From the Editor

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The clinical research transparency journey

It has been a long road to get here. Figure 1 shows my humble attempts in documenting the data transparency journey in clinical research.

The 2000 version of the Declaration of Helsinki was first to highlight the need for publicly sharing research results.

"Authors have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. Negative and inconclusive as well as positive results should be published or otherwise made publicly available".[1]

The US was at the forefront, with the creation of ClinicalTrials.gov registry, primarily driven by the FDA Modernization Act of 1997.[2]

In Europe, the driver legislation was already in place in 2001. Regulation (EC) No 1049/2001 stipulates the fundamental right of EU citizens to information access and governs public access to documents of the European Parliament, Council and all other institutions, including the EMA.[3]

Once the wheels started turning, there was no holding back Europe. The so-called "access to information" law was the foundation of the EMA Policy 0043 (2010),[4] the EU Clinical Trials Register (2011),[5] EU CTR (2014),[6] and EMA Policy 0070 (2016).[7]

It was in the autumn of 2016 when the EMA clinical data site went live.[8] It was a landmark event in the field of data transparency and public disclosure, when clinical study reports, for the first time, saw the light of day. The bar was set. Health Canada quickly followed suit in 2019, with the launch of the Public Release of Clinical Information (PRCI) initiative.[9]

Here we are in 2024. There have been hitches and glitches, snags and setbacks. But we have made a lot of progress!

There are currently over half a million studies registered on ClinicalTrials.gov,[2] and over 4000 on the recently launched EU Clinical Trials Information System (CTIS).[10] There are approximately 430 marketing authorisation procedures on the EMA clinical data website[11] and over 650 records on the Health Canada PRCI.[9] For each entry in these public databases, there is at least one document that a medical writer has worked on – a study protocol, a study report, a safety narrative, a clinical summary.

Today, medical writers stand proud to see their documents in the public domain.

EMWA has accompanied us on this journey right from the start – and just to name a few initiatives:

- Intensive discourse between the regulators and the industry at the full day symposium

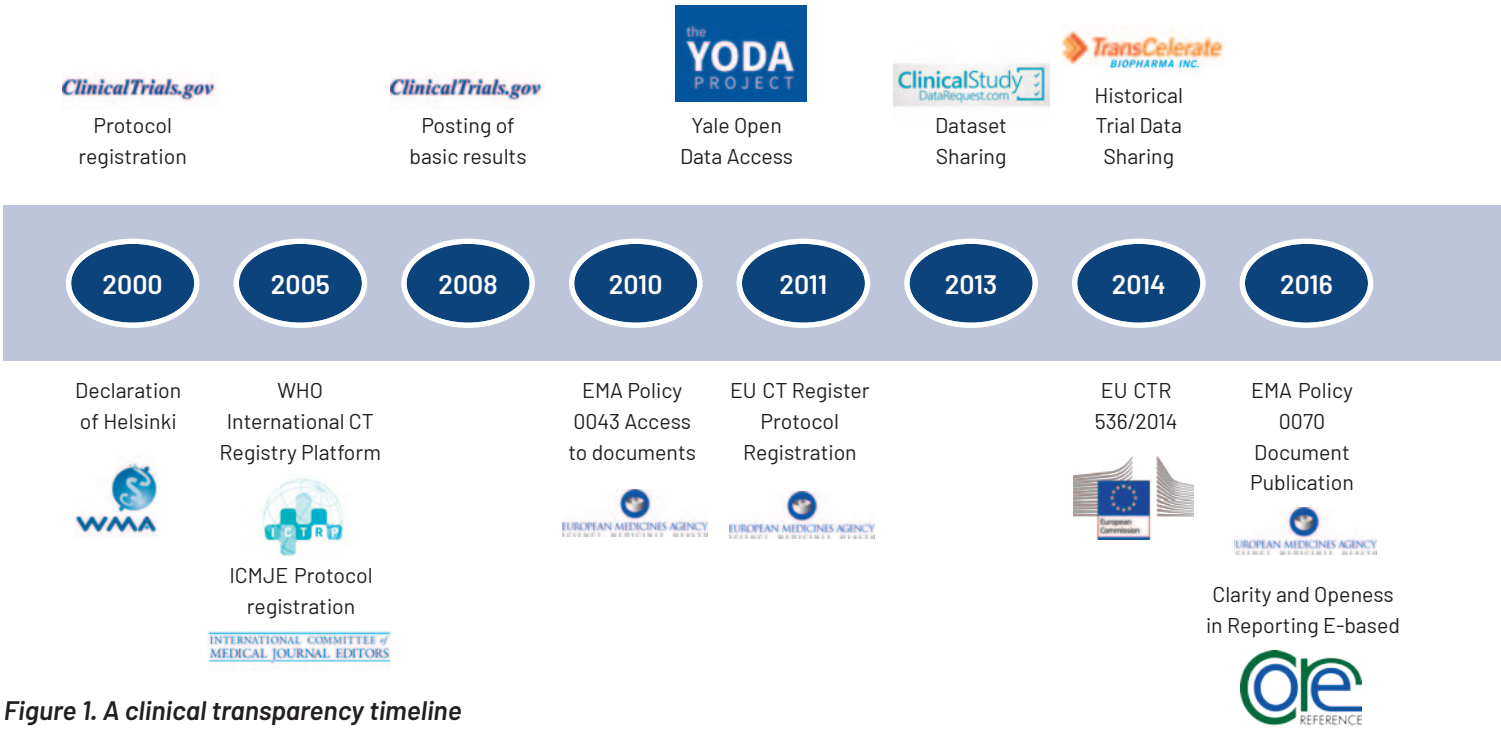

Figure 1. A clinical transparency timeline

"Transparency of clinical data – where does medical writing fit in?" at the 2014 Spring Conference in Budapest;

- Rollout of several EMWA workshops on data transparency at the November 2016 go-live date conference, in sync with the go-live date of the EMA clinical data website;
- Also in 2016, launch of CORE Reference (Clarity and Openness in Reporting E3 based), a collaborative work of EMWA and AMWA, now designated as an EMWA special project;
- Several symposia since 2014 that focused on this topic, e.g., "Transparency and Disclosure of Clinical Regulatory Documentation" (2017), "Plain Language Summaries for Scientific Publications" (2022), and the "EU CTR and CTIS" (2023);
- Several issues of the EMWA journal related to data transparency, e.g., "Public Disclosure" June 2018, "The Data Economy", June 2020, "Open Science and Open Pharma", Dec 2022, and of course, this issue. Our sincere thanks to Alison McIntosh and Holly Hanson and our contributors for the great work in putting together this edition.

The journey continues – transparency and disclosure are still nascent in other fields of research. Clinical research in medical devices and in vitro diagnostics is still awaiting a fully functional European Database for Medical Devices (EUDAMED) to be on par with medicinal products.

Our roles and responsibilities as medical writers have evolved with the new disclosure requirements. We used to be bound to trade secrecy and data confidentiality. We now have become protectors of patient personal data, stewards of data and document utility, and advocates of plain language communications. Our texts have become leaner and more focused, written with public disclosure in mind.

Medical writers are the proud champions of data transparency and public disclosure in health care. And this issue stands witness to this. Happy reading.

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