

International Conference on Clinical Trials

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PSI International Inc., USA

Workshop on MedDRA and WHO DD terminology

The capture of safety data in the health care/life sciences context involves the use of many diverse terminologies. The purpose of these many terminologies is varied, ranging from capturing adverse events to categorizing diagnoses and procedures. The most important use of these terminologies involves the performance of good quality coding. Employing high quality and superior standards of coding translates into choosing terms within the respective terminology that most closely and accurately captures the concept observed or captured. Whether that concept is a product name in the case of pharmaceuticals or expression of an adverse event, the principle objective remains the same: Maintaining the integrity of information. The primary purpose of developing coding terminologies is to provide a uniform, consistent and reliable methodology to express concepts without losing expression of the integrity of the event. The correct use of coding terminology allows for the capture of “good” data and the production of aggregate results that lend themselves to reliable and meaningful analysis. Such a process ensures accurate signal detection that is neither diluted nor magnified. Because there are numerous terminologies, this workshop focuses on those described in the Medical Dictionary for Regulatory Activities (“MedDRA”) which is often used to capture adverse events after drug exposure and the World Health Organization’s Drug Dictionary (“WHO-DD”) which is used to capture concomitant medications often used in pre and post marketing. The structure and content of each terminology will be discussed as well as demonstration of good coding practices. Common coding challenges will also be discussed and best practices employed in the industry.

Biography

Samina Qureshi is the Medical Director of the Health Sciences Division at PSI International Inc. She is a physician and is also pursuing an Advanced degree in Regulatory Science at the prestigious Johns Hopkins University. She is also an expert in various dictionaries, including the Medical Dictionary for Regulatory Activities (MedDRA), the World Health Organization Drug Dictionary (WHO-DD) and International Classification of Disease (ICD 9/10). She has supported Clinical and Pharmacovigilance activities at a senior level with over 20 pharmaceutical clients, the World Health Organization- Uppsala Monitoring Center as well as the US Food and Drug Administration (FDA) *Center for Drug Evaluation and Research (CDER)* Adverse Events Reporting Programs Support; National Institutes of Health (NIH) and at U.S. Army Medical Materiel Development Activity (USAMMDA). providing training to data management staff.

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