# **Trends in regulatory writing:** A brief overview for aspiring medical writers

**Surayya Taranum, PhD** 4Clinics, Paris, France

#### Correspondence to:

Surayya Taranum, PhD 4Clinics 18 rue Goubet 75017 Paris +33 648214454 surayya.taranum@gmail.com

## Abstract

The EU regulatory system is undergoing a major overhaul. Several new pieces of legislation are now in place to enforce harmonisation and transparency in clinical trials while ensuring data security and individual privacy. New and aspiring medical writers need to be aware of trends in the regulatory landscape to adapt to new requirements in technical documentation. This article is an overview of the evolving trends in EU regulations for medical devices (Medical Device Regulation and In-Vitro Device Regulation) and data compliance (General Data Protection Regulation and EMA Policy 0070), and the impact of artificial intelligence (AI) on the global medical writing market.

## Background

The European market comprises of 28 member states of the European Union (including the UK), the European Economic Area (Iceland, Liechtenstein, and Norway), Switzerland, and Turkey. As free movement of goods is a key strength of the European Single Market, there are critical regulations (as listed in the 2016 version of the Blue Guide on EU products) in place to ensure safety and quality of products.<sup>1</sup> Pharmaceutical and medical device regulations are important to ensure safety and efficacy of medicines, and protect public health. The EU has witnessed considerable overhaul of the



regulatory system for clinical trials and medical devices in the last few years to create a centralised and transparent procedure of assessment that can be implemented across member states. Biopharma and medical device companies are required to submit documents for approval of both new and existing products that are in line with regulations. The following sections discuss key regulations and trends that are of interest to medical writers.

# New EU medical device regulations

The European medical devices market is the second largest in the world after the US, worth around \$115 billion in 2017, with nearly half a

million different types of medical devices made by more than 27,000 companies.<sup>2</sup> The Active Implantable Medical Devices Directive (AIMDD) 90/385/EEC,<sup>3</sup> the Medical Devices Directive (MDD) 93/42/EEC<sup>4</sup> were introduced in 1992, and the In-Vitro Diagnostics Directive (IVDD) 98/79/EC<sup>5</sup> was introduced in 1998 to ensure harmonised standards to compliance. These directives defined the "essential requirements", which are standards met by the manufacturer for the design and production of the device, its risk assessment and product marketing to get the *Conformite Européenne* (CE) marking on the device. The MDDs defined three categories of devices based on risk assessment:

• Low-risk Class I devices for which the



manufacturer is allowed to affix the CE mark and register it with the national authority, which will check if the manufacturer has complied with all the requirements.

• High-risk Class II and III devices controlled through conformity assessment and market surveillance procedures by a Notified Body (NB, which is an accredited organisation that conducts conformity assessment of a medical device and issues the CE mark) and Competent Authority (CA, which is a the government body in a member state responsible for transposing the MDD into national law, and for specifying the NBs in that member state).

The EU has witnessed considerable overhaul of the regulatory system for clinical trials and medical devices in the last few years, in order to create a centralised and transparent procedure of assessment that is valid throughout the EU.

Under the MDD, once a medical device receives its CE mark in one country, the manufacturer is free to market it to other countries within the EU. Thus, the MDDs supported the creation of a single market for medical devices in Europe. However, their interpretation and implementation was left to the discretion of national governments.

In 2010, a global scandal erupted over breast implants, when it was discovered that the French company *Poly Implant Prothèse* was using silicone to fill rupture-prone implant units.<sup>6</sup> In 2012, the US FDA published a report on medical devices approved in Europe but not in the US due to safety concerns.<sup>7</sup> Several other adverse events linked to medical devices were reported between 2015 and 2018 that exposed the need for a regulatory overhaul in the EU.

#### Medical Device Regulation and In-Vitro Device Regulation

New medical device regulations were introduced in May 2017 (to replace the MDDs)<sup>8,9</sup> to overcome weaknesses that allow medical devices to stay on the market without sufficient clinical evidence of their safety and performance, and to ensure greater harmonisation in implementation across EU member countries. First, the European MEDDEV 2.7.1 Rev. 4 guidance on clinical evaluation reports (CER) was published in June 2016 and was a critical component in submissions for product approvals. Next, to establish a more robust EU legislative framework to ensure patient health and safety, the European Parliament approved two key regulations on May 25, 2017:

- Medical Devices Regulation (MDR 2017/745)<sup>10</sup>
- In-vitro Device Regulation (IVDR 2017/746)<sup>11</sup>

The MDR provides a 3-year transition period to May 26, 2020, and the IVDR a 5-year transition period to May 26, 2022. By these dates, certification of all new devices and recertification of existing devices must comply with these regulations. The regulations will take effect in every EU member state, and will not require any national legislation for implementation.

#### Impact of the EU MDR and IVDR

The MDR incorporates features from the MEDDEVs that will oversee a shift from a preapproval method toward CE marking, to a product life-cycle approach to improve robustness, transparency, and traceability of the regulatory system. The regulation emphasises on responsibility for all actors in a product's lifecycle to establish high levels of product safety and performance. The regulatory transition will affect all stages of device development including production, distribution, and monitoring. Major changes include:

#### Reclassification of some medical devices

There are additional classification rules to consider when classifying a medical device, and some revisions to the existing rules. The term "medical device" is now expanded to include products meant for disease diagnosis, implanted cosmetic devices, and products that do not have a direct medical intent (e.g., sterilisation products, condoms, fillers). The changes in classification of medical devices may mean that many devices will be placed in a higher-risk class and subject to additional regulatory requirements. Another major amendment is the recognition of software that is used to diagnose or treat disease (both standalone and embedded in a device) as a medical device, and subject to conformity assessment based on its developmental cycle, risk management, and validation. Devices that are introduced to or absorbed by the body are placed in a separate classification system. The key changes brought about in the IVDR include genetic testing, performance evaluation, reference laboratory testing and a new risk classification system for in-vitro devices (IVDs), and NB involvement in majority of IVD certifications.

#### Role of economic operators

The new regulation provides guidelines on the responsibilities of all economic operators (including manufacturers, distributors, suppliers, subcontractors, assemblers, and authorised representatives) in the supply chain for a medical device with regard to its Whether technical documentation, labell-AI can be ing, complaint submissions, and sophisticated post-marketing surveillance.

enough to replace the

#### Changes to notified bodies

medical writers NBs will be subjected to remains to be greater scrutiny by CAs; strict designation requirements and seen. evaluation of NBs to monitor and assess their capabilities may mean that a number of NBs may not be re-notified. Designated NBs will work closely with the European Commission to ensure that their clinical evaluation and post-market clinical followup plans are adequate before gaining certificates for certain classes of devices, and will be required to follow stricter procedures in conformity assessments of high-risk Class III medical devices.

#### Unique Device Identifiers (UDIs) and implant cards

Manufacturers are required to include UDI trackers along with the technical documentation for the device. The UDI is the key identifier of a medical device in the manufacturer's database and distribution chain, in the European Database on Medical Devices (EUDAMED), on certificates, and on the Declaration of Conformity. The UDI will be used in reporting serious incidents and safety correction actions, and in identifying counterfeit devices. Implant cards are required to carry information on the device lifetime and follow-up procedures for all implantable devices.

#### **Clinical evidence**

Under the EU's MDD 93/42/EEC, clinical

evaluation reports (CERs) and CE certifications were based on product equivalency. The new MDR requires technical documents relevant to each stage of the product cycle. In addition, the MDR requires all existing "legacy" medical devices to undergo conformity assessment according to the level of risk, even if previously approved under the MDD/AIMDD i.e., no "grandfathering" of devices will be considered. Stronger clinical data, including post-market safety and performance data are required for the certification and recertification of medical and in-vitro devices. There will be tighter regulations for compliance based purely on equivalence, requiring in-depth assess-

ments and increased expectations of NBs, and rigorous technical documentation methods.

#### Post-marketing safety and surveillance

Unlike pharmaceutical drugs, the control point of medical devices is through post-marketing surveillance rather than pre-marketing tests. The EU, under the MDDs, relied on

a decentralised approach where national regulators were responsible for collecting incident reports, and devices were reassessed if safety issues were raised. Under the MDR, it is no longer sufficient for manufacturers to review and analyse complaints registered on their databases. Companies are required to be proactive in gathering information about their devices. Technical documentation under the MDR now requires a post-market surveillance (PMS), post-market clinical follow-up plan (PMCF) and periodic safety update reports (PSUR) that address two main concerns:

- Is the device safe and does it perform its intended function?
- How can the device be improved?

#### The EUDAMED database

EUDAMED stores regulatory information from manufacturers and NBs and serves as an information exchange platform (a registry for manufacturers, medical devices, adverse incidents, authorized representatives, and Declarations of Conformity) between the European Commission and Competent Authorities of the member states. Under the MDR, it will also store information on postmarketing safety and surveillance activities, PSURs, safety and clinical performance reports (SSCP), device registrations, NBs, certificates, serious incidents, clinical investigation data, and UDI Information.

Ultimately, the MDR aims to bring postmarket surveillance of devices into a continuous product evaluation and improvement cycle that is linked to risk management information on the EUDAMED platform.

#### The challenges ahead

The MDR requires adherence to stricter regulations to ensure quality and safety of medical devices; it also requires all medical devices to conform to the regulation by May 26, 2020. While companies will have until May 26, 2022 before the IVDR takes effect, ensuring compliance under this regulation will be a bigger challenge; under the IVDR, nearly 85% of IVDs (an estimated 35,000 IVDs) will require clinical evidence for regulatory approval, compared to 7% under the IVDD.

The MDR/IVDR also requires all NBs functioning under the MDDs to apply for their NB designation, which must be approved before the NBs can proceed with conformity assessment procedures for devices. Due to stringent requirements for NB designation, the number of NBs could be much lower than before; the EC estimates designating 20 NBs by the end of 2019.<sup>12</sup> Brexit adds another layer of complexity as the UK NBs certify a substantial number of medical devices for the EU market; the EC states that in case of no-deal Brexit, all devices certified by UK NBs must comply with the EU import requirements.<sup>13</sup> Further, as of July 2019, the EC has designated only two NBs for the MDR (BSI UK and TÜV SÜD)<sup>14</sup> and none for the IVDR, which will increase the NB workload and add to the challenges that manufacturers will face in ensuring compliance.

Medical devices typically have short lifecycles (2-5 years), fast development timelines, and tough market competition. The rigorous requirements for certification under the MDR/IVDR, and the increased demand for clinical and safety data for medical devices are likely to delay their CE marking, and increase barriers to entry in the European market. Companies may have to review their portfolios to assess whether there will be sufficient return on investment for certain products to remain



viable. Upgrading and implementing a quality management system to encompass the entire lifecycle of a device can also require significant financial investment, which will have an impact on small and mid-sized companies. As a result, some estimates indicate that the number of certified devices entering the EU market could reduce by 30%, and that up to 50% of devices could die out.<sup>15</sup>

Traditionally, the EU was the first market to receive new medical technology, as the MDDs provided quicker channels to implementation for new medical devices than the FDA. One consequence of the MDR/IVDR would be that companies seek to develop and launch their products outside Europe at first, and enter the European market once they have gathered sufficient clinical and post-market surveillance data. Companies that relied on EU certification to market their products in other countries (e.g., Australia and the US) may re-evaluate their sales strategies and opt to obtain market clearance outside the EU.<sup>16</sup> The US FDA has announced its strategic priorities during the 3-year MDR transition period to take steps to "reduce the time and cost of generating clinical evidence, typically the most expensive and lengthy regulatory requirement for marketplace entry" while balancing pre-market and post-market data collection to make the system easier to navigate.<sup>15</sup> Meanwhile, Latin American countries with faster marketing approval processes are also emerging as an attractive option for medical device companies.<sup>17</sup>

The months leading to May 27, 2020, when the MDR takes effect will present a lot of uncertainty and challenges for medical technology companies. At the same time, the increase in documentation required for medical device approval means that more medical writing opportunities will become available. Medical writers will be able participate in developing technical documentation for entire product lifecycles, and gain deeper insights into the fastdeveloping, innovative medical technology industry.

## GDPR vs. EMA Policy 0070 – A balancing act

The EU General Data Protection Regulation (GDPR)<sup>18</sup> is a set of compliance regulations that came in effect on May 25, 2018, to harmonise data protection and privacy of all EU citizens across all member states. According to the

GDPR, personal data are:

... any information relating to an identified or identifiable natural person ("data subject"); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural, or social identity of that natural person.

The GDPR applies to any organisation that handles data that comes from EU citizens, including companies based in the EU and those that collect (controllers) or process (processors) data from EU citizens. It is a complex regulation that identifies data as anything that can identify an individual directly or indirectly; non-compliance can result in significant financial penalties. The scope of GDPR in healthcare broadly encompasses these key takeaways:

• Strict definition of patient consent while acquiring personal data – organisations are expected to obtain explicit consent for the collection and storage of all personal data, and to be transparent about its intended use.



The EU Clinical Trial Regulation 546/2014 (which replaced the EU Clinical Trial Directive No. 2001/20/EC) aims to harmonise clinical trial submission and assessment across EU member states, and ensure highest standard of safety for trial participants and transparency of information sharing.

- Removal of patient data or the patient's right to be forgotten – organisations can no longer hold personal data indefinitely and are required to delete all information permanently upon a patient's request.
- Data protection all organisations that collect and store patient data must take measures to ensure security, pseudonymisation, and data privacy to avoid compromising patient data. Risk assessment procedures must be in place to address any data breaches.

The EU Clinical Trial Regulation 546/2014 (which replaced the EU Clinical Trial Directive No. 2001/20/EC) aims to harmonise clinical trial submission and assessment across EU member states, ensure highest standard of safety for trial participants, and transparency of information sharing.<sup>19</sup> EMA Policy 0070 (released in March 2016) enables access to clinical trial documents by academics and researchers to enrich scientific expertise and innovation within the pharmaceutical industry.<sup>20</sup> Under EMA Policy 0070, companies are required to make GDPR-compliant public disclosure of selected clinical trial documents in a public portal. The policy is applicable to trials conducted within and outside the EU; including approved, disapproved, and withdrawn marketing authorisation applications.

The two legislations make it imperative for organizations to find the right way to balance data protection and privacy requirements with transparency and public disclosure. Anonymisation of participants is essential to ensure privacy and prevent re-identification of patients in trial documents that are disclosed to the public. To ensure highest standard of data protection, clinical trial documents under EMA 0070 policy will be disclosed in two phases:

- Phase I concerns disclosure of common technical document (CTD) clinical overview (Module 2.5), clinical summaries (Module 2.7), Clinical Study Reports (CSR) and its appendices (including the protocol and its amendments, case report forms, and statistical analysis plans).
- Phase II will include the publication of anonymised individual patient data, and will be implemented after Phase I disclosures are complete.

This requires the practice of rigorous methodology and anonymisation techniques in preparing trial documents. Proactive anonymisation can be used by removing (e.g., patient name and geographic location) or replacing sensitive information (e.g., banding, where age is replaced by age range, or calendar dates by relative dates) to avoid redaction during public disclosure of documents. To ensure transparency during redaction, an anonymisation report that includes the methods of redaction and their impact on data quality is required.<sup>21,22</sup> A risk assessment plan is also critical for mapping out the procedures to follow in case of a re-identification attack.

In addition to ensuring compliance in clinical trial documents, it is essential that information on all other platforms (e.g., journal publications, company websites, regulatory agency websites, congress abstracts and posters, patient organisation websites) is consistent with clinical trial data on public databases. Medical writers have a critical role in ensuring a balance between public disclosure of trial documents without compromising GDPR compliance, maintaining transparency, and gaining public trust.

# Artificial intelligence and medical writing

The fast-evolving artificial intelligence (AI) technology has the potential to disrupt every stage of the \$63 billion clinical trials market, from drug design, patient recruitment and medication adherence, to gathering real-world evidence.<sup>23,24</sup>

Some of the challenges that AI-enabled technology can be used to address include:

#### The challenge of real-world evidence

Traditional clinical trials are the gold standard for evaluating a drug's risk/benefit profile, but are not comprehensive enough to explain how the drug will perform in the 'real world' with a heterogeneous patient population. Real-world evidence (RWE) is information derived from real world data (RWD), or health data acquired outside of a clinical trial i.e., during clinical practice. The need for RWD exists because conventional approaches to drug development are time and cost-intensive (exceeding 8 years in development with costs of over \$2 billion), and come with no guarantee for success. Therefore, it is important to analyse and integrate RWE in healthcare to empower physicians, and provide patient-focused treatments while reducing healthcare costs.

The second annual RWE Benchmarking Survey from Deloitte reports that 90% of pharmaceutical companies are building RWE analytic capabilities through the entire product cycle via investments, technology, and external collaborations.<sup>25</sup> RWE is useful both in improving clinical trial design and execution through upstream incorporation of RWE-driven expertise (e.g., use of synthetic control arm instead of an actual control arm), as well as monitoring post-launch safety of drugs.

The process of collecting and using RWE is not straightforward, and there is a dearth of standardised and reliable procedures that can be integrated in clinical studies. Typical sources of RWD include insurance claims, electronic health records (EHR), patient registries, patientgenerated data (e.g., mobile and wearables, or "Internet of Things" devices), patient-reported outcomes, and social media insights. How useful data can be extracted from these diverse channels and analysed for clinical investigations in a GDPR-compliant manner remains a challenge.<sup>26</sup> Automation of data extraction, retention and expiry can help ease the burden of regulatory compliance while enabling companies to capture and evaluate valuable RWD.

#### Data mining in pharmacovigilance

The WHO defines pharmacovigilance (PV) as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drugrelated problem".27 With the advent of digital media, the number of adverse events (AEs) reported has increased dramatically; in 2017, the FDA received reports of over 1.8 million AEs related to drug use, a 400% increase from the 363,171 reports it received in 2007.28 To build robust drug safety surveillance systems, pharma companies are seeking to mine "big data" to identify AEs from other electronic data sources, including EHRs, medical literature, and social media.<sup>29</sup> The sheer volume of available data raises the cost of collecting, evaluating, processing, and reporting of AEs. Companies are increasingly turning to PV automation to streamline process steps, reduce time and labour costs, and speed information delivery while ensuring compliance. Examples include robotic automation of manual steps that do not require human intervention, and AI-enabled approaches where the PV system can interpret and analyse the source documents, perform seriousness assessment and medical review on appropriate content.

# Can AI-enabled technology replace medical writers?

Given the range of AI-enabled functions, there is now an increasing interest in its applications in regulatory documentation. The ultimate concern for medical writers is whether AI and machine learning can replace their role in preparing technical documents.

Following the EMA 0070 policy, there is interest in using AI applications in redacting sensitive information from clinical trial documents. While AI-enabled automation so far has not made major inroads into regulatory writing, technologies that enable automation of at least part of the regulatory document preparation are already available. For example, Synchrogenix has developed an innovative platform combining SaaS-based AI and naturallanguage processing technology that uses context-based understanding in automated authoring tasks.<sup>30</sup> The Synchrogenix AI tool is capable of taking information from previous study documents including CTDs, statistical analysis plans, tables, and figures, and placing them under the right sections of a CSR. Recent reports about the first AI-generated textbook using machine learning,<sup>31</sup> automation of scientific writing and literature research through neural networks<sup>32,33</sup> carry the promise of speeding up scientific and technical document preparation, and are likely to be widely used by medical writers in the future.

The sweeping regulatory changes in recent years are proving to be a rich opportunity for growth in medical writing. In fact, according to a report by Acumen Research and Consulting, from 2019–2026, the global medical writing market is expected to grow to US\$3.6 billion.<sup>34</sup> For PhDs seeking to transition outside academia, there has never been a more exciting time to be a medical writer!<sup>35</sup>

#### **Conflicts of interest**

The author declares no conflicts of interest.

## References

- European Commission. The 'Blue Guide' on the implementation of EU products rules. 2016 [cited 2019 Aug 05]. Available from: https://eur-lex.europa.eu/legalcontent/EN/TXT/PDF/?uri=CELEX:52 016XC0726(02)&from=BG.
- MedTech Europe. The European Medical Technology Industry 2019. [cited 2019 August 05. Available from: https://www.medtecheurope.org/wpcontent/uploads/2019/04/The-European-Medical-Technology-Industry-in-figures-2019-1.pdf.
- EUR-Lex. Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices. 1990 [cited2019 August 05]. Available from: https://eur-lex.europa.eu/legalcontent/EN/TXT/?uri=CELEX%3 A31990L0385.
- EUR-Lex. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. 1993 [cited 2019 August 05]. Available from: https://eurlex.europa.eu/LexUriServ/LexUriServ.do? uri=CONSLEG:1993L0042:20071011: EN:PDF.
- EUR-Lex. Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. 1998 [cited 2019 August 05]. Available from: https://eur-lex. europa.eu/eli/dir/1998/79/2012-01-11.
- Frumento C. French breast implants, the Medical Device Regulation, and a theoretical case study. Med Writ. 2017;26(2):39–40.
- US Food and Drug Administration. Unsafe and ineffective devices approved in the EU that were not approved in the US. Silver Spring, MD: US Food and Drug Administration; 2012 [cited 2019 August 05]. Available from: http://www.elsevierbi.com/~/media/ Supporting%20Documents/The%20Gray

%20Sheet/38/20/FDA\_EU\_Devices\_ Report.pdf.

 European Commission. Press release – New EU rules to ensure safety of medical devices. 2017 [cited 2019 August 05]. Available from: http://europa.eu/ rapid/press-release\_MEMO-17-848\_en.htm.

- European Commission. Regulatory framework. [cited 2019 August 05]. Available from: https://ec.europa.eu/ growth/sectors/medical-devices/ regulatoryframework\_en#new\_regulations.
- Eur-Lex. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. 2017 [cited 2019 August 05]. Available from: https://eur-lex.europa.eu/eli/ reg/2017/745/oj.
- Eur-Lex. Regulation (EU) 2017/746 of the European Parliament and the Council of 5 April 2017 on in vitro diagnostic medical devices. 2017 [2019 August 05]. Available from: https://eur-lex.europa.eu/legalcontent/EN/TXT/PDF/?uri=CELEX:32 017R0746&from=EN.
- Emergo. State of flux: European Notified Body numbers decrease further ahead of MDR, IVDR. 2019 [cited 2019 August 05]. Available from: https://www.emergobyul.com/blog/2019 /07/state-flux-european-notified-bodynumbers-decrease-further-ahead-mdr-ivdr.
- Mondaq.com. European Union: Update On The Implementation Of The European Medical Devices Regulation And In Vitro Diagnostics Regulation. 2019 [cited 2019 August 05]. Available from: http://www.mondaq.com/unitedstates/x/ 832142/Healthcare/Update+On+The+Im plementation+Of+The+European+Medica l+Devices+Regulation+And+In+Vitro+Di agnostics+Regulation.
- 14. RAPS. EU MDR/IVDR: US Raises
  'Serious Concerns,' Urges 3-Year
  Implementation Delay. 2019 [cited 2019 August 05]. Available from: https://www.raps.org/news-andarticles/news-articles/2019/8/eumdrivdr-us-raises-serious-concerns-urges-3
  ?utm\_source=MagnetMail&utm\_medium
  =Email%20&utm\_campaign=RF%20Toda y%20%7C%202%20August%202019.
- Vascular News. Europe braces for harder times in medical device innovation while US FDA eases regulations. 2018 [cited 2019 August 05]. Available from: https://vascularnews.com/europe-bracesfor-harder-times-in-medical-device-

innovation-while-us-fda-easesregulations/.

- Parenteral Drug Association. European Implementation of Medical Device and IVD Regulations - Implications for Australia. 2019 [cited 2019 August 05]. Available from: https://pda.inloop.com/en/ article/123034?id=123034.
- Martinez-Clark JG. Latin America Offers Welcoming Entry Market Amid Tighter EU Regulations. 2019 [cited 2019 August 05]. Available from: https://www.meddeviceonline.com/doc/ latin-america-offers-welcoming-entrymarket-amid-tighter-eu-regulations-0001.
- GDPR.EU. Complete guide to GDPR compliance. [cited 2019 August 05]. Available from: https://gdpr.eu/.
- Thomas KB. Clinical trial disclosure and transparency: Regulation EU No. 536/2014, Public disclosure at the clinical trial level. Med Writ. 2018;27(2):7–17.
- European Medicines Agency. European Medicines Agency policy on publication of clinical data for medicinal products for human use (EMA Policy 0700). 2019 [cited 2019 August 05]. Available from: https://www.ema.europa.eu/en/document s/other/european-medicines-agencypolicy-publication-clinical-data-medicinalproducts-human-use\_en.pdf.
- Billiones R. Anonymisation reports from 2016 to 2017: A preliminary analysis. Med Writ. 2018;27(2):22–6.
- Martinsson L. Preparing anonymisation reports in general and for an orphan drug in particular. Med Writ. 2018;27(2):27–30.
- 23. CB Insights. The clinical trials industry needs a makeover. Here are the technologies looking to shake up the \$65B market. 2019 [cited 2019 August 05]. Available from: https://www.cbinsights.com/research/clinical-trials-technologies/.
- 24. CB Insights. The future of clinical trials: how ai & big tech could make drug development cheaper, faster, & more effective. 2018 [cited 2019 August 05]. Available from:

https://www.cbinsights.com/research/ clinical-trials-ai-tech-disruption/

25. Deloitte. Getting real with real-world

evidence (RWE). 2018 [2019 August 05]. Available from: http://learn.deloitte.com/ rwe-survey-deloitte-insights.

- 26. Cynober T. Artificial intelligence in oncology: Fantasy or reality? Labiotech.eu 2019 [cited 2019 August 05]. Available from: https://labiotech.eu/features/ artificial-intelligence-oncology/?utm\_ source=twitter&utm\_medium=social&ut m\_campaign=meetedgar.
- World Health Organization. Looking at the pharmacovigilance: ensuring the safe use of medicines. [cited 2019 August 05]. Available from: http://apps.who.int/ medicinedocs/pdf/s6164e/s6164e.pdf.
- Clark R. 62% of Drug Safety Experts Say They're Using AI to Improve Adverse Event Reporting. 2018 [cited 2019 August 05]. Available from: https://www.copyright. om/blog/drug-safety-using-ai-adverseevent-reporting/.
- Ventola CS. Big data and pharmacovigilance: Data mining for adverse drug events and interactions. 2018 [cited 2019 August 05]. Available from: https://www.ncbi.nlm.nih.gov/pmc/

articles/PMC5969211/.

- Brennan Z. Synchrogenix acquires AI-assisted medical writing company ClinGenuity. Outsourcing-pharma 2015 [cited 2019 August 05]. Available from: https://www.outsourcingpharma.com/Article/2015/01/07/Synchr ogenix-acquires-AI-assisted-medicalwriting-company-ClinGenuity.
- 31. Vincent J. The first AI-generated textbook shows what robot writers are actually good at. The Verge 2019 [cited2019 August 05]. Available from: https://www.theverge. com/2019/4/10/18304558/ai-writingacademic-research-book-springer-natureartificial-intelligence.
- Chandler DL. Can science writing be automated? MIT News 2019 [cited 2019 August 05]. Available from: http://news.mit.edu/2019/can-sciencewriting-be-automated-ai-0418.
- 33. Extance A. How AI technology can tame the scientific literature. Nature 2018 [cited 05 August 2019]. Available from: https://www.nature.com/articles/d41586-018-06617-5.

- 34. GlobalNewswire. Medical writing market size worth around US\$ 3.6 billion by 2026. Acumen Research and Consulting 2019 [cited 2019 August 05]. Available from: https://www.globenewswire.com/newsrelease/2019/06/11/1867022/0/en/Medi cal-Writing-Market-Size-Worth-Around-US-3-6-bn-by-2026.html.
- Alechine E, Basu S, Chang C. Cheeky medical writers: Transitioning from academia to medical writing. Med. Writ. 2018; 28(1):20–3.

# Author information

**Surayya Taranum**, PhD, is a Scientific Writer at 4Clinics. She is also Director for Membership at the Healthcare Businesswomen's Association (HBA) Paris Chapter, and Communications Lead at the HBA Entrepreneurship Group.

