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Presentation

‘No man’s land’- fragmentations and the privatisation of the responsibility in the regulation of first in-human clinical trials in the UK

Speaker

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Abstract

Recent work in sociology of ignorance has shown how ignorance serves as a productive asset for individuals and institutions to command access to resources and also avoid responsibility in the face of disasters (Mcgoey 2012). Building on such debates this paper explores the organisation and structure of regulation of first in-human clinical trials involving healthy volunteers. It seeks to demonstrate ways in which implicit claims to ignorance and a tendency to ‘passing the buck’ permeate the UK regulatory system of clinical trials. This results in what I have called a ‘fragmented’ regulatory system in which issues affecting healthy volunteers in such trials are pushed into the ‘no man’s land’ of regulation. Drawing on data on a recent PhD looking into regulatory and ethical dimensions of human involvement in clinical trials, the paper argues that rather than seeing gaps in the regulatory system as oversights or as ignorance on the part of regulators on these gaps, these gaps are actually part of the wider neoliberal approach to regulation in which safety and welfare are privatised to the individual. In doing so, any clinical trial that goes wrong becomes part a responsibility of the individual and not the state or regulators.