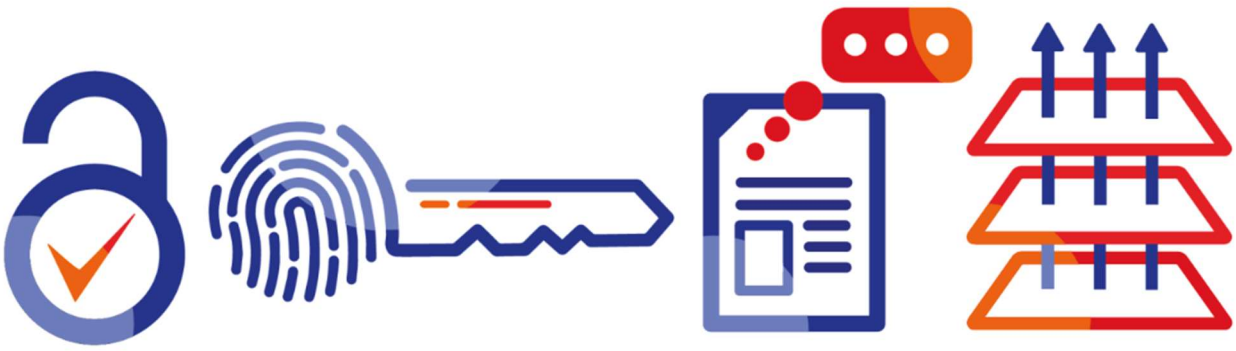
OpenPharma

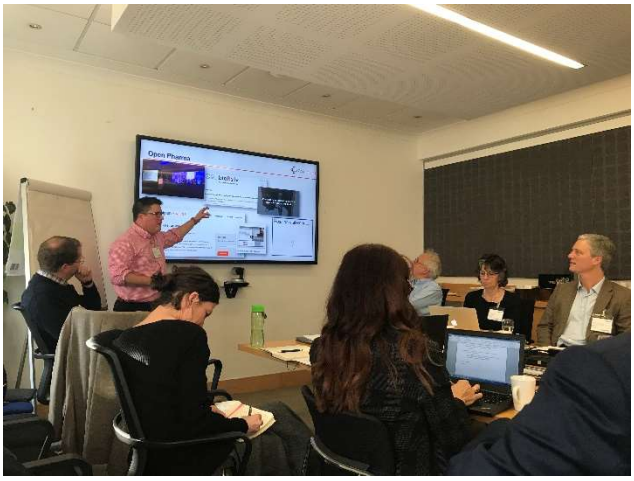
Innovations in Medical Publishing

Report from the Roundtable Meeting

January 2019



Open Pharma is grateful to *The BMJ* for hosting this roundtable meeting at its Head Office at BMA House in London. We are also grateful for the time committed to the discussions at the meeting by our members, supporters and advisers.



Open Pharma is very grateful for the contributions it has received, in the form of both grants and services from AstraZeneca, GSK, Novo Nordisk, Oxford PharmaGenesis, Oxford University Press, Pfizer, Roche, Shire, UCB Pharma, the Wellcome Trust and Wiley.

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

Executive summary

Open Pharma brings together pharma, publishers and other stakeholders in health care to explore how innovations in publishing can improve the speed, accessibility and transparency of pharma-funded medical research. Since 2017, four workstreams have been evaluating opportunities for change in open access, systems for author information, preprints and post-publication peer review, and layered publication models.

In January 2019, current and prospective funders of Open Pharma and a diverse group of advisers met for a roundtable meeting at BMA House in London, UK, to discuss the latest information and stakeholder positions on open access and layered publication platforms. Before the meeting, several members of Open Pharma met a representative from ORCID to discuss the potential integration of ORCID into pharma publication management systems.

This report summarizes the discussions that took place at the roundtable meeting as well as during the pre-meeting discussion.

Workstream 1: open access

- Since Shire (now part of Takeda) introduced its open access policy, the proportion of Shire-funded articles published open access has increased from 80% to 91%.
- The Wellcome Trust and the Bill & Melinda Gates Foundation have joined cOAlition S.
- Open Pharma members and supporters could support a position statement advocating publishers to allow commercially funded research to be published under a Creative Commons Attribution (CC BY) licence, provided that the sponsor buys reprints from the publisher.
- **The next step** is to draft a position statement on open access publishing.

Workstream 2: ORCID, CRediT and Convey (pre-meeting discussion)

- Integration of ORCID into publication management systems could help to identify and track researchers' contributions, provide automated information-sharing and cross-system interoperability, and improve recognition and discoverability of research.
- **The next steps are to:**
  - discuss whether Open Pharma should join as an ORCID member (US $5150)
  - form a working group comprising Open Pharma, ORCID and Envision Pharma Group
  - develop a value proposition for ORCID integration into publication management systems.

Workstream 3: preprints and post-publication peer review

- This workstream was not discussed at the meeting summarized in this report.

Workstream 4: layered publication platforms

- Creation of a layered publication platform would make research outputs easily discoverable and interoperable for different audiences.
- Education of publishers and the research community about the value of metadata and the requirement to include metadata on all published materials could provide the means for future innovators to develop platforms that will link together different research outputs.
- **The next steps are to:**
  - develop plans on how Open Pharma can help to improve metadata usage
  - discuss whether we should advocate a platform that will link research outputs using metadata
  - contact regulators, including the European Federation of Pharmaceutical Industries and Associations (EFPIA), the European Medicines Agency (EMA) and the Food and Drug Administration (FDA), to advocate the inclusion of references in original research and clinical trial registration numbers in drug registration documents such as the Summary of Product Characteristics document produced by the EMA.

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Workstream 1: open access

Impact of the Shire open access policy

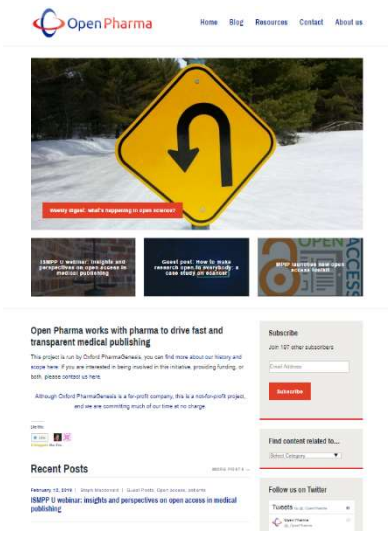
- Since January 2018, Shire (now part of Takeda) has required that all Shire-supported research manuscripts are submitted to "journals that offer public availability via open access".
    - Open access may refer to articles made available on publisher platforms and repositories and by self-archiving.
    - Shire encourages open access publication using the Creative Commons Attribution (CC BY) 4.0 licence over more restrictive Creative Commons (CC) licences, such as CC BY-non-commercial (-NC) and CC BY-NC no derivatives (-ND).
- An analysis of the Shire-supported manuscripts (excluding investigator-initiated manuscripts) published before (January–December 2017) and after (January–December 2018) implementation of Shire's open access policy showed the following.
    - Of the 120 manuscripts published **before implementation of the policy**, 96 (**80%**) were **published open access** and 26% were published under a CC BY licence.
    - Of the 77 manuscripts published **after implementation of the policy**, 70 (**91%**) were **published open access** and 35% were published under a CC BY licence.
    - Of the seven manuscripts published non-open access after implementation of the policy, four had been submitted before the policy started, one was governed by a collaborative research agreement, one had an exception granted because the investigators had already decided where to publish it, and one had had open access requested.
    - The CC BY licence was chosen for all manuscripts if the option was available to Shire after implementation of the policy.
- It was noted that internal education at Shire on the CC licence types has improved substantially since implementation of the policy.
- The Shire researchers observed that the main publishers included in the analysis were Elsevier, Wiley and Taylor & Francis, but the results were not stratified by publisher.
- Shire will investigate the impact that its policy has had on the number of downloads of articles published open access.

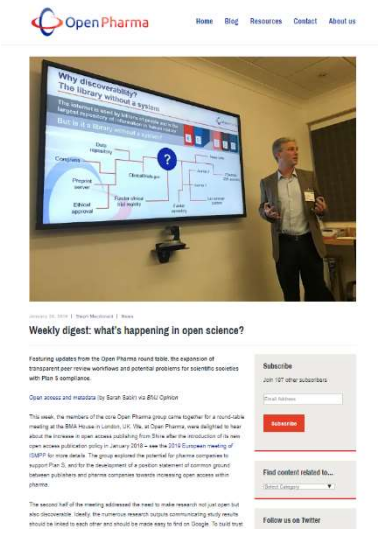
The Wellcome Trust open access policy and Plan S

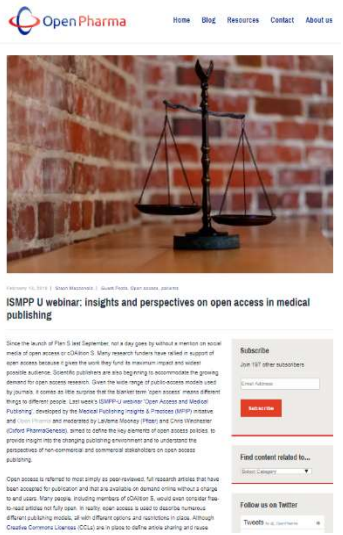
- The Wellcome Trust is currently updating its open access policy, which will be effective from 1 January 2020. A summary of the policy is as follows.
    - All articles must be made available open access at the time of publication (previously, a 6-month embargo was acceptable).
    - All articles must be published under a CC BY licence.
    - Publication costs will be covered by the Wellcome Trust for fully open access journals and platforms.
    - Preprinting of manuscripts that are relevant to public health emergencies is mandatory.
    - Recipients of Wellcome Trust funding must adhere to The San Francisco Declaration on Research Assessment (DORA) principles.
- The Wellcome Trust and the Bill & Melinda Gates Foundation have joined cOAlition S to support the principles of Plan S.
- Given that much of pharma-funded research is still paywalled, openly available after an embargo period or not licensed for reuse, pharma companies were encouraged to require some form of open access, preferably immediate open access with unlimited reuse rights (under a CC BY licence), and to commit to supporting Plan S.
  Approximately 80% of Wellcome Trust grantees are compliant with its current open access policy. Those grantees who are not compliant cannot apply for future funding.

Ongoing open access activities

- A white paper on open access coordinated by ISMPP and supported by Oxford PharmaGenesis will be released in the near future.
- A research paper developed by Oxford PharmaGenesis on the open access policies of high-impact factor medical journals has been recommended for publication at *BMJ Open* by the peer reviewers
- The Open Pharma blog includes a weekly digest of news that focuses on open access.
- There was an ISMPP U webinar on open access on 30 January 2019, which was co-developed by Open Pharma and Medical Publishing Insights & Practices (MPIP).
- Projekt DEAL – Wiley recently made a 3-year deal with German universities that allows all participating research institutions to have free access to all articles published in its journals.







Roundtable discussion

- The patient perspective on open access was highlighted as very important for the future of publishing. Many patients are unhappy that they have limited access to published research. While some patients would like information to be presented in lay terms, others want to be able to access full research articles.
- Shire's open access policy has been publicly praised, and Shire has been asked by interested parties to relay its experience with implementing the policy, including any obstacles encountered.
- The representatives from pharma agreed that their companies already publish at least 50% of their research manuscripts open access. Companies represented in the room other than Shire currently **strongly encourage open access publishing** and are in the process of deciding whether to develop an open access policy.

- The group agreed that Open Pharma could write a **position statement** saying that **pharma companies should be allowed to publish the research they fund under a CC BY licence, provided that they commit to buying reprints from the publisher**. However, many publishers, including in the Open Pharma group, could not agree to this under current policies. Ideally, additional publishers such as Springer Nature, journals such as *The Lancet* and *The New England Journal of Medicine*, and pharma companies should join Open Pharma and/or sign such a position statement.

- Representatives of the publishers at the meeting were open to further conversations with pharma about allowing commercial funders to publish research manuscripts under a CC BY licence. **However**, the publishers were concerned that the **sustainability of society-owned journals** would be jeopardized if these journals supported open access publishing under a CC BY licence because they would lose revenue from selling reprints of published articles and permissions for figure/table reuse.
- The publishers' biggest issue with Plan S is that it does not allow manuscripts to be published in hybrid journals. Publishers believe that the hybrid model is appropriate for certain journals.
- Technically, reprints of articles published under a CC BY licence can be printed and sold by a third-party company, which would mean that the publisher would lose out on reprint revenue. However, the pharma company representatives agreed that their commercial teams would not want to buy from third-party sellers, and wanted the proprietary, branded reprints.
- It was noted that if publisher **reprint revenue** is not affected by allowing commercially funded research to be published under a CC BY licence, then CC BY publishing will not be an issue.
- There was no suggestion from pharma companies during the roundtable discussion that they would join cOAlition S at this time.
- At the end of the discussion, it was noted that there are multiple stakeholders in publishing that all have separate open access policies (e.g. publishers, funders, the Research Excellence Framework). It would be much less confusing to researchers if there was a universal open access policy that would apply to all publishing stakeholders.

- It was noted that if pharma companies **collectively** require open access publishing under a CC BY licence:
  - journals that do not allow commercially funded research to be published under a CC BY licence may be forced to change their open access models
  - pharma research would be allowed to be published under a CC BY licence in the journals that allow publishing under a CC BY licence, when the funder requires it (e.g. *The BMJ*).

Next steps

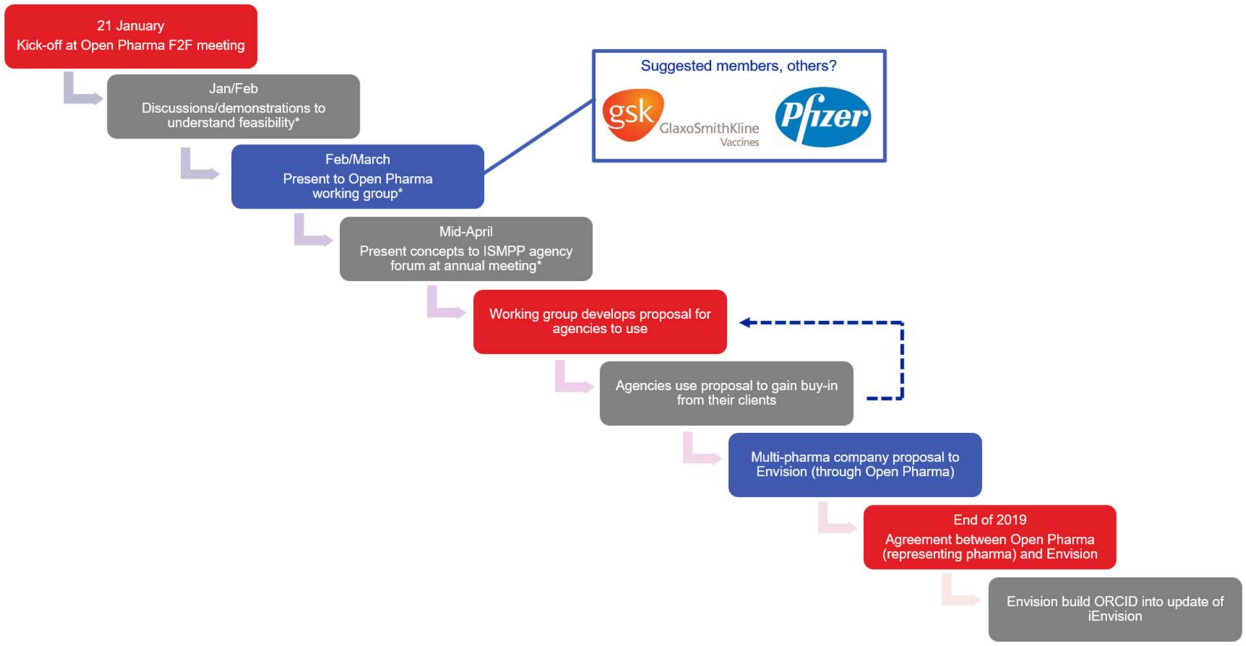
- Draft an Open Pharma position statement on open access publishing by pharma.
  - Invite representatives from additional pharma companies and publishers to draft and sign the position statement.

Workstream 2: ORCID, CRediT and Convey

Pre-meeting discussion on the potential integration of ORCID into pharma solutions

- Before the Open Pharma roundtable meeting, several members of Open Pharma (see attendee list on pages 13 and 14; * denotes attendance at pre-meeting discussion) met with Matthew Buys, Director of Engagement at ORCID, to discuss the potential integration of ORCID into publication manager systems used by pharma.
- ORCID is a not-for-profit organization that enables researchers to create a unique ORCID identifier (iD) and an associated publication record. This means that authors with the same name can be distinguished from one another and that the accuracy of author name listings can be improved.
- The benefits of ORCID integration into publication systems include:
    - seamless **identification**, **tracking** and **reporting** of researchers' contributions
    - benchmarking **organization contributions** across pharma and academia
    - **automated information-sharing** and **cross-system interoperability**
    - improved recognition and **discoverability** of research.
- The members agreed that integration of ORCID into publication manager platforms would increase the uptake of ORCID, and Matthew Buys said that ORCID would be keen to take part in the project.
- Integration should involve user authentication for metadata to be retrieved and pulled into the system; further discussions are needed to decide upon additional requirements.
- During the meeting, a proposal and a timeline (**Figure**) for integration of ORCID into the iEnvision platform was presented. The proposal involved a working group, including Open Pharma, ORCID and Envision Pharma Group, discussing the value and feasibility of ORCID integration into iEnvision before presenting a value proposition at the annual meeting of ISMPP in 2019 to encourage medical communications agencies to gain support from their pharma company clients. Envision Pharma Group could then integrate ORCID into its platform, ensuring consistency across pharma.

Figure. Actions and timeline for ORCID integration into publication manager platforms.



*Russell Traynor (Envision Pharma Group) and Matthew Buys (ORCID) with support from Paul Farrow and Sarah Sabir from Oxford PharmaGenesis.

- Although all members use iEnvision, the group agreed that Open Pharma should arrange a meeting to engage all publication management platform providers, including PubsHub and Sylogent, to determine whether they are interested in ORCID integration.
- Platform providers should fund ORCID integration themselves because such integration would improve the platforms and increase their use.
- Open Pharma could advocate the integration of ORCID into publication management systems in the upcoming Good Publication Practice 4 guidelines to encourage faster integration.

Next steps

- Open Pharma, interested pharma companies and a publisher to discuss with ORCID the additional features and benefits that ORCID can offer through integration.
- Develop a value proposition for ORCID integration into publication management systems that will be presented at the annual meeting of ISMPP.
- Discuss whether Open Pharma should join as an ORCID member (US$5150).
- Form a working group comprising Open Pharma, ORCID and Envision.

Workstream 3: preprints and post-publication peer review

- Workstream 3 was not discussed at this roundtable meeting following agreement at the November 2018 Open Pharma US and European workshops that Open Pharma has gathered sufficient information relating to preprints and post-publication peer review and will aim to keep up to date with future developments rather than pushing for action.

Workstream 4: layered publication platforms

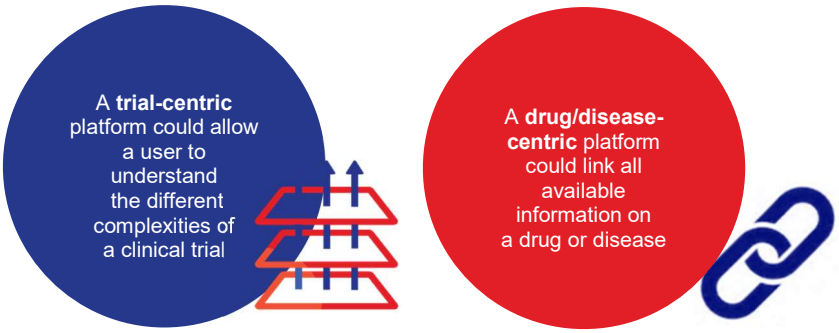
- At the Open Pharma workshops held in November 2018, it was agreed that the problems that we are aiming to address with a layered publication platform would be discussed at the meeting summarized in the present report.
- In the past, pharma has been criticized for not disclosing clinical trials; however, the information is often available but not discoverable.
- The main purpose of a layered publication platform would be to **make research outputs more easily discoverable and interoperable for different audiences** rather than only being open and accessible.
- Aside from publications, there are many sources of clinical data and research outputs available on the internet (e.g. explanatory videos, infographics, plain language summaries, posters, protocols, preprints) that are generally not linked together. Connecting these outputs can provide a more complete picture of a piece/pieces of research.
- Previously, we have discussed the following layered publication platform models.
    - **Threaded model** – research outputs are linked either manually or using artificial intelligence by curating their metadata.
    - **Layered model** – research outputs for different audiences are layered together on a single organizational platform.

- However, these are ‘solutions’, and we have not yet addressed the ‘problem’.
- The main **problem** identified by the group that a layered publication platform could address was the **lack of trust in research data and pharma** across all audiences, including medical professionals and, importantly, patients. A layered publication platform could direct different audiences to relevant information and data and could assure them that they can be trusted by linking the information to the source (**Table**).

Table. Potential uses of a layered publication platform by different target audiences.

Audience	Use
Patient/general public	To read **reliable**, **full** and **up-to-date** information on a given drug or study that will provide answers to questions that a general practitioner may not necessarily be able to answer
General practitioner	**To broaden understanding** and **knowledge** of a drug or study in order to enhance informed decision-making and **better inform patients**
Research scientists/pharma companies	To **easily access** current research on a particular drug or disease in order to progress new studies
Funders	To easily access the results of the studies that they have funded

- The consensus at the roundtable meeting was that journal articles currently offer ‘limited real estate’ and that related information is generally difficult to find.
- A layered publication platform could layer research outputs related to a particular clinical trial or a particular drug or disease.



- The group felt that a layered platform would make research more **transparent**, **usable** and **understandable**. Research could also have **greater impact** if outputs are linked to the source, and a layered publication platform could be used to provide metrics on how different research outputs are used.
- It was agreed that the creation of an individual layered publication platform using the **layered model** would be challenging, expensive and would very quickly become outdated.
- The creation of a platform could be made easier in the future by **increasing and encouraging the use of metadata**, which are digital tags attached to published materials (e.g. author, date, subject, type of material) that make them easy to find. Medical

communications relating to a clinical trial can be connected through the clinical study identifier, which could be added to metadata on published materials to increase their discoverability.

- The use of metadata provides:
  - a **cheaper** and **easier** solution than developing individual platforms
  - an **interoperable** and **persistent link** to make all data discoverable.
- However, metadata attached to published materials are often incomplete and not of sufficient quality to provide enough information for research outputs to be linked together. Therefore, **publishers should improve their use of metadata** in published materials.

- Suggested ways to increase **metadata use** and **research discoverability** included**:**
  - providing **education** to publishers and the research community about the value of metadata
  - requiring the addition of **complete metadata** and **digital object identifiers** to all published materials at the time of publishing
  - encouraging regulators including EFPIA, EMA and the FDA to advocate the **inclusion of references to original research and clinical trial registration numbers in drug registration documents** such as the Summary of Product Characteristics document produced by the EMA.

- The group discussed the possibility of approaching Crossref again to help improve metadata usage because it is involved in the Metadata 2020 collaboration. However, it was decided that Open Pharma objectives related to this workstream should be further refined before re-approaching Crossref. It was agreed that searching for the 'problem' that a layered publication platform could address is difficult because the problems are disparate. However, providing the easy 'solution' of linking research outputs with metadata will address the 'problem' for many different needs.
- Effort could be placed into encouraging the consistent use of metadata, which would allow future innovators to develop platforms that will link together information and provide quality assurance for readers.

Next steps

- Refine our thoughts on how Open Pharma can help to improve metadata usage.
- Discuss whether we should advocate a platform that links research outputs using metadata.
- Contact regulators including EFPIA, EMA and the FDA to advocate the inclusion of references in original research and clinical trial registration numbers in drug registration documents such as the Summary of Product Characteristics document produced by the EMA.

Roundtable meeting attendees

Meeting chair

Richard Smith*	Former Editor of the *BMJ,* Chair of Patients Know Best, Former Board Director of Public Library of Science

Pharma:

Andrew Freeman	GSK
Christine Vanderlinden	GSK
Christopher Rains*	Shire (now part of Takeda)
LaVerne Mooney *(listening by teleconference)*	Pfizer
Lise Baltzer*	Novo Nordisk
Rikke Egelund Olsen	Roche
Santosh Mysore	GSK
Slavka Baronikova*	Shire (now part of Takeda)
Valerie Philippon*	Shire (now part of Takeda)

Publishing

Deborah Dixon	Oxford University Press
Gavin Sharrock	Wiley
Liz Allen	F1000
Mary Yianni	Taylor & Francis
Matthew Buys*	ORCID
Mike Taylor	Digital Science
Robert Kiley	Wellcome Trust
Sally Rumsey	Bodleian Library
Stuart Taylor	Royal Society
Tessa Richards	*The BMJ*
Theo Bloom	*The BMJ*

Other stakeholders

Chris Winchester*	Oxford PharmaGenesis
Pali Hungin	Newcastle University

Facilitation, meeting, management and reporting

Paul Farrow*	Oxford PharmaGenesis
Sarah Sabir*	Oxford PharmaGenesis
Tim Ellison*	Oxford PharmaGenesis
Tim Koder*	Oxford PharmaGenesis
Tom Rees*	Oxford PharmaGenesis
Zoe Watts*	Oxford PharmaGenesis

*Present at the pre-meeting discussion on the potential integration of ORCID into pharma solutions