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Theme: Life Sciences/Biotechnology

Assessment of risks and benefits in FIH trials of nanomedicine

Nanomedicine has tremendous potential for early and accurate disease diagnosis and targeted drug delivery, giving strong reasons to test these applications in first in human (FIH) trials. But the risk associated with this novel technology has to be accounted for at least at three levels: the potential risks to trial participants, the probability of these risks manifesting, and the seriousness of any adverse effects in terms of magnitude and harm. The decisions of research ethics committees are based on assessing risk-benefit balance but the question remains: how can we assess risks and benefit using pre-clinical data and animal studies and extrapolate it to humans, and achieve an objective evaluation of both risks and benefits to ensure scientific and technological progress and alleviate human suffering?

This paper presents the background, methodology and preliminary results of our empirical interdisciplinary research to explore the views, perceptions and methods of risk assessments used by various stakeholders involved in FIH trials with nanomedical applications. Forty in-depth qualitative interviews will be conducted within Switzerland and in Europe to document diverse views and perceived needs of the technology experts, nano-scientists and the ethicists. These insights could lead to formulation of technology-specific ethical evaluation guidelines for FIH trials which in future can also be applied to other emerging technologies.

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