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Short communication

Regulatory standards and key challenges in developing preclinical and clinical expert reports

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Introduction

Preclinical and Clinical Expert Reports are essential regulatory documents that provide a structured scientific evaluation of non-clinical and clinical data supporting the safety, efficacy, and benefit–risk balance of medicinal products. These reports are a critical component of regulatory submissions and must comply with international standards set by authorities such as the European Medicines Agency (EMA) (EMA, 2002), International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) (EMA 2000a,b) and Eurasian Economic Union (EAEU) (EEC, 2016).

Preclinical vs clinical expert reports

Preclinical expert reports focus on the systematic evaluation of pharmacology, pharmacokinetic (PK), and toxicological data from in vitro and in vivo studies. They provide the scientific foundation for early drug development by supporting understanding of biological activity, target engagement, dose–response relationships, safety margins, and potential organ toxicity. They are also essential for first-in-human studies, as they justify initial dose selection, exposure limits, and safety monitoring strategies. The quality and clarity of preclinical data interpretation directly impact regulatory confidence in advancing a compound into clinical development. Clinical expert reports, in contrast, integrate evidence from clinical trials across all phases of development, as well as real-world data where available. Their main purpose is to evaluate therapeutic efficacy, safety profile, and overall benefit–risk balance in humans. They combine data from controlled studies, subgroup analyses, and post-marketing surveillance to provide a scientifically sound and regulatorily compliant interpretation of clinical outcomes. A key challenge in both types of reports is ensuring scientific consistency and maintaining a clear, traceable link between preclinical and clinical findings. The translational bridge between nonclinical and clinical data can be complex due to differences between animal models and human physiology, variability in exposure–response relationships, and unexpected safety signals emerging during clinical development. Effective integration therefore requires critical scientific judgment, transparent methodology, and a structured narrative that connects mechanistic preclinical evidence with observed clinical behavior. This continuity is essential for robust regulatory decision-making and a coherent benefit–risk assessment throughout the product lifecycle.

Data quality and evidence generation

High-quality expert reports depend on the integrity and reliability of underlying data. Challenges include incomplete datasets,

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heterogeneity of study designs, and variability in reporting quality. Maintaining transparency in data selection, analysis, and interpretation is essential to ensure regulatory credibility and scientific robustness.

Literature search and scientific databases

A systematic and structured literature search is a cornerstone of expert report development. Reliable sources include biomedical and regulatory databases such as PubMed, Micromedex, Google scholar and Wiley Online Library, among others. Effective search strategies require the use of keywords, MeSH terms, and predefined inclusion/exclusion criteria to ensure reproducibility and minimize bias. Critical appraisal of retrieved literature is necessary to assess study quality, relevance, and methodological rigor.

Common challenges and pitfalls

Frequent issues in developing expert reports include: inadequate integration of preclinical and clinical data, poorly documented or non-reproducible literature searches, lack of critical evaluation of scientific evidence, weak justification of benefit–risk conclusions, inconsistencies in regulatory formatting and structure, etc. These challenges can lead to regulatory queries, delays, or rejection of submissions.

Best practices and regulatory compliance

Best practices in the preparation of regulatory documents CTD-based expert reports include the consistent use of structured reporting templates that ensure completeness, harmonization of content, and clarity of scientific communication across all sections of the dossier. A systematic literature review methodology is equally essential, as it ensures that all relevant scientific evidence is identified, appraised, and transparently documented. This includes the use of predefined search strategies, clearly defined inclusion and exclusion criteria, and reproducible screening processes across validated scientific databases. Critical appraisal of retrieved literature is necessary to assess methodological quality, reduce bias, and ensure that only robust and clinically relevant data are included in regulatory assessments. Strict adherence to international regulatory guidelines remains a cornerstone of high-quality submissions. Compliance with requirements from the European Medicines Agency (EMA), the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), the Medicines and Healthcare products Regulatory Agency (MHRA), and the Eurasian Economic Union (EAEU) ensures that regulatory expectations are consistently met across different regions. Alignment with these regulatory frameworks enhances the scientific robustness, transparency, and global acceptability of submissions. Ultimately, the integration of structured documentation, systematic evidence generation, and strict regulatory compliance strengthens the overall quality of pharmacovigilance outputs and supports efficient, globally harmonized decision-making.

Conclusion

The development of high-quality preclinical and clinical expert reports requires a combination of rigorous data evaluation, systematic literature review, and strong regulatory awareness. The role of the medical writer is central in ensuring clarity, scientific accuracy, and compliance. Strengthening these processes enhances the reliability of regulatory submissions and supports the safe and effective development of new therapies.

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