ISMPP European Meeting 2018

Congress Report

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ISMPP European Meeting 2018 Report

The 2018 European Meeting of the International Society for Medical Publication Professionals (ISMPP) was held in London, UK, on 23rd–24th January, and brought together delegates from industry, academia, publishing and independent communications agencies.

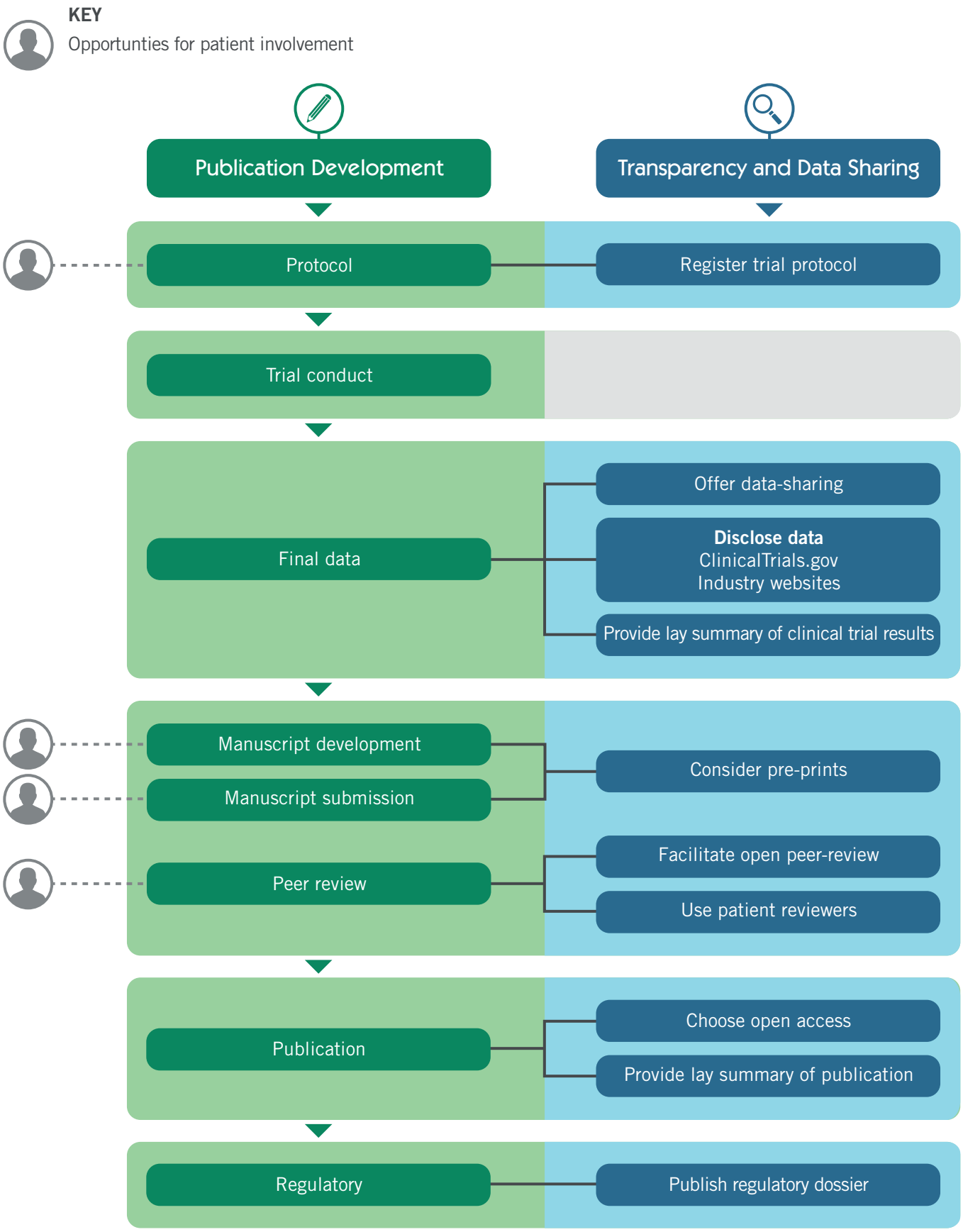
The theme of this year's conference was "**Advancing Medical Publications in a Complex Evidence Ecosystem.**"

This year's report covers the key topics from the conference:

Costello Medical at the ISMPP European Meeting 2018

Discussions and symposia revolved around incorporating industry, research, publishing and patient perspectives in the evolution of medical publications and communications. In particular, there was a strong focus on transparency and data sharing planning throughout all stages of publication development **(Figure 1)**.

Figure 1. Integrated Data Disclosure Planning : Transparency Throughout Publication Development



Transparency and Open Access

Transparency continues to be a key issue for ISMPP delegates. This year, the specific focus was on prioritising open data and open science throughout the data generation and dissemination pathway **(Figure 1)**. Discussions highlighted that we are moving away from traditional publication planning and into an age of integrated data disclosure. Many of the measures discussed have already been adopted by the pharmaceutical industry, such as protocol registration through central databases (such as ClinicalTrials.gov). Increasingly common disclosure methods, such as data sharing on request, pre-prints and open peer-review, were also highlighted throughout the meeting.

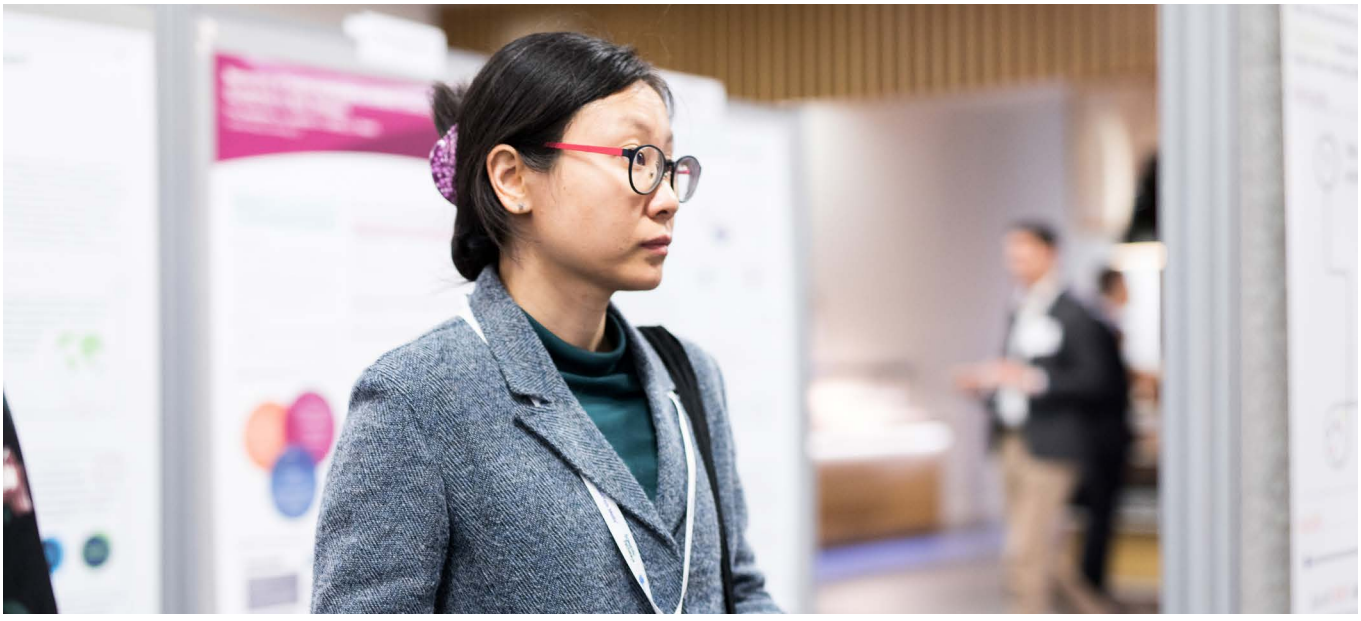
Data Sharing and Availability

Data sharing was discussed at length, triggered in part by the latest update to the International Committee of Medical Journal Editors (ICMJE) guidelines,[1] published December 2017, which will make data sharing statements obligatory in all ICMJE journals by 1st July 2018. These statements should indicate which individual anonymised participant data will be shared, the availability of additional trial-related documents, the period of data availability, and access criteria for shared data. The updated guidelines also mandate a data sharing plan for all trials enrolling patients from 1st January 2019.

An increasing number of pharmaceutical companies are making data available to researchers on request. Katherine Tucker (Data Sharing Lead, Roche Products Ltd) discussed www.ClinicalStudyDataRequest.com (CSDR), including the progress made in making redacted individual patient data available through a common platform across pharmaceutical companies, and overcoming issues such as investment, disparate data formats and compliance processes. Slavka Baronikova, (Publications Lead, Shire) explained that companies that focus on treatments for rare diseases often share data through bespoke platforms, to minimise the risk of patient identification. To date, CSDR has received 362 requests for data through research proposals, only 33 of which have been rejected; however, just 17 (5%) have resulted in a publication to date.[2]

Multiple pharmaceutical companies reiterated their commitment to making trial data publicly available, despite recent criticism of company-funded study publication rates. It was noted that although full publication through peer-reviewed journals was still the gold-standard for data dissemination, publishing negative or non-confirmatory results can be challenging; journals are less likely to accept manuscripts that do not report novel or significant results, and companies have limited resources. In such cases, data are often made available through summaries on ClinicalTrials.gov or via company websites. While this does ensure data are released into the public domain, this format may not be captured by top-line studies of data reporting.

The notion of expanding publications planning into integrated data disclosure planning was explored in depth. The relevance and sequence of redaction of patient information, data sharing, and publishing in both peer-reviewed journals and other platforms could benefit from a holistic planning approach. Creative solutions for evidence dissemination may be developed by considering where clinical study-related information, such as study protocols and reports, can be shared with wider audiences.



Open Access, Pre-Prints and Open Peer Review

Strategies to improve transparency within the peer review publishing framework were discussed, including the growing popularity of pre-prints, where manuscripts are uploaded and reviewed online prior to submission to a journal (e.g. bioRxiv.org). Similarly, journals such as F1000Research seek to refine the process of peer-review by making articles publicly available shortly after submission and conducting open rounds of peer-review and author resubmissions, until the article is agreed to be 'final'.

Appropriate journal selection is also essential to ensure that published articles can be found by their target audience. Research by Eleanor Thurtle (Medical Writer, Costello Medical) and colleagues noted that improving accessibility to orphan disease literature is particularly essential for the rare disease community.[3] Her research showed that only a small proportion of rare disease articles are published in open access journals, with fewer still providing accompanying lay summaries. This is particularly important, since Anna Georgieva (Program Director, Excerpta Medical) found that lay summaries can help patients interpret published research findings and discuss treatment options with healthcare professionals (HCPs).[4]

It was generally acknowledged that while pharmaceutical companies prefer to fund open access, they do not feel comfortable being overly prescriptive on journal choice when working with external authors. In addition, some high-impact journals still do not allow fully open access options for studies funded by pharmaceutical companies, or they only allow such articles to publish under a more restrictive CC-NC (non-commercial) licence. Delegates were encouraged to favour the CC-BY contracts where possible, which allow the widest dissemination of the publication with appropriate citation.

This year, Shire has formalised their commitment to open science by announcing that open access publication is a requirement in all company-funded study contracts going forward, similar to the funding conditions imposed by non-commercial grant providers such as the Wellcome Trust and the Gates Foundation.

Patient Involvement

Patient involvement was a key topic, with a wide range of dedicated research posters and presentations investigating considerations for the inclusion of patients in research and communication. In his keynote address,[5] Mohammad Al-Ubaydli (Founder and CEO, Patients Know Best) highlighted that many patients want to take an active role in treatment decision-making and educate themselves about their disease to become their own advocates. Patients are entitled to access their complete health records which puts them in the ideal position to collate and share these with HCPs, to enable their best possible care.

In 2014, *The BMJ* launched their patient partnership strategy, which requires authors of research publications to document the involvement of patients in their research, as well as including patients in the peer-review process.[6] Anne Clare Wadsworth (Global Business Unit Head, Envision Pharma) presented an analysis of articles published by *The BMJ* and found that 'patient involvement' reporting rates had increased since the establishment of this requirement, however, only 57.7% of articles thanked patients for their participation in the published studies.[7] This issue was again highlighted by patient representative Rafal Swierzewski (Expert and Consultant, European Cancer Patient Coalition), whose presentation emphasised that patients face difficulties accessing scientific findings, even if they participated in the published studies, unless research is published open access.[8]

While the majority of surveyed HCPs and medical communication professionals saw patient involvement with the pharmaceutical industry as beneficial,[9] further development of guidance and practical tools is required to enable publication professionals to confidently engage patients as publication partners. Antonio Ciaglia (Policy Manager, International Alliance of Patients' Organisations [IAPO]) also encouraged the use of existing practice guidelines, such as the Association of the British Pharmaceutical Industry Code of Practice, and the consensus framework for ethical collaboration between patients, HCPs and industry partners, as co-developed by IAPO and the International Federation of Pharmaceutical Manufacturers and Associations.[10]

Publication Metrics

A wide range of publication metrics are increasingly being used to monitor the reach of new medical literature. Aimée Hall (Medical Writer, Costello Medical) reported that manuscript abstracts using buzzwords related to adherence with publication guidelines may be cited more frequently, providing further motivation to include trial registration numbers and clear primary outcomes in abstracts.[11] Dr Jürgen Wiehn (Director of Scientific Publications, Shire) suggested that citation rates for articles may also be predicted by their social media footprint.[12] The greatest amount of social media interest (defined by Altmetric Attention Score) was observed over the first month after online publication, with more attention received by open access articles.

Article reach was improved via publication in journals that actively support social media activity, suggesting that social media presence of journals and publishers should be considered when choosing where to publish. However, representatives from the pharmaceutical sector described the difficulties associated with compliance when using social media to improve the reach of publications, highlighting the risk of drug promotion pre-approval.

Online activity associated with congresses was also praised in a poster presented by Andy Shepherd (Senior Medical Writer, Caudex Medical) for extending the reach of important information beyond conference delegates, whilst encouraging feedback collection and online debate during the event. Despite this, a study presented by Neil Venn (Associate Scientific Director, Prime Global) found that over 40% of poster presenters did not utilise the opportunity to share their data further than the conference by uploading electronic supplementary material, raising questions as to whether researchers are happy to publish enduring online material prior to full publication.[13]

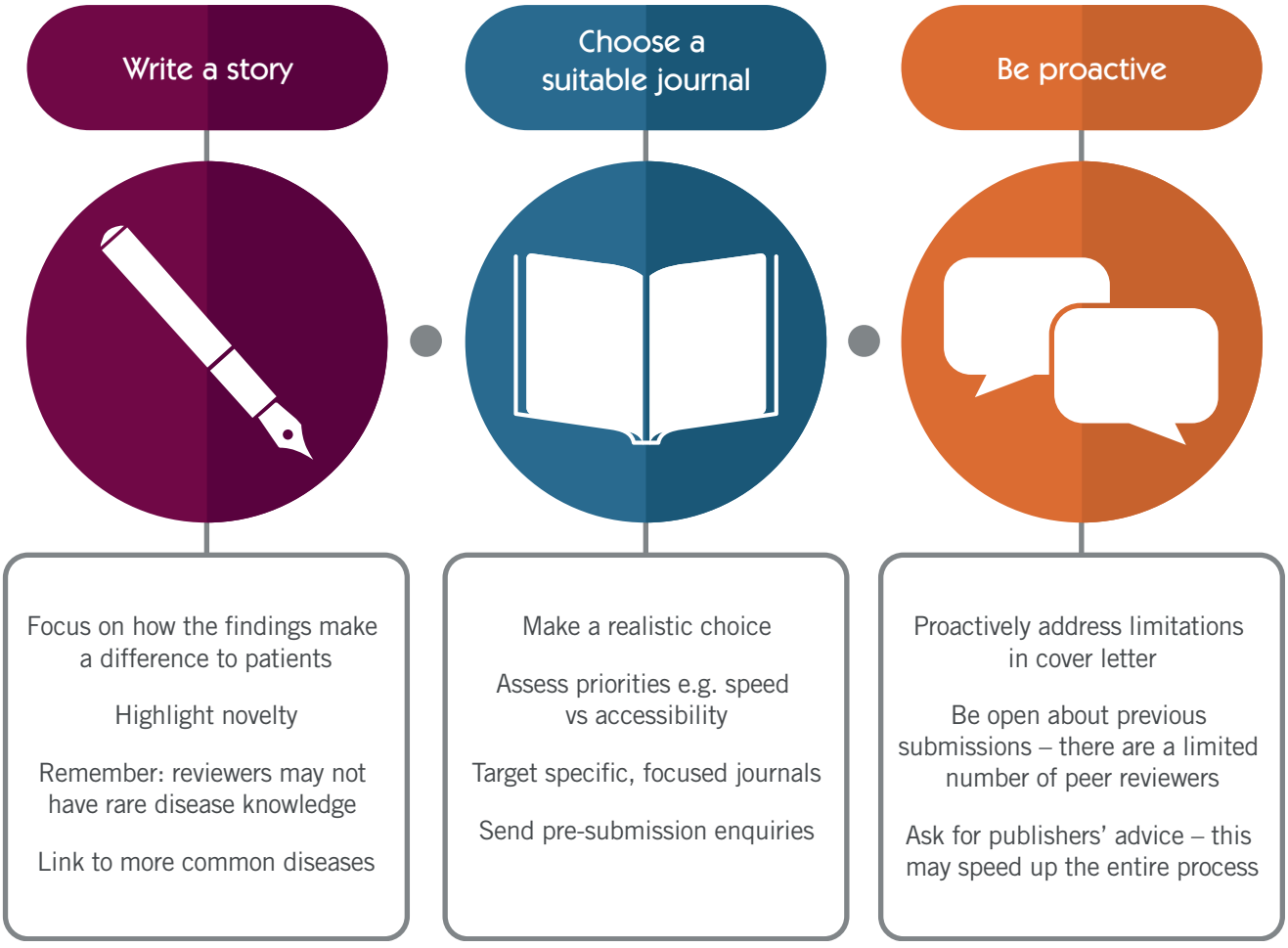
Specialised Publications

Rare Diseases

Andy Powrie-Smith (Executive Director of Communications and Partnerships, European Federation of Pharmaceutical Industries and Associations) noted that while many rare disease patients can be especially concerned by the risk of being identifiable in the public domain, there are a range of individual opinions regarding acceptable data sharing procedures. Many patients request that their data is deleted; others ask to share their information widely to support research.[7] Further publication challenges specific to rare diseases can delay or prevent research becoming accessible, particularly small study samples, prohibitive open access costs and a limited pool of knowledgeable peer reviewers.

Danielle Sheard (Head of Publications, Costello Medical), used her experience in manuscript development to share advice regarding how to successfully publish rare disease research **(Figure 2)**.[14] The lack of data from randomised controlled trials in rare diseases can be mitigated by using well-designed Delphi studies[15] to establish consensus and develop relevant clinical guidelines. However, research by Henrike Resemann (Senior Analyst, Costello Medical) found that the majority of identified manuscripts reporting Delphi studies in rare diseases lacked the level of detail recommended by relevant guidelines, such as the Appraisal of Guidelines for Research and Evaluation (AGREE) Reporting Checklist.[16, 17] Paying close attention to Delphi methodology standards and reporting requirements could aid in the establishment of high quality and impactful consensus guidelines related to rare diseases and orphan drugs.

Figure 2. Tips for Publishing Success in Rare Diseases



Health Economics and Outcomes Research

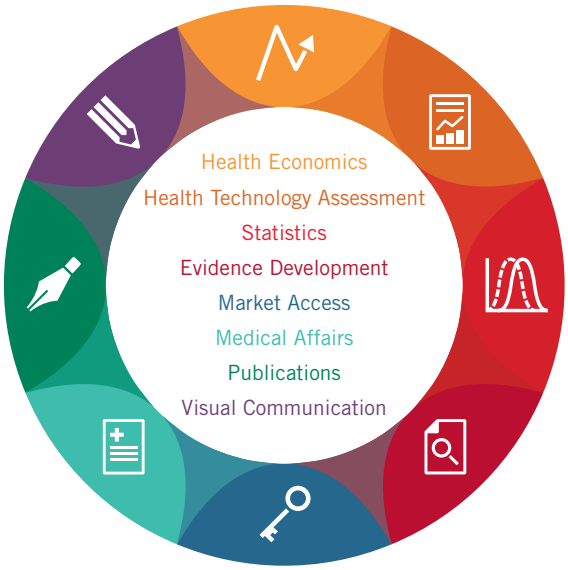
During the parallel sessions, Witold Wiecek (Statistical Project Manager, Analytica LA-SER) discussed the increasing interest of regulators and payers in safety and efficacy data from post-authorisation, real-world evidence studies.[18] These studies allow the modelling of data from patients observed under realistic conditions. Health Economics Outcomes Research (HEOR) publication plans are usually developed by HEOR teams, but there is often limited interaction with the medical or publications team who develop the global publication plan. Medical communications agencies can therefore facilitate the interaction between medical writers and HEOR teams, particularly in raising awareness of Good Publications Practice guidelines.[19]

It was noted during the roundtable sessions that HEOR teams should contribute ideas in advance of yearly strategic publications planning meetings, to enable the discussion and prioritisation of HEOR publications alongside clinical publications. The overall message of these publications should focus on the impact of the treatment on clinical outcomes and patients' quality of life.

Costello Medical

Costello Medical provides scientific support to the healthcare industry in the analysis, interpretation and communication of clinical and health economic data. Due to growing demand across an increasing range of service offerings and geographies, Costello Medical has grown organically since its foundation in 2008 to a team of over 100 based in Cambridge, London and Singapore.

Alongside our evolving technical and creative capabilities, we remain committed to our core values of high quality scientific work coupled with exceptional customer service at competitive and transparent prices. Our talented team has experience with a variety of leading pharmaceutical and device companies across an extensive range of therapy areas and geographies, including Europe, Asia Pacific and North America. In addition to our provision of services broadly across the pharmaceutical industry, we also have dedicated teams with specific areas of expertise, for example medical devices and rare diseases, and can provide the full range of our services for customers specific to these areas. For more information on our services, please visit our website at www.costellomedical.com.



Further Assistance

If you would like any further information on the themes or research presented above, please do not hesitate to contact Danielle Sheard, Head of Publications at: danielle.sheard@costellomedical.com.

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