**Data sharing policies: a cross-sectional study protocol**

**TITLE**

Data sharing policies: a cross-sectional study protocol

**INTRODUCTION**

**Objectives**

The aim of this cross-sectional study is to systematically synthesise existing policies for data sharing and categorically converge the overarching principles at an aggregate level. This will involve assessing whether data sharing policies exist, whether they recommend or require data sharing, and summarising characteristics of existing policies.

**METHODS**

**Protocol and registration**

The research protocol for this cross-sectional study will be prospectively registered, and thereafter accessible, on the Open Science Framework (OSF) (<https://osf.io/>). Any amendments to the research protocol will be contemporaneously documented on the OSF.

**Eligibility criteria**

We will include data sharing policies by various stakeholders in data sharing that sit at different stages in the life cycle of clinical trials. These stakeholders will include health research funders, research ethics committees, clinical trial registries, peer-reviewed scientific journals, and research data repositories.

*Health research funders*  
Health research funders will be stratified into public and philanthropic funders, and private funders. Public and philanthropic funders will be included on the basis of their annual health research expenditure as identified by Viergever & Hendriks (2016)(1). An equivalent number of private funders will be included on the basis of their annual health industry research and development expenditure as identified by the European Union Industrial Research and Development Investment Scoreboard (<https://iri.jrc.ec.europa.eu/scoreboard/2021-eu-industrial-rd-investment-scoreboard>). A total of 55 major public and philanthropic funders (49 major public national or regional funders and 6 major philanthropic funders), and 55 major private funders (44 pharmaceutical and biotechnology companies and 11 health care equipment and services companies) will be included. Data will be collected on the name, type and country of funder. The health research funders are summarised in Table S1.  
  
*Research ethics committees*National ethics committees will be included as identified by Hummel et al (2021).(2) A total of 124 national ethics committees will be included, with 41 national research ethics review committees (i.e., review research protocols and projects), 12 national research ethics committees (i.e., develop research policies and guidelines), 50 national bioethics committees (i.e., work on general bioethical issues), 16 multi-purpose national ethics committees (i.e., more than one function) and 5 non-specific national ethics committees (i.e., unclear function).(2) Data will be collected on the name, type and country of committee.   
  
*Clinical trial registries*Clinical trial registries will be identified by the World Health Organisation (WHO) Registry Network (International Clinical Trials Registry Platform) (<https://www.who.int/clinical-trials-registry-platform/network>) and the United States (US) Department of Health and Human Services’ (HHS) Office for Human Research Protections (OHRP) (<https://www.hhs.gov/ohrp/international/index.html>), including their listing of clinical trial registries (<https://www.hhs.gov/ohrp/international/clinical-trial-registries/index.html>) and their International Compilation of Human Research Standards (<https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html>). Clinical trial registries will be included if they are a primary registry or data provider, in accordance with the International Committee of Medical Journal Editors’ (ICJME) clinical trial registration policy which only accepts registration of clinical trials in a primary registry or ClinicalTrials.gov (<http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html>). Clinical trial registries which are partner registries, disease-specific, device-specific, procedure-specific or other databases will be excluded. A total of 18 clinical trial registries will be included, with 17 primary registries and 1 data provider. Data will be collected on the name, type and country of registry. The clinical trial registries are summarised in Table S2.  
  
*Peer-reviewed scientific journals*Peer-reviewed scientific journals will be included if they are ranked in the top five journals by Journal Impact Factor in each of the 59 categories in clinical medicine in the 2020 Journal Citation Reports. The online author instructions and editorial policies for included journals will be reviewed. Data will be collected on the name, ISSN, eISSN, category and 2020 Journal Impact Factor of journals. Data may be collected on the volume of publications, model of publication (e.g., open access or subscription), type of journal publisher (e.g., commercial or non-commercial) and geographical location of journal publisher. A total of 295 peer-reviewed scientific journals will be included  
  
*Research data repositories*Research data repositories will be included if they were registered in re3data in 2021 and their specific subject is medicine. Data will be collected on the name, identifier, country, size and language of repositories, the type of provider, the name and country of institution, and other variables (e.g., type of regulations to (a) accessing the research data repositories (open, restricted, closed or embargoed), (b) accessing the research data provided by the research data repositories (open, restricted or closed), and (c) submitting research data to the research data repositories (open, restricted or closed)). A total of 410 research data repositories will be included  
 **Information sources**Informational sources will include the official website, online reports and other information sources. Data will be confirmed with the representatives of the stakeholders. Stakeholders will be advised of the data we have collected and the information sources from where the data was collected, and asked to add, amend or confirm the data.   
  
**Data collection process**In the initial stage of the data collection process, data collection will be piloted and performed in duplicate by two independent reviewers, with resolution of disagreements by discussion and a third reviewer. In the subsequent stage of the data collection process, data collection will be performed by a single reviewer. Data will be extracted using a pre-piloted data extraction form developed and piloted by the reviewers (Appendix X). If required, authors of included policies will be contacted to request missing or additional data.   
  
**Data items**Data sharing policies will be assessed by their presence or absence, and by the magnitude of their recommendations or requirements. This is summarised in Table 1.

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| **Table 1. Assessment of data sharing policies\*** |
| **1 Absent data sharing policy**  No data sharing policy |
| **2 Weak data sharing policy: mention**  Data sharing policy which neither recommends nor requires data sharing |
| **3 Moderate data sharing policy: recommendation**  Data sharing policy which recommends, but does not require, data sharing  This could be subcategorised into data sharing policies which encourage data sharing   and those which expect data sharing (i.e., mandate a data availability statement) |
| **4 Strong data sharing policy: requirement**  Data sharing policy which requires data sharing  Thiscould be subcategorised into data sharing policies which also mandate data peer-  review |
| \*Not applicable to commercial health research funders because, rather than recommend or require data sharing, these internal policies typically advise how external researchers can request data |

Data sharing policies which recommend or require data sharing will be described by the **(a)** studies, data and documents to be shared, and the exceptions, **(b)** start and stop of data sharing, **(c)** people to share with, **(d)** purpose for sharing data, and **(e)** distribution of shared data. These are summarised in Table 2.

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| **Table 2. Description of data sharing policies which recommend or require data sharing** | |
| **What** |  |
| **1 Studies**  What studies are  recommended or  required to share data? | **1** All studies  **2** Only interventional studies  **3** Only observational studies |
| **2 Data**  What data are  recommended or  required to be shared? | **1** All collected IPD  All IPD collected during the study  **2** Only underlying IPD  Only IPD underlying the published results  **3** Not specified |
| **3 Documents**  What supporting  documents (excluding  the data dictionary) are  recommended or  required to be shared? | **1** Study protocol  **2** Statistical analysis plan  **3** Informed consent form  **4** Clinical study report  **5** Ethical approval  **6** Analytic code  **7** Not specified |
| **4 Exceptions**  What are the  exceptions to  recommendations or  requirements to share  data? | **1** Justified  **2** Unjustified  Examples include proprietary interests, incentives for commercial development, and agreements with third parties |
| **When** |  |
| **5 Start**  When are data  recommended or  required to start being  shared? | **1** Immediately following publication  Immediately following publication **2** Before pre-determined period  Before a pre-determined period following publication (e.g.,   after an embargo or exclusive access period)  **3** Not specified |
| **6 Stop**  When are data  recommended or  required to stop being  shared? | **1** No end date  No end date **2** After pre-determined time  After a pre-determined period following publication  **3** Not specified |
| **Who** |  |
| **7** **People**  Who are data  recommended or  required to be shared  with? | **1** Any person  Anyone who wishes to access the data  **2** Research proposal  Only researchers who provide a methodologically sound  proposal, with ethical approval if appropriate  **3** Independent committee  Investigators whose proposed use of IPD has been   reviewed, assessed and approved by an independent data   access committee identified for this purpose  **4** Scientific journal  Scientific journal  **5** Investigator discretion  Case-by-case basis at the discretion of the principal  investigator  **6** Known colleague  Colleagues only  **7** Sponsor discretion  Case-by-case basis at the discretion of the primary sponsor **8** Not specified |
| **Why** |  |
| **8 Purpose**  What are data  recommended or  required to be shared  for? | **1** Any purpose  Any purpose  **2** Research proposal  Only to achieve the aims in the approved proposal, with  ethical approval if appropriate  **3** IPD meta-analysis  For IPD meta-analysis +/- systematic reviews  **4** Exploratory analysis  For exploratory analysis  **5** Investigator discretion  Case-by-case basis at the discretion of the principal  investigator  **6** Replication  Replication of results only  **7** Sponsor discretion  Case-by-case basis at the discretion of the primary sponsor  **8** Not specified |
| **How** |  |
| **9 Distribution**  What are the   mechanisms by which   data are   recommended or   required to be shared? | **1** Third party website  Unrestricted access through a third party website  **2** University data warehouse  Access through a university data warehouse  **3** Publishing journal website  Access through the publishing journal website (e.g.,   supplementary material to a journal article)  **4** Principal investigator contact  Access subject to approval by the principal investigator  **5** Primary sponsor contact  Access subject to approval by the primary sponsor  **6** Principal investigator or primary sponsor contact  Access subject to approval by either the principal  investigator or primary sponsor  **7** Principal investigator and primary sponsor contact  Access subject to approval by both the principal investigator  and primary sponsor  **8** Not specified |
|  | |

**Summary measures**

The principal summary measures will be descriptive statistics (e.g., frequency and proportion). The results of the search and policy selection (e.g., number of policies screened, assessed for eligibility, included in the review and excluded at each stage with reasons) will be reported with a flow diagram. For each policy, the characteristics for which data were extracted will be reported in a table.

The policy themes identified by Blasimme et al (2018)(3) will be coded from the full text of each policy by two independent coders using qualitive research software (Nvivo). The agreement and kappa between the two coders will be calculated.

**Synthesis of results**

Data will be managed throughout the review in Microsoft Excel. Policies will be narratively described, qualitatively synthesised and visually represented as a map or framework. The main findings will be summarised, and their relevance to key groups will be considered. The limitations at policy and outcome level, and at review-level (e.g., incomplete retrieval of identified policies or reporting bias) will be discussed. A general interpretation of the results in the context of current evidence, practice and policy, implications of the review and recommendations for future research will be provided.

**FUNDING**

There are no sources of financial support for this study.

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| **Table S1. Major health researcher funders** | | |
| **Type of funder** | **Name of funder** | **Country of funder** |
| **Public** | | |
| Public | National Institutes of Health (NIH) | United States |
| Public | European Commission (EC) | European Union |
| Public | UK Medical Research Council (MRC) | United Kingdom |
| Public | Institut national de la santé et de la recherche médicale (Inserm) | France |
| Public | United States Department of Defense (US DoD) | United States |
| Public | Canadian Institutes of Health Research (CIHR) | Canada |
| Public | Australian National Health and Medical Research Council (NHMRC) | Australia |
| Public | Deutsche Forschungsgemeinschaft / German Research Foundation (DFG) | Germany |
| Public | National Natural Science Foundation of China (NSFC) | China |
| Public | Centre National de la Recherche Scientifique (CNRS) | France |
| Public | UK Department of Health / National Institute for Health Research (NIHR) | United Kingdom |
| Public | Japan Society for Promotion of Science (JSPS) | Japan |
| Public | Bundesministerium für Bildung und Forschung / Federal Ministry of Education and Research of Germany (BMBF) | Germany |
| Public | Ministero della Salute / Ministry of Health of Italy | Italy |
| Public | Instituto de Salud Carlos III (ISCIII)e | Spain |
| Public | Ministry of Health of China | China |
| Public | Japan Science and Technology Agency (JST)e | Japan |
| Public | Singapore National Medical Research Council (NMRC) | Singapore |
| Public | Korean National Research Foundation (NRF) | South Korea |
| Public | Consejo Nacional de Investigaciones Científicas y Técnicas (CONICET)e | Argentina |
| Public | Vetenskapsrådet-Medicine / Swedish Research Council | Sweden |
| Public | Swiss National Science Foundation (SNSF) | Switzerland |
| Public | ZonMw / Netherlands Organisation for Health Research and Development | Netherlands |
| Public | Sao Paulo Research Foundation (FAPESP)e | Brazil |
| Public | Indian Council of Medical Research (ICMR) | India |
| Public | Fund for Scientific Research - Flanders (FWO) | Belgium |
| Public | Korea National Institute of Health (KNIH) | South Korea |
| Public | Forskingsrådet / Research Council of Norway | Norway |
| Public | Conselho Nacional de Desenvolvimento Científico e Tecnológico (CNPq) | Brazil |
| Public | Fonds zur Förderung der wissenschaftlichen Forschung / Austrian Science Fund (FWF) | Austria |
| Public | South African Medical Research Council (SA MRC) | South Africa |
| Public | Health Research Council of New Zealand | New Zealand |
| Public | Danish Council for Independent Research / Medical Sciences | Denmark |
| Public | Russian Foundation for Basic Research (RFBR) | Russia |
| Public | Danish Council for Strategic Research (two programmes: Individuals, Disease and Society & Health, Food and Welfare) | Denmark |
| Public | Consejo Nacional de Ciencia y Tecnología (CONACYT) | Mexico |
| Public | South African Department of Science and Technology (DST) | South Africa |
| Public | Agencia Nacional de Promocion Cientifica y Technologica (Agenica - ANPCyT) | Argentina |
| Public | Biomedical Research Council of the Singapore Agency for Science, Technology and Research (BMRC of A\*STAR) | Singapore |
| Public | Ministry of Science and Technology of China (MOST) | China |
| Public | Indian Department of Biotechnology (DBT) | India |
| Public | Indian Department of Science and Technology (DST) | India |
| Public | King Abdulaziz City for Science and Technology (KACST) | Saudi Arabia |
| Public | Le Fonds de la Recherche Scientifique (FNRS) | Belgium |
| Public | Lipi Indonesian Research Council | Indonesia |
| Public | Ministry of Healthcare of the Russian Federation | Russia |
| Public | National Research Foundation South Africa (NRF SA) | South Africa |
| Public | Tubitak / Scientific and Technological Research Council of Turkey | Turkey |
| Public | Turkish Academy of Sciences (TUBA) | Turkey |
| **Philanthropic** | | |
| Philanthropic | Wellcome Trust | United Kingdom |
| Philanthropic | Howard Hughes Medical Institute (HHMI) | United States |
| Philanthropic | Bill & Melinda Gates Foundation (BMGF) | United States |
| Philanthropic | Institut Pasteur | France |
| Philanthropic | Oswaldo Cruz Foundation (Fiocruz) | Brazil |
| Philanthropic | Rockefeller foundation | United States |
| **Private (pharmaceuticals and biotechnology)** | | |
| Private (p&b) | ROCHE | Switzerland |
| Private (p&b) | JOHNSON & JOHNSON | United States |
| Private (p&b) | BRISTOL-MYERS SQUIBB | United States |
| Private (p&b) | MERCK US | United States |
| Private (p&b) | PFIZER | United States |
| Private (p&b) | BAYER | Germany |
| Private (p&b) | NOVARTIS | Switzerland |
| Private (p&b) | SANOFI | France |
| Private (p&b) | ABBVIE | United States |
| Private (p&b) | GLAXOSMITHKLINE | United Kingdom |
| Private (p&b) | ASTRAZENECA | United Kingdom |
| Private (p&b) | GILEAD SCIENCES | United States |
| Private (p&b) | BOEHRINGER SOHN | Germany |
| Private (p&b) | TAKEDA PHARMACEUTICAL | Japan |
| Private (p&b) | ELI LILLY | United States |
| Private (p&b) | AMGEN | United States |
| Private (p&b) | BIOGEN | United States |
| Private (p&b) | MERCK DE | Germany |
| Private (p&b) | ABBOTT LABORATORIES | United States |
| Private (p&b) | NOVO NORDISK | Denmark |
| Private (p&b) | DAIICHI SANKYO | Japan |
| Private (p&b) | INCYTE | United States |
| Private (p&b) | ASTELLAS PHARMA | Japan |
| Private (p&b) | OTSUKA | Japan |
| Private (p&b) | UCB | Belgium |
| Private (p&b) | VERTEX PHARMACEUTICALS | United States |
| Private (p&b) | EISAICO | Japan |
| Private (p&b) | BEIGENE | China |
| Private (p&b) | ALEXION PHARMACEUTICALS | United States |
| Private (p&b) | CSL | Australia |
| Private (p&b) | TEVA PHARMACEUTICAL INDUSTRIES | Israel |
| Private (p&b) | SERVIER | France |
| Private (p&b) | SEAGEN | United States |
| Private (p&b) | MODERNA | United States |
| Private (p&b) | SAREPTA THERAPEUTICS | United States |
| Private (p&b) | ILLUMINA | United States |
| Private (p&b) | FOSUN INTERNATIONAL | China |
| Private (p&b) | BIOMARIN PHARMACEUTICAL | United States |
| Private (p&b) | H LUNDBECK | Denmark |
| Private (p&b) | ONO PHARMACEUTICAL | Japan |
| Private (p&b) | VIATRIS | United States |
| Private (p&b) | BIONTECH | Germany |
| Private (p&b) | MERIEUX ALLIANCE | France |
| Private (p&b) | SHIONOGI | Japan |
| **Private (health care equipment and services)** | | |
| Private (hce&s) | MEDTRONIC PUBLIC LIMITED | Ireland |
| Private (hce&s) | THERMO FISHER SCIENTIFIC | United States |
| Private (hce&s) | BOSTON SCIENTIFIC | United States |
| Private (hce&s) | BECTON DICKINSON | United States |
| Private (hce&s) | CARL ZEISS | Germany |
| Private (hce&s) | STRYKER | United States |
| Private (hce&s) | FRESENIUS | Germany |
| Private (hce&s) | EDWARDS LIFESCIENCES | United States |
| Private (hce&s) | ESSILORLUXOTTICA | France |
| Private (hce&s) | OLYMPUS | Japan |
| Private (hce&s) | INTUITIVE SURGICAL | United States |

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| **Table S2. Clinical trial registries** | | |
| **Primary registries** | | |
| **1** | ANZCTR | Australian New Zealand Clinical Trials Registry (<https://www.anzctr.org.au/>) |
| **2** | ReBec | Brazilian Clinical Trials Registry ([www.ensaiosclinicos.gov.br](http://www.ensaiosclinicos.gov.br)) |
| **3** | ChiCTR | Chinese Clinical Trial Registry (<http://www.chictr.org.cn/enIndex.aspx>) |
| **4** | CRiS | Clinical Research Information Service, Republic of Korea  (<https://cris.nih.go.kr/cris/info/introduce.do?search_lang=E&lang=E>) |
| **5** | CTRI | Clinical Trials Registry – India (<http://ctri.nic.in/Clinicaltrials/login.php>) |
| **6** | RPCEC | Cuban Public Registry of Clinical Trials (<https://rpcec.sld.cu/en/home>) |
| **7** | EU-CTR | EU Clinical Trials Register (<https://www.clinicaltrialsregister.eu/ctr-search/search>) |
| **8** | DRKS | German Clinical Trials Register (<https://www.drks.de/drks_web/>) |
| **9** | IRCT | Iranian Registry of Clinical Trials (<https://www.irct.ir/>) |
| **10** | ISRCTN | ISRCTN (<https://www.isrctn.com/>) |
| **11** | JPRN | Japan Primary Registries Network (<https://rctportal.niph.go.jp/en/>)  **1** │JapicCTI │ Japic Clinical Trials Information (<https://www.japic.or.jp/>)  **2** │JMACCT CTR │ Japan Medical Association Centre for Clinical Trials Clinical Trial Registry (<http://www.jmacct.med.or.jp/en/>)  **3** │jRCT │ Japan Registry of Clinical Trials (<https://jrct.niph.go.jp/>)  **4** │UMIN CTR │ University hospital Medical Information Network Clinical Trial Registry (<https://www.umin.ac.jp/ctr/>) |
| **12** | LBCTR | Lebanese Clinical Trials Registry (<https://lbctr.moph.gov.lb/>) |
| **13** | TCTR | Thai Clinical Trials Registry (<https://www.thaiclinicaltrials.org/>) |
| **14** | NTR | The Netherlands Trial Register (<https://www.trialregister.nl/>) |
| **15** | PACTR | Pan African Clinical Trial Registry (<https://pactr.samrc.ac.za/>) |
| **16** | REPEC | Peruvian Clinical Trial Registry (<https://ensayosclinicos-repec.ins.gob.pe/en/>) |
| **17** | SLCTR | Sri Lanka Clinical Trials Registry (<https://slctr.lk/>) |
| **Data providers** (excluding primary registries) | | |
| **18** | ClinicalTrials.gov | ClinicalTrials.gov (<https://clinicaltrials.gov/>) |
| **Partner registries** (not included) | | |
|  | CCRBCTR | Centre for Clinical Research and Biostatistics – Clinical Trials Registry (<https://www2.ccrb.cuhk.edu.hk/web/?page_id=746>) |
|  | AMCTR | Acupuncture-Moxibustion Clinical Trial Registry ([www.acmctr.org](http://www.acmctr.org)) |
| **Other databases** (not included) | | |
|  | HC CTD | Health Canada's Clinical Trials Database (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/health-canada-clinical-trials-database.html>) |
|  | SNCTP | Swiss National Clinical Trials Portal (<https://www.kofam.ch/en/snctp-portal/searching-for-a-clinical-trial/>) |
|  | PHRR | Philippine Health Research Registry (<https://registry.healthresearch.ph/index.php/registry>) |
|  | SANCTR | South African National Clinical Trial Register ([www.sanctr.gov.za](http://www.sanctr.gov.za)) |
|  | TzCTR | Tanzania Clinical Trial Registry (<http://www.tzctr.or.tz/faq.php>) |
|  | NMRR | National Medical Research Register (<https://www.nmrr.gov.my/fwbLoginPage.jsp>) |
|  | ReNIS | National Registry of Health Research (<https://www.argentina.gob.ar/salud/registroinvestigaciones>) |
|  | NCTR | Nigerian Clinical Trials Registry (<https://nhrec.net/nigeria-clinical-trials-registry/>) |

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