Regulatory Matters

Trends in medical writing

Changes in the regulatory landscape and changes in our professional environment make this an exciting time to be part of the regulatory medical writing community. It is a time when new opportunities are presenting and when, like never before, the medical writing community has chosen to come together to conscientiously shape our professional landscape. As this happens, we recognise and value well-established approaches, reinforce innovations in practice, and secure the future for our profession.

The regulatory landscape

Medical writers have been adapting to changing regulatory directives for decades. This history of flexibility positions us well for the latest evolutions.

No place is more dynamic than China, where changing regulatory procedures, ICH adoption, and a potential marketplace of historic proportions make the clear, concise, and compliant communication of all aspects of drug development essential. Beginning with the clinical trial application, documentation increasingly plays a critical role in a shortened approval timeline. An example? In China today, if no comments have been received from regulatory authorities 60 working days after the written submission of a clinical trial application, that trial may move forward. With a plan to implement eCTD in 2020, review and approval of marketing applications will likely move more quickly as well.

In Europe, pending exit of the United Kingdom from the European Union, we anticipate continued changes with the European Medicines Agency (EMA) and the United Kingdom's Medicines and Healthcare Products Regulatory Agency. From its new headquarters in Amsterdam, the EMA has maintained core public health work, as well as the evaluation and supervision of medicines. Some other activities, such as guidance development and transparency initiatives, have been temporarily scaled back.[1] Now is no time for health agencies and the pharmaceutical industry to let up on proactive measures such as allowing for preparation of slightly different sets of regulatory documents for the two agencies when they part ways.

The Food and Drug Administration (FDA) in the United States has launched a pilot programme exploring real-time data review for oncology marketing applications (called, of course, the Real-Time Oncology Review programme).[2] The FDA also newly sponsors participation in the written preparation of its Assessment Aids for marketing applications. The two programmes require new ways of working with data and information, and they provide a directional signal as to possible modifications to the review processes of the future.

Regulators also continue to emphasise the importance of meeting the needs of trial participants. We see moves towards more transparency for clinical documentation and more health literacy materials. These developments allow medical writers to expand our scope and skills, and they offer opportunities to explore how technology can support the development of regulatory deliverables. We see for informed consent, in particular, a need to re-evaluate the content and volume of information provided to trial participants in support of their critical decision-making process.

SECTION EDITOR

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The professional landscape

Leaders in the American Medical Writers Association (AMWA) and the European Medical Writers Association (EMWA) work closely with medical writing industry executives to assess the state of the profession and to develop plans to ensure vibrant growth and development of our workforce. Activities kicked off at the AMWA annual conference in 2018 included systematic group conference calls, surveys of organisational members, and the development of new and innovative educational programmes. Our efforts aim to prepare the next generation of medical writers, develop leadership capabilities in these future standard-bearers, build partnerships in technological advances for regulatory communication, and quantify the value of medical writing to the drug-development industry.

We also sense within medical writing organisations an increase in adoption of competency guides such as the "Pharmaceutical Medical Writing Competency Model"[3,4] in an effort to establish standard expectations for writing skillsets. This model, first published in 2011 and updated in 2017, helps establish hiring and performance evaluation criteria and also can be

aligned with a training plan for career development – all in support of medical writing. Another growing option for establishing credibility is the Medical Writer Certified (MWC®) credential, earned through an AMWA exam.[5] The credential acknowledges core competencies in medical writing and a commitment to continued professional development.

Conclusion

Our trend line in medical writing points upward and outward. Today we can seize immediate opportunities to redefine our value and expand our scope of work in ways that highlight our scientific and clinical expertise, regulatory acumen, communication skills, and project management mastery. With the right vision and execution, this exciting – even exhilarating – time in our profession can turn out to be historically important. We simply need to go after our medical writing goals with determination… and the right attitudes and right aptitudes.

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Medical Communications and Writing for Patients

SECTION EDITOR

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Editorial

Dear all,

The more eagle eyed among you will have noticed that we are changing the title of this section to "Medical Communications and Writing for Patients". Not the shortest of titles, I know, but hopefully it is a more accurate reflection of the content that will be included in the section.

In this issue of the journal, I am delighted to present a feature article I co-wrote with Trishna Bharadia (Lay summaries and writing for patients: Where are we now and where are we going? p. 46). Given the topic, we thought it best to present it as an open access feature article, rather than running it in our members-only section.

As a *The Spark Global* consultant, Trishna works with multiple stakeholders (including pharma, patient associations/charities, clinicians, patients and the healthcare industry) in the UK and internationally, to bring the patient voice into the healthcare journey, addressing issues that affect both specific and cross-patient communities, as well as issues affecting the healthcare industry. She is very well connected, and her work has taken her to, or involved her with, organisations from the Netherlands, France, Austria, Portugal, the Czech Republic, Romania, Northern Ireland, Switzerland, Germany, Spain, England, Poland, and the USA, among others.

We both felt that the time was right to look at what has happened in the arena of writing for patients, and we offer suggestions for where the industry might be heading in this regard. I hope that you enjoy the article. As always, I would be delighted to hear any thoughts, suggestions, or proposals for articles.

Bestest,

Lisa