

Drug development and medical writing in the digital world

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Abstract:

Artificial intelligence and digital health open a new chapter in the pharmaceutical industry. The digital technologies improve work efficiency, lower research and development costs, optimise medical research processes, and increase R&D outputs. The digital revolution had a significant impact on almost every aspect of drug development from pre-clinical to clinical studies with digital endpoints and post-market surveillance of safety events, and even for medical education. In the area of medical writing, digital technologies led to the transparency of medical research and close scientific communications in the paperless systems and offered more possibilities for scientific collaborations between study sponsors and clinical practitioners. The writing styles and publishing media became more diverse along with the use of mobile health apps. In parallel, new technologies also offer wider career pathways; therefore, writing professionals with multiple skills are needed in the digital world.

Development of artificial intelligence and digital health

Together with gene engineering and nanotechnology, artificial intelligence (AI) is mentioned as one of three cutting-edge technologies of the 21st century.¹ AI is defined as an area of developing computer systems that are able to perform multiple tasks in scientific and business environments that normally would require

human intelligence.² As a milestone of the fourth industrial revolution (or technological revolution), AI and digital health (DH) have created a new era in drug development and the pharmaceutical industry. It has penetrated almost every aspect of drug discovery and development, ranging from target selection, hit identification, lead optimisation, preclinical studies, and clinical trials to pharmacovigilance and monitoring of treatment adherence.^{3,4}

In the past 40 years, China's industry outputs continuously increased. In 2000, the expenditure for the healthcare sector accounted for 4.6% of the total GDP and is estimated to increase to

8.5% in 2020. The healthcare investment in 2020 is estimated to be 22-fold higher than in 2000.⁵ In a business report by the Deloitte consulting firm, the expenses of a new drug from research & development (R&D) to market launch were \$1.19 billion in 2010 while the costs increased to \$2.17 billion in 2018. However, the return on investment was merely 3.2% of the total R&D costs.⁶ Therefore, given higher costs and relatively lower market outputs, optimisation of R&D processes, methods, and resource allocations are on the agenda of medical professionals, stakeholders, and investors. The concepts of AI and DH bring wider and more



innovative perspectives to medical specialists and business players on R&D of drugs that are leading to improving medical research processes and transforming business models.

Links between drug development, AI, and DH

In the digital world, drug development experienced earthshaking innovations. The categories of medical research became more heterogeneous. The digital progress brought more possibilities into medical research (e.g., real-world and health economics studies) and collaborations among study sponsors, clinical investigators, and database service providers. Clinical data collection can be easily realised via electronic health records (EHRs) and personal health records (PHRs). The changes were not

limited to the clinical phases of medical research. For instance, in the pre-clinical phase, a digital polymerase chain reaction method was developed to perform DNA sequencing and bone marrow sampling to evaluate disease progression and manage disease risks.⁷ In the clinical phase, digital study endpoints drive innovations and reduce costly late-stage drug development failures. The study design involvements with digital endpoints are evaluated by regulatory agencies [e.g., US FDA (United States, Food and Drug Administration)] as innovative practices. In a study that was conducted by Boehme et al.,⁸ smartphone apps were used to track

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mobility patterns and a MOBILISED-D algorithm was created to detect real-world walking speeds. Given that the parameter of gait speed is associated with patients' survival, a walking test, as a surrogate mobility test, was

designed to evaluate the patient survival status by measuring the number of steps over time.^{9,10} In addition to involving digital endpoints in clinical studies, the importance of remote monitoring (e.g., monitoring of adverse events) and digital patient management (e.g., medication guidance, treatment compliance, and medical educations) have already been recognised by the US FDA.

Except for medical research, in the digital design areas of pharmaceutical manufacturing, the technology of 3D printing, instead of tablet compression, is applied to 3D drug products to improve safety, efficacy, and accessibility to medicines.¹¹ The competitive advantages of 3D printing exist in complex and personalised products, and products made on demand. The US FDA approved the first digital drug (ReSETM) in 2018 for treating patients with substance use disorders.¹² In China, traditional medicines stepped into global markets via business models of telemedicines (i.e., purchasing medicines online).¹³ More and more local high-tech digital and IT companies initiated collaborations with the industry, universities, and institutes to explore interprofessional innovations.^{13,14} In a survey of local physician communities involving 7,395 questionnaires, approximately 94% of physicians showed interests in DH wearables.¹⁵

Medical writing in the digital world

In the area of medical writing, the digitalisation progresses seem to have slower paces. In China, since 2008, the digital electronic archive systems of regulatory documents are being implemented by several global pioneer pharmaceutical companies. Since 2013, paralleled editing software (e.g., PleaseReview) was recommended for reviewing and editing regulatory documents. In 2019, the local health authority promised to launch an electronic system of regulatory submission following global electronic clinical



technical document (eCTD) standards. With the implementation of these new systems, regulatory and R&D professionals will be responsible for drafting, editing, reviewing, finalising, and publishing regulatory documents. The finalised documents will be sent out for consolidations with eCTD standards. The steps are completed by official regulatory vendors, and the application dossiers (including all the regulatory-compliant documents) will be submitted to the regulatory authority for reviews and approvals.

The benefits of digitalised regulatory writing consist of regulatory information sharing, improving work efficiency, lowering regulatory submission budgets, and creating new employment opportunities. In the e-system, the draft and intermediate versions can be edited, and all the changes are traceable, in compliance with global archival requirements. On the other side, information security, intellectual properties of regulatory documents, and electronic system compatibility are potential risks of digital writing. These potential issues, as well as public availability of medical research information, access to confidential regulatory documents, and qualifications of the professionals who can access confidential regulatory documents, are the questions that still need to be discussed.

In the US, social media use among adults increased from 5% in 2005 to nearly 70% in 2016.¹⁶ In 2017, 32% of social media consumers already had at least one health app on their smartphone or tablet, a percentage that had doubled since 2013.¹³ According to a published business analysis report released in 2016,¹⁷ the

top 3 mobile health app categories with the greatest market potential were remote monitoring (32%), diagnostic apps (31%), and medical condition management (30%). The content on social media covers drug development, clinical trial recruitment, therapy administration, adherence, information sharing of side effects, and responses. Therefore, medical writers with these skills and knowledge are needed and will be required in the employment market. For example, a mobile app (SBIRT: screening, brief intervention, and referral to treatment),¹⁸ as a highly promoted approach to identifying and treating individuals at risk for alcohol or drug problems, was developed to offer information on medical knowledge and skills from a classroom setting to clinical practice. The app was designed to focus on addressing alcohol and drug uses, and commonly co-occurring issues such as depression and anxiety.

Digitalisation pushes medical writing scopes to become more diverse. Some medical writers may prefer working on regulatory documents that are more formal and need to be compliant with International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use guidelines, while those who are interested in physician and patient education may prefer publishing in the area of medical education for lay audiences on social media or apps. For patient education materials on social media, medical writers need to master the skill of simplifying complex medical knowledge and medical education

information into plain language that is suitable for patients without medical expertise. In the area of remote monitoring, application of cloud-connected web portals and electronic mobile systems assist reviewing, reporting and analysing real-time patient data, observing drug-related problems during home visits, and communicating drug-related problems to general practitioners (GPs) and pharmacists.^{4,8,19} The content of public health awareness education is likely to be diverse since the audiences are not limited to patients, GPs, and pharmacists, but also to caregivers, babysitters, and patients' relatives with lower levels of literacy. Thus, simple, concise, and friendly information (i.e., what you see, is what you get) is important.

To be a qualified writer in the area of social health media, authors need to understand the users' reading habits and their psychological characteristics. Digital health media mainly focuses on the general public and those without formal medical education; therefore, the writing style should be adapted to the target audience. In some cases, even cartoons, videos, or interactive programs or games can be used to help deliver scientific knowledge more effectively. For instance, in the treatment of pain, epilepsy, stroke, dementia, and other chronic medical conditions, digital technologies are used to deliver music-

based interventions in combination with drug administration.²⁰ For example, in stroke treatments, a music-based video game (MusicGlove) received regulatory clearance by the US FDA following a pivotal clinical study. In developing such kinds of mobile health tools, knowledge of music therapy, composition skills, and script-writing ability would be advantageous strengths for job hunting and career developments. The career of DH writing may offer a new career pathway for those medical writing professionals who possess multiple talents and skills. The technologies of AI and DH add value and create more possibilities for medical writers (e.g., scientific scriptwriters in healthcare sectors of DH companies) and will be trends for writing professionals with diverse strengths and educational backgrounds.

In the digital era, scientific writing will be a core competency for a writing professional and multiple skills are encouraged in industry environments evolving at a fast pace.



Summary

We are in a transition period from traditional R&D business models to innovative ones. Application of AI and DH pushes the industrialisation of medical research more rapidly with higher efficiency. The career of medical writing thus become wider and more diverse due to technological progress. In the digital era, scientific writing will be a core competency for a writing professional and multiple skills are encouraged in industry environments evolving at a fast pace.

Conflicts of interests

The author declares no conflicts of interests.

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