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Coding in Pharmacovigilance Using MedDRA: A Review

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Abstract: This review explain process what is used for medical coding in Pharmacovigilance and, in brief, most commonly used medical dictionary MedDRA. The purpose of this paper is a modest contribution to easier and more successful understanding of the encoding process in clinical data management in the field of Pharmacovigilance. There may be severe result if there is miscategorise of adverse events in clinical trials. For the purpose of decreasing the scope for interpretation several steps are involved such as from subject adverse event experience to presentation in tablets should be possibly standardised. MedDRA is a predefined dictionary where adverse events, signs, symptoms, diseases and diagnosis and statistical analysis are categorized. Coding is a process in which the universal dictionary is which is required for translating the event which is reported by the investigator into a standard term. For the hunt for safety signal frequencies and incidences of adverse events can be scrutinized once the adverse events have been accurately coded.

Keywords: Adverse events, MedDRA MSSO, MSSO, System Organ Class (SOC), High Level Group Term (HLGT), High Level Term (HLT), Preferred Term (PT), Lowest Level Term (LLT), Scope, Languages, Maintenance of MedDRA

REFERENCES

- [1]. Pramod V. Burakale, Dr.Suresh G. Sudke "Concise Course in Pharmacovigilance", PV Publication, Page no. 1-73
- [2]. Elizabeth B. Andrews, Nicholas, "Mann's Pharmacovigilance" Wiley Publishers
- [3]. S K Gupta, Jaypee Brothers "Textbook of Pharmacovigilance", Medical Publishers
- [4]. Satyajeet et al. 2015 world journal of pharmacy and pharmaceutical sciences, Review on Pharmacovigilance, Volume 4, Issue 06, 266-275
- [5]. G. Srilekha, Yanapu Naga Venkata Satya Anusha, Int. J. Pharm. Sci. Rev. Res., 62(2), May-June 2020; Article No.17, Pages: 108-112 ISSN 0976 – 044X
- [6]. ICH: MedDRA, Available from: https://www.ich.org/page/meddra
- [7]. Deven Babre et al. 2010 "Medical Coding in Clinical Trials" Perspect Clin Res. 2010 Jan-Mar; 1(1): 29–32.PMCID: PMC3149405
- [8]. https://www.appliedclinicaltrialsonline.com/view/medical-coding-procedures-clinical-research-amarex-safety-and-pharmacovigilance-perspective

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[9]. https://www.meddra.org/how-to-use/basics/hierarchy