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Brief Opinion

ASTRO Journals' Data Sharing Policy and Recommended Best Practices

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Abstract

Transparency, openness, and reproducibility are important characteristics in scientific publishing. Although many researchers embrace these characteristics, data sharing has yet to become common practice. Nevertheless, data sharing is becoming an increasingly important topic among societies, publishers, researchers, patient advocates, and funders, especially as it pertains to data from clinical trials. In response, ASTRO developed a data policy and guide to best practices for authors submitting to its journals. ASTRO's data sharing policy is that authors should indicate, in data availability statements, if the data are being shared and if so, how the data may be accessed.

Note - Earn CME credit by taking a free online assessment at https://academy.astro.org/

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Introduction

Researchers are increasingly expected to make their data findable, accessible, interoperable, and reusable (FAIR),[1] with the goal of generating new scientific insights that ultimately benefit patients. This is especially true for publicly (eg, National Institutes of Health [NIH]) funded research and was further evidenced by the Open Government Data Act that went into effect on July 15, 2019.[2] Given the symbiotic relationship that exists between science and society, scientific journals can play an important role in cultivating a culture of data sharing. Journals bear much responsibility for facilitating scientific discovery and maintaining credibility with the public by publishing studies that embrace transparency and invite reproducibility. Although dialogue surrounding data sharing should also occur further upstream (eg, during funding and research proposal stages), journal editorial teams and publishers can play a key role in educating authors about the benefits of data sharing and related best practices. Policies and approaches to data sharing may slightly vary by funder or publisher, nevertheless ASTRO strives to minimize ambiguity around data sharing and highlight approaches that maximize transparency, discovery, and scientific reuse of data.

ASTRO Journals' Data Sharing Policy

ASTRO does not require data sharing. In the interest of transparency and in support of FAIR data principles, however, authors are asked to include a data availability statement with their submitted work. Data availability statements should indicate whether the data are being shared and if so, how the data may be accessed. Data availability statements will be published alongside articles submitted after this policy goes into effect (on January 1, 2020).

Data Availability Statements

Data availability statements are short descriptions included with scientific publications that provide readers with the conditions surrounding access to data underlying the research being reported. The overarching goals of publishing data availability statements are to facilitate quick identification of relevant data in a study, to promote transparency in all instances of access or restriction, and to increase awareness of data availability statement structure.

A data availability statement should include (1) a description about the data underlying the article (eg, the type of data analyzed in the study); (2) a declaration of whether the data are available for reuse, and how readers may access the data (including but not limited to licensing or proposal review); (3) the name of the repository or platform hosting the data and a persistent identifier link to the data object(s)—typically a digital object identifier (DOI); and (4) if applicable, a statement on data sharing restrictions or unavailability (eg, embargoed data).

Data included in data availability statements should be cited within the text and listed in the references section. Examples of data availability statements are shown in Table 1.

Research Data Sharing Best Practices

ASTRO encourages authors to share research data at the minimum that is necessary to understand, evaluate, replicate, and build upon reported findings by the time of publication, following health information privacy standards,[3] and scholarly publishing community best practices around data deposition and citation.[4] The definition of research data here is derived from the United States Office of Management and Budget,[5] which states:

> Research data means the recorded factual material commonly accepted in the scientific community as necessary to validate research findings, but not any of the following: preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues. This "recorded" material excludes physical objects (eg, laboratory samples). Research data also do not include (i) Trade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law; and (ii) Personnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study.

In practice, data sharing may not only be considered at subject level data but may consist of derived data and data products such as software or code used to generate, process, or interpret data that are reported in an article (eg, figures and analyses). Ideally, data sets will be deposited in discipline-specific, community-recognized repositories, cited in text and listed in the reference section after the Joint Declaration of Data Citation Principles.[6] Previously published methods and data should likewise be cited. An example data set citation is:

Le Noury JC, Nardo JM, Healy D, Jureidini J, Raven M, Tufanaru C, Abi-Jaoude E. (2015) Data from: Restoring Study 329: Efficacy and harms of paroxetine and imipramine in treatment of major depression in adolescence. Dryad Digital Repository. Available at: https://doi.org/10.5061/dryad.bv8j6. Accessed May 29, 2019.

Data must be uniquely identifiable and persistent to be findable and accessible by machines and humans. DOIs,

Table 1 Data availability statement examples

Category	Example statement(s)	Published in
All data available	1. Clinical study reports, detailed data tables, and programming code are available on the Dryad Digital Repository (https://doi.org/10.5061/dryad.bv8j6) and at www.Study329.org/.	*British Medical Journal*
	2. Patient level data for this study is available at: http://www.gsk-clinicalstudyregister.com/study/29060/329.	GlaxoSmithKline Study Register
	3. All data generated and analyzed during this study are included in this published article (and its supplementary information files).	
Third-party data	1. This study was based on the English national cancer registry data. The authors do not own these data and hence are not permitted to share them in the original form (only in aggregate form, eg, publications). At the time of request data were provided by the Office for National Statistics but now all cancer registrations are owned and maintained by Public Health England.	*British Medical Journal*
	2. Data are available from the UK Biobank for researchers who meet the criteria and gain approvals to access the research database from the UK Biobank access management committee at the University of Oxford. Applications are reviewed and approvals granted subject to meeting all ethical and research conditions set forth by the UK Bio Bank. Information on access procedures, general enquiries, and contact information can be found online: https://www.ukbiobank.ac.uk/key-uk-biobank-contacts/. The full code for the analysis is available at: https://github.com/PRISM-UoN/UK-Bio-Bank-Machine-Learning-Project.	*PLOS One*
Restricted access (commercial)	Data for these analyses were made available to the authors through third-party license from Optum and Truven, 2 commercial data providers in the United States. As such, the authors cannot make these data publicly available due to data use agreement. Other researchers can access these data by purchasing a license through Optum and Truven. Inclusion criteria specified in the Methods section would allow other researchers to identify the same cohort of patients we used for these analyses. Interested individuals may see https://www.optum.com/solutions/prod-nav/product-data.html for more information on accessing Optum data and https://marketscan.truvenhealth.com/marketscanportal/for more information on accessing Truven data.	*PLOS Med*
Restricted access (legal/ethical)	It is Novartis Policy not to share data from interim trial results, even if a Health Authority approval has been granted based only on interim trial data. Novartis will share data when the trial CSR is completed, and the results published.	Clinical Study Data Request

which have been commonly used for indexing scholarly articles, are unique and persistent, and are able to be assigned to data (as shown in the example reference above). It is prudent to deposit data into a repository that issues a DOI. Studies that provide underlying data via a persistent identifier have been shown to have a 25% citation advantage over studies that do not point to underlying data at all.[7] The growth of data citation practices are further evidenced by Clarivate Analytics' launch of Data Citations Index.[8] DOIs are essential for providing the linkages that allow data and other digital outputs to be discovered and referenced.

One misconception about FAIR data is that all data should be open. This is not the case; one should describe

how data can be accessed. If data sharing restrictions exist, the data availability statement should describe to readers what the limitations are and how qualified persons, if applicable, may be approved to access data for research purposes. As an example, commercially sponsored research terms that require an embargo to ensure proper management of trade secrets may restrict access to data.

Furthermore, ASTRO Journals share the International Committee of Medical Journal Editors belief that there is an ethical obligation to responsibly share data generated by interventional clinical trials. As such, ASTRO supports the International Committee of Medical Journal Editors' requirement that a data sharing plan be included in the trial's registration and that the article reporting clinical trial results should include a data sharing statement indicating whether deidentified participant data (including data dictionaries) will be shared; whether additional, related documents will be available (eg, study protocol, statistical analysis plan, etc.); when the data will become available and for how long; and by what access criteria data will be shared (including with whom, for what types of analyses and by what mechanisms).[9]

Data repositories

Authors should select repositories most appropriate for their research; in particular, domain repositories that host data from their discipline or subdiscipline should be considered (see also NIH-supported data repositories[10] and Data Cite's FAIR data repository finder).[11] If such a repository is not available, general repositories that assign DOIs or institutional repositories can be used. A list of potential repositories is also provided in Table 2 as a general resource. Additional educational resources on data, metadata standards, journals and funder data sharing policies are available at https://fairsharing.org/.

Data sharing restrictions

Sharing research data may be restricted due to intellectual property or privacy concerns determined by national laws, research sponsor policies, and copyright licensing agreements. More commonly, restrictions may be attributed to data disclosure risks or third-party data.

- Data disclosure risks: Institutional or commercially sponsored research will typically include trained data curators who apply anonymization standards to protect confidentiality. If there are possible data disclosure risks, that is, where privacy or legal concerns exist, authors should specify in their data availability statement if restricted-use data are available (eg, through a data use agreement) and identify the group to which requests should be submitted. The reasons for restrictions provided through the data availability statement should be unambiguous. It is not best practice for the authors to be the sole named individuals responsible for ensuring data access.
- Third party data: Third-party data refers to data that cannot be legally distributed by the authors. Authors should share any data specific to their analysis that they can legally distribute. If authors do not have the rights to distribute the data, they should include all necessary contact information in the data availability statement to gain access to the relevant data. If permission is required to use a third-party data set, authors should include the third-party source and verification of permission in the data availability statement, as well as provide proper acknowledgment in the article. (Adapted from Earth Science Information Partners CC BY.)[26]

When access to data is restricted, authors should disclose terms of use or unavailability in their article's data availability statement. Note that several data repositories listed in Table 2 support restricted access.

Data anonymization and intellectual property

Barriers to productive reuse of sensitive data can be reduced through standardized data anonymization; careful review of sponsored research agreements; and clear marking of reuse permissions by rightsholders.

Direct and indirect identifiers that risk research subject's confidentiality should be masked and randomized to ensure compliance with privacy laws and guidelines, thus allowing data to be shared for research purposes. Section 164.514(a) of the Health Insurance Portability and Accountability Act of 1996 Privacy Rule provides a standard for deidentification of protected health information using either the Expert Determination or Safe Harbor methods.[27] The European General Data Protection Regulation also provides guidance on deidentification.[28] Novartis, a global pharmaceutical company, provides a comprehensive example on how to generate compliant deidentified data sets.[29]

Researchers considering sharing or reusing data may raise questions about intellectual property. Data sharing restrictions are commonly attributed to commercial trade secrets (or proprietary information), patents, and copyright. Proprietary data from industrial or commercially sponsored research may have implications for future patents; as a result, a researcher collaborating with a pharmaceutical company may be contractually bound to embargo their research data for a set period.[30] Sponsored

Table 2 Potential data repositories*

	Description	DOI provided?
Clinical Study Data Request (CSDR)	A consortium of clinical study sponsors or funders. CSDR facilitates restricted access to patient-level data from clinical studies.[12]	N/A
Dryad	General repository. Dryad collects a data publishing charge of $120 upon data publication, unless there is a sponsor or fee waiver in place. Additional charges apply to data packages in excess of 20 GB. See also frequently asked questions.[13]	Yes
Figshare	Free to use general repository, which allows up to 5 GB per file upload.[14] Supports restricted access and can accommodate double-blind review.[15]	Yes
Mendeley Data	A free to use general repository (up to 10 GB per data set). See also frequently asked questions.[16]	Yes
OpenScience Framework	Free to use general repository, which allows up to 5 GB per file upload.[17]	Yes
Project Data Sphere	Nonprofit, online platform that facilitates sharing and analysis of historical, patient-level data from academic and industry phase III cancer clinical trials. Deidentification of patient level data are the responsibility of the data provider.[18]	No
Synapse	Open source biomedical research platform for data sharing, analysis, and collaboration. Supports restricted access.[19]	Yes
The Cancer Imaging Archive (TCIA)	TCIA hosts an archive of cancer imaging for public consumption. Their Clinical Trials Processor software performs deidentification and curation according to Digital Imaging and Communications in Medicine (DICOM) standards.[20,21]	Yes
Genomic Data Commons (GDC)	The GDC contains National Cancer Institute (NCI)-generated data from some of the largest and most comprehensive cancer genomic data sets, including The Cancer Genome Atlas and Therapeutically Applicable Research to Generate Effective Therapies.[22]	No
Sequence Read Archive (SRA)	The SRA is NIH's primary archive of high-throughput sequencing data and is part of the International Nucleotide Sequence Database Collaboration that includes at the NCBI SRA, the European Bioinformatics Institute, and the DNA Database of Japan. Data submitted to any of the 3 organizations are shared among them.[23]	No
Vivli	Nonprofit, data sharing and analytics platform created to sharing of individual participant-level data from completed clinical trials. Vivli partners with Privacy Analytics, who assists with anonymization.[24]	Yes
Zenodo	General repository. Zenodo accepts up to 50 GB per data set. Monetary donations are encouraged to maintain the repository.[25] Can accommodate double-blind review.[15]	Yes

* ASTRO does not endorse any specific repositories and is not responsible for any data deposited. The list of potential repositories is provided as a general resource from and for the scientific community. If your repository of choice is not listed and would like to submit a recommendation for ASTRO's data sharing frequently asked questions page, please e-mail journals@astro.org.

research agreements and institutional or hospital intellectual property policies would establish guidelines for ownership and disclosure of proprietary information.[31,32]

Copyright allows owners of the copyrighted work(s) to govern proposed use and ensures proper attribution. Licenses for copyrighted data can be tailored to accommodate conditional reuse; alternatively a standard Creative Commons Attribution (CC BY) license can be applied.[33] Researchers should be aware of the ability to use a contract to enable data reuse through licensing, while protecting intellectual property rights (eg, granting permission for access while restricting downstream reuse).[34] Clinical Study Data Request provides a contract template that can be adopted for executing a data use agreement.[35]

Clearly noting data terms of use, not overstating disclosure risks, and carefully reviewing sponsorship agreements help limit unnecessary time and confusion for researchers seeking to productively share or reuse data.

Standard Nomenclatures for Radiation Therapy

Besides Findability and Accessibility which was the focus of the previous sections, another important aspect of FAIR is interoperability, which refers to the ability of data sets to be combined with other data. A fundamental component of interoperability is adherence to standard nomenclature and formats. As the leading organization in radiation oncology, ASTRO encourages good stewardship of radiation therapy–specific data elements. The radiation therapy community has begun to publish standard nomenclatures, such as AAPM TG 263, that recommend naming conventions for the regions of interest used for treatment planning.[36] When data are shared, where and when possible, the data should adhere to community-recognized standards and formats (Table 3). When it is not possible to align with standard nomenclatures, it is critical to be clear of the meaning of each data element provided in the shared data. Additional efforts in ASTRO are underway on defining the minimum data elements that should be available on all radiation therapy treatments.[40] These initiatives are expected to improve the information on radiation treatments administered in clinical trials and in other studies, thereby allowing cross-study comparisons of radiation treatments.

Conclusions

Although ASTRO journals do not require data sharing, ASTRO is committed to research integrity and transparency. The sharing of research data is one way to embrace these important principles. The best practices described in this article reflect increasingly common aspirations of publishers, funders, and research institutions, which aim to foster better data stewardship and facilitate scientific discovery by making data FAIR. In conjunction with FAIR data principles, the NIH released its program,

Table 3 Standard nomenclature and formats recognized in radiation therapy

Resource	Description
NCI Thesaurus (NCIt)	"NCI Thesaurus (NCIt) is NCI's reference terminology and ontology. NCIt provides responsive, science-based terminology concepts used in NCI semantic infrastructure and information systems. It covers terminology for clinical care, translational, and basic research, and public information and administrative activities."[37]
American Association of Physicists in Medicine Task Group 263: Standardizing Nomenclatures in Radiation Oncology	"Nomenclature guidelines and values in radiation oncology for use in clinical trials, data-pooling initiatives, population-based studies, and routine clinical care by standardizing: (1) structure names across image processing and treatment planning system platforms; (2) nomenclature for dosimetric data (eg, dose-volume histogram-based metrics); (3) templates for clinical trial groups and users of an initial subset of software platforms to facilitate adoption of the standards; (4) formalism for nomenclature schema, which can accommodate the addition of other structures defined in the future."[36]
DICOM-RT and Its Utilization in Radiation Therapy	"In addition to the protocol used in the DICOM standard, 7 DICOM-RT objects—namely, RT Image, RT Structure Set, RT Plan, RT Dose, RT Beams Treatment Record, RT Brachy Treatment Record, and RT Treatment Summary Record—have been created, each with a well-defined data model. The data models set the standard for integration of radiation therapy information for an electronic patient record and would facilitate the interoperability of different radiation therapy systems, thus making possible the sharing of information from different systems."[38]
Radiation Oncology Ontology (ROO)	The Radiation Oncology Ontology (ROO) aims to cover the radiation oncology domain with a strong focus on reusing existing ontologies. ROO models terms including: uniform and nonuniform margins; ROI target volumes and organs-at-risk; dose-volume histogram parameters (Dx, Vx, MLD, etc.); and online or off-line setup protocols.[39]

New Models of Data Stewardship, in hopes of accelerating biomedical research.[41] ASTRO members and affiliates are encouraged to also familiarize themselves with the NIH strategy for data science which provides a roadmap for NIH-funded biomedical data.[42]

Authors submitting to ASTRO's journals can help enable FAIR data by doing the following: (1) adhere to anonymization, nomenclature, and format standards; (2) deposit research data into a trusted FAIR repository; (3) cite and link to the data in the article, following the Joint Declaration of Data Citation Principles;[6] (4) include a data availability statement describing how the data underlying published findings can be accessed, if data are unavailable, and or if restrictions exist.

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