



House of Commons  
Science and Technology  
Committee

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**Research integrity:  
clinical trials  
transparency**

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**Tenth Report of Session 2017–19**

*Report, together with formal minutes relating  
to the report*

*Ordered by the House of Commons  
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## Science and Technology Committee

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## Summary

Selective non-publication of the results of research distorts the published evidence base and is a threat to research integrity. In the case of clinical trials, non-publication of results means that information on the efficacy of new drugs or other medical interventions cannot be used. Falling short on 'clinical trials transparency' in this way presents risks to human health, contributes to research wastage and means that clinical decisions are made without access to all the available evidence.

A range of UK and EU rules and guidelines are now in force to improve clinical trials transparency, in terms of tackling non-registration, non-reporting and mis-reporting. However, despite these rules, around half of clinical trials are currently left unreported, clinical trial registration is not yet universal in the UK, and reported outcomes do not always align with the original study proposal.

Our predecessor Committee concluded in 2013 that it had "not been impressed" by the Government's efforts to resolve the problem of un-registered, non-reported and mis-reported clinical trials. We believe that while there have been some improvements there is still much more to be done. The Ebola epidemic prompted political attention in the UK to the risks to public health of non-publication of clinical trial results, with the then Prime Minister David Cameron making commitments to clinical trials transparency in 2015. Since then, progress has slowed in the UK at a political level. Clinical trials transparency is as much a question of political will as it is a technical issue.

The Health Research Authority (HRA) has been explicitly responsible for "promoting research transparency" as part of its statutory objectives since 2014, but this does not appear to have brought about significant change in this area over the last four years. The Government should 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. The performance of the HRA should then be explicitly measured on this basis through its annual report.

Non-compliance with reporting rules is not currently documented by public bodies on a trial-by-trial basis. Official publication of such information would expose where there are weaknesses in compliance and where best practice within the sector could be found and shared. The HRA should be provided with funding to establish a national programme to audit 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. In the first instance this should focus on providing information on whether any results have been published in an academic journal following global best practice, building on the automated methods already developed by others.

We are disappointed that the HRA does not believe it can secure funding for a more comprehensive form of audit focusing on mis-reporting of trials and does not see this as a priority. Even if the cost of fully assessing reported trial outcomes against the original specification in the application for ethical approval amounts to £2.4m per year, as the HRA suggested in evidence to us, this is a small price to pay compared with the sums of

money involved in policy decisions that draw on clinical trials evidence. 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.

Meanwhile, the HRA appears to be reluctant to enforce its transparency rules, or to make previous compliance with transparency legislation a pre-requisite for ethical approval of future trials. As a result, there are currently no sanctions imposed on sponsors or investigators who fail to comply with HRA rules, or even on those who fail to respond to the HRA when their non-compliance is queried. The HRA should 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, and the Government should consult specifically on whether to provide the HRA with the statutory power to fine sponsors for non-compliance.

Compliance with transparency rules varies by sponsor—while pharmaceutical companies have good rates of reporting within a reasonable timeframe, the picture is much more mixed for universities. It is particularly disappointing that trusted bodies such as Public Health England and a range of NHS Foundation Trusts are also failing to report results from clinical trials. Public trust in medicine could easily be eroded by failures in clinical trials transparency from such important parts of the health system. Public Health England should write to us with an explanation and the steps it will take to correct this.

# 1 Introduction

1. In July 2018 we published our Report on research integrity, exploring a range of threats to the rigour, accuracy, honesty and transparency of research. These included ‘fraud, fabrication and plagiarism’ and a range of ‘questionable research practices’, any of which can lead to unreliable research being published.<sup>1</sup> However, during that inquiry we were told that selective non-publication of research results—or ‘publication bias’—was also a threat to the integrity of the evidence base and should be considered as part of our work.<sup>2</sup> Indeed, the Concordat to Support Research Integrity produced by Universities UK and signed by the higher education funding councils and research councils states that “refusing to publish negative research findings” is “harmful to the reputation and quality of UK research, and to the research record”.<sup>3</sup>

2. Further exploration of the issue of publication bias during our inquiry into research integrity revealed an opportunity for us to follow up on work by our predecessor Committee from 2013 on clinical trials.<sup>4</sup> One of the issues our predecessor explored was the extent to which the results of clinical trials of drugs, vaccines and other health interventions are made available to scientists, clinicians and members of the public—often referred to as ‘clinical trials transparency’.<sup>5</sup> Our predecessor Committee noted “long-standing concerns” that the results of many trials “currently remain hidden from public view”, which, according to campaigners, “undermines public trust, breaks the ethical pact between scientists and those participating in trials and leads to clinical decisions being made on the basis of incomplete evidence, potentially leading to poorer outcomes for patients”.<sup>6</sup> They concluded that:

many of the clinical trials taking place in the UK remain unregistered and unpublished and their data continue to be unavailable to both the general public and the scientific community. This is unacceptable and we have not been impressed by the Government’s efforts to resolve this important issue.<sup>7</sup>

3. Underlining the need to explore clinical trials transparency as part of our work on research integrity, Dr Ben Goldacre, a medical doctor and Director of the Evidence-Based Medicine DataLab at the University of Oxford, argued that, five years on from that Report, clinical trials transparency remains a significant issue, with non-publication of results distorting the evidence base on which important decisions are made:

[Academic] fraud is not the most important issue. The culture of incomplete and inaccurate reporting of research has greater impact on patients and society [...] [Clinical] Trials are large expensive research projects used to generate knowledge that is then used, in clinical practice, to make

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1 Science and Technology Committee, Sixth Report of Session 2017–19, [Research integrity](#), HC 350

2 Work on research integrity began during the 2015 Parliament, under the previous Committee. Written evidence received by that Committee (i.e. prior to the 2017 General Election) is labelled with ‘RIN’ prefixes; evidence received by the current Committee is labelled with ‘RES’ prefixes. All oral evidence for the inquiry took place during the 2017 Parliament. For further details see link in footnote 1.

3 Universities UK, [The concordat to support research integrity](#) (July 2012), p17

4 Science and Technology Committee, Third Report of Session 2013–14, [Clinical trials](#), HC 104

5 Science and Technology Committee, Third Report of Session 2013–14, [Clinical trials](#), HC 104, Chapter 4

6 Science and Technology Committee, Third Report of Session 2013–14, [Clinical trials](#), HC 104, para 4

7 Science and Technology Committee, Third Report of Session 2013–14, [Clinical trials](#), HC 104, para 125

vitaly important decisions; and yet trials are commonly left unreported, or misreported. This is a waste of money, and distorts the evidence underpinning medical practice.<sup>8</sup>

4. We were told that “around half” of clinical trials currently go unreported (see Chapter 2), and that results from clinical trials with positive results were twice as likely to be published as others.<sup>9</sup> We were also provided with some explicit examples of non-publication of clinical trials results leading to wasted public expenditure in the UK and even patient deaths in other countries. Two examples are set out below:

- Dr Simon Kolstoe, a researcher at the University of Portsmouth and chair of two Research Ethics Committees, highlighted the case of the UK Government spending £424m to stockpile Tamiflu in response to the H1N1 ‘Swine Flu’ epidemic in 2009. He explained that “eight out of the ten trials that were used by the company to show the drug was useful in preventing complications such as pneumonia had never actually been peer reviewed or published”, which meant that governments were “relying on a marketing spiel claiming successful trials of this drug rather than being able to consider the actual evidence of the drug efficacy for themselves”.<sup>10</sup> The House of Commons Public Accounts Committee investigated this decision in 2014 and concluded that there was “a lack of consensus over how well Tamiflu works, in particular whether it reduces complications and mortality,” and that evidence-based policymaking had been “hampered because important information about clinical trials is routinely and legally withheld from doctors and researchers by manufacturers”.<sup>11</sup>
- The AllTrials Campaign told us that “a heart drug called Lorcainide was tested in a trial in 1980. The results showed that the people who were taking Lorcainide were far more likely to die than those not taking it. But those results weren’t published until 1993 [...] in those thirteen years, doctors continued to give patients medicines in the same drug class as Lorcainide and it is estimated that 100,000 people in the US died as a result.”<sup>12</sup>

5. On this basis, we took oral evidence from Dr Goldacre, Dr Kolstoe and the AllTrials Campaign as part of our research integrity inquiry. We also took evidence from the Health Research Authority to explore solutions to the non-publication of clinical trials results. Given the significance of this topic as a public health issue, we agreed to produce this separate short Report on clinical trials transparency,<sup>13</sup> drawing on the evidence we received during our work on research integrity and providing an update on our predecessor’s 2013 Report. We are grateful to everyone who contributed to this aspect of our work.

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8 Dr Ben Goldacre ([RIN0073](#)) para 0

9 AllTrials campaign ([RIN0067](#))

10 Dr Simon Kolstoe ([RIN0022](#)) para s3

11 Public Accounts Committee, Thirty-Fifth Report of Session 2013–14, [Access to clinical trial information and the stockpiling of Tamiflu](#), HC 295

12 AllTrials campaign ([RIN0067](#))

13 Science and Technology Committee, Sixth Report of Session 2017–19, [Research integrity](#), HC 350, para 13



## 2 The current state of clinical trials transparency and related legislation

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### Definitions

6. The World Health Organization (WHO) defines a clinical trial in broad terms as “any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes”. Specifically, the WHO definition includes “drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc”.<sup>14</sup>

7. ‘Clinical trials transparency’ is typically discussed in terms of three interconnected issues:

- ensuring that details of all clinical trials are recorded in advance in a publicly-accessible registry (i.e. with legislation and rules designed to tackle ‘non-registration’);
- ensuring that at least summary results are published within a set timeframe following the end of the trial (i.e. with rules to tackle ‘non-reporting’); and
- ensuring that all the results from a trial are reported, rather than just those with significant results (i.e. tackling ‘selective reporting’ or ‘mis-reporting’).

### Existing legislation, rules and current compliance

8. Clinical trials are heavily regulated, and a wide range of relevant rules and initiatives exists to address non-registration, non-reporting and mis-reporting. However, despite the existence of these “innumerable regulations, edicts, reports, guidelines and strategy documents” relating to clinical trials transparency, Dr Goldacre told us that “none have been enforced or implemented, and breaches are not documented”.<sup>15</sup> Examples to illustrate this are explored below.

### Non-registration

9. In 2013, the Health Research Authority (HRA) made it a condition of a trial receiving a ‘favourable opinion’ from a research ethics committee that the trial<sup>16</sup> must be registered—or a deferral for specific reasons requested<sup>17</sup>—before participants are

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14 World Health Organization, ‘[Health topics: clinical trials](#)’, accessed 31 August 2018

15 Dr Ben Goldacre ([RIN0073](#)) para 3

16 The requirement encompasses: clinical trials of an investigational medicinal product; clinical investigations or other study of a medical device; combined trial of an investigational medicinal product and an investigational medical device; and other clinical trials to study a novel intervention or randomised clinical trial to compare interventions in clinical practice.

17 Reasons for deferral could include commercial sensitivity. There is an expectation that the trial will be registered when the reason for the deferral is no longer valid or immediately should the trial be terminated early for safety reasons.

recruited.<sup>18</sup> The HRA subsequently conducted several audits of registration, with follow-up contact with lead investigators where non-compliance was found. These demonstrated that registration was still not universal, even among trials that had received a favourable opinion, and that some who fell short on their compliance ignored contact from the HRA. The HRA's 2017 audit revealed that 32% of 599 studies that received a 'favourable opinion' (and no agreed deferral) could not be found on a publicly accessible registry.<sup>19</sup> Moreover, of the 194 lead researchers contacted regarding non-registration, 73 failed to respond to the HRA within a week to provide an explanation or take steps to register.<sup>20</sup> The HRA concluded that "awareness that the requirement to register a clinical trial as a condition of favourable opinion was variable. Many responders did not know how or where to register their study and what was an acceptable register for their study type".<sup>21</sup> Four of the non-respondents related to phase I drug trials;<sup>22</sup> we were told that the current status of these trials had been explored further after the audit: one was already on the US public register, clinicaltrials.gov, two were taking action to register publicly, prompted by the HRA's follow-up, and the other trial did not start so it did not need public registration.<sup>23</sup>

### Non-reporting

10. Since July 2014 the European Commission has required all trials on the EU Clinical Trials Register (i.e. trials of medicinal products) to post results to the registry within 12 months of completion, with a final compliance date of 21 December 2016.<sup>24</sup> The first analysis of compliance with this requirement was undertaken by Dr Goldacre and his team at the Evidence-Based Medicine DataLab this year. That study identified 7,274 trials where it could be verified that results were now due. Of these, just 49.5% had reported results.<sup>25</sup> This further reinforces the assessment made by the AllTrials campaign made that "around half" of trials go unreported, drawing on a range of research on this topic.<sup>26</sup> The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for ensuring that sponsors provide results for drug trials (i.e. a subset of all clinical trials) in the UK that are registered in the European Clinical Trials Register. The HRA told us that it would "seek to work with the MHRA to understand better the situation regarding the trials they regulate".<sup>27</sup>

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- 18 Health Research Authority, [Clinical Trial Registration: Audit of compliance for period 1 January 2016 to 30 June 2016](#) (August 2017), p1. The registration condition applies throughout the UK as a result of the HRA's coordination with the Devolved Administrations, as per [s111\(4\)](#) of the Care Act 2014.
- 19 Health Research Authority, [Clinical Trial Registration: Audit of compliance for period 1 January 2016 to 30 June 2016](#) (August 2017), p4
- 20 Health Research Authority, [Clinical Trial Registration: Audit of compliance for period 1 January 2016 to 30 June 2016](#) (August 2017), p8. The audit report notes that "The response rate from investigators / sponsors when contacted regarding study registration was reasonably good, given the short response window (one week from when the email was sent and no reminder emails were issued)".
- 21 Health Research Authority, [Clinical Trial Registration: Audit of compliance for period 1 January 2016 to 30 June 2016](#) (August 2017), p11
- 22 'Phase I' refers to a therapy being given to a group of people for the first time.
- 23 Health Research Authority ([RES0047](#))
- 24 European Medicines Agency, '[Posting of clinical trial summary results in European Clinical Trials Database \(EudraCT\) to become mandatory for sponsors as of 21 July 2014](#)', accessed 24 August 2018
- 25 Goldacre, B. "[Compliance with requirement to report results on the EU Clinical Trials Register: cohort study and web resource](#)", *The BMJ*, 2018; 362:k3218
- 26 AllTrials campaign ([RIN0067](#))
- 27 Health Research Authority ([RES0047](#))

11. Reporting requirements are also specified by UK funders. In October 2016 the Medical Research Council (MRC) clarified its policy on clinical trials reporting, including a requirement for award holders to ensure that findings are publicly available within 12 months of completion of the trial.<sup>28</sup> This appears to have been successful as compliance rates are relatively high for MRC-funded trials. In 2017, the MRC examined reporting rates for trials funded between 2011 and 2016, finding that 33 out of 40 trials (~82%) that had been completed for at least a year had reported in at least one publication.<sup>29</sup> The Government referred several times during our inquiry to the relatively high compliance rate for MRC-funded trials.<sup>30</sup> However, the MRC's role in clinical trials is relatively small; it funds around 120 clinical trials each year,<sup>31</sup> representing less than 3% of the 4,568 studies reviewed by the HRA in 2017/18.<sup>32</sup>

12. The current EU Clinical Trials Directive<sup>33</sup> (incorporated into UK law via the 2004 Medicines for Human Use (Clinical Trials) Regulations<sup>34</sup>) will soon be superseded by a new EU Clinical Trials Regulation.<sup>35</sup> This Regulation includes new transparency requirements regarding publication of trial results and requires Member States to lay down rules on penalties for non-compliance.<sup>36</sup> Although the new Regulation entered into force on 16 June 2014, the point at which it becomes applicable to the Member States is contingent on the completion of a new EU clinical trials portal and database; the Regulation becomes applicable six months after the European Commission publishes confirmation that the portal and database are fully functional. This is expected to happen in 2019, after the UK leaves the EU, and so the Regulation will not be incorporated into UK law by the EU (Withdrawal) Act. The Government has stated that it will “align where possible with the [new Regulation] without delay when it does come into force in the EU, subject to usual parliamentary approvals”.<sup>37</sup> What this commitment to “align” with the Regulation will mean in the context of forthcoming clinical trials transparency requirements (and any corresponding penalties for non-reporting) is currently unclear.

### Mis-reporting

13. A multi-journal initiative exists to ensure that the full results from trials are reported. The Consolidated Standards of Reporting Trials (CONSORT) statement, first published in 1996 and updated in 2010, sets out “a standard way for authors to prepare reports of trial findings, facilitating their complete and transparent reporting, and aiding their critical appraisal and interpretation”.<sup>38</sup> Its checklist requires all outcomes to be defined and identified, and results to be reported for each outcome.

28 Medical Research Council (RES0041) para 1.1

29 MRC, *MRC Clinical Trials Transparency Review Final Report (November 2017)*, (November 2017), para 14 Q598 [Sir Mark Walport], Department for Business, Energy and Industrial Strategy (RES0057),

30 MRC, *MRC Clinical Trials Transparency Review Final Report (November 2017)*, (November 2017), para 17

31 Health Research Authority, *Health Research Authority Annual Report and Accounts 2017/18*, HC 1284

32 Council Directive [2001/20/EC](#)

33 The Medicines for Human Use (Clinical Trials) Regulations 2004 ([SI 2004/1031](#))

34 Council Regulation (EC) No. 536/2014

35 For further details see ‘[Clinical trial regulation](#)’, European Medicines Agency, accessed 24 August 2018, and Article 94 of Council Regulation (EC) No. 536/2014.

36 ‘[Guidance: How medicines, medicinal devices and clinical trials would be regulated there’s no Brexit deal](#)’, gov.uk, 23 August 2018

37 <http://www.consort-statement.org/>

14. Despite “over 500 individually named academic journals”<sup>39</sup> having formally endorsed the CONSORT guidelines for trial reporting, mis-reporting remains an issue. A study of the work of Hampshire A research ethics committee by Dr Kolstoe found that 57% of publications associated with trials approved by the committee showed “inconsistencies with the outcomes originally declared in the ethics application”.<sup>40</sup> Similarly the Medical Research Council told us that while reporting rates for the trials it funds were high, in its most recent audit of corresponding publications “only half of these appeared to include the main trial results”.<sup>41</sup>

15. **A range of UK and EU rules and guidelines are in force to improve clinical trials transparency, in terms of tackling non-registration, non-reporting and mis-reporting. Despite these rules, around half of clinical trials are left unreported, clinical trial registration is not yet universal in the UK and reported outcomes do not always align with the original study proposal. Further action is needed to improve reporting and registration of clinical trials, as we set out in this Report. The Government should not rely on the higher reporting rates for trials funded by the Medical Research Council to suggest that the problem is being addressed, as these represent a small proportion of the total number of clinical trials undertaken in the UK.**

16. *The Government should explicitly commit to introducing the clinical trials transparency requirements in the EU Clinical Trials Regulation that are expected to be applied in the EU shortly after Brexit.*

## Compliance rates by sponsor

17. Dr Goldacre’s recent work has also revealed that compliance with reporting requirements varied by sponsor—i.e. the “individual, company, institution, organisation or group of organisations that takes on responsibility for initiation, management and financing (or arranging the financing) of the research”.<sup>42</sup> Trials with a commercial sponsor were substantially more likely to post results than those with a non-commercial sponsor (68.1% vs 11.0%). In particular, “compliance among pharmaceutical companies has been good; while universities have performed poorly”.<sup>43</sup> However, the study found considerable variation between universities. The University of Dundee, for instance, has a compliance rate of 82%, whereas the equivalent figure for the University of Nottingham is 5.9%.<sup>44</sup>

18. Dr Patrick Vallance, the Government’s Chief Scientific Adviser, told us that his message to universities with low trial reporting rates was to “sort it out”.<sup>45</sup> The Science Minister, Sam Gyimah MP, agreed with this message.<sup>46</sup> The work being undertaken by Universities UK to review the Concordat to Support Research Integrity in response to our earlier Report on this subject represents an important opportunity to press for progress on this issue.<sup>47</sup>

39 Dr Ben Goldacre ([RIN0073](#)), para 1.3

40 Dr Simon Kolstoe ([RIN0022](#))

41 Medical Research Council ([RES0041](#)) para 3.3

42 Health Research Authority, ‘[Roles and responsibilities](#)’, accessed 30 August 2018

43 Goldacre, B. “[Compliance with requirement to report results on the EU Clinical Trials Register: cohort study and web resource](#)”, *The BMJ*, 2018; 362:k3218

44 According to data published at <https://eu.trialstracker.net> as at 22 October 2018

45 [Q661](#)

46 [Q663](#)

47 See Science and Technology Committee, Sixth Report of Session 2017–19, [Research integrity](#), HC 350, para 43

19. **Compliance with transparency rules varies by sponsor—while pharmaceutical companies have good rates of reporting within a reasonable timeframe, the picture is much more mixed for universities. We welcome the Science Minister and the Government Chief Scientist’s call for universities to deal with this problem and expect universities to take heed. Every university should aim for 100% compliance. We recommend that the updated and strengthened Concordat to Support Research Integrity being developed by Universities UK should include requirements on universities to ensure that all trials are reported, and that efforts are made to share best practice in achieving compliance with reporting rules within the university sector.**

20. The ‘EU Trials Tracker’ website set up by Dr Goldacre and colleagues at the Evidence-Based Medicine Data Lab also reveals that Public Health England has three overdue trials dating from 2010–2016 relating to meningitis vaccines.<sup>48</sup> Meanwhile, many NHS Trusts have high numbers of unreported clinical trials according to the site: the Manchester University NHS Foundation Trust has 13 overdue trials, NHS Greater Glasgow and Clyde has 12 that are due to have reported, and both Newcastle upon Tyne Hospitals NHS Foundation Trust and Hull and East Yorkshire Hospitals NHS Trust have 11 outstanding trials.<sup>49</sup>

21. **It is particularly disappointing that trusted bodies such as Public Health England and a range of NHS Foundation Trusts are also failing to report results from clinical trials. Public trust in medicine could easily be eroded by failures in clinical trials transparency from such important parts of the health system. Public Health England should write to us with an explanation and the steps it will take to correct this.**

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48 See <https://eu.trialstracker.net/sponsor/public-health-england> accessed 22 October 2018.

49 Data taken from <https://eu.trialstracker.net> accessed 22 October 2018.

## 3 Improving clinical trials transparency

### Developments since 2013 and the need for high-level political leadership

22. Since our predecessor's Report, clinical trials transparency has been discussed "at the highest levels",<sup>50</sup> with a number of international and intergovernmental organisations releasing statements on this issue:

- In April 2015, the World Health Organization published a statement on the public disclosure of clinical trial results. The WHO statement defined reporting timeframes, called for results-reporting of older but still unpublished trials, and outlined steps to improve linkages between clinical trial registry entries and their published results.<sup>51</sup>
- In September 2016, the UN Secretary-General's High-Level Panel on Access to Medicines placed the responsibility for making progress on this issue with national governments. It recommended that "Governments should require that the unidentified data on all completed and discontinued clinical trials be made publicly available in an easily searchable public register established and operated by existing mechanisms such as the WHO Clinical Trials Registry Platform, clinicaltrials.gov or in peer reviewed publications, regardless of whether their results are positive, negative, neutral or inconclusive".<sup>52</sup>
- In May 2017 the WHO produced a joint statement on public disclosure of results from clinical trials, with 21 signatories committing to "develop and implement a policy with mandated timeframes for prospective registration and public disclosure of the results of clinical trials" that they fund, co-fund, sponsor or support within 12 months of completion. Moreover, the signatories committed to "monitor registration and endorse the development of systems to monitor results reporting on an ongoing basis", with outputs from the monitoring process being made publicly available. UK signatories include the Medical Research Council, the Department for International Development and the National Institute for Health Research.<sup>53</sup>

23. The issue was also previously discussed at the highest level within the UK. Following the Ebola epidemic, in 2015 the then Prime Minister David Cameron told a G7 summit that:

The UK will be the first country in the world to require clinical trials and disease control operations to be fully transparent. From now on any UK-funded research, data or operation will be made openly available and the

50 [Q319](#) [Síle Lane]

51 World Health Organization, '[WHO statement on public disclosure of clinical trials results](#)', accessed 23 August 2018

52 United Nations Secretary-General's High-Level Panel on Access to Medicines, '[Promoting innovation and access to technologies](#)' (September 2016), para 4.3.5

53 World Health Organization, '[Joint statement on public disclosure of results from clinical trials](#)', accessed 23 August 2018



UK will look to develop an international agreement—via the G7—that would see the publication of results of all clinical trials of vaccines for relevant diseases.<sup>54</sup>

However, the focus for this commitment was specifically trials relating to potential global pandemics, and there does not appear to be any tangible progress even on this more limited aspect. In particular, Dr Goldacre told us that “there are many trials of both treatments and vaccines for Ebola that have completed but not reported results, including I believe some from the UK”.<sup>55</sup>

24. We were told that further political attention in the UK was required to make progress on this issue. TranspariMED argued that “so far, the systematic distortion of evidence generated by clinical trials has been largely framed as a technical issue, rather than as a political issue”.<sup>56</sup> Dr Goldacre warned that the public were “increasingly aware that serious problems [with transparency] have been left unaddressed: that trial results are routinely withheld, that there has been little serious effective effort to fix the issue over decades, that the biggest players in the ecosystem of scientific research are not taking adequate action”. He argued that an ongoing failure to address these problems “[laid] fertile ground for quacks, anti-vaccination conspiracy theorists, and climate change denialists”.<sup>57</sup>

25. **Our predecessor Committee concluded in 2013 that it had “not been impressed” by the Government’s efforts to resolve the problem of un-registered, non-reported and mis-reported clinical trials. We believe that while there have been some improvements there is still much more to be done.**

26. **We welcome the recent statements and recommendations from the WHO and the UN on clinical trials transparency aimed at improving registration and reporting rates. The Ebola epidemic prompted political attention in the UK to the risks to public health of non-publication of clinical trial results, with the then Prime Minister David Cameron making commitments to clinical trials transparency in 2015. Since then, progress has slowed in the UK at a political level. Clinical trials transparency is as much a question of political will as it is a technical issue. *We recommend that the Government explicitly re-commit to tackling clinical trials transparency, perhaps through a focused ministerial speech on this issue. This should set a clear time limit for institutions to fully comply with clinical trials transparency requirements and make clear what the consequences will be of failing to meet that deadline.***

## Improving registration and reporting rates through auditing

27. An approach to improving clinical trials transparency emphasised by our witnesses was publishing better information on which clinical trials have reported and which have not. Dr Goldacre explained that “we need to know which researchers are the best and the worst, and which institutions are the best and the worst, because that is information we can act on. Assuming good faith, I hope that the institutions that have fallen behind would want to learn from those doing well at reporting their clinical trials”.<sup>58</sup>

54 Gov.uk, ‘[Prime Minister calls for ‘wake-up to the threat from disease outbreak’](#)’, 7 June 2015

55 [Q341](#)

56 TranspariMED ([RIN0018](#)) para 7

57 Dr Ben Goldacre ([RIN0073](#)) para 2

58 [Q323](#)

28. Recent attempts to provide such information are described in Chapter 2. Surprisingly, information on whether an individual trial has published results is not readily available online without secondary analysis. Such work has been undertaken by Dr Goldacre and others to match information in clinical trial registries with publications records, with information on sponsor compliance rates published online.<sup>59</sup> Despite the scope for using audits to drive improvements in compliance rates, Dr Goldacre found that his attempts to put trial-by-trial information in the public domain were seen as subversive. He told us that:

When you finish an audit showing which institutions in the UK are best and worst at reporting their clinical trial results at all, and which are best at reporting their clinical trial results on time, people sometimes respond as if you are doing something that somehow is transgressive or confrontational, which shows how far we have to go. It would be a very straightforward thing to fix. This Committee could write to the Health Research Authority and say, “We want you to audit every trial that you approve; we want you to publish line by line; we want you to identify the individual trials and trialists who have not published their results”.<sup>60</sup>

29. Our witnesses argued that an appropriate official provider of trial-by-trial information on registration and reporting compliance was the Health Research Authority (HRA), drawing on its oversight and coordination of research ethics committees (RECs) in the UK.<sup>61</sup> Under both the EU Clinical Trials Directive 2001 and UK governance arrangements, in order to obtain clinical trial authorisation, all UK trials must first be evaluated and approved by an accredited REC. RECs therefore hold large amounts of information on proposed trials, albeit with some aspects being confidential for commercial reasons.<sup>62</sup> Indeed, our predecessor Committee recommended in 2013 that “Research Ethics Committees should have a role in considering and monitoring compliance with transparency policies”.<sup>63</sup>

30. We asked Professor Jonathan Montgomery, the non-executive Chair of the HRA, whether there were any barriers to the HRA publishing all the information it holds on which clinical trials have reported and which have not. He told us that:

We hold data that comes through in relation to projects, some of which is commercially sensitive, and within our processing systems we need to respect the basis on which people have given that to us. [...] However, going forward in relation to whether trials have resulted in publication, I see no reason why we cannot match publicly available data.<sup>64</sup>

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59 See <https://eu.trialstracker.net>

60 [Q318](#)

61 Responsibility for regulation of most health and social care research in Wales, Scotland and Northern Ireland remains with each Devolved Administration, since health and social care are themselves devolved matters. However, the HRA performs various functions relating to research ethics committees on behalf of the Devolved Administrations by arrangement, as per the Care Act 2014 Schedule 7 paragraph 15.

62 Dr Simon Kolstoe ([RIN0022](#)) para s5

63 Science and Technology Committee, Third Report of Session 2013–14, [Clinical trials](#), HC 104, para 110

64 [Q498](#)



He also told us that he was “not in favour of naming and shaming” organisations with poor compliance records but would nevertheless be “very keen to make transparent who has and has not published” as a prompt to encourage publication.<sup>65</sup>

**31. Non-compliance with reporting rules is not currently documented by public bodies on a trial-by-trial basis. Official publication of such information would expose where there are weaknesses in compliance and where best practice within the sector could be found and shared. We welcome recent efforts by Dr Goldacre and the AllTrials campaign to make information on reporting rates available online. However, it should not be left to researchers and campaigners to collate and publish this information themselves. We turn to the issue of who should produce this information later in this chapter.**

## Models for auditing compliance

32. We heard about a range of possible models for auditing compliance. A joint submission from STOPAIDS, Healthwatch UK, Universities Allied for Essential Medicines UK and TranspariMED described various options for questions that an audit could seek to address, and the relative difficulty of conducting such an exercise.

**Table 1: Types of audit**

Audit question	Audit methodology
Was this clinical trial prospectively registered?	Easy to audit. There are only 16 WHO-recognised primary registries that the HRA needs to search for each trial.
Were the summary results of this clinical trial published on all the registries where it is registered within 12 months of study completion?	Very easy to audit. The HRA can quickly check the already identified registry entries for trial results.
Has this clinical trial published results in an academic journal following global best practices [including referencing the unique ID number of the trial issued by the registry in the abstract of the corresponding journal article]?	Very easy to audit. The HRA can quickly search journal databases for the trial number.
Are the registration and results data for this trial consistent across different registry entries?	For trials registered in more than one registry the HRA can check whether key trial data is consistent across different registries. This requires no specialist skills, but does require manual comparison.
Has this trial ever reported its results anywhere?	Time intensive to audit. The HRA would need to follow a lengthy search protocol for every trial. No specialist skills required.
Has this trial accurately reported its results?	Time intensive and difficult to audit. The HRA would need to conduct a trial-by-trial analysis. This requires specialist skills.

Source: STOPAIDS et al ([RES0036](#))

33. We explored some of these options and the relative costs with our witnesses. Dr Goldacre argued that the HRA could use automated tools which searched databases for publications to answer the question of whether a trial had published results in an academic journal. However, Dr Kolstoe argued that this approach would “solve less than half of the problem”, since “determining whether results have been posted does not address whether they appropriately represent the study that was actually conducted”.<sup>66</sup> He argued that, since the HRA had access to all of the confidential research protocols, it could also support the research ethics committees to compare outcomes reported in publications with the objectives specified in the original protocols to check for mis-reporting or selective non-reporting.

34. Dr Kolstoe told us that while it could be “relatively cheap and easy” to audit non-publication using automated software and data held by the HRA, in order to address “outcome reporting bias” a manual comparison would need to be made of the final study reports against the original proposal.<sup>67</sup> He had conducted such an audit for the Hampshire A Research Ethics Committee to demonstrate that it was possible to do this. He argued that those with access to REC records were “in a particularly powerful position to detect publication and reporting bias in contrast to similar attempts conducted by research funders or systematic review organisations who do not have immediate access to such a wide range of otherwise confidential protocols”.<sup>68</sup>

35. Dr Kolstoe noted that “extra resources would be needed if individual RECs or those managing them were to take on this role more comprehensively”.<sup>69</sup> The HRA claimed that the total cost of undertaking this work would be £2.4m, but did not provide a basis for this estimate.<sup>70</sup> They warned that “without a significant increase in our funding, any active monitoring of all research projects approved by the HRA using this methodology would we believe have a detrimental impact on other areas of our services, such as approval timelines”.<sup>71</sup> Jonathan Montgomery from the HRA told us that he thought it would be unlikely to ever secure such additional funding, and that it would not be “a sufficient priority against all the other things we are doing if we did have that money to deal with it”.<sup>72</sup> He contrasted this cost with “about £250,000” for an IT-based solution, albeit one which would not address the question of whether the matched publication addressed the full aims of the trial or was a partial report.<sup>73</sup>

***36. 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. In the first instance this should focus on providing information on whether any results have been published in an academic journal following global best practice, building on the automated methods already developed by others. We recognise that there are other dissemination routes for clinical trials results beyond academic journals that automated methods might not capture.***

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66 Dr Simon Kolstoe ([RES0030](#))

67 Dr Simon Kolstoe ([RES0030](#))

68 Dr Simon Kolstoe ([RIN0022](#))

69 Dr Simon Kolstoe ([RIN0022](#))

70 Health Research Authority ([RES0040](#)) para 12

71 Health Research Authority ([RES0040](#)) para 12

72 [Q517](#)

73 [Qq517-519](#)

*Where alternative means have been used to publish information the HRA can use this process to prompt lead investigators to provide details of where the results have been posted so that the entry for that trial can be corrected as necessary.*

37. We are disappointed that the HRA does not believe it can secure funding for a more comprehensive form of audit and does not see this as a priority. Even if the cost of fully assessing reported trial outcomes against the original specification in the application for ethical approval amounts to £2.4m per year, as the HRA suggested in evidence to us, this is a small price to pay compared with the sums of money involved in policy decisions that draw on clinical trials evidence, such as the £424m the Government spent on stockpiling Tamiflu without full access to evidence on its effectiveness. *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.*

38. *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.*

## Sanctions for non-compliance

39. Our predecessor Committee in 2013 recommended that the HRA should introduce “penalties for non-compliance” with registration and reporting rules.<sup>74</sup> We asked Professor Montgomery, non-executive Chair of the HRA, whether the HRA had the statutory power to impose meaningful sanctions for non-compliance. Professor Montgomery told us that “we do not have sanctions as part of the HRA, other than refusing permissions [...] we do not employ the researchers so our only real powers are to withhold [ethical] permissions or refer to those who do have those powers”.<sup>75</sup>

40. Naturally the ethical permission for a trial cannot be withheld after the research has taken place as a response to non-reporting. However, the REWARD Alliance, an international alliance focused on reducing wastage in research, suggested to us that research ethics committees could refuse to approve proposals for further research unless the sponsor or researcher can show that their previous research had been reported.<sup>76</sup> Dr Goldacre agreed that “ethics committees should not allow researchers to have access to patients unless they can show that they have published the results of all the trials they have previously conducted”.<sup>77</sup> We asked Professor Montgomery whether this would be possible:

74 Science and Technology Committee, Third Report of Session 2013–14, [Clinical trials](#), HC 104, para 110

75 [Q515](#)

76 REWARD Alliance ([RIN0013](#)) para 8.3

77 [Qq316–317](#)

I think that would be tricky. [...] We took to our research ethics committee members the question of whether we should make it a condition of a new application that results had been published within 12 months of completion of the previous ones. There was quite strong resistance to that. There was a group that simply told us it did not think it should happen; a group that thought it would not be possible to deliver on it; and a group that thought it was too ambiguous.<sup>78</sup>

Instead he argued that others could make decisions based on non-compliance information if it were made available, as we recommend (at paragraph 36):

I am not convinced that the ethics committee is the right bit of the system to do that. [...] I would expect sponsors to be interested in whether their money had been well spent previously and led to the reported outcomes. I would expect the hosts of research to want to know it was worth hosting that research, so we should be providing them with the opportunity to ask whether they trust a particular research group or sponsor to deal with it.<sup>79</sup>

**41. The HRA appears to be reluctant to enforce its rules, or to make previous compliance with transparency legislation a pre-requisite for ethical approval of future trials. As a result, there are currently no sanctions imposed on sponsors or investigators who fail to comply with HRA rules, or even on those who fail to respond to the HRA when their non-compliance is queried. 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.**

## Allocating responsibility for driving improvement

42. Our predecessor Committee recommended that the Government make the promotion of research transparency a statutory objective of the Health Research Authority.<sup>80</sup> As a result, in 2013 the Government tabled an amendment to the Care Bill at Report stage which made it explicit that the HRA's main objective of "protecting and promoting the interests of participants, potential participants and the public by facilitating the conduct of safe, ethical research" included "promoting transparency in research".<sup>81</sup> The Bill which became the Care Act 2014 clarified that 'transparency' included the registration of research and the publication and dissemination of research findings and conclusions.<sup>82</sup> Our Chair was the lead Minister for the Bill at the time.

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78 [Qq511–512](#)

79 [Q520](#)

80 Science and Technology Committee, Third Report of Session 2013–14, [Clinical trials](#), HC 104, para 109

81 Department of Health, *Government response to the Science and Technology Committee inquiry into clinical trials*, [Cm 8743](#), November 2013, para 27

82 Care Act 2014, [section 110 \(7\)](#)

43. The HRA's 2017/18 annual report listed "being a champion for transparency in research" as part of its strategic objectives, and noted that a "key risk" for the HRA related to "expectations around transparency and the HRA's ability to deliver within its current remit".<sup>83</sup> Nevertheless, the HRA told us that "as far as our regulatory remit is concerned, we feel that we have sufficient scope to act within the existing legislation".<sup>84</sup>

44. The annual report also stated that further work to consider transparency was underway, "with closer links with key partners being made to support the delivery of the transparency agenda together with refreshed key performance indicators for 2018/19".<sup>85</sup> There are currently no measurable performance indicators relating to transparency in the report. The two achievements listed for the year in its "performance scorecard" are that the HRA had "performed an audit of clinical trial registration and published the findings report on [the HRA's] website" (as it has done for several years, at a summary level), and "compiled a list of accepted clinical trial registers with [its] Transparency Forum and published this list on our website".<sup>86</sup>

**45. The Health Research Authority has been explicitly responsible for "promoting research transparency" as part of its statutory objectives since 2014, but this does not appear to have brought about significant change in this area over the last four years. 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. We also recommend that the Government write to the HRA to clarify that it should interpret the Care Act 2014 to mean that it is responsible for driving improvements in clinical trials transparency—as opposed to 'promoting' transparency as a virtue. The performance of the HRA should then be explicitly measured on this basis through its annual report, including through specific measurable performance indicators. If further financial resource for the HRA is required to tackle clinical trials transparency then the Government should consider favourably such requests.**

**46. We recommend that the Government consult further with the HRA on whether it is capable of delivering the improvements to clinical trials transparency needed within its current remit. If necessary its remit should be extended through introducing legislation which amends the provisions of the Care Act 2014.**

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83 Health Research Authority, [Health Research Authority Annual Report and Accounts 2017/18](#), HC 1284

84 Health Research Authority ([RE50040](#)) para 13

85 Health Research Authority, [Health Research Authority Annual Report and Accounts 2017/18](#), HC 1284

86 Health Research Authority, [Health Research Authority Annual Report and Accounts 2017/18](#), HC 1284

## Conclusions and recommendations

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### The current state of clinical trials transparency and related legislation

1. A range of UK and EU rules and guidelines are in force to improve clinical trials transparency, in terms of tackling non-registration, non-reporting and mis-reporting. Despite these rules, around half of clinical trials are left unreported, clinical trial registration is not yet universal in the UK and reported outcomes do not always align with the original study proposal. Further action is needed to improve reporting and registration of clinical trials, as we set out in this Report. The Government should not rely on the higher reporting rates for trials funded by the Medical Research Council to suggest that the problem is being addressed, as these represent a small proportion of the total number of clinical trials undertaken in the UK. (Paragraph 15)
2. *The Government should explicitly commit to introducing the clinical trials transparency requirements in the EU Clinical Trials Regulation that are expected to be applied in the EU shortly after Brexit.* (Paragraph 16)
3. Compliance with transparency rules varies by sponsor—while pharmaceutical companies have good rates of reporting within a reasonable timeframe, the picture is much more mixed for universities. We welcome the Science Minister and the Government Chief Scientist’s call for universities to deal with this problem and expect universities to take heed. Every university should aim for 100% compliance. *We recommend that the updated and strengthened Concordat to Support Research Integrity being developed by Universities UK should include requirements on universities to ensure that all trials are reported, and that efforts are made to share best practice in achieving compliance with reporting rules within the university sector.* (Paragraph 19)
4. It is particularly disappointing that trusted bodies such as Public Health England and a range of NHS Foundation Trusts are also failing to report results from clinical trials. Public trust in medicine could easily be eroded by failures in clinical trials transparency from such important parts of the health system. Public Health England should write to us with an explanation and the steps it will take to correct this. *Public Health England should write to us with an explanation and the steps it will take to correct this* (Paragraph 21)

### Improving clinical trials transparency

5. Our predecessor Committee concluded in 2013 that it had “not been impressed” by the Government’s efforts to resolve the problem of un-registered, non-reported and mis-reported clinical trials. We believe that while there have been some improvements there is still much more to be done. (Paragraph 25)
6. We welcome the recent statements and recommendations from the WHO and the UN on clinical trials transparency aimed at improving registration and reporting rates. The Ebola epidemic prompted political attention in the UK to the risks to public health of non-publication of clinical trial results, with the then Prime Minister



David Cameron making commitments to clinical trials transparency in 2015. Since then, progress has slowed in the UK at a political level. Clinical trials transparency is as much a question of political will as it is a technical issue. *We recommend that the Government explicitly re-commit to tackling clinical trials transparency, perhaps through a focused ministerial speech on this issue. This should set a clear time limit for institutions to fully comply with clinical trials transparency requirements and make clear what the consequences will be of failing to meet that deadline.* (Paragraph 26)

7. Non-compliance with reporting rules is not currently documented by public bodies on a trial-by-trial basis. Official publication of such information would expose where there are weaknesses in compliance and where best practice within the sector could be found and shared. We welcome recent efforts by Dr Goldacre and the AllTrials campaign to make information on reporting rates available online. However, it should not be left to researchers and campaigners to collate and publish this information themselves. We turn to the issue of who should produce this information later in this chapter. (Paragraph 31)
8. *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. In the first instance this should focus on providing information on whether any results have been published in an academic journal following global best practice, building on the automated methods already developed by others. We recognise that there are other dissemination routes for clinical trials results beyond academic journals that automated methods might not capture. Where alternative means have been used to publish information the HRA can use this process to prompt lead investigators to provide details of where the results have been posted so that the entry for that trial can be corrected as necessary.* (Paragraph 36)
9. We are disappointed that the HRA does not believe it can secure funding for a more comprehensive form of audit and does not see this as a priority. Even if the cost of fully assessing reported trial outcomes against the original specification in the application for ethical approval amounts to £2.4m per year, as the HRA suggested in evidence to us, this is a small price to pay compared with the sums of money involved in policy decisions that draw on clinical trials evidence, such as the £424m the Government spent on stockpiling Tamiflu without full access to evidence on its effectiveness. *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)
10. *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)
11. The HRA appears to be reluctant to enforce its rules, or to make previous compliance with transparency legislation a pre-requisite for ethical approval of future trials. As a result, there are currently no sanctions imposed on sponsors or investigators

who fail to comply with HRA rules, or even on those who fail to respond to the HRA when their non-compliance is queried. *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)

12. The Health Research Authority has been explicitly responsible for “promoting research transparency” as part of its statutory objectives since 2014, but this does not appear to have brought about significant change in this area over the last four years. *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. We also recommend that the Government write to the HRA to clarify that it should interpret the Care Act 2014 to mean that it is responsible for driving improvements in clinical trials transparency—as opposed to ‘promoting’ transparency as a virtue. The performance of the HRA should then be explicitly measured on this basis through its annual report, including through specific measurable performance indicators. If further financial resource for the HRA is required to tackle clinical trials transparency then the Government should consider favourably such requests.* (Paragraph 45)
13. *We recommend that the Government consult further with the HRA on whether it is capable of delivering the improvements to clinical trials transparency needed within its current remit. If necessary its remit should be extended through introducing legislation which amends the provisions of the Care Act 2014.* (Paragraph 46)



# Formal minutes

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**Tuesday 23 October 2018**

Members present:

Stephen Metcalfe, in the Chair

Vicky Ford      Carol Monaghan

Bill Grant      Damien Moore

Darren Jones      Graham Stringer

Draft Report (*Research integrity: clinical trials transparency*), proposed by the Chair, brought up and read.

*Ordered*, That the draft Report be read a second time, paragraph by paragraph.

Paragraphs 1 to 46 read and agreed to.

Summary agreed to.

*Resolved*, That the Report be the Tenth Report of the Committee to the House.

*Ordered*, That the Chair make the Report to the House.

*Ordered*, That embargoed copies of the Report be made available, in accordance with the provisions of Standing Order No. 134.

[Adjourned till Tuesday 30 October at 9.00 am

## Witnesses

The following witnesses gave evidence. Transcripts can be viewed on the [inquiry publications page](#) of the Committee's website.

### Tuesday 24 October 2017

Question number

**Professor Dorothy Bishop**, Professor of Developmental Neuropsychology, University of Oxford; **Dr Arnaud Vaganay**, Director, Meta-Lab; and **Professor Dame Ottoline Leyser FRS**, former Chair, Steering Group on the Culture of Scientific Research, Nuffield Council on Bioethics

[Q1–47](#)

**Dr Elizabeth Wager**, Publications Consultant, Sideview, and Honorary Co-ordinator, the REWARD Alliance; **Professor Sir Ian Diamond**, Research Policy Network, Universities UK; **Professor Ian Walmsley**, Pro Vice Chancellor for Research Working Group, Russell Group; and **Dr Peter Wilmshurst**, Consultant Cardiologist, Royal Stoke University Hospital

[Q48–114](#)

### Tuesday 21 November 2017

**Professor David Hand**, Royal Statistical Society; **Dr Damian Pattinson**, Vice President of Publishing Innovation, Research Square; and **Wendy Appleby**, Registrar and Head of Student & Registry Services, University College London

[Q115–212](#)

**Dr Trish Groves**, Director of Academic Outreach, British Medical Journal; **Dr Elizabeth Moylan**, Senior Editor for Peer Review Strategy and Innovation, BioMedCentral (representing the Committee on Publication Ethics); **Catriona Fennell**, Director of Publishing Services, Elsevier (representing The Publishers Association); and **Dr Alyson Fox**, Director of Grants Management, Wellcome Trust

[Q213–276](#)

### Monday 4 December 2017

**Dr Ivan Oransky**, Co-Founder, Retraction Watch, and Distinguished Writer in Residence, New York University Arthur Carter Journalism Institute; and **Professor C K Gunsalus**, Director, US National Centre for Professional and Research Ethics

[Q277–310](#)

**Dr Ben Goldacre**, DataLab, Department of Primary Care, University of Oxford; **Dr Simon Kolstoe**, Senior Lecturer and University Ethics Adviser, University of Portsmouth, and Independent Chair of Hampshire A (NHS) and the MOD research ethics committees; and **Sile Lane**, Head of International Campaigns and Policy, Sense about Science

[Q311–360](#)

### Tuesday 30 January 2018

**Professor Sir Bernard Silverman**, Chair of Trustees, UK Research Integrity Office; and **James Parry**, Chief Executive, UK Research Integrity Office

[Q361–433](#)

**Dr Tony Peatfield**, Director of Corporate Affairs, Medical Research Council, and Chairman, RCUK Good Research Conduct Network; and **Dr Steven Hill**, Head of Research Policy, Higher Education Funding Council for England

[Q434–496](#)

**Professor Jonathan Montgomery**, Chair, Health Research Authority

[Q497–531](#)

**Tuesday 6 March 2018**

**Professor Sir Mark Walport**, Chief Executive, UK Research and Innovation (UKRI)

[Q532–615](#)

**Tuesday 8 May 2018**

**Mr Sam Gyimah MP**, Minister for Universities, Science, Research and Innovation; and **Dr Patrick Vallance**, Government Chief Scientific Adviser and Head of Government Science and Engineering Profession, Government Office for Science

[Q616–693](#)

## Published written evidence

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The following written evidence was received and can be viewed on the [inquiry publications page](#) of the Committee's website.

RES numbers are generated by the evidence processing system and so may not be complete.

- 1 Australian Research Council ([RES0050](#))
- 2 Bullied into Bad Science ([RES0002](#))
- 3 Carmen Helena Coxon ([RES0035](#))
- 4 Cell and Gene Therapy Catapult ([RES0033](#))
- 5 Cell and Gene Therapy Catapult ([RES0054](#))
- 6 Collated responses from Departmental Chief Scientists ([RES0048](#))
- 7 Collated responses from UUK members regarding Concordat compliance ([RES0059](#))
- 8 Department for Business, Energy and Industrial Strategy ([RES0057](#))
- 9 Dr Dominic Edward ([RES0027](#))
- 10 Dr Gesche Huebner ([RES0010](#))
- 11 Dr Hugh Llewelyn ([RES0024](#))
- 12 Dr Paola Di Maio ([RES0039](#))
- 13 Dr Paul Marchant ([RES0042](#))
- 14 Dr Paul Taylor and Dr Daniel Barr, RMIT University, Melbourne ([RES0051](#))
- 15 Dr Peter Wilmshurst ([RES0025](#))
- 16 Dr Sarah Starkey ([RES0018](#))
- 17 Dr Simon Kolstoe ([RES0030](#))
- 18 Dr Venu Kumar ([RES0012](#))
- 19 EIS ([RES0013](#))
- 20 Health Research Authority ([RES0040](#))
- 21 Health Research Authority ([RES0047](#))
- 22 HealthWatch UK & Universities Allied for Essential Medicines UK & TranspariMED & Dr Simon Kolstoe (joint submission) ([RES0008](#))
- 23 Innovate UK ([RES0044](#))
- 24 Mathias Willumsen ([RES0043](#))
- 25 Medical Research Council ([RES0032](#))
- 26 Medical Research Council ([RES0041](#))
- 27 Meta-Lab ([RES0021](#))
- 28 Miss Tessa Burrington ([RES0011](#))
- 29 Professor David J Hand ([RES0028](#))
- 30 Professor Donald S Kornfeld ([RES0037](#))
- 31 Professor Dorothy Bishop ([RES0019](#))
- 32 Professor Marcus Munafò ([RES0049](#))
- 33 Professor Patricia Murray and Raphael Lévy ([RES0022](#))

- 34 Professor Patricia Murray and Raphael Lévy ([RES0045](#))
- 35 Professor Patricia Murray and Raphael Lévy ([RES0053](#))
- 36 Roger Shinton ([RES0046](#))
- 37 Russell Group ([RES0056](#))
- 38 Samuel Denyer and Dr Simon Peck ([RES0031](#))
- 39 Sense about Science ([RES0034](#))
- 40 STOPAIDS, HealthWatch UK, Universities Allied for Essential Medicines UK and TranspariMED ([RES0036](#))
- 41 The Academy of Medical Sciences ([RES0005](#))
- 42 The Royal Society ([RES0014](#))
- 43 Tony Mayer, Professor Lex Bouter, and Professor Nick Steneck ([RES0026](#))
- 44 TranspariMED ([RES0058](#))
- 45 UK Research and Innovation ([RES0055](#))
- 46 UK Research Integrity Office ([RES0023](#))
- 47 UK Research Integrity Office ([RES0052](#))
- 48 Universities UK ([RES0020](#))
- 49 Wendy Appleby on behalf of UCL ([RES0029](#))

## List of Reports from the Committee during the current Parliament

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All publications from the Committee are available on the [publications page](#) of the Committee's website. The reference number of the Government's response to each Report is printed in brackets after the HC printing number.

### Session 2017–19

First Report	Pre-appointment hearing: chair of UK Research & Innovation and executive chair of the Medical Research Council	HC 747
Second Report	Brexit, science and innovation	HC 705
Third Report	Genomics and genome editing in the NHS	HC 349
Fourth Report	Algorithms in decision-making	HC 351
Fifth Report	Biometrics strategy and forensic services	HC 800
Sixth Report	Research integrity	HC 350
Seventh Report	E-cigarettes	HC 505
Eighth Report	An immigration system that works for science and innovation	HC 1061
Ninth Report	Flu vaccination programme	HC 853
First Special Report	Science communication and engagement: Government Response to the Committee's Eleventh Report of Session 2016–17	HC 319
Second Special Report	Managing intellectual property and technology transfer: Government Response to the Committee's Tenth Report of Session 2016–17	HC 318
Third Special Report	Industrial Strategy: science and STEM skills: Government Response to the Committee's Thirteenth Report of Session 2016–17	HC 335
Fourth Special Report	Science in emergencies: chemical, biological, radiological or nuclear incidents: Government Response to the Committee's Twelfth Report of Session 2016–17	HC 561
Fifth Special Report	Brexit, science and innovation: Government Response to the Committee's Second Report	HC 1008
Sixth Special Report	Algorithms in decision-making: Government Response to the Committee's Fourth Report	HC 1544
Seventh Special Report	Research integrity: Government and UK Research and Innovation Responses to the Committee's Sixth Report	HC 1563
Eighth Report	Biometrics strategy and forensic services: Government's Response to the Committee's Fifth Report	HC 1653
Ninth Report	An immigration system that works for science and innovation: Government's Response to the Committee's Eighth Report	HC 1661