



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## EudraCT v9.0 Release Notes

EudraCT Main version: 8.4.9.1

EudraCT Results version: 9.0.0.0

Goal: Major release

Release Date: 09/10/2013

### Release Notes for EudraCT v9.0 Public

The newly released EudraCT version 9.0 contains the following changes compared to the previous released version:

- The graphical appearance of the User Interface has been changed.
- A new module, EudraCT Results has been added that enables registered users to prepare and post Clinical Trial summaries in EudraCT in line with the Commission Guideline (2012/C 302/03) and the technical guidance on the format of the data fields of result-related information on clinical trials submitted in accordance with article 57(2) of regulation (EC) No 726/2004 and article 41 (2) of regulation (EC) No 1901/200.
- Instructions about how to use the Result module are added to the Help.

The other functions of the system (creating EudraCT number and Clinical Trial Applications) did not change.

### Known issues in release 9.0.0.0

- When the user of the Results module attaches several summary files to the result, in certain cases an error message is displayed. If this happens, the user is advised to go back and to repeat the attachment procedure.
- In the Results module, warning messages for serious and non-serious adverse events are not displayed when values for subjects exposed are not equal to the total number of subjects exposed for a reporting group.
- It may take several seconds for EudraCT to switch from the Results module to the Clinical Trial Application module. This delay is observable for the first time only, subsequent switches are quicker.

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7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom

**Telephone** +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8669

**E-mail** [info@ema.europa.eu](mailto:info@ema.europa.eu) **Website** [www.ema.europa.eu](http://www.ema.europa.eu)

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- Age continuous list of units is not standardised with EUTCT.
- After a user has pressed the 'confirm' button to update a finalised result, the application sometimes takes a while to proceed to the next step. If the user presses the 'confirm' button again while waiting for the application to process the confirm request, the following error message is displayed: "An unexpected application error has occurred".
- There are a few tool tips missing or misplaced within the Results module.
- Some of the graphical elements are misplaced in certain screen resolutions in the CTA module due to the refreshed appearance.