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DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HMA
Heads of Medicines Agencies

Joint Letter by the European Commission, EMA and HMA

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LETTER TO STAKEHOLDERS REGARDING THE REQUIREMENTS TO PROVIDE RESULTS FOR AUTHORISED CLINICAL TRIALS IN EUDRACT

Clinical trials are the key drivers of medical innovation and progress in patient-care and disease prevention. A sufficient level of scrutiny and transparency in clinical trials is essential to protect public health and to foster innovation in the medical research field. In order to achieve this, all relevant protocol and results related information regarding clinical trials that are authorised in the EU needs to be kept in the EU Clinical Trials Database (EudraCT) and publicly available through the EU Clinical Trials Register. This is particularly true for the timely publication of clinical trial result summaries, including information on the objectives, design and main conclusions and results of a given study. Comprehensive access to summary results has been regarded an essential feature for clinical trials in order to allow patients, practitioners, policy makers and other economic operators to make well-informed decisions about health-care and medical research.

The requirements for publishing clinical trial summary results in the EU Clinical Trials Database are included in the European Commission Guideline 2012/302 03/EC[1]. Accordingly, as of July 2014, result-related information should be posted within one year (6 months for paediatric trials) after the end of a clinical trial[2]. The submission of the results to EudraCT is the direct responsibility of the sponsors. Once the sponsor submits the result in EudraCT, the information, with about 2-week delay, is automatically fed into the European Union Clinical Trials Register and become available for public scrutiny.

These provisions will remain applicable with a clear legal basis under the European Clinical Trials Regulation (No 536/2014[3]). The EU Portal and Database foreseen in this Regulation, as a single entry

[1] Guidance on posting and publication of result-related information on clinical trials in relation to the implementation of Article 57(2) of Regulation (EC) No 726/2004 and Article 41(2) of Regulation (EC) No 1901/2006

[2] Please note that although EudraCT contains results for phase I-IV trials, results for those Phase 1 trials, which are conducted solely in adults and are not part of an agreed PIP, will not become public in the EU Clinical Trials Register.

[3] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJXXXXXX)

point for the submission and maintenance of clinical trials by the sponsors, will be a key instrument to realise this aim.

As of April 2019, there are 27,093 clinical trials completed out of 57,687 trials included in the EudraCT database, of which 18,432 should have results posted. This means that 68.2% (12,577) are in compliance with the publication rules whereas 31.8% (5,855) of the trials have missing results. This is an encouraging trend, though there is still significant progress to be made. In particular, the reporting compliance for non-commercial sponsors is much lower than for commercial sponsors (77.2% for commercial sponsors vs 23.6 % for non-commercial sponsors)[4].

Underreporting in general and selective reporting of trials with positive outcome may lead to potentially avoidable redundancies in the conduct of clinical trials and compromise the economic and scientific efficiency of clinical research. In addition, unreported clinical trials with unfavourable outcome can have negative public health implications. Academic and other non-commercial sponsors are particularly encouraged to post the results of their trials in EudraCT in order to maximise their valuable contribution to meet public health needs and to advance clinical research especially where commercial interest is weaker.

In order to improve compliance on the posting of results, the primary aim of this communication is to remind all sponsors about their obligation for the reporting of clinical trial summaries in the EU Clinical Trials Database. In the spirit of the EU legislation, it is important that all stakeholders act together to ensure compliance as soon as possible for the promotion of public health.

The following materials and tools are available for stakeholders in order to provide them with information and guidance on reporting trial results to EudraCT:

- Results information documentation: https://eudract.ema.europa.eu/result.html
- EudraCT & EU-CTR Question and Answer table "Results" section (Q&A 34-62): https://eudract.ema.europa.eu/docs/guidance/EudraCT%20FAQ_for%20publication.pdf
- Technical guideline on the format of the data fields of results-related information on clinical trials: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/2013_01_22_tg_en.pdf

Additional resources:

- Multi-media tutorials: https://eudract.ema.europa.eu/multimedia_tutorials.html
- Training material (Q&As from previous training): https://eudract.ema.europa.eu/training.html
- List of fields contained in EudraCT to be made public for paediatric and non-paediatric trials: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/eudract_nonpaediatric_listoffields_en.pdf (non-paediatric trials)

[4] Please note that the data available in the EU Clinical Trials Register is a subset of the data from EudraCT.

https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/eudract_paediatric_listoffields_en.pdf (paediatric trials)

We trust your commitment to ensure transparency and sufficient public scrutiny and thank you for your efforts to report clinical trial results in a timely manner.

Signature:

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