Science for all: Is it all about the publication of data, or beyond?

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Abstract

This article presents an overview of open access initiatives by researchers, journals, government bodies, and regulatory authorities. Open access initiatives are valuable to the scientific community and have increased the amount of clinical research information available to the general public. Sharing this information in a manner that is understood by those without scientific training is important. This article discusses plain language summaries, their requirements and benefits, and what additional steps should be taken to improve transparency in clinical research.

Background

"*None of the main issues which humanity is facing will be resolved without access to information*," Christophe Deloire (Secretary-General of Reporters Without Borders) stated during a presentation at the International Programme for the Development of Communication.[1] Although his statement is related to improving access to information across countries for sustainable development, it also applies to scientific research.

Open access initiatives (Table 1) increase transparency, enhance access to scientific information, and expand the utility of research beyond what is possible within conventional peer-reviewed, subscription-based journals. Open access initiatives:

- Promote transparency in experimental methodology, observation, and collection of data, which in turn improves scientific collaboration.
- Increase the value to society of fundamental scientific research.
- Enhance public confidence in research.
- Increase patient participation in clinical research.[2]

Open access also benefits researchers in publishing their work. It allows authors to retain more control over and rights to their work, meet publication mandates from funding partners, collaborators, or research institutions, and increases the likelihood of funding for future research projects.

Despite the benefits, there are also some challenges with open access. First, there is no clearly defined quality mechanism or rigorous peer-review process for open access publishing[3] as there is for a conventional, subscription-based journal. Secondly, as journals accept a publication fee from authors, open access may create a potential conflict of interest where publishers may want to maximise revenue by accepting a publication fee for anything and everything, and thereby unprofessionally exploit the "author-pay" model of open access publishing.[4] Therefore, it is important that authors select a legitimate open access journal for their publication.

In contrast, the open access movement is supported by regulatory authorities in their drive to make more information on clinical research publicly available (Table 2). This has resulted in new regulatory requirements for sponsors to publish summary results of clinical trials (e.g., on clinicaltrials.gov, EudraCT, and other regional registries) and clinical trial documents (e.g., protocols, statistical analysis plans, clinical study reports, clinical overviews, and summaries). This approach includes robust validation and controls, where the information is reviewed either by a regulatory reviewer or validated through automated system controls. Study sponsors have the opportunity to redact confidential business information before publishing. To help preserve the scientific utility of the documents, regulatory authorities require a justification for information that is to be redacted.

Further open access initiatives within clinical research are driven by pharmaceutical companies, universities, and non-government organisations (Table 3). These allow researchers to request individual patient data from clinical studies in order to conduct secondary, independent analyses.

A relatively recent step forward has been a drive to communicate clinical trial results to patients in an understandable format. These plain language summaries (PLS) have been mandated in Article 37 of the EU CTR 536/2014. This new requirement is accelerating the need to write more documents in plain language and supports greater transparency (e.g., plain language protocol synopses and plain language summaries of publications [PLSPs]). These documents are another step forward for the open access movement by providing clinical research information in a format that is understandable to a wider audience.

Open access initiatives in publications and clinical trial data

Open access has received growing attention and recognition globally.[5] Several methodologies for

open access to publications have also been discussed:

- **Green open access**: The authors self-archive the pre- and post-prints of their publication
- **Gold open access**: Publications are fully accessible through open access journals
- **Hybrid access**: Payment of a publication fee (as an article processing charge) to the publisher to publish an article as open access in an otherwise subscription-based journals.

Through these methodologies, the number of open access journals and publications is increasing.

The objective of open access initiatives is not limited to publications. To improve transparency, regulatory health authorities of various countries have also mandated the publication of clinical documents. These documents provide detailed information about the design, conduct, and analysis of clinical trials, and more comprehensive information on trial results than more traditional publicly available sources such as journal manuscripts. Publication of clinical data enables a comprehensive and independent analysis of clinical trial results. In addition, the availability of such information offers new perspectives and ideas that may lead to innovative insights that can bring additional learning opportunities and better serve humanity.

> There is no clear mechanism to incentivise open access publications coming from original research.

Tables 1, 2, and 3 provide a comprehensive overview of various initiatives taken for open access for publications, public release of clinical trial documents by regulatory authorities, and data sharing by pharmaceutical companies and industry groups, respectively.

Global pattern of international collaboration and open access

In the digital era, academicians and researchers can easily publish their work, which in turn brings them more recognition. However, open access also has certain limitations, such as the author-pay model, no or less quality control,[3] predatory publishing,[3] and providing less incentive for academic researchers.[6] Financial stability, reputation, and resources are important to academic researchers, however, there is no clear mechanism to incentivise open access publications coming from original research. In a blog, Dan Gezelter delivers a harsh verdict on open access, *"… Scientific productivity is measured by the number of papers in traditional journals with high impact factors, and the importance of a scientist's work is measured by citation count. Both these measures help determine funding and promotions at most institutions, and doing open science is either neutral or damaging by these measures…"*.[6]

Despite these issues, open access offers mutual benefits: it permits researchers in developing countries to participate in international collaborative research projects, while researchers from developed countries get to know about local/regional research.[7] The executive summary

Table 1. Open access (OA) initiatives for publications

Initiatives Date	Implementation date	Aspects covered/Comments	Website/ Reference link
arXiv.org	August 1991	• Curated research-sharing platform open to all • Hosts more than two million scholarly articles in eight subject areas (physics, mathematics, computer science, quantitative biology, quantitative finance, statistics, electrical engineering and systems science, and economics)	https://arxiv.org/
Budapest Open Access Initiative (BOAI)	December 2001	• Provides a statement of principle, a statement of strategy, and a statement of commitment to OA • Includes research articles in all academic fields. Recommends two strategies – self-archiving and OA journals	www.budapestopenaccessinitiative.org
Directory of Open Access Journals (DOAJ)	2003	• Covers all areas of science, technology, medicine, social sciences, arts, and humanities • Open access journals from all countries and in all languages are accepted for indexing	www.DOAJ.org
Registry of Open Access Repositories (ROAR)	2003	• Promotes the development of OA by providing timely information about the growth and status of repositories throughout the world	www.roar.eprints.org
Bethesda Statement on Open Access Publishing	June 2003	• Builds on the BOAI by saying how OA would be enacted • Indicates that OA is a property of individual works, not necessarily journals or publishers • Provides statements from three working groups: Institutions and Funding Agencies Working Group, Libraries and Publishers Working Group, and Scientists and Scientific Societies Working Group	Bethesda Statement on Open Access Publishing (earlham.edu)
Berlin Declaration on Open Access	October 2003	• Outlines concrete steps to promote internet as a medium for disseminating global knowledge • Has been signed by over 750 research institutions, libraries, archives, museums, funding agencies, and governments from around the world (as on Aug 25, 2022)	www.berlin9.org/about/declaration
SHERPA Fact SHERPA/RoMEO SHERPA/Juliet OpenDOAR	February 2004	• SHERPA Fact checks the compliance of funder OA policies with a particular journal • SHERPA/RoMEO gives a summary of publishers' OA archiving conditions for individual journals • SHERPA/Juliet enables researchers and librarians to see funders' conditions for open access publication • OpenDOAR enables the identification, browsing, and search for repositories within SHERPA services	About Sherpa Romeo - v2.sherpa
The Registry of Open Access Repositories Mandatory Archiving Policies (ROARMAP)	2005	• A searchable international registry charting the growth of OA mandates adopted by universities, research institutions, and research funders that require their researchers to provide open access to their peer-reviewed research article output	http://roarmap.eprints.org
Open Access Scholarly Publishing Association (OASPA)	October 2008	• Develops and disseminates solutions that advance OA and ensure a diverse, vibrant, and healthy open access community	https://oaspa.org

Initiatives Date	Implementation date	Aspects covered/Comments	Website/ Reference link
OA2020	2015	Aims to: • Transform scholarly journals from subscription to OA publishing • Practice this transformation process by converting resources spent on journal subscriptions into funds to support sustainable OA business models • Engage all parties involved in scholarly publishing to achieve an efficient transition	https://oa2020.us/oa2020-the-eoi
PlanS	September 2018	• Supported by cOAlition S, an international consortium of research funding and performing organisation working under the European Commission • Suggests that scientific publications that result from research funded by public grants must be published in compliant OA journals or platforms without embargo	www.coalition-s.org

of the National Science Foundation (2019) indicates that international collaborations have increased over the last 10 years. A review of scientific literature published in 2018 showed that one out of every five publications has co-authors from multiple countries (23%),[8] indicating a 7.4% increase from 2020.[9] The main reason for this increasing collaboration is that authors in countries that have limited scientific publications have accelerated their global publication output in the last 10 years.[8]

A recent study by Lee and Haupt (2020)[10] evaluated the nature of international collaborations during the COVID-19 pandemic when researchers across the world worked towards a common objective (scientific globalism). This study concluded that scientific globalism improved due to an increase in international collaboration and open access publications during the pandemic. Countries that were impacted more by COVID-19 and had lower GDPs, participated more in scientific globalism than their counterparts in developed countries.

The above findings were confirmed by Moskovin et al. (2021),[11] who conducted a systematic quantitative analysis to evaluate open access instruments and initiatives and developed a methodology for calculating the involvement of countries in the open access movement. They concluded that scientists from low-income countries are more motivated than those from high-income countries to publish their articles in open access journals or platforms partially because their articles may be poorly cited, if not accessible publicly. Countries with the most records in nine open access registries (SHERPA/RoMEO, DOAJ, ROAR, OPEN DOAR, ROARMAP, Berlin Declaration, BOAI, SHERPA/Juliet, OA2020 Initiative) included developed countries (USA, UK, Germany, etc.), developing countries (Indonesia, Brazil, India, Turkey, etc.), and countries with transition economies (Russia, Ukraine, Poland, etc.). Furthermore, based on the selection of 25 countries by the total number of records in open access registers, this study also concluded that developed countries, and developing plus transition economy countries (grouped together), are approximately equivalent in their degree of involvement in the open access movement.

There have also been several initiatives to enhance open access to research by governments and international bodies. In November 2021, UNESCO released its recommendation for Open Science and indicated that by making science more transparent and more accessible, research would be more equitable and inclusive.[12] In August 2022, the US government announced that starting in 2026, any scientific publication that receives federal funding will need to be openly accessible on the day it is published.[13]

Are we doing enough? Value of open science for trial participants

Over the last few years, effort has been focussed on making scientific information not just more available but also more readable. While several clinical documents, including clinical study reports (CSRs), are now published in the public domain (e.g., EMA Policy 0070, HC PRCI), these documents contain scientific jargon that can be impenetrable to a non-scientific audience. More patients want to be fully involved in their health decisions and are eager to learn about the advancements in science and the latest treatments.[14,15] This was highlighted during the COVID-19 pandemic when the latest updates on the COVID-19 drug and vaccine development became living room discussion topics.

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Even before the pandemic, patient advocates have consistently voiced a need to access information on clinical research in easy-to-understand language and in an easy-to-follow format. These voices are being heard by the regulatory bodies and we are seeing increasing regulatory requirements and/or recommendations for plain language documents of clinical trials (e.g., informed consent forms [ICFs], plain language summaries[PLSs] of clinical trial results, and plain language protocol synopses) across regions and countries, such as Europe, UK, and Turkey. More scientific journals are encouraging plain language summaries of publications (PLSPs) to be submitted as a supplement to a manuscript or as a stand-alone publication. Certain publishers, like Future Medicine, are going the extra mile by providing a dedicated platform for PLSPs with the aim of making scientific and medical research more accessible. They also provide several resources to help scientists and medical writers write high-quality PLSPs.[16]

Some sponsors are making plain language documents available in different formats, for example, traditional PDFs, infographics, comics,

Table 2. Initiatives for improved transparency and open access of clinical trial data by regulatory authorities

Regulatory authority	Policy/Initiative/ Rule/ Database	Publication date	Aspects covered and current status	Website links
Pharmaceutical and Medical Devices Agency (Japan)	Disclosure of Information	November 1999	• All Module 2 documents of Common Technical Documents, clinical study report synopses and mini-narratives for serious adverse events • Full clinical study reports are out of scope	Pharmaceuticals and Medical Devices Agency (pmda.go.jp) https://www.jpma.or.jp/english/about/parj/eki4g600000078c0-att/2020.pdf
European Medicines Agency (EMA)	European Union Drug Regulating Authorities Clinical Trials Database (EudraCT) through EU Clinical Trial Register	September 2011	• Publication of protocol and results information on interventional clinical trials	EudraCT Public website - Home page (europa.eu)
EMA	EU Clinical Trial Regulation 536/2014	April 2014	• Harmonisation of the processes for assessment and supervision of clinical trials throughout the EU • Information-sharing and collective decision-making on clinical trials • Transparency of information on clinical trials • High standards of safety for all participants in EU clinical trials • Implemented on Jan 31, 2022	Clinical Trials Regulation | European Medicines Agency (europa.eu)
EMA	EMA Policy 0070	October 2014	• Public scrutiny and secondary analysis of clinical trials • Protection of personal data (PPD) and company confidential information (CCI) • Respect for the boundaries of patients' informed consent • Consequences of inappropriate secondary data analysis, and that such analysis results should also be published • Protecting the Agency's and the European Commission's deliberations and decision-making process • On-halt since September 2018, except for COVID-19 studies	0070 Policy - Publication and access to clinical-trial data (europa.eu)
National Institute of Health (NIH)	Final Rule (42 CFR Part 11)	January 2017	• Protocol registration of applicable clinical trials (ACT) • Disclosure of trial results • Disclosure of full protocol and statistical analysis plan (SAP), after appropriate redactions • Consequences of non-compliance	ClinicalTrials.gov Final Rule (42 CFR Part 11) Information
Food and Drug Administration (US FDA)	Clinical Data Summary Pilot Programme	January 2018	• Pivotal Phase III clinical study reports • Pilot programme was run on a single clinical study report which was completed and learnings from this were shared – further information awaited	Clinical Data Summary Pilot Program | FDA
Health Canada	Public Release of Clinical Information	March 2019	• Anonymised clinical information in drug submissions and medical device applications to be publicly available for non-commercial purposes • Protection of personal information (PI) and confidential business information (CBI) • Secondary and independent analysis of clinical data	Public Release of Clinical Information: guidance document - Canada.ca

Table 3. Data sharing initiatives by pharma companies and industry groups

Initiative	Originator	Implementation date	What it is about?	Website link
Clinical Study Data Request (CSDR)	GlaxoSmithKline	May 2013	• A consortium of clinical study sponsors • Offers facilitation of the responsible sharing of patient-level data from a range of clinical study sponsors through a researcher-friendly platform, including an independent review of proposals, and protection of patient privacy and confidentiality	ClinicalStudyDataRequest.com
The Yale University Open Data Access (YODA) Project	Yale University	October 2014	• Offers responsible sharing of clinical research data, open science, and research transparency • Committed to support research focused on improving the health of patients and informing science and public health	The YODA Project (yale.edu)
Vivli	Multi-Regional Clinical Trials (MRCT) Centre of Brigham and Women's Hospital and Harvard	November 2016	• Includes an independent data repository, in-depth search engine, and a secure research environment • Users can search listed studies, request data sets from data contributors, aggregate data, or share data of their own	https://vivli.org

and videos. With the intention to design these documents with purpose, they are constantly innovating and improving their delivery methods to provide the best experience to their audiences.

While sponsors are producing PLSs and PLSPs that are intended to be easy-to-understand and engaging, there remains a need to measure the impact these documents have on patients and the public. More effort is needed to raise awareness of the availability of plain language information about clinical research. A co-ordinated effort to raise awareness and making these documents available on shared platforms would advance open access and science for all. However, to do this effectively we may need to develop metrics to further evaluate:

- If the information about clinical trials is useful and understandable to the public
- If and how data are being shared and/or reused
- If the patient community and public can contribute to and track the scientific value of generated clinical trial data

Conclusion

Open access offers more transparency and accessibility to research data and drives global collaboration in clinical research. Clinical trial information is currently made public in different formats: research publications in scientific journals; synopses of individual studies on pharmaceutical companies' websites, or through private and controlled portals such as CSDR and Vivli; availability of clinical summaries and clinical documents through a regulatory-driven, easy to understand approach on regulatory authority's dedicated websites (e.g., EMA, Health Canada, PMDA); and plain language documents shared with clinical trial participants. Although these documents are developed for a diverse audience, they serve a common objective – bringing more transparency to clinical research. However, in addition to making more information available to the public, we need to measure understanding and improve awareness amongst the public about the availability of this information. In the coming years, further advances driven by regulatory requirements, publication practices, and global scientific coalitions/ alliances are expected towards open access to research and public availability of data.

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