately resourced to deliver fully” the #MakeItPublic strategy. This highlights that not only patients and clinicians, but also the wider medical research community and industry, are strongly supportive of effective transparency measures in this field.

Fully delivering on the Health Research Authority’s #MakeItPublic strategy would require a very small investment into strengthening HRA’s capacity.

Aligning the transparency requirements for medicinal product and medical device trials could be done at no cost and would not require parliament to pass new legislation.

Please see the annexes to this letter (appended below) for more details.

We would welcome an opportunity to meet with your policy team to discuss the government’s plans for ensuring that all clinical trials conducted in the UK are registered and reported.

Thank you for your time, we look forward to meeting with your team,

• Action against Medical Accidents
• Cochrane Collaboration
• Consilium Scientific
• HealthSense UK
• Sense about Science
• Sling the Mesh
• Transparency International Global Health
• Dr Nicholas DeVito, Bennett Institute for Applied Data Science, University of Oxford

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ANNEX 1. Fully deliver on the Health Research Authority’s #MakeItPublic strategy

The #MakeItPublic strategy sets out to ensure that all clinical trials in the UK are registered and make their results public. Specifically, the strategy states that:

- “[T]he HRA will register clinical trials on behalf of the sponsor using data that applicants submit for their study to be approved [by ethics committees]”
- The HRA will ensure that all sponsors make trial results public within 12 months of study completion

The strategy forms part of global commitments made by the UK in the framework of the UK National Action Plan for Open Government 2021-2023.

While the HRA appears fully committed to the strategy and has achieved significant progress in many regards, implementation appears to have stalled due to lack of resources:

- The HRA has still not set a launch date for the central registration of all clinical trials. (Currently only trials of medicinal products are being registered centrally, as they have been for many years.)
- An HRA report published in March 2023 indicates that the HRA is still not able to effectively monitor whether clinical trial results are made public as required.

The HRA report cited above shows that 8% of trials are still not being adequately registered, in violation of HRA requirements that have been in place since 2013. The percentage of trials that do not make their results public as required is probably significantly higher, but no relevant monitoring data are available.

The #MakeItPublic strategy’s aim of ensuring that all UK clinical trials are registered and their results rapidly made public cannot and will not be achieved without additional resources. Fully delivering on the #MakeItPublic strategy would require a very limited investment in strengthening the HRA’s trial registration and compliance monitoring capacity, probably the equivalent of adding between one and two full-time positions to the HRA’s payroll. That cost could be reduced further if HRA mandates results reporting specifically on trial registries as recommended by the WHO because compliance is easier to monitor on registries. The planned creation of a UK national clinical trial ‘directory,’ suggested by the recent Lord O’Shaughnessy review, may offer an opportunity to fully automate monitoring in future.

As Parliament has noted, the costs of ensuring transparency in this area are marginal compared to the benefits they generate. Notably, complete and timely data from all UK trials would allow NICE to reliably compare the benefits of different treatment options, and thereby translate into substantial savings in NHS procurement. For example, stockpiling Tamiflu alone cost the UK £242 million.

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12 Tamiflu: “a nice little earner”. 2014. https://www.bmj.com/content/348/bmj.g2524
ANNEX 2. Align the transparency requirements for medicinal product and medical device trials

The government earlier this year announced its intention to make it a legal requirement to register and make public the results of clinical trials involving medicinal products, and to specifically mention in the legislation that non-compliance with new transparency requirements will constitute grounds for non-acceptance of a request for authorisation. We strongly welcome the proposed new requirements.

Identical requirements should also be adopted for clinical trials of medical devices.

There is no sound regulatory, scientific, clinical or ethical rationale for applying different transparency standards to clinical trials of medicinal products and clinical trials of medical devices. Patients participating in both types of trials, and patients receiving both types of medical interventions, should be able to expect that the same high standards are applied across the board. Put differently, there is no reason why a clinical trial of a pacemaker should be subject to lower transparency standards than a clinical trial of aspirin.

In addition, introducing a legal requirement to register and make public the results of clinical trials involving medical devices would enhance UK regulatory alignment with continental Europe and the United States. Both the EU Medical Device Regulation and United States legislation mandate the registration of medical device studies and the disclosure of their results, and give regulators the power to impose sanctions in the case of non-compliance.

As noted above, the HRA already requires all clinical trial results to be made public. Putting this requirement on a solid legal footing would therefore not create any additional reporting requirements or red tape for industry or non-commercial sponsors.

Introducing a legal requirement to register and make public the results of clinical trials involving medical devices would not require Parliament to pass new legislation. The requirement could be adopting following the same pathway used to legislate transparency for medicinal products, by using the provisions set out in the Medicines and Medical Devices Act 2021.

[DOCUMENT ENDS.]

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14 The MDR sets out common transparency requirements for the entire European Union. The MDR requires all EU Member States to enshrine sanctions for non-compliance with these standards within national law, to be enforced by national regulatory agencies. [Link](https://clinicaltrials.gov/ct2/manage-recs/fdaaa)

15 Food and Drug Administration Amendments Act of 2007, Section 801. [Link](https://clinicaltrials.gov/ct2/manage-recs/fdaaa)