# Regulation and governance of health research: five years on

Summary of a joint workshop held by the Academy of Medical Sciences, Cancer Research UK and the Wellcome Trust – November 2016

The Academy of Medical Sciences

## The Academy of Medical Sciences

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Opinions expressed in this report do not necessarily represent the views of all participants at the event, the Academy of Medical Sciences, or its Fellows.

All web references were accessed in November 2016.

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# Executive summary

On 1 November 2016, the Academy of Medical Sciences, Cancer Research UK and the Wellcome Trust held a FORUM workshop on the 'Regulation and governance of health research: five years on'. This meeting was held as a follow-up to the Academy's 2011 report on 'A new pathway for the regulation and governance of health research', to explore progress in the regulation and governance landscape for health research and any new challenges arising. Participants were drawn from across the life sciences sector to discuss three areas in particular: Health Research Authority (HRA) Approval; regulation of clinical trials; and privacy and data governance. The discussions were considered in the context of the UK's departure from the EU and the potential impact of this on the regulatory landscape.

Key points highlighted by participants over the course of the meeting included:

- Improvements in the **simplification and coordination of NHS research governance** driven through the establishment of the HRA and HRA Approval, with a reduction in timelines for NHS permissions and study set up.
- Importance of striving to **embed a research culture within the NHS**, building on the progress made in improving research delivery timelines.
- Challenges caused by **inflexible interpretation and implementation of guidance** and the **urgent need for more proportionality in application of principles** to overcome risk-averse behaviour across all aspects of health research from study set-up and research approval to inspections and application of ICH guidelines. In addition, the frequent disconnect between those making high-level decisions and those implementing them on the ground.

- The need to **address remaining burdensome or ineffective aspects of trials regulation** including those in the EU Paediatrics Medicine Regulation and a potential review of ICH Good Clinical Practice guidance.
- **The anticipated improvements to the regulatory environment for clinical trials** such as increased proportionality and better coordination across member states enabled by the incoming EU Clinical Trials Regulation. The importance of the UK maintaining harmonisation with the EU system was agreed including continued access to the EU portal and database for clinical trials, whilst considering opportunities for more flexibility in some areas of regulation such as for single state trials.
- Importance of a **whole systems approach to regulation, supported by metrics spanning the entirety of the research pathway** from grant award through to study completion, to promote the UK as a location of choice for research as well as enabling identification of any delays in the pathway.
- **Communication with, and engagement of, patients** in the regulation and governance infrastructure including on relevant bodies overseeing research governance and around use of health data.
- **Access to health data remains a critical barrier.** Some measures have been introduced to facilitate access including the Confidentiality Advisory Group (CAG). However, there remains a need to establish a simplified, transparent infrastructure for health data access and use to build trust and confidence across stakeholders, and to address the overly complex and fragmented data governance landscape that still exists.

# Introduction

In 2010, the Academy of Medical Sciences undertook an independent review of the regulation and governance of health research in the UK. The purpose of the review was to address the increasingly burdensome and complex regulatory framework for health research, with recommendations to transform and streamline this framework to ensure that the UK maintained its outstanding reputation for research.[1]

Five years on from the publication of 'A new pathway for the regulation and governance of health research', the Academy of Medical Sciences, Cancer Research UK and the Wellcome Trust brought together leading figures from across the health research sector to discuss progress with implementing the recommendations of the report and highlight areas where improvements are still needed. New issues which have arisen since 2010 were also identified.

It was agreed that there has been significant progress in improving the regulation and governance of health research in the UK since 2010, but there are still areas where improvements can be made. Several overarching themes emerged during the meeting:

- As the UK prepares to leave the EU, it is important that the regulation and governance environment in the UK continues to support the outstanding research base and enables it to compete at an international level.
- A whole systems approach to regulation and governance, with metrics that capture the whole pathway, is essential to support competitive UK research.

[1] Academy of Medical Sciences (2011). *A new pathway for the regulation and governance of health research.* https://acmedsci.ac.uk/file-download/35208-newpathw.pdf

- There seems to be a disconnect between those making high-level decisions on how regulations should be applied and those implementing them on the ground. This disconnect often leads to decision-making that is overly rigid and risk-averse.
- There is a need to establish systematic routes for patient input into the development and function of regulatory structures.

This report summarises the discussions held at the meeting. The views expressed in this document are the views of the delegates who attended the meeting and are not necessarily the positions of the Academy of Medical Sciences, Cancer Research UK or the Wellcome Trust.

# Health Research Authority Approval

## Establishment of the Health Research Authority

The Health Research Authority (HRA) was established in December 2011, less than a year after the publication of the Academy's report. The HRA has since assumed a number of roles, including:

- Streamlining ethics and other research approvals.
- Incorporating the National Research Ethics Service (NRES) and hosting the Integrated Research Application System (IRAS).
- Developing principles of good practice in the management and conduct of health and social care research (UK Policy Framework) to replace the devolved Research Governance Frameworks.
- Developing compatibility arrangements for UK-wide research.
- Providing advice and decisions on the use of data via the Confidentiality Advisory Group (CAG).

## HRA Approval

HRA Approval is a process for study set-up in the NHS in England that brings together the assessment of governance and legal compliance of studies, undertaken by dedicated HRA staff, with independent Research Ethics Committee (REC) opinion provided through a UK-wide ethics service. It is designed to simplify the overall initial set-up process for studies, eliminate duplicate application and approval routes and speed up study completion, all using fewer resources. For clinical trials, Technical Assurance assessments for pharmacy and radiation review are being tested and are due to be incorporated. In addition, Ethical Approval and clinical trial authorisation from the Medicines and Health Care products Regulatory Agency (MHRA) are currently provided separately but will be incorporated within the single HRA Approval in the future, including all the necessary approvals for trial initiation. If the EU Clinical Trials Regulation is implemented in the UK, there will be further integration to a single application for a single authorisation.

### Introduction

Obtaining NHS permissions was identified as the single greatest barrier to health research and the rate-limiting step for many studies in the Academy's 2011 report, with examples of site activation being delayed by up to a year. The report recommended the establishment of the HRA, and its subsequent creation has allowed a supportive framework for health research to be put in place, including parallel research set-up and a drive towards shorter study set-up times. Delegates strongly supported the development of HRA Approval, which could significantly reduce study set-up time and enhance the UK's attractiveness to organisations deciding where to initiate research and clinical trials. However, the relatively recent roll out of HRA Approval means that it has not yet fully bedded down and there is not yet an evidence base for demonstration of long-term impact. In addition, delegates noted that there remain areas for improvement and an ongoing need to push for culture change, particularly amongst NHS R&D Offices.

### Proportionality and avoiding 'over-implementation'

Delegates highlighted the need to embed proportionality in all aspects of health research regulation. Researchers, HRA assessors, RECs, R&D Officers and sponsors need to understand what constitutes acceptable risks and avoid overly risk-averse behaviour. Principles and guidelines should not be interpreted and implemented as inflexible rules and by definition, principles and guidelines support a degree of discretion in implementation, so long as this can be justified relative to the overall objectives at stake.

It was noted that staff involved in study set-up and management need to feel empowered to make such proportionate decisions and supported in taking a flexible and pragmatic approach where appropriate. There is a broad understanding of the concept and importance of proportionality but so far there is little evidence of this being delivered on the ground. This will require senior staff leading by example to create a supportive culture, including making proportionate regulation an integral part of core business practices and mission statements.

Mechanisms for evidencing that staff are appropriately trained to carry out delegated responsibilities was given as an example of where a more proportionate approach should be explored. Delegates questioned the need to collect CVs/Good Clinical Practice (GCP) certificates under all circumstances. Furthermore, it was argued that generic GCP training is too general and does not equip most staff to be GCP compliant when undertaking their specific roles. It was noted by one delegate, however, that the generic GCP training was introduced for the purpose of reducing the burden of repeated study-specific GCP training.

## A whole systems approach supported by metrics

Participants heard that when making decisions about trial location, industry looks at overall 'recruitment to time and target' data, and so it is vital that these data are readily available and actively promoted. This information is not currently available and participants suggested that addressing this gap should be a priority.

In addition, participants raised concerns that simply measuring study set-up times may encourage delays to be shifted to other parts of the pathway. For instance, in order to meet the '70 days to first patient recruited' benchmark set by NIHR, delegates heard that some applicants are only commencing site activation processes once a patient has been identified. In addition, in order to expedite approval through the HRA, applicants may not be listing all participating sites in the initial application, and only including the most established sites which are most likely to get fast approval. The additional participating sites are then added later as an amendment to the application. Numerous concerns were expressed about the appropriate and timely discharge of responsibilities of upstream actors such as sponsors and R&D offices, where a failure to prepare a study or a research application thoroughly can lead to downstream delays and process blockages.

Therefore there needs to be a whole systems approach to regulation and governance that facilitates research from design through to health improvement delivery, supported by metrics that reflect the whole pathway to make sure that they capture delays that are simply being shifted and subject to 'gaming'. This also ensures that all actors in the system are collectively responsible for the smooth and efficient operation of the system.

## Contracts

Contractual agreements between sponsors and NHS Trusts were highlighted as a continuing and significant cause of delay. Delegates agreed that model contracts are the most streamlined option, and the HRA has been working to bring existing model contracts up-to-date. Delegates acknowledged the time and resource required for their development, and the need for adoption of these contracts by all sites in order to be effective in reducing delays.

## NHS R&D Offices

Significant improvements in NHS R&D Office practices since the publication of the Academy's report were highlighted, but it was noted that further efficiencies could be made. HRA Approval has been designed to remove review and approval burdens, so it is vital that feasibility assessments are completed rapidly with no duplication of review by R&D Offices. Their increasing role as enablers of research as HRA Approval is embedded, was discussed.

Delegates called for harmonising working practices and improving joined-up decision-making between R&D Offices/departments to realise the full benefits of single HRA Approval. Issues with cross-border research causing significant delays were identified. The HRA noted that they are working to resolve this but it will be important for the research community to continue to monitor the situation. One delegate suggested that a system of mutual recognition of approvals could be considered for further investigation.

Delegates also called for clear mechanisms to indicate problems or crisis points during study set-up in order to address delays, including an escalation process to flag significant issues upwards from R&D Offices. It was suggested this could be done through existing NHS management structures.

## Supportive Technology

Participants noted that the central REC review and IRAS systems are strong assets for UK research. It was highlighted that the closure of the NIHR Coordinated System for Gaining NHS Permission (CSP) – frequently used as an online document repository and application sharing tool – with the introduction of HRA Approval has left a critical gap. Delegates heard that the HRA is working to design a new repository to address this issue.

## Suggested next steps

- NHS Trusts and R&D Offices should ensure that staff are trained and supported to make risk-proportionate decisions and avoid overly risk-averse behaviour, with senior managers helping to effect such culture change. A risk proportionate approach should also be encouraged by sponsors.
- HRA should work with funders and sponsors to develop effective end-to-end trial timelines that include metrics which span the whole system and start from the moment of grant award.
- The sector should work together to support the HRA in development and uptake of model contracts and if necessary advocate for the HRA to receive additional resource to complete this vital task.
- NHS Trusts should ensure that R&D Offices are not duplicating the review carried out under HRA Approval.
- R&D Offices should work with the HRA to establish clear escalation pathways for researchers so that delayed studies can be expedited.
- The HRA should establish a centralised repository for documents such as NHS staff CVs, GCP certificates and other standard documentation necessary for study set-up.

# Regulation of clinical trials

## Clinical Trials Regulation

The new Clinical Trials Regulation (CTR) will come into operation in 2018, offering the opportunity to overcome some of the significant past challenges with the EU Clinical Trials Directive 2001/20/EC including:

- Application across all member states so that there are no separate national requirements, addressing the issue posed by divergent application of the Directive in member states.
- Simplification of application and approval procedures such as a single EU portal and database for submission, and co-ordinated assessment for multi-state trials. This will decrease the administrative burden for clinical trials and support transparency.
- Taking into consideration, and providing further clarity on, a more proportionate risk-based approach to trial authorisation and management which again will help to alleviate unnecessary administrative burden for low risk trials.

The UK will start processes for operating under the CTR up until departure from the EU, with associated costs for implementing these changes borne by key stakeholders including, industry, academia and regulators. EU initiatives have been established to increase guidance on, and harmonisation of, transposition. At the UK level, the MHRA has played an active role in shaping EU legislation and there have been multiple UK initiatives to improve the clinical trials landscape

including legislation for trials in emergency settings; improved reporting of suspected unexpected serious adverse reactions; and guidance on proportionality including adoption of a risk-based approach to trials and implementation of GCP requirements.

## Regulation of paediatric research

The EU Paediatric Medicines Regulation has not yet supported delivery of innovation in paediatric disease. Whilst it was intended to ensure that all drugs are considered for paediatric use and that trial data is subsequently generated for those of relevance, class waivers or delays with paediatric investigation plans have most often prevented this from occurring. The EMA has now revised the class waiver list so that more drugs will be considered for paediatric disease. However, there are still challenges to encouraging paediatric investigation if the licenced indication does not exist in children, even though the same drug target, and thus drug, could be involved in a different childhood disease. It has been proposed that regulation should be improved by basing it on drug mechanism rather than the disease, alongside the need to reduce delays in submission of paediatric investigation plans and better incentivise paediatric drug development.

## Introduction

The Academy's 2011 report recommended that the EU Clinical Trials Directive be revised to address some of the significant barriers to conducting clinical trials. The incoming CTR will help to overcome many of these challenges. For example, delegates recognised the benefit of improved consistency across member states and the valuable opportunity to extend this coordinated approach internationally in the future. It was noted that the UK played a prominent role in the CTR negotiations and many of the changes that will be brought in by the new Regulation have already been implemented at the national level.

In addition, as recommended in the 2011 report, an increasingly risk-adaptive approach to trials has been taken. Delegates emphasised the importance of continuing to enhance proportionality in low risk interventional trials and observational studies. The effectiveness of flexible regulatory processes such as the Early Access to Medicines Scheme was also described.[2] However, there are some emerging challenges that need to be addressed to continue to maintain a leading UK environment for clinical trials.

## The clinical trials landscape following the UK's exit from the EU

For global organisations, ensuring that the UK is included in multi-state trials is essential, particularly with the shift towards a more international approach to research and development. Delegates agreed that UK must find a mechanism to ensure harmonisation with the EU system, including maintaining access to the EU portal and database which will form the gateway to harmonised electronic submission and assessment processes for multi-state trials.

Whilst harmonisation with CTR is critical, it was suggested there may be a potential opportunity for the UK by diverging from EU regulation in specific areas, such as more flexibility for single state trials sited in the UK. It was also suggested that the UK could lead on addressing some of the more burdensome requirements in the CTR where appropriate. For example, one delegate argued that the Annual Safety Report, which mandates data collection on off-label use of drugs, could impede important safety signals and should be reviewed. However, others called for careful

[2] www.gov.uk/government/publications/early-access-to-medicines-scheme-eams-how-the-scheme-works

consideration of the opportunity cost of implementing different requirements for UK trials as any benefit could be offset by the difficulties companies might face in navigating different regulations in the EU and the UK. Finally, delegates highlighted the importance of the UK maintaining a strong national regulator for clinical trials in the form of the MHRA.

## ICH guidance

Delegates discussed The International Conference for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use's (ICH) Guidance on Good Clinical Practice (specifically ICH GCP E6) for multi-state clinical trials. They noted that, importantly, ICH GCP is intended as guiding principles and is not mandatory – adherence to the 12 broad-based GCP principles is expected but there is flexibility in the interpretation of the detailed guidance.[3]

Some participants suggested that ICH GCP E6 fails to address some key aspects of trials such as source data verification, 'intention-to-treat', and the role of data monitoring committees in safety monitoring. In addition to missing key areas, the guidance was described as lengthy and confusing in places. This has led to variation in interpretation and unnecessary administrative burden such as over-reporting of safety data. Despite recent amendments, the guidance was not thought to be fit-for-purpose and some attendees called for a complete review and update of the current guidance. One delegate proposed the Clinical Trials Transformation Initiative as a possible exemplar for driving practices to enhance the quality and efficiency of clinical trials. [4]

It was agreed that at a governance level, there is a need to include academic and patient representation on ICH so that all key stakeholders are involved in development of the guidance. It was suggested that this would also help to address some of the issues surrounding the interpretation of ICH guidance.

## GCP inspections

GCP inspections need to be seen as constructive rather than a strongly prescriptive check of compliance, and although this is the stated position of the MHRA, delegates noted that it does not seem to be effectively understood at the grass-roots level. Participants highlighted the overly strict adherence of GCP inspectors and sponsors to GCP guidelines which leads to over-interpretation of guidance by Clinical Trial Units (CTUs) and research sites. It was also noted that whilst positive findings are communicated to senior staff at the close of inspections, GCP inspection reports only list negative findings. As these reports form the enduring record after an inspection, sites are not encouraged to adopt risk proportionate approaches.

## Engaging patients in clinical trials

There was strong recognition of the importance of a patient-centric approach to trials, with the need to drive an understanding of the factors and measurable outcomes that are important to patients before a trial is carried out. In addition, patient involvement in clinical trials has greatly improved over recent years with lay representatives now participating on various MHRA groups and with better outreach to charities. The HRA's effective processes for engagement and involvement of patients could be used as an exemplar for this wider patient involvement in trials. Finally, it was argued that patient groups should be central to invoking change in regulation, and the US was described as a model for success in delivering patient-focused regulation.

[3] The MHRA has produced a guidance document on interpretation and implementation of GCP and has established a GCP forum for sharing of best practice.
[4] www.ctti-clinicaltrials.org/

## Suggested next steps

- The UK should maintain and support a strong national regulator for clinical trials.
- In preparing for the UK's exit from the EU, the MHRA, HRA and other stakeholders in the UK health research ecosystem must prioritise continued harmonisation/compatibility with the EU regulatory/clinical trials system and access to the EU portal and database.
- The potential for establishing further regulatory flexibility for single state trials in the UK should be explored, whilst continuing to ensure compatibility with EU regulation.
- Clear communication is needed from regulators on how ICH guidelines should be implemented – including highlighting that these are not a legal requirement – to ensure that they are not over-interpreted. R&D offices to also ensure that staff are aware of these expectations.
- There should be academic and patient representation/input on the ICH and its separate working groups, and increased transparency around production of ICH guidelines and ICH decision-making processes.
- MHRA, funders, and CTUs to work together to promote a culture of constructive criticism and develop a mechanism for recognition of good practice during GCP inspections.
- Patient involvement or input in clinical trials and associated regulation should be ensured where possible.

# Patient data for health research

## Data Protection Regulation

A new EU General Data Protection Regulation (GDPR), which supersedes the EU Directive and associated UK Data Protection Act, takes effect in May 2018. In October 2016, the Government confirmed that they expect the Regulation to be implemented in the UK and to take effect before the UK leaves the EU. They will *'then look later at how best we might be able to help British business with data protection while maintaining high levels of protection for members of the public'.*

## Duty of Confidentiality

The common law duty of confidentiality is based on legal precedents from court cases rather than legislation. It prevents those who are given information from disclosing that information without the information provider's consent, in circumstances where it is expected that a duty of confidence applies. In England and Wales, Section 251 of the NHS Act 2006 allows the Secretary of State for Health to make regulations to set aside the common law duty of confidentiality for

defined medical purposes.[5] Scotland has a similar public interest-based approach, not based in statute.

The HRA took on responsibility for Section 251 in April 2013, and established the Confidentiality Advisory Group (CAG) function. CAG provides review and advice on research proposals seeking to access confidential patient information, as well as training and guidance for applicants to simplify the procedure for applying for Section 251 support. The Care Act 2014 also gave CAG a new role of advising NHS Digital on data disclosure. This has required CAG membership to be expanded, but it still acts as a single committee to promote consistency.

## NHS data governance

Following concerns about the governance of the Health and Social Care Information Centre (HSCIC now NHS Digital) there have been two reviews led by Dame Fiona Caldicott the National Data Guardian. The first report promoted the idea that the duty to share patient data was as important as patient confidentiality.[6] Following public concerns about NHS England's care.data programme – which was later cancelled – the second report in 2016 focused on data security and opt-outs to the use of patient data.[7] This report proposed new security standards to be followed by all organisations using health and social care data, and a new opt-out model for patients if they object to their identifiable data being used.

### Introduction

In the Academy's 2011 report, regulation and governance of access to patient data was identified as overly complex, with challenging legal frameworks and multiple organisations involved in data release. As a result, there has been a lack of clarity for patients and the public, and researchers have been unable to access data in a timely manner. Five years on from the report, delegates stressed the need for a joined up, coherent approach between those implementing the new GDPR, the CAG and NHS Digital.

Some measures that have already been undertaken to facilitate data access for research were highlighted. Delegates heard how the Information Commissioner's Office (ICO) – the UK data regulator – recognises the importance of *'safe and useable'* data being made available for research. The ICO has taken a facilitative approach, for example by publishing the Anonymisation Code of Practice which provides lay explanations of the legal issues and a practical guide for fulfilling the obligations created by the Data Protection Act with regards to anonymisation.[8]

Delegates also discussed how CAG has an important enabling role as it facilitates the use of data for research that would not otherwise be permitted. CAG has a strong lay membership, which is particularly important for ensuring that decisions on use of data are likely to be acceptable to, and will resonate with, patients. Participants agreed CAG should receive recognition for the progress it has made in facilitating access to confidential patient information in a structured way that can be explained to the public.

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[5] www.hra.nhs.uk/about-the-hra/our-committees/section-251/
[6] www.gov.uk/government/uploads/system/uploads/attachment_data/file/192572/2900774_InfoGovernance_accv2.pdf
[7] www.gov.uk/government/uploads/system/uploads/attachment_data/file/535024/data-security-review.PDF
[8] Information Commissioner's Office (2012). *Anonymisation: managing data protection risk code of practice.* https://ico.org.uk/media/for-organisations/documents/1061/anonymisation-code.pdf

## Data protection law

Delegates discussed how implementation of the new EU GDPR in the UK provides an important opportunity to simplify the legal framework for research and clarify the relationship between data protection legislation, common law duty of confidentiality and NHS data governance. Currently, this is a challenge and causing confusion for those holding datasets as well as patients.

## NHS data governance

Some delegates raised concerns about the opt-out approach proposed in the most recent review by the National Data Guardian, as it was noted that some GP practices have had high opt-out rates which could compromise the accuracy and validity of research. However, others noted that at present, this offers the only viable option given the low levels of patient trust around data sharing. Attendees therefore agreed on the importance of an opt-out approach that is appropriately implemented and a coordinated approach to building public and GP trust, as discussed below.

Attendees also highlighted how, following concerns about the release of data from the HSCIC (now NHS Digital), release of data held by HSCIC was stopped which impacted research. Data flows have now resumed but delegates noted ongoing issues such as the requirement for annual approvals, timely release of data on deaths, and difficulties in onward sharing of research outputs. Researchers were encouraged to inform funders of any problems encountered so they could continue to feed back issues to NHS Digital. Delegates heard that in Scotland, the Scottish Health Informatics Programme has developed a decision-making tool to support risk management in data sharing and address risk aversion.[9]

## Transparency and accountability

Data protection legislation and CAG approval provide important legal alternatives to consent. However, there are legal and ethical obligations for transparency around data use. Trust in the storage, access and management of data is essential to support its use. However, the failure around care.data reduced public trust in the use of patient data.

Delegates discussed how transparency and accountability around use of NHS patient data in research needs to be improved, with clear new NHS data governance arrangements to support this. Where individuals do not have control over how their data is used, it was thought to be crucial that there are robust arguments to support this approach and clear justification of use of this data in terms of public benefit. Patient involvement in governance mechanisms was discussed as one approach to provide assurance to individuals, for example in holding researchers to account in justifying data use and meeting public interest requirements. CAG has successfully used this model and some called for this to be adopted in other governance mechanisms, such as NHS Digital's advisory group, the Independent Group Advising on the Release of Data.

## Communication and engagement

The Academy's 2011 report recommended improving communication on the use of patient data, reflecting similar recommendations dating back to 2005, but delegates noted that limited progress has been made. Generally, studies show that the more information people have on the use of their data, the more accepting they are of its use.[10] With reduced levels of trust, it is more important than ever that communication is clear to ensure that patients can make informed choices.

Delegates discussed the need to inform patients on what type of data is being collected and shared, from whole records through to aggregated statistics, for purposes beyond individual care. There should be communication on the purpose, benefits and risks of using the data and the safeguards in place in an accessible and meaningful way. New

[9] www.scot-ship.ac.uk/
[10] Academy of Medical Sciences (2005). *Personal data for public good: using health information in medical research.* https://acmedsci.ac.uk/file-download/34792-Personal.pdf

approaches to communicate complex data processes/terms such as identifiability, pseudonymisation and anonymisation in ways that are meaningful to patients and the public must be found.

Participants noted the new Understanding Patient Data initiative, supported by Wellcome, the Medical Research Council, the Economic and Social Research Council, the Department of Health, Public Health England and the Academy of Medical Sciences. It aims to improve open and honest communication about the use of data by developing tools such as case studies and descriptions of what different types of data look like, and adopting clear, consistent language to talk about data.

## Suggested next steps

- The research community and patient groups should be given an opportunity to input towards Government's plans for implementation of the GDPR, in order to ensure that it is implemented effectively.
- With the implementation of the GDPR, Government should use this opportunity to further simplify and provide clarification on the data governance landscape.
- NHS Digital should continue to work with stakeholders to address concerns about data flows
- Clarity is needed on the implementation of the new opt-outs (and what will happen to existing opt-outs for patients) that will be proposed in response to the Caldicott Review, and Government needs to work with all stakeholders including the research community on implementation and delivery of these opt-outs.
- All stakeholders must recognise the importance of building and maintaining public trust in the use of patient data, and support this wherever possible. The Understanding Patient Data initiative is working to develop tools and resources to support this.

# Annex 1: Participant list

Chairs and speakers
**Dr David Gillen (co-chair)**, Vice President, Vertex Pharmaceuticals
**Professor Peter Johnson FMedSci (co-chair)**, Chief Clinician at Cancer Research UK and Chair of Medical Oncology, University of Southampton
**Professor Graham Laurie FRSE FMedSci (co-chair)**, Professor of Medical Jurisprudence, University of Edinburgh
**Mr Iain Bourne**, Group Manager, Information Commissioner's Office
**Professor Peter Brocklehurst FMedSci**, Professor of Women's Health and Director, Birmingham Clinical Trials Unit, University of Birmingham
**Professor Sir Rory Collins FRS FMedSci**, BHF Professor of Medicine and Epidemiology, University of Oxford
**Dr Ian Hudson**, Chief Executive, Medicines and Healthcare Products Regulatory Agency
**Dr David Jefferys**, Senior Vice President Global Regulatory Affairs, Eisai
**Professor Pamela Kearns**, Director of the Cancer Research UK Clinical Trials Unit, University of Birmingham
**Professor Sir Robert Lechler PMedSci**, President, Academy of Medical Sciences
**Dr Janet Messer**, Director of Research Systems, Standards and HRA Approval Programme, Health Research Authority
**Ms Nicola Perrin**, Head, Patient Data Taskforce
**Dr Jonathan Sheffield OBE**, Chief Executive, NIHR Clinical Research Network
**Mr Richard Stephens**, Consumer Lead, National Cancer Research Institute
**Dr Mark Taylor**, Chair, HRA Confidentiality Advisory Group
**Dr Birgit Whitman**, Head of Research and Governance, University of Bristol

Participants
**Dr Christiane Abouzeid**, Head of Regulatory Affairs, BioIndustry Association
**Ms Aisling Burnand**, Chief Executive, Association of Medical Research Charities
**Mr Richard Carter**, Deputy Director, Research Standards and Support, Department of Health
**Dr Adrienne Clarke**, Head of Monitoring, GlaxoSmithKline
**Dr Elizabeth Coates**, Head of Research Governance, Public Health England
**Mr Gary Coleman**, Head of Data Management Services, NHS Digital
**Professor Jack Cuzick FRS FMedSci**, Director Wolfson Institute of Preventive Medicine, Queen Mary University of London
**Mr Simon Denegri**, Chair, INVOLVE
**Dr Allison Jeynes Ellis**, Non-Executive Director, Health Research Authority
**Professor Stephen Evans**, Professor of Pharmacoepidemiology, London School of Hygiene and Tropical Medicine
**Ms Steph Garfield-Birkbeck**, Assistant Director, NIHR Evaluation Trials and Studies Coordinating Centre, NIHR
**Ms Emma Greenwood**, Head of Policy Development, Cancer Research UK
**Ms Christine Holmes**, Member, HRA sponsor team, Department of Health
**Ms Heather House**, Head of Clinical Trials and Research Governance, University of Oxford
**Ms Lindsey Hughes**, Senior Manager, Research and Innovation Unit, NHS England
**Professor Margaret Johnson**, Academic Vice President, Royal College of Physicians
**Professor Kay-Tee Khaw FMedSci**, Professor of Clinical Gerontology, University of Cambridge
**Dr Rosie Lovett**, Technical Adviser, National Institute for Health and Care Excellence
**Dr Stephen Mak**, Information Governance Manager, Clinical Practice Research Datalink
**Dr Natasha McCarthy**, Head of Policy, Data, Royal Society
**Ms Christine McGrath**, Director of Research and Development, University Hospital Southampton NHS Foundation Trust
**Dr Clare Morgan**, Research Delivery Director, NIHR Clinical Research Network
**Dr Martin O'Kane**, Head of Clinical Trials Unit, Medicines and Healthcare Products Regulatory Agency
**Dr Maria Palmer**, Director, NHS Research and Development Forum
**Mr Colin Pavelin**, Head of Regenerative Medicine and Rare Diseases Policy, Department of Health
**Dr Sheuli Porkess**, Chair, ABPI Medical Expert Network and Medical Director Northern Europe, Almirall
**Professor Sir Michael Rawlins FMedSci**, Chair, Medicines and Healthcare Products Regulatory Agency
**Mr Justin Riordan-Jones**, Deputy Director, Research Information and Intelligence, NHS Digital

**Professor Sir Nilesh Samani FMedSci**, Medical Director, British Heart Foundation
**Mr Jonathan Sellors**, Legal Counsel, UK Biobank
**Ms Trudi Simmons**, Senior Manager Research Finance and Programmes, Department of Health
**Dr Jacintha Sivarajah**, Head of Medical Affairs, Association of the British Pharmaceutical Industry
**Dr Rachael Smith**, Programme Manager (Training and Partnerships), MRC Regulatory Support Centre
**Dr Tim Sprosen**, Associate Professor and Head of Communications, Regulation and Knowledge Transfer, University of Oxford
**Professor Paul Stuart FMedSci**, Dean of Medicine, University of Leeds
**Professor Nalin Thakker**, Board Member, Health Research Authority
**Dr Peter Thompson**, Chief Executive, Human Fertilisation and Embryology Authority
**Dr Martyn Ward**, Group Manager in Licensing Division, Medicines and Healthcare Products Regulatory Agency
**Professor Sir Simon Wessely FMedSci**, Head of the Department of Psychological Medicine and Vice Dean for Academic Psychiatry, King's College London
**Ms Elaine Williams**, Director of Research Delivery and Impact, NIHR Evaluation Trials and Studies Coordinating Centre
**Professor Ian Young**, Chief Scientific Advisor, Department of Health Northern Ireland
**Professor Maria Zambon FMedSci**, Director, Reference Microbiology Services, Public Health England

**Secretariat**
**Dr Edward Blandford**, Policy Advisor, Cancer Research UK
**Dr Ben Bleasdale**, Policy Officer, Academy of Medical Sciences
**Ms Liberty Dixon**, Policy Officer, Academy of Medical Sciences
**Ms Katharine Fox**, Policy Intern, Academy of Medical Sciences
**Dr Beth Thompson**, Senior Policy Adviser, Wellcome
**Dr Naho Yamazaki**, Head of Policy, Academy of Medical Sciences

# Annex 2: Agenda

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|---|---|
| 09.00-09.30 | **Registration with refreshments** |
| 09.30-09.50 | **Welcome and introduction**<br>Professor Sir Robert Lechler PMedSci, President, Academy of Medical Sciences |
| 09.50-10.00 | **Patient perspective on health research**<br>Richard Stephens, Consumer Lead, National Cancer Research Institute |
| 10.00-10.10 | **NHS culture for health research**<br>Dr Jonathan Sheffield OBE, Chief Executive, NIHR Clinical Research Network |
| **Regulation of clinical trials**<br>Chair: Professor Peter Johnson FMedSci, Professor of Medical Oncology, University of Southampton | |
| 10.10-10.25 | **MHRA perspective, including implementation of the Clinical Trials Regulation**<br>Dr Ian Hudson, Chief Executive, Medicines and Healthcare Products Regulatory Agency |
| 10.25-10.35 | **Researcher view – academic perspective**<br>Professor Sir Rory Collins FRS FMedSci, BHF Professor of Medicine and Epidemiology, University of Oxford |
| 10.35-10.45 | **Researcher view – industry perspective**<br>Dr David Jefferys, Senior Vice President Global Regulatory Affairs, Eisai |
| 10.45-10.55 | **Paediatric research – opportunity to review EU legislation**<br>Professor Pamela Kearns, Director of the Cancer Research UK Clinical Trials Unit, University of Birmingham |
| 10.55-12:00 | **Panel discussion** |
| 12.00-13.00 | **Lunch** |
| **HRA single approval: Ethics and NHS approvals**<br>Chair: Professor Graeme Laurie FRSE FMedSci, Chair of Medical Jurisprudence, University of Edinburgh | |
| 13.00-13.15 | **HRA perspective**<br>Professor Jonathan Montgomery, Chair, Health Research Authority |
| 13.15-13.25 | **Sponsor perspective (HEI)**<br>Dr Birgit Whitman, Head of Research Governance, University of Bristol |
| 13.25-13.35 | **Clinical trials unit perspective**<br>Professor Peter Brocklehurst FMedSci, Professor of Women's Health and Director, Birmingham Clinical Trials Unit, University of Birmingham |
| 13.35-14.40 | **Panel discussion** |
| 14.40-15.00 | **Refreshments** |
| **Privacy and data governance**<br>Chair: Dr David Gillen, Vice President, Vertex Pharmaceuticals | |
| 15.00-15.15 | **The future relevance of information rights law in health research**<br>Iain Bourne, Group Manager, Information Commissioner's Office |
| 15.15-15.25 | **Confidentiality Advisory Group**<br>Dr Mark Taylor, Chair, HRA Confidentiality Advisory Group |
| 15.25-15.35 | **Patient data task force**<br>Nicola Perrin, Head, Patient Data Taskforce |
| 15.35-16.40 | **Panel discussion**<br>Speakers and Professor Graeme Laurie FRSE FMedSci, Chair of Medical Jurisprudence, University of Edinburgh |
| 16.40 | **Close** |


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