1. The Health Research Authority (HRA) is a non-departmental public body sponsored by the Department of Health (DH). Our statutory objective, as set out in the Care Act 2014, is to protect and promote the interests of patients, service users and the public in health and social care research. Our statutory functions include:

- co-ordinating and standardising the regulation of health and social care research with a view to promoting proportionate regulation;
- operating the Research Ethics Committees (RECs) whose review of health and social care research proposals is required;
- approving the processing without consent of confidential patient information for medical research, on the advice of the independent Confidentiality Advisory Group (CAG); and
- functioning as a member of the UK Ethics Committee Authority as set out in the Medicines for Human Use (Clinical Trials) Regulations 2004.

2. We welcome the opportunity to provide further evidence regarding unreported trials data. As the national regulator of health and social care research, we strongly support and promote transparency around research, in particular the publication of all research findings. Transparency is important because it reduces waste in the health system, avoids participants taking part in unnecessary studies and promotes public confidence in research.

3. Our own insights support the findings of the study carried out by Kolstoe and Begum: that the proportion of research studies which result in publication is low (though it is worth noting that results can be disseminated in a variety of ways, not just publication in a peer-reviewed journal). We share others’ concerns about this and are committed to doing what we can to increase the publication rate, to the benefit of other research teams, the health system and, ultimately, future patients.

Existing requirements and initiatives

4. The UK Policy Framework for Health and Social Care Research\(^1\) sets out clear guidance for researchers, including the role of HRA in setting standards and issuing guidance, but not enforcement. We also record breaches to the protocol, research fraud and misconduct and non-compliance with approval requirements. Such breaches may result in a request from the REC for action to address the issue, to ensure that participants are protected throughout the duration of the research.

5. Some transparency requirements already exist. Since July 2014 it has been mandatory for sponsors of clinical trials of investigational medicinal products (ie, drugs) to post trial results in the EudraCT database for trials that ended on or after July 2014\(^2\), although this requirement does not apply to Phase 1 studies. A subset of the data included in EudraCT is made available to the public in the European Union Clinical Trials Register. The European Medicines Agency has,

\(^1\)www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research

since October 2016, published clinical reports from pharmaceutical companies to support their regulatory applications for marketing of human medicines under the centralised procedure.

6. However, clinical trials of drugs make up only 20% of the research studies that we process, and commercial marketing trials are a sub-set of these, so it is important that we encourage transparency of other types of research, particularly all clinical trials. In September 2013, leading the way globally in research transparency, we introduced a specific condition of the research ethics committee favourable opinion for all types of clinical trials that the trial is registered, or a deferral for specific reasons is requested, before recruitment of the first participant. The purpose of creating this ‘line in the sand’ is to sharpen focus and awareness of the ethical obligation to ensure all trials are registered. Public registration of all clinical trials allows researchers and others to know what published trial results should be expected.

7. We ask applicants to describe their intentions for dissemination and publication for consideration by the research ethics committee, effectively making compliance with the plans part of the study’s approval.

8. Beyond conditions that we place on research applicants, we:
   - are working with partners in the Transparency Forum to promote research transparency and understand opportunities, obstacles and levers
   - will examine the findings of our latest trial registration audit
   - are working with stakeholders to explore transparency arrangements if UK adopts different clinical trials regulation from the EU following EU exit; and
   - are having further discussions with Drs Kolstoe and Goldacre about what we can do in this area.

Emerging requirements

9. Beyond existing requirements and the steps that we are taking to promote and encourage increased research transparency, forthcoming legal requirements and our own service improvement programme will increase published information about research findings.

10. The forthcoming EU Clinical Trials Regulation will impose increased transparency requirements on researchers. The regulation will require publication, for all drug trials (including phase I), of both a technical and a lay summary on the publicly accessible EU clinical trials database. Member States will be able to set local penalties for non-compliance. However, the regulation will now almost certainly only apply in the EU after the UK leaves the EU. Building on our existing leading position in transparency, it will be important to consider equivalent arrangements for registration and publication if the UK does not implement the EU Clinical Trials Regulation.

11. For device studies, both the EU Medical Device Regulation 2017/745 and the EU Regulation on In Vitro Diagnostic Medical Devices 2017/746 (IVDR) also include strengthened transparency requirements regarding the publication of study reports within one year of the end of the clinical

---

3www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-and-research-project-identifiers
Written evidence submitted by the Health Research Authority (RES0040)

investigation. As with CTIMPs, these are to be accompanied by a lay summary published on the European database on medical devices (Eudamed) which will go live in 2020.

Enhancing the publication rate

12. Dr Kolstoe’s suggestion that we could actively monitor and catalogue publications arising from approved projects to ensure that approved studies result in publication is well made. However, as Dr Kolstoe observes, significant additional resources that would be required to carry out this monitoring. Outline budget estimates based on Dr Kolstoe’s pilot study would suggest an increase in our staffing budget alone of approximately £2.4m per annum (20% of our annual budget). Our funding comes from Department of Health grant-in-aid and we currently face cuts to our budget of around 4% per annum in line with other arm’s length bodies. 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.

13. As far as our regulatory remit is concerned, we feel that we have sufficient scope to act within the existing legislation. We already have a duty under the Care Act 2014 to promote the interests of those participants and potential participants and the general public by facilitating the conduct of research that is safe and ethical (including by promoting transparency in research). The Act further states that transparency in research includes promoting ‘the publication and dissemination of research findings and conclusions’.

14. We believe that we can achieve an increase in the rate of reporting of trials without a significant increase in expenditure or a change to our regulatory remit. We will be redesigning the Integrated Research Application System (IRAS) in the coming year and are currently exploring ways of using the new research system to better track publications emerging from completed studies and follow up where such publications are missing. This includes:

- reviewing the questions that researchers are asked when submitting a study for approval, taking into account recommendations from the independent EQUATOR Network regarding publication and dissemination best practice
- exploring with the Devolved Administrations whether we expect dissemination of study findings to be a prerequisite to research ethics committee approval – researchers would need to demonstrate that they have a satisfactory track record of making their previous research findings known before the new study will be considered for ethics approval
- exploring whether we can use the redesigned IRAS system to make registration of studies (particularly studies other than trials) easier, and to enable applicants to publicly post study information submitted to HRA such as approved protocols, primary and secondary objectives, and technical and lay reports
- exploring, with others, ways to automate the tracking of publications and follow up with research teams, supported by the use of unique identifiers that follow a study’s journey.

---

15. As far as sanctions are concerned, we believe from our own audits that there may be dissemination routes other than publication of papers in medical journals which need to be factored in to any change proposals. We want the research community to see publication as a public good that it supports rather than a regulatory requirement. However, this may be something to consider in future if the work that we are planning over the coming year does not have the desired effect.

January 2018