How FAIR are pharma publication data?

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Abstract
Sharing research data increases reusability, reduces waste, supports reproducibility and promotes innovation. In medical research, sharing data also promotes transparency and access to information relevant to patient care.

While important advancements have been made in data sharing by regulators, the pharmaceutical industry and academic publishers, several barriers remain. Some of these barriers stem from concerns about data privacy and patient safety, but others are related to the need for confidence in sharing, which can be improved through agreed standards and systems for reuse of research data, including the application of FAIR (findable, accessible, interoperable, and reusable) principles and the overarching principle of “as open as possible, as closed as necessary”.

Medical writers, who are key links between the pharmaceutical and publishing industries, can contribute to making pharma publication data FAIRer. They also have an important role in educating others about the path to more findable, accessible, interoperable, and reusable data.

Introduction
Good data management is essential in a healthy research ecosystem. Greater access to appropriately shared data increases reusability, reduces waste of resources, supports reproducibility, and promotes innovation.

The landscape of healthcare data sharing has changed considerably over the past decade. Registration of clinical trials and disclosure of the results of many types of trials are mandatory in the US, the EU, UK and other countries.¹–² Publicly available lay language summaries of clinical trials are also mandatory in the EU.³ The data sharing policies of most pharma companies adhere to the principles and positions developed by industry bodies such as the Pharmaceutical Research and Manufacturers of America (PhRMA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA).³–⁵ These commitments include publishing all human trial results, including “negative” results, in appropriate peer-reviewed journals.

While the principles of registering and disclosing clinical trial results are now widely accepted, even if incompletely adopted,⁶ sharing individual patient data is more complex. The principles of open science and open data championed by many funders, regulators, and national and international policy organisations have to be balanced with responsibilities towards patient privacy, legal consent, data ownership, and intellectual property.⁷–²¹

The use of repositories that meet data sharing requirements while protecting individual privacy can help ensure that research data are “as open as possible, as closed as necessary”. This statement is often associated with the FAIR principles, which state that research data should be findable, accessible, interoperable, and reusable by both humans and machines (Table 1).²²–²³ The FAIR principles...
seek to address the rising need to strengthen the infrastructure supporting the reuse of scholarly data, so that data use can be automated and standardised. Importantly, FAIR principles apply to both the raw data and to their associated metadata – the data that enable discovery, linkage, and reuse across multiple systems.

The FAIR principles are domain-agnostic, and can be applied to many types of data including clinical trial and healthcare data.24 As medical writers have key roles in communicating research findings, and preparing data to be shared, they are well placed to influence data sharing best practice in publications and promote FAIR data sharing efforts where possible.

FAIR principles in medical publishing
Most medical publishers have endorsed the International Committee of Medical Journal Editors (ICMJE) recommendations on data sharing.25–26 Authors of articles that report clinical trials must submit a data sharing statement with their manuscript and, for all trials that began enrolment after January 1, 2019, they must also include a data sharing plan when registering the trial.

Some publishers have also endorsed the FAIR principles, at least for a subset of their journals (Table 2), and more journals may join them as the support for FAIRer data grows.

How findable are pharma publication data?
Findability refers to how easily identifiable published data are. Table 1 highlights the four aspects of this principle.

Aggregated and summary data produced by pharma companies are fairly easy to discover through platforms such as ClinicalTrials.gov31 and publications. The link to the raw data used to produce these summary outputs, however, is not always obvious.

Pharma companies often deposit patient-level data from clinical trials on repositories that are used by multiple companies or institutions. These repositories include Vivli,32 ClinicalStudyDataRequest.com,33 and the Yale University Open Data Access (YODA) Project.34

On Vivli, for example, all data sets are assigned a unique digital object identifier (DOI), in line with the F1 criterion. Furthermore, Vivli uses patient population, intervention, comparison and outcomes (PICO) searches designed to yield more precise search results from broader clinical questions to optimise findability. Vivli has a process to extract and curate metadata from source documents and other indexing platforms, although the current catalogue does not yet enable highly precise search and browse functionality.

Some pharma companies also use company-specific databases to hold and share some types of data, such as non-interventional trial data. In these cases, it is often unclear whether F1–F4 criteria are being met.

Journals with more stringent data sharing

<table>
<thead>
<tr>
<th>Table 1. The FAIR principles22</th>
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<tbody>
<tr>
<td><strong>Findable</strong></td>
</tr>
<tr>
<td>F1. (Meta)data are assigned a globally unique and persistent identifier.</td>
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<td>F2. Data are described with rich metadata (defined by R1 below).</td>
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<tr>
<td>F3. Metadata clearly and explicitly include the identifier of the data they describe.</td>
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<td>F4. (Meta)data are registered or indexed in a searchable resource.</td>
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<tr>
<td><strong>Accessible</strong></td>
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<tr>
<td>A1. (Meta)data are retrievable by their identifier using a standardised communications protocol.</td>
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<tr>
<td>A1.1 The protocol is open, free, and universally implementable.</td>
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<tr>
<td>A1.2 The protocol allows for an authentication and authorisation procedure, where necessary.</td>
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<tr>
<td>A2. Metadata are accessible, even when the data are no longer available.</td>
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<tr>
<td><strong>Interoperable</strong></td>
</tr>
<tr>
<td>I1. (Meta)data use a formal, accessible, shared, and broadly applicable language for knowledge representation.</td>
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<td>I2. (Meta)data use vocabularies that follow FAIR principles.</td>
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<td>I3. (Meta)data include qualified references to other (meta)data.</td>
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<td><strong>Reusable</strong></td>
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<td>R1. (Meta)data are richly described with a plurality of accurate and relevant attributes.</td>
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<td>R1.1 (Meta)data are released with a clear and accessible data usage license.</td>
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<td>R1.2 (Meta)data are associated with detailed provenance.</td>
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<tr>
<td>R1.3 (Meta)data meet domain-relevant community standards.</td>
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How FAIR are pharma publication data?

Accessibility supports data reuse and integration. Importantly, accessible data are not the same as open data. Data that are not in the public domain but that are accessible to qualified researchers, after evaluation by a review panel, are not open but can be FAIR. Two FAIR criteria address the principle of accessibility (Table 1).

Criterion A1 refers to the ability of retrieving data or metadata using an open, free, and standardised protocol that also includes an authorisation and authentication process when necessary. Following regulatory and industry guidelines, pharma companies have committed to deposit summary results for eligible trials conducted in the US on the ClinicalTrials.gov platform and for all trials conducted in the EU on the EudraCT platform within specified time frames. The next step towards accessibility is to continue to increase the rates of clinical trial data sharing on these platforms by both pharma and academic researchers.

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Increasing the accessibility of patient-level data is a harder issue to tackle. Pharma companies have justifiable concerns about data privacy and patient safety. They must also overcome hurdles associated with the costs of data management and curation, and the potential delays in publication timelines that may result from preparing data to be shared in appropriate formats and deposited in specific platforms.

However, even heavily protected and private data can be FAIR, if the metadata clearly states the data privacy requirements restricting access to data. The YODA repository provides detailed information on frequent reasons data access requests may be denied, such as restrictions arising from informed consent agreements with patients.

Vivli stores data for up to 10 years and maintains the persistent DOI associated with the description of a data set even after the data set is

Unusual or complex data sets might be more difficult to standardise owing to the time and costs involved in data curation.

<table>
<thead>
<tr>
<th>Policy type</th>
<th>Data sharing</th>
<th>Data citation</th>
<th>Data availability statement</th>
<th>Peer review of data</th>
<th>Licence applied to data set</th>
<th>FAIR standards for data</th>
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<td>Optional</td>
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<td>Author’s choice</td>
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<td>Encourages data sharing with evidence</td>
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<tr>
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<td>Author’s choice</td>
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<tr>
<td>Mandates data sharing and peer review of data</td>
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<td>Required</td>
<td>Required</td>
<td>Author’s choice</td>
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<td>CC0, CC BY or equivalent (open data)</td>
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<tr>
<td>Mandates data sharing and peer review of data, which must be open and fully FAIR</td>
<td>Required</td>
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<td>Required</td>
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<td>CC0, CC BY or equivalent (open data)</td>
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The table shows an overview of data sharing policies, combining information from four publishers: Taylor & Francis, Springer Nature, Wiley, and the Public Library of Science (PLOS). Springer Nature and Wiley have four tiers of data sharing for different journals, whereas Taylor & Francis has five tiers. PLOS has a single data sharing policy for all its journals.

CC0, Creative Commons Zero; CC BY, Creative Commons Attribution.
no longer accessible, supporting the A2 criterion. Whether metadata are accessible after the data are no longer available in other repositories is less clear. Unification and standardisation of repository accessibility criteria could help to increase FAIRness.

Journals that mandate data sharing often recommend authors use an external repository, which can help meet A1.1 and A1.2 criteria. Journals do not typically require publication-associated data to meet criterion A2, although publications in some Taylor & Francis journals must meet fully FAIR criteria.

At the bridge between pharma research and publishers, medical writers are uniquely positioned to help pharma companies prepare even protected data in the most accessible way possible and support authors with information they may need to overcome data accessibility barriers.

How interoperable are pharma publication data?
Interoperable data can be integrated with other data, applications, or workflows for analysis, storage, and processing. Table 1 shows the three criteria within this principle.

Pharma companies are making increasing efforts to structure and annotate their data in a way that enables and facilitates interoperability and reuse. Enabling interoperability of data from multiple sources is also one of the main stated goals of the Vivli platform. Despite these advances, it is often difficult to reuse and reanalyse data across different systems, even when the data are accessible. The COVID-19 pandemic, which highlighted the healthcare benefits of data sharing at scale, spurred several pharma voices to call for greater efforts to increase interoperability of data across the industry.

Medical writers can advance this FAIR principle by helping to produce data and metadata in standardised formats and with controlled vocabularies that make them easy to integrate in multiple workflows, users and systems. Using standard file types, machine-readable text rather than PDFs and open-source software rather than proprietary software for storing data (for example, .csv rather than Excel) can help, as well as clearly annotating table headings, scales and other elements that make the data easy to reuse across systems. In addition to preparing data for publications, medical writers can also help to promote repositories that favour interoperable data.

How reusable are pharma publication data?
Publishing (meta)data in a manner that increases its use(ability) for the community is the primary objective of FAIRness. This FAIR principle has one criterion with three components.

Criterion R1.1 states that (meta)data are released with a clear and accessible data usage licence. The extent to which this criterion is being met across all pharma publication data is unclear, but the Pistoia Alliance, an industry collaboration, does recommend that there are always human-readable and machine-readable pointers in the metadata to the data owner or license.

Several journals, including the most prestigious medical journals, request that protocols and statistical analysis plans are available for clinical trial publications, and there is evidence that researchers, including pharma companies, are complying with this requirement. In addition, many publishers require data citations (Table 2), in alignment with the Joint Declaration of Data Citation Principles. These efforts support criterion R1.2, which recommends that data and metadata are associated with their provenance.

The data sets published as part of a pharma publication typically adhere to domain-relevant community standards, in line with criterion R1.3. Those data sets that are submitted to a known repository do so as well, as the requirements for data submission and entry into these platforms encourage standardisation. However, unusual or complex data sets might be more difficult to standardise owing to the time and costs involved in data curation. Recognition of the value of data curation and an appropriate set of incentives for this type of work could promote further adherence to R1.3.

Conclusion
Open Pharma exists to improve the transparency, accountability, accessibility, and discoverability of pharma publications; this ultimately has an impact on patient care. Responsible data sharing supports all of these goals and can increase trust in the pharma industry and its research outputs.

Responsible data sharing recognises the public health benefits of access to reusable data, but also the rights of patients and other people involved in clinical research. To make data available while protecting the personal information of research participants, researchers may need to anonymise or randomise data, and even omit data that, when shared, would be likely to reveal a patient’s identity. Any data sharing increases transparency, but not all data sharing enables reproducibility and reuse.
While pharma publication data cannot always be open, for legal, privacy and safety reasons, there’s an opportunity to make them FAIRer. Improvements are in progress but there is still much to be done, including: standardisation of data structure, metadata and systems to enable interoperability; unification of policies across regulators, publishers, pharma companies, and other research data producers; clearer guidance about metadata that advances all four FAIR principles while decreasing the burden of data management; and education of authors on the benefits of FAIRer data for their research.

Medical writers, linking academic authors, pharma companies, and publishers, are in an influential position to drive these changes.

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Disclosures and conflicts of interests

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