President's Message

From scurvy to Covid-19: The role of clinical trials, and medical writing's crucial role in the process

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Dear EMWA friends and colleagues,

The medical writing community is intrinsically involved in regulatory documentation that spans the entire timeline of clinical research – from study protocols and informed consent to clinical study reports and even post-market pharmacovigilance. Hence, it is indeed apposite that the theme of this issue is Clinical Trials.

Medical research has come a long way since James Lind's scurvy trial in the 18th century to the first double-blind randomised controlled trial in 1946 investigating streptomycin in pulmonary tuberculosis. In the present day, clinical trials represent one of the most highly regulated activities of medical research, with an emphasis not only on scientific rationale but also on ethics in human experimentation. Although regulatory agencies, medical professionals, ethics bodies, and trial sponsors each have a role in the planning, design and execution of clinical trials, the key role is the one of the trial volunteers – the lay persons with a certain amount of motivation to get involved in the scientific process. While the Nuremberg Code of 1947 laid the foundations for including informed consent, the ethical principles integral to clinical trial methodology have since been refined to establish the Good Clinical Practice (GCP) guidelines. What this evolution has essentially underpinned is the need to principally bear in mind at all times the safety of the clinical trial volunteer. An informed trial participant is key to the success of a clinical trial, for on it depends participant adherence.

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The last 20 years have witnessed a steady growth in the number of clinical trials conducted worldwide with the most recent estimate from the World Health Organization's International Clinical Trial Registry Platform showing over a half million clinical studies registered worldwide in 2021. Although this is perhaps an unexpectedly large number, it gives a misleading impression that clinical research is spread across all regions of the world homogeneously; the majority of clinical research is conducted in the global north. This in itself does not come as a surprise since the cost and technical expertise required for running clinical trials makes it restrictive to the underdeveloped parts of the world. It is encouraging to note that in the last 10 years or so, various Asian countries are turning into clinical research hubs; currently China, India and the Republic of Korea feature in the top 15 countries by the number of ongoing clinical trials. This benefits clinical research in numerous ways mainly by promoting international collaborations, increasing diversity in the studied population, and speeding up the process. A stellar example of this in action is the rapidity with which Covid-19 vaccines could be investigated and brought to the public, thereby averting a much higher mortality that would have ensued in the absence of the vaccine. Needless to say, the world collectively owes gratitude to the volunteers who participated in these trials. Indeed, the clinical trial process is one where humankind volunteers to benefit others.

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Happy reading!

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