Proportionality and shared responsibility for Dutch trial reviews

To the Editor — As of 2018, the National Institutes of Health (NIH) will apply a revised definition of a clinical trial, as a research study in which human subjects are prospectively assigned to interventions (which may include a placebo or other control), to evaluate the effects of those interventions on health-related biomedical or behavioural outcomes. The new NIH definition is close to the legal description of clinical trials in the Netherlands.

One important objective of this decision is to increase transparency, because clinical trials must be registered on ClinicalTrials.gov. There is little to argue against improvement of transparency, considering the low publication rate of clinical studies[1]. However, a debate has arisen about the practical and financial implications of the NIH proposal, because for many experimental studies in humans, it may not always be necessary to reach the standards that are applied to clinical trials.

Similar discussions occurred in Europe after the implementation of the European Clinical Trial Directive 2001/20/EC and Regulation 536/2014, which were meant to harmonize procedures and improve subject protection. The directive set the level for clinical trials close to that of drug registration studies, including for non-commercial and non-drug-related clinical trials. Critics argued that the requirements were bureaucratic, and that the increased costs and complexities did not contribute to the quality and safety of studies[2,3].

The Netherlands dealt with these issues by setting up a system that applies high-quality standards for health research in humans, while maintaining an equilibrium between these standards and research objectives.

Standards for clinical research in the Netherlands are set by independent governmental institutions, in which formally appointed external stakeholders advise on medical, scientific, legal, ethical, societal and methodological issues. The same system applies to all accredited local medical research ethics committees (MREC), which are overseen by the Central Committee on Research Involving Human Subjects (CCMO), which also functions as an MREC for more complicated study types. Health research is independently funded by the Dutch Organization for Health Research and Development (ZonMw).

This shared responsibility of recognized stakeholders diminishes the need for a centralized governmental structure to guard the interests of society in health research. The close involvement of all parties fosters an ongoing discussion between the communities of researchers and regulators, stimulating continuous improvement of practical systems for health research. Scientific and regulatory guidance documents are developed with experts from different fields (http://www.ccmo.nl/en/publications). CCMO and ZonMw also collaborate with all major medical, scientific, patient and industry organizations in the Dutch Clinical Research Foundation on standard procedures for clinical research (patient informed consent, study contracts, recruitment and so on).

Within agreed legal, ethical and scientific boundaries, this approach can be tailored to different kinds of research supporting various types of infrastructure and strategy. We promote open science, including (pre) registration of trials, training of researchers in Good Clinical Practice and data management, reporting in open source and in open data, registers of public funders. At that, it is important to constantly keep an eye on the relevance of the information for a specific research domain and for society as a whole. ❐

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Competing interests

The authors declare no competing interests.