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Medical Writing

Preclinical Studies

Nonclinical and preclinical research: A roadmap to unfamiliar terrain

Welcome to this special issue about nonclinical and preclinical research. Nonclinical and preclinical research is the first step toward new drug development, where scientists investigate mechanism of action, pharmacokinetics, and safety. Many medical writers spend their careers in the regulated world of registered clinical trials, where there are well-defined rules, endpoints, and guidelines for writing documents. To these writers, reporting the countless methods, standards, and models used in nonclinical and preclinical studies may seem complex and daunting. A writer may have to learn methodological details of X-ray crystallography, drug interaction models, genetically modified species, and cell culture. Experiments in a single manuscript may involve multiple animal models, in species that may vary from apes to mice to woodchucks to zebrafish. Guidelines for reporting these methods and models may be hard to find or nonexistent, and many journals offer only sparse reporting instructions. In other words, to a medical writer accustomed to clinical trials, reporting nonclinical and preclinical research may at first seem like the Wild West.

However, the various disciplines that make up nonclinical and preclinical research, such as toxicology, genetics, structural biology, pharmacokinetics, and pharmacodynamics have their own rules and guidelines that may be unfamiliar to members of other disciplines. Thus, behind the chaos of this Wild West is a loose structure, woven together from the threads of many disciplines. Yes, nonclinical and preclinical studies are often complicated, but they are integral for advancing new therapies and medications through clinical development. Clear, concise, and ethical communication of this research can guide discovery, reduce research costs, and, perhaps, contribute its own small bit to saving lives.

GUEST EDITOR

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This issue on nonclinical and preclinical studies begins with an article by **Jennifer Honek**. She explains the basics of drug development and the path new therapies must travel to move from bench to bedside. **Alexander Nürnberg and Hélène Pierre** introduce the growing world of nonclinical regulatory writing, explaining the distinct challenges that nonclinical research poses to the writer. **Heidi Lightfoot** argues for clear and routine reporting of all research, whether the outcome is positive or negative, and **Sandra Tillmann** uses practical examples to explain the importance of clear and concise methods in animal experiments. **Laia Pedro-Roig and Christoph H. Emmerich** follow with an article about the economic and scientific impact of the reproducibility crisis, offering practical solutions for improvement in preclinical research. Finally, **Anna Buryakina** and **Natalie Merkulova** cover problems and caveats associated with regulatory documents and preclinical studies in Russia.

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In addition to nonclinical and preclinical studies, this issue also has articles on other topics. **Ben Rogers, Jonathan Oliver, and Elsa Lewis** offer advice on surviving the Brexit as a medical writer. **Satoru Mogami and associates** report research on designing patient lay summaries for Japanese audiences. **Christian Kressmann and Stefan Lang** follow with an article about presenting and writing about science. Finally, **Claire Hawksworth and company** discuss the differences between medical writing and medical journalism.