NEW Perspectives

ISMPP European meeting 2017: highlights

The Evolving Role of Publication Professionals in a Multi-Stakeholder Environment

More than 250 delegates from industry, healthcare communications agencies and publishing gathered in London for the 2017 European Meeting of ISMPP.

This 2-day meeting entitled "The Evolving Role of Publication Professionals in a Multi-Stakeholder Environment" addressed the latest trends and developments in medical publishing, with a focus on the practical skills that drive successful publication delivery. Ashfield Healthcare Communications brings you the highlights of the meeting!

ISMPP International Society for Medical Publication Professionals™

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Ashfield Healthcare Communications

2016: the year in review

Martin Delahunty of Springer Nature gave an informative presentation on the key events that took place over the year. A summary by quarter is provided below.

Quarter 1

January

- The ICMJE announced their proposal that de-identified individual patient data from clinical trials should be shared within six months of trial publication. This ambitious proposal represents a significant challenge given the need to gain the agreement of thousands of journals – as such, data transparency represented a key theme of this year's ISMPP EU programme.

February

- William Gattrell's article "Professional medical writing support and the quality of randomised controlled trial reporting: a cross-sectional study" was published (Gattrell WT, et al. BMJ Open 2016;6:e010329). The study found that medical writing support can increase the quality of clinical trial reporting, making an important contribution to the field.

March

- The Springer Nature group of journals enabled wider sharing of subscription-only content through platforms such as Read Cube.

Quarter 2

April

- The 12th Annual ISMPP US meeting on the topic of "Medical Publications in a Data-Rich World: Enhancing Quality and Transparency" took place.

May

- Republican Senator John Barrasso of Wyoming introduced the "Protect Continuing Physician Education and Patient Care Act of 2016", a measure intended to exempt pharmaceutical companies and medical device manufacturers from reporting transfers of value made to physicians for receiving continuing medical education, medical journals, or textbooks. If enacted, the Barrasso amendment would override the CMS reporting requirements.

June

- The UK voted to leave the European Union, with consequent implications for the pharmaceutical industry.
- Aaron Carroll's article "Undue influence: the P value in scientific publishing and health policy"

2016: the year in review

was published on the JAMA Forum, which evaluated the misunderstandings around P values and their impact on interpretation of study findings.

- The first disclosures of physician payments declared under the EFPIA Disclosure Code came into effect. Depending on the country, access is either via a central database (eg, the ABPI) or the websites of individual pharma companies.
- Cindy Hamilton's article "Ghostwriting prevalence among AMWA and EMWA members (2005 to 2014)" was published (Hamilton CW, et al. Medical Writing 2016;25:6–14), which reported rates of medical writing disclosure in the literature.

Quarter 3

July

- The chief executives of GSK and AstraZeneca – Andrew Witty and Pascal Soriot – were appointed as co-chairs of a ministerial working group on life sciences, in the pharmaceutical industry's first response to Brexit.

August

- Senator Elizabeth Warren of Massachusetts published an editorial in the NEJM endorsing the ICMJE proposal for data sharing (N Engl J Med 2016;375:401–3). A competing editorial by the International Consortium of Investigators for Fairness in Trial Data Sharing in the same issue argued that the proposal would have the opposite effect than intended (N Engl J Med 2016;375:405–7).

September

- The final rule for FDAAA 801, expanding the scope of trials for which summary results must be submitted, was released on 16 September, and became effective on 18 January 2017.
- ISMPP issued a swift response to the article on ghostwriting by Alastair Matheson published in the BMJ in August.

Quarter 4

October

- The Thomson Reuters Intellectual Property & Science division, which calculates Impact Factors for publications, was sold and rebranded as Clarivate Analytics.

November

- The AllTrials campaign founded by Ben Goldacre announced the launch of the automated TrialsTracker, which identifies trials on ClinicalTrials.gov that haven't published results two years following trial completion. The TrialsTracker reports that 45% of trials conducted by major sponsors over the last decade are missing results.
- Results of the US election saw Republican Donald Trump being elected as President. He quickly announced the appointment of Tom Price as Secretary of Health and Human Services, taking control of the NIH, CDC and FDA.

December

- It was announced that President-Elect Donald Trump is considering Scott Gottlieb alongside Jim O'Neill to head the FDA.
- With Trump set to challenge the US pharmaceutical industry on drug pricing, we head into 2017 with the outlook uncertain, prompting Mr Delahunty to conclude with the words of his personal hero David Bowie "changes… turn and face the strain".

Real-world evidence publications

Whereas publications on randomised clinical trials (RCTs) are upheld as the shining light of medical publications, real-world evidence (RWE) publications, based on observational analyses, are viewed with uncertainty. Nonetheless, steps can be taken to mitigate poor public perception and develop valuable publications to a high standard. RWE data are important and complement RCT data in a real-world setting. As such, RWE publications can be influential in informing and bolstering reimbursements, for example.

To adequately address the concerns around RWE publications, the barriers to credibility need to be considered. These include an increased risk of bias due to lack of randomisation, questions around the representativeness of the selected datasets, concerns about cherry-picking the "best" data from numerous analyses and conflicting results from different studies. These issues can be addressed through the cohesive multidisciplinary collaboration of key experts to generate robust data, by following appropriate guidelines and by the transparent, accurate and clear (no technical jargon!) representation of the study methodology and outcomes. As always, transparency is key.

In short, the same rigorous approach should be applied to the development of RWE publications as to those reporting RCTs – plan, review and publish.

Sharing patient-level data: what are the implications?

A panel of relevant stakeholders discussed the pros and cons of the latest proposal from the International Committee of Medical Journal Editors (ICMJE) for sharing patient data, from different perspectives. The proposal dictates that all patient data must be freely available within six months of publication.

A couple of examples were used as background as to why the ICMJE proposal was coming into effect and the underlying problem that needed to be resolved. In some cases, not all available clinical data had been initially made public, leading to potentially over-optimistic estimates of efficacy and tolerability.

Greater transparency of data in general and an agreed system of data sharing are required. The current system can be considered by some to favour the sponsor rather than all relevant stakeholders.

Patient privacy and patient consent must remain guiding principles, so patient-level data should be de-identified and anonymous. However, an open database would allow sharing of data for research purposes and to learn from similar and same molecule trials that had or had not been published. At present there is no collective consensus on what transparency is or how to share the data. How far can we go to make patient-level data publicly available and for what purpose?

There are many benefits to sharing patient data. The challenge is communicating this to the patient and public in order to get buy-in, especially in a language that they understand and in a concise and clear way.

There is also time and cost associated with pulling such data together within a short timeframe. Spending resources on such transparency activities may restrict the number of trials that can be undertaken (especially where they are funded by research institutions rather than pharma).

Some may question the need for such data sharing. Patients may want access to their information and how it compares to others but will they want to analyse it? Thorough reasoning and justification are required for the proposal; there should be a societal debate with all interested parties and stakeholders involved so that it is not harmful, ineffective or unnecessary.

Panel question 1

What is the status and timeline for the proposal?

A consultation has taken place. A third of respondents are in favour, a third neutral and a third are against (mainly the clinical trial community). The aim will be to data share but the timelines need to be more relaxed to allow all changes to be implemented.

Panel question 2

How do we move forward in a timely fashion?

The panel agreed that a consensus view with the collaboration of all relevant parties is desirable, and preferable to independent statements by separate bodies. One option for the proposals is to apply them only to trial data that might directly affect clinical practice. Pharmaceutical companies need to be transparent with their research data. Data sharing in principle is a good thing, but we need to look at whether sharing data could be harmful in some cases if misused.

There is still confusion around the reasons and benefits of sharing patient data. More consultation is required and all stakeholders need to have an equal voice.

Parallel sessions

Scientific communication platforms: best practices, challenges and insights

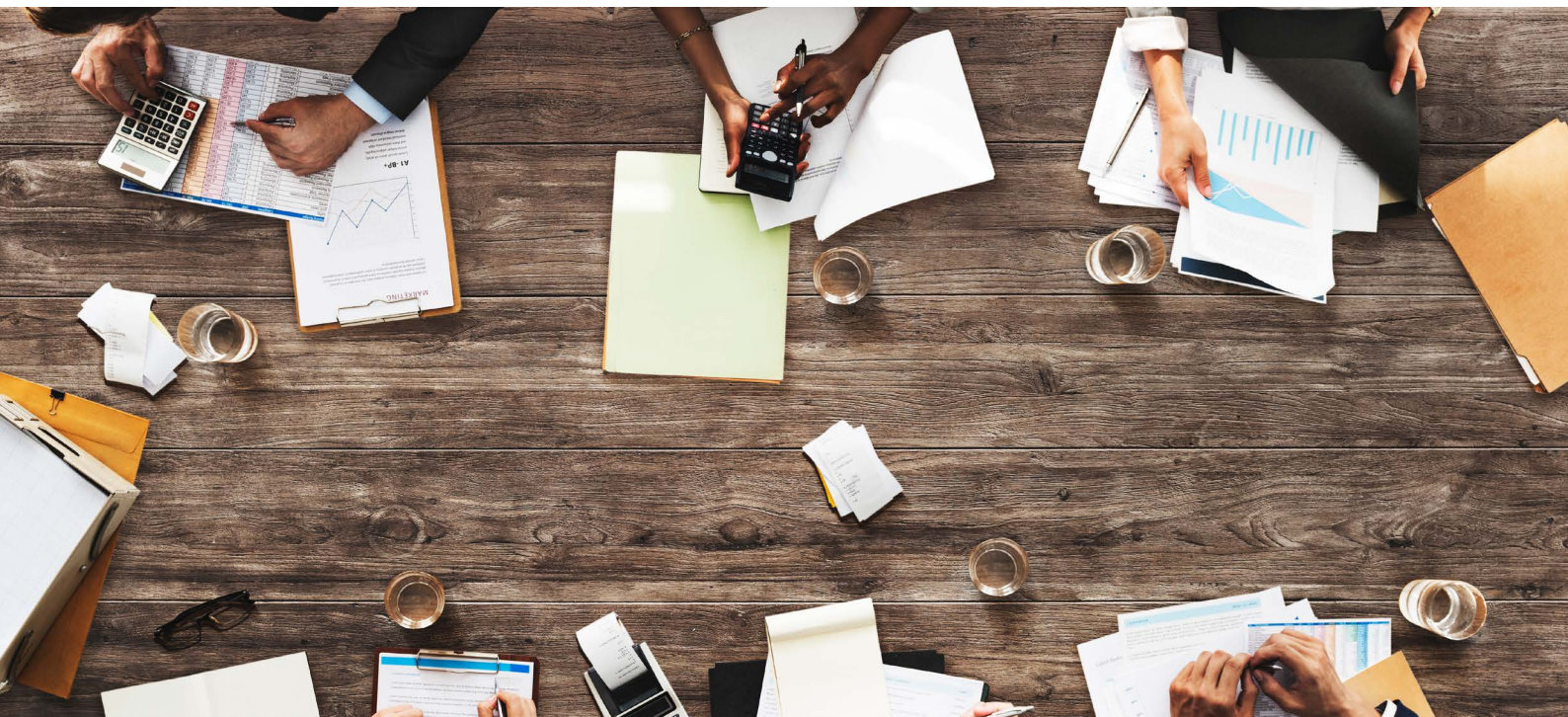
To ensure consistency and to guide publications across the life cycle for a product, scientific communication platforms are used within medical affairs as guidance documents. These internal resource documents provide a reference point that facilitates consistent communication of the disease state, product profile and value of the product.

Three key foundations characterise scientific communication platforms: pillars which define the top-line communication topics; communication objectives for each pillar supported by statements that are underpinned by data, or aspirations if early in the product life cycle; and consistency in delivery, all of which are supported by a scientific story, lexicon and scientific statements.

Ideally these documents are developed at phase II/III, and should be revisited when new data are available (eg, pivotal data or sub-analyses), there is a major change in the programme (eg, failure to meet key endpoint or new indication), or shifts in the landscape (eg, new competitor data or new data milestone). These documents are not without challenges, which include establishing the value across stakeholders, implementation, data availability, and prompting unintentional plagiarism.

Overall, four key points were identified for effective and efficient development of scientific communication platforms:

- Establish value: interview stakeholders to identify goals and outputs, in order to establish engagement, partnership and alignment
- Define the approach: outline the process and assemble the stakeholders
- Develop the platforms: drafting, vetting with experts and revisiting as appropriate. Output formats include PowerPoint, interactive PDFs and Word, after dissemination using internal intranets
- Facilitate the implementation: train the team (including agencies) and monitor its application.



Parallel sessions

Data transparency update: the European perspective in a global context

The EMA has implemented a new standard for clinical data transparency, known as Policy 70,[1] that aims to publish to the public both clinical trial reports and anonymised patient-level data. Making this data available should facilitate independent data analysis as well as future innovation.

EMA Policy 70 on "Publication of clinical data for medicinal products for human use", published 2 October 2014, applies to market authorisation applications and extensions, from 1 January 2015. Phase I includes CSRs and summaries, including notes on anonymisation method and phase II will cover individual patient data; material will be redacted for commercially confidential information. The EMA is contacting companies proactively 2–4 months before redacted material is due.

Two levels of access will be available: general (requiring just an email address) granting screen view only, and academic/non-commercial (requiring detailed identification) granting in-depth access, downloading etc. "Commercial" is defined in the EMA Q&A.

Examples were provided from two companies. Shire is proactively preparing clinical trial reports to comply: redaction takes time and the internal stakeholder team covers 12 departments. Anonymisation (an extensive task) is handled by a vendor.

Celgene has a clinical transparency initiative, as posted on their website,[2] which covers publication of clinical trial results, provision of patient lay summaries, and access to clinical study report synopses. Through the website, Celgene invites requests for data access from institutions or researchers to address specific research questions.

References

1. http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/10/WC500174796.pdf
2. https://www.celgene.com/research-development/clinical-trials/clinical-trials-data-sharing/

Parallel sessions

Transfer of value

Healthcare professionals (HCPs) provide the pharmaceutical industry with valuable expert knowledge that makes an important contribution to the industry's efforts to improve the quality of patient care. While HCPs should be fairly compensated for the legitimate expertise and services they provide, these interactions should also meet the high standards of integrity that patients, governments and other stakeholders expect. On day one of the 2017 European Meeting of ISMPP, Antonia Panayi (Shire International GmbH) and Marie-Claire Pickaert (European Federation of Pharmaceutical Industries and Associations [EFPIA]) offered an expert overview of eight current guidance regarding transfer of value reporting from a European perspective.

In 2014, EFPIA supplemented its existing Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals with a Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations, which aims to promote transparency without sacrificing the legitimate privacy interests of HCPs. Each member company is obliged to document and disclose any transfers of value it makes, either directly or indirectly, to HCPs, preferably at an individual HCP level.

The EFPIA Disclosure Code aimed to provide a simple and easy-to-implement process for reporting transfers of value. Frequently asked questions regarding scope of the Code are provided on the EFPIA website, and offer specific advice about whether publication support should be included in Transfers of Value reporting. Nevertheless, there have been a number of learnings and challenges since the first public transfer of value disclosures in Europe in 2016, and in particular, disclosure of medical writing support through what is termed "intangible services" is still subject to interpretation by the pharmaceutical company doing the reporting, with different companies taking different views on what should and what should not be disclosed due to the indirect nature of the transfer of value. Refinement of the code is an ongoing process and this issue in particular remains to be resolved.

Parallel sessions

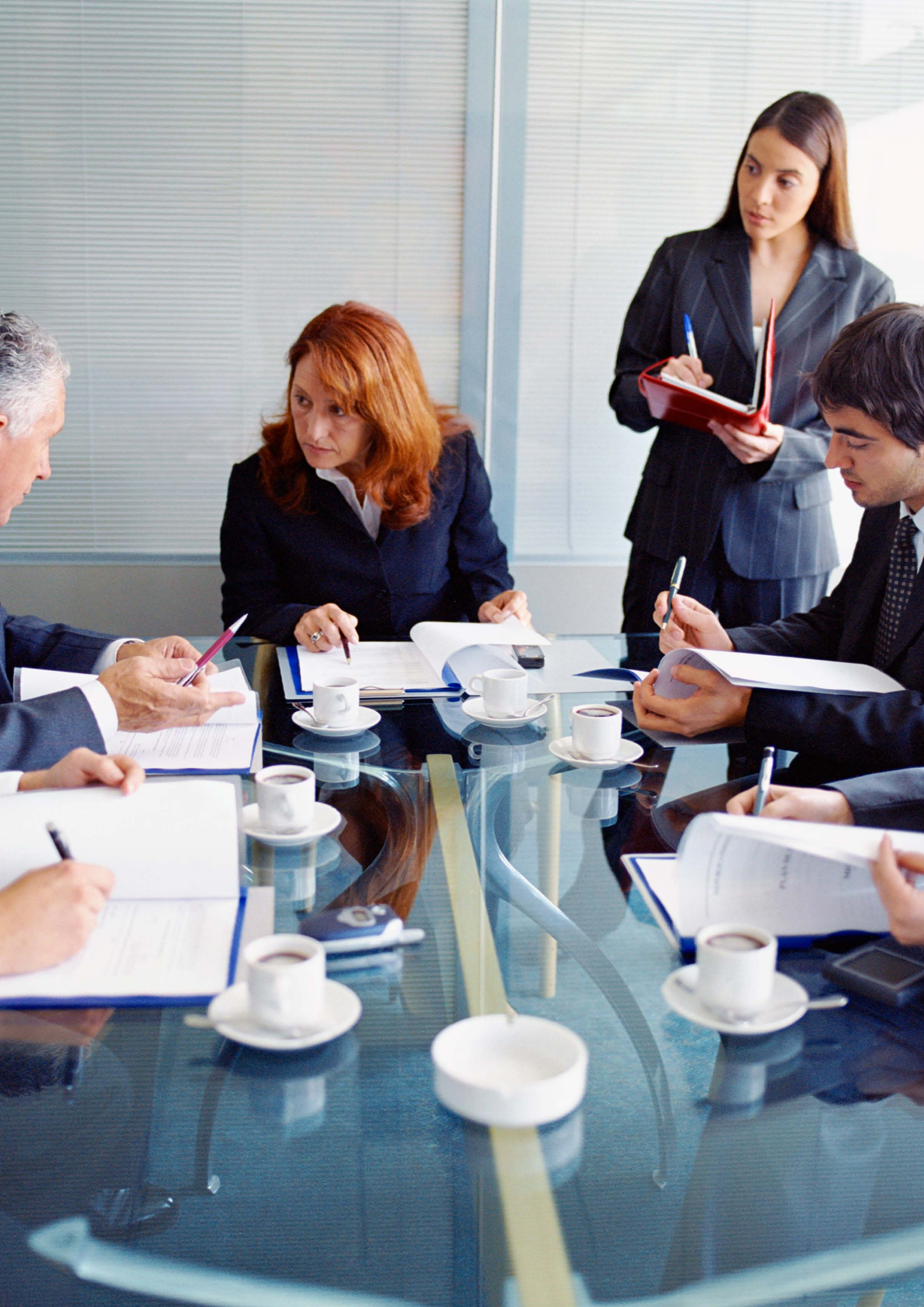
Patient engagement: health literacy – how can publication professionals help improve it?

In this digital age of "Dr Google", patients (and their carers) have access to a wide range of healthcare information but being able to access this information is only one side of the coin; people need to be able to understand it in order to act upon it. Unfortunately, this may be an area in which publication professionals are failing. For example, a study published in 2015 found that four in 10 patients in the UK do not understand the information in medical leaflets given to them by their doctor. There are however, a few simple things that publication professionals can do to help when developing such materials:

- Use simple language; write as if for a reader 9–11 years old
- Use short sentences
- Simplify numerical information; for example, say "half the patients" rather than "50%"
- Use images; a picture tells a thousand words
- Think about the formatting of the materials; is it easy to find the most important information?
- Get patients to review the materials. Want to know if a patient understands a leaflet? Show it to them and ask them.

Publication planning in smaller companies

Asa Lommele (Alexion Pharma GmbH) and Susan Scott (Consultant) shared their experiences of publication practice within small companies. Because biotechs may have fewer (if any) products, and are more susceptible to reputational influences than larger companies, both speakers agreed that the spotlight on biotech publications may entail both great opportunities and potential risks: anything negative and all will know, anything positive and all will know – so it is very important to set up correctly. Establishing where publications sit in the company, putting in place a coordinated plan (including across any alliances/partnerships) and creating an audited tracking and documentation system for activities is important. This is not always easily done, however, as there can be conflicting opinions with senior management and/or commercial teams. If all parties are to be convinced of the importance and need for good publication practice, sharing some of the well-publicised cases of poor publication practice and the serious ramifications can be very helpful!



Speed research member presentations

From a record 25 posters presented, the abstract sub-committee selected the top six for oral presentation during the "speed" research session. During this quick-fire discussion, authors were invited to present their research in seven minutes, followed by an audience Q&A moderated by Ryan Woodrow (Aspire Scientific). Selected highlights are summarised below.

Santosh Mysore, GSK Vaccines

Selection toolkit to support target journal determination: GSK in-house experience

Introduction – Timely disclosure of clinical trial data is essential for transparency and scientific advancement. It is documented that not all data from randomised trials are published. Editorial feedback suggests that the reason for this is inappropriate choice of a targeted journal.

Objectives – Manuscript rejections resulting from inappropriate target journal selection can delay public disclosure of clinical trial findings, lead to unmet sponsor commitments and put an additional burden on authors, editors, sponsors and peer-reviewers. The GSK Vaccines publication database was used to develop a toolkit to support others in objectively selecting suitable target journals.

Research design and methods – A sample of GSK-sponsored clinical trial publications submitted to journals between 2012 and 2014, with a journal decision (accepted/rejected) was chosen. Sixty-three out of 130 manuscripts were selected, disclosing GSK-sponsored clinical trial data submitted to journals with a wide range of impact factors (1–60). Manuscripts were scored (1–5) on trial outcome, novelty and public health impact, based on prespecified scoring criteria. These scores were weighted (phase III papers weighted more than phase IV; novelty and public health impact were weighted twice as much as trial outcome) to determine the relative importance of each and a cumulative manuscript score was calculated.

Results – When novelty and public impact scores were weighted twice as heavily as trial outcome, the correlation between manuscript score and journal impact factor explained 83% of variance for accepted submissions. No correlation was found for rejected submissions. For submission to higher impact factor journals (IF >7), manuscript scores of rejected submissions were clearly below the predicted acceptance-curve, whereas for submissions to lower impact factor journals, this was not apparent.

Conclusions – It was shown that an "objective" manuscript score can be calculated to obtain an appropriate impact factor range from which to select a target journal for submission of clinical trial data. Combined with other journal characteristics and the intended target audience, the toolkit can help authors target an appropriate journal. The prospective impact of this toolkit will continue to be evaluated.

Speed research member presentations

Steve Smith, Cello Health Communications, IS Health Group

Are medical publishers and the pharmaceutical industry optimising the use of patient-centric market research?

This work assessed the importance of publishing market research data, and any potential barriers to publication. Data from market research projects involving patients and/or carers across 22 rare diseases were reviewed – the studies provided insights on patient pathways, treatment impact, disease understanding and management, and patient unmet needs. In comparison, published clinical research across the same 22 rare diseases focused mainly on treatment efficacy and safety, thus differing greatly from the real-world experience of patients. Market research has its own code of conduct but journals seem to have no guidance for its use in publications. Publication of market research data, as well as clinical trials, could make a meaningful contribution to clinical practice. Market research often starts without publications in mind, so the advice is to think at the outset if research might be published, then construct (and document) the methodology appropriately.

Martin Neuner-Jehle, Sincope GmbH

Innovative impact model for optimisation of scientific communications in healthcare

IMPACTS™, a unique interactive modelling tool designed for the planning of scientific communications, considers cognitive, emotional and social intelligence to optimise the overall impact of a publication. Retrospective impact evaluations are planned to refine this tool further.

Simon Page, Costello Medical Consulting Ltd

The role of scientific interns as medical publication professionals

Access to roles in medical publications can be challenging for applicants without formal experience. Scientific internships can help provide the first opportunity for individuals to become medical publication professionals. In this presentation, Simon Page gave a brief overview of a study that sought to understand the attributes of a successful scientific internship at a medical communications agency, and to provide evidence-based recommendations for agencies considering an internship programme.

Data were collected from applications made to a paid internship programme run by Costello Medical Consulting Ltd from July 2012 to October 2016. Analysis of the data showed that during this period, 58 interns were hired. Of these, 12% were still actively enrolled in the internship programme, 24% moved to permanent roles within the company, 24% pursued further education and 40% sought other employment. In 2015, a total of 484 applications were made for the scientific internship role. Of these, eight (1.7%) were successful. Among the successful applicants, 25% were postgraduates, while the remaining 75% held an undergraduate qualification. A survey carried out in 2016 showed that all of the nine interns interviewed indicated that the programme provided a good understanding of the variety of work within medical communications, with 78% of these interns working on a project from inception to completion.

This small study suggested that scientific internships can be an important entry route into a career in medical publishing. Additionally, interns can provide valuable support to medical communications agencies and therefore can play a key role in the development of medical publications.

Roundtables

Biosimilars

It is clear that knowledge of biosimilars is evolving, hence the focus of the roundtable revolved around building greater awareness. A biosimilar is highly similar to an already approved biologic (reference product), and must have no safety and efficacy differences from the reference product. However, biosimilars are approved by a different process to the reference product, known as the "abbreviated pathway" in the USA. All studies are conducted versus the reference product, and involve substantial preclinical studies, phase I clinical studies assessing pharmacokinetic equivalence, safety and efficacy, and phase III studies assessing efficacy, safety and immunogenicity (phase II clinical studies are not conducted); data from all the studies must be similar to the reference product.

Data from biosimilars can be extrapolated to other disease indications provided that the reference product has an indication in that disease; this extrapolation is scientifically justified if the key disease features, and the mode of action of the biosimilar, are similar in the two conditions. Such extrapolation is cost-effective and encourages the generation of biosimilars by organisations. It was clear that journals are keen to publish articles on this topic, providing evidence for prescribers, confirming the quality and comparability of biosimilars.

Biosimilars are marketed at a lower price to increase patient access to these treatments, hence are cost-effective, allowing funds to being freed up for other research or treatments for patients.

Roundtables

Ensuring publication excellence in emerging markets

As in all areas of the world, publication of scientific data in peer-reviewed journals remains an integral part of improving healthcare decisions in emerging markets.

However, not all investigators in these countries may be familiar with guidelines such as CONSORT, ICMJE and Good Publication Practices, which are critical to the ethical development of publications. In addition, investigators may require support in selecting the most appropriate target journal, or in submitting to international journals if English is not their first language.

Clearly there is an important role for experienced publication professionals to help educate authors in these countries on best practice regarding manuscript development, and to support them in getting their work published in appropriate journals.

Roundtables

Integrating HEOR into your publication plan

Health economics and outcomes research (HEOR) is used to guide decision makers regarding patient access to specific drugs and services. For a given treatment, HEOR involves economic modelling, real-word evidence, comparative effectiveness and patient-reported outcomes. HEOR publications can progress rapidly once data are available. For example, with economic modelling, the models are created and then await drug pricing information; once pricing is released and programmed into the model, the aim is to publish immediately to maintain momentum in the field, which can compromise publication quality if there is excessive urgency in the development of the publication. To ensure scientific credibility of the published work, establishing an early partnership between HEOR/market access teams with the clinical/medical teams is vital to assist with understanding the HEOR team's communication objectives.

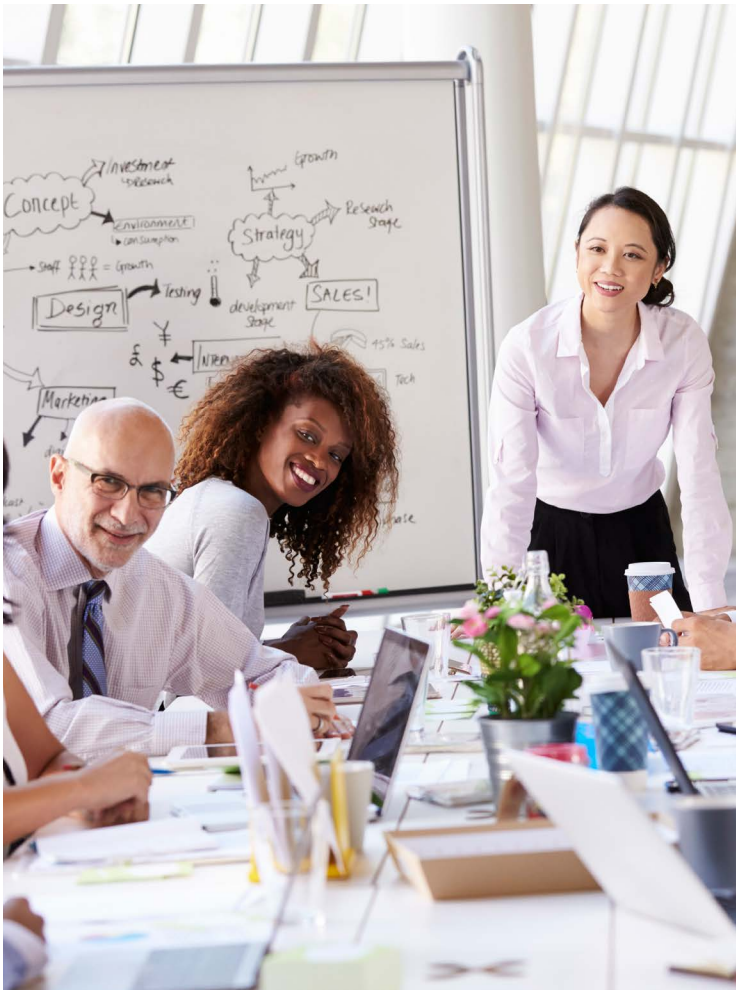
Integrating HEOR teams into clinical development planning could also help in guiding study designs, to ensure the inclusion of clinically relevant endpoints that are likewise relevant for HEOR regulatory requirements.

Medical devices

The discussion was led by an expert panel of Steven Walker (St Giles Medical), Patrice Becker (Medtronic) and Beatrix Dörr (CORIUVAR).

On 1 July 2016, MEDDEV 2.7.1 Revision 4 was released. The European Commission's guidance document is available at: https://www.bsigroup.com/meddev/LocalFiles/en-GB/Documents/MedDev-2.7.1-Rev-4.pdf. This revision provides stringent recommendations on clinical evaluations, particularly those using an equivalent device. In addition, substantial improvements in the standards of clinical evaluation reports are recommended. An updated directive on medical devices for the USA is expected in April 2017.

The new MEDDEV guidance represents a significant regulatory hurdle to market access and will require substantial investment from device manufacturers to implement. It may represent a new opportunity for professional medical writers in the preparation of submission dossiers, although specific qualifications/experience are required to support in this capacity.



Roundtables

Meta-analyses, big data reviews: summarising the evidence in a data-rich world

Recent years have seen an explosion in the amount of healthcare data being published. But is it all "good" data? What do we do when there are conflicting reports? Is there a danger that important information simply gets lost in a vast sea of information?

In this data-rich world, it is essential that we are able to summarise findings from numerous trials into a cohesive body of evidence to support healthcare decisions. In this respect, systematic reviews, which use a predefined and robust methodology to answer specific clinical questions, are key weapons in our armoury.

As the volume of data continues to grow, it is increasingly important that publication professionals are well versed in guidelines such as PRISMA that provide guidance on how to conduct systematic reviews; this will support authors and investigators in the pursuit of a truly evidence-based approach to medicine.

Patient lay summaries

With patient lay summaries becoming a regulatory requirement in 2018, few at this roundtable had real experience. Of those who did, the key message was to ensure user testing before release. Preparation recommendations include talking to patients, visiting patient websites and reviewing common query threads to identify hot topics in that disease. Summaries must be more than box-ticking exercises, and need to be easily located. There are no guidelines on how to write for acute, chronic and population-specific conditions which will all need different approaches. Recommended reading age is 9–11 years old, to encompass the majority of the public: a lay summary is not a clinical summary without the long words.

Helpful sites were recommended:

- NIHR Dissemination Centre (http://www.dc.nihr.ac.uk/) provides 2–4 slide summaries of research for patients to take to their GPs
- University of Glasgow has a website on how to assess a medical article (http://www.understandinghealthresearch.org/)
- Text can be assessed for ease of readability by the SMOG factor (http://www.readabilityformulas.com/smog-readability-formula.php).

Roundtables

Rare diseases

During this session, facilitated by Asa Lommele and Mirkka Schaller from Alexion Pharma GmbH, we discussed some common issues or considerations faced when publishing content for a rare disease. The first issue highlighted was where to place the content, as with many rare diseases the various symptoms could fall across a lot of therapy areas, making journal selection difficult. Another factor is the smaller audience base interested in the content, often reducing the attractiveness of rare-disease articles to journal editors. A good cover letter is therefore all the more important!

Authorship is another important consideration in a field where there may only be 3–4 potential authors. It can be hard to confirm or manage the busy schedules of authors, and even harder again to select peer reviewers. Should there be any difference of opinion between the authors, it can bring some articles to a standstill. Some journals are not happy if the same author has been involved too many times, which in rare diseases can be difficult to avoid.

We then get on to the articles themselves. For rare diseases, a majority of publications are focused on disease awareness, but being less exciting than original research, how and where to publish can prove very troublesome. Fortunately there has been a shift in interest of rare diseases and the need for treatments, which will hopefully continue to translate into greater journal access.

Keynote address

ISMPP EU delegates were treated to a fascinating presentation on the impact of clinical trial research on evidence-based clinical practice by Professor Carl Heneghan. As a GP himself, Professor Heneghan reflected on the number of changes in practice by his peers provoked by new evidence rather than the total number of clinical trials carried out. Asking what level of impact should be expected from the 31,000+ trials ever completed with posted results, and why the impact seems to translate into so few changes in clinical practice, Professor Heneghan drew inspiration from a model developed by Dr Sackett and focused on a key factor of impact being the clarity and accuracy of the research outcomes.

Checking through trial data and the publications, he could demonstrate that a number of trials had outcomes that were badly chosen, badly collected, selectively reported or inappropriately reported; a number of trials demonstrated surrogate outcomes or switched outcomes. This can contribute to a sizeable body of evidence that is unreliable and unclear, therefore creating a "bias" which affects the clinical practice impact. Unfortunately he found that when presenting his findings to the publishers of the trial data, few were willing to make the corrections, while others did so after significant periods of time, with the inaccurate papers being available to readers in the meantime. Professor Heneghan concluded that transparency of clinical research is key and fundamental moving forward, and that he is continuing to undertake his "trial checking".

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Look out for future editions of **New Perspectives** in 2017, with insights from upcoming industry meetings and key areas of relevance to the healthcare community

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