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Reporting of adverse drug reactions and the Clinical Trials Regulation (Regulation (EU) No 536/2014): What will change?

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Clinical trial regulation (CTR) No 536/2014 will come into force on 31 January 2022. The CTFG (Clinical Trials Facilitation and Coordination Group) safety subgroup has published a draft CTR (EU) NO 536/2014 DRAFT QUESTIONS & ANSWERS, VERSION 4. This document will be applicable once CTR comes into force and should be used for all the trials submitted and conducted under CTR. The document clarifies that if an administrative procedure is an essential part of the Investigational Medicinal Product, an adverse reaction (AR) that is reported due to such procedure should be considered as an AR. A difference between severity, the intensity of the AR, and seriousness, the outcome of AR, is clarified. An updated example of the reference safety information (RSI) table, which now should include the frequency of serious adverse reactions (SARs) from postmarketing experience, and should state 'not applicable' for frequency of fatal and/or life-threatening SARs, if they are considered unexpected, is provided. It is stressed that a sponsor is expected to provide a robust justification for adding a new SAR to the RSI, especially if it is observed only once or were life-threatening. The SmPC section 4.8 can be used as the RSI for the study, however the RSI section should be used if the IMP have not yet get marketing approval. It was underlined that it is advised to submit an annual safety report before or in parallel with an update of the investigator's brochure (IB). Under the CTR the IB will be considered approved for the trial under question when the first member of state concerned approves it.

Biography

Dr. Elena Prokofyeva is head of the drug safety unit at the Department of Research & Development, DG PRE, the Federal Agency for medicines and health products (FAMHP), Brussels, Belgium. She represents Belgium within the CTFG safety subgroup. She initiated and led an update of the Q&A-RSI document within the CTFG. She is a part of working group organized by the European Commission for preparation of the implementing regulation for the CTR. In addition, Dr. Prokofyeva is a part of GCP IWP subgroup in charge of 'DMC guidelines revision'. Dr. Prokofyeva holds a research doctorate from the University of Tuebingen, Germany, a Ph.D. and an M.D. from the Northern State Medical University, Arkhangelsk, Russia, and a Master of Public Health from the University of Umea, Sweden. Prior to joining the FAMHP in 2016 she conducted research at Inserm, Paris and worked at a pharmaceutical consulting company in London.