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).

<table>
<thead>
<tr>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Is it a medicinal product?</strong>&lt;sup&gt;1&lt;/sup&gt;</td>
<td><strong>Is it not a medicinal product?</strong></td>
<td><strong>What effects of the medicine are you looking for?</strong></td>
<td><strong>Why are you looking for those effects?</strong></td>
<td><strong>How are you looking for those effects?</strong></td>
</tr>
<tr>
<td>If you answer no to all the questions in column A, the activity is a non-interventional clinical trial on a MP.</td>
<td>If you answer yes to any of the questions below go to column B.</td>
<td>If you answer no to all the questions in column C the activity is a clinical trial under the scope of Directive 2001/20/EC.</td>
<td>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.</td>
<td>If you answer yes to any of the questions below go to column E.</td>
</tr>
<tr>
<td>If you answer yes to any of the questions below go to column C.</td>
<td>If you answer no to the question below in column B the activity is not a clinical trial on a MP.</td>
<td>If you answer no to all the questions in column B the activity is not a clinical trial on a MP.</td>
<td>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.</td>
<td>If you answer yes to any of the questions below go to column E.</td>
</tr>
</tbody>
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2. Substance is any matter irrespective of origin e.g. human, animal, vegetable or chemical that is being administered to a human being.
3. This does not include derivatives of human whole blood, human blood cells and human plasma that involve a manufacturing process.
4. 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.
5. 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.
6. The cosmetic Directive 76/768/EEC, 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 cleansing them, perfuming them or protecting them in order to keep them in good condition, change their appearance or correct body odours.
7. 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.
8. Assignment of patients to a treatment group by randomisation planned by a clinical trial protocol cannot be considered as current practice.