Open Pharma summit 2023

Insights report

OpenPharma

Introduction

The Open Pharma summit took place in November 2023 and consisted of three sessions, each aligned with one of the Open Pharma working groups

- Session 1: PLS and discoverable content
- Session 2: Open access
- Session 3: Data and metadata

Each session featured a series of guest presentations by external speakers alongside showcase presentations from Members highlighting developments made across each topic area

To conclude each summit session, the participants engaged in a workshop during which they discussed their endorsements, recommendations, reservations and barriers regarding statements proposed to support the development of a new Open Pharma vision. At the end of the workshop, attendees made personal commitments related to these statements

This document provides an overview of the content presented in each summit session and the subsequent workshop discussions. The summaries presented here are intended to support the task force who will develop the new Open Pharma vision statement

PLS, plain language summary(ies)

Session 1
PLS and discoverable content

Friday 3 November | 14:00 GMT

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Summit session 1
PLS and discoverable content

Guest presentations

Vicky Gardner and Jo Wixon
Could PLS help us find answers to today's challenges?

Rachel Daley
A caregiver's perspective on plain language summaries

Richard Stephens
Plain language summaries – a writer reflects

Pharma showcase

Sally Dews
Patient involvement and the importance of using plain language

Sarah Thomas
Ipsen commitment: plain language summaries

Slávka Baróniková
*Publisher perspectives on PLS: an Open Pharma survey**

Workshop

Statement 1
100% of medical research/phase 3 trial publications should include a PLS

Statement 2
Patients should be involved in the development of all medical research/phase 3 trial publications

*A recording of this presentation is not currently available

PLS, plain language summary(ies)

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Workshop discussions
Statement 1

100% of medical research/phase 3 trial publications should include a PLS

Endorsements and recommendations

- Outputs presenting human data or results that may have an implication on clinical decisions should include PLS
- The statement could be expanded to include:
  - all clinically relevant data
  - trial documentation
  - data from phase 1–4 trials and beyond
- Those who are most knowledgeable about the data are best placed to produce the accompanying PLS, as they can ensure that accuracy is maintained while content is simplified
- Diverse formats should be prioritized to ensure accessibility for the intended audience. This includes:
  - translation into languages other than English
  - development of alternative formats (e.g. video or audio)

Reservations and barriers

- Publishers could do more to support broader PLS coverage (e.g. through actively encouraging submission)
- Discoverability remains a concern
  - PLS should be openly available even if the rest of the publication isn't
  - Measures of improving discoverability should consider the end user – PubMed tagging will only support those who know how to use the platform
- Are PLS the appropriate medium through which patients should be accessing research outcomes, or would it be better for systematic reviews (as an example) to be produced in plain language instead?
- Consensus as to what a PLS is should be reached
  - Until a consensus is reached, mandating PLS for publications could lead to the production of poor-quality content and additional author burdens
- 100% implementation would be cost-prohibitive
- Guidance on peer review practices and reviewer selection would need to be developed for consistency within publishing

PLS, plain language summary(ies)

Workshop discussions

Statement 2

Patients should be involved in the development of all medical research/ phase 3 trial publications

Endorsements and recommendations

- Implementation of the statement has the potential to improve the quality of medical research
  - Involvement of patient groups should be encouraged to clarify what patients want from publications and research
- The statement should be altered to clarify what is meant by 'involvement'
  - It may not always be appropriate to include patient authors
  - Patients/patient groups could be consulted and included in the acknowledgement section
  - Addition of a 'patient voice' section to the paper may be more appropriate
  - Involving patient authors may promote the embedding of plain language throughout the publication
- Existing resources (e.g. ISMPP training) should be expanded to allow for the inclusion of patient contributors
- Publishers should insist that papers include a patient involvement statement

Reservations and barriers

- There are responsibilities associated with authorship that may not be appropriate to confer upon patients
- Recognition of the expertise offered by patients is required to dispel a persistent attitude that patients should not have access to research
- Engagement with patients can be erroneously perceived as promotional
- Guidance on the consultation of patients would be required to ensure compliance
  - Patients should be selected for their involvement based on recognized expertise
  - Consulting patients should be segregated from the participant population
  - Compensation of patient contributors can present an internal barrier to compliance

Workshop discussions
Participant commitments

Related to PLS

- Create a special interest group and host a webinar to facilitate further discussions on PLS
- Pharma companies to increase the quality and quantity of PLS for internal publications, and to ensure that they are openly available
- Pharma colleagues responsible for publications to collaborate with MSLs to understand how PLS could be used
- Encourage the uptake of measurable metrics where PLS are involved
- Publishers to provide authors with guidance on PLS development
- Authors to encourage journals that do not currently accept PLS to do so
- Integrate PLS policies into the journal selection process
- Pharma and publishers to educate authors on the importance of PLS
- Develop PLS for all primary phase 3/registrational trials and advocate the inclusion of PLS in all publications
- Publishers to explore methods of improving PLS discoverability
- Remind colleagues to consider plain language principles for the whole publication

Related to patient involvement

- Increase the involvement of patients in PLS development
- Develop internal guidelines for the inclusion of patient authors
- Liaise with journals to advocate the inclusion of patient authors

MSL, medical science liaison; PLS, plain language summary(ies)

Session 2
Open access

Wednesday 8 November | 14:00 GMT

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Summit session 2
Open access

Guest presentations

Malavika Legge
Equity in open access: views from OASPA

Johan Rooryck
Roads towards more open access

Sarah Roughley
Supporting open infrastructure: ensuring open content and data are discoverable and accessible

Durhane Wong-Rieger
Why are we still debating open access to academic research?

Pharma showcase

Seth James
*Pfizer's commitment to open access**

Susan Wieting
*Advancements in open access publication policy in Takeda**

Workshop

Statement 1
100% of papers should be made immediately open access upon publication

Statement 2
100% of papers should be made immediately open access under a CC BY licence upon publication

*A recording of this presentation is not currently available

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Workshop discussions

Statement 1 (1/2)

100% of papers should be made immediately open access upon publication

Endorsements and recommendations

- The majority of attendees agreed with the goal of 100% open access publishing but highlighted a need to be realistic
- A mixed model is likely to persist for some time owing to the barriers involved

Reservations and barriers

Pharma barriers

- Authors frequently favour top-tier journals that do not provide immediate open access for pharma-funded research
- Pharma companies may be reluctant to mandate open access owing to perceived fears of conflict of interest
  - Pharma companies need to view themselves as research funders – academic funders already have open access mandates, and academics have become familiar with these stipulations
  - Open access stipulations should be built into the research process from the start (e.g. author letters, agreements, contracts) and should be highlighted as an authorship standard in author kick-off calls
- The top 5% of publications (e.g. primary results from phase 3 trials) may represent a sticking point in the drive for open access, given the pressure to publish in top-tier journals
- However, for the remaining 95% of publications (e.g. secondary endpoints, sub-analyses, patient journeys, disease landscape or observational studies), there are many high or medium impact factor journals that offer open access publishing to pharma
  - Identifying and prioritizing these publications for open access publishing may help to lay the groundwork for a shift to 100% open access publishing

Workshop discussions
Statement 1 (2/2)

100% of papers should be made immediately open access upon publication

Reservations and barriers

Pharma barriers (continued)

- There is a need to increase external visibility of open access mandates or commitments
  - Companies are encouraged to make such commitments publicly available and register on Sherpa Juliet, as this may improve access to open access publishing options
- There is also a need for internal education for all relevant internal stakeholders to highlight the importance of open access with regard to research equity, visibility, transparency and reproducibility, as well as patient and HCP centricity
- APC costs may be challenging for publication budgets, particularly on a regional level, so there is a need for upper management and finance teams to be aware of the benefits of open access to allow appropriate funds to be built into publication budgets

Publisher barriers

- There is a need for broader awareness of the pharma demand for open access in the publishing community
- There is a need to leverage publishers to recognize pharma as a legitimate funder
  - Pharma companies may need to ask directly for open access publishing options, using open access mandates or commitments as a bargaining tool

APC, article processing charge; HCP, healthcare professional

Workshop discussions

Statement 2

100% of papers should be made immediately open access under a CC BY licence upon publication

Reservations and barriers

- The current financial model incentivizes some publishers to withhold CC BY licences for pharma-funded research
  - Reprints and figure permissions continue to generate substantial revenue for publishers, so there is often little motivation to offer these licences for pharma-funded publications
  - Some publishers have also started offering CC BY licences for pharma-funded research at an inflated cost
- Lack of internal awareness of CC licences and their consequences also poses a considerable challenge
  - There is a need for internal education with regard to the cumulative cost of reprints and figure permissions, particularly for educational activities or symposia, which can be costly
  - Internal education should demonstrate the value of CC BY licences for pharma companies, including flexibility of reuse and potential long-term cost savings
  - There is a persistent fear that needs to be addressed with regard to competitor misuse or manipulation of CC BY licensed content
- Notably, many mid-tier journals offer open access under a CC BY licence to pharma, so there is a need for pharma companies to consider when they should prioritize publication impact over reusability/long-term cost savings

CC, Creative Commons; CC BY, Creative Commons Attribution

Workshop discussions
Participant commitments

Related to open access

- Continuing the dialogue around open access and CC licensing to raise and increase awareness of the importance of open access
- Starting an internal dialogue about increasing the visibility of company commitments in the public domain as well as registering these commitments in Sherpa Juliet
- Pushing internally towards a 100% open access publishing goal and driving internal mindset change, for both globally and regionally funded research
- Ensuring authors are educated on the importance of open access, what it means and what different licence types are, and the importance of selecting the right one
- Engaging with the publishers to advocate open access for pharma-funded research and facilitating dialogue to understand the barriers to publishing under a CC BY licence
- Bringing open access issues more to the forefront of a patient community to improve awareness of open access challenges and how patients may be able to support
- Reviewing journal portfolios to see if any need to be updated with respect to offering of CC BY licences
- Continuing to remember pharma as a key stakeholder

CC, Creative Commons; CC BY, Creative Commons Attribution

Session 3
Data and metadata

Friday 10 November | 14:00 GMT

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Summit session 3
Data and metadata

Guest presentations

Shawna Sadler
ORCID for Open Pharma

Alice Meadows
Why are PIDs and their metadata are having a moment and why you should care!

Giovanni Nisato
How much longer can we afford not to have FAIR data?

Ellie
*Patient journey**

Pharma showcase

Santosh Mysore
Open Pharma ORCID analysis

Mark Landis
*Open Pharma data sharing survey**

Workshop

Statement 1
100% of authors should have and report ORCID IDs

Statement 2
100% of publications should include Crossref DOIs for grants and ROR ID affiliation details for all contributors and funders

Statement 3
All health research data should be made as open as possible, as closed as necessary in line with the FAIR framework

*A recording of this presentation is not currently available
DOI, digital object identifier; FAIR, findability, accessibility, interoperability and reusability; ID, identifier; ORCID, Open Researcher and Contributor iD; ROR, Research Organization Registry; PID, persistent identifier

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Workshop discussions
Statement 1

100% of authors should have and report ORCID IDs

Endorsements and recommendations

- Laudable sentiment that aligns with open research principles and transparency; shares author details and disambiguates authors
- Framing is required (e.g. make the statement specific to industry publications)
- Engagement and education are more important than achieving 100% compliance
- There is a need to educate:
  - authors and other stakeholders of the value of ORCID IDs so that uptake is voluntary and effective, e.g.
    - a tool to track research activity and serve as a CV shorthand for researchers
    - future possibilities to pre-populate data fields and expedite manuscript submission
  - authors that they have control over their record and what is written on it
- Engagement could begin early in researchers' careers (e.g. at university level)
- Librarians may have a role to play in communicating the value of ORCID IDs
- ORCID IDs could be a solution to current questions of provenance of publications – whether machine- or human-generated

Reservations and barriers

- Privacy is a growing concern with the increasing ability for AI to triangulate information
- For something to be successfully mandated, it has to be extremely easy to implement – busy researchers may:
  - not see the value of ORCID
  - be frustrated by registration if it causes administrative delays or disrupts submission workstreams
- It is better to encourage than to mandate
  - The technical barriers are low, but enforced registration may result in suboptimal use (e.g. duplicate records for the same researcher)
- 100% compliance is a long way off

AI, artificial intelligence; CV, curriculum vitae; ID, identifier; ORCID, Open Researcher and Contributor iD

Workshop discussions

Statement 2

100% of publications should include Crossref DOIs for grants and ROR ID affiliation details for all contributors and funders

Endorsements and recommendations

- Laudable sentiment that, like ORCID IDs, aligns with open research principles and that can help to verify and disambiguate research and funding source(s)
- All PIDs support improved transparency and authentication of research and its origins
- The statement needs to be refined so that it:
  - does not refer to Crossref specifically (i.e. is more solution-agnostic)
  - refers to publication grants
- Engaging with PIDs wherever possible is good idea. When technology permits, there will be opportunities to triangulate the information and realize real benefits, e.g.
  - for authors: during publication submission or when submitting grant applications, entering a previous grant number, selecting the linked study and machine-readable information, pre-populating thereafter
  - for funders: tracking activity associated with grants and monitoring impact of funding and compliance with the funding requirements

Reservations and barriers

- There are two bodies that currently assign PIDs for grants – Crossref and DataCite – one should not be recommended over the other
- There is a need to establish and embed registration practices within workflows to drive registration/uptake
- Within pharma:
  - IISs may be funded through specific grants that could be registered
  - CISs are not funded through specific grants
  - there is limited appetite within pharma to pay external bodies to ‘mint’ PIDs for funding, especially if this increases the administrative burden around studies
- 100% implementation would have substantial time and cost implications for publishers

CIS, company-initiated study; DOI, digital object identifier; ID, identifier; IIS, investigator-initiated study; ORCID, Open Researcher and Contributor iD; PID, persistent identifier; ROR, Research Organization Registry

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Workshop discussions

Statement 3

All health research data should be made as open as possible, as closed as necessary, in line with the FAIR framework

Endorsements and recommendations

- All data sharing conversations must make clear what is being discussed:
  - ‘data’ or ‘information’; ‘patient-level’ or ‘aggregate data’; ‘for publication’ or ‘post publication’
- Sharing as much information as possible brings with it global benefits and company benefits; it positions the information provider (often pharma) as a credible source of information
- FAIR outlines positive driving principles that are intentionally ambitious. The principles can facilitate a lot of discussions
- Consent can be dynamic – it can change and be enabled by new technologies (prospective and retrospective consent)
- Consent forms should be updated to cover anonymous data sharing on the Internet or within a data repository
- Some journal policies are not well tailored to health research, but no publisher is trying to make health research data more open than is ethical or legal – there will generally be policy exemptions to explore

Reservations and barriers

- This statement is subject to interpretation and could be used to argue against data sharing in situations where it is challenging or costly, even if still ethical and responsible, e.g.
  - where consent for primary sharing of data and secondary use of data is not in place, it is sometimes feasible to secure consent retrospectively, but it may not be practical
- The statement is somewhat distant from the principles of FAIR: findable, accessible, interoperable, reusable
  - There is need for training around what FAIR actually means
- Interoperability requires standardized data architecture, data dictionaries, common data models – a grand ambition
- There are huge risks for failing to protect patient privacy, especially in the age of AI (GDPR fines are substantial)
- Requirements to anonymize and share data safely are complex and differ for different data types and contexts
- Data anonymization and data verification are hugely resource-intensive for both the data sharer and the publisher; there must be value in the process to justify the effort for both parties

AI, artificial intelligence; FAIR, findability, accessibility, interoperability and reusability; GDPR, General Data Protection Regulation

Workshop discussions
Participant commitments

Related to PIDs (including ORCID)

- Ensure all company employees register with ORCID
- Pharma companies to commit to writing to ORCID
- Provide more explicit guidance for authors and key stakeholders to communicate better the value of ORCID IDs and other PIDs
- Educate colleagues about ORCID and encourage them to register
- Support conversations about ORCID and FAIR principles to make sure that they are aligned
- Conduct Open Pharma research around ROR ID use among the top 20 pharma companies – raise awareness of ROR IDs and their value
- Make better use of the Open Pharma ORCID toolkit, e.g. use it during manuscript kick-off calls and start the conversation with authors about ORCID registration at the start of the publication process
- Audit internal systems to understand where data reside and how open and feasible it is to export or transfer data across/between platforms and other systems – establish whether the systems have APIs that could be built out to speak to Crossref, ORCID and ROR APIs
- Publishers to continue to explore mandating ORCID IDs

Related to data sharing

- Raise awareness internally of company practices and commitments around data sharing, and their value
- Support education around the challenges that exist within data sharing and how these differ between data types and between different data sharing contexts
- Work towards finding an optimal data sharing approach that can be supported/implemented by journals while still making data available for reuse
- Continue to have conversations about responsible data sharing
- Explore opportunities to overcome barriers to data sharing
- Support more regular communications about data sharing between the relevant stakeholders (publishers, authors, researchers and funders)
- Work towards developing data sharing statements that are transparent
- Publishers to use the results of the Open Pharma data sharing survey to improve data sharing guidance and policies

API, application programming interface; FAIR, findability, accessibility, interoperability and reusability; ID, identifier; PID, persistent identifier; ORCID, Open Researcher and Contributor iD; ROR, Research Organization Registry