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Press Office

Press release

European Medicines Agency launches a new version of EudraCT

Summary results of clinical trials soon to be available to the public

The European Medicines Agency has launched a new version of the European Clinical Trials Database (EudraCT). This new version, EudraCT V9, marks the initial step of a process through which summary clinical trial results will be made publicly available through the EU Clinical Trials Register (EU CTR).

EudraCT already contains protocol-related information submitted by sponsors for interventional clinical trials conducted in European Economic Area countries and/or in third countries, when the clinical trial is part of an agreed Paediatric Investigation Plan (PIP). As of today, clinical-trial sponsors are encouraged to register on the EudraCT website to start uploading summary results. Results posted by sponsors in EudraCT will start to become publicly available once the Agency has launched the complementary new version of the EU CTR towards the end of the year. The content and level of detail of the summary results is set out in a European Commission guideline and in its technical guidance.

This initial release of EudraCT will be followed by further updates to the system in 2014 which will provide improved functionalities for sponsors and EU regulatory authorities. With the launch of these further iterations of EudraCT by mid-2014, the modalities and timing of posting of result-related information as described in the EC guideline will apply, and sponsors will then be required to post result-related information.

The Agency supports international standardisation of data requirements for clinical trial registration. EudraCT's data requirements are already substantially aligned with those of ClinicalTrials.gov and the Agency works closely with the National Institutes of Health (NIH) of the United States, which operate ClinicalTrials.gov and with stakeholders to progress this objective.

The Agency will make the data descriptions and technical specifications available to enable stakeholders to build systems that can generate structured data sets and upload them electronically into EudraCT.

About EudraCT and the EU Clinical Trials Register

EudraCT is a database used by national competent authorities to enter protocol-related information on clinical trials submitted by clinical trial sponsors, but also includes protocol-related information on

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clinical trials in third countries if they are included in a PIP. The database is hosted by the European Medicines Agency.

A subset of this data is made available through the EU Clinical Trials Register which the Agency manages on behalf of the EU.

Users are able to view the description of phase-II to phase-IV adult clinical trials where the investigator sites are in the EEA, as well as any clinical trials in children with investigator sites in the EU and any trials that form part of a PIP, including those where the investigator sites are outside the EU.

Clinical Trial Transparency in Europe

This new feature of EudraCT is another step towards increasing clinical trial transparency in Europe and will allow sponsors to provide summary results of all interventional trials already published in the EU CTR. This is a separate initiative to the Agency's goal of publishing clinical data included in a marketing authorisation application submitted via the centralised authorisation procedure for medicines, and for which the decision phase of the marketing authorisation process has been completed.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Guidance on the content of protocol-related and results-related information is available here: http://ec.europa.eu/health/files/eudralex/vol-10/2009_c28_01/2009_c28_01_en.pdf

   http://ec.europa.eu/health/files/eudralex/vol-10/2008_07/c_16820080703en00030004_en.pdf
3. The guideline on the posting and publication of result-related information on clinical trials is available here: http://ec.europa.eu/health/files/eudralex/vol-10/2012_302-03/2012_302-03_en.pdf
4. Technical guidance on the format of the data fields of result-related information on clinical trials can be found here: http://ec.europa.eu/health/files/eudralex/vol-10/2013_01_22_tg_en.pdf
5. The EudraCT website is available here : https://eudract.ema.europa.eu/
6. The EU Clinical Trials Register is available here: https://www.clinicaltrialsregister.eu/
7. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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