

**Innovation in scientific publishing
and the pharmaceutical industry**

**Report from an exploratory round-table meeting**

09:00–16:00, Thursday 19 January 2017

Room 303, Wellcome Trust, Gibbs Building,
215 Euston Road, London, NW1 2BE

‘Is now the time to transform the model for dissemination of the findings of medical research funded by the pharmaceutical industry?’

‘Yes’

# Summary from Richard Smith

Posted on the *BMJ Blog* on 31 January 2017

<http://blogs.bmj.com/bmj/2017/01/31/richard-smith-time-for-pharmaceutical-companies-to-help-improve-the-publishing-of-science/>

Competing interest: RS helped to organize the meeting and chaired it, for which he was paid. He has also been a paid adviser to *F1000Research* and has a pension from the British Medical Association, which receives income from publishing journals. The meeting was funded by Oxford PharmaGenesis with support from GSK Vaccines, Shire, UCB and the Wellcome Trust.

**Time for pharmaceutical companies to help improve the publishing of science**

There’s a growing consensus that publishing science through journals is a broken system. But who has the power to change it? Those who fund research have most power, which includes pharmaceutical companies. So far they have not exercised this power, but should they? A meeting in London last week organised by Oxford PharmaGenesis <http://www.pharmagenesis.com/> addressed this question.

The meeting included stakeholders from all the relevant groups: academics, patients, editors and publishers of traditional journals, entrepreneurs producing new ways of publishing science, pharmaceutical companies, regulators, and public funders of research.

I have blogged many times on the failures of the current system, <http://blogs.bmj.com/bmj/2015/10/22/richard-smith-a-better-way-to-publish-science/> but perhaps the most important failures are that most research is not accessible to many, data are not shared, peer review and editorial decision making are not transparent, papers are usually required to be short, results are scattered through thousands of journals, much of what is published is of low quality yet much that should be published is not published, and the system is slow, inefficient, corrupt, wasteful, and expensive.

Many entrepreneurs have recognised these failings and are developing ways to overcome them. These developments are happening fast, and the figure below summarises some of them. Source: <http://www.healthsciencelive.com/UK/987041>



The developments include data sharing, open access, fully transparent real time peer review, abolition on restrictions of length, inclusion of video, article level metrics, and extensive links with social media. The use of preprints--whereby studies are shared before submission to a journal and before peer review--is rapidly gathering pace <http://blogs.plos.org/absolutely-maybe/2016/05/01/breaking-down-pros-and-cons-of-preprints-in-biomedicine/>; the system has been used in physics, mathematics, and astronomy for decades but has until recently failed to appeal to authors in biomedicine.

One thing maintains traditional journals and blocks development: that universities and others continue to use journal impact factors (or at least the status of journals) as the prime means for assessing the quality of their researchers. This has long been recognised as unscientific in that there is little or no correlation between the impact factor of journals and the citations of individual articles within the journals--because the impact factor is largely driven by small numbers of articles that are highly cited. Almost everybody, including researchers, university authorities, and even editors of high impact journals, bemoans the use of impact factors, and it’s long seemed absurd to me that universities should effectively outsource such a core function to an expensive, arbitrary, and corrupt system.

But no individual university or researcher, no matter how eminent, has the power to break the system and allow new ways of publishing science to flourish. One group that does potentially have the capacity is funders of research, and some funders are leading the way. The Wellcome Trust has been in the forefront, requiring all the research they fund to be open access and creating *Wellcome Open Research* <https://wellcomeopenresearch.org/>, which converts the publishing of science from a process controlled by journals, editors, and publishers to a service for researchers. The Gates Foundation earlier this month took the bold step of requiring all the research they fund to be open access immediately--not with the usual delay of six months or more that allows journals to maintain their dominance.

A big proportion of biomedical research, probably more than half, is funded by pharmaceutical companies, but they have largely shied away from using their position to promote innovation in publishing. As the meeting learnt, this is not because they are content with the present system; they have essentially the same complaints as others. They have too the special circumstance that for their drugs to be licensed they must submit to regulatory authorities every piece of data and every detail of their clinical trials, and increasingly all of that information is publicly available; what appears in journals are scattered fragments of the research, with a perhaps inevitable bias towards the positive. They also have the special circumstance that in order to avoid off label promotion, it has become convention not to discuss research beyond the approved indications for their products outside the safe harbour of peer reviewed journals and academic meetings.

What holds companies back from following other funders of research in using their muscle to encourage new and better ways of publishing science? One constraint is a worry that paying for research to be open access might be viewed by regulators as promotion in an unlicensed indication (which is illegal worldwide), or promotion to patients (which is illegal outside the USA, New Zealand and Brazil) but the meeting, which included regulators, concluded that this was not a serious problem.

A greater problem is that much of the research funded by pharmaceutical companies is conducted by academics who like all academics need to publish in high impact journals to advance their careers. Unlike non industry funders though, pharmaceutical companies are competing with each other to work with leading academics, and current Good Publication Practice guidelines (GPP3, <http://www.ismpp.org/gpp3>) state that manuscript authors should choose the journal, not study sponsors. The companies are therefore much more nervous than funders like Wellcome and Gates of requiring researchers to publish in open access journals or to publish in an equivalent to *Wellcome Open Research* that would be branded with their name. This nervousness probably also has its roots in the prevailing narrative that sees pharmaceutical companies as “bad guys”—despite the fact that, unlike academics, they are required to provide full data and detail of their clinical trials.

The mood of the meeting was that pharmaceutical companies should be bolder and join the movement to try and improve the publishing of science. The next question is how, and that will be the question addressed at future meetings.

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# Participants

**Present**

**Chair:** Richard Smith (Chair, Patients Know Best; Chair of the Board of Trustees, International Centre for Diarrhoeal Disease Research, Bangladesh; former Editor, *British Medical Journal*)

Jodi Cusack (Project Manager, Oxford PharmaGenesis)

Deborah Dixon (Global Editorial Director, Medicine & Science Journals, Oxford University Press)

Juan García Burgos (Head of Medical and Health Information, European Medicines Agency)

Fiona Godlee (Editor-in-Chief, *British Medical Journal*)

Robert Kiley (Head of Digital Services, Wellcome Trust)

Tim Koder (Communications Director, Oxford PharmaGenesis)

Azeem Majeed (Professor of Primary Care, Imperial College London)

Erik Michels (Director and Head of Scientific Public Disclosure and Literature Intelligence, UCB)

LaVerne A Mooney (Director and Team Leader, External Medical Communications, Publications Management, Pfizer)

June Raine (Director of Vigilance and Risk Management of Medicines, Medicines and Healthcare products Regulatory Agency)

Chris Rains (Vice President, Global Medical Affairs, Shire Pharmaceuticals)

Rosamund Snow (Patient Editor, *British Medical Journal*)

Stuart Taylor (Publishing Director, The Royal Society)

Katherine Tucker (Senior Manager, Patient-level Data Sharing, Roche)

Vitek Tracz (Chairman, Science Navigation Group; Founder, *F1000Research*)

Christine Vanderlinden (Director and Head of Publications Management, Vaccines Office of Medical Governance and Bioethics, GSK Vaccines)

Elizabeth Wager (Publications Consultant; Co-Editor-in-Chief, *Research Integrity and Peer Review*)

Al Weigel (President, International Society for Medical Publication Professionals)

Amy Williams (Project Coordinator, Oxford PharmaGenesis)

Chris Winchester (Managing Director, Oxford PharmaGenesis; Honorary Associate of the School of Medicine, Pharmacy and Health, Durham University)

**Pre-recorded video presentation**

Ulrich Pöschl (Editor, *Atmospheric Chemistry and Physics*)

**Apologies**

Carl Heneghan (Professor of Evidence-Based Medicine, University of Oxford)

Ken Stein (Professor in Public Health, University of Exeter)

# The need for change and options for the future

* Our group met to:
* understand current problems with publishing science
* review innovations and to discuss what more might be needed
* discuss whether the pharmaceutical industry might have a role in encouraging innovation, and if we think that there is such a role, to discuss what it might be and agree next steps.
* Please refer to the presentation slides for a thorough summary of the various issues with the current model of publishing and information on the diverse new models. The poster by Williams *et al*. (2017) also describes the most relevant new models (available from: <http://www.healthsciencelive.com/UK/987041>).
* This report focuses on the discussion within the group, examining what the various issues and the new models mean for the pharmaceutical industry and what role the industry should play in the changing publishing landscape.

## The need for change

* The current model of journal publishing is not ideal, causing problems for academic, pharmaceutical, regulatory and publishing stakeholders.
* Academics need to publish to be successful.
	+ There is pressure to publish in the ‘top’ medical and scientific journals (as measured by journal impact factor [IF]).
	+ Careers are heavily influenced by the results of research assessments based on impact factor metrics, such as the UK University Research Excellence Framework.
	+ There is pressure to publish a high volume of papers, particularly for researchers in the early stages of their career.
* The current model involves:
	+ long delays before papers are accepted and published (particularly with smaller journals)
	+ arbitrary and inconsistent pre-publication peer review
	+ reliance on unpaid volunteer peer reviewers, leading to ‘reviewer fatigue’
	+ failure of authors (and journals) to respond to critical comments about papers
	+ slow publication and lost resource due to rejections and resubmissions
	+ lack of post-publication peer review
	+ subjective article selection (novelty bias)
	+ lack of transparency.
* Impact factor is ‘poison’. Developed for librarians, the original purpose has been supplanted and now every institution uses it to judge quality of research, even if they say they do not.
* Audiences are accessing journal both online and in print. Many are accessing articles through their mobile phones, but few read papers from start to finish; every audience needs access to different levels of information.
* The results are that many publications are poor quality, and the research is not reproducible, slow and inefficient.

## Gradual change

* Even with the many innovations discussed at this meeting, the pace of change for medical publications, especially those sponsored by the pharmaceutical industry, has been slow. In the past 10 years, there has been little change in criticism of peer review, its inherent bias, lack of speed and poor capacity to identify error or fraud.

## Improvements in the past 10 years

* Guidelines and checklists have been created and applied, including:
	+ those developed by the Enhancing the QUAlity and Transparency Of health Research (EQUATOR) Network (<http://www.equator-network.org/>), e.g. Consolidated Standards of Reporting Trials (CONSORT)
	+ Good Publication Practice (GPP) guidelines (<http://www.ismpp.org/gpp3>)
	+ author and contributor statements
	+ conflict of interest (COI) statements (NB the point was made that the high prevalence of COI statements normalizes conflict for some people; for others, COI statements simply flag publications that they will never trust).
* Open access has been a game-changer, but its application has been inconsistent.
	+ Open access policy has itself become a topic for academic research and transparency discussions[[1]](#footnote-1)
* Growing use of ORCID (Open Researcher and Contributor ID), a persistent digital identifier that distinguishes authors from each other (<https://orcid.org/>).
* Development of the [Convey®: Global Disclosure System](https://www.linkedin.com/company/convey-global-disclosure-system?actionToken=p%3Dp%253Dbiz-showcase-login%2526c%253D7421d931-5266-4f35-b351-9d7539a5db5c%2526m%253Dcompany_feed%2526n%253D0%26t%3Da%253DisFolloweeOfPoster%25253Dfalse%252526distanceFromActor%25253D-1%252526actorType%25253D%252526likedByUser%25253Dfalse%252526targetId%25253D%252526recentCommentUrns%25253D%252526targetType%25253D%252526sponsoredFlag%25253DORGANIC%252526verbType%25253Dlinkedin%2525253Ashare%252526objectType%25253Dlinkedin%2525253Aarticle%252526totalShares%25253D0%252526activityId%25253Durn%2525253Ali%2525253Aactivity%2525253A6141623737641947136%252526recentLikerUrns%25253D%252526actorId%25253Durn%2525253Ali%2525253Acompany%2525253A10653768%252526totalComments%25253D0%252526relevanceScore%25253D0%2E0%252526recentCommenterUrns%25253D%252526isPublic%25253Dtrue%252526time%25253D-1%252526totalLikes%25253D0%252526objectId%25253Durn%2525253Ali%2525253Aarticle%2525253A8054899358488558530%252526distanceFromNestedActor%25253D-1%2526s%253DORGANIC%2526u%253Durn%25253Ali%25253Aactivity%25253A6141623737641947136&atv=2)(<http://www.convey.org/>) to streamline the process for authors to report their financial conflicts of interest.
* Rapid response systems have been adopted by some journals, such as the *BMJ.*
* Retraction Watch (<http://retractionwatch.com/>), a blog community that explores details of why articles have been published and retracted, and examines other issues of quality in scientific publishing
* Article level metrics and other transparency advocacy initiatives have been introduced, however all of them are inconsistently applied.
* For publishers, subscription revenue will continue to decrease and open access revenue will continue to increase; it is in publishers’ interests to keep up with the changes. Some funders (e.g. the Wellcome Trust) and societies (e.g. the Royal Society, the UK’s national academy of science) are focused on changing the model. For the pharmaceutical industry, new models offer potential solutions to the ever-increasing demands for transparency and speed; however, there are many barriers to their uptake in this highly regulated, risk-averse environment. With the pharmaceutical industry dependent on academics to publish its trials, the pressures on academics are very relevant to any discussion about new models for pharmaceutical publications.

## How are academics assessed?

* Impact factor is still the most important measure by which quality of research is judged in academic institutions.

“*Isn’t it crazy that universities outsource the core function of judging what’s good?*”

* + Funders such as the Wellcome Trust and the Bill & Melinda Gates Foundation, however, have moved away from judging research based on impact factor.
	+ Publishers such as *F1000Research* and the American Society for Microbiology journals also actively reject IFs and do not include them on their websites.
* Junior researchers are judged more on volume of research than on impact factor.
* Our group is currently very Euro-centric, and authors in other countries may have different priorities.
	+ In China, researchers have been paid large bonuses for publishing in top-tier journals.[[2]](#footnote-2)
	+ A recent manuscript from Korea was proposed to have 30 full authors (not as a ‘group on behalf of …’).
		- It is unlikely that 30 authors will all be able to fulfil International Committee of Medical Journal Editors (ICJME) authorship criteria.
		- Journals need to enforce limits, such as on number of authors, where appropriate. In some research areas, such as physics and genetics, large authorship lists are legitimate and normal practice.
* Royal Society has two working groups that may be relevant to our discussions:
	+ The Science Policy Centre’s major project on research culture, looking at rewards and incentives, research misconduct, careers progression and reproducibility of results as they impact on the culture and conduct of research
	+ The Industry Engagement Committee, with representatives from the pharmaceutical industry (AstraZeneca, Heptares and Pfizer).
* *Cureus* (<http://www.cureus.com/>), an innovative medical publishing platform, has its own measure, the Scholarly Impact Quotient, which measures a variety of parameters including novelty and quality of data, written communication and methodology. The review is crowd sourced, with a higher weighting given to reviewers with expertise than to those without.

## Patient needs

* Patients are very rarely provided with any information on the results of the trials in which they took part, even though this would be a strong motivator to engage in further trials.

“*The statistician won’t know if the research question was worth asking – the patient will*.”

* The pharmaceutical industry is heavily restricted from talking to patients, to avoid promotion.
* Patient lay summaries are now mandatory for all new trials under the regulations of the European Medicines Agency (EMA).
	+ Companies are engaging with specialist suppliers to create the summaries.
	+ Summaries are stored on specific patient websites, rather than with the academic materials.
	+ Neither the summaries nor the websites are very user-friendly.
* Many members of the group came to the meeting with the understanding that the key audience is scientists; however, some patients also wish to see the full research papers but are often prevented from doing so by paywalls.
* Patients want to know:
* Was the research worth doing?
* Was it done well?
* Has it made anything change?
* In the era of big data, patients are connecting with each other and beginning to decide where to put their data.

## Perceptions of bias

“*Good research output is wasted if the reader doesn’t trust it*.”

* Bias is inherent in all research and in all publications; however, many people specifically distrust pharmaceutical industry-sponsored research and publications, and bias in pharmaceutical industry publications has been demonstrated by published analyses.
* Publication bias has a downstream effect on reproducibility of results.
* Some believe that late-stage clinical research should be performed only by public bodies, rather than by the pharmaceutical industry.
* All clinical studies must be registered on ClinicalTrials.gov or other registries, although the degree of detail required varies.
* There is a perception that ghostwriting is alive and well, that the pharmaceutical industry has changed the way they do things but just legitimised it.
* Citations are not necessarily an indicator of quality; poor research can be heavily cited.

Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products

## The needs of the pharmaceutical industry

* Discussion of drug action outside the approved indication must be in a scientific environment and must avoid promoting off-label use.
	+ The current consensus is that peer-reviewed publication (including meeting proceedings) is the only safe harbour for legitimate, public scientific exchange before marketing authorisation, or covering off-label use after authorisation. This is, however, not statutory or specified in relevant industry guidelines.
* The US Food and Drug Administration is currently running a consultation process[[3]](#footnote-3)  as part of which they released a memorandum on 18 January 2017 with a rationale for their position against off-label promotion, recognizing that this is a complex area with conflicting interests.
	+ - The memorandum and its context is well summarised by this article by [Neil O'Flaherty](http://www.lexology.com/665/author/Neil_O_Flaherty/) and [Jur Strobos](http://www.lexology.com/665/author/Jur_Strobos_MD/): <http://www.lexology.com/library/detail.aspx?g=ff4a19cd-dfd6-4bf1-a7a5-ccacddaeda87>, last accessed 17 February 2017
		- The FDA memorandum does not comment specifically or on the safe habour or otherwise of peer-reviewed publication
* Citations are important to pharmaceutical companies: it is not possible to make any product claim without the support of very specific evidence that has been published in a peer-reviewed publication.
* Speed of publication is key; for example, if citation is needed in time for inclusion in:
	+ a submission to a regulator (evidence is considered stronger if it has been published in a peer-reviewed publication)
	+ promotional material at a congress.
* Pharmaceutical companies are not interested in impact factor as a measure of staff performance.
	+ For employees (e.g. preclinical/clinical pharmacologists) and vendors (e.g. contract research organisation staff), recognition is given to those who deliver good research, on time.
	+ UCB has trialled the use of Plum, an altmetric organization; however, metrics for activities such as social media have disadvantages in the context of the pharmaceutical industry.
* Preclinical pharmaceutical research is closer to the academic world than the clinical pharmaceutical world, in which publication as an author is seen as much less important for internal staff than contribution to a successful study.
* Pharmaceutical companies depend on academic collaborators to design, execute, analyse and report studies, and the academics want to publish in high-impact factor journals.
	+ ‘Aspirational journal syndrome’, the selection of journals with inappropriately high IFs, is not under the control of pharmaceutical companies, and is a frustrating cause of delays in the publication of data.
* GPP3 and individual company policies state that human studies should be published within 12–18 months of completion, but this can often be difficult when studies are not considered interesting, however important they may be (e.g. phase 4 commitment post-authorization safety studies [PASS]).
* The Oxford PharmaGenesis survey of individuals working on industry-sponsored scientific publications showed that 70% thought there were no issues with using the new platforms.
* Pharmaceutical industry studies are often too big and complex for a single publication.
	+ All endpoints should be reported, but there is rarely space for all of them in one paper.
	+ Methods sections are too short to provide enough transparency to ensure reproducibility of data; however, most journals rarely accept methods manuscripts.
	+ Multiple publications from a single trial may been seen as inappropriate.
* All human trials should be published, but this may be difficult to achieve if the result did not disprove the null hypothesis or was not as expected, even if the research is of good quality. (Such studies should not be regarded as ‘negative’, although this term is sometimes used.)
* Specific ‘negative’ research journals exist.
	+ BioMedCentral’s [*Journal of Negative Results in BioMedicine*](http://jnrbm.biomedcentral.com/) (<http://jnrbm.biomedcentral.com/>).
	+ *Journal of Pharmaceutical Negative Results* (<http://www.pnrjournal.com/>).
		- This journal is open access under the CC BY-NC licence that allows free, attributed reuse of the material but not for commercial purposes.[[4]](#footnote-4)
	+ Elsevier recently closed a journal of negative results, the *New Journal of Negative Plant Science* (<https://www.journals.elsevier.com/new-negatives-in-plant-science/>), which had been launched in March 2015 (<https://www.elsevier.com/reviewers-update/story/innovation-in-publishing/why-science-needs-to-publish-negative-results>).
* Academics collaborating with the pharmaceutical industry are often not motivated to publish negative research. However, not to publish can be seen as misconduct.

## Highlights of current best practice in the industry

* Shire is the only one of 291 trial sponsors on the TrialsTracker portal, promoting transparency in reporting, that has shared the results of every eligible trial (96 in total) over the past 10 years.[[5]](#footnote-5)
* The internal publications policies of Shire and GSK Vaccines recommend, but do not require, open access.

## Regulatory viewpoints

* There might well be no problem with preprints – this should be investigated further.
* It will be hard to abandon the old system.
* There is no intention to impede scientific discourse.
* The UK Medicines and Healthcare products Regulatory Agency (MHRA) aims for timeliness, transparency and completeness – goals that we should also aim for with publications.

# New models and how to make change happen

## Post-publication peer review

* *F1000Research* is an open-access publishing model, offering fast, low-cost publication with post-publication peer review.

“*The future role of publishers is providing platforms not journals*.”

* Review comments have DOIs (digital object identifiers) and can themselves be cited.
* *Wellcome Open Research* (<https://wellcomeopenresearch.org/>) was launched in November 2016, built on the *F1000Research* model.
	+ Of 51 submissions to this platform, 39 have been published.
	+ 50% have passed peer review and were indexed on PubMed at the time of this meeting on 19 January 2017.
* Wellcome Trust researchers must publish both their data sets and research articles in an open-access format with a CC BY licence (<https://creativecommons.org/licenses/by/4.0/>) within 6 months of the journal publisher’s official date of final publication.
	+ *Wellcome Open Research* is the easiest way for them to do this but it is currently not mandatory.
	+ Compliance is currently 75–80%.
	+ A 6-month embargo is still allowed.
* The Wellcome Trust can apply sanctions if researchers publish in non-open-access media, but they do not have a mechanism for tracking whether research has been published at all.
	+ For reference, the UK Health Technology Assessment Programme withholds 10% of funding until publication.
* The Wellcome Trust currently spends £6 million per year on open-access fees, and forecasts this will rise to £10 million over the next few years – still a tiny percentage of the trust budget of over £1 billion.[[6]](#footnote-6)
* Stakeholders were worried that reviews might be anodyne, but they have been very detailed and specific; they can be cited.

## Data repository

* The Wellcome Trust developed Europe PMC (https://europepmc.org/; originally UK PubMedCentral) in collaboration with the European Bioinformatics Institute.
* The Wellcome Trust also provides a secretariat function for <https://clinicalstudydatarequest.com/>, a study data repository that can be accessed on request by anyone with a clear rationale.
	+ Pharmaceutical companies committed to sharing through this portal are: Astellas, Bayer, Boehringer Ingelheim, Daiichi Sankyo, Eisai, GSK, Lilly, Novartis, Roche, Sanofi, Takeda, UCB and ViiV Healthcare.

## Preprints

* Preprints are becoming normal in academic research, with large platforms now maturing, in particular:
	+ PeerJ (<https://peerj.com/>)
	+ BioRXiv (<http://biorxiv.org/>)
	+ ASAPbio (<http://asapbio.org/>).
* The benefits to academic authors could also be applicable to pharmaceutical companies and their collaborating authors.
	+ Fast sharing – key for fast-moving fields such as immuno-oncology, in which delays to publication slow down access to new medicines for critically ill patients.
	+ Fast citation.
	+ Can cite a full manuscript in a letter to ask a journal about suitability for submission.
* Most journals do not count preprints as previous publication when considering whether to accept a paper in the context of the ‘Ingelfinger Rule’, named after the editor of the *New England Journal of Medicine* (*NEJM*) at the time of the publication of the rule in 1969, of considering a manuscript for publication only if its substance has not been submitted or reported elsewhere.[[7]](#footnote-7)
* Only *NEJM*, The *Journal of the American Medical Association* (*JAMA*) and a small number of others forbid preprints of manuscripts to be posted if the manuscript is submitted to their journals.[[8]](#footnote-8)

## Layered model

* CSRs, publications, data repositories and other information arising from clinical trials are stored disparately and not systematically, and a system to link all information would be welcome to all audiences.
* Different audiences do not want the same information, but it would be useful to know what is available. For example:
	+ most clinicians will not want to open the full data set or even the full paper, and would prefer a digest; however, having the full data set or full paper readily available for expert inspection would give them confidence in the clinical meaning
	+ patient information is usually stored completely separately from specialist scientific information.
* Could an innovative platform be developed that allows information aimed at different audiences to be housed together? Would this be compatible with pharmaceutical industry compliance requirements?

## Open access

* There are many variants of open access publishing, and Jisc (formerly known as the UK Joint Information Systems Committee) has collected and created helpful background materials here: <https://www.jisc.ac.uk/guides/an-introduction-to-open-access>.
* There are two major models of open access publishing: gold and green (see Figure 1).
	+ Pharmaceutical industry manuscripts have so far typically been published through the gold model, where the author pays an ‘article processing charge’ to the publisher to make the article accessible to readers without charge.
	+ Green open access platforms are often provided by institutions, or preprint archives, such as BioRXiv (<http://biorxiv.org/>) as mentioned above, and guidelines vary on what can be hosted. Articles hosted on green open access platforms can also be submitted for peer-reviewed publication; alternatively, articles already submitted for peer-review publication can be hosted on green open access plaforms. There may be an embargo.



Figure 1: two models of open access publishing

* Most pharmaceutical company publications using the gold open access model are through ‘hybrid’ open access publishers, traditional, subscription-based journals that offer open access as a paid-for option, rather than on platforms that are fully open access. There are objections to hybrid open access publishing, the key problem in the non-industry research sphere being the direct cost borne by the funders. There is also potential for ‘double-dipping’, where a publisher is charging both the authors and the readers; some publishers have developed subscription discount policies in an attempt to address this issue.[[9]](#footnote-9)
	+ Some non-industry funders are not simply mandating open access publication but also not accepting hybrid models.
	+ Of the funds set up to support open access, 55% do not allow hybrid publishing as of October 2016, an increase from 39% in 2014.[[10]](#footnote-10)
* Open access does not necessarily mean faster publication than other models.
* The group agreed that open-access publication should not be considered promotional, but recognized that other stakeholders may see it that way.
* Some journals charge pharmaceutical companies more for open access (e.g. a charge of US$15 000) than they charge academic authors.
* Internal publications policies of Shire and GSK Vaccines recommend but do not require open access, because Publications Managers need to balance all views.

# Role of the pharmaceutical industry

## Common principles

* How the research is communicated should ideally be governed by consensus.
	+ The power of the pharmaceutical industry to effect substantial change will be much greater in collaboration than as individual companies.
* Collaboration between pharmaceutical companies could take place within existing groups, such as TransCelerate or the International Society for Medical Publication Professionals (ISMPP); however, these groups do not currently have the same balance of stakeholders as our round-table group.
* The group debated evolution versus revolution, and while some participants favoured a revolutionary approach, the pharmaceutical industry participants agreed that evolution was more likely to succeed, given the risk-averse nature of the medical functions in the industry and the sometimes conservative nature of academic collaborators.
	+ Small steps would be easiest to implement (e.g. introducing open peer review but with reviewers remaining anonymous, as a transition stage).
* The researchers, not the publishing platform, should be free to decide what they want to communicate; however, there are some things that must be communicated.
* The pharmaceutical industry could set some of the rules.
* The group discussed whether researchers should be free to choose where they communicate, or can/should pharmaceutical companies explicitly influence this decision? A conclusion was not reached.
* Industry work falls into three categories, which may need to be treated separately.
1. Basic research – often with mainly internal company authors.
2. Clinical trials – normally with high-level academic authors.
3. Observational – often with epidemiologists, health economics experts and healthcare providers.

## Barriers for the pharmaceutical industry

* Both open access and preprints could be seen as promotional, potentially both:
	+ off-label
	+ to patients.
* Academic collaborators need high impact factor citations to advance their careers.
* Top-tier journals such as *NEJM* and *JAMA* do not allow preprints.
* Mandatory open access would restrict journal choice.
* Pharmaceutical companies compete with each other to attract the best academic collaborators to run their trials, so tend to defer to the academics’ wishes.
* According to GPP3, choice of journal lies with the authors, not the sponsoring company, and company authors can be reluctant to influence journal choice.
* Pharmaceutical companies risk damage to their reputation if they are seen as seeking to influence the publication process.
* There is a confusing variety of models with no common standard, even outside of the pharmaceutical industry.
* Cost.
* Risk of unknowns.
* Administrative burden.

## Planning change

To make change happen, we will need to communicate:

* a sense that we need change
* a vision of the future
* what we can do right now.

# Action points

## Potential actions for pharmaceutical companies

1. Introduce a mandatory open-access policy.
* Many pharmaceutical companies recommend open access but do not require it.
* The Wellcome Trust, Bill & Melinda Gates Foundation, etc. already require it.
* The Wellcome Trust is willing to share its policy as a basis for pharmaceutical companies to build their own.
1. Require authors to use ORCID (Open Researcher and Contributor ID).
* Wiley requires ORCID.
* Could start with internal authors.
* (Might there one day be an ORCID-based single sign-on for publications and other academic interaction?)
1. Require authors to declare potential conflicts of interest on [Convey®: Global Disclosure System](file:///%5C%5CUK-FS-01%5CServer%5CPOLICY%5COxford%20Project%5COHPF023%20The%20Oxford%20Project%20%28Multi%20Sponsor%29%5CRound%20table%20meeting%5CReport%5CConvey%C2%AE%3A%20Global%20Disclosure%20System)(<http://www.convey.org/>).
2. Ask regulators to clarify the position on preprints and/or post-publication peer review.
3. Develop a specific publication platform, similar to *Wellcome Open Research*.

To make the case for each action, we could develop a brief rationale, including evidence supporting the need for this action (e.g. open access increases readership/impact/speed) and also outlining the principles guiding the solution and a publication platform (linking through from data availability to disclosure to specific audiences of clinicians, patients, systematic reviewers, etc.).

## Actionable evidence gaps

To strengthen the case for change, and for specific actions, the group agreed that it would be good to have citable evidence for relevant factual statements, such as those relating to the topics listed below.

* The effect of open access on readership/impact/speed of publication.
* Industry-sponsored biomedical research/publications as a percentage of all relevant research/publications.
* Extent of delay due to journal choice.
* Slow processes.
* Rejection and resubmission.
* Collation of the current literature on effectiveness of peer review, publication bias, effects of pharmaceutical funding, etc. (we should read material by and approach Ian Chalmers, in the first instance).

Members of the group could take responsibility for addressing the evidence gaps; alternatively, we could publish what the gaps are and encourage other parties to research and publish (e.g. through ISMPP).

One caveat though – looking for evidence is what government commissions do to delay things. We want change now, and there is consensus that change is happening.

## Potential actions for the group

* **Unilateral changes** at single pharmaceutical companies, which could include:
	+ mandatory open access
	+ trying a preprint with a study that is not of high strategic value
	+ trying a publishing platform not based on impact factor (e.g. *F1000Research* or *Cureus*) for publication of a study initially with internal authors.
* **Workstreams** – action points to be divided among volunteers, see below.
* **Initial survey** – attitudes and experiences survey sent to ISMPP industry members (many thanks Al Wiegel for allowing this project to use the list), from which an abstract will be written for submission to the Peer Review Congress 2017.
* **In-depth survey** – potential survey of ISMPP members covering topics from the workstreams to be set up (see below).
* **Public engagement** – initial blog by Richard Smith, posted on 31 January 2017 (<http://blogs.bmj.com/bmj/2017/01/31/richard-smith-time-for-pharmaceutical-companies-to-help-improve-the-publishing-of-science/>) and circulated via social media by group members, to be followed by further communications. Separate tweet from Azeem Majeed to outline the problems of publishing, as shown at this meeting.
* **This report in full or a shorter kick-off statement** from the group for a public audience – launched with a press release before or at the ISMPP meeting in May 2017, with authorship open to whoever in the group wants to be publicly identified.
	+ Some round-table attendees were there as observer-participants and are not to be identified as speaking for their organization.
	+ **Stakeholders** –should we engage now with a wider group of stakeholders, including other pharmaceutical companies, regulators and publishers? This should also include Pali Hungin, President of the British Medical Association.
* **Supporters** – depending on the scale of work required, we should approach other organizations to ask for their financial support.
* **Do we need a name for our group?**

## Workstreams

With the oversight of a project steering committee, yet to be defined, the group agreed the creation of four workstreams.

1. Open access.
2. ORCID and Convey®.
3. Preprints and post-publication peer review.
4. Layered publication model.

We will invite participants to volunteer for one or more workstreams, and roles will be agreed once we have a list of those willing to take part.

##

## Potential collaborations

* ISMPP would be happy to circulate a survey among members – would a position paper through ISMPP also be suitable?
* TransCelerate (USA) and Innovative Medicines Initiative (EU) are industry ‘pre-competitive’ bodies that could be contacted.
	+ TransCelerate is focused on clinical trial processes, and although publications are part of the trial process, there are many publications that are not associated with clinical trials.
* Medical Publishing Insights & Practices (MPIP) may have an interest.
* European Federation of Pharmaceutical Industries (EFPIA) – for benchmarking.
* Centre for Evidence Based Medicine (CEBM) – Carl Heneghan was not able to attend the round-table meeting but data quality and transparency are key themes for CEBM.
* PHARMO Institute for Drug Outcomes Research.
* Association of the British Pharmaceutical Industry (ABPI).

# Further reading

Kingsley D. Unlocking Research. [In conversation with Wellcome Trust and CRUK](https://unlockingresearch.blog.lib.cam.ac.uk/?p=528). 2016. Available from: <https://unlockingresearch.blog.lib.cam.ac.uk/?p=528>

Last accessed 17 February 2017.

Coyne JC. Five reasons you should upload a preprint to a repository before submitting to a journal. Available from: <https://jcoynester.wordpress.com/2017/01/24/five-reasons-you-should-upload-a-preprint-to-a-repository-before-submitting-to-a-journal/>

Last accessed 17 February 2017.

Lauer MS, Krumholz HM, Topol EJ. [Time for a prepublication culture in clinical research?](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2815%2901177-0/fulltext) *Lancet* 2015;386:2447–9. DOI: [http://dx.doi.org/10.1016/S0140-6736(15)01177-0](http://dx.doi.org/10.1016/S0140-6736%2815%2901177-0)

[Bastian](http://blogs.plos.org/absolutely-maybe/author/hbastian/) H. Breaking down pros and cons of preprints in biomedicine. 1 May 2016. PLOS Blogs. Available from: <http://blogs.plos.org/absolutely-maybe/2016/05/01/breaking-down-pros-and-cons-of-preprints-in-biomedicine/>. Last accessed 1 February 2017.

# Agenda

Please see the associated PDF file for slides presented by each of the speakers below, with the exception of Vitek Tracz, who spoke without slides.

|  |  |  |
| --- | --- | --- |
| **09:00–09:30** | **Registration, tea and coffee** |  |
| **09:30–09:40** | Welcome and introductions | Richard Smith |
| **09:40–09:45** | Objectives of the meeting | Richard Smith |
| **09:45–09:55** | Problems with the present methods of publishing science: an academic view | Azeem Majeed |
| **09:55–10:05** | Problems with the present methods of publishing science: a pharmaceutical company view | Chris Rains |
| **10:05–10:10** | Any problems not yet mentioned | Richard Smith |
| **10:10–10:30** | Questions and discussion |  |
| **10:30–11:00** | **Break** |  |
| **11:00–11:10** | Developments in publishing science in the past decade | Fiona Godlee |
| **11:10–11:25**  | Recent innovations in publishing science: an overview | Amy Williams |
| **11:25–11:35** | Results of a survey of pharmaceutical company views on publishing of science | Amy Williams |
| **11:35–11:50** | Developments in science publishing at the Wellcome Trust, including *Wellcome Open Research* | Robert Kiley |
| **11:50–12:00** | Health Technology Assessment monographs | Ken Stein |
| **12:00–12:10** | *Atmospheric Physics and Chemistry* | Ulrich Pöschl |
| **12:10–12:20** | *F1000Research* | Vitek Tracz |
| **12:20–12:45** | Questions and discussion |  |
| **12:45–13:30** | **Lunch** |  |
| **13:30–14:30** | **Facilitated discussion** |  |
|  | * Do we agree that there is a need to improve the publishing of science?
* What do we think of current innovations?
* What other innovations are needed?
 |  |
| **14:30–14:35** | **Break** |  |
| **14:35–15:45** | **Facilitated discussion** |  |
|  | * Does the pharmaceutical industry have a role?
* If so, what might that role be?
* What are the barriers to action from the pharmaceutical industry?
* Do we want to take this forward? If so, how?
 |  |
| **15:45–16:00** | Agree next steps (if any) |  |
| **16:00** | **Close** |  |

1. For example, statistics on open access policies are available on the SHERPA/JULIET project <http://www.sherpa.ac.uk/juliet/stats.php?la=en&mode=simple>, last accessed 17 February 2017. [↑](#footnote-ref-1)
2. For example, Zhejiang Chinese Medical University awards 200 000 RMB (£23 000) for first authorship in *Science* or *Nature.* <http://onlinelibrary.wiley.com/doi/10.1087/20110203/epdf> [↑](#footnote-ref-2)
3. Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products, Docket ID: FDA-2016-N-1149. <https://www.regulations.gov/docket?D=FDA-2016-N-1149>, last accessed 17 February 2017. [↑](#footnote-ref-3)
4. The Creative Commons Attribution Non-Commercial 3.0 Unported licence is available here: <https://creativecommons.org/licenses/by-nc/3.0/>. Last accessed 17 February 2017, [↑](#footnote-ref-4)
5. Data from: <https://trialstracker.ebmdatalab.net/>. Last accessed 4 January 2017.Eligible trials defined by TrialsTracker as clinical trials registered on ClinicalTrials.gov.
 [↑](#footnote-ref-5)
6. The Wellcome Trust Annual Report 2016 shows total gross spend on charitable activities in 2016 was £1,033.5m, of which £713.0m was allocated to science. Report available at <https://wellcome.ac.uk/sites/default/files/WellcomeTrustAnnualReportFinancialStatements_160930.pdf>, last accessed 17 February 2017. [↑](#footnote-ref-6)
7. See Angel and Kassierer (1991) for the *NEJM* position on the Ingelfinger rule; this article has not been updated to consider preprints. <http://www.nejm.org/doi/full/10.1056/NEJM199111073251910#t=article>. [↑](#footnote-ref-7)
8. A Wikipedia page of academic journals by preprint policy exists here: <https://en.wikipedia.org/wiki/List_of_academic_journals_by_preprint_policy>; however, it is flagged as having multiple issues and we have not used it. [↑](#footnote-ref-8)
9. Kingsley D. Hybrid open access – an analysis. *Unlocking Research* 2016. Available from: <https://unlockingresearch.blog.lib.cam.ac.uk/?p=969>. (Last accessed 1 February 2017). [↑](#footnote-ref-9)
10. Kingsley D, Boyes P. Who is paying for hybrid? *Unlocking Research* 2016. Available from: <https://unlockingresearch.blog.lib.cam.ac.uk/?p=1002>. (Last accessed 1 February 2017). [↑](#footnote-ref-10)