SITC follow-up session on clinical trial transparency

Dear Mr Clark,

In 2018, the Science and Technology Committee conducted an enquiry into clinical trial transparency. The 2018 Committee found that many clinical trial results continued to remain unpublished because key recommendations made by a similar Committee enquiry in 2013 had not been implemented.

Five years on, history is in danger of repeating itself. While there has been excellent progress in the reporting of drug trial results, many clinical trials of medical devices and other healthcare interventions such as surgical techniques or physiotherapy continue to make their results public late or not at all.

The 2018 enquiry succeeded in dramatically improving the transparency of drug trials, partly due to very strong engagement from MHRA. Going forward, considering the planned introduction of new legislation and MHRA’s apparent willingness to enforce it, we are optimistic that the UK will soon become the first country worldwide to comprehensively resolve the problem of non-reporting of drug trial results.

There have also been significant improvements in the transparency of non-drug trials. The #MakeItPublic strategy, developed by the Health Research Authority (HRA) in response to the 2018 enquiry, is excellent. Significant progress has been achieved. Thanks to the HRA’s efforts, the UK has become the first country worldwide to systematically monitor trial registration on a national level, an innovative regulatory approach that is now attracting attention across Europe. In addition, NIHR and MRC have adopted strong safeguards to ensure that the clinical trials they fund are registered and rapidly make their results public.

However, major transparency gaps persist for non-drug trials involving UK patients:

- According to the latest HRA figures, 8% of non-drug trials are currently not being adequately registered. Central registration of all trials by the HRA could resolve this problem, but this element of the #MakeItPublic strategy has not yet been implemented.
- A 2021 study documented continued shortfalls in the reporting of non-drug trial results by many major UK universities.
  - The first step to resolving this problem would be for the HRA to systematically monitor trial reporting, but this element of the #MakeItPublic strategy has not yet been implemented.
  - The second step to resolving this problem would be for the HRA to impose sanctions for non-compliance, but this repeatedly emphasised 2018 Committee recommendation (first proposed by the Committee in 2013) has not yet been implemented.
These problems persist because key recommendations made by the Committee in 2018, including recommendations codified in the subsequently adopted #MakeItPublic strategy, have still not been implemented.

The HRA has not yet set a timeframe for the delivery of central trial registration, for monitoring reporting requirements, or for the introduction of sanctions. In combination, these measures would make the UK the first country worldwide to resolve the problem of unregistered and unreported trials once and for all.

In 2019, your predecessor Norman Lamb MP wrote an open letter to the incoming Committee:

“We know the consequences of non-compliance with reporting requirements: wasted money and research, publication bias and risks to human health… The Committee’s work has led to a real momentum in this area, but there is a risk of this diminishing if scrutiny of relevant bodies and organisations is not maintained… I hope that you might be able to take up… this work in the new Parliament.”

The Committee’s 2018 enquiry into clinical trial transparency demonstrated that Parliamentary attention to this problem can have a strong positive impact on an issue of crucial importance for NHS patients. However, as your predecessor had feared, momentum diminished just as the UK was approaching the finishing line.

As the government response to the Committee’s 2018 report stated, “[u]nless research is conducted with integrity our outstanding scientists cannot build on the works of others, patients may suffer and money may be wasted repeating research that has already been conducted but not published.”

We ask you to convene a one-day follow-up session of the Committee to enquire whether the HRA has received the resources it requires to fully implement the #MakeItPublic strategy, to clarify the timeline for the strategy’s full implementation, and to revisit the issue of sanctions.

Thank you for your time, we look forward to hearing from you,

- 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

Contact for correspondence: Till Bruckner, TranspariMED, tillbruckner@gmail.com
ANNEX: Key Committee recommendations that have not yet been implemented

<table>
<thead>
<tr>
<th>Committee recommendation 2018</th>
<th>Implementation status June 2023</th>
</tr>
</thead>
<tbody>
<tr>
<td>“We recommend that the Health Research Authority (HRA) should be provided with funding to establish a national audit programme of clinical trials transparency, including the publication of a single official list of which UK trials have published results and those which are due to but have not.” (Paragraph 36)</td>
<td>The HRA has begun publishing annual audit reports, but these do not identify how many trials fail to publish results because HRA does not capture these data.</td>
</tr>
<tr>
<td>“We recommend that the HRA undertake further work to determine an accurate figure for the cost of such an audit and prepare a funding proposal for the Government to consider. The cost should be weighed against the potential public savings made by tackling mis-reporting, in terms of reduced ‘research wastage’ and the scope for better procurement decisions. If this model is pursued, then the results should be published trial-by-trial rather than simply at the summary level.” (Paragraph 37)</td>
<td>To the best of our knowledge, the HRA has not provided the government with a comprehensive cost estimate and funding proposal. HRA’s failure to collect reporting data (see above) and centrally register trials (see further below) suggests that adequate funding is not available. Note that neither approach is technically challenging, but implementation may require additional staff time.</td>
</tr>
<tr>
<td>“The Government should direct the HRA to publish information on trials that have received ethical approval but are not registered in a publicly-accessible register, on a trial-by-trial basis.” (Paragraph 38)</td>
<td>The HRA now audits trial registration and publishes summary data, but does not disclose the information on a trial-by-trial basis. Freedom of Information requests to the HRA have established that there is no legal barrier to trial-by-trial disclosure.</td>
</tr>
<tr>
<td>“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.” (Paragraph 41)</td>
<td>The HRA has not introduced sanctions, and has so far not announced any plans to do so. Sponsors that continue to fail to register and/or report the results of non-drug clinical trials, including trials of medical devices, continue to be able to violate the rules with impunity. (The government plans to introduce sanctions for drug trials only, to be enforced by the MHRA.)</td>
</tr>
<tr>
<td>“We recommend that the Government ask the HRA to publish, by December 2019, a detailed strategy for achieving full clinical trials transparency, with a clear deadline and milestones for achieving this.” (Paragraph 45)</td>
<td>The HRA has published and partially implemented the excellent #MakeItPublic strategy. However, the strategy currently lacks deadlines for (a) direct registration of all clinical trials directly by the HRA, which would resolve the problem of non-registration, and (b) monitoring of non-reporting, which is the key to ensuring full compliance with trial reporting requirements.</td>
</tr>
</tbody>
</table>