During my recent evidence to the Committee’s inquiry on research integrity, I undertook to write to you on three matters, as outlined below.

The question of whether the Concordat has been ‘tightened' since 2012. (Q618)

The text of the Concordat has not changed since its publication in 2012. However, since its publication, both institutional and funder policies have developed, and supplementary good practice guidelines have been produced by the community, for example UKRIO, which build on and further the aims of the Concordat. Collectively, these efforts have helped to refine what good compliance looks like and have contributed to tightening research integrity in publicly-funded research.

As Sir Mark Walport pointed out in his evidence to the committee (response to Q550), the work of Universities UK (UUK) with its members to increase compliance also plays an important part in progressing the aims of the Concordat. The percentage of institutions providing one annual statement has doubled from 26% in 2016 to 54% by 2018. That is a trend in the right direction, and my personal expectation of every vice-chancellor is that there should be 100% compliance.

Is the Minister backing the campaign to make sure that all trial results become known. The suggestion was that, at a minimum, people who routinely do not publish their trial results should find it more challenging to receive public funding for future trials. (Q671)

I think it is important to emphasise that there is a much higher rate of publication for Medical Research Council (MRC)-funded trials awards than suggested by Ben Goldacre in his multi-funder analyses:

- In 2017, the MRC reviewed publications from its awards for clinical trials:
  - Of 95 trials funded 2009-2012, 98% had published by 4 years after award end, 88% published within 2 years and 71% within 1 year.
  - Of 40 completed trials funded 2011-2016, 33 (82%) had already published findings and only 3 unpublished trials had been completed for more than 2 years.

This indicates that only very few MRC-funded trials (2%) never publish results. The MRC also found that contacting investigators about unpublished trials led to them putting summary results on a website or submitting them for publication, which demonstrates that active enquiry about publication by funders has a positive effect.

Delayed publication for MRC-funded trials can occur when the funding award includes early feasibility studies followed by a trial. If feasibility studies fail, or the trial start is delayed, then the publication of trial results is consequently delayed or occurs during a subsequent funded award. It is important to bear this in mind when considering future funding applications as delayed publication may not indicate a failure to publish.

Certainly, more emphasis should be placed on timely publication (within 2 years), and to this end, in the annual monitoring exercise in February 2018, the MRC wrote individually to all lead investigators for clinical trials awards and highlighted that a further audit of publication would be undertaken. This offers an opportunity to re-evaluate publication rates and compare progress with the 2017 review to understand the value of ‘prompting’ investigators to publish, and the urgency of introducing sanctions, such as making publication of previous trials a condition of future funding.
Therefore, based on the current evidence, the need to bar individuals who have not published trial results has not arisen, but this remains an option.

Has the HRA come to you with a request for funding to enable it to conduct its audit? Would you like it to do that, so that we achieve the transparency you have both said you are committed to? (Q672)

In terms of the resource costs required for the HRA to carry out an audit and chase up publications, I have not had a request for funding from the HRA. However, the MRC have devoted significant dedicated staff resources to find and analyse the data on MRC-funded clinical trials. The MRC will be able to share this experience with HRA via its representative on the HRA Transparency Forum which is a forum for funders, registries and regulatory bodies to share information and good practice on research transparency.

The findings from the reviews undertaken by the MRC in 2017 that were reported to the committee are publicly accessible on the MRC website.

I hope this is helpful.

May 2018