Session Report

Navigating Regulatory Medical Writing in an Evolving Clinical Landscape

Speaker
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On May 3rd, Andrea Clark, PhD, shared the importance of preparing scientific documents for drug and medical device development. As Manager of Regulatory Medical Writing at Aroga Biosciences Inc., she provides insight, clarity, and organization to documents submitted to regulatory agencies, ensuring they meet global regulatory guidelines. Andrea is a dedicated member of the medical writing community.

Regulatory Medical Writing supports pharmaceutical research from start to finish, encompassing the discovery phase, preclinical testing, and clinical trials. Clinical trials are a critical part of drug development, designed to evaluate the safety and efficacy of medicinal products in human participants. These trials, conducted in phases (Phase 1-3 for approval and Phase 4 post-approval), generate data essential for evidence-based healthcare decisions and regulatory review.

Regulation of Clinical Trials: Historically, clinical trials were poorly regulated until global authorities (FDA, EMA, MHRA, and PMDA) stepped in to protect participants' rights and ensure the reliability of trial results. Although not a regulatory body, the International Council for Harmonization (ICH) delivers harmonized guidelines for global pharmaceutical development. These guidelines, including the Declaration of Helsinki's ethical principles, provide a framework for conducting ethical and scientifically sound trials.

ICH E6 Guideline on Good Clinical Practice: Established in 1996 and updated through ICH E6(R2) in 2016, the ICH E6 guideline sets international, ethical, scientific, and quality standards for trials involving human participants. The primary goal is to protect participants' rights while ensuring the credibility of clinical trial data.

ICH E6(R3) 2023 Updates refine previous guidelines to accommodate modern clinical practices and technological advancements, emphasizing flexibility and risk-based approaches and enhancing sponsors' ability to use innovative trial designs and technologies. The following sections were implemented:

1. **Trial Design Considerations**

Decentralized Clinical Trials (DCTs) conduct trial-related activities at locations beyond traditional sites, using Digital Health Technologies (DHTs) to capture data directly from participants. This approach reduces participation barriers and improves enrollment. For instance, remote consent and expanded definitions of investigator sites (including local pharmacies) are encouraged.

Real-World Evidence (RWE) incorporates data from diverse sources, such as electronic health records and medical claims, into trial planning and execution. This approach supports dynamic modifications during the trial, enhancing efficiency and significance.

Adaptive Trial Design allows real-time modifications based on prespecified rules, such as eliminating ineffective treatment arms or reallocating participants to more promising interventions.

2. Expansion of Ethics
The ICH E6(R3) update ensures the protection of participants' rights and safety, even in decentralized and real-world data contexts. It advocates for clear, concise, informed consent forms and prevents unnecessary exclusion of patient populations.

3. Risk-Based Monitoring
The guideline emphasizes risk proportionality in clinical trials, ensuring trial processes align with the inherent risks and the importance of the information collected. It highlights the need to focus on participant risks beyond standard medical care and prospectively manage risks to critical quality factors. Additionally, data capture, management, and analysis systems must be fit for purpose and proportionate to participant risks and data significance.

4. Transparency and Data Security
The updated guideline underscores the need for reliable results, efficient record management, and public transparency. It requires clinical trials to be registered in publicly accessible databases.

By implementing these guidelines, pharmaceutical companies can enhance trial efficiency, protect participant rights, and meet regulatory requirements to advance drug development and public health.

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