

Summary

- Clinical and health research is vital to the health and wealth of the UK. The Academy of Medical Sciences has been at the forefront of calls to strengthen the support, regulation and governance of this area.
- The Clinical Trials Regulation is an improvement to the Clinical Trials Directive, although outstanding concerns remain. A major barrier to clinical research in the UK is the delay and duplication in obtaining research permissions from each NHS Trust involved in a trial.
- The Academy welcomes the establishment of the Health Research Authority. Although too early to judge success, we are supportive of the HRA's initial plans.
- We welcome the debate on, and efforts to improve, clinical trials transparency. Inevitably the results of clinical and health research are influenced by chance and other sources of variation. If only research with extreme, or favourable, results reach the public domain, a biased conclusion regarding interventions will be drawn. Transparency about the methods and results of all research is the best guard against such biased conclusions.
- The existence, methods and results of clinical and health research involving patients whether positive or negative should be made swiftly available for patient, social and scientific benefit. Many mechanisms to promote transparency, including registries, are best tackled in a coordinated and consistent manner at an international level involving the wide range of stakeholders.
- The Academy believes that the results of clinical and health research should be placed in the public domain through peer-reviewed media such as scientific journals. Validated research summary reports and clinical study reports without patient level data should be posted on a public web-based database, after regulatory approval and where relevant. Further consideration should be given to mechanisms to allow access to more detailed data given the need to protect patient confidentiality and to ensure that data is intelligible, assessable, reliable and usable.
- The Academy would be happy to give oral evidence to the Committee.

Introduction

1. The independent Academy of Medical Sciences promotes advances in medical sciences and campaigns to ensure that these are converted into health benefits for society. Our elected Fellowship includes some of the UK's foremost experts in medical science some of whom provided advice on this response (see annex 1).

2. Clinical and health research improves the health and wealth of the UK.¹ Recently the UK's strength in health research has been threatened. Our global market share of patients in pharmaceutical trials has fallen from 6% to 1.4% and there has been a similar experience in academic trials.² Central to this decline has been inappropriate regulation that prevents many clinical trials starting quickly and causes unnecessary costs. A proportionate and appropriate system of regulation and governance is essential to improving patient and public health by supporting UK clinical trials and attracting clinical trials from abroad. The Academy has played a leading role in streamlining research regulation through our reports and consultation responses.³

The Clinical Trials Regulation (CTR) and the main barriers to conducting clinical trials in the UK and EU

Strengths of the proposals for the CTR

3. The Academy believes that the proposals for the new CTR are an improvement on the current Clinical Trials Directive (CTD). Particularly welcome are:
 - Greater proportionality and greater scope for risk adaptation.
 - Formal introduction of co-sponsorship to help partnerships between universities and hospitals, between EU countries, and within the UK.
 - Ambitious timelines to speed up the approval process that should be retained and encompass UK-specific assessments.
 - The use of a Regulation rather than a Directive that will reduce differing national interpretations.
 - Single submission via an EU portal that will facilitate multi-national trials.
4. We welcome the Medicine and Healthcare products Regulatory Agency's (MHRA's) engagement with stakeholders and the establishment of a reference group on which the Academy is represented.
5. Despite the above improvements a number of concerns remain:

Clarity and clarification

6. Five areas that require further clarification are:
 - How European institutions will create and implement the IT systems required to establish a single application portal and single application dossier. The publication of plans to deliver these systems would provide reassurance.
 - How personal data will be protected in the new public database and EU portal; and further information on the timing of the disclosure of such data.

¹ Academy of Medical Sciences (2010). *Biomedical research – platform for increasing health and wealth in the UK* <http://www.acmedsci.ac.uk/p48prid84.html>

² NESTA (2011) *All together now: improving cross sector collaboration in the UK biomedical industry.* http://www.nesta.org.uk/library/documents/Report_67_Biomed_web.pdf

³ Further information is available from: <http://www.acmedsci.ac.uk/index.php?pid=47&prid=88>
<http://www.acmedsci.ac.uk/index.php?pid=47&prid=118>
<http://www.acmedsci.ac.uk/p100puid220.html> <http://www.acmedsci.ac.uk/p100puid176.html> and
<http://www.acmedsci.ac.uk/p100puid256.html>

- Whether the US National Institute of Health (NIH) register clinicaltrials.gov will be included among the World Health Organization (WHO) accredited primary registries on which clinical trials are required to be registered. Clinicaltrials.gov is the main registry used worldwide by sponsors but is not listed as a WHO primary register. We are keen to avoid unnecessary proliferation of registries, see paragraphs 36 and 44.
 - An assessment of whether allowing sponsors to choose the National Competent Authority (NCA) to which they apply means that stronger NCAs, such as the MHRA, receive many more applications. This could lead to excessive burdens on some NCAs that might impede their ability to regulate research nationally.
 - That insurance arrangements for multi-state trials (while welcome) will not be too cumbersome.
7. Although legally and internally consistent, some of the definitions in the CTR are different from those used by scientists. For example, the term 'low intervention trials' is not widely recognised scientifically. Confusion around terminology may lead to conservative interpretations of the CTR that could inhibit research. We therefore strongly encourage clearer guidance and communication with stakeholders and an accepted glossary of terms.

Proportionality and established treatments

8. While measures to increase the proportionality of the CTR are welcome, we are keen that this will be reflected in practice. For example, measures to introduce proportionality should ensure that trials testing established treatments with good safety profiles for novel uses should be considered low risk if the case for this is made. Where the safety profile of an intervention is very well known, adding burdens of monitoring does not benefit public health.

Increased focus on trial conduct and oversight

9. The CTR should focus more on the facilitation of overall trial conduct and oversight, including:
- More efficient approaches to trial conduct and monitoring in non-commercial settings that focus less on approaches derived from the International Conference on Harmonisation guidelines for Good Clinical Practice ('ICH-GCP'). The interpretation and implementation of ICH-GCP in practice has focused on specific aspects of its wording rather than its overarching intended objectives. This has resulted in rigid procedures that have been unduly prescriptive and obstructive. We welcome the HRA's recent statement that GCP training for researchers should be appropriate and proportionate to the type of research undertaken.⁴
 - The requirement for prior interview for consent that would pose a challenge to some studies where the only contact with participants is by post or electronically. A solution might be to change the text from 'prior interview' to

⁴ HRA (2012). Training requirements for researchers. <http://www.hra.nhs.uk/hra-news-and-announcements/training-requirements-for-researchers/>

'prior dialogue' as this would allow greater choice in the method of communication.

Streamlined research generates results and data for further analysis

10. As discussed in a later section, we welcome the debate on, and efforts to improve, transparency around the existence, methods and results of clinical trials. It is important that the resource requirements of any new systems in the CTR to improve transparency are proportionate.

Additional barriers to clinical trials

11. The Academy's 2011 report on the regulation and governance of health research identified delay and duplication inherent in obtaining research permissions from each NHS Trust involved in a trial as the greatest barrier to health research in England (see also paragraph 16).⁵ Largely this barrier remains, however, we welcome recent steps by the National Institute for Health Research (NIHR) to incentivise reductions in the timeline. This includes the introduction of benchmarks for the approval and delivery of clinical trials linked to NIHR's funding of NHS organisations.
12. Other barriers include a lack of understanding about the complex regulatory and governance framework and lack of a 'one stop shop' or single portal for application and guidance.

The role of the Health Research Authority (HRA) in relation to clinical trials

13. We support the initial plans of the HRA, although it is too early to judge whether it will be successful. The HRA is currently being established in primary legislation in the draft Care and Support Bill that has provided an opportunity to see how the HRA compares to our vision of a single regulator.^{6,7}
14. We welcome the HRA's focus on promoting the co-ordination and standardisation of the regulation and governance pathway of health and social care research in the UK and, as with the CTR, in seeking to ensure that such regulation is proportionate. This should help to reduce bureaucracy.
15. The HRA and MHRA have recently announced that they will not continue development and launch of e-submissions at this time, which formed a core component of the HRA's vision of a single unified process for applications.⁸ This vision was also articulated in our report. Further clarity is needed on how the HRA

⁵ Academy of Medical Sciences (2011). *A new pathway for the regulation and governance of health research*. <http://www.acmedsci.ac.uk/p47prid88.html>

⁶ Academy of Medical Sciences (2013). *Response to the joint scrutiny committee inquiry on the draft care and support bill*. <http://www.acmedsci.ac.uk/p100puid264.html>

⁷ Academy of Medical Sciences (2012). *Response to the Department of Health consultation on the draft Care and Support Bill*. <http://www.acmedsci.ac.uk/p100puid256.html>

⁸ Further information on this topic can be found at: <http://www.hra.nhs.uk/hra-news-and-announcements/future-of-iras/>

will coordinate the activities of review bodies, with sufficient authority and levers to provide a single route for all approvals and permissions.

16. Our vision for the HRA included the creation of a National Research Governance Service within the HRA that would support NHS Trusts and researchers by undertaking all **study-wide NHS research governance checks** just once. This was to ensure common standards and a consistent interpretation of the requirements. This recommendation was not taken forward and the Care and Support Bill does not explicitly mention the HRA's role in facilitating NHS research governance.⁹
17. We welcomed the HRA's recent announcement of a feasibility project that will explore whether it can support NHS Trusts by providing them with a simplified, streamlined and quality assured assessment for all research in the NHS.¹⁰ If successfully implemented, this would address the major barrier to research identified in our report.
18. The HRA should have a role in **developing metrics and indicators** for the regulation and governance pathway as a whole, and monitoring these to ensure that improvements are being made. It will be important to ensure that the timeline is not being manipulated (e.g. by 'stopping the clock' more often) and that the introduction of new benchmarks for Trust's research performance does not discourage them from undertaking certain types of research (e.g. more complex trials or those on rare diseases). Reliable metrics are extremely important both in terms of providing feedback on the success of initiatives but also in communicating success internationally to companies and researchers seeking locations for clinical trials.
19. In fulfilling its roles and functions, the HRA needs to **engage with a wide range of stakeholders**. The HRA has been in dialogue with patients and their representatives since its establishment and we welcome the establishment of the HRA's Collaboration and Development group, on which the Academy is represented.
20. The recent transfer of responsibility for the research use of **confidential patient information** to the HRA provides a good opportunity to reduce complexity in this area of regulation and governance that has led to conflicting interpretations of it by researchers, Trusts, patients and other stakeholders.
21. We welcome the HRA's announcement of plans to follow up the commitments that researchers make to research ethics committees relating to the registration and **publication of trials** (see below).

⁹ Academy of Medical Sciences (2013). *Response to the joint scrutiny committee inquiry into the draft Care and Support Bill*. <http://www.acmedsci.ac.uk/p100puid264.html>

¹⁰ HRA (2012). *HRA given go-ahead for feasibility study: HRA assessment for approval of research in the NHS*. <http://www.hra.nhs.uk/hra-news-and-announcements/hra-given-go-ahead-for-feasibility-study-hra-assessment-for-approval-of-research-in-the-nhs/>

Clinical trials transparency and disclosure of data

The importance of openness

22. The Academy strongly supports efforts to increase transparency around the existence, methods and results of clinical and health research. There is an excellent case for making the findings of research that involves patients available, because:
- Individuals often contribute to research for altruistic reasons and expect the results to be accessible by all.
 - Failure to do so may mean that patients are unnecessarily put at risk in studies when results are already known.
 - Under-reporting of research can lead to avoidable harm to patients and can waste limited healthcare and research resources.¹¹
 - Greater access to appropriately controlled data for valid scientific inquiry offers significant scientific benefits and helps ensure scientific validity, particularly for large studies where replication is more difficult.
 - It helps to develop hypotheses and improves trust in clinical and health research.
23. Transparency is an important issue for all those who conduct, fund, participate in and utilise the results of clinical trials in industry, academia, the NHS, charities and elsewhere. Solutions will therefore require the involvement of a wide range of stakeholders. The increasing number of cross-sectoral collaborations between these groups means that responsibility for transparency is increasingly shared.
24. Single studies rarely provide definitive evidence to answer important clinical questions.¹² Looking at a series of studies helps to address the effect of chance and other variation in results. It is usually necessary to combine results of studies to obtain reliable answers. If only research with extreme, or favourable, results reach the public domain, a biased conclusion regarding interventions will be drawn. Transparency about the methods and results of all research is the best guard against such biased conclusions.
25. Much discussion about transparency to date has focused on clinical trials to develop pharmaceuticals. However, clinical and health research is also conducted in other areas where transparency is important such as those involving surgery; devices; psychological, educational or organisational interventions; and understanding the causes and mechanisms of disease.
26. The wide range of types and size of clinical and health research means that developing appropriate and generalisable guidelines and regulations will require considerable thought.

¹¹ Chalmers I & Glasziou P (2009). *Avoidable waste in the production and reporting of research evidence*. *Lancet* 374, 86-89.

¹² Ioannidis JPA (2005). *Why Most Published Research Findings Are False*. *PLoS Med* **2(8)**, e124. doi:10.1371/journal.pmed.0020124

Clarity around transparency

27. Transparency in clinical and health research can cover many different sorts of activity some of which are undertaken at the present time and some of which are not, these include:
- public registration of trials, including their methods and protocols.
 - public posting of progress of trials and summaries of results.
 - publication of trials in journals.
 - public posting of clinical study reports.
 - providing access to individual patient level data.
28. Clarity about which aspect of transparency is being discussed is important as each presents different issues. It can also be helpful to distinguish between data, information and knowledge as is described in the recent Royal Society report '*Science as an open enterprise*'.¹³
29. Currently sponsors of clinical trials involving pharmaceuticals in the UK are expected to provide the MHRA and the relevant ethics committee with a report 12 months from the end of a trial.¹⁴ Funders often require the wider publication of trial results as part of their terms and conditions, and research ethics committees ask how researchers plan to publish their data and results before approving projects. Many medical journals endorse the CONSORT statement that encourages transparent reporting and describes ways in which this can be achieved.¹⁵ The European Union Drug Regulatory Authorities Clinical Trials (EudraCT) database of all recent EU clinical trials of investigational medicinal products does not collect the results of clinical trials and there is no single place where clinical trial results are published. However, we are aware of plans to collect results and make them publicly available.¹⁶

Models for transparency

30. The Academy believes that clinical and health research should be presented in a form that is intelligible, assessable, reliable and usable.¹⁷ The gold standard mechanism to achieve this goal is peer-review, which often takes place through journals. The results of clinical and health research should be placed in the public domain through peer-reviewed media such as scientific journals. Validated research summary reports and clinical study reports with patient level data removed should be posted on a public web-based database, after regulatory approval and where relevant. The resource implications of this proposal are considered in paragraph 33. Further consideration should be given to mechanisms to allow access to more detailed data to address issues such as patient confidentiality, particularly

¹³ Royal Society (2012). *Science as an open enterprise*.

<http://royalsociety.org/policy/projects/science-public-enterprise/report/>

¹⁴ Association of Medical Research Charities (2013). *Registration of clinical trials*.

<http://www.amrc.org.uk/home/>

¹⁵ Further information about CONSORT is available from: <http://www.consort-statement.org/>

¹⁶ Association of Medical Research Charities (2013). *Registration of clinical trials*.

<http://www.amrc.org.uk/home/>

¹⁷ Royal Society (2012). *Science as an open enterprise*.

<http://royalsociety.org/policy/projects/science-public-enterprise/report/>

in small studies or for studies of rare diseases, and to ensure that data is intelligible, assessable, reliable and usable.

31. Careful consideration should be given to the storage and management of more detailed data from clinical and health research to tackle issues such as applications from countries that do not have as robust regulatory and governance frameworks as the UK.
32. As discussed in paragraph 24, when important issues of treatment or outcome effect have been studied in several trials, reliable systematic reviews are the preferred method for presenting summary data. Results from a single study may be misleading. This should be considered when thinking about open access to data of individual trials.

Resource requirements

33. Any initiatives or regulation around transparency should be proportionate and seek to maximise net patient and social benefit. One important consideration is the resources required to achieve the different sorts of transparency discussed earlier. This will need to be balanced against the benefits that greater transparency could bring, for example by preventing research in areas shown to be unproductive. Thought needs to be given about who should pay for creating and maintaining the requisite infrastructure and for any costs to researchers for uploading data. This is a particular challenge for non-commercial funders that often have less resources than industry. The issue of resource requirements for transparency are considered in the Royal Society's report on '*Science as an open enterprise*'.¹⁸

Roles and responsibilities for clinical trials transparency

34. GSK recently committed to a system of transparency where clinical study reports, are made publicly available through their clinical trials register.¹⁹ In a separate initiative, GSK will also provide a system to request access to anonymised patient level data for further research, with requests reviewed by a committee that GSK has announced will be composed of independent experts. GSK hopes that this will be a first step to a model whereby researchers can access trial data from multiple sponsors from industry, academia and charities to conduct further research. This initiative has been welcomed by many, although some have argued that responsibility for providing access to clinical trial data that has been authorised for marketing should be independent from the sponsor. The regulator might fulfil this role as this might engender greater public trust, although EU/UK regulators might not have the full dataset and this would only cover trials submitted as part of the market authorisation dossier. Furthermore, the UK regulator is only responsible for some types of medical intervention that might be the subject of clinical trials, such as drugs, but not others, such as changes to health education.

¹⁸ Royal Society (2012). *Science as an open enterprise*.

<http://royalsociety.org/policy/projects/science-public-enterprise/report/>

¹⁹ Further information on GSK's announcement can be found at: <http://www.gsk.com/media/press-releases/2013/GSK-announces-support-forAll-Trials-campaign-for-clinical-data-transparency.html>

35. The European Medicines Agency's (EMA's) commitment to make clinical research data more available is welcome and we are keen to participate in the multi-stakeholder conversation about how this might be achieved.²⁰ We also welcome the BMJ's recent commitment to only publish trials where there is access to data on 'reasonable request'.²¹

The role of registries

36. Appropriately accredited public trials registries offer a useful mechanism for monitoring and encouraging transparency around clinical trials. There is a legal responsibility for all trials applying for clinical trial authorisation to be registered on the private EudraCT clinical trials database.²² We are aware of a number of different registries in different countries and different fields so are keen that these initiatives are coordinated and coalesce to avoid duplication of effort and to increase simplicity (see paragraphs 6 and 44).²³ Patient friendly information should be available for all trials that are open for recruitment as is currently the case for all cancer trials recruiting people in the UK through Cancer Help, and via the UK Clinical Trials Gateway.^{24,25} Evaluative tools such the services provided by the company Research Fish and Research Council UK's Gateway to Research can also help monitoring.^{26,27}

Negative results

37. While the results of much clinical and health research with positive results are currently available, the results of much research with negative results or research that closed early are not.²⁸ This has major consequences for unbiased assessment of the totality of evidence on a clinical or public health question. Non-publication can result from factors such as:
- competition for space in journals.
 - lack of capacity or willingness by researchers in industry and public service to spend time preparing such research for publication.
38. The Academy is a supporter of Universities UK's Research Integrity Concordat that commits to ensuring rigour, transparency and open communication when reporting research data, including the sharing of negative results.²⁹ The publication of negative results can help:

²⁰ EMA (2012). *Access to clinical trials data and transparency workshop report*. EMA, London.

²¹ Godlee F (2012). Clinical trial data for all drugs in current use.

<http://www.bmj.com/content/345/bmj.e7304>

²² Association of Medical Research Charities (2013). *Registration of clinical trials*.

<http://www.amrc.org.uk/home/>

²³ Examples of registers include: Clinical Trials.gov: <http://www.clinicaltrials.gov/> EudraCT:

<https://eudract.ema.europa.eu/> and Current Controlled Trials: <http://www.controlled-trials.com/>

²⁴ Further information is available from: <http://www.cancerresearchuk.org/cancer-help/>

²⁵ Further information on the UK Clinical Trials Gateway is available from:

<http://www.ukctg.nihr.ac.uk/default.aspx>

²⁶ Further information on Research Fish is available from: <https://www.researchfish.com/>

²⁷ Further information on RCUK's Gateway to Research is available from:

<http://www.rcuk.ac.uk/research/Pages/gtr.aspx>

²⁸ For the purposes of this response the term 'negative results' refer to those studies where there is no evidence of the intended effect but are nevertheless scientifically useful.

²⁹ Universities UK *et al* (2012). The concordat to strengthen research integrity.

<http://www.hefce.ac.uk/whatwedo/rsrch/rinfrastruct/concordat/>

- ensure that time and resources are not spent pursuing unproductive areas of research.
 - identify alternative uses for drugs or highlight patterns in responders and non-responders that might indicate sub-populations where the drug might be more effective.
39. A non-journal based portal with peer-review to ensure quality might help facilitate the publication of negative results. We are also aware of, and welcome, journals dedicated to publication of negative findings, such as the Journal of Negative Results in Biomedicine, or commitments by journals to publish negative results, such as from PLOS ONE.^{30,31}

Ensuring timely publication

40. Publication of clinical and health research in journals should happen as swiftly as practically possible once studies are complete and the results validated. However, we believe that setting a single deadline for publication of results of all clinical and health research in journals would not be helpful because:
- Researchers require time to rigorously analyse their findings.
 - A single study may generate several papers that each may take time to prepare.
 - Different journals have different times for peer-review.
 - A paper may not be accepted by the first journal to which it is submitted.
 - Researchers should have some initial degree of exclusivity to results otherwise there will be significantly less incentive to conduct important studies as the reward will be accrued by others.
41. As discussed in the previous section, we welcome the HRA's plans for research ethics committees to follow up publication plans with researchers and hope these will be proportionate.
42. We are aware of calls for retrospective registration and reporting of the full methods and results of all trials.³² Resources could be a key constraint in this regard and are considered further in paragraph 32. The Academy believes that the focus should be on developing mechanisms to ensure rapid prospective posting and publication of current and future trials as this can be practically addressed more swiftly.

Tackling clinical trials transparency and data disclosure internationally

43. As a result of globalisation clinical trials are increasingly conducted both within and between more countries than ever before. Transparency therefore needs to be tackled at the international level. This would:
- improve coordination
 - increase simplicity
 - reduce duplication
 - help ensure that the UK remains scientifically competitive

³⁰ Further information is available from: <http://www.jnrbm.com/>

³¹ Further details of PLOS ONE is available from: <http://www.plosone.org/>

³² Further information is available from: <http://www.alltrials.net/>

44. We are aware that national and regional regulators, such as the MHRA and US Food and Drugs Administration (FDA), are already in regular communication on the matter of clinical trials transparency. Moreover, the Academy is discussing joint work on this issue with the US Institute of Medicine (IOM), our sister academy in the USA. There is an opportunity for the UK to take an important role in this area through engagement with others at an international, particularly European, level. However, we also understand that there are already many international measures that require the registration of trials and posting of results. It is therefore important to avoid duplication, particularly with UK specific solutions, see paragraphs 6 and 36.
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This response was prepared by Christian Markus Hüber (Medical Science Policy Intern) and Laurie Smith (Medical Science Policy Manager). A draft was considered by Council and the final draft was signed off on their behalf by the President. For further information, please contact Dr Rachel Quinn (rachel.quinn@acmedsci.ac.uk; +44 (0)20 3176 2163).

Declaration of interests

Many of the Academy's Fellows and experts who contributed to this response are involved directly or indirectly with academia, life sciences industries and the NHS. Further details are available upon request.

The Academy of Medical Sciences

The Academy of Medical Sciences promotes advances in medical science and campaigns to ensure these are converted into healthcare benefits for society. Our Fellows are the UK's leading medical scientists from hospitals and general practice, academia, industry and the public service.

The Academy seeks to play a pivotal role in determining the future of medical science in the UK, and the benefits that society will enjoy in years to come. We champion the UK's strengths in medical science, promote careers and capacity building, encourage the implementation of new ideas and solutions – often through novel partnerships – and help to remove barriers to progress.

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