EUROPEAN MEDICINES AGENCY
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Press Office

Press release

EU Clinical Trials Register goes live

Public online register gives access to information on clinical trials

The EU Clinical Trials Register (https://www.clinicaltrialsregister.eu) was launched today by the European Medicines Agency (EMA). The online register gives for the first time public access to information on interventional clinical trials for medicines authorised in the 27 EU Member States and Iceland, Liechtenstein and Norway. The database also allows the public to search for information on clinical trials authorised to be carried out outside the EU if these trials are part of a paediatric investigation plan.

The information contained in the EU Clinical Trials Register is extracted from EudraCT, the EU clinical trials database. It is provided by the sponsor of the clinical trial, and is a component of its application to a national medicines regulatory authority for authorisation to conduct a trial. The information from the sponsor is loaded into the EudraCT database by the national medicines regulatory authority. The authority adds to this information the authorisation of the clinical trial and the opinion from the relevant ethics committee. Information on third-country trials that are listed in a paediatric investigation plan (PIP) is provided by the PIP addressee directly, via the EMA, to the system.

Throughout the project the Agency worked together with stakeholders, including patients and healthcare professionals, to ensure that their needs were taken into account, to the extent possible at this stage, when designing the register.

Lise Murphy, co-chair of the Agency's Working Party with Patients' and Consumers' Organisations said: "We welcome the launch of the EU Clinical Trials Register. It increases transparency of medical research and will make it much easier for patients to find information about clinical trials taking place in Europe. We are committed to continue working with the EMA to further develop the system so that it becomes a valuable and useful resource for patients across the EU."

The Agency will continue to work with stakeholders to improve the functioning of the EU Clinical Trials Register, in particular by enhancing the quality and completeness of data, and improving the search functionality. Plans for the future also include the publication of summaries of clinical trial results, on which draft guidance has already been published for consultation by the European Commission. Publication of trial results summaries will require a major upgrade to the existing system, the start of which will depend on finalisation of the guideline and availability of budget and resources.

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Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The clinical trials register is part of the EudraPharm, the Community database of authorised medicinal products. More information on EudraPharm is available here: http://eudrapharm.eu/eudrapharm
3. The data in the EU clinical trials register are extracted from EudraCT, the EU clinical trials database. More information on EudraCT is available here: https://eudract.ema.europa.eu/
4. The "Draft Implementing technical guidance - List of fields for result-related information to be submitted to the 'EudraCT' clinical trials database, and to be made public, in accordance with Article 57(2) of Regulation (EC) No 726/2004 and Article 41 of Regulation (EC) No 1901/2006 and their implementing guidelines 2008/C168/02 and 2009/C28/01" is available here: http://ec.europa.eu/health/files/clinicaltrials/technical_guidance_en.pdf
5. The approval of clinical trials applications in the European Union is the responsibility of the member states. More information on clinical trials in the EU is available here: http://ec.europa.eu/health/human-use/clinical-trials/index_en.htm
6. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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