Abstract Template

Project title

Review of adverse event publishing for clinical trials conducted in Ireland

Institution

University College Dublin

Project details (max 250 words)

Much discrepancy exists in the reporting of clinical trial adverse events (AEs) in the scientific literature and on clinical trial registries such as EudraCT. This is particularly the case for investigator-led trials, where often a lack of awareness exists on how to report AEs, despite available ICH guidelines. The incorrect reporting of AEs can have implications for the consideration of the safety of interventions.

The aims of this project are to assess the extent of erroneous AE reporting and to create simple guidelines for this. To achieve these aims, this project consists of two stages.

The first stage of this project is to review how AEs for Irish clinical trials are reported in the published literature and on the clinical trial registries. This will assess the proportion of trials with errors in the AE reporting, the type of errors made, whether medical dictionaries were used and differences in AE reporting between the scientific literature and clinical trial registries.

The second stage of the project is to compile a set of simple instructions for AE reporting that can help train investigators in this process. Furthermore, template AE tables will be created which can be integrated into the Safety Assessment and Safety Reporting sections of clinical trial protocols.

This project will be of significant relevance particularly for investigator-led clinical trials, as the resources and training for AE reporting often are often minimal when compared to industry-led trials.

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