# Open research for clinical trials and public health interventions

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*5 September 2023*

# Medical Research Council's mission is to:

- encourage and support research to improve human health

- produce skilled researchers

- advance and disseminate knowledge and technology to improve the quality of life and economic competitiveness of the UK

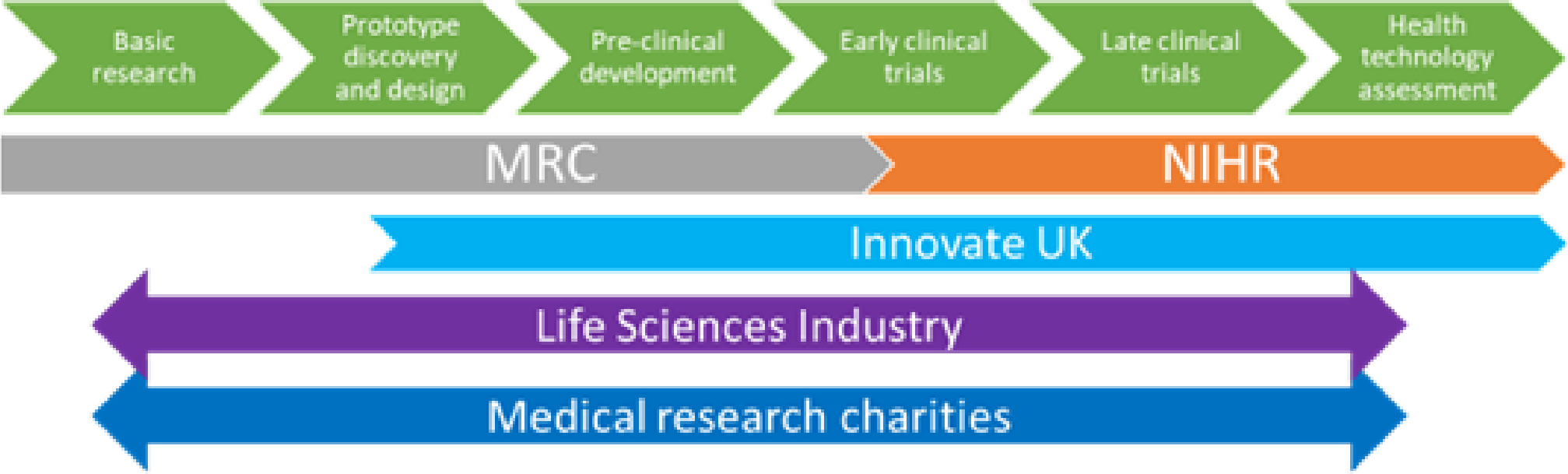- promote dialogue with the public about medical research.



Higher Education and Research Act 2017

CHAPTER 29

Explanatory Notes have been produced to assist in the understanding of this Act and are available separately

£23.25

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# Medical research funding in the UK



Source: MRC

# Open science in political context



**1. Respect for freedom and inclusiveness in scientific research and promotion of open science**

The G7 will collaborate in expanding open science with equitable dissemination of scientific knowledge and publicly funded research outputs including research data and scholarly publications in line with the Findable, Accessible, Interoperable, and Reusable (FAIR) principles. This is so that researchers and people throughout the world can benefit from them as well as contribute to the creation of new knowledge, stimulation of innovation, democratization of access to knowledge by society and the development of solutions for global challenges. This will also help to build more reproducible and trusted research results.

**UNESCO Recommendation on Open Science**

Recommendation of the Council concerning Access to Research Data from Public Funding

**OECD Legal Instruments**

# Not quite going according to plan…



U.S. Department of Health and Human Services
**Office of Inspector General**

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Copies can also be obtained by contacting the Office of Public Affairs.

## The National Institutes of Health Did Not Ensure That All Clinical Trial Results Were Reported in Accordance With Federal Requirements

08-12-2022 | A-06-21-07000 | Complete Report | Report in Brief



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## Most scientists 'can't replicate studies by their peers'

By Tom Feilden
Science correspondent, Today programme

22 February 2017

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# Fake news and distrust of science could lead to global epidemics

Distrust in scientific expertise puts public health at risk

Wired: January 2018

Medical Research Council



UK Parliament

## Committees

UK Parliament > Business > Committees > Science and Technology Committee (Commons) > News Article

## Failing to publish data from clinical trials presents risk to human health

30 October 2018

# Open science in focus in 2023
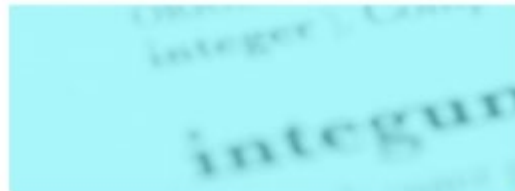


UK Parliament

## Committees

UK Parliament > Business > Committees > Science, Innovation and Technology Committee > Reprodu

## Reproducibility and research integrity

Inquiry

allea

**The European Code of Conduct for Research Integrity**

REVISED EDITION 2023

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Administration    Priori

The Biden-Harris Administration ha... ...en bold steps to advance the principles of open research and open government. In January 2021, the President affirmed the Administration's commitment to evidence-based decision-making, guided by the best available science and data. This laid the foundation for OSTP's updated policy guidance, *Ensuring Free, Immediate, and Equitable Access to Federally Funded Research*, to increase public access to federally funded research, foster greater collaboration and innovation, and strengthen public trust.
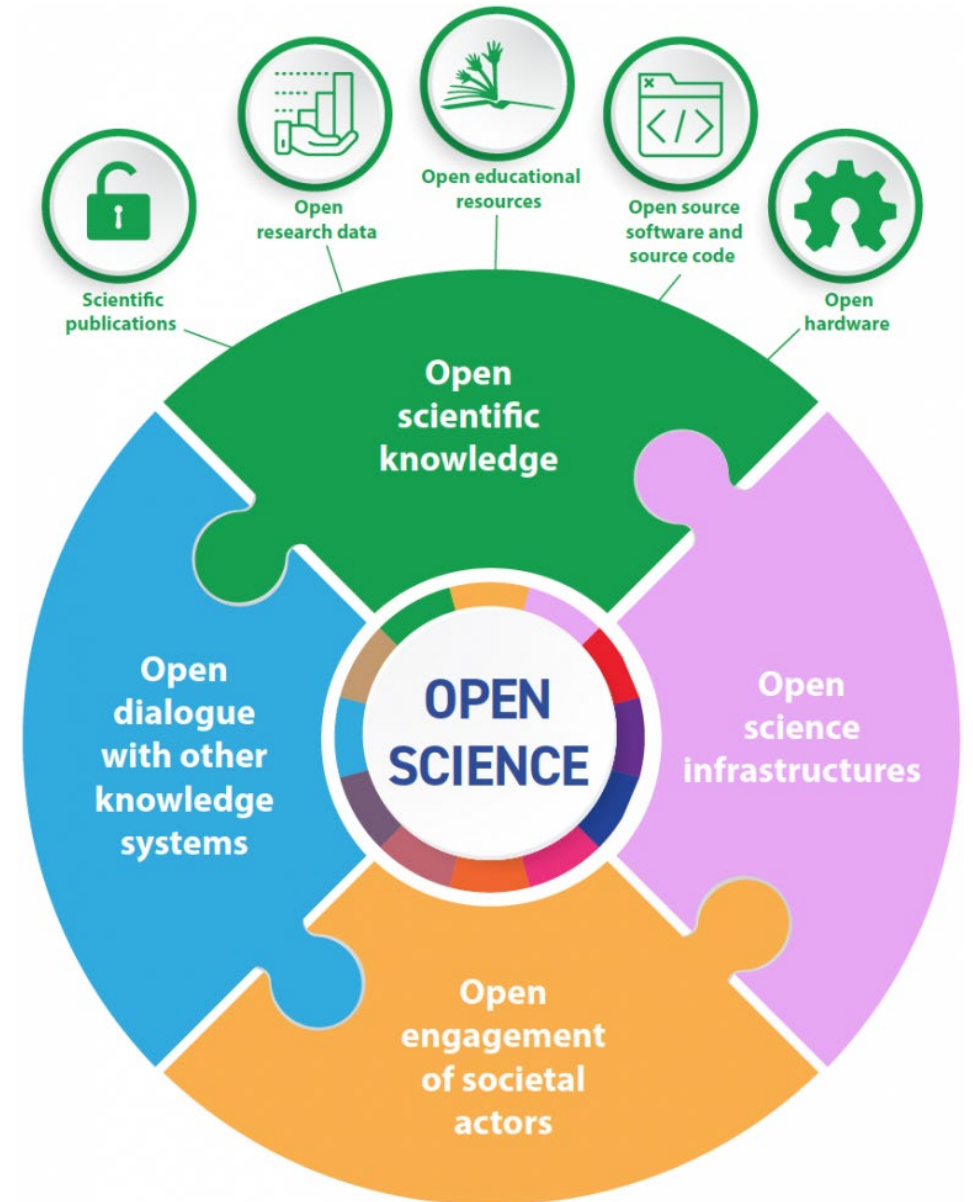
**The Administration's actions include:**

- **OSTP** and **the National Science and Technology Council (NSTC)** today released an official definition of open science for use across the U.S. government: *"The principle and practice of making research products and processes available to all, while respecting diverse cultures, maintaining security and privacy, and fostering collaborations, reproducibility, and equity."* A unified, official definition will galvanize federal efforts, promote interagency collaboration, and drive progress.
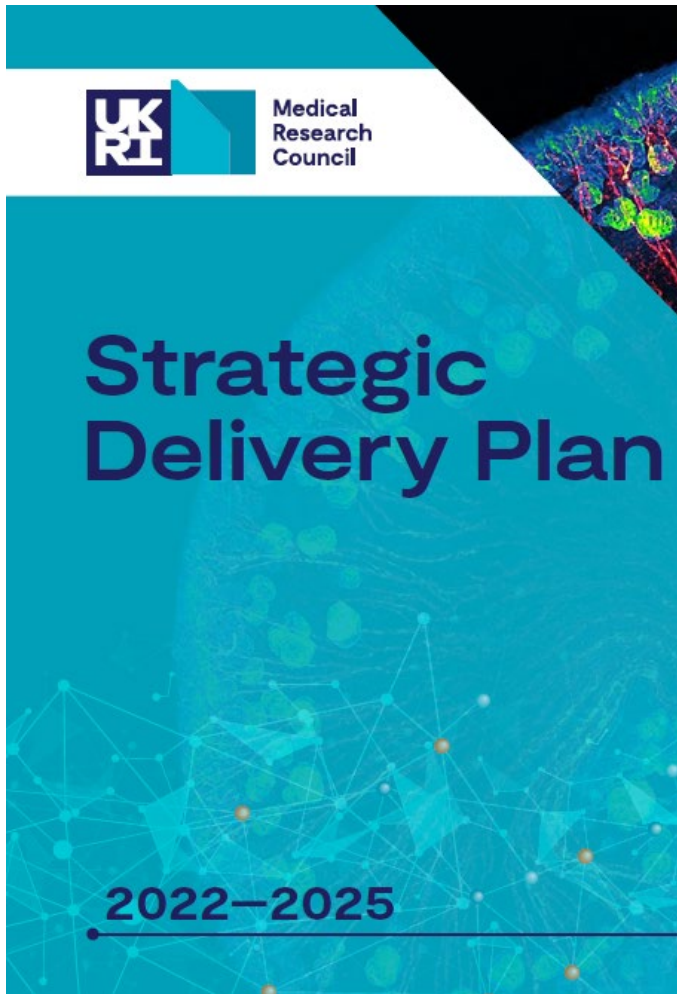
# Open science to support positive research culture

Open access to journal article not enough, must go beyond

- Preprint
- Data
- Code
- Protocols
- Methods
- …

# What can funders do?



Strategic Delivery Plan 2022–2025 — Medical Research Council (UKRI)

**1.2: Advance an open and collaborative research and innovation culture**

## 1.2: Advance an open and collaborative research and innovation culture

Our ambitions can only be realised with a research culture that drives reproducible, ethical, and high-quality research and innovation, and involves and benefits people from diverse backgrounds. We will strengthen our efforts to build a culture within MRC and its research community where equitable and inclusive public and patient involvement and engagement is an integral part of research. We aim to embed diversity and inclusivity in research design, strengthen open science practices, and ensure the highest ethical standards. In all of these, we will build on and inform UKRI-wide research culture frameworks and strategies, in the context of biomedical health research, and work with a range of partners and research communities.

**We will:**

- review current MRC and wider public involvement and engagement activities and use the outcomes to develop an MRC strategy that sets out clear principles, expectations, and good practice for public involvement and engagement in biomedical research, within the wider framework of the forthcoming UKRI Public Engagement Strategy.

- evolve our existing policies and incentives to promote all aspects of open science, initially focussing on Data Management Plans to support the implementation of FAIR (Findable, Accessible, Interoperable and Re-usable) data principles, and Data Access Statements in publications.

- consult with the research community, and work in partnership across funders and other stakeholders to develop new policy and guidance on increasing diversity in research design involving human participants and embedding greater consideration of sex in experimental design of animal and in vitro studies.

- work with partners to horizon-scan the ethical challenges of tomorrow. Expand our work with regulators and continue to review and evolve

our ethical policies, guidance, and support for researchers, including the work of the MRC Regulatory Support Centre, and contributing to the development of a multi-disciplinary UKRI Good Research Resource Hub.

- recognise the impacts of those who are leading advancements in open science, team science and early career researchers who are pioneering approaches to improve research culture, through new annual prizes.

### Achieving diversity in data science careers

The Health Data Science Black Internship Programme has increased opportunities for Black early career data scientists, with many of the interns from the original intake in 2021 securing short-term or permanent jobs, or joining doctoral programmes across the UK. It has also positively impacted gender diversity: 30 of the 48 interns in 2021 were women, and this trend has been echoed in 2022. Led and delivered by Health Data Research UK and the UK Health Data Research alliance, in partnership with the 10,000 Black Interns initiative, the programme used a short questionnaire, rather than a traditional CV, to screen the candidates in a blind manner. This skills-based approach has now been rolled out to wider recruitment within Health Data Research UK to increase ethnic and gender diversity in data science.

**Case studies**

10

# What can funders do? (2)

**UK Research and Innovation**

## UKRI Open Access Policy

**Contents:**
Policy scope
Requirements for research articles
Requirements for long-form publications
Monitoring and compliance
Open access funding
Further information
Additional information on policy definitions and scope – Annex 1
Technical requirements for research articles – Annex 2
Guidance for authors on using policy exemptions for long-form monographs, book chapters and edited collections – Annex 3
Glossary
Version Control

## Preprints

The Medical Research Council (MRC) requires that the results of the research it funds are published, ideally in peer-reviewed journals; also that all such articles, whether published in an open access or subscription-based journal, must be archived in Europe PubMed Central (Europe PMC) and made freely available as soon as possible, and in any event within six months of the first online publication.

MRC is now also actively encouraging researchers to share their pre-peer reviewed manuscripts via established preprint servers. To this end, we are allowing researchers to cite preprints in their grant and fellowship applications.

**UKRI Medical Research Council**

# Data management and sharing

## Policy

- **MRC data sharing policy**
- **MRC policy and guidance on sharing of research data from population and patient studies**
- **MRC policy on open research data from clinical trials and public health intervention studies**
- **UKRI data sharing principles (including Concordat on Open Research Data)**

## Guidance for researchers

Good practice principles for sharing individual participant data from publicly funded clinical trials:

- **data management plans, guidance for applicant**
- **data management plan template**
- **data management plan, FAQs and guidance**
- **data management plan, guidance to reviewers (p.10)**
- **UKRI guidance on best practice in the management of research data**
- **supporting research data management through grant funding**
- **MRC good research practice guidance**, section B, data: management, integrity, retention and preservation (pp. 9-12)

# MRC data sharing policy

"Data must be made available with as few restrictions as possible, to maximise the value of the data, improve research reproducibility and for patient and public benefit. Data must be shared in a timely and responsible manner and in line with relevant legal, policy and ethical standards, including when operating internationally. "

*Chronology*

- 2005 1st Data sharing policy

- 2012 MRC guidance on sharing research data from population and patient studies

- 2016 MRC policy on open research data: clinical trials and public health intervention studies

- 2016 Concordat on Open Research Data

- 2023 (TBC) refresh data sharing policy and guidance

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# Human participants & data sharing

## To consider

- Ethical concerns & consent

- Data protection legislation – international research

- Public trust

## To enable

- Sharing data from research can enhance the use of existing data, avoid duplication of research effort and stimulate new discoveries



Credit: National Institute of Allergy and Infectious Diseases, NIH  Public Domain Mark 1.0

# Specific Policies & Guidance

## Good practice principles for sharing individual participant data from publicly funded clinical trials (2015)

- Data sharing models – open vs controlled

- How to design study following good data management principles throughout

- What to include in a study-level data sharing policy

- List of 28 potential patient identifiers in datasets

- Example Anonymisation Standards

## Policy on Open Research Data from Clinical Trials and Public Health Intervention Studies (2016)

- Registration of Clinical and Public Health Intervention Studies

- Publishing the Study Protocol and Statistical Analysis

- Publishing Study Results

- Data Sharing and Transparency: Individual Participant Data

- Secondary Use of Data

- Yearly monitoring process and follow-up

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# Specific infrastructure

## Controlled access data vs open data

- FAIR – Findable, Accessible, Interoperable, Re-usable,

- Trusted Research Environments

Health Data Research
Innovation Gateway

MRC Medical Research Council

Regulatory Support Centre

**Identifiability, anonymisation and pseudonymisation**

**Guidance note 5**
This guidance was developed with the participation of the Information Commissioner's Office.

Dementias Platform UK

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Research hub / Accessing the Data Portal

## Accessing the Data Portal

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# From public health emergency to common practice

## UKRI Additonal Terms and Conditions for Covid-19 rapid response calls

- requirement to publish research finding in preprint as soon as possible and before publishing in journals

- when publishing in journals, must make openly available at the time of publication with CCBY licence

- all submissions (to platforms, preprint servers and journals) must include clear statements regarding the availability of underlying data and/or software/code

- interim and final data is shared as rapidly and openly as possible – as soon as it is appropriately quality assured, in line with any ethics requirements, disciplinary good practice and irrespective of the timing of journal publication.

- Software, analysis scripts or modelling codes are shared as rapidly and openly as possible.

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# Role of medical librarians – key complementary skills

## Supporting positive research culture

- Facilitate access to and implementation of policies and guidance – opportunity to work with funders

- Provide training and advice, as well as being embedding in teams

- Develop and maintain infrastructures

- Evaluation of platforms and data repositories – trusted advisor

- Representing users needs in negotiation with publishers –increasingly moving into data management

- FAIR (Findable, Accessible, Interoperable, Reusable)

➢ Metadata, catalogues, registers, archiving formats = specialist skills which are needed at every stage



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# Questions?