Universität Basel

Research Project

Ethical challenges of translational research in Nanomedicine with focus on first in human (FIH) clinical trials: An exploratory qualitative research within Switzerland and globally.

Third-party funded project

Project title Ethical challenges of translational research in Nanomedicine with focus on first in human (FIH) clinical trials: An exploratory qualitative research within Switzerland and globally.
Principal Investigator(s) Satalkar, Priya ;
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Translational research involves long arduous path aimed at bringing promising discoveries from various scientific disciplines into clinical applications. This loop of translational research is often described as the research from 'the bench to the bedside'. First in human (FIH) clinical trials is a critical moment in translational pathway when a new medical application either diagnostic or therapeutic is tested in human beings for the first time after having collected sufficient data on toxicity and safety from animal models. These trials are often conducted on adult healthy volunteers or people suffering with terminal illness such as cancer who do not have any other therapeutic options and who are willing to undergo such a research on a voluntary basis. Nanomedicine is a novel technology which has potential to improve our existing therapeutic and diagnostic modalities and to alleviate human suffering. Advances in basic research in nanotechnology cannot transform into useful clinical applications without well planned and implemented clinical trials including first in human clinical trials. These trials will gather sufficient data on safety, tolerability and adverse effects of nanomaterials and nanoformulations and also allow the scientists to modify the formulations and make them better targeted. Nanoparticles by their sheer size and novel physical chemical, electromagnetic properties create possibilities for improved medical applications but also bring the concerns of penetration of particles into deep body spaces which are impermeable to particles at larger size scale. There is a valid concern of long term accumulation of these particles in human body leading to chronic toxicity. Decision to begin a first in human trial with such novel medical application of nanotechnology often involves various stakeholders who have to work together in a well- coordinated manner in spite of various conflicting interests. The overall goal is to improve human health and wellbeing but at the same time it is essential to ensure that no human beings are harmed or exploited in the process of these early clinical trials. This interdisciplinary exploratory study aims at documenting challenges of translational research in nanomedicine with particular focus on first in human clinical trials from the perspectives of various stakeholders involved such as industry, academia, drug regulators, ethics committees, patient organizations and clinical research organizations. This study also takes into account differences in various national and international guidelines and respondents would be selected from Switzerland, EU as well as the US. Our aim is to gather, analyze and synthesize various challenges, including risk benefit evaluations. To the best of our knowledge, there is no other empirical research in this field that has looked at these same questions and using the same methodology.

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