

03 April 2013

Information and Communications Technology

EudraCT Public Web Report for March 2013

Introduction:

The following statistics were taken from the EudraCT Database on 31 March 2013.

Unless otherwise indicated they are cumulative totals since the database went into operation 1st May 2004.

It must be stressed that these totals do not represent the total number of Clinical Trials commenced during this period because of a number of factors including the different dates of implementation of the Directive in individual Member States and the on-going integration of the database into the business and IT processes of the Member States and the Sponsors.

These totals do not include Clinical Trials that were already on-going on 1 May 2004, with at least one site in the Community, as these are not required to be entered in the EudraCT Database.

| No. | Description* | Total |
|-----|--|----------------|
| 1 | Number of Clinical Trials recorded in the EudraCT Database: | 36402 |
| 2 | Total number of Clinical Trial Applications recorded by Member State, Competent Authorities in the EudraCT Database: | 76482 |
| 3 | Last Assigned EudraCT Number in 2013 to date: | 2013-001518-13 |
| 4 | Total of EudraCT Numbers issued in 2013 to date: | 1448 |
| 5 | Clinical Trials recorded per Sponsor Type: | |
| | Commercial: | 79% |
| | Non-Commercial: | 20% |
| | Not indicated: | 1% |
| 6 | Total number of Clinical Trial Site Inspections: | 4146 |
| 7a | Total number of EudraCT Numbers requested in response to the question: "Is it anticipated that this EudraCT Number will be used for a Clinical Trial conducted in a third country (outside of the EU/EEA)?" | 283 |
| 7b | Total number of EudraCT Numbers requested in response to the question: "Is it anticipated that this EudraCT Number will be used for a Clinical | 65 |

| No. | Description* | Total |
|-----|--|-------|
| | Trial contained in an agreed Paediatric Investigation Plan?" | |

* A Description Key can be found [below](#)

Historical Information – Previous to Current Year (2013 - 2004):

| | |
|--|------------------------|
| FINAL Assigned EudraCT Number in 2012: | 2012-005849 -## |
| FINAL Total of EudraCT Numbers issued in 2011: | 5399 |

| | |
|--|-------------------------|
| FINAL Assigned EudraCT Number in 2011: | 2011-0006344 -## |
| FINAL Total of EudraCT Numbers issued in 2011: | 6011 |

| | |
|--|-------------------------|
| FINAL Assigned EudraCT Number in 2010: | 2010-0024665 -## |
| FINAL Total of EudraCT Numbers issued in 2010: | 5914 |

| | |
|--|-------------------------|
| FINAL Assigned EudraCT Number in 2009: | 2009-0018297 -## |
| FINAL Total of EudraCT Numbers issued in 2009: | 6441 |

| | |
|--|-------------------------|
| FINAL Assigned EudraCT Number in 2008: | 2008-0009334 -## |
| FINAL Total of EudraCT Numbers issued in 2008: | 9334 |

| | |
|--|------------------------|
| FINAL Assigned EudraCT Number in 2007: | 2007-0007987-## |
| FINAL Total of EudraCT Numbers issued in 2007: | 7987 |

| | |
|--|------------------------|
| FINAL Assigned EudraCT Number in 2006: | 2006-0007124-## |
| FINAL Total of EudraCT Numbers issued in 2006: | 7124 |

| | |
|--|------------------------|
| FINAL Assigned EudraCT Number in 2005: | 2005-0006170-## |
| FINAL Total of EudraCT Numbers issued in 2005: | 6214 |

| | |
|--|------------------------|
| FINAL Assigned EudraCT Number in 2004: | 2004-0005297-## |
| FINAL Total of EudraCT Numbers issued in 2004: | 4613 |

*Description Key

| Number | Description |
|--------|--|
| 1 | <p>Number of Clinical Trials recorded in the EudraCT Database:</p> <p><i>A Clinical Trial may involve one or more Member States but has only one EudraCT number. Therefore the number of trials recorded in the EudraCT Database includes trials involving several Member States but each EudraCT Number is counted once.</i></p> |
| 2 | <p>Total number of Clinical Trials recorded by Member State, Competent Authorities in the EudraCT Database:</p> <p><i>As indicated in 1 above, a clinical trial may involve several Member States. Each Member State creates a record; therefore several records may exist for one clinical trial representing each of the Member States involved. The total given here represents the number of individual Member State records of clinical trials and is therefore higher than the number of separate trials provided under "1" above.</i></p> |

| Number | Description |
|--------|---|
| 3 | <p>Last Assigned EudraCT Number in 2005:</p> <p>EudraCT numbers are generated as a simple numerical sequence that restarts at "1" each year prefixed by the year.</p> <p><i>Not all numbers are actually issued to Sponsors due to the technical processes involved in issuing them over the WEB. Therefore the actual quantity (See 4 below) is smaller than the highest EudraCT Number might imply.</i></p> |
| 4 | <p>Quantity of EudraCT Numbers issued in 2005:</p> <p><i>This is the actual total quantity of individual EudraCT Numbers issued to users of the system.</i></p> |
| 5 | <p>Clinical Trials recorded per Sponsor Type (Commercial, Non-Commercial or not indicated)</p> <p><i>The Sponsor type is recorded with each Member State record; therefore the total here equals the total provided under "2" above.</i></p> <p><i>From now on, this figure is being shown as a percentage of the total.</i></p> |