

Implementation of a Centralized Pharmacovigilance System in Multi-Country European Clinical Trials: Points to Consider for Academic Sponsors and Lessons Learnt from EU-Response and Connect4Children Consortia

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October 17, 2022

Abstract

Setting-up a high quality and efficient pharmacovigilance (PV) system in multi-country clinical trials can be more challenging for academic sponsors than for industrials. Generating high-quality safety data, compliant with legal and regulatory standards such as European or World Health Organization (WHO), places special requirements on the PV system. The scenario becomes more complicated when dealing with multi-country European clinical trials where heterogeneity on safety process can be encountered. Some Sponsors face these challenges are even more difficult for pediatric trials. A possible solution to ensure that the safety of all participants is equally guaranteed and the PV system fulfills all regulations could be to set up a centralized PV system. This paper introduces the key points to consider when implementing and organizing such system in multi-national European clinical

trials. It is based on the Inserm-ANRS MIE pharmacovigilance department's experience and aims to harmonize and anticipate the needs, in particular by implementing safety procedures and a network of local safety officers. This system is very useful to respond to the challenges of a European clinical trial, notably when considering the complexity of local safety requirements of each country, signal management and the specificities of paediatric regulation.

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