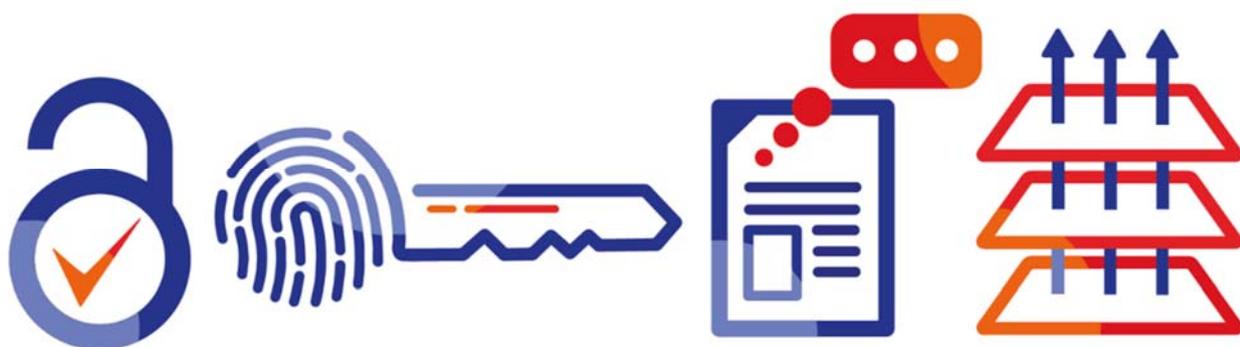




Innovations in Medical Publishing

Report from the Roundtable Meeting

January 2020



We would like to thank GSK for hosting this roundtable meeting at GSK House in London. We are also grateful for the time committed to the discussions at the meeting by our Members, Supporters and Advisers.



Open Pharma is very grateful for the contributions it has received, in the form of both grants and services from Alexion, AstraZeneca, Galápagos NV, Gilead Sciences, GSK, Novartis, Novo Nordisk, Oxford PharmaGenesis, Pfizer, Roche, Takeda, UCB and Wiley.

Open Pharma is a project of Oxford PharmaGenesis. Although Oxford PharmaGenesis is a for-profit company, this is a non-profit-seeking project, and we are committing much of our time at no charge.



Executive summary

Open Pharma brings together pharma, publishers and other stakeholders in healthcare to explore how innovations in publishing can improve the speed, accessibility and transparency of pharma-funded medical research.

In January 2020, current and prospective Members and Supporters of Open Pharma and a group of Advisers met for a roundtable meeting at GSK House in London, UK, to discuss the latest information and stakeholder positions on open access, patient and public involvement in medical communications and the visibility of publications.

This report summarizes the discussions that took place during the roundtable meeting.

Session 1: shaping policy with the Open Pharma position statement

- The position statement is intended as a framework for discussion to encourage the provision of open access by journals/publishers. It is not intended to represent a mandatory position.
- There has been wide support and coverage of the position statement, but endorsement from large pharma companies remains low. Current pharma endorsers of the position statement allow open access in the broadest sense to retain author choice in target journal selection.
- Barriers identified by pharma against mandating open access included the high cost, perception of cherry-picking, retention of author freedom and concern about discoverability.
- The next steps are to:
 - continue to work with publishers to develop their open access models
 - work with institutions/libraries who are in close contact with the authors
 - communicate with authors and provide education on open access.

Session 2: patient and public involvement

- Publication enhancements ensure that research reaches the right audiences through appropriate channels.
- Pharma attendees agreed that it is acceptable for pharma to increase research discoverability and accessibility by using enhancements, with a view to ensuring that peer-reviewed content is used as a trusted source of information.
- Strategies for developing publication enhancements should be aligned across pharma and, if possible, across journals and publishers.
- **The next step is to** engage with additional publishers to discuss enhanced publishing options for pharma.

Session 3: visibility of publications

- The uptake of preprints is increasing. However, there were concerns over the scientific integrity of preprints and the level of expertise of those providing feedback. It was agreed that pharma is not ready to adopt preprints for clinical trials yet.
- Self-archiving repositories could provide a practical way for pharma to make their research outputs accessible.
- Researchers, organizations and funders need education to understand the options available for publishing research via the green open access route.
- **The next step is to** continue to work with pharma to facilitate the understanding of different open access publishing routes.

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Session 1: shaping policy with the Open Pharma position statement

Endorsement, communication and impact

- The **Open Pharma position statement on open access** calls for the highest quality peer-reviewed evidence to be available to anyone who needs it, anywhere in the world. It lists two objectives (Figure 1).

Figure 1. Open Pharma position statement objectives.



- Since its launch in October 2019, the position statement has:
 - been extensively covered by Open Pharma via the Open Pharma blog, Twitter and LinkedIn channels
 - received wide external coverage from *The Telegraph*, *F1000 Research Ltd*, *ecancer*, *Future Science Group*, *The MAP Newsletter* and *Frontiers Media SA*
 - been **viewed 1815 times** across the Open Pharma blog and figshare pages, and **downloaded 107 times** from the Figshare page (correct as of 8 January 2020)
 - received **78 individual** endorsements, **15 organization** endorsements and **6 publisher** endorsements.
- Updated guidelines developed by the International Committee of Medical Journal Editors in December 2019 state that dictating where an author can or cannot publish violates their academic freedom.
 - Attendees noted that this seems strange given that many research funders have already imposed some publishing stipulations – for example, authors are told not to publish their work in predatory journals.

Comment from Galápagos NV and Wiley on why they chose to endorse the position statement as companies

- Pharma company endorser, **Galápagos NV**, stated that:
 - Galápagos NV is a small biotechnology company that is agile and open
 - endorsement of the position statement did not pose a challenge
 - they allow the broadest sense of open access to give authors the choice to publish in higher impact journals, such as *JAMA* and *The Lancet*, which offer green open access
 - they are working towards a mandatory open access policy
 - Galápagos NV teams actively discuss open access with their collaborators and external partners.
- Publisher endorser, **Wiley**, stated that:
 - their journals already conform to the immediate priorities of the position statement
 - they were happy to commit to the long-term goal, especially because there are no time limits stated in the position statement
 - there is no corporate benefit to distinguishing between commercial and not-for-profit funders
 - transition arrangements are taking place journal by journal for each of their thousands of titles

- the main barrier to Wiley making research outputs available under a Creative Commons Attribution (CC BY) licence is the revenue generated from the commercial reuse of material (under a CC BY-NonCommercial licence or similar).

Roundtable discussion: promoting mandatory open access, benchmarking and overcoming barriers

- The drive for open access in pharma publication policies is currently limited by what journals/publishers allow, but Open Pharma discussions could help to align positions.
- Pharma attendees from companies without mandatory open access policies stated that they **generally recommend open access** and **provide guidance** on how to publish open access to their authors; the number of publications that are published open access is still high.

Barriers to mandating open access from a pharma perspective

- The **budget** required to publish a high volume of papers open access.
- The perception of **cherry-picking** if only certain articles are published open access.
- The loss of **author freedom** of journal choice.
- Concern about **discoverability** of data if self-archiving via a green open access route.
- The **research assessment system** means that authors want to publish in high-impact journals, irrespective of the open access options available.

- **Takeda hopes to have an open access policy in place by April 2020.** They accept that not all research will be published under a CC BY licence, so they will commit to open access in the broadest sense with 'readability' as the key driver of the policy. Takeda also noted that securing copyright for internal reuse is important too.
 - It was discussed that Shire (now part of Takeda) has a 96% compliance rate. Author agreements are put in place with investigators stipulating that they should publish open access. The journal choice is not restricted.
- It was noted that more journals are allowing green open access with no embargo.
- Currently, open access policies tend to be journal as opposed to publisher specific. Attendees agreed that it would be beneficial for open access policies to be streamlined by the publisher.
- Funders increasingly award grants that comply with initiatives such as the San Francisco Declaration on Research Assessment that seek to improve how research is assessed. Over time, impact factor may become less important to authors.
- Although unconfirmed, a US government mandate stating that federally funded research should be published with green open access with no embargo, could force a change to journal open access policies, to mitigate the risk of losing authors.

Factors that could influence the transition of a journal from NC to CC BY

- The **proportion of uptake** of open access versus subscription content.
- The **demand** for alternative licences from authors.
- An appropriate business model that doesn't take away from **revenue streams**.

- It was discussed that if authors retained **copyright ownership** of their publications, then that could be a way of distributing research.
 - Publishers in the room stated that is dependent on the journal, but for the vast majority, journals do not retain the copyright.
 - Pharma attendees stated that securing copyright for reuse by the company was important for internal databases, but not necessarily for distribution of reprints.
- It was suggested that the representatives from pharma companies involved with Open Pharma should continue to have internal discussions around organizational endorsement of the position statement.
 - One concern holding back some organizational endorsements is the lack of embargo period in the immediate priority objective. Larger companies could not sign up to a policy with which they could not 100% comply (and would be highlighted in audits).

- Further discussion concluded that the position statement is short, clear and outlines future aspirations.
- It was clarified that the position statement is intended as a framework for discussion to encourage provision of open access by journals/publishers. It is not intended to represent a mandatory position.
- Education plans are being implemented for internal and external pharma colleagues on open access.
- Highlighting of the position statement could continue through social media channels, education and panel discussions.

Next steps

- Follow up with the European Federation of Pharmaceutical Industries and Associations about their internal discussions on the position statement and confirm whether they intend to endorse the statement.
- Identify additional companies to approach for endorsements.
- Continue to work with publishers on their models.
- Work with institutions/libraries who support authors.
- Highlight and provide education on open access.

Session 2: patient and public involvement

How do we communicate with different publication audiences?

Peer-reviewed publications remain the primary method of communication within the medical community. However, as we (pharma companies, funders and publishers) receive requests from the wider public for **access to research**, should we explore different ways to communicate?

- Publication professionals have a responsibility to ensure that publicly available research is translated and utilized appropriately.
 - This includes making sure that research is made clear to healthcare professionals (HCPs), who may have a limited amount of time to read about new research that could improve clinical practice.
- Publication enhancements are a way to ensure that content reaches the right audience through appropriate channels; these include video abstracts, infographics, webinars and local editions of journals.
 - All enhancements are digitally linked to the original peer-reviewed publication.
- Wiley has shown that video abstracts can accelerate the reach and impact of publications based on Altmetric Attention Score, abstract views and full-text views.
- Many journals offer the same options to all authors, regardless of funding source, for publication enhancements.
 - Peer review of pharma-funded publication enhancements can mitigate compliance concerns around promotion.
- As with full-text manuscripts, the submission process and requirements for publication enhancements varies between journals and publishers.
 - Attendees expressed concerns about spending time and budget developing enhanced content when the final manuscript may not be accepted. A significant amount of reworking may be required to meet the requirements of the new journal.
 - A format-neutral submission process could overcome this limitation.
- The publisher representatives suggested that more input from authors was needed to **devise a clear process for developing publication enhancements**.
 - Publication enhancements should be discussed with the publishers before submitting the manuscript. This enables publishers to embed the enhancements within the full-text HTML or PDF and may reduce additional cost for authors.
 - Publishers can be flexible as to whether the publication enhancements are created in-house or by the authors.
 - Resources can be provided for authors who wish to create their own content.

- In terms of copyright, publication enhancements tend to be covered under the same licensing agreement as the abstract of a full-text article (meaning that although it will be accessible, reuse rights may still apply).
 - Some publishers allow the authors to retain copyright on publication enhancements.
 - Publishers in attendance recommended that authors proactively ask to retain copyright of enhancements, particularly when the copyright licence needed is different to that associated with the full-text article.
 - Attendees questioned whether different parts of a publication, such as figures, should be associated with individual licences.
- Although enhanced content can make research more accessible, some attendees questioned whether this would lead to the perception of ‘cherry-picking’ of results to feature in videos and infographics.
- It was noted that enhanced content should not detract authors from ensuring that article abstracts are written in accessible language that can be translated for non-native English speakers.
 - Submitting abstracts to platforms such as **Crossref** will ensure that abstracts are discoverable through text mining.

Plain language summaries (PLSs)

- PLSs are jargon-free summaries of full-text articles.
 - They can be used by a **wide range of audiences** from patients to HCPs.
 - Journals and publishers have different options available for PLSs.
 - There is no standard format for a PLS.
 - Use of a **review panel** is recommended to ensure that PLSs are suitable for the end users.
 - As with all resources intended for the general public, it is key that PLSs are **discoverable** and **accessible**.
- Producing content for the general public comes with compliance concerns for pharma.
 - There should be a clear medical objective for all PLSs.
 - An independent peer-review panel should be used.
- Some pharma companies have already used PLSs in publications. However, there is currently limited understanding about the value of PLSs.

Questions surrounding the practicality of PLSs

- Are journals the best place to host PLSs?
- Should publishers be the creators of PLSs, or should it be the authors?
- What is the ideal word count for a PLS?
- Should PLSs be translated into other languages and, if so, how should we deal with different local prescribing labels?
- Should the language in which a PLS is written change depending on the target audience (HCPs versus policy makers, patients or patient advocates)?
- Should the language and content of a PLS be standardized across journals and publishers?
- Does a PLS need a unique digital object identifier (DOI)?
- Do patients view PLSs as credible sources of information?
- Should medical writers take a more prominent role in the development of PLSs?

- PLSs can also be shared through alternative platforms such as figshare.
 - Attendees discussed whether pharma should share PLSs online, or whether this could be a role for the publisher, medical writer or an organization such as Open Pharma.

Roundtable discussion: who is the audience for research outputs, and how do we best communicate with them?

- Attendees agreed that a standardized approach to enhanced content across publishers would be the best way to maximize uptake.
- It was agreed that all ‘points of entry’ to PLSs, and publication enhancements in general, should be **tagged** and **linked to the primary peer-reviewed publication**.
- Attendees agreed that it is acceptable for pharma to increase research discoverability and accessibility through the use of publication enhancements, including PLSs. Sharing content with

pages outside of the publisher/journal platform should be performed by the publisher, an external organization such as Open Pharma, or patient advocacy groups.

- More guidance is also needed on which platforms should be used to amplify entry points to enhanced content.
- Attendees highlighted the need for reliable metrics to demonstrate the effect of publication enhancements on article reach and impact.
- It was agreed **that PLSs should be written primarily for HCPs** but should be understood by the general public.
 - However, the need to understand the role of patient societies and patient advocacy groups in the development of PLSs was also noted.
 - Some attendees suggested that PLSs could be mandatory for publications in the future.
 - New **guidance from the European Commission due in Q1 2020 requires trial results summaries to be posted alongside the clinical study report (specific to regulatory requirements, not journal articles)**.
 - Attendees agreed that the Open Pharma Members and Supporters should align their strategies for developing publication enhancements towards a common goal.

Next steps

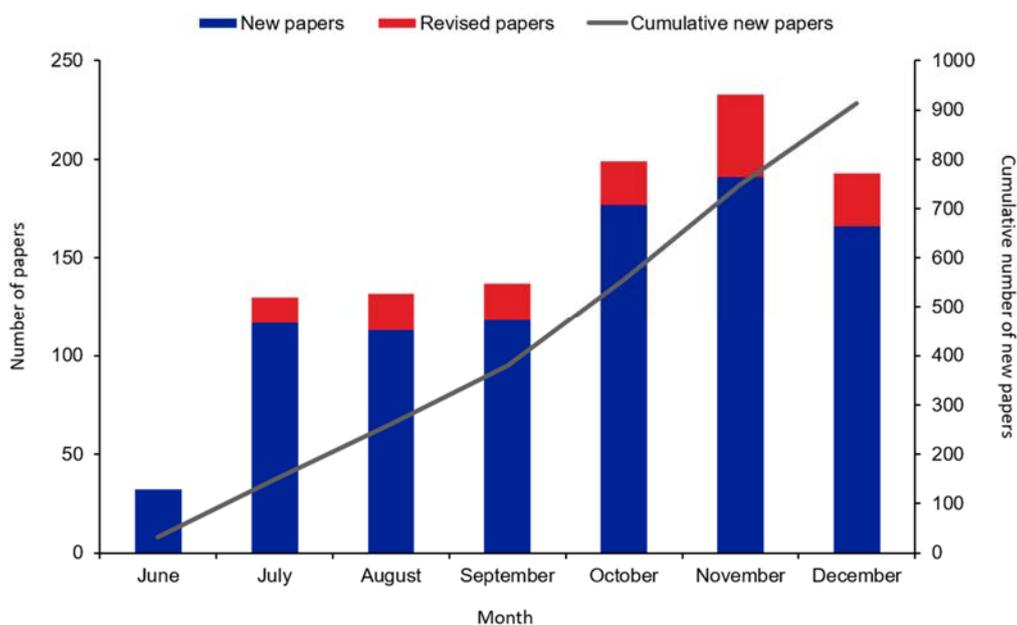
- Open Pharma to continue to work with publishers to try and establish a standardized approach to the format and dissemination of publication enhancements.
- Open Pharma to conduct a survey of patient/patient advocate groups to establish the best format for PLSs.
- Open Pharma to engage with additional publishers to continue to facilitate discussions about PLS publishing options for pharma.

Session 3: visibility of publications

The use of preprints and the uptake of medRxiv

- Preprints can speed up scientific communication, enabling pre-publication peer review and increasing research accessibility (providing a potential route to green open access); however, **the lack of official peer review has caused concern over the scientific integrity of preprints**.
 - Pharma-funded preprints may appear promotional, being outside the 'safe harbour' of formal peer review
- **medRxiv** is a specialist preprint server for healthcare research.
 - Papers submitted to medRxiv are subject to **additional screening questions** to those submitted to bioRxiv.
 - Does the content of the paper pose a public health risk?
 - Is there a benefit to sharing now, as a preprint, versus after peer review?
 - So far, only a small number of papers were rejected from medRxiv over concerns that they may cause changes in behaviour affecting public health.
- As of December 2019, over 1000 papers (new and revised) have been submitted to medRxiv (Figure 3).
 - Submissions covered a range of subject areas.
 - A small number of publications were from pharma, including at least one for which the lead author was a pharma employee.
- Stakeholders (pharma and publishers) had mixed opinions about whether preprints should be adopted for pharma research.
- Pharma representatives expressed concern about the level of expertise of those providing feedback on preprints.
 - Queries were also raised as to how comments posted to a preprint server should be addressed and whether previous submissions to peer-reviewed journals should be disclosed

Figure 3. Uptake of medRxiv 6 months after its launch.



- Stakeholders (pharma and publishers) had mixed opinions about whether preprints should be adopted for pharma research.
- Pharma representatives expressed concern about the level of expertise of those providing feedback on preprints.
 - Queries were also raised as to how comments posted to a preprint server should be addressed and whether previous submissions to peer-reviewed journals should be disclosed.
- Some attendees highlighted that there should be a clear distinction between **preprint servers** and **self-archiving repositories**.
 - Preprint servers have the potential to become platforms for housing ‘unpublishable research’ and that this practice should not be encouraged.
 - Attendees agreed that preprints should be reserved for their intended purpose, including scientific discussion around the data.
 - Separate repositories for preprints and manuscripts that have been rejected from peer-reviewed journals (including negative and replication studies) were suggested as a workaround.
 - Other stakeholders highlighted a clear preference for research to be made available by whatever means.
- While some pharma companies have published early clinical research as preprints, it was concluded that, for now, **pharma is not ready to adopt preprints for clinical trials**.
 - It is possible that this will change in the future, and that preprints will soon become a standard part of the scientific exchange.
 - Pharma attendees noted the importance of balancing discoverability with version control, making sure that the preprint is properly linked to the final version of the manuscript and that the correct citation is used.

Self-archiving repositories and green open access

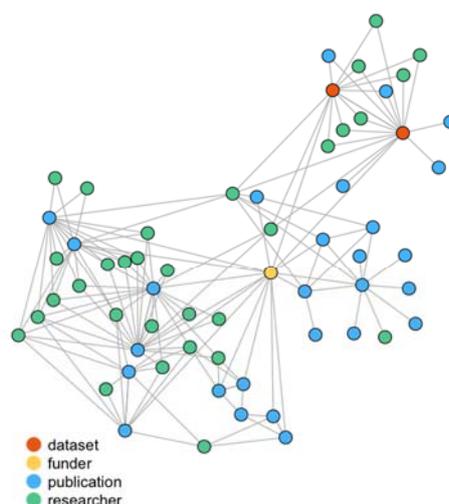
- Institutional repositories **increase research discoverability** and provide an **accessible** and **legal** version of a research output (as opposed to the full-text PDFs uploaded by authors to sites such as ResearchGate, which are often in breach of copyright). Most publishers permit the author’s accepted version of the article to be made freely available via repositories – some under an embargo, some without an embargo.
 - Repositories provide **legal green open access** to research outputs, providing an alternative open access route for pharma companies who are not able to commit to gold open access
 - Green open access options offer authors a wide choice of journals in which they can publish their research.
 - All research outputs, not just peer-reviewed publications, can be hosted on repositories using a common infrastructure.
 - Research outputs with an embargo are released when this time period ends.

- Repository (library) staff are experienced in collating and describing research (i.e. creating item records to common standards) and have knowledge of legal requirements for hosting and disseminating research.
- Repositories give those who either do not have permissions to access or cannot/do not wish to pay for access the ability to read research outputs. If the end user has the financial means and incentive, they can then choose to pay for a copy held behind a paywall – there is usually a link to the publishers' version on the repository item record.
- However, more needs to be done to help researchers, organizations and funders understand the options available for publishing research through the green open access route.
- Attendees agreed that repositories could be a practical way for pharma to make their research outputs accessible by archiving the final version of a manuscript or an open access version legally available elsewhere.
 - Attendees noted the importance of version control and the correct linkage of different versions of an article to ensure maximum discoverability for the end user.
 - It was also agreed that **pharma would not necessarily need their own repository** to do this, given that there are repositories such as **SHARE**
 - This would help pharma to comply with **Plan S** without restricting journal choice.

Making the most of existing platforms

- The British Library, together with **five other national heritage organizations**, have created a cross-disciplinary **repository** to enhance the discoverability of their research. As an organization, the British Library are committed to publishing their research open access and encourage their researchers to use **ORCID** iDs. ORCID is a unique digital identifier for authors.
- The self-contained platform took a year to create using open source software from **Samvera Hyku**; research from all six organizations is now available on a single shared platform.
- All digitized materials uploaded to the repository are vetted by an internal committee to confirm copyright status and review ethical compliance.
- Data uploaded to the repository are tagged. Each version of a research output is assigned its own DOI to help with metadata linkage and version control. This ensures that researchers using repository data can cite the correct version of the resource from which they took their information.
 - All text is converted by an optical character reader to machine-encoded text to allow for data mining.
 - All research associated with a funder, organization or individual is **linked** through the use of **persistent identifiers (PIDs)** (Figure 4).

Figure 4. Linking research using PIDs to support metrics and search navigation and increase impact.



PID, persistent identifier
Figure courtesy of Project FREYA

- Attendees concluded that pharma may have a role to play in encouraging authors to use self-archiving repositories.
 - It was suggested that green open access could be a way for more companies to introduce mandatory open access policies
- ORCID iDs are another way to increase the discoverability of research outputs by linking them back to authors.
- Some organizations systematically ask authors to register for an ORCID iD. For GSK, this includes internal and non-GSK authors.
- Takeda's publication team register for ORCID iDs on behalf of their employees.
- Journals are increasingly requesting ORCID iDs for submission, but not all request this as it may be seen as a barrier or might put authors off.
 - Attendees agreed that this is a low barrier and once all authors use ORCID, it would have many positives, including the ability to drive content to them (e.g. grants and publications).

Next steps

- Open Pharma has presented on the uptake and use of ORCID by pharma at the 2020 European Meeting of International Society for Medical Publication Professionals (ISMPP). Work with publishers to identify areas within manuscript submission systems that can be improved.
- Continue working with ORCID to implement a single sign-on for publication management systems.
- The use of ORCID within pharma will be discussed at the Open Pharma Virtual Roundtable Meeting on 23 April 2020.

Open Pharma – report from the January 2020 roundtable meeting

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