Is it a clinical trial of a medicinal product?

This algorithm and its endnotes will help you answer that question. Please start at column A and follow the instructions. Additional information is provided in the notes at the end of the chart. If you have any questions do not hesitate to contact the METc VUmc (020-4445585) or the CCMO (070-3406700).

A	B	C	D	E
A CLINICAL TRIAL OF A MEDICINAL PRODUCT?				A NON-INTERVENTIONAL CLINICAL TRIAL?
Is it a medicinal product (MP)?[i]	Is it not a medicinal product?	What effects of the medicine are you looking for?	Why are you looking for those effects?	How are you looking for those effects?
If you answer no to all the questions in column A, the activity is not a clinical trial on a MP. If you answer yes to any of the questions below go to column B.	If you answer yes to the question below in column B the activity is not a clinical trial on a MP. If you answer no to this question below go to column C.	If you answer no to all the questions in column C the activity is not a clinical trial under the scope of Directive 2001/20/EC. If you answer yes to any of the questions below go to column D.	If you answer no to all the questions in column D the activity is not a clinical trial under the scope of Directive 2001/20/EC. If you answer yes to any of the questions below go to column E.	If you answer yes to all these questions the activity is a non-interventional trial which is outside the scope of Directive 2001/20/EC. If your answers in columns A, B, C & D brought you to column E and you answer no to any of these questions the activity is a clinical trial within the scope of the Directive.
A.1 Is it a substance[ii] or combination of substances presented as having properties for treating or preventing disease in human beings? A.2 Does the substance function as a medicine? i.e. can it be administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action or to making a medical diagnosis or is it otherwise administered for a medicinal purpose? A.3 Is it an active substance in a pharmaceutical form?	B.1 Are you only administering any of the following substances? • Human whole blood[iii]; • Human blood cells; • Human plasma; • Tissues except a somatic cell therapy medicinal product[iv]; • A food product[v] (including dietary supplements) not presented as a medicine; • A cosmetic product[vi]; • A medical device	C.1 To discover or verify/compare its clinical effects? C.2 To discover or verify/compare its pharmacological effects, e.g. pharmacodynamics? C.3 To identify or verify/compare its adverse reactions? C.4 To study or verify/compare its absorption, distribution, metabolism or excretion?	D.1 To ascertain or verify/compare the efficacy[vii] of the medicine? D.2 To ascertain or verify/compare the safety of the medicine?	E.1 Is this a study of one or more medicinal products, which have a marketing authorisation in the Member State concerned? E.2 Are the products prescribed in the usual manner in accordance with the terms of that authorisation? E.3 Does the assignment of any patient involved in the study to a particular therapeutic strategy fall within current practice and is not decided in advance by a clinical trial protocol[viii]? E.4 Is the decision to prescribe a particular medicinal product clearly separated from the decision to include the patient in the study? E.5 Will no diagnostic or monitoring procedures be applied to the patients included in the study, other than those which are applied in the course of current practice? E.6 Will epidemiological methods be used for the analysis of the data arising from the study?

[i] Article 1.2 of Directive 2001/83/EC is replaced by Article 1.1 of Directive 2004/27/EC which provides the definition of 'medicinal product' which applies for the purposes of Directive 2001/20/EC.
[ii] Substance is any matter irrespective of origin e.g. human, animal, vegetable or chemical that is being administered to a human being.
[iii] This does not include derivatives of human whole blood, human blood cells and human plasma that involve a manufacturing process.
[iv] Somatic cell therapy medicinal products use somatic living cells of human (or animal) origin, the biological characteristics of which have been substantially altered as a result of their manipulation to obtain a therapeutic, diagnostic or preventative effect (in humans) through metabolic, pharmacological and immunological means.
[v] Any ingested product which is not a medicine is regarded as a food. A food is unlikely to be classified as a medicine unless it contains one or more ingredients generally regarded as medicinal and indicative of a medicinal purpose.
[vi] The cosmetic Directive 76/768/EC, as amended harmonises the requirements for cosmetics in the European Community. A 'cosmetic product' means any substance or preparation intended for placing in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and mucous membranes of the oral cavity with the view exclusively or principally to cleaning them, perfuming them or protecting them in order to keep them in good condition, change their appearance or correct body odours.
[vii] Efficacy is the concept of demonstrating scientifically whether and to what extent a medicine is capable of diagnosing, preventing or treating a disease and derives from EU pharmaceutical legislation.
[viii] Assignment of patients to a treatment group by randomisation planned by a clinical trial protocol cannot be considered as current practice.

Algoritme van de Europese Commissie ter classificatie van geneesmiddelenonderzoek. Bron: http://pharmacos.eudra.org/F2/pharmacos/docs/Doc2006/04_2006/clinical_trial_qa_april_2006.pdf.