

TITLE: GENERAL PRINCIPLES FOR THE DECLARATION OF INTERESTS BY APPLICANTS AND THE MANAGEMENT OF (POTENTIAL) CONFLICTS OF INTEREST IN KCE-FUNDED CLINICAL TRIALS

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General principles for the declaration of interests by applicants and the management of (potential) conflicts of interest in KCE-funded clinical trials

1. PURPOSE

KCE Trials is a public health research programme that aims to fund non-commercial clinical trials to generate independent, high-quality clinical data that serve the general public interests, and particularly the interests of patients and health care payers.

In this respect, KCE Trials expects the research teams involved in KCE-funded clinical trials to apply high standards of independence and scientific integrity.

Conflicts of interest (COIs) in KCE-funded trials may not only raise doubt on the integrity and impartiality of the research team's decisions, but may also undermine the credibility of the KCE Trials programme and compromise the possible use of the trials' results by public health authorities.

Therefore, KCE Trials requires applicants to declare all their interests in relation to the proposed clinical trial at the time of their application and throughout the whole duration of the trial. Possible conflicts will be assessed by KCE Trials and, in case there is no consensus, a decision will be made by the Prioritisation Group.

This policy aims to ensure timely and appropriate disclosure and management of COIs in all KCE-funded clinical trials.

2. SCOPE

This policy clarifies and details the general requirements that already apply to all KCE-funded trials (via the applicable legislation on clinical trials, the call text and the Research agreement). It therefore applies to all ongoing and future KCE-funded clinical trials.

3. ACRONYMS

NA.

4. PRINCIPLES

Definition of a conflict of interest

An interest does not necessarily indicate a *conflict* of interest. Experts often have interests precisely because they are specialists in a field. However, a conflict of interest occurs when someone involved in the design, conduct, analysis or reporting of a clinical trial has secondary interests that influence or may be perceived to influence or compromise their objectivity in doing so. Conflicts of interest can, for example, lead to undue influence on the choice of device or drug studied or on the choice of comparator, to manipulation of the randomisation process, or to underreporting of negative results.

The perception of a conflict of interest can be considered as important as an actual conflict because it can affect public trust and confidence just as significantly. In some circumstances, even if there is no actual conflict, the mere appearance of it can raise doubts about the integrity and impartiality of the trial's results and, potentially, the policy decisions based thereon.

What interests should be declared and who should declare them?

The Sponsor, the Chief Investigator and any member of the research team involved in the design, conduct, analysis or reporting of the clinical trial must declare any interest that may affect or be perceived to affect the conduct of this trial in their application dossier (and during the course of the clinical trial if new potential conflicts arise subsequently).

Interest can be financial or non-financial. Financial conflicts of interest involve any financial relationships or interests that could potentially influence the design, conduct, or reporting of a clinical trial. Examples include (non-exhaustive list):

- direct or indirect funding of a member of the research team by a pharmaceutical company or another commercial entity;
- shareholdings or other financial interests in organisations which might benefit from the research (e.g. the company that manufactures or commercialises a drug, product, treatment or device being studied or used in the trial);
- consulting fees received from industry partners;
- directorship, honoraria, or significant research collaboration (including grants, sponsoring, etc.) by a member of the trial team (or their department) with a company or organisation that develops or markets a drug, product treatment, or device that will be evaluated or used in the trial;
- holding patents or other intellectual property rights related to the trial intervention or comparator;

Non-Financial Conflicts of Interest are interests that do not involve direct financial gain but may still impact the trial, for instance (non-exhaustive list):

- previous involvement in the development of the product or intervention that will be used or studied in the trial;
- chairs or any consultancy position in a company that might benefit from the trial (even if the position is unpaid)

Furthermore, applicants are required to declare any interests of their institutions or relatives that may appear to a reasonable person to influence their own independence and objectivity in the proposed clinical trial. Family members or relatives do not need to be identified by name. In case of doubt, an interest should always be declared.

How will KCE Trials assess (potential) conflicts of interest ?

KCE Trials staff will review the declaration of interests made by the applicants. In addition, the KCE Trials staff are entitled to use any available information and may request additional details from applicants at any time during the selection process or during the course of the trial.

Should KCE Trials staff identify a potential conflicts of interest that could impact the clinical trial, the individual(s) in question or his/her institution will be asked to provide detailed information and will be promptly invited to a meeting (virtual or in person) with the Head of KCE Trials and at least two additional KCE Trials team members. In the event that no consensus is reached amongst them regarding the existence of or management of a (perceived) conflict of interest, the interest will be assessed and a decision will be taken by the Prioritisation Group.

In its assessment of the risk of bias, KCE Trials will also consider the risks associated with a trial being of lower quality due to a lack of access to appropriate knowledge and skills.

In the event that the interest is deemed to have the potential to influence the design, conduct, analysis or reporting of the clinical trial, KCE Trials is entitled to request measures to mitigate the risk or to manage the COI or to terminate the selection process. Furthermore, in accordance with the Research Agreement signed with KCE, ongoing funding may also be terminated.

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