P9 - Analysis of adverse events in early phase trials. A medical writing perspective.

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INTRODUCTION

Despite the low risk of severe harm in Phase 1 studies, accurate collection, reporting, and transcription of safety remains a priority. This analysis aims to provide a context for safety reporting in Phase 1 studies, from a medical writing perspective.

METHODS

Safety data from 16 studies conducted in Europe between January and December 2023 were collected and analysed descriptively.

RESULTS

A total of 648 participants were included in the analysis. Of those, 370 experienced 928 adverse events (AEs). The majority of the AEs were mild, and were experienced by 374 participants; 265 (71.6%) participants had AEs considered related to the study drug. Two SAEs (one mild and one severe) not related to the study drug were reported by 2 (0.5%) participants. No deaths were reported. The most commonly occurring AEs were nervous system disorders (headache), general disorders and administration site conditions (fatigue), and gastrointestinal disorders (diarrhoea).

CONCLUSIONS

Most of the AEs were mild and the 2 SAEs reported were not related to the study drugs, suggesting that Phase 1 studies do not pose great risk. This analysis contributes to the knowledge of risk stratification for interpretation of safety data and facilitates a comprehensive approach for safety reporting of early phase studies.