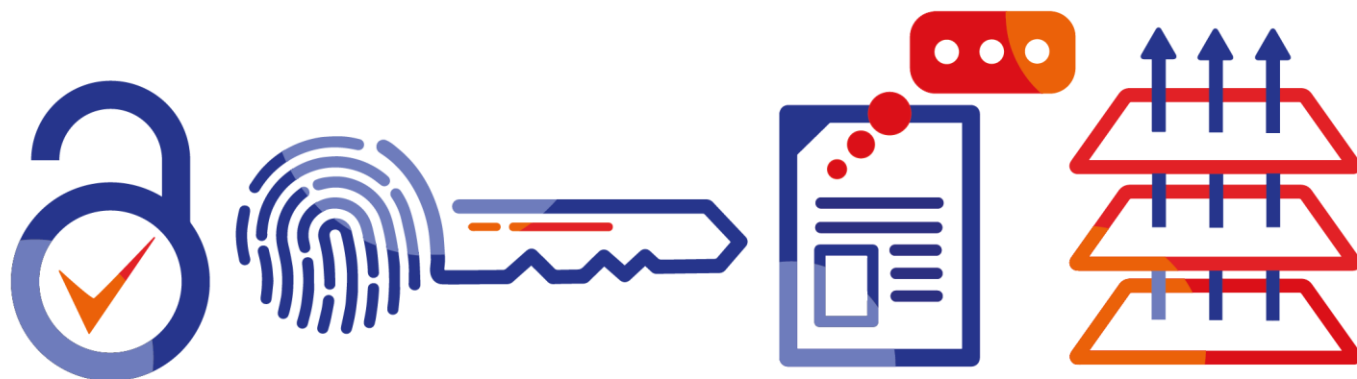




Innovations in Medical Publishing

Report from a round-table meeting
on 20 November 2017



Executive summary

Open Pharma is a collaboration between pharma, publishers and other stakeholders in healthcare, exploring where innovations in publishing could improve the speed, accessibility and transparency of dissemination of industry-funded medical research.

At an initial round-table meeting in January 2017, the group decided that pharma had a role to play in changing the publishing model. We set up four workstreams to investigate the opportunities for change in open access, systems for maintaining author information, preprints and post-publication peer review, and layered publication models. From May to November, the four workstreams directed discussions and research, leading to a report with information, talking points and proposals for consideration at a second round-table meeting.

The current document includes the information from that report and the key conclusions and decisions made at the second meeting on 20 November 2017. In summary, we will:

- continue the Open Pharma collaboration
 - continuing work on live topics of discussion such as open access and author information systems by email and *ad hoc* meetings, but not with monthly workstream meetings
 - discussing further the suitability and scope for new workstreams on patient engagement and data transparency, but a new workstream on real-world evidence will not be pursued
 - driving uptake of ORCID and advocating for inclusion of CRediT in the fourth version of the Good Publication Practice guidelines
- expand the reach of Open Pharma and our communication with the open science community
 - encouraging more publishers and pharmaceutical companies to be involved, and helping them to implement open science innovations
 - engaging with stakeholders at the European ISMPP session in January 2018 and a round-table meeting in the USA
 - continuing to encourage pharmaceutical companies to develop an open access policy and to look at how they can build preprints into their publishing activities
- publish research and consensus communications to help drive change
 - developing a general position statement on open access publishing by pharma, which will be signed by Open Pharma
 - submitting for peer-reviewed publication a manuscript describing open access options available to pharma
 - submitting an abstract describing preprint use by pharma to the Annual meeting of ISMPP in National Harbor, Maryland, USA, 30 April – 1 May 2018.

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Introduction

In January 2017, 22 key stakeholders met to answer a crucial question: does the pharmaceutical industry have a role to play in helping to improve the publishing of science? The meeting was chaired by Dr Richard Smith, former Editor of the *BMJ* (who afterwards wrote a piece about it for the *BMJ* opinion blog); the interdisciplinary group comprised publishers, journal editors, academics, funders, regulators, patients and representatives from pharma. And the answer from the stakeholders to the question being posed was a resounding 'yes'.

The group decided to name the overall project 'Open Pharma', reflecting its parallels with the wider open science movement, and all present agreed to the creation of four workstreams to explore aspects of open science that could be relevant to pharma.

The four workstreams are as follows.

**Open
access**



**ORCID, CRediT
and Convey**



**Preprints and post-
publication peer review**



**Layered publication
platforms**



Oxford PharmaGenesis has organized monthly virtual meetings for each workstream. External speakers have included representatives from organizations such as ASAPbio, Convey, Crossref, F1000Research and ORCID. A key aim of each workstream meeting has been to identify gaps in current knowledge that can be researched by Oxford PharmaGenesis and then discussed by the workstream. For example, Oxford PharmaGenesis has researched journal policies and educational materials on open access and preprints, and conducted a survey on layered publication platforms.

Pharmaceutical companies have also conducted their own research and provided feedback on the uptake of the innovations discussed in the workstreams: one analysed the open access status of its publications, and another reported on its trials of ORCID and the post-publication peer review platform F1000Research.

Oxford PharmaGenesis publishes summary reports from the workstream meetings and other relevant material on the Open Pharma website (<https://openpharma.blog/>) and on Twitter, and also helps to develop internal communications with participating organizations.

This document combines summary information from the workstreams, as reported at the second round-table meeting on 20 November 2017, and the key points from discussions at that meeting, including opportunities and challenges associated with specific open science innovations, and how the Open Pharma project can progress in the future.

Workstream 1: open access

The academic community and major non-pharma funders such as the Wellcome Trust and the Bill & Melinda Gates Foundation have been moving towards open access publishing for more than 10 years with the aim of increasing the openness, speed and transparency with which research is disseminated. Pharma has also been working with open access but more cautiously, for reasons outlined below.

The Budapest definition of open access (see Appendix) is a comprehensive specification favoured by open access advocates. Journals and publishers, however, use a range of specifications, making a simple overall understanding of open access impossible.

Historically, the most 'open' licence that journals offer is the CC BY licence (see Appendix), which allows free distribution and adaptation of the original work, even commercially, as long as the original authors are credited.

During the workstream meetings, challenges associated with open access publishing were identified, including clarifying inconsistent terminology and defining a level of openness suitable for pharma (Table 1). Actions were then planned to address these challenges (Table 2 and Table 3).

Open access policies of high impact factor journals

To help address the issue of inconsistent open access terminology, we tabulated the open access policies of journals with an impact factor of at least 15 using information available from journal websites and email contact. These policies fell into 'gold' and 'green' categories. Gold open access means free access to a CC-licensed article provided by the journal immediately on publication. Green access means free access to a non-CC-licensed article; there is usually an embargo period.

- Relevant information was obtained from all 37 journals.
- Of these journals, 23 (62%) offer gold open access with a CC BY licence.
 - Only one of these journals had an open access policy that potentially offered a CC BY licence to research supported by commercial funders/pharma.
- All 37 journals permit some form of green access within 12 months after publication.
- Journals do not use consistent terminology.

This research will be presented as a poster at the 2018 European Meeting of ISMPP; a manuscript will be posted as a preprint in time for this meeting.

Open access data from a major pharmaceutical company's publications

In a preliminary study, data were assessed from a major pharmaceutical company's publication records from January 2016 to August 2017.

The majority of the journals in which the research funded by the company was published offered open access with a CC BY licence. However, the company only published a small proportion of articles with a CC BY licence; this is because publishers did not always make this option available to the company, and because the company did not always choose this option.

It was concluded that the company needs to have clear rules on open access publishing and that publishers should offer fewer copyright licence types (preferably only CC BY) and not deny CC BY licences to pharma-funded research.

Possible reasons for publishers not allowing pharma to publish with a CC BY licence

- Ethical considerations – published data subject to a CC BY licence could be selectively reused, which could be potentially harmful to patients

- Pharma has not asked for it – publishers do not know pharma's open access requirements
- Maintenance of journals' revenue streams – if pharma publishes with a CC BY licence, publishers would lose revenue through the sale of reprints and permission fees for reuse of published data

At the autumn round-table meeting of Open Pharma, the consensus among participants was that maintaining journals' revenue streams through the sale of reprints is likely the major reason for restricting pharma from publishing with a CC BY licence. However, the true impact on publishers' revenue streams has been questioned.

The representatives from publishers suggested that publishers' policy may change if pharma mandates the use of a CC BY licence, and that there should be an explanation as to why the CC BY-NC licence is insufficient for pharma.

Pharma's open access policies

A major pharmaceutical company is implementing a formal open access policy (effective from 1 January 2018): publications that this company supports will be required to be published open access. The company is not currently stipulating that the publications have a CC BY licence because not all publishers will allow this; the company is therefore taking a more pragmatic approach at this time. In order to ensure that external authors comply with the policy, authors must sign an agreement to publish open access.

This company does not use reprints; some pharmaceutical companies do still buy large volumes of reprints.

Other pharmaceutical companies recommend that authors publish open access but do not have a formal policy or are considering developing a policy.

Educational materials on open access

Oxford PharmaGenesis assessed the availability and quality of current educational materials on open access (see Appendix).

- Current resources tend to overlap, are neither evidence-based nor engaging and have not been published within the past 12 months.
- No information was found about the role that pharma can play in promoting open science.
- Therefore, it may be valuable to develop materials that could educate pharma stakeholders.

Perspectives on open access

Publishers/funders

Publishers tend to have different open access policies for different journals, depending primarily on the academic editors. During the workstream meetings, representatives from publishers agreed that there should be more consistency with terminology but pharma has not yet made clear its requirements for open access.

A representative from a key research funder noted that control of open access lies with funders, who must set a clear and consistent policy and negotiate with publishers. For example, the Bill & Melinda Gates Foundation has paid the American Association for the Advancement of Science to ensure that all articles supported by them are published with a CC BY licence.

One open access advocate from a publishing group stated that it is not legitimate for publishers to deny CC BY licences to pharma-funded research.

Pharma

One pharmaceutical company's long-term aim is for all of its articles to be published with a CC BY licence. External academic authors generally agree although, in some cases, they prefer journals with a high impact factor even though these may have more restrictive access policies than journals with a lower impact factor.

Pharma representatives support the need for education on open access, are aiming for all articles to be published open access, and agree that publishers should have more uniform open access policies.

The idea of listing publishers that do not offer CC BY licences was suggested by workstream participants.

Position statement

At the workstream meeting held in November, the content of a draft position statement from pharma representatives on open access publishing was discussed. Key concepts discussed were as follows.

- Many pharmaceutical companies are willing to pay for open access.
- Pharma should aspire towards gold open access publishing, as this is the ideal model for optimum transparency.
- The statement could imply that journals without open access policies might see research being published elsewhere.

At the autumn round-table meeting of Open Pharma, participants were reluctant to endorse the statement in its current form, but agreed that a more general statement on what

Open Pharma is working on could be more appropriate. It was suggested that a unanimous demand for mandated open access publishing in a particular therapy area might be effective at driving change in publishers' policies. Representatives from publishers suggested that a statement should be worded carefully so as not to surprise publishers and not include erroneous information. Pharma and publishers should work together, and not against each other.

Next steps

- Draft a statement on open access from Open Pharma.
- Encourage more pharmaceutical companies to adopt an open access policy.
- Present research on open access policies of high impact factor journals at the 2018 European Meeting of ISMPP and submit as a manuscript to an open access journal
- Consider including open data as a topic in this workstream.



Table 1. Opportunities and challenges that were identified during the workstream meetings.

Opportunity	Associated challenge(s)
Clarify terminology surrounding open access	<ul style="list-style-type: none"> Organizations using open access terminology do not collaborate with each other We have no authority
Define and establish a level of openness suitable for pharma publishing	<ul style="list-style-type: none"> Pharma wants true gold open access (CC BY without restriction or embargo) Publishers and journals do not allow this for commercial organizations

Table 2. Actions to clarify terminology surrounding OA.

Action	Status	Benefits and challenges
Investigate open access terminology and journal policies	Completed	<ul style="list-style-type: none"> Increased understanding Forms the basis for ISMPP abstract and position statement
Develop educational materials about open access	Ongoing	<ul style="list-style-type: none"> Authors and other stakeholders may be more likely to publish in gold open access journals (Academic) authors focus on journals with a high impact factor Session at ISMPP EU 2018

Table 3. Actions to define and establish a level of openness suitable for pharma publishing.

Action	Status	Benefits and challenges
Establish mandatory open access policy for a major pharmaceutical company	Completed	<ul style="list-style-type: none"> Facilitation of wider adoption of open access Potentially negative impact on the relationship between pharma and academic authors Other pharmaceutical companies to follow this company's lead
ISMPP EU 2018 abstract (submitted) and manuscript (in development)	Ongoing	<ul style="list-style-type: none"> Provides citation for evidence relating to open access policies
Develop joint position statement	Ongoing	<ul style="list-style-type: none"> Publishers treating all research the same regardless of its funding source <ul style="list-style-type: none"> Potential adoption of CC BY without embargo Proposition of a unified open access terminology There may be a pushback from publishers, journals and the public

Workstream 2: ORCID, CRediT and Convey

At the first round-table meeting, we identified four tools of interest to pharma that could help enhance the transparency surrounding authorship and disclosures in medical publishing: ORCID (Open Researcher and Contributor ID), CRediT (Contributor Roles Taxonomy), Convey and Publons. Table 4 gives an overview of these initiatives.

ORCID

ORCID is a not-for-profit organization that enables researchers to create a unique identifier (the ORCID identifier [iD]) and associated publication record. This avoids the problems associated with different authors having the same name. The publication record is automatically expanded and updated through the individual user's interactions with organizations. Publishers, funding bodies, universities, pharmaceutical companies and other organizations can use the records to collate information relating to, for example, grants, patents and peer-review activities.

In 2016, publishers and funders published an open letter declaring their intent to mandate the use of ORCID. Signatories now include 33 publishing and funding organizations interested in improving the transparency of the connection between funding and publishing. Publishers and commercial/academic funders are propagating the use of ORCID, and the Royal Society is making the unique identifiers mandatory for anyone applying for research funding. In a survey that was conducted in 2016 (Plant A *et al.* Poster presented at ISMPP EU 2017) across 45 different journals, 4.4% required ORCID iDs for manuscript submissions, 68.9% allowed ORCID iDs to be added and 31.1% did not mention ORCID. To increase awareness and adoption of ORCID among pharma stakeholders, we explored several avenues in the workstream (Table 5).

ORCID is actively seeking to collaborate with pharmaceutical companies interested in using the system. Two companies represented at the workstream meetings currently recommend creating an ORCID iD only if submitting to publishers or journals that

mandate ORCID. In the future, one of these may recommend that all authors create such an identifier.

Within a major pharmaceutical company, an initiative to integrate ORCID into company publishing processes was launched in July 2017 initially for internal authors on publications sponsored by the company. The results of this study have been accepted for poster presentation at the European meeting of ISMPP in 2018. The initiative will be extended and registration for ORCID will be sought from authors not employed by the company from early 2018.

The company used a free-text box in Datavision to record ORCID iDs. All Open Pharma stakeholders agreed that it would be good to integrate ORCID with the new version of Datavision currently in development. Open Pharma has contacted Envision, a company that provides publication planning technology, and also rival platform developers PubsHub and Sylogent (Pubstrat) to suggest a specific field for identifiers in their platforms.

Envision confirmed that ORCID is being built into future versions of its platforms. Sylogent has committed to explore the integration of ORCID. A response is awaited from PubsHub.

At the autumn round-table meeting of Open Pharma, attendees agreed that given its usefulness and success in growing the user base, it is a 'no-brainer' to support the drive for adoption of ORCID into pharma systems. However, the value proposition still needs work and there were differences of opinion on whether it should be made mandatory in policies (taking time and negotiation) or implemented informally as the benefits to the user are clear.

The ORBIT (ORCID Reducing Burden and Improving Transparency) initiative, a collaboration between ORCID and the US National Institutes of Health (and including several other international funding organizations), will strive to reduce the administrative burden on researchers as they seek funding. Pharma has not been involved so far; however, such a system could be extremely useful in supporting funding applications for investigator-initiated research

– enabling similar efficiency as when applying for academic funding.

It was suggested that ISMPP could raise awareness of ORCID and help to drive its adoption.

CRediT

The CRediT contributorship model is an alternative to classic authorship accreditation, with 14 different roles that describe the contributions of individuals in detail. It was agreed that integrating ORCID with CRediT could aid transparency in (medical) publishing. Table 6 shows potential actions to drive adoption of CRediT.

The concept of CRediT originated in 2011 at a workshop involving the Wellcome Trust and Harvard University, and the model was developed in consultation with the International Committee of Medical Journal Editors (ICMJE). In a survey of more than 250 authors, most found the taxonomy equally or more useful than the existing system; the findings were published as a commentary in *Nature* (Allen L *et al.* *Nature* 2014;508:312–13).

CRediT has received a lot of interest from organizations such as PLOS, Cell Press and F1000Research, which have all mandated its use. In addition, Aries Systems has integrated it into the submission process in Editorial Manager. Some journals, such as *The Lancet*, prefer free-text contributorship declarations.

There is willingness among publishing and pharma stakeholders to use CRediT, along with ORCID and Convey. Its use could be recommended in the next update of the Good Publication Practice (GPP) guidelines or mandated by the ICMJE. Medical writing support could be added as a category of contribution.

At the autumn round-table meeting of Open Pharma, attendees agreed that ISMPP should explore incorporation of the CRediT nomenclature into the next version of the GPP guidelines. The authorship group will reconvene in 2018 and CRediT will be added to their list for consideration.

Convey

We set out to raise awareness about Convey among the Open Pharma stakeholders (Table 7).

Convey is a collaboration between the Association of American Medical Colleges, the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard, and the *New England Journal of Medicine*. It is a tool for disclosing financial interests, which can be used globally, comprising a web-based repository in which individuals can create a free account to maintain records of financial interests and disclose them directly to organizations that use the Convey system. When the system is used to submit disclosures for the second time and/or to another member organization, users can access previous disclosure information and easily tailor it to the needs of the new organization. All member organizations pay a subscription to capture disclosure information about authors and applicants.

ORCID integration in Convey would be beneficial from a pharma perspective (e.g. to link disclosure information with an individual's publication record easily). The current extent of integration is that Convey can capture a user's ORCID iD; the two organizations are considering additional information that could be linked to make disclosures more useful and transparent.

Adoption of Convey is an ongoing voluntary and collaborative process, and the focus for integration has been on academia and publishing. ORCID will be looking to collaborate with commercial funders over the next year and may involve Convey in these conversations.

At the autumn round-table meeting of Open Pharma, attendees agreed that Convey could be a useful document to support researchers but it may struggle for wide adoption as publishers and journals would be required to pay a subscription to be able to access authors' disclosure information; currently this is done on trust, with authors completing a simple online or paper form. The responsibility for the accuracy of information lies with the authors and pharma representatives suggested that there would be little interest

from their organizations to hold or get involved in policing disclosure information (it could lead into data protection territory). The attendees agreed that Open Pharma should adopt a 'wait and see' approach to Convey.

Publons

Publons was developed to incentivize people to peer review scientific content by publicly recognizing their work. Peer reviews in Publons need not be open reviews but, if they are, a link to the review is provided. There is currently no way of scoring the quality of reviews. In the future it may be worth considering integration of an individual's peer review record with ORCID. We may expand on Publons in the workstream in the future (Table 7).

Next steps

The four systems appear to have the potential to function well together. Ultimately, the aim would be to link all the publication information of an individual or group of individuals with their ORCID iD(s) and their source of funding across different management systems. In this way, information about users (e.g. doctors and researchers) would always be up to date, regardless of the system used, ultimately saving time and money that could be used to focus on what really matters: helping and treating patients.

It was agreed that Workstream 2 has provided sufficient information and connections to help Open Pharma participants drive uptake of ORCID, and include CRediT in GPP4. There will not be any further meetings for Workstream 2, and information on major developments will be circulated as appropriate.



Table 4. Opportunities and challenges that were identified during the workstream meetings.

Opportunity	Associated challenge(s)
Accelerate adoption of ORCID by pharma	<ul style="list-style-type: none">• Awareness and understanding of ORCID among pharma stakeholders is low• Unknown value to pharma
Explore adoption of CRediT in medical publishing	<ul style="list-style-type: none">• Awareness of CRediT is low and there is little drive for its adoption• CRediT is not aligned with ICMJE guidance on authorship
Convey and Publons	<ul style="list-style-type: none">• Awareness of Convey and Publons among pharma stakeholders is low

Table 5. Actions to drive adoption of ORCID.

Action	Status	Benefits and challenges
Increase awareness of the adoption of ORCID by publishers	Completed	<ul style="list-style-type: none">• Presentations by various groups that use ORCID to raise awareness of the progress that is being made• ORCID is increasingly used by publishers, although, for most, its use is optional for the journal• Reassurance from the Royal Society may help to accelerate the mandatory use of ORCID
Establish a value proposition for use of ORCID by pharma	Completed	<ul style="list-style-type: none">• Mandatory use of ORCID is likely to be driven by funders and publishers• ORCID may be useful for managing conflicts of interest
Oxford PharmaGenesis pilot of ORCID iDs for company authors	Completed	<ul style="list-style-type: none">• Within the company, 106 of 173 employees registered for an ORCID iD (accurate on 23 March 2017)
Communication to Envision (and others) to encourage incorporation of ORCID into their systems	Completed	<ul style="list-style-type: none">• Inclusion of ORCID within standard systems will encourage new customers to use ORCID• Potential for other changes suggested by Open Pharma to be incorporated
A pharmaceutical company's pilot of ORCID iDs for company authors	Ongoing	<ul style="list-style-type: none">• Pilot study ongoing• Case study may be used to encourage other pharmaceutical companies to follow suit

Table 6. Actions to drive adoption of CRediT.

Action	Status	Benefits and challenges
Increase awareness of CRediT by pharma and publishing stakeholders	Completed	<ul style="list-style-type: none"> • Presentation of CRediT and its use by various organizations
Integrate CRediT with other transparency systems (e.g. ORCID)	Ongoing	<ul style="list-style-type: none"> • ORCID is looking at CRediT roles to see whether there are any that should be added to account for materials other than manuscripts and will work with Casrai to incorporate them into the standard model • Representatives from ORCID and F1000Research will investigate opportunities to integrate CRediT with ORCID
Incorporate CRediT into the GPP and/or ICMJE guidelines and pharma publication policies	Potential	<ul style="list-style-type: none"> • CRediT is not completely aligned with ICMJE guidance on authorship: this may lead to confusion • Integration of authorship into CRediT is a more realistic medium-term goal than replacement of authorship with contributorship

Table 7. Opportunities related to Convey and Publons.

Action	Status	Benefits and challenges
Increase understanding of Convey among Open Pharma stakeholders	Completed	<ul style="list-style-type: none"> • Convey presented to Workstream 2
Support uptake of Convey by publishers	Potential	<ul style="list-style-type: none"> • Open Pharma stakeholders to highlight the value of Convey to publishers
Increase understanding of Publons among Open Pharma stakeholders	Potential	<ul style="list-style-type: none"> • Publons to be invited to present to Workstream 2



Workstream 3: preprints and post-publication peer review

Preprint servers enable researchers to share their papers with the academic community ahead of their official publication in a peer-reviewed journal. They are used widely in physics and computer science, and increasingly in biology. Funders such as the Wellcome Trust, the Bill & Melinda Gates Foundation and the Chan Zuckerberg Initiative are leading the way in the use of preprints; they have been used more sparingly by pharma.

Post-publication peer review is a process in which transparent peer review occurs after publication; articles are only indexed once peer review has been completed. This system aims to avoid the problems with traditional pre-publication peer review, namely:

- delays
- limited access to data
 - reproducibility challenge
 - introduces bias in understanding of science
 - lack of transparency in decisions
- research waste (some research is not published at all).

Opportunities for pharma to increase usage of preprints and post-publication peer review, as well as to promote pharma's support for improving the way research is evaluated, were identified during the workstream meetings (Table 8). To address the challenges associated with these opportunities, various actions were planned and discussed (Table 9).

Benefits of preprints

Representatives from ASAPbio (**A**ccelerating **S**cience and **P**ublication in **biology**), an initiative that promotes the use of preprints, and the preprint server for biology, bioRxiv, outlined the benefits of preprints for pharma.

- The rate of scientific progress is accelerated by making information available to the research community more quickly.
- There are increased opportunities for feedback.

- Negative results can be made public more easily.
- Multiple versions of the article plus links to the final journal publication can be made available.
- Funding bodies are accepting preprints as supporting references in grant applications; could pharma do the same in time-sensitive contexts such as healthcare technology assessment submissions?

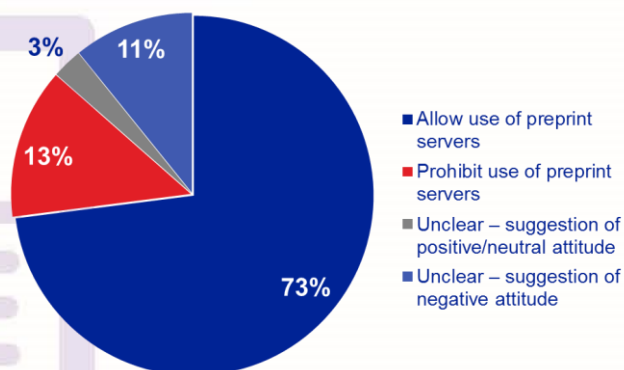
Potential problems with the use of preprints by pharma

- The use of preprints carries a risk of disseminating medical misinformation as published findings are often subsequently shown to be incorrect.
- Pharma could be criticized for:
 - communicating about unlicensed drugs or uses of drugs outside the 'safe harbour' of peer review
 - off-label promotion of drugs to patients.

Journal policies on preprints

Oxford PharmaGenesis conducted research into the preprint policies of scientific journals with an impact factor of at least 15 (n = 37). Review journals were excluded from the analysis. Data were extracted from journal websites and by email contact.

Of the 37 journals analysed, 73% stated that they permit the use of preprint servers (e.g. *Nature*, *Cell* and *The Lancet*); five journals explicitly stated that they do not permit the use of preprint servers (e.g. *New England Journal of Medicine*, *CA: A Cancer Journal for Clinicians*, *JAMA*).



Educational materials on preprints

Oxford PharmaGenesis assessed the availability and quality of current educational materials on preprints (see Appendix).

There were noticeably more educational materials on preprints than on open access but there was a severe lack of materials aimed at a pharma audience. This finding suggests that it may be valuable to develop materials that could educate pharma stakeholders.

Pharma perspectives on preprints

Advantages

- Preprints increase the speed of dissemination of research.
- Transparency: preprints may help to address the stigma of pharma's perceived lack of transparency and practice of not publishing negative results.

Disadvantages

- There could be legal implications: use of preprints may be considered off-label promotion rather than 'scientific exchange' owing to their being outside the 'safe harbour' of peer review – even though the safe harbour is by convention rather than in law or guidelines.
- Preprints may not be suitable for potentially practice-changing phase 3 clinical trials.
- Inappropriate communication (e.g. press releases, news stories) could happen before peer review.

Examples of post-publication peer review models

- F1000Research is an open research publishing platform that supports a preprints model with integrated peer review by nominated reviewers, rather than being open to public comment as are pure preprint servers such as bioRxiv.
- F1000Research operates on the premise that publishing should be author-driven and that 'gatekeeping' by the publisher slows down the dissemination of research.
- Wellcome Open Research, Gates Open Research and UCL Child Health Open

Research have been developed to provide post-publication peer review to researchers receiving funding from or otherwise linked to these organizations.

- F1000Research encourages other publishers and organizations to develop similar models with more innovation.

Pharma perspectives on post-publication peer review

Advantages

- Speed and transparency are increased.
- Article usage can be tracked with metrics.
- Research waste is reduced.
- Credit can be given to peer reviewers.

Disadvantages

- Publishing before peer review – same disadvantages as for preprints.
- It takes time to find suitable reviewers – although it was noted by a representative of F1000Research that the platform does not find it hard to attract open reviewers compared with their experience with blinded review in previous roles.
- Detractors have a public forum.
- Some reviewers may be reluctant to be named alongside reviews that are either critical or not critical of pharma-funded research.

Pharma's experience with F1000Research (in 2015)

A pharmaceutical company represented in the workstream published a commentary on a previously published article on the F1000Research platform and, although the journal took longer than expected to find suitable referees, the time taken to publish was not long.

Note: Oxford PharmaGenesis has successfully used F1000Research both to publish its own research and to comment on the research of others.

The launch of MedArXiv

bioRxiv was not originally intended for preprints reporting clinical research, and preprints of clinical work began to be allowed in 2016. Mindful of the special considerations needed for clinical research, MedArXiv, a dedicated preprint server for medical research, will be launched in 2018. Policies on which types of research can be posted to the server need to be defined but are likely to follow those of bioRxiv. In this case, manuscripts reporting results from potentially practice-changing phase 3 clinical trials are to likely be disallowed.

DORA

DORA (Declaration on Research Assessment) is a worldwide initiative to improve the ways in which scientific

research outputs are evaluated by funding agencies, academic institutions and other parties. Open Pharma has encouraged pharmaceutical companies to consider signing up to DORA, to improve the perception of the industry.

Next steps

- Continue discussions on the legal implications of pharma's use of preprints and post-publication peer review.
- Pharma participants to consider trialling low-risk papers on preprint servers (e.g. on-label unmet need/burden of illness studies).
- Since the autumn meeting, a preprint has been posted on bioRxiv reporting a phase 2a trial sponsored by Novartis (<https://www.biorxiv.org/content/early/2017/12/11/230813.article-info>), and Open Pharma has contacted the lead author to ask for her insights.



Table 8. Opportunities and challenges that were identified during the workstream meetings.

Opportunity	Associated challenge(s)
Increase pharma's use of preprints and number of submissions to journals that use post-publication peer review	<ul style="list-style-type: none"> US, UK and EU law do not rule on use of preprints or post-publication peer review for clinical research, and this is also the case for guidelines such as the ABPI, so pharma would have to trial posting preprints and assessing the reaction It will be necessary for Oxford PharmaGenesis to facilitate closer and more varied collaboration between pharma participants and provide guidance
Promote pharma's support for improving the way research quality is evaluated	<ul style="list-style-type: none"> It will be necessary for Oxford PharmaGenesis to facilitate closer and more varied collaboration between pharma participants and provide guidance

Table 9. Actions to increase pharma's use of preprints and post-publication peer review.

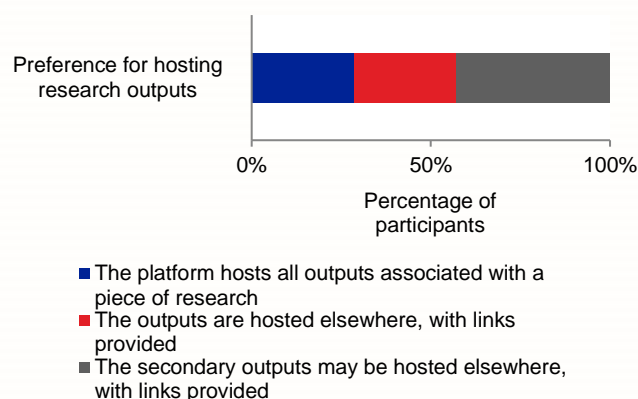
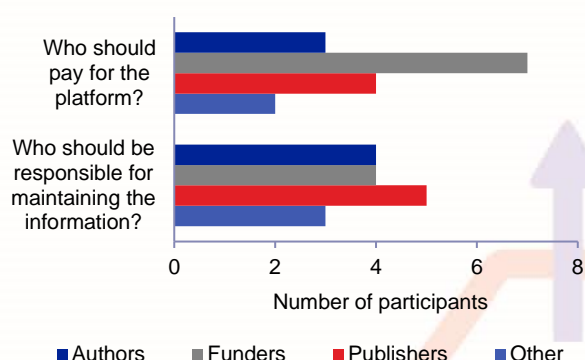
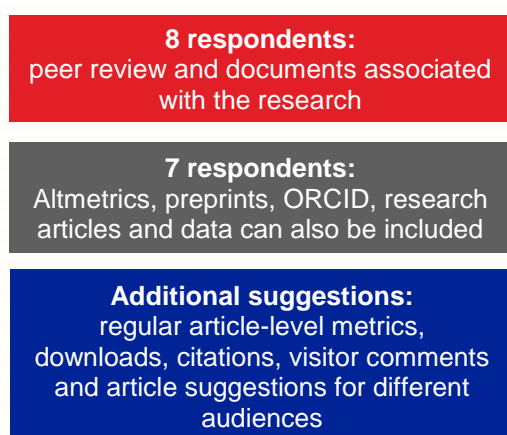
Action	Status	Benefits and challenges
Assess the suitability of digital platforms for publishing studies funded by pharma	Completed	<ul style="list-style-type: none"> Collaboration between digital publishers and pharma has the potential to improve the dissemination of medical research ISMPP 2017 poster on publishing platforms (Williams A et al.)
Learn more about post-publication peer review on F1000Research	Completed	<ul style="list-style-type: none"> Increases the group's understanding Persuading researchers to move away from publishing in high impact factor journals
Investigate and communicate journal policies on preprints	Completed	<ul style="list-style-type: none"> Increases the group's understanding Some journals prohibit the use of preprint servers Preprints are not always appropriate for pharma publications
Discuss legal and regulatory issues relating to the use of preprints and post-publication peer review	Completed	<ul style="list-style-type: none"> There is no clear direction in law or guidelines in the USA, UK or EU, either for or against Close engagement with pharma participants is required to clarify what could be appropriate for pharma publications
Identify types of publication that are most suitable for preprint publication	Ongoing	<ul style="list-style-type: none"> Begins to make a case for pharma preprint publications Need to coordinate with pharma participants
Receive feedback on pharma's experiences	Ongoing	<ul style="list-style-type: none"> Influences other pharma teams Experiences may not always be positive
Develop educational materials about preprints	Potential	<ul style="list-style-type: none"> Authors and other stakeholders may be more likely to publish preprints Dissemination Session at ISMPP EU 2018

Workstream 4: layered publication platforms

At the outset, workstream members were not clear what was meant by a layered publication model (Table 10), so our primary focus was on finding out more about available models and the ways in which a platform or linking system could work for pharma.

A quick survey among the participants of workstream 4 found that there was a broad spectrum of opinion. A selection of the findings is displayed below.

Which of the below do you think should be available via a layered publication model?



The group proposed the following ideal specification for a layered publication model.

We want the whole scientific process, from research proposal to peer review, presented as fully and openly as possible, ideally in real time

Rationale, methods and findings presented in various forms and languages for different audiences, in the context of related research

A list of outputs that could be usefully linked via these platforms was also agreed upon. These were:

- study protocol and notes on deviations
- data set
- preprint
- research paper (and drafts)
- peer-review comments
- author ORCID iDs
- patient lay summary
- Altmetric score.

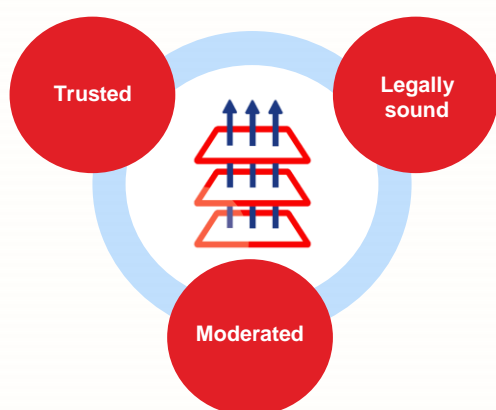
Another area of agreement within the workstream was that Open Pharma should not seek to 'reinvent the wheel' as this would be costly, risky and unnecessary.

Considerations for a pharma-specific model

When considering the prospect of a layered publishing platform for pharma, it was agreed that there were several fundamental issues that had to be taken into account.

- All materials must be peer reviewed.
- The model must be used by other reputable institutions.
- A clear awareness and avoidance of off-label promotion must inform the development of the platform.
- It must be easily usable for specialists and non-specialists alike.

In basic terms, it was agreed that the platform must be trusted, legally sound and moderated by a reputable third party.



The group also raised the issue that posting protocols ahead of publication may undermine competition between peer companies by disclosing confidential strategy. As such, a phased model was proposed in order to build towards a goal rather than implementing a unilateral solution all at once. It was agreed that the outputs of this workstream would constitute long-term goals.

The importance of moderation was a key area of discussion owing to the strict compliance guidelines by which pharmaceutical companies abide. It was agreed that the management of data and the task of ensuring that they are up-to-date represent a significant burden, and that this would need to be considered in any plan to adopt a layered model for publishing.

The benefits of layered publication models for pharma were clear in the context of making the disclosure of non-novel research easier. By hosting information publicly after a set number of journal rejections, disclosure of all research within the GPP3 guideline of 2 years could be guaranteed.

The A1chieve platform was discussed and it was agreed that, because the data are presented with no conclusions, this did not constitute promotion.

Examples of platforms

Various experts in the field of funder-specific platforms gave presentations over the course of the workstream meetings, showcasing the work of other funders working towards the goal of a layered model (Table 10). Some of these examples were deemed more suitable than others for addressing the needs outlined in this workstream.

The A1chieve site was considered as an example of an existing public platform for pharma. Key features include:

- study data available and can be interrogated by country
- hosted by a respected journal
- additional interpretations and outputs such as videos also available
- links to all papers from the study.

However, the model has too many disadvantages to become a standard route for pharma data for the following reasons.

- It is very expensive.
- Focusing on one study may lead to vital context from other company's outputs being overlooked.
- There are copyright restrictions on non-open access information.
- The model is less suitable for product data.
- There are no defined 'success criteria'.
- It is debatable whether this information should be available to patients.
- The patient voice is not represented.
- The platform is popular with clinicians but not other audiences.

F1000Research was another platform that was considered as a prototype for the development of a pharma-specific model.

Having already formed the basis of a funder-specific platform that is being adopted by a growing number of funding bodies and organizations, it seems that this type of platform has more scope for adaption.

Specific attention was also paid to the Wellcome Open Research platform, which uses the F1000Research model to host all of the research funded by Wellcome.

The F1000Research and Wellcome Open Research models both have:

- gold open access licensed under CC BY
- integrated open peer review with:
 - named reviewers
 - open access review reports alongside the publication
- open data mandates
- willingness to publish non-standard outputs (e.g. research notes)
- fast publishing times
- integrated 'preprint' style hosting while peer review is underway
- facilities for open commenting in real time
- availability of all drafts of the publication alongside the final article.

Although these platforms could provide many benefits to pharma, much uncertainty still exists around the compliance implications of posting on such platforms. As such, it was agreed that key next steps would be to experiment with the F1000Research model using low-risk publications.

Linking outputs

Experts in the use of the Crossref platform gave presentations to the group outlining how the metadata of pharma-funded publications could be used to link related outputs, including the trial registration number. One of the main difficulties facing advocates of linked publications at present is the inconsistency of authors in providing, and of journals in collecting, metadata. It was thus agreed that, due to the superior capacity of pharmaceutical companies to regulate the collection of metadata, pharma may be well placed to lead in this area.

Copyright of metadata is a tricky issue: all metadata are CC BY but publishers retain the power to make any edits, updates or additions

to the metadata of their publications. Although publishers are keen to retain control over the maintenance of the metadata on their publications, they frequently do not have the resources to implement all of the required changes.

Crossref is an indexing and cross-linking platform that links related publications together and allows users to search metadata. It is more closely moderated than other platforms such as Google Scholar.

Representatives from pharma were 'guardedly keen' to have all of their outputs in one place. Given that pharma puts money into developing these materials, and that linking them together could have the positive outcomes of making the materials more accessible and pharma more transparent, the possibility of a layered publishing model for pharma seems worthy of further exploration (Table 11).

Metadata was one of the primary points of discussion from the autumn meeting for Workstream 4, and the group agreed that only through consistent metadata would we see a threaded model reliable enough for pharma. At present metadata are inconsistently captured and stored, and rarely updated if there are any changes following initial publication. It was agreed that this would be the most relevant aspect of the workstream investigation to focus on in the near future.

It was also discussed that there may be additional data fields that are not typically recorded that would be beneficial to pharma. One such field would be funding source and whether the study was instigated by the investigator or the funder company.

The work of the European Bioinformatics Institute to build the BioStudies database has been an encouraging step in this area. This database contains short summaries of biological studies and links to the data upon which they are based.

It was also mentioned that Wellcome Open Research already represents a comprehensive layered publication platform, which is easily customizable to meet funder demands.

Next steps

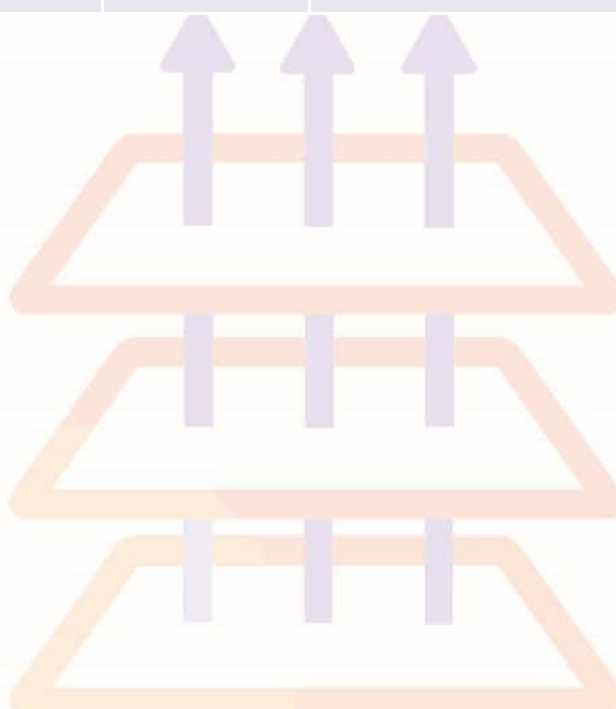
- Experiment with using F1000Research for low-risk research.
- Provide queries for publications research that could be powered by Crossref.
- Pharmaceutical companies to investigate the opportunities offered by Crossref.

Table 10. Actions to define a layered publication model.

Opportunity	Associated challenge(s)
Define a layered publication model	<ul style="list-style-type: none"> • It is a nebulous term and frequently misunderstood • Any ideal model would be incredibly difficult to implement
Explore previously untapped benefits of layered models for pharma	<ul style="list-style-type: none"> • As these platforms have not yet been used, they are more of a compliance risk • Many authors are still determined to publish in high impact factor journals and pharma cannot dictate where they publish

Table 11. Actions to explore existing layered publication models.

Action	Status	Benefits and challenges
Invite representatives from various platform developers to present	Completed	<ul style="list-style-type: none"> • Enables developers of platforms to better understand the needs of pharma and <i>vice versa</i>
Test these new platforms using appropriate papers and resources	Ongoing	<ul style="list-style-type: none"> • Builds pharma confidence in these platforms slowly without them needing to 'take the plunge'



Next steps

Workstreams: stop, start, continue

Following the autumn round-table meeting, everyone agreed to continue the Open Pharma collaboration in some form. Work will continue on live topics of discussion, such as open access and author information systems, by email and *ad hoc* meetings rather than monthly workstream meetings.

Efforts will be concentrated on:

- developing a general position statement on open access publishing by pharma, which will be signed by Open Pharma
- encouraging pharmaceutical companies to develop an open access policy and to look at how they can build preprints into their publishing activities
- driving the uptake of ORCID and advocating for its inclusion in GPP4

There is also scope for new workstreams to be created on patient engagement and data transparency, but it was decided that a new workstream on real-world evidence will not be pursued.

Communication

We aim to expand the reach of Open Pharma and our communication with the open science community. More publishers and pharmaceutical companies will be encouraged to be involved to help speed up our progress, and we can help them to implement open science innovations.

There will be opportunities to engage with stakeholders at the European ISMPP session in January 2018, at a round-table meeting in the USA and at the Annual Meeting of ISMPP in National Harbor, Maryland, USA in April–May 2018. It was agreed that the current balance of the group is good, but that adding academic, patient, and US-based funders would also be beneficial, alongside additional pharma and publishing representatives.

Publications

Research and consensus communications will be published to help drive change. We will:

- present a poster on open access at the European ISMPP meeting in January 2018
- submit for peer-reviewed publication a manuscript describing open access options available to pharma
- submit an abstract describing preprint use by pharma to the Annual Meeting of ISMPP in National Harbor, Maryland, USA, 30 April – 1 May 2018
- continue to identify and pursue new opportunities to generate evidence needed to drive improvements to the model for medical publishing.

Appendix

Reading materials per workstream

Below is a selection of resources published over the course of the last year that are relevant to the discussions that took place in each of the four workstreams and open science more generally.

General

[An evidence-based case for innovation in scholarly communication](#) via ScienceOpen

This collection of research articles on ScienceOpen includes publications that focus on various aspects of scholarly communication.

[Does Elsevier's acquisition of Bepress reflect a new direction for big-name publishers?](#) via The Scholarly Kitchen

This year Elsevier announced its acquisition of Bepress, a leading provider of institutional repository services, raising discussion of whether this approach will be adopted by other big-name publishers.

[What are pharma's policies on transparency?](#) via the *BMJ*

Research from Ben Goldacre and colleagues in the *BMJ* focusing on the transparency policies of pharmaceutical companies. Their findings? It's a very mixed bag.

[Resources for creating open publishing policies and initiatives](#) via Open Research Funders Group

This page offers explainers, research and case studies on the implementation of open publishing initiatives for funders to use when developing their own positions.

[Building trust in medicines](#) via the *BMJ*

This speech, delivered by Joe Freer, highlights the difficulties of evaluating drug efficacy when so many healthcare professionals and members of the public distrust research funded by pharmaceutical companies.

[Is scientific publishing bad for science?](#) via The Guardian

This article examines the publishing industry and its profitability with a focus on Elsevier: 'the business the internet could not kill'.

[The open science movement should not fear for-profit supporters](#) via LSE Impact Blog

Some have been sceptical of including non-profit organizations in open science initiatives but this article suggests that, on the right terms, investors and industry could lend great support to the open science movement.

[The dog who edits journals](#) via Perth Now

This is the simultaneously funny and frightening story of Dr Olivia Doll, the Staffordshire terrier who sits on the editorial boards of several peer-reviewed medical journals.

[Time for pharmaceutical companies to help improve the publishing of science](#) via the *BMJ* Opinion

Richard Smith explores the current challenges in publishing and the role that pharmaceutical companies can play.

Open access

[A summary of open access resources](#) via Open Pharma

This post evaluates the resources available for those keen to learn more about open access, and suggests that a new approach may be needed to maximize engagement.

[How to reclaim copyright ownership of your research](#) via Authors Alliance

Authors Alliance and Creative Commons jointly developed a Termination of Transfer tool that is designed to support US authors in regaining rights over the distribution of their work so that they can share it without restriction.

[What are Creative Commons licences and why are they important?](#) via Zenodo

This frequently asked questions document will tell you all you need to know about Creative Commons licensing and open access.

[Elsevier weigh in on the transition to open access](#) via Elsevier

Elsevier released a position statement on how to transition towards open access by default. The article was controversial for suggesting that 'geoblocking' might be introduced to allow open access only to certain countries.

[Evaluating funders' open access policies](#) via Science Metrics

This article provides a preview of a study conducted on behalf of the European Commission with the aim of evaluating how effective open access policies are at boosting rates of open access publishing.

[Researchers need a practical alternative to Sci-Hub](#) via Forbes

Sci-Hub has met a growing demand for free access to research from those who have grown impatient with paywalls or simply cannot afford to pay, but it cannot sustain quality if traditional journals begin to become obsolete. This article argues that publishers are not, at present, sustainable, but must become so if they are to retain their role.

[Open science won't be built in a day](#) via Authorea

This article argues that the best path forward for research sharing is to work within the system by using addendums to retain re-use rights and opting, whenever possible, for a CC BY licence over a CC BY-NC. This article nicely complements the parallel discussions going on within Open Pharma with regard to securing the same rights for industry-funded research.

[German researchers propose new model for funding open access](#) via Science

A consortium of more than 150 German libraries, universities and research institutes resolved to negotiate a new funding model for open access. While some publishers have been receptive to their proposals, Elsevier, publisher of *Cell* and *The Lancet*, has been resistant.

[Can we end 'bronze' and delayed open access?](#) via A Way of Happening: a Research Library Blog

This blog post provides a commentary on the recent PeerJ preprint 'The state of open access', in which the authors discuss the notion of 'bronze' open access. The blogger looks at what we can do to push for full and instant open access and avoid settling for a "half-revolution".

[Is a transition to open access financially sustainable for journals?](#) via Open Science

As journals begin to break away from big-name publishers with the aim of being able to offer fairly priced open access options to researchers, this article looks at the feasibility of these moves from a

financial perspective and argues that, without a significant alternative funding stream, this goal may not be achievable.

The full cost of open access publishing via *Journal of the Association for Information Science and Technology*

This study examines the complex landscape of gold open access for higher education institutions in the UK, and the rising expenditure on this category of access.

Funders need to talk less and act more to achieve progress on open access via Science Business

Although generally supportive of the widening discussion on open access, this article stresses that funders must begin to match their actions to their words otherwise change won't happen.

Academic, economic and societal impacts of open access via F1000Research

This article aims to make an evidence-based case for open access, evaluating academic, economic and societal impacts. It suggests that the best path forward for broadening access to research is for researchers to support newer platforms, rather than to try to force the existing journals to change.

Disagreement about the definition of open access via The Scholarly Kitchen

This article explores the diversity of open access definitions and its implications.

Open access licences: what drives publisher options? via Caudex

Publishers and editors were surveyed about their open access licences, the available Creative Commons licences and potential future development. Policy was found to be the strongest driver of licence choice.

Publishing priorities of biomedical research funders via *BMJ Open*

Semi-structured interviews were conducted with 12 employees of 10 UK biomedical research funders (of which two were commercial) to identify their publishing priorities.

ORCID, CRediT and Convey

5 years of ORCID via ORCID

ORCID celebrated its 5th year, and marked the occasion with the launch of new resources that make it easier than ever before to use an ORCID iD.

Cultivating ORCID at the Royal Society via Open Pharma

Stuart Taylor provides an overview of the Royal Society's decision to mandate that authors submitting research include their ORCID iD, and also outlines the results of this policy.

Remarq™ integrated with ORCID via RedLink

RedLink announced the integration of its collaboration tool Remarq with ORCID. This integration enables pre-population of Remarq user profiles with their ORCID credentials.

Tools supporting ethics and integrity in submission and review via Open Pharma

In this article, Alison O'Connell of Aries Systems provides an overview of the transparency tools that are available as part of the Editorial Manager system and explains their potential to improve academic publishing.

How can we recognize contributions to research? via F1000 blog

This piece explores the various roles involved in the creation of a manuscript, reflects on the importance of recognizing individuals who, at present, would not necessarily be mentioned in the

author list, and promotes the CRediT system as having the potential to make sure credit is given where it is due.

MyScienceOpen launched via STM Publishing News

MyScienceOpen is a networking platform that is integrated with ORCID to provide a comprehensive picture of the impact of researchers' work using a variety of metrics. It also enables the addition of non-specialist summaries to research publications in order to promote accessibility.

Nature embraces ORCID via The Scientist

Springer Nature has announced the launch of a 6-month trial period of mandating the use of ORCID iDs by researchers submitting manuscripts to their journals.

ORCID adoption by journals in 2016 via Caudex

This research focuses on the extent of ORCID adoption by medical journals and its implications for medical communication agencies.

Convey: financial disclosures made easy via Association of American Medical Colleges News

A useful backgrounder about Convey.

Pre-prints and post-publication peer-review

What is open peer review? via F1000Research

The authors of this systematic review analysed the ways in which the term 'open peer review' has been used in different contexts and reached a pragmatic conclusion: that it is an umbrella term encompassing various methods by which organizations have attempted to open up the peer review process.

When will preprints take off in medicine? via Open Pharma

This blog post from Open Pharma provides introductory and educational resources about what preprints are and how they can be best used.

MedArXiv, the new preprint server for medicine and health sciences via The Publication Plan

It was announced this year that MedArXiv will soon be launched to provide a preprint server for medical research papers.

Crossref will assign DOIs to peer review-related content via The Publication Plan

Crossref, an organization that interlinks a variety of online research content by using DOIs, has this year extended its service to include referee reports, decision letters and author responses, as well as post-publication reviews. In January this year preprints were also added to its list of linked resources.

Authors prefer open peer review via Science

These data, presented at the 2017 **International Congress on Peer Review and Scientific Publication** from a study conducted by the Nature Publishing Group, suggest that authors, when given the option, will opt for open peer review seven times out of eight.

A review of peer review via F1000Research

This paper surveys the past and present of peer review, looks to its future, and provides a thorough background for anyone interested in knowing more about preprints.

[Open peer review study flops](#) via Open Pharma blog

Richard Smith provides a response to a study on open peer review published in *PLoS One*, outlining some of the shortcomings of research evaluating novel platforms and emphasizing the importance of objectivity when researching these important topics.

[Introducing Papr: Tinder for preprints](#) via ScienceInsider

An introduction to a new app, Papr, a self-proclaimed ‘Tinder for preprints’. Papr aims to make it easier for researchers to keep abreast of the latest research in their fields, and to promote interdisciplinary working.

[Pros and cons of preprints in biomedicine](#) via PLOS Blogs

Hilda Bastian aims to answer some of the key questions surrounding preprints based on an ASAPbio meeting held in early 2016.

[The case for open preprints in biology](#) via PLOS Biology

This article describes the various potential benefits of preprints including speed of disseminating evidence and unbiased (public) peer review.

[Preprints: a new model for publishing medical evidence](#) via *The Lancet*

Authors Lauer, Krumholz and Topol propose using preprints in medical publishing.

[Editor’s perspectives on preprints: the good, the bad and the ugly](#) via CardioBrief

Several editors of traditional journals respond to the preprint proposal by Lauer, Krumholz and Topol. Opinions of, for example, the *New England Journal of Medicine* and *Heart* are detailed.

[It’s not all sunshine: a critical response to the preprint proposal](#) via *the Lancet*

This response to the preprint proposal by Lauer *et al.* highlights the risks that are associated with preprints.

[A list of academic journals by submission policy regarding the use of preprints](#) via Wikipedia

[Layered publication models](#)

[An introduction to Open Research Central](#) via F1000 blog

Open Research Central – ORC for short – is a portal through which research in any field can be submitted for publication on an open research publishing platform. Will this free researchers from the “prisons of academic journals”?

[Vivli receives funding to build the first data-sharing platform for global clinical trials](#) via Business Wire

The Laura and John Arnold Foundation has contributed US\$2 million to Vivli, a Massachusetts-based not-for-profit organization, to support the launch of its platform for sharing global clinical trial data from 2018 onward.

[Metadata2020: a new collaboration for richer metadata](#) via Metadata2020.org

In this blog post, Ginny Hendricks from Crossref introduces Metadata2020, a campaign by the scholarly community that advocates richer and better-quality metadata, and invites readers to get involved in the project.

[Analysis of the first 100 papers published on the Wellcome Open Research platform](#) via Wellcome Open Research

Robert Kiley, Head of Open Research at the Wellcome Trust, provides an overview of the research that has been published since the launch of Wellcome Open Research in December 2016.

[How F1000Research puts authors in control](#) via F1000Research blog

A post by Editorial Director of *F1000Research*, Sabina Alam, discussing the significance of putting authors first in the F1000 publishing platform and explaining how the platform has been tailored with funders in mind.

[Rapid publication of useful information: a case study in genetic medicine](#) via Transforming Genetic Medicine Initiative

This article outlines the submission of a scientific paper to the Wellcome Open Research platform, explaining how the paper was submitted, published, reviewed and approved in only 3 weeks.

[Making the most of 'plain English' summaries](#) via *Research Involvement and Engagement*

The importance of plain English summaries has grown in recent years and this is nowhere more evident than in the pharmaceutical industry, with trial registries requiring that a lay summary be posted alongside the trial summary for all studies. This paper suggests two ways in which the quality of plain English summaries could be improved: provision of clear guidance for authors and the use of professional medical writing support.

[Should pharma publish clinical studies via digital platforms?](#) via HealthScienceLive

This survey explores the suitability of publishing medical evidence on digital platforms against 14 evaluation criteria.

[Proposing formal, invited and transparent post-publication peer review on digital platforms](#) via F1000Research

The founders of F1000Research state their case for online publishing platforms.

[Data sharing models in the pharma industry](#) via *Circulation: Cardiovascular Quality and Outcomes*

Krumholz and colleagues give an overview of the policies that pharmaceutical companies have implemented to drive open science and data sharing.

Disclosures

Although Oxford PharmaGenesis is a for-profit company, this is a not-for-profit project and we are committing much of our time at no charge.

Finances

Open Pharma is very grateful for the contributions received, both in the form of grants and services, from GSK Vaccines, Pfizer, Novo Nordisk, Oxford PharmaGenesis, Shire, UCB Pharma and the Wellcome Trust.

The Budapest definition of open access

By “open access” to [peer-reviewed research literature], we mean its free availability on the public internet, permitting any users to read, download, copy, distribute, print, search, or link to the full texts of these articles, crawl them for indexing, pass them as data to software, or use them for any other lawful purpose, without financial, legal, or technical barriers other than those inseparable from gaining access to the internet itself. The only constraint on reproduction and distribution, and the only role for copyright in this domain, should be to give authors control over the integrity of their work and the right to be properly acknowledged and cited.

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Published materials

- ISMPP 2017 poster
- Open Pharma website (blog articles on educational materials for open access and preprints included below)
- 2018 European Meeting of ISMPP open access poster (awaiting publication)
- 2018 European Meeting of ISMPP ORCID poster (awaiting publication)
- Open access manuscript (awaiting publication)

Surveying the evolving models of digital publishing: where does pharma fit?

Amy Williams,¹ Christopher Winchester,¹ Lucy Robinson,¹ Tim Koder,¹ Christopher Rains² and Richard Smith³

¹Research Evaluation Unit, Oxford PharmaGenesis, Oxford, UK; ²Shire, Lexington, MA, USA; ³Patients Know Best, Cambridge, UK

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OBJECTIVE

- Digital publishing platforms have the potential to facilitate efficient and transparent dissemination of medical research.¹ Our aim was to assess the suitability of these platforms for publishing studies funded by the pharmaceutical industry.

RESEARCH DESIGN AND METHODS

- Digital platforms publishing medical research were identified through web searches (Google), interviews with publishing professionals and the authors' personal libraries (conducted between 1 August and 30 September 2016).
- Innovative English language digital platforms were selected; in order to showcase a range of new publishing models, some platforms which were similar to those featured were excluded.
- PubMed searches were used to gauge current usage of these platforms. We searched all articles in each of our chosen platforms indexed on PubMed for affiliations with the 15 largest pharmaceutical companies, by revenues, profits, assets and market value, in 2015.²
- Shortlisted platforms were assessed against 14 criteria, listed in Table 1, defined by author consensus to highlight emerging trends in digital publishing.
- Data were collected from platform websites, PubMed, the Directory of Open Access Journals, press releases and responses to email enquiries.



Table 1. Evaluation of digital publishing platforms against 14 criteria designed to highlight emerging trends in digital publishing.

Evaluation criteria	Cureus	eLife	Europe PMC	F1000 Research	Peerage of Science	PeerJ	PeerJ Preprints	ResearchGate	Royal Society Open Science	Science Matters	The Winnower
	Journal	Journal	Database	Journal	Peer review platform	Journal	Preprint server	Social network	Journal	Journal	Publishing platform
Background	PubMed indexed	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Peer review	Launched after 2010	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Peer review	Open peer review ^a	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Peer review	Pre-peer review publication	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Peer review	Commenting post-publication	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Content specifications	No length restrictions	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Content specifications	Non-traditional outputs ^b	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Audience	Open access ^c	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Audience	Content shared via social media	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Audience	More than 100 000 users ^d	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Audience	Provide article-level metrics	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Publication	Publish within 4 weeks	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Publication	Publication fee < £200	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

✓ Yes ✗ No □ Not applicable

^aOpen peer review was defined as publication of all peer-reviewer comments alongside the reviewed publication. ^bNon-traditional outputs included posters, slide sets and research notes. ^cOpen access included 'gold' open access, whereby there is no embargo period before publication, and 'green' open access, whereby the authors may self-archive their work onto a public site. ^dWeb traffic to the domain of each platform was calculated using www.similarweb.com. ^eArticles are made open access immediately but not PubMed indexed until they have passed peer review. ^fService is free but does not publish reviewed manuscripts. ^gReviews are carried out privately, but reviewers may choose to sign their reviews, and authors may choose to share review history upon publication. ^hPeer Preprints shares a domain with PeerJ. ⁱMembership fees to the journal can make the cost per published article lower than £200. ^jArticle processing charge for non-members is £890. ^kAuthors opt for either open or closed review. ^lExcerpts from the peer-review report are published. ^mIntention to publish within 2 weeks. ⁿArticles up to 1000 words are \$150 (£120) per submission. Longer articles exceed this £200 threshold.

Case studies

F1000 Research Publishes the data on which the article is based and the identity of reviewers and their comments along with each article. Wellcome Open Research, launched in October 2016, also uses this model.	Peerage of Science A free peer review service. Articles are uploaded to the site and approved reviewers select articles they wish to review. Following review, journals can make direct publication offers, or authors may export the review to a journal of their choosing.	PeerJ Preprints A preprint service for biomedical sciences that allows authors to host drafts or final versions of abstracts, posters or articles ahead of formal peer review. These are critiqued by the community and feedback is incorporated into subsequent drafts.	ResearchGate An open-access social media platform on which authors can host their own scientific outputs, pre- or post-review, for distribution to the authors' followers. The followers can then post comments on the article.	Europe PMC An online database which hosts millions of full-text articles published by biomedical and life-science journals.
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RESULTS

Evaluation of digital publishing platforms

- Eleven innovative digital platforms in the life sciences were evaluated: 6 journals (Cureus, eLife, F1000 Research, Science Matters, PeerJ, Royal Society Open Science), a social network (ResearchGate), a publishing platform (The Winnower), a database for articles published in journals (Europe PMC), a preprint platform (PeerJ Preprints) and a peer review service (Peerage of Science) (Table 1).
- Of the 11 platforms assessed, 5 are indexed in PubMed. Europe PMC exclusively contains articles indexed on PubMed.
- Overall, the platforms assessed met 3–13 of our 14 criteria.

Peer review

- Peer review is integral in 8 of the 11 platforms.
 - There is no peer review prior to publication in PeerJ Preprints and ResearchGate; they enable commenting on articles following publication.
- The peer review comments are open access on 6 of the 8 peer-reviewed platforms and pre-peer-review publication is available on 4 of these 8.

Content

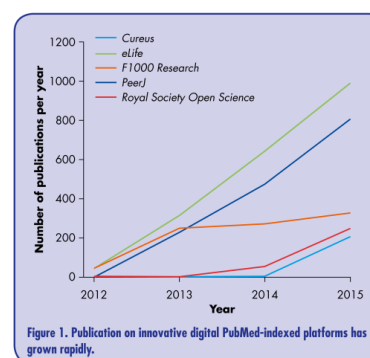
- There are no length restrictions for articles on 10 of the 11 platforms.
- Six platforms are willing to publish non-traditional outputs not associated with a traditional article, such as posters, data notes and slide sets.

Audience

- Of the 11 platforms assessed, 9 are open access; Peerage of Science does not host manuscripts.
- Six platforms had a cumulative total of more than 100 000 users between 1 April 2016 and 30 August 2016.
 - ResearchGate had 60.3 million users during this period.
- All platforms have social media accounts; 7 of the platforms enable article sharing via 3 or more social media sites.
- Article-level metrics are available on 9 of the 11 platforms.

Growth in publication on innovative digital platforms

- Many of these platforms have been established relatively recently, with 10 of the 11 having been set up since 2010. ResearchGate was launched in May 2008.
- The rate of publication on the platforms assessed has grown rapidly.
 - The total number of articles published on those platforms indexed on PubMed increased from 98 in 2012 to 2579 in 2015 (Figure 1).
- During December 2014–August 2016, articles from the top grossing 15 pharmaceutical companies accounted for only 0.5% of articles published on the digital platforms we assessed.



CONCLUSIONS

The volume of medical research published on the digital platforms studied has risen sharply since 2010. These platforms provide various means of improving the exchange of scientific knowledge. The pharmaceutical industry is an important contributor to medical research, but has been reluctant to follow non-industry researchers in publishing outside traditional journals. Collaboration between digital publishers and pharmaceutical companies has the potential to improve the dissemination of medical research in general, and to promote these innovative methods of information sharing.

Disclosures

A Williams, C Winchester, L Robinson and T Koder are employees of Oxford PharmaGenesis, Oxford, UK. C Winchester owns shares in Oxford PharmaGenesis Holdings Ltd and AstraZeneca Ltd. C Rains is an employee and shareholder of Shire, Lexington, MA, USA. R Smith is a consultant to F1000 Research.

References

- Tracz V, Lawrence R. F1000Res 2016;5:130.
- Forbes. 2015 Global 2000: the world's largest drug and biotech companies. 2015. Available from: <http://www.forbes.com/sites/liyanchen/2015/06/04/2015-global-2000-the-worlds-largest-drug-and-biotech-companies/#488a557e5768> (Accessed 4 December 2016).

Presented at the 13th Annual Meeting of the International Society for Medical Publication Professionals (ISMPP) May 1–3, 2017, National Harbor, MD, USA

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Open access education: time for a new approach?

2 August 2017

Open access publishing is on the rise, providing both opportunities and challenges for publishers, academics, funding bodies and pharma. However, academic authors collaborating with pharma prefer to publish in journals with the highest impact factor possible, and open access is not necessarily the authors' priority.

In our Open Pharma workstreams, we have identified a strong need to clarify the terminology and benefits of open access – information that both academic authors and pharmaceutical companies can use to inform their publishing choices. Therefore, we investigated what educational resources already exist; our search method is at the bottom of this article.

Among the resources we identified were the following, which readers may find helpful.

- Videos aimed at a general audience, such as '[Open access explained!](#)' by PHD Comics.
- University library resources for students and academics:
 - [Cornell University Library](#)
 - [Leeds University Library](#).
- Guides, reports, tools and webinars/workshops from open science initiatives such as:
 - [Jisc](#)
 - [Open Access Academy](#)
 - [Center for Open Science](#)
 - [Foster Open Science](#)
 - [Open Access Scholarly Information Sourcebook](#)
 - [Open Access Scholarly Publishers Association](#)
 - [The Right to Research Coalition](#)
 - [The Scholarly Publishing and Academic Resources Coalition](#), who produced the [Open Access Spectrum Evaluation Tool](#), which quantifies the 'openness' of scientific journals.

We found that the available educational materials on open access covered the basics; however, there was a lot of overlap in content, the resources were scattered and not cross-referenced, and most materials were more than a year old. Furthermore, most materials were text-based, making them unengaging and unlikely to attract much interest from audiences who are new to the concept of open access. Interestingly, although there were educational materials from or aimed at a range of stakeholders, including research scientists, publishers and funders, no such materials involved pharma.

The terminology used for open access and the available copyright licences was not covered in depth by any of the educational materials. Individual journals and publishers do provide this information but the terminology is opaque and inconsistent.

We are considering the need for Open Pharma to develop educational material on open access specifically for pharma audiences. This is an opportunity for pharma to join the conversation, to promote transparency in scientific research and to fill relevant knowledge gaps.

What kind of material would be useful for you? Please get in touch [here](#) to share your thoughts.

Next week, look out for our summary of materials that we found about preprints.

Search method

We conducted a Google search for educational materials about open access and preprints using the search terms 'what is open access', 'open access education', 'why open access', 'what are preprints', 'preprint education' and 'why preprints'. We also searched for '#openaccess' and '#preprints' on Twitter. We manually selected items on the basis of relevance.

When will preprints take off in medicine?

14 August 2017

Use of preprints, the public posting of research articles before peer-reviewed publication, is increasing rapidly, with the number of preprints posted to repositories each month almost doubling in the past year. Researchers post preprints to help quickly disseminate their latest scientific findings and lay claim to their discoveries, and to gather feedback from the scientific community that they can use to improve their manuscripts before submitting them for peer review. Discussions in the Open Pharma project have identified preprints as one of the major recent innovations in publication practice that increases the transparency, speed and openness of scientific research, which could benefit academics, pharma and other stakeholders in medical research.

Despite these potential benefits, at the moment, preprints are very rarely posted for work sponsored by pharma. Unlike open access, the concept is not well known in the industry, and the first barrier to use of preprints is lack of awareness of what they are. To begin to address this, we investigated current educational resources on preprints to add to those we posted on open access last week. Our search method is at the bottom of this article. The most useful resources we found were:

- videos aimed at research scientists and the general public, such as [Youreka Science's 4-minute animation](#) made in collaboration with ASAPbio
- webinars, such as the [Center for Open Science's](#) 45-minute 'Introduction to preprints'
- blogs and news articles, such as the Crosstalk piece 'Let's talk about preprint servers'
- a range of resources on the [ASAPbio](#) website, including the preprint policies of journals and funders.

Educational materials about preprints overlapped in content, just like the open access materials. There were, however, noticeably more videos and webinars about preprints than about open access, and they were informative and easily accessible. We identified ASAPbio, a key initiative for promoting the use of preprints in life sciences, as the major repository for preprint educational materials.

Currently, the materials are aimed at a range of stakeholders, including researchers, societies, publishers and funders, but not pharmaceutical companies or their academic collaborators. We are therefore considering the need to develop educational material on preprints specifically for pharma audiences, alongside potential materials covering open access.

Please comment below or contact us here to share your thoughts on what material would be useful for you.

Search method

We searched Google using the terms 'what is open access', 'open access education', 'why open access', 'what are preprints', 'preprint education' and 'why preprints'. We also searched for '#openaccess' and '#preprints' on Twitter. We manually selected items on the basis of relevance.

