Aims and challenges of clinical trial data sharing

Facilitating data access to non-industry funded research

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Competing interests

I’m editor in chief of BMJ Open and Head of Research at The BMJ, a wholly owned subsidiary of the BMA

BMJ (the company) receives revenues from drug & device manufacturers through advertising, reprint sales, & sponsorship

I receive a bonus based partly on the financial performance of The BMJ. Both The BMJ and BMJ Open publish all research with open access, supported by article publication fees

The BMJ was a co-founder of the AllTrials campaign

The BMJ is campaigning for reproducible research
IoM 2015 recommendation 1: principles

Stakeholders in clinical trials should foster a culture in which data sharing is the expected norm, and should commit to responsible strategies aimed at maximizing the benefits, minimizing the risks, and overcoming the challenges of sharing clinical trial data for all parties.

Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk
http://www.iom.edu/Reports/2015/Sharing-Clinical-Trial-Data.aspx
IoM 2015 recommendation 2: what to share when

- **data sharing plan**: before first participant enrolled, at trial registration
- **results** (summary level data and lay summary): no later than 12 months after study completion
- **full data package** (incl full analyzable data set, full protocol, full statistical analysis plan, and analytic code): no later than 18 months after completion
- **post-publication data package** (including the subset of the analyzable data set supporting the findings, tables, and figures in the publication and the full protocol, full statistical analysis plan, and analytic code that supports the published results): no later than 6 months after publication
- **post-regulatory data package** (including full analyzable data set and redacted CSR, with full protocol, full statistical analysis plan, and analytic code): 30 days after regulatory approval or 18 months after study completion, whichever occurs later.
IoM 2015 recommendation 3: safeguards

- **data use agreements** aimed at protecting clinical trial participants, advancing goal of producing scientifically valid secondary analyses, giving credit to investigators who collected the clinical trial data, protecting intellectual property interests of sponsors, and improving patient care

- **other privacy protections:** in addition to de-identification and data security

- **independent review panel** (incl lay members) if requests for access to clinical trial data will be reviewed for approval; with public reporting of panel’s members, structure, policies, procedures

- **public reporting of** summary of decisions on requests for data access, including number of requests and approvals and reasons for disapprovals

- **data on outcomes** of data sharing policies, procedures, and technical approaches (including benefits, risks, costs); share information and lessons

[Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk](http://www.iom.edu/Reports/2015/Sharing-Clinical-Trial-Data.aspx)
Clinical trial registration: ethical rationale

- respects the investigator-participant covenant to contribute to biomedical knowledge by making trial methods and results public
- provides global open access to information
- reduces unnecessary duplication of invested research resources through awareness of existing trials
- assures accountability with regard to global standards for ethical research
- enables monitoring of adherence to ethical principles and process

International Committee of Medical Journal Editors (ICMJE): principles of data sharing

- data can be understood and reanalyzed by others
- authors should share data on reasonable request
- all data that underpin the published results, incl. recent/current data on harms, should be shared
- de-identified individual patient data, data dictionary statistical plan & code used to analyze the data
- IRBs should ensure patient informed consent covers all this
- journals may investigate breaches, express concern, retract
- data users must commit to making results of their analyses public, report methods, credit source

Data sharing policies at The BMJ

- for all research papers: data sharing statements *

- for all clinical trials: mandatory commitment to share de-identified patient level data on reasonable request (also mandatory prospective trial registration, protocol submission, and CONSORT checklist *)

- data deposition option: Dryad data repository *

* at BMJ Open too. BMJ Open has 122 datasets in Dryad
The whole debate on sharing clinical study data has focused on transparency, reproducibility, and completing the evidence base for treatments.

Yet public health emergencies such as the Ebola and MERS outbreaks provide a vitally important reason for sharing study data, usually before publication or even before submission to a journal, and ideally in a public repository.

Not just from randomised controlled trials, but from case series and samples, lab testing studies, surveillance studies, viral sequencing, genomic work, and other epidemiological observational studies too.”