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Medical Writing

The data economy

Data are economic assets that power the so-called fourth industrial revolution. The healthcare industry is at the forefront of this "data economy". Medical writers should understand how to use these data appropriately and responsibly. This issue of *Medical Writing* is dedicated to our vital place in the data economy. A glossary of relevant data-related terms is provided on p. 3.

Medical writers and communicators support data generation by writing and reviewing documents that report clinical trial data and the methods used to collect them. Real-world data (RWD) are also increasingly collected outside the controlled environment of clinical trials through mobile devices and patient registries, and the US FDA and EMA encourage their use as evidence to support efficacy and safety of health products. Leveraging big RWD to develop therapeutics is challenging for the medical writing community, which is more accustomed to smaller clinical trials databases; we need to learn about the reliability of RWD and how they can be used. In their article on p.16, **Kelly Goodwin Burri** and **Adrian Spoerri** describe how health registries are used to collect RWD for the clinical evaluation of medical devices.

The healthcare industry is at the forefront of the data economy ... As medical writers, we need to collect, use, and share data wisely and responsibly.

Regulatory authorities are aware of the problem of lack of generalisability of clinical trials and are implementing strategies to support the clear message of ICH E8(R1) General Considerations for Clinical Trials, 08 May 2019 that clinical trial protocols need to explore non-conventional data sources including "big data". The US FDA recognises that to make clinical trials more generalisable, they must suggest trial designs that better reflect the populations that medicines serve. The June 2019 Draft FDA Guidance for Industry "Enhancing the Diversity of Clinical Trial Populations – Eligibility Criteria, Enrollment Practices, and Trial Designs" addresses the enrichment of clinical trials. Among the many suggested strategies is early engagement with patient advocacy groups to elicit their suggestions for clinical trial design. In June 2019, the EMA announced a collaboration with European primary care doctors to gather RWD on medicines typically used in the primary care setting to strengthen the pharmacovigilance research base. Further, in January 2020, the Heads of Medicines Agency-EMA Big Data Task Force announced ambitious plans to unlock big data for public health benefit. Their 10 recommendations are topped by a plan to "…deliver a sustainable platform to access and analyse healthcare data from across the EU (Data Analysis and Real World Interrogation Network-DARWIN)". Further, the EMA's Information Management Strategy 2020 to 2022 prioritises "…dialogue with stakeholders on big data, real world data and artificial intelligence to ensure EMA is informed on opportunities for collaboration and able to facilitate data access and analytics".

So how might all this affect the daily work of medical writers? At the very least, we need to rethink conventional clinical trial design. In their article on p. 22, **Hyunjoo Kim and colleagues** explore this idea as well as the impact on protocol and clinical study report authoring, and they provide general insights on how big data might change the clinical-regulatory medical writing landscape.

In the midst of the COVID-19 global outbreak, effective real-time data collection is crucial for the healthcare system to prepare and respond to unfolding events. **Derk Arts and colleagues** discuss this problem and present solutions on p. 32.

The pandemic has created significant disruptions in protocol-specified procedures, data collection, analysis, and reporting for ongoing clinical trials. Regulatory bodies were quick to react and released emergency guidance documents in March 2020, such as the FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic and the EMA Guidance on the Management of Clinical Trials during the COVID-19 (Coronavirus) Pandemic, which were subsequently updated as events

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About the Guest Editors

Dr Sam Hamilton is a post-doctoral virologist, currently Global Head of Medical and Regulatory Writing and Public Disclosure for the CRO, Clinipace. With 26 years in clinical and regulatory medical writing roles in the pharmaceutical industry, Sam is independently responsible for her wider professional interests. Sam's interest in public disclosure of clinical-regulatory documents has grown since chairing the EMWA-AMWA group who delivered open-access www.core-reference.org in May 2016. A long-time supporter of EMWA, Sam has served in various roles, notably as Freelance Advocate; Editorial Board member for *Medical Writing*; Workshop Leader; Expert Seminar Series Chair; and Vice President and President of the Executive Committee. Sam was elected an EMWA Lifetime Fellow in 2018 for her services to the association, and is currently *Medical Writing* Section Editor for the "Regulatory Public Disclosure" Section and on the Advisory Panel of the Regulatory Public Disclosure Special Interest Group.

Raquel Billiones, PhD Biology, has been a regulatory writer for more than 14 years, covering both pharmaceuticals and medical devices. Her core competencies include clinical trials and submissions documents, data disclosure and protection, and project and people management. Over the years, she took on a wide range of industry positions, as freelancer, employed regulatory writer, and as head of medical writing departments in the CRO and big pharma settings. Raquel is an active EMWA member, serving in various roles, including as Executive Committee member (2015–2017), journal Associate Editor, workshop leader, EPDC member, Medical Device SIG chair, and Sustainability SIG co-founder.

unfolded. We can be sure that the data generated by the COVID-19 pandemic will provide a rich and extensive big data archive.

As medical writers, we consume health data: we use data to communicate study results to the authorities, the scientific community, and the public. And data begets data as we process and analyse data collected and use the results of those analyses to generate more data and move medical and scientific research forward. **Shiri Diskin and colleagues** describe the multidisciplinary approach of integrating different datasets into cohesive summaries that support market authorisation of medicinal products (p. 36), and on p. 42, **Jasminka Roth** expounds the merits of meta-analysis of multiple clinical studies to support a medical device's certification for market access.

In addition to consuming health data, in the era of data transparency and disclosure, we help disseminate data. But data sharing comes with the responsibility to protect the privacy of the individual data subject. Previously a reluctant player, the pharmaceutical industry is now taking a lead role in sharing data proactively and responsibly. There are myriad ways and platforms to share clinical data, as disclosure experts **Patrick Cullinan and Liz Roberts** present on p. 46.

On the social media front, misinformation and disinformation are rampant, highlighting the importance of reliable data sources. In the context of the COVID-19 outbreak, tropical disease expert **Melvin Sanicas** shares his views on responsible social media sharing of health information and the data sources that he uses on p. 52.

The GDPR aspect of big data sharing is explored in two regulatory-related articles that begin on p. 56. **Sam Hamilton** engages two experts: **An Vijverman,** a Brussels-based lawyer and expert in the legalities of health data processing, and **Cathal Gallagher** of EMA's Technical Anonymisation Group.

We need to collect, use, and share data wisely. The data economy is dominated by big data, characterised by high **v**olume, high **v**elocity, and wide **v**ariety. However, big health data exist in different structures and are stored in different repositories. Despite the common use of computers and artificial intelligence in healthcare, the three "Vs" of big data still present a major challenge. According to data scientists, for data to be used effectively, it must be Findable, Accessible, Interoperable, and Reusable (FAIR). **Erik Schultes** explains the FAIR data guiding principles in health and medicine on p. 60, using the COVID-19 outbreak as an example.

So who owns all the health data collected? Are these data given freely by individual subjects? The **MyData group** presents a plea for human centric control over health data on p. 64.

Finally, how does the future of medical writing and communications look in the data economy? **Menorca Chaturvedi**, recipient of the EMWA Geoff Hall Scholarship explains on p. 70 how the workplace is dominated by "hybrid jobs" that require data literacy and communication skills.

We want to end our introduction to this complex topic with a big Thank You to all our contributors. To our readership, we hope that you learn as much as us in reading about big data and the data economy as we learned in putting this issue together. Enjoy!