Thinking Ahead: The Evolution of Scientific Communication

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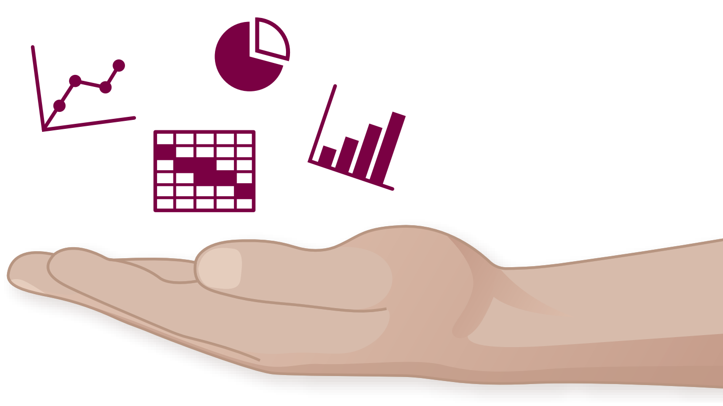
This year's ISMPP European meeting highlighted the need to consider publications planning in the context of a wider "ecosystem". Data are increasingly available and connected online through clinical study identifiers and metadata, and clinical trial reporting will continue to be scrutinised. Consistency of communication is essential, from the study protocol, to results posting and through to the final manuscript.

The forward-planning that strategic publications planning allows is, therefore, more important than ever before. Publication professionals must adapt to the overall shift in thinking towards communications strategy, which should be developed in collaboration with a wide group of stakeholders, incorporating medical communications objectives, transparency of data dissemination, the need to engage and communicate with patients, and real-world evidence.

Key Themes:

Transparency



As ICMJE's data sharing guidelines have recently come into effect (data sharing statements are required in all manuscripts published in ICMJE journals as of 1st July 2018 and a data sharing plan is required in trial registration as of 1st January 2019),[1,2] it is crucial for publications professionals to incorporate data dissemination into strategic publications planning.

There are several options for increasing transparency and data disclosure to support traditional publications:

1. Introduction and/or support of **mandatory open access policies** for company-sponsored research
2. Identification of opportunities to **share clinical study-related documents** e.g. clinical study reports (CSRs), protocols
3. **Data repository use** e.g. TrialShare, Clinical Study Data Request (CSDR)
4. **Preprints** – A preliminary version of a publication that is made available online ahead of peer review, which can ensure data are shared in the community more rapidly

Considerations for publication professionals:

- Could premature sharing of data jeopardise future journal submissions?
- Who can patient-level data be shared with, and for what purpose? Developing internal policies to ensure this is handled consistently may be useful
- Studies with small population sizes may require bespoke data-sharing platforms to avoid patient identification (e.g. rare diseases)

Enhanced Publication Content

In an era of information overload, medical publication professionals must adapt to changing ways in how information is consumed and by whom.

Beyond condensing or summarising the content of publications, efforts are needed to increase reader engagement and access across different platforms, and improve the clarity of communication for a wide audience including patients, payers and non-specialist healthcare professionals.

Summarise, simplify, explain

Identify the most confusing aspect of a manuscript for the reader and think about how best to present this using a digital enhancement. This could be an innovative way to address peer-review comments!

For more ideas about how to develop visual summaries, have a look at **this report**.[3]

Visual abstracts in tweets increase engagement with scientific articles[4]

To be most effective, enhanced content should be planned from publication kick-off, rather than considered as an after-thought:

- **Planning ahead** ensures that the necessary budget is set aside, and potential compliance issues can be tackled ahead of deadlines (although some journals allow enhanced content to be developed after submission)
- **Internal training or external collaborations** can be set up to overcome lack of experience
- Focus on **maintaining quality** and ensuring that enhanced content is rigorously peer-reviewed
- Identifying the **most appropriate metrics** for assessing impact on the intended audience

Patient Involvement

Patient involvement across all stages of medical research helps ensure publications and research meet patients' needs, empowering them to take control of disease management. Subsequently, medical publications need to be **accessible** and **comprehensible**.

Challenges around patient involvement

1. Pharmaceutical companies are concerned that communicating directly with patients is perceived as promotional

   Maintain transparency and adhere to regulations/guidelines set out to ensure responsible patient engagement[7]

2. Contractual obligations associated with use of patient authors and reviewers

   Medical communications agencies can maximise and build networks of 'Patient Opinion Leaders' to overcome pharmaceutical contracting issues

3. Plain language summaries are often difficult to find and understand due to a lack of guidelines[5,6]

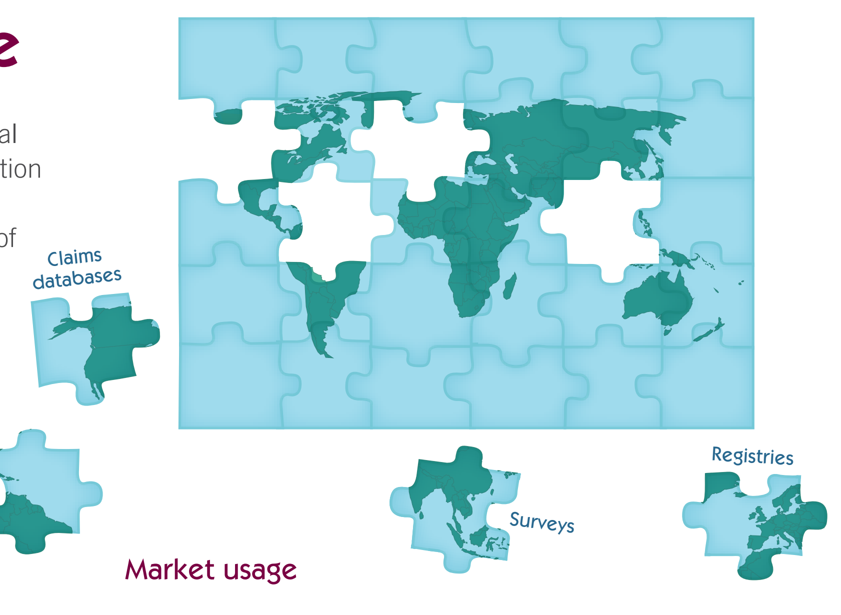
   Involving patient authors and reviewers throughout the development of manuscripts and plain language summaries can help ensure summaries are understandable from a patient perspective[6,8]

   Lay summaries should be tailored to the appropriate audience, taking into account patient age, education and disease-specific considerations e.g. cognitive issues

   ! An **infographic** format was preferred over plain language summaries of varying complexity in an online patient survey[6]

Real-World Evidence

As the role of real-world evidence (RWE) in medical research becomes increasingly important, publication professionals need to know how to analyse and communicate data on the use, benefits and risks of medicines in order to gain a more representative understanding of standard clinical practice.



! Real-world evidence **complements** clinical trial data

Pre-approval

- Expedited access pathways and temporary reimbursement schemes (e.g. the **NICE Cancer Drugs Fund**[9]) allow RWE to support permanent drug approval
- When placebo-controlled trials are deemed to be unethical, registry data can be used to replace control groups[10]

Market usage

- Smart technology and patient-generated data could turn normal drug use into continuous clinical studies/updates
- Data from both large/diverse patient populations and specific subpopulations can be more clinically relevant and may aid treatment management for more complex health conditions

Analysis and interpretation considerations

- Develop strategies to manage bias and missing data
- Publish protocols and statistical analysis plans
- Make complex methodology clear using infographics

Readers must understand real-world data in order for the data to make an impact and drive behaviour changes

Medical Writing – Staying One Step Ahead

As technological capabilities continue to evolve, publication professionals will need to understand how best to leverage these innovative tools to improve the efficiency of publication development. During the European Meeting a range of emerging technologies and their implications for medical writing in the future were explored:

Machine learning-guided manuscript development

- The technology already exists to generate the first draft of a clinical study report from an existing protocol within 24 hours
- Publication professionals will need to develop new skills as trainers, explainers and sustainers
- As less time is required for manuscript development, publication professionals can focus on ensuring that publications deliver strategy
- The publications community can turn their attention to enhanced publication content development

AI collection and collation of real-world data as part of a large, ongoing clinical study

- Publication professionals will need to consider earlier publication opportunities as early stage data becomes more meaningful

Fully-automated systematic literature reviews (SLRs)

- Fully-automated SLR processes will allow publication professionals to focus on placing literature review results in context and understanding the significance of the results/how any identified gaps can be addressed

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Costello Medical provides scientific support in the analysis, interpretation and communication of clinical and health economic data.

For more information on Costello Medical and our publications services, please visit our website **www.costellomedical.com**.

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