KCE glossary of terms

Advisory panel	Group of experts who give advice on and prioritisation of clinical topics for their importance to patients and the healthcare system. These same experts may provide additional advice during the call for proposals or development and evaluation of proposals to address these questions or topics.
Belgian coordinating centre (BCC)	Centre (sometimes referred to as 'Local sponsor') responsible for coordinating Belgian participation in an international study with the lead centre (sponsor) situated in another country. Some tasks this centre may perform could include managing the submission of the study to the applicable bodies and translating and adapting documentation for Belgium.
Belgian national number	NL = rijksregisternummer (RN) or sometimes RRN FR = numéro national (NN) or sometimes NRN
BMBF	German Federal Ministry of Education and Research
Chief Investigator (CI)	The person (authorised health professional) who takes overall responsibility for the design, conduct and reporting of a study if it is at one site; or if the study involves researchers at more than one site, the person who takes primary responsibility for the design conduct and reporting of the study whether or not that person is an Investigator at any particular site. Sometimes also referred to as Principal investigator (PI).
Clinical study	There are two main types of clinical studies: clinical trials (also called interventional studies) and observational studies.
Clinical Trials	In a clinical trial, participants receive specific interventions according to the research plan or protocol created by the investigators. These interventions may be medical products, such as drugs or devices; procedures; or changes to participants' behavior, such as diet. Clinical trials may compare a new medical approach to a standard one that is already available, to a placebo that contains no active ingredients, or to no intervention. Some clinical trials compare interventions that are already available to each other. When a new product or approach is being studied, it is not usually known whether it will be helpful, harmful, or no different than available alternatives (including no intervention). The investigators try to determine the safety and efficacy of the intervention by measuring certain outcomes in the participants. For example, investigators may give a drug or treatment to participants who have high blood pressure to see whether their blood pressure decreases.
Commissioning brief	A detailed description of a question to be answered by new research. In responding to a commissioning brief, researchers outline what studies they would undertake to obtain the information required.
Conflict of interest (COI)	A conflict of interest is a situation in which financial or other personal considerations have the potential to compromise or bias professional judgment and objectivity.
ECRIN	European Clinical Research Infrastructure Network http://www.ecrin.org/

Expression of interest (EoI)	The expression of interest is the form in which investigators summarise the trial that they propose to answer the specific clinical question. Generally it consists of 3 elements; 1 a summary of the trial including the key information, 2 information on the feasibility of conducting the trial which covers both the expertise and infrastructure of the proposed sponsor and feasibility at clinical sites and 3 a draft budget.
Full research proposal (FRP)	Full research proposal contains all necessary information to assess the trial research proposal. Generally it consists of 3 elements; 1 the trial protocol, 2 information on the feasibility of conducting the trial and 3 the final budget.
FWO - Fonds Wetenschappelijk Onderzoek - Vlaanderen	Research Fund – Flanders http://www.fwo.be/en/
Health Technology Assessment (HTA)	Health Technology Assessment research produces independent research information about the effectiveness, costs and broader impact of healthcare treatments and tests for those who plan, provide or receive care.
KCE	Federaal Kenniscentrum voor de Gezondheidszorg Centre Fédéral d'Expertise des Soins de Santé Belgian Health Care Knowledge Centre
KCE Trials Prioritisation Group (PG)	KCE trials prioritisation group is composed of independent experts in clinical trials in part delegated by the KCE Board members, who advise and offer their expertise to the KCE Trials programme. They prioritise the competing proposals and make the funding decisions. Overall decision making however remains with the KCE Board.
KCE Trials Board (TB)	KCE Trials Board is a multidisciplinary group composed of experts in clinical trials methodology and topic areas, and includes representatives of patients and public. The Trials Board reviews Expressions of Interest (EoI) and Full Research Proposals (FRP) and makes a recommendation to the Prioritisation Group.
KCE Trials Commissioned workstream	KCE Trials funds three different research approaches. The commissioned workstreams is one of them which focuses on funding trials that will answer clinical questions which have been identified and prioritised for their importance to patients and the healthcare system. This can be described as a 'top-down' approach.
KCE Trials International workstream	KCE Trials funds three different research approaches. The international workstream is when KCE Trials funds Belgian participation in international trials for selected International trials which ask questions that are also important for the Belgian healthcare system.
KCE Trials programme	Many questions in healthcare are currently not sufficiently studied using clinical trials, despite their high societal importance. KCE concluded in the summer of 2015 that public funding of such trials would be beneficial ("**Report 246-2015**") under certain conditions. These trials not only contribute to a better care for the patient but also to a more efficient use of public means.

	The Minister of Public Health Maggie De Block decided in the fall of 2015 that KCE should start a programme of pragmatic and practice-oriented clinical trials which is known as the KCE Trials programme.
KCE Trials researcher-led workstream	KCE Trials funds three different research approaches. The researcher-led workstream consists of open calls for researchers to apply for funding for their own topics and questions. These applications are prioritised in terms of information need in a process similar to that of the commissioned workstreams. Applications are assessed for scientific quality, feasibility and value for money. This approach can be described as a 'bottom-up' approach.
KKS Coordinating Centres for Clinical Trials	German academic CTU network - professional clinical trials support network embedded in University hospital centres http://www.kks-netzwerk.de/en/clinical-trials.html
NIHR	UK National Institute for Health Research http://www.nihr.ac.uk/
Observational Studies	In an observational study, investigators assess health outcomes in groups of participants according to a research plan or protocol. Participants may receive interventions (which can include medical products such as drugs or devices) or procedures as part of their routine medical care, but participants are not assigned to specific interventions by the investigator (as in a clinical trial). For example, investigators may observe a group of older adults to learn more about the effects of different lifestyles on cardiac health.
PICO	Patient group, intervention, comparator, outcome(s)
PREMs	patient reported experience measures
PROMs	patient reported outcome measures
TBM/FWO	TBM (Applied Biomedical Research with a Primary Social finality) projects / Research Fund – Flanders http://www.fwo.be/en/fellowships-funding/research-projects/tbm-projects/
Trial sponsor	An individual, company, institution, or organisation which takes responsibility for the initiation, management, and / or financing of a clinical trial. ICH-GCP guidelines (CPMP/ICH/135/95)
ZonMw	The Netherlands Organisation for Health Research and Development