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Causality assessment of Serious Adverse Events in Phase 3 clinical trial by Ethics Committee-Initial experiences (304)

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Background: a study of the initial experiences in causality assessment of SAE by EC. Methods: Retrospective review of EC's 'minutes of SAE meetings', 2022-23. Results: A 1 year old EC reported 7 SAEs in 4 Phase-3 regulatory clinical trials. These included two deaths. EC members were GCP certified, but with no prior experience of, or formal training in causality assessment of SAE. Its SAE review sub committee used WHO-UMC, CDSCO Sugam portal (India), and ISCR online training; and solicited a) global breakup of SAE data from the sponsor, b) opinion of an independent specialist, c) sponsor's DMC report. The global SAE data, provided assurance that the SAE deaths did not exceed those at other centres. The EC decided to permit the study to continue. The regulatory authorities subsequently awarded compensation, based in part on the EC's SAE death reports. The EC SOP was updated. Conclusions: training of EC members, adherence to procedures, and online resources were helpful for correct causality assessment of SAE.

Rethinking Legal Personhood for Nonhuman Animals: Moving Beyond Rights-Based Approaches (229)

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This poster presentation explores the concept of legal personality and its potential application to nonhuman animals. While granting legal personality to animals may provide some legal protections, it has several limitations and challenges, such as determining eligibility and enforcing rights and protections. We argue that seeing animals as legal persons ignores their inherent differences from humans and that a new concept is needed to address their legal status. We propose a non-dualistic view that acknowledges animals' intrinsic value and moral weight and calls for recognizing their interests and respect, even if it does not serve a human function. Our argument is based on the idea that human beings have ethical responsibilities towards other animals, and that the law must protect those interests, even if the interest holder has no rights. We conclude by advocating for a multiplicity approach based on responsibilities rather than rights, recognizing the limitations of legal mechanisms and the need for education and public awareness. This approach acknowledges the complexity of the relationship between humans and animals and calls for a shift in legal and ethical frameworks towards a more inclusive and compassionate understanding of nonhuman.

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Duty to Rescue: A Healthcare Perspective (303)

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The service and care of patients are engrained in the training and practice of the healthcare providers that care for them. But what happens when a provider witnesses an emergency outside of their clinical setting? The question subsequently becomes, to what extent is the healthcare provider required by law to render assistance when removed from the context of their service location? Therefore, the "duty to rescue" doctrine - or the "duty of beneficence" - plays an important role in this conversation. At its core, the American tort law "duty to rescue" principle implies that there is no legal obligation to rescue a stranger in need. When considering the oaths and societal contracts providers enter into, it is important to examine the influence of this doctrine. Though specialists have analyzed the significance both inside and outside the clinical context, this article demonstrates a comprehensive integration of medicine and law surrounding the idea of rescue. With an understanding of this doctrine, of the legal circumventions of liability, and of the ethical foundations of medicine, we aim to illustrate the importance of this analytic exercise in more thoroughly understanding the overlapping nature of these distinct yet intertwined academic spheres.



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