**EUDRACT - LIST OF ADDITIONAL FIELDS CONTAINED IN EUDRACT (REASONS FOR NEGATIVE OPINIONS OF THE ETHICS COMMITTEE)**

**Document history:**

<table>
<thead>
<tr>
<th>Date of meeting of “Ad-hoc group for the development of implementing guidelines for the ‘Clinical Trials Directive’ 2001/20/EC”:</th>
<th>13 October 2010</th>
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<td>Date of publication by the Commission:</td>
<td>9 November 2010</td>
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<tr>
<td>Date of coming into operation:</td>
<td>Launch of Version 8.0 of EudraCT</td>
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<td>Reasons for revision:</td>
<td>N/A</td>
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**Keywords:** EudraCT, disclosure of data fields, Reasons for negative opinions of Ethics Committees
1. **INTRODUCTION**

In accordance with point 3.3. of Commission Guidance 2009/C28/01\(^1\), where a negative opinion has been issued by an Ethics Committee, the information on the trial will be published, together with a field indicating the reason for the negative opinion.

To this end, EudraCT is going to contain the following fields.

2. **LIST OF REASONS**

- Relevance of the Clinical Trial
- Evaluation of the anticipated benefits and risks
- Investigators and staff
- Facility in a monocentre-trial
- All facilities in a multicentre-trial
- Facility/ies (one or more, but not all, in a multicentre-trial)
- Inclusion and exclusion criteria
- Control group
- Recruitment procedure
- Patient Information Sheet and consent form and procedure
- Measures to minimise pain, discomfort and fear
- Insurance and/or indemnity (injury or death / liability)
- Compensations to subjects
- Compensations to investigators
- Agreement between sponsor and site
- Inclusion of persons incapable of giving informed consent or other vulnerable populations
- Data protection and confidentiality
- Compliance with GCP
- Fulfilment of administrative requirements
- Other (Please specify - free text)
- Not Specified

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