

# International Committee of Medical Journal Editors' requirements for sharing individual participant data from interventional clinical trials



Kathy B. Thomas<sup>1</sup> and Robert A. Paarlberg<sup>2</sup>

1 Medical & Scientific Writing & Publication Services, Meersburg, Germany

2 Paarlberg & Associates LLC, Canton, GA, USA

## Correspondence to:

Kathy B. Thomas, PhD  
Medical & Scientific Writing & Publication Services  
Meersburg, Germany  
medicalwriter-ktu@t-online.de

## Abstract

Sharing of deidentified/anonymised individual participant data is rapidly becoming the norm. The International Committee of Medical Journal Editors recently implemented requirements for data sharing as a condition for considering publication of clinical trial reports in member journals. These requirements are: 1. manuscripts that are based on results of a clinical trial submitted on or after July 1, 2018, must contain a Data Sharing Statement at the manuscript submission stage; and 2. interventional

clinical trials that began enrolling participants on or after January 1, 2019, must include a Data Sharing Plan in the trial's public registration record. The full effect of these data sharing requirements and the resolution with other legal provisions still need to be resolved, especially regarding protection of personal information of clinical trial participants and commercially confidential information for clinical trial sponsors. Nevertheless, sharing of deidentified individual participant data from clinical trials will continue to expand.

## Introduction

Most sponsors of clinical trials around the world are aware of the legal requirements to disclose information about their clinical trials in a publicly accessible database or databases on the Internet. Disclosure of information is based on the trial protocol for *new* clinical trials (*trial registration*) and on the clinical trial report for *summary results* of completed trials (*trial results posting*).

Complex legal mechanisms emerge when it comes to sharing deidentified/anonymised individual participant data (IPD) generated during a clinical trial. The recently introduced EU General Data Protection Regulation (GDPR) is a case in point: EU member states may have different interpretations of the GDPR when it comes to sharing data from clinical trials for purposes other than just the initially intended analyses (primary use) or evaluation of trials for further research activities (secondary use).

This article discusses the requirements of the International Committee of Medical Journal Editors (ICMJE) on Data Sharing Statements and plans for the sharing of deidentified/anonymised IPD from clinical trials. The topic is relevant to medical writers working on regulatory and medical communication documents as well as to data managers and statisticians who participate in collating and processing IPD. Of course, other stakeholders involved in planning, implementation, and reporting of clinical trials should understand the implications of IPD sharing and the commitments on data sharing that are expected to be made by the trial sponsors upfront *before* the trial has actually started. Upper management of the clinical trial sponsor also needs to be aware about these decisions and processes because, as described below, the data sharing commitments have wide and long-term implications for drug development and life cycle.

## Legal requirements for public disclosure of information on clinical trials

The legal requirements for public disclosure of information from clinical trials are based on Regulation EU 536/2014 in the EU/European Economic Area (EEA)<sup>1</sup> and in the US on FDAAA Section 801<sup>2</sup> and its Final Rule 42

CFR Part 11.<sup>3</sup> Failure to comply with Regulation EU 536/2014 (Articles 94 and 95 of the Regulation EU 536/2014<sup>1</sup>) or the FDAAA/Final rule could result in civil monetary penalties or withholding of research funding.<sup>4–7</sup>

Clinical trials may need to be registered and results posted at multiple sites. Some parts of the world have regional or country-specific requirements and expect the sponsor to register the clinical trial at a regional or national level. Moreover, in some cases, in addition to registration, summary results must be reported at study completion or after reaching a particular milestone in the trial conduct (e.g., after completing the primary endpoint; FDAAA 801/Final Rule).<sup>3</sup> Keeping up with the various disclosure and transparency requirements can be a challenge – especially for sponsors of multinational trials.<sup>5</sup>

## ICMJE requirements

In addition to the legal requirements for public disclosure, some organisations, such as the ICMJE, previously known as the Vancouver Group, also have recommendations and requirements for public disclosure. The ICMJE is a group of currently 16 full members (journal editors and representatives of related organisations), working together to improve the quality of medical science and its reporting.<sup>8</sup>

Over the past several decades, the ICMJE has implemented requirements for publishing in professional scientific and clinical journals, which is entitled “*Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals*”. The ICMJE also endorses the dissemination of information based upon the World Health Organization (WHO) definition of clinical trials as “*any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes*”.<sup>9,10</sup> The ICMJE recommendations and requirements have been adopted by many other journals<sup>10</sup> and although the recommendations and requirements are not legally binding, they will influence the likelihood of publishing results in peer-reviewed journals.

## Prospective registration of clinical trials in a public registry

One of the ICMJE’s earlier requirements (in 2004) was that clinical trials be registered in a publicly accessible database *before enrolment of the first patient*. Since then, such “prospective registration” is a condition for publication of trial results in all journals that have adopted the ICMJE principles, as evident in their instructions for authors.<sup>9–12</sup> This applies to *all* interventional clinical trials (*including* Phase I trials) that began on or after July 1, 2005.<sup>10</sup> The ICMJE accepts trial registration in ClinicalTrials.gov<sup>13</sup> as well as in any of the primary registries that participate in the WHO International Clinical Trials Registry Platform.<sup>14</sup>

Registering new clinical trials in an ICMJE-accepted register is now an established procedure for most clinical trial sponsors. Since this ICMJE initiative was introduced, registrations of clinical trials skyrocketed<sup>15</sup> and opportunities for subsequent selective or biased reporting of trials plummeted.<sup>16,17</sup> Timely registration (*before the first subject enrolment in the clinical trial*) can be easily established because all trial registries include the dates when the trial was first registered as well as when the first study subject was enrolled or randomised. These dates are routinely cross-checked by the journal’s editorial staff when a manuscript is submitted for publication.

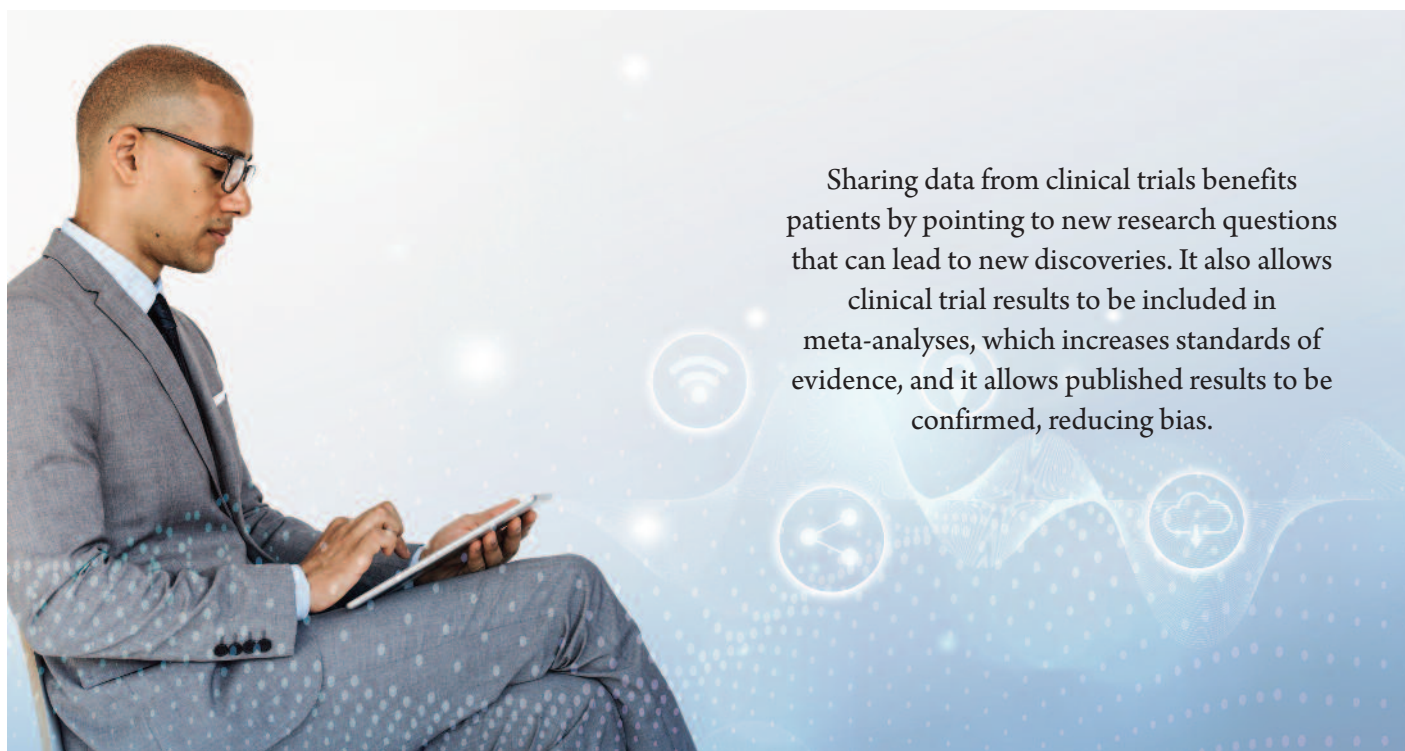
Some journals may reject manuscripts that do not fulfil the ICMJE public registration criteria, while others may be more lenient. Nevertheless, in our experience, all journals insist on trial registration in an ICMJE-accepted public registry as a condition for manuscripts review, even if the trial is registered retrospectively.

## Data sharing

Sharing of deidentified/anonymised IPD from clinical trials is not new. An obligation to share IPD has been encouraged for some time by many stakeholders, including academic institutions, the pharmaceutical industry, health regulatory authorities, medicinal product pricing agencies, patient lobby groups, investigative journalists, and public media representatives.<sup>18–22</sup>

Sharing data from clinical trials benefits patients by pointing to new research questions that can lead to new discoveries. It also allows clinical trial results to be included in meta-

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analyses, which increases standards of evidence and it allows published results to be confirmed, reducing bias. Furthermore, data sharing provides a noble way to honour the generosity of clinical trial participants by increasing the utility of their data and thus the value of their contribution.<sup>21,23–25</sup>

On January 1, 2014, EFPIA and PhRMA released a joint “*Principles for Responsible Clinical Trial Data Sharing*”.<sup>26</sup> These principles allow researchers to submit proposals to receive access to patient level data, protocols, and clinical study reports for new medicines approved in the US and EU after January 1, 2014. Similar commitments were adopted on January 15, 2018, by the IFPMA, in their “*Principles for Responsible Clinical Trial Data Sharing*”.<sup>27</sup>

After an active and turbulent public discussion on the IPD sharing proposal by the ICMJE in January 2016, the ICMJE announced in June 2017 two requirements on sharing IPD, generated during interventional clinical trials:<sup>16,28</sup>

1. Authors of manuscripts based on results of a clinical trial submitted on or after July 1, 2018, are asked to submit a Data Sharing Statement at the manuscript submission stage.
2. Interventional clinical trials that began enrolling participants on or after January 1, 2019, must include a Data Sharing Plan in the

trial’s public registration record.

In line with these ICMJE requirements (November 2017), the WHO International Clinical Trials Registry Platform expanded the Trial Registration Data Set to incorporate four new data elements that include a new field for the IPD sharing statement.<sup>14</sup>

The US-based ClinicalTrials.gov registry has added the IPD Data Sharing field in their “Protocol Registration Data Element Definitions” for new trial registrations.<sup>13</sup> For interventional studies, a “Yes” or “No” answer is expected for Plan to Share IPD. Although the response to Plan to Share IPD is optional in the Protocol Registration and Results System, it is required by the ICMJE as part of the registration information for interventional studies.

It should be noted that EudraCT, the EU/EEA-based clinical trials register, does *not* have a dedicated field for the Data Sharing Statement. The EudraCT database is currently used for registering clinical trials and for posting results of trials that are under the EU/EEA jurisdiction.

The EudraCT database will be replaced by a new Clinical Trials Information System (CTIS) for all EU/EEA-relevant clinical trials, as specified in Regulation EU 536/2014. However, implementation of the CTIS has been delayed due to technical issues that should be resolved by late 2020. In the meantime, it is not

clear how the sponsors of trials performed in the EU/EEA will comply with the ICMJE data sharing requirements, given the lack of a data sharing field in EudraCT database.

The ICMJE expects that the Data Sharing Statement and the Data Sharing Plan will include the items listed below. Examples of possible responses are available in the editorial by ICMJE and on the ICMJE website.<sup>9</sup>

1. Whether individual de-identified IPD (including data dictionaries) will be shared
2. What data will be shared
3. Whether additional, related documents will be available
4. When the data will become available and for how long
5. What access criteria will be used to decide if data will be shared (e.g., with whom, for what types of analyses, and by what mechanism).

As stated by the ICMJE, data sharing requirements are not mandatory:

*These initial requirements do not yet mandate data sharing, but investigators should be aware that editors may take into consideration data sharing statements when making editorial decisions.*

Thus, if the authors of a manuscript are not prepared to share their data, a short statement, such as, “Data will not be shared”, should satisfy the new requirements. Nevertheless, as noted above, the authors’ response to Data Sharing

Data-sharing platforms are an alternative option for clinical trial sponsors to share IPD.



Statement may affect the editorial decision.

Similarly, describing the Data Sharing Plan is not required to register a trial in the ClinicalTrials.gov database, although a clear “Yes” or “No” is expected and the responses will be visible to the public as part of the trial registration record and history of changes. Furthermore, the Data Sharing Plan – including all changes to it – will be reflected in the subsequent Data Sharing Statement when the results of the trial are submitted to a journal for publication.

The final decision on how to deal with a submitted manuscript and the Data Sharing Statement rests with the editor of each journal. So far, it appears that many journal editors that follow the ICMJE requirements will grant manuscript authors a grace period and do not insist on a clear “Yes” to data sharing as a condition for publishing a manuscript. Nevertheless, some ICMJE member journals already maintain, or may choose to adopt as a condition of publication, stringent requirements not only for a positive Data Sharing Statement but also submission of the trial protocol and data analysis plan and their amendments at the time of manuscript submission. The latter is meant to avoid selective reporting, endpoint switching, or distorted interpretation of statistically non-significant results (“spin”), which continue to persist despite editorial advice and the existence of clinical trial registries.<sup>29–31</sup>

Recently, several companies reported that editors of JAMA have asked for an *unredacted* trial protocol and statistical analysis plan as part of their review of submitted manuscripts. Redacted documents, however, will probably be made available to the public when a manuscript is published. Another company reported that, after submitting a manuscript to the *New England Journal of Medicine* together with proposed redactions to the trial protocol and statistical analysis plan, the company was asked for all commercial confidential information to be unredacted; the journal allowed for the personal protected data to remain redacted. The editors also asked for justification for all redactions.

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## Highlights from a recent session on ICMJE requirements on Data sharing

At a Drug Information Association Medical Affairs (DIA) and Scientific Communications Forum held in Orlando, Florida, on March 18–20, 2019, it was noted that some ICMJE journals such as *PLoS* and *British Medical Journal* already require data sharing as a condition for publication. Other ICMJE journals have not yet taken a position on this; the expectation is, however, that further ICMJE

journals will do so in the future, as illustrated above by the recent experiences with manuscript submissions to JAMA and the *New England Journal of Medicine*.

The ICMJE requirements do not provide a set or prescribed time from when and for how long the IPD will be available. Rather, the decision is up to the individual trial sponsors when they register the trial. If a clinical trial sponsor indicates at the original registration stage that they are *not* willing to share data, this could have ramifications if the compound or product used in a clinical trial is out-licensed or partnered in a co-development agreement. For example, this could affect a decision to in-license the compound, the publication strategy for the compound, who is responsible for changing the “No” to “Yes” for sharing data in the registry, or who will provide the rationale of the change when the manuscript is submitted. Initial decisions regarding data sharing will very likely lead to further discussions between the sponsor and the in-licensing company or the co-development partner.

It was also clear from the speakers’ messages at the DIA meeting that clinical trial sponsors need to have well-defined, established internal processes with clear responsibilities for 1. the Data Sharing Plan and 2. evaluating data sharing proposals submitted by external researchers. The internal stakeholders responsible for these two items could include teams from Clinical Trial Disclosure, Therapeutics, Regulatory, Legal, Intellectual Property and Patents, and

Publication Planning. Finally, the time scale affecting these processes should be kept in mind; it can take more than 4 years to proceed from the initial trial registration and the Data Sharing Statement (e.g., on ClinicalTrials.gov) to submission of the manuscript to a journal for publication.

## Responsibilities and expectations from users performing secondary use research analyses from shared data

The ICMJE acknowledges that some issues of IPD sharing remain unresolved. These include questions such as:

- What constitutes appropriate evaluation of the data (for secondary use)?
- How should scholarly credit be given to those who share data?
- What resources are needed for data access?
- How should data requests be transparently processed?
- How should data be archived?

The ICMJE welcomes creative solutions to such questions.<sup>28</sup> Many publications elaborating the underlying principles on the advantages and disadvantages of data sharing are already available. They highlight the perspectives and concerns of both researchers generating data (trialists) and the data users (external requestors wishing to repurpose the initial data for secondary use and analyses).<sup>24,32–34</sup>

IPD sharing and its consequences are relevant not only to medical writers who collate and describe the trial data but also to data managers and statisticians who are an integral part of collecting, collating, and processing IPD. Statisticians should move from their classical role as data gate-keepers to be data facilitators. The technical and statistical challenges of accessing research data for reanalyses and other secondary uses are not trivial. Specific skills and techniques are required to convert the initially collected data into sets that can be used for analysis by external researchers.<sup>32,35</sup>

## GDPR and sharing of IPD from clinical trials

The main goal of IPD sharing is to enable other researchers to repurpose the data for secondary uses and applications. Access to the data can allow for the study to be independently replicated, prevent duplicative studies, provide the basis of



generating or testing new hypotheses, and generally advance medicine and biology.<sup>36</sup>

In the US, the Office for Human Research Protections has indicated that sharing of *deidentified* IPD from clinical trials does not require separate consent from trial participants, provided that the appropriate conditions are met by those receiving the IPD.<sup>28</sup> In contrast to the situation in the US, some concerns have recently arisen in the EU on how to consolidate the data sharing principles for information from clinical trials with Regulation (EU) 2016/679, better known also as the EU GDPR, which has been in force only since May 2018.

It appears that some EU member states have taken different positions on the GDPR when it comes to deciding whether the Patient Consent Form should be the *only* legal grounds for processing and sharing deidentified/anonymised IPD from clinical trials for secondary use. There is legal uncertainty about whether the consent to participate in a clinical trial is equivalent to the consent for secondary processing of the data. International legal experts and members of the European Data Protection Board are currently evaluating ways to harmonise interpretation across the EU for GDPR and sharing of IPD from clinical trials for secondary use.<sup>37–39</sup> In April 2019, the European Commission Directorate-General for Health and Food Safety released a Question and Answer document on the interplay between the Regulation EU 536/2014 and the GDPR, clarifying that informed consent obtained under these legislative instruments serves different purposes.<sup>40</sup>

Describing requirements in the various countries regarding clinical data sharing is out of scope for this article. Nevertheless, it should be recognised that globally, the EU GDPR is not the only recently updated or introduced legislation dealing with citizens' data protection. Personal information protection laws similar to the EU GDPR also exist elsewhere, for example, the Japan Personal Information Protection Act and the Canada Personal Information Protection and Electronic Documents Act. Interestingly, the US does not have an equivalent to the EU GDPR; the topics are governed by a mixture of different state and federal rules rather than by a central authority or rule.

### Sponsors of clinical trials and their policies on data sharing

Many sponsors of clinical trials (pharmaceutical industry and academic institutions), including those in the industry that are not members of pharmaceutical associations, have updated their general policies on disclosure and transparency to include consideration of data sharing with qualified external parties. For most pharmaceutical industry sponsors, sharing of clinical data is specified in their company policies, for example, data may only be shared for products that are approved (in US *and* in EU) or for trials that have been completed (whereby some trials may have many years of follow-up before they are considered as completed).

### Data-sharing platforms

Data-sharing platforms are an alternative option

for clinical trial sponsors to share IPD. This can be done through different repositories recently developed by several joint initiatives. Sponsors subscribing to such a platform(s) provide the platform administrator with the relevant documents and datasets from selected clinical trials. For external requestors interested in performing secondary or meta-analyses, each platform has conditions as to what a data sharing request should contain, in which format the data sets will be provided, and which working site can be used for secondary data analysis.<sup>5,25,32,33</sup>

Clinical trial sponsors pay a fee for participating in some of these platforms, which provide most of the services relevant to assessing and processing the data sharing requests for IPD. These platforms help clinical trial sponsors meet the ethical obligations for sharing of deidentified/ anonymised IPD. Some current data-sharing platforms include the ClinicalStudyDataRequest consortium,<sup>41</sup> the YODA Project,<sup>42</sup> Vivli,<sup>43</sup> Project Data Sphere (does not charge any fees),<sup>44</sup> and DataCelerate.<sup>45</sup> Furthermore, several other clinical data-sharing platforms concentrate their efforts at a national or institutional level (e.g., US National Institutes of Health), or at a disease-specific level (e.g., Alzheimer's Disease Neuroimaging Initiative).<sup>46</sup>

Although the efforts to set up and maintain the clinical trial sharing platforms are highly commendable, it is still too early to make definitive conclusions about their effectiveness to fulfil the high aims of clinical IPD sharing. This is because membership in these data-sharing platforms is relatively low, membership costs are high, platforms are not interoperable, and availability of the

In June 2017, the ICMJE announced two additional requirements on sharing IPD generated during interventional clinical trials:

1. Authors of manuscripts based on results of a clinical trial submitted on or after July 1, 2018, are asked to submit a Data Sharing Statement at the manuscript submission stage.
2. Interventional clinical trials that began enrolling participants on or after January 1, 2019, must include a Data Sharing Plan in the trial's registration record.

IPD from sponsor-selected clinical trials is fragmented. As such, identifying, obtaining, and evaluating all relevant documents remains challenging for external requesters.

## Conclusions

Clinical data sharing can be justified on scientific, economic, and ethical grounds. Large IPD repositories and improved technologies that can cope and analyse large datasets are becoming available. Current legal questions regarding national interpretations of the laws surrounding IPD sharing will be resolved and harmonised. Clearly, sharing of deidentified/anonymised IPD from clinical research is here to stay and will continue to develop and expand.

Finally, while appreciating "*The Importance – and the Complexities – of Data Sharing*",<sup>47</sup> it is essential to keep in mind the benefits to patients offered by clinical data sharing, while respecting and ensuring privacy of the clinical trial participants who contribute their data.<sup>5,32,34,36,48</sup>

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The opinions expressed in this article are the authors' own and not necessarily shared by EMWA.

## Conflicts of interest

The authors declare no conflicts of interest related to this article.

## References

1. European Parliament and Council of the European Union. New Regulation No 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance. Official Journal of the European Union. 2014;L 158:1–76.
2. United States Congress. Public Law 110–185 – SEPT. 27, 2007. Public Law 110–185. 110th Congress. An Act to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and for medical devices, to enhance the postmarket authorities of the Food and Drug Administration with respect to the safety of drugs, and for other purposes. Title VIII–Clinical Trial Databases; 2007.
3. Department of Health and Human Services: Clinical Trials Registration and Results Information Submission; Final Rule. 42 CFR Part 11. Federal Register 2016;81(183):64981–65157
4. Thomas KB: Clinical trial disclosure and transparency: Ongoing developments on the need to disclose clinical data. in Medical writing the backbone of clinical development. International Clinical Trials 2017;63–70.
5. Roberts L, Cutting A, Allard R, Root N, Holtzople A, Kroll S, Pfitzer C: Clinical trial transparency and disclosure: A global view. 2019 [cited 24 April 2019]. Available from: <https://www.phusewiki.org/docs/Deliverables/PhUSE%20White%20Paper-%20A%20Global%20View%20-%20FINAL%20v1.0.pdf>
6. Zarin DA, Tse T, Williams RJ, Carr S. Trial reporting in ClinicalTrials.gov – the final rule. N Engl J Med. 2016;375(20):1998–2004.
7. McIntosh A. Public disclosure. Medical Writing. 2018;27(2):1–2.
8. International Committee of Medical Journal Editors. Uniform requirements for manuscripts submitted to biomedical journals: writing and editing for biomedical publication. 2018 [cited 24 April 2019]. Available from: [http://www.icmje.org/requirements/archives/2008\\_urm.pdf](http://www.icmje.org/requirements/archives/2008_urm.pdf).
9. International Committee of Medical Journal Editors. Clinical trials. 2018 [cited 24 April 2019]. Available from: <http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html>.
10. International Committee of Medical Journal Editor. Frequently asked questions (FAQs). 2018 [cited 24 April 2019]. Available from: <http://www.icmje.org/about-icmje/faqs/>.
11. International Committee of Medical Journal Editor: Recommendations. 2018 [cited 24 April 2019]. Available from: <http://www.icmje.org/recommendations/>.
12. Taichman DB, Backus J, Baethge C, Bauchner H, de Leeuw PW, Drazen JM, et al. Sharing clinical trial data: a proposal from the International Committee of Medical Journal Editors. JAMA. 2016;315:467–8.
13. National Institutes of Health: database. 2018 [cited 24 April 2019]. Available from: <https://prsinfo.clinicaltrials.gov/definitions.html>.
14. WHO: International Clinical Trials Registry Platform. Trial registration data set. WHO website. 2019. [cited 24 April 2019]. Available from: <https://prsinfo.clinicaltrials.gov/trainTrainer/WHO-ICMJE-ClinTrialsgov-Cross-Ref.pdf>.
15. Zarin DA, Tse T, Williams RJ, Califf RM, Ide NC. The ClinicalTrials.gov results database – update and key issues. N Engl J Med. 2011;364:852–860.
16. Horton R: Offline: Data sharing-why editors may have got it wrong. Lancet. 2016;388:1143.
17. Zarin DA, Tse T: Trust but verify: trial registration and determining fidelity to the protocol. Ann Intern Med. 2013;159:65–7.
18. Godlee F: Goodbye PubMed, hello raw data. BMJ. 2011;342: d212.
19. Sharfstein JM, Miller JM, Davis AL, Ross





- JS, McCarthy ME, Smith B, et al. Blueprint for transparency at the U. S. Food and Drug Administration: recommendations to advance the development of safe and effective medical products. *J Law Med Ethics*. 2018;45(2 suppl):7–23.
20. Arzberger P, Schroeder P, Beaulieu A, Bowker G, Casey K, Laaksonen L, et al. An international framework to promote access to data. *Science*. 2004;19303(5665):1777–8.
  21. Smith LS. Why sharing matters for electrophysiological data analysis. *Brain Res Bull*. 2015;119:145–9.
  22. Zarin DA. Participant-level data and the new frontier in trial transparency. *N Engl J Med*. 2013;369:468–9.
  23. Yale Collaboration for Research Integrity and Transparency. Promoting transparency in clinical research: Why and How [white paper]. 2017 [cited 24 April 2019]. Available from: [https://law.yale.edu/system/files/area/center/crit/document/crit\\_white\\_paper\\_november\\_2017\\_best\\_.pdf](https://law.yale.edu/system/files/area/center/crit/document/crit_white_paper_november_2017_best_.pdf).
  24. Ohmann C, Banzi R, Canham S, Battaglia S, Matei M, Ariyo C, et al. Sharing and reuse of individual participant data from clinical trials: principles and recommendations. *BMJ Open*. 2017;7:e018647.
  25. Lo B, DeMets DL. Incentives for clinical trialists to share data. *N Engl J Med*. 2016;375:1112–5.
  26. European Federation of Pharmaceutical Industries and Associations (EFPIA) and Pharmaceutical Research and Manufacturers of America (PhRMA). Joint EFPIA-PhRMA principles for responsible clinical trial data sharing. 2014 [cited 24 April 2019]. Available from: <https://www.efpia.eu/media/25189/principles-for-responsible-clinical-trial-data-sharing.pdf>.
  27. International Federation of Pharmaceutical Manufacturers & Associations. IFPMA Principles for responsible clinical trial data sharing. 2018 [cited 24 April 2019]. Available from: [https://www.ifpma.org/wp-content/uploads/2010/11/IFPMA-Principles\\_Data-Sharing-FINAL-w-QA-vF.pdf](https://www.ifpma.org/wp-content/uploads/2010/11/IFPMA-Principles_Data-Sharing-FINAL-w-QA-vF.pdf).
  28. Taichman DB, Sahni P, Pinborg A, Peiperl L, Laine C, James A, et al. Data sharing statements for clinical trials: a requirement of the International Committee of Medical Journal Editors. *Ann Intern Med*. 2017;167:63–5.
  29. Chan AW, Hrobjartsson A. Promoting public access to clinical trial protocols: challenges and recommendations. *Trials*. 2018;19:116.
  30. Diong J, Butler AA, Gandevia SC, Heroux ME. Poor statistical reporting, inadequate data presentation and spin persist despite editorial advice. *PLoS One*. 2018;13:e0202121.
  31. Li G, Abbade LPF, Nwosu I, Jin Y, Leenus A, Maaz M, et al. A systematic review of comparisons between protocols or registrations and full reports in primary biomedical research. *BMC Med Res Methodol*. 2018;18:9.
  32. Alfonso F, Adamyan K, Artigou JY, Aschermann M, Boehm M, Buendia A, et al. A new editorial initiative of the International Committee of Medical Journal Editors. Implications for the Editors' Network. *Acta Cardiol Sin*. 2017;33:315–22.
  33. Peterson ED, Rockhold FW. Finding means to fulfill the societal and academic imperative for open data access and sharing. *JAMA Cardiol*. 2018;3:793–4.
  34. MRCT Multiregional Clinical Trials and European Medicines Agency. Data Anonymization – A key enabler for clinical data sharing [workshop report]. 2018.

Available from: [https://www.ema.europa.eu/en/documents/report/report-data-anonymisation-key-enabler-clinical-data-sharing\\_en.pdf](https://www.ema.europa.eu/en/documents/report/report-data-anonymisation-key-enabler-clinical-data-sharing_en.pdf).

35. Manamley N, Mallett S, Sydes MR, Hollis S, Scrimgeour A, Burger HU, et al. Data sharing and the evolving role of statisticians. *BMC Med Res Methodol*. 2016;16 Suppl 1:75.
36. Bierer BE, Crosas M, Pierce HH. Data authorship as an incentive to data sharing. *N Engl J Med*. 2017;377:402.
37. O'Donoghue C. UK: The Interplay Between The Clinical Trials Regulation And The GDPR. 2019 [cited 24 April 2019]. Available from: <http://www.mondaq.com/uk/x/781196/Data+Protection+Privacy/The+Interplay+Between+The+Clinical+Trials+Regulation+And+The+GDPR>.
38. Pountney D, Binns R. Planning ahead in the EU: the impact of the GDPR on clinical trials and research. 2018 [cited 24 April 2019]. Available from: <https://pink.pharmaintelligence.informa.com/PS122336/Planning-Ahead-In-The-EU-The-Impact-Of-The-GDPR-On-Clinical-Trials-And-Research>.
39. Peloquin D, Massey R, DiMaio M, Bierer B, Barnes M. Guidance regarding interaction between GDPR and EU Clinical Trial Regulation leaves several questions unanswered. Professional perspective. 2019 [cited 24 April 2019]. *Bloomberg Law*. Available from: <https://www.ropesgray.com/en/biographies/p/david-peloquin>.
40. European Commission, Directorate-General for Health and Food Safety. Question and Answers on the interplay between the Clinical Trials Regulation and the General Data Protection Regulation. 2019 [cited 24 April 2019]. Available from: [https://ec.europa.eu/health/sites/health/files/files/documents/qa\\_clinicaltrials\\_gdpr\\_en.pdf](https://ec.europa.eu/health/sites/health/files/files/documents/qa_clinicaltrials_gdpr_en.pdf).
41. ClinicalStudyDataRequest.com. Welcome to ClinicalStudyDataRequest.com. 2019 [cited 24 April 2019]. Available from: <https://www.clinicalstudydatarequest.com/Default.aspx>.
42. Yale University. The YODA Project. 2019 [cited 24 April 2019]. Available from: <https://yoda.yale.edu>.
43. Vivli Center for Global Clinical Research Data. A global clinical research data sharing platform. 2019 [cited 24 April 2019]. Available from: <https://vivli.org/>.
44. Project Data Sphere. 2019 [cited 24 April 2019]. Available from: <https://projectdatasphere.org/projectdatasphere/html/home>.
45. TransCelerate Biopharma Inc. DataCelerate. DataCelerate. 2019 [cited 24 April 2019]. Available from: <https://www.transceleratebiopharmainc.com/datacelerate/>.
46. ADNI: Alzheimer's Disease Neuroimaging Initiative. 2019 [cited 24 April 2019]. Available from: <http://adni.loni.usc.edu/>.
47. Drazen JM, Morrissey S, Malina D, Hamel MB, Campion EW. The importance – and

the complexities - of data sharing. *N Engl J Med*. 2016;375:1182–3.

48. Tucker K, Branson J, Dilleen M, Hollis S, Loughlin P, Nixon MJ et al. Protecting patient privacy when sharing patient-level data from clinical trials. *BMC Med Res Methodol* 2016;16 Suppl 1:77.

## Author information

**Kathy B. Thomas**, PhD, is an independent consultant and medical writer with more than 20 years of experience in the pharma industry and academia; she has extensive knowledge of clinical trial disclosure USA and EU laws and processes, as well as clinical trial database entries, internal guidelines and processes to assure compliance. Previous appointment includes Head of Medical Writing at Altana Pharma AG in Konstanz, Germany.

**Robert A. Paarlberg** is the Principal of Paarlberg & Associates LLC, a consultancy founded in 2010 that specialises in U. S. and EU clinical trial disclosure strategy and operations as well as regulatory policy and intelligence. Bob has more than 35 years of pharmaceutical industry experience in US and international regulatory affairs. He is the former Chair of DIA's Clinical Trial Disclosure Community (2013 – 2018). Bob can be contacted at [rpaarlberg@comcast.net](mailto:rpaarlberg@comcast.net).

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