

# The EudraCT Database

## Purpose of EudraCT Database

- Database of trials being conducted in the European Community
- Facilitation of communication between Regulatory Authorities
- Overview of IMP development
- Links with EudraVigilance database (tracking safety data for trials registered on EudraCT)

## EudraCT Number

- [One number per trial](#)
- The EudraCT number generator is available at <http://eudract.emea.eu.int>
- The EudraCT number is the main identifier for the trial and should be used on all correspondence with the MHRA and ethics committees and when reporting amendments, SUSARs etc.
- Trials that commenced before 1<sup>st</sup> May 2004 do not need a EudraCT number and should use their CTA number in any correspondence with MHRA.

## Process

- See attached flow diagram
- Explanations of footnotes on diagram are given below

## EudraCT database

- The data entered on the EudraCT database can only be accessed by the MHRA/Competent Authorities
- System will check for duplicate entries
- System will have an audit trail to identify the date, time and source of the original entries and any changes
- Where appropriate, reasons for change will be recorded (with standard reasons provided via a picklist)
- English should be used where possible.
- EudraCT database will log when inspections are carried out