

# THEME ARTICLE

# Open Pharma: Driving Positive Change in the Communication of Pharma-Sponsored Research

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#### **ABSTRACT**

Open Pharma is a non-profit-seeking collaboration that aims to make the communication of pharma-sponsored research faster, more transparent, more accessible, and more sustainable, focusing on open science principles such as open access and plain language. Open Pharma includes 16 Member and Supporter companies representing the pharma and publishing industries and is facilitated by Oxford PharmaGenesis, a HealthScience consultancy. We believe that innovating the current publications model for pharma research is essential to accelerate medical progress, improve patient care, and increase trust in evidence from the pharma industry.

Open Pharma works as a think tank that seeks to "move the needle," a research hub that produces evidence, a knowledge-sharing "club," and a forum for member voices. Our research, resources, and events are designed to educate, broaden perspectives, and foster connections. We also seek to identify needs and solutions and to develop guidance that supports best practice and positive change across the sector.

Medical writers are uniquely positioned to understand the benefits of open science and to communicate them to their clients. They have an important part to play in promoting the innovations that will increase the quality, transparency, and accountability of medical research communication, which Open Pharma supports.

#### THE ORIGINS OF OPEN PHARMA

Open Pharma is a multisponsor collaboration that aims to drive positive change in the communication of pharma-sponsored research. Trust in pharma industry research was, and still is, estimated to be low, 1,2 despite pharma companies funding at least half of the biopharmaceutical research carried out in the United States and the United Kingdom. 3,4 Established in 2016, Open Pharma was set up in recognition that improving trust in pharma research publications is a goal shared by multiple stakeholders working across the pharmaceutical, publishing, and medical communication sectors, and one only realized through collective action.

Oxford PharmaGenesis, as an independent HealthScience consultancy working across these sectors, was well-positioned to listen to and connect conversations from different stakeholder groups that share a commitment to improving the pharma publications model. Thus, Open Pharma was launched as a member-led, non-profit-seeking project facilitated by Oxford PharmaGenesis. We strive to improve the pharma publications model by connecting pharma with innovations in publishing to increase transparency and broaden access to research outputs.

#### **KEY OBJECTIVES AND MISSION**

Open Pharma is a collaboration of forward-thinking representatives from organizations working across health care research communication. Members and Supporters contribute to Open Pharma financially at different levels. Members advise and vote on the strategic direction for Open Pharma, and both Members and Supporters are involved in discussions, events, and research projects. Current Open Pharma Members include AstraZeneca, Boehringer Ingelheim, Galápagos, Gilead Sciences, GSK, Janssen, Novartis, Novo Nordisk, Oxford PharmaGenesis, Pfizer, Takeda, and UCB, and current Supporters include Bristol Myers Squibb, Ipsen, Roche, and Taylor & Francis.

Nonpaying stakeholders include advisors and followers. Advisors represent policy groups, publishers, academic funders, patients, and open science innovators and take part in meetings and other activities. Open Pharma followers are the varied group of people who read our blog and newsletter, engage with us on Twitter, LinkedIn, and YouTube, take part in our public events, and use the information and resources available on our website.

Open Pharma has clearly defined aims (set out in a charter) that support the goal of improving the pharma publications model. We believe that pharma company–funded research should be published in a way that is transparent, accountable, accessible, and discoverable (Figure 1). Operationally, Open Pharma works on multiple levels: as a think tank that seeks to move the needle, as a research hub

that produces evidence, as a *knowledge-sharing "club,*" and as a *forum* for member voices. A varied range of activities support our road map to open science in this space (Figure 2).

#### **OPEN PHARMA: A THINK TANK**

# **Open Access Position Statement**

Open Pharma promotes publishing with open access to ensure that high-quality, peer-reviewed evidence is available to anyone who needs it, anywhere in the world, without charge. Publishing open access improves transparency, advances medical science, and, we believe, ultimately improves patient care (Figure 3). However, access to pharma company research is often more restricted by journal paywalls than research funded by other sources.

The first landmark achievement of Open Pharma was our open access position statement. In the statement, we highlight as an immediate priority the need to secure authors publishing company-funded research the same right to publish open access as authors publishing research funded by other sources so that all research can be made free to read from the date of publication. We also state that our long-term goal is to secure the same licensing terms for authors publishing company-funded research and authors publishing research funded by other sources, including using the most permissive Creative Commons license, Creative Commons Attribution license (CC BY), for all articles.

As of May 4, 2023, our position statement has been endorsed >250 times by individual and institutional stakeholders – including publishers, pharma companies, patient



Figure 1. The aims of Open Pharma. PLS, plain language summary.



Figure 2. Open Pharma road map to open science for pharma research communication. ORCID, Open Researcher and Contributor ID; PLS, plain language summary.



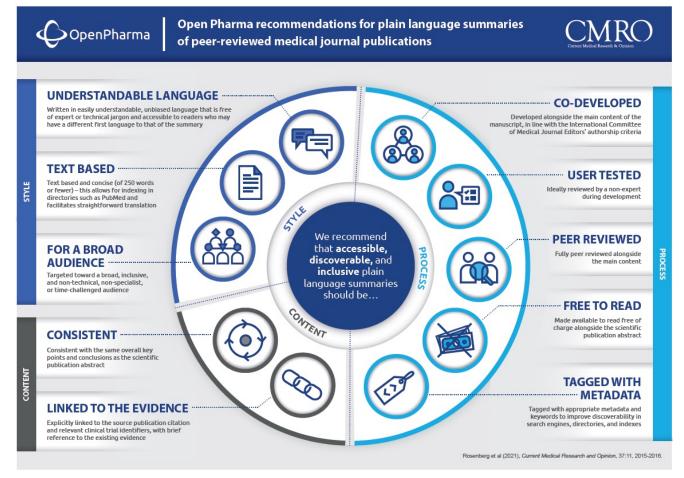
**Figure 3.** Benefits of open access. Adapted from Kingsley D and Brown S.<sup>11</sup> CC BY, Creative Commons Attribution license.

advocacy groups, and organizations engaged in open scholarship. Many Open Pharma Members and Supporters have used the statement to raise awareness of open access within their companies and set open access targets, which is likely to have contributed to the rise in open access publishing observed across the sector in recent years.

#### **Plain Language Summary Recommendations**

Plain language summaries (PLS) are now an accepted way to make the content of medical research articles accessible to nonspecialist and time-challenged readers. Until 2020, however, consistent guidance on how to develop PLS was lacking, which limited their use.

Open Pharma recognized this unmet need and responded by organizing a roundtable of experts and a public consultation to discuss the issue and went on to develop and publish a PLS recommendations article and infographic (Figure 4).<sup>5-7</sup> With >10,000 views and 8 citations to date (as of May 25, 2023), we believe that our recommendations article is contributing to important changes in research publications, including an emerging consensus



**Figure 4.** Infographic: Open Pharma recommendations for plain language summaries of peer-reviewed medical journal publications. Adapted/Reprinted from Rosenberg A et al.<sup>6.7</sup> PLS, plain language summaries.

about PLS best practice among some publishers,<sup>8</sup> adoption of mandatory policies or recommended PLS practices by pharma companies,<sup>9</sup> and an update to the Good Publication Practice Guidelines for Company-Sponsored Biomedical Research advising publication of PLS for all clinical research articles.<sup>10</sup>

# **OPEN PHARMA: A RESEARCH HUB**

### **Educational Material**

Open Pharma has developed a bank of resources that are freely available on our website for anyone to use. This material can help medical writers, pharma companies, and publishers to become more aware of open science and implement open science practices in their day-to-day work. Resources include a crib sheet for developing plain language documents, a toolkit for adopting Open Researcher and Contributor IDs (ORCID) in publications, and educational slides about open access.

## **Research Projects**

Open Pharma research poster presentations are also freely available on our resources page. These posters summarize various analyses of open access for pharma company-supported articles, use of ORCIDs in pharma-affiliated publications, and discoverability of PLS. Here, we highlight 3 examples of recent or ongoing Open Pharma research.

Discoverability of PLS. Concise text-based PLS can assist a nonexpert and time-constrained audience to find and use published research. PubMed is one of the most widely used platforms for accessing biomedical research and, since 2019, text-based PLS hosted on this platform can be discovered when tagged (electronically labeled) with a PLSspecific label, the <plain-language-summary> metatag. 12 To assess how PLS are being indexed (labeled and organized) on PubMed, Open Pharma carried out an automated search of the presence and use of the PLS metatag. Our results uncovered an unmet need for explicit guidance on both the processes of indexing and the correct use of the <plain-language-summary> tag, which could help improve uptake and correct tagging.<sup>13</sup> The findings show an opportunity for everyone, including medical writers, to increase the impact of their content and reach a broader audience by ensuring article PLS are tagged appropriately on PubMed. A version of the conference poster presentation is available on YouTube.

*Open Access Benchmarking.* Open access publications are more likely to be discovered and accessed by a broad audience. <sup>14</sup> Since Open Pharma's launch and the publication of our position statement, the open access landscape

has changed. Several major public research funders have implemented mandates requiring that their grant recipients publish their findings with immediate open access (eg, UK Research and Innovation, 2021; National Institutes of Health, 2023). In the private sector, pharma companies Takeda (formerly Shire; press release in 2018), Ipsen (press release in 2019), and Galápagos (press release in 2020), all part of Open Pharma, have also implemented open access mandates. However, a subset of high-impact journals do not offer open access or do not offer the least restrictive open access license, CC BY, to authors of pharma-funded research.

To investigate this possible open access bias, we needed to benchmark and track open access publication patterns in different research settings in an objective and automated way. Since 2018, we've analyzed and reported on open access rates of pharma-funded research using both manual and automated methods. 13,15-17 This year, we collaborated with the Lens platform to develop a free-to-use, publicly available open access dashboard that benchmarks and compares open access rates, types, and licenses between publications with authors affiliated to universities and those with authors from pharma companies. We presented a snapshot of the initial data as a poster at the 20th Annual (US) Meeting of the International Society for Medical Publication Professionals (ISMPP) (2023). 18

Our research suggests that articles with university-affiliated authors are published with the most permissive license (CC BY) more often than articles with pharma companyaffiliated authors. However, our analysis was not designed to determine whether this difference is driven by journal or author policy. The Open Pharma dashboard will now help us to assess how changing perceptions of open access translate into changes in practice.

Data Sharing Survey. The potential benefits of coordinated data sharing are undisputed (eg, improved research transparency and efficiency of research), but so is the importance of protecting patient privacy. In some instances, intellectual property and data ownership may also be relevant considerations. <sup>19</sup> Expanding access to clinical study results and source data has important implications for research sponsors, authors, publishers, and patients, and most biomedical research journals now have data sharing requirements as a prerequisite of publication.

Open Pharma designed a survey to assess the ease with which those involved in submitting pharma research for publication are able to implement current journal data sharing policies and to understand if there are barriers to implementation (eg, challenges in relation to certain study or data types) and related implications. To make sure our

10

survey was intuitive to complete and that we were asking the right questions, it was also reviewed by the ISMPP Global Transparency and Trends Committee.

Our results will help indicate whether there is a need to work with journals and publishers to optimize current data sharing policies for the benefit of all and, if so, where efforts should be focused.

# OPEN PHARMA: A KNOWLEDGE-SHARING "CLUB"

#### **Open Pharma Events**

Many conversations about the communication of pharma research take place in the absence of the voices of important stakeholders. This makes it difficult to understand their challenges and needs and to come up with appropriate solutions. To help bridge this communication gap, Open Pharma seeks to develop events that stimulate debate between stakeholders who do not often have the opportunity to meet and to bring fresh voices into the conversation.

As an example, one of our highlights in 2022 was the Open Pharma Satellite Symposium held at the Association of Learned and Professional Society Publishers Annual Conference and Awards 2022. In the session "Who Can We Trust? Open Science and Pharma Research," presenters and audience members representing the pharma, publishing, and medical communication industries, as well as patient advocates, discussed the role of open science in building trust in pharma research, with a focus on open access publishing and accessible summaries.<sup>20</sup> A video of the symposium is available on YouTube, and a meeting report was published in a special issue of *Medical Writing* on the topic of "Open Science and Open Pharma."<sup>21</sup>

More recently, in February 2023, Open Pharma ran 2 virtual talk shows facilitated by Richard Smith (Open Pharma Chair, former Editor of the *BMJ*, and former Chief Executive of the BMJ Publishing Group) that brought together patient advocates, doctors, policy advisors, charitable funders, open access advocates, and publishers. Guests included Richard Horton (Editor-in-Chief, *The Lancet*) and Christine Laine (Editor-in-Chief, *Annals of Internal Medicine*). The discussions, which are available on YouTube, were energetic and thought-provoking. <sup>22</sup> Bringing together such a wide range of views made it a unique event that will continue to spark further debate and collaboration.

#### **Presence at Congresses and Other Meetings**

Open Pharma is a regular presence at international meetings and events involving pharma industry professionals, publishers, and medical writers. In 2022 and 2023, we've held roundtables, workshops, and session presentations on open access and PLS at the European and annual (US) meetings of ISMPP, the Council of Science Editors meeting,

and the Berlin and Riga meetings of the European Medical Writers Association.

# **Open Pharma Blog**

Open Pharma delivers open science news and commentary via our blog and e-newsletter. In addition to a weekly digest of short news stories, the blog features opinion and commentary pieces from expert guests (Table 1).

Our blog is a platform for discussing key issues and trends in open science for pharma research and to sign-post everyone to events of interest and useful tools and resources.

Table 1. Highlighted Guest Blog Posts From the Open Pharma Blog

# **Guest Blogs in 2022**

How Pharma Will Help Move the Needle on Open Research Mark Hahnel (Founder and CEO of Figshare)

Perceptions and Insights on Clinical Trial Participation: Results From the 2021 CISCRP Study

Jessica Cronin (Center for Information and Study on Clinical Research Participation)

Open Science: Reflecting Upon Real-World Impact (podcasts) Martin Delahunty (Founder and Managing Director of Inspiring STEM Consulting)

#### **Guest Blogs in 2023**

#### Improving Equity Through Open Access Education

Catherine Skobe (Senior Director, Pfizer Publications Innovative Solutions Lead), Adam Watson (Director, Pfizer Medical Excellence Lead in Inflammation & Immunology Medical Affairs), and J.R. Meloro (Global Head of Transparency, Pfizer Worldwide Medical and Safety)

The Changing Open Research Landscape: A Publisher's Perspective Priti Nagda (Publications Development Manager at Taylor & Francis) and Simon Horton (Policy and External Affairs Manager at Taylor & Francis)

Improve Research Discoverability to Support Health Literacy Catherine Skobe (Senior Director, Pfizer Publications Innovative Solutions Lead) and Sally Dews (Senior Medical Affairs Manager at Pfizer Patient Partnerships)

CEO, Chief Executive Officer; CISCRP, The Center for Information and Study on Clinical Research Participation; STEM, science, technology, engineering, and mathematics.

#### **OPEN PHARMA: A FORUM FOR MEMBER VOICES**

# Topic Meetings, Roundtables, and Working Groups

Open Pharma has a program of discussion meetings that provide opportunities for Members and Supporters to explore specific topics internally and with external guests. Members and Supporters also take part in working groups, which develop projects in several areas of open science. All these activities help the group identify unmet needs and potential solutions in the communication of pharma research.

For example, the virtual roundtable meeting Pharma and Publishers Forum on June 24, 2022, cochaired by Caroline Sutton (Chief Executive Officer of STM Publishing) and Richard Smith, brought together participants from the publishing and pharma sectors to discuss 4 core topic areas in open science – PLS, open access, discoverability, and data sharing. The participants identified several unmet needs and potential solutions in these areas (Table 2), which the Open Pharma working groups and other organizations can help to address.

# ON THE HORIZON FOR OPEN PHARMA

As the open access movement taking place across the publishing industry reaches new heights, Open Pharma will continue to campaign for equitable open access opportunities for all researchers. Beyond open access, Open Pharma will continue to address other aspects of open science (and open research) by advocating for behaviors that promote greater transparency throughout the research life cycle.

A key topic of interest is how to make research more accessible and discoverable, with nonexpert public and patient audiences being increasingly recognized as valid audiences for pharma research. The growth in plain language documents within and beyond research publications will also require more precise use of the terminology used to refer to these documents.<sup>20,23</sup> Open Pharma will continue to champion best practice and cross-stakeholder collaboration in this area, working to expand the use and usefulness of PLS.

The use of natural language processing tools, including artificial intelligence (AI), in medical publications is a rapidly changing area, with many applications emerging for publication development, quality assessment, and regulation. Open Pharma will help keep our stakeholders abreast of this field and support them in using AI tools to improve research communication while maintaining publication integrity.

#### **SUMMARY THOUGHTS**

Medical writers can help to set standards of quality, transparency, and accountability in medical publications.

Through their work with researchers, authors, pharma publication teams, and publishers, medical writers can under-

Table 2. Unmet Needs and Potential Solutions Identified at the Open Pharma Roundtable Pharma and Publishers Forum in June 2022

Open Science Topic	Identified Need	Possible Solutions
PLS	Establish methods for evaluating how much easier it is for nonexpert audiences to find and understand publications when these are accompanied by PLS     Develop quality standards for PLS     Explore ways of reducing the extra work that PLS represent to publishers	Continue to perform research and thought leadership on PLS value and readership     Convey the value of PLS to stakeholders by sharing these efforts at conferences and in the literature     Educate using Open Pharma's best practice recommendations article
Open Access	Improve author appreciation of the value of open access publishing; reduce the traditional author focus on journal impact factor or citation score     Simplify, or educate authors on, open access licensing agreements     Explore issues of open access publication bias associated with article processing charges and possible solutions	<ul> <li>Provide evidence of the value of open access and existing bias through data-based research projects</li> <li>Provide training on the different types of publication license and what each means in terms of reuse, distribution, and adaptation</li> <li>Continue to promote mandatory open access publishing for industry-sponsored research</li> <li>Campaign for fee-waiving schemes for small pharma companies or companies from lower-income countries that may not have the budgets to pay high article processing charges</li> <li>Work with publishers on ways to update their systems to incorporate funder and pharma workflows for bulk publishing to reduce the administration burden and ensure use of intended licenses</li> </ul>
Discoverability	Explore search engine optimization for research outputs so that scientific data reach a wider range of audiences     Explore the use of article-level metrics for assessing publication impact	Ensure that keywords are carefully chosen and provided during submission to optimize discoverability of articles through search engines     Promote use of text-based PLS that are fully incorporated into the main manuscript alongside the abstract so they are hosted in front of any paywall and indexed on PubMed     Discourage hosting of PLS in supplementary material or on third-party content sites that are less likely to be accessed and read unless explicitly distributed to readers through other means
Data Sharing	Educate authors on optimal data sharing practices     Harmonize pharma and publisher perspectives on preferred data storage platforms     Explore the benefit of developing a universal data sharing guideline, including guidance around implications of     different data protection regulations among countries     disparities between pharma and publisher policies on data sharing	Campaign for alignment to FAIR data management guidelines     Develop training toolkits for authors on data sharing early in the research process     Survey the industry to understand barriers to implementing current journal data sharing policies     Create and share universal data sharing guidelines to help to build researcher and institutional confidence in complying with data sharing best practices

 $FAIR, Findability, Accessibility, Interoperability, and Reuse of digital \ assets; PLS, plain \ language \ summaries.$ 

stand the challenges of closed publications systems and witness the benefits of more open, collaborative, and audience-centric approaches.

We invite the readers of this article to engage with Open Pharma by endorsing our open access position statement, encouraging your clients to use our resources and tools, and staying abreast of developments in the field by signing up to receive our newsletter. Please contact us directly if you find any resources or activities that may be relevant to the Open Pharma audience or to discuss a collaboration.

We believe that the appropriate application of open research principles can improve the quality and transparency of pharma research communication and, ultimately, improve patient care and increase health equity globally. Everyone involved in the publication process can, and should, play a part.

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13