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Review Article

A REVIEW ON MEDICAL CODING IN CLINICAL TRIAL

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ABSTRACT

On the data collection tool Case report Form / Electronic Case Report Form, investigators at various sites in various countries record data generated in all clinical trials. In multicentric clinical trials, recording the medical term(s) uniformly is a big challenge because different investigators or medically competent experts are from different sites / centers. Medical coders from the clinicaldata management team process these phrases and execute medical coding. Medical coding is a method of organizing and categorizing medical language in order to examine and review it. The method of medical coding in clinical data management, as well as the two most often used medical dictionaries, MedDRA and WHO-DDE, are briefly discussed on this page. It is anticipated that it will assist medical coders in their comprehension of the system.

KEYWORDS:

Coding, Data collection, Live Project Coding, Regulatory Activities Medical Dictionary (MedDRA).

INTRODUCTION:

Data collecting instruments (DCIs) known as Case Record Forms / Report Forms (CRFs) in paper- based studies and electronic Case Record/ Report Form (eCRF) in web-based trials are used to record all clinical

trial data. These trials collect and report Adverse Events (AE), Medical History (MH), and Concomitant Medications (CM) administered in addition to the research medication on applicable DCIs. A multicentric clinical study involves multiple trial locations and a broad group of investigators from various ethnic backgrounds. Medical/scientific data is expected to be captured in a variety of ways as a result of the involvement of investigators and clinical research specialists from various countries/regions. All of the data generated during these trials is analyzedat some point. The purpose of this article is to describe how standardized medical coding dictionaries are used to perform medical coding in clinical trials. [1]

In this article the attempt is made

1. to explain how standardized medical coding dictionaries are used in clinical trials for medicalcoding.
2. to briefly describe two of the most widely used dictionaries by most regulatory offices and the vast majority of professionals in the pharmaceutical/CRO business.
3. to describe the medical coding process and to highlight some of the usual issues that a coderencounters when coding.

1. COSTART (Coding Symbols for Adverse Reaction Terms Thesaurus)
2. International Classification of Diseases, Ninth Revision Clinical Modification (ICD9CM)
3. Medical Dictionary for Regulatory Activities (MedDRA)
4. World Health Organization Adverse Reactions Terminology (WHO-ART)
5. World Health Organization Drug Dictio-nary Enhanced (WHO-DDE)

Two of the most widely used medical coding dictionaries for categorizing medical terminology generated in clinical trials are MedDRA and WHO-DDE. Maintaining uniformity in reporting a term in any clinical study is nearly impossible. However, it is difficult for a coder to ensure that the words recorded/reported on a data collection instrument (CRF/eCRF) are coded correctly. It is a well-known fact that these dictionaries are costly, and medical coding organizations should have the necessary licenses in place. Different user groups have been given different licenses for each of the dictionaries.[2]

Medical coding procedures

Precoding Process

Any medical coding dictionary, as well as any subsequent modifications, must be properly imported / loaded into the appropriate coding tool by the database development team. Oracle Clinical (OC) uses the Thesaurus Management System as a coding tool (TMS). After the dictionaries are imported / loaded, the development team double-checks if all tables/records are successfully loaded in the tool. This process is only performed once for the dictionary version provided. The operational team runs a user acceptance test (UAT) once the programming team confirms that the tool's import tables and records are correct. Members of the operational team.ensure that the dictionary loaded in the tool is producing the desired output. Once the operational team has been assembled.[3]

Check the following items at a minimum before allocating a dictionary to a project or research:

- Despite the availability of a newer version, the policy / requirement of utilizing the sameversion of dictionaries provided in the coding tool for the life of the project.
- Upgraded versions will be made available as they become available throughout theproject's life cycle.
- upgrade versions as and when they become available over the project's life cycle.[4]

Live Project Coding

"Data Review and Discrepancy Management" data managers should preferably code validated and cleansed data. Any phrases not "auto-coded" by the project's medical coder must be coded "manually." The following is a brief overview of two coding methods: automatic and manual. Auto Coding: The phrase entered by the investigator on the data collection device is automatically coded if it completely fits the right term in the medical lexicon. Auto coding fails when terms do not meet the appropriate degree of hierarchy in the medical lexicon. All of these conditions must be adhered to.[5]

Regulatory Activities Medical Dictionary (MedDRA)

Maintenance and Support Services Organization established the Medical Dictionary for Regulatory Activities (MedDRA®), a medical coding dictionary (MSSO). The International Conference on Harmonization (ICH) on Technical Requirements for Registration of Pharmaceuticals for Human Use is a supporter of MedDRA®. There was no internationally agreed medical vocabulary for biopharmaceutical regulatory purposes prior to the development of MedDRA. Medical terminology generated during all phases of a clinical study, excluding animal toxicity, are coded using MedDRA. Therapeutic indications include signs, symptoms, illnesses, diagnosis, or prevention of disease, and function modification.[6]

- coding investigation names and quantitative results, surgical operations, and medical/social/family background.
- In a given year, MedDRA releases two versions: one in March and the other in September. Annually, by renewing a membership, one can gain access to the MedDRA terminology.

Each membership includes all MedDRA updates, which include approved additions andchanges.

MedDRA has five hierarchical levels as listed below:

- Preferred Tem (PT)
- Low Level Term (LLT)
- High Level Term (HLT)
- Group Tem at a High Level (HLGT)
- Classification of System Organs (SOC)
- The lowest level of terminology is the Low Level Term (LLT). Only ONE PT is attachedto each LLT. A PT specifies the characteristics of a symptom, sign, condition, diagnosis, therapeutic indication, investigation, surgery, or medical procedure, as well as medical, social, or family history.
- HLT is a superordinate descriptor for PTs that are linked to it. A superordinate descriptor for one or more

HLTs that are associated by anatomy, pathology, physiology, aetiology, or function is a High Level Group Term (HLGT). The highest level of hierarchy is the System Organ Class (SOC). The SOCs are divided into three categories: origin, manifestation place, and purpose. [7]

Common problems faced by medical coding expert while coding:

unreadable verbatim terms • misspellings • abbreviations

- Multiple signs and symptoms are recorded as distinct events, which may lead to a diagnosis (for example: signs and symptoms recorded as running nose, cough and fever may lead to diagnosis of Pneumonia)
- Multiple medical notions were recorded at the same time. To code, the terms must be separated.
- The occurrence is reported without noting the location, for example, an ulcer is documented without any extra information such as a moth ulcer or a leg ulcer.
- Several medical ideas were documented, including the surgical process and the rationalefor the damage. However, the rationale for the injury, as well as the nature and location of the injury, are unknown.
- a drug phrase is mentioned, but there is no mention of an allergy caused by the medication or the allergy's consequence.[8]

Other dictionaries that are frequently used The Uppsala Monitoring Centre maintains and updates the World Health Organization Drug Dictionary (WHODRUG) (UMC). This is the most complete dictionary with information about pharmaceutical products. Drug regulatory agencies, pharmaceutical corporations, and contract research groups all use it (CROs). The dictionary includes proprietary and non-proprietary pharmaceutical product names from over 90 nations. The WHODRUG lexicon has gone through a lot of changes. We currently have three different sorts of dictionaries.[9]

1. WHO Drug Dictionary (WHO-DD)
2. WHO Drug Dictionary Enhanced (WHO-DD Enhanced)
3. WHO Herbal Dictionary (WHO-HD)

The WHO DD and WHO DD Enhanced mostly offer information on conventionalpharmaceutical items, however they also include the following product types:

Vaccine Medicinal productHerbal cure Supplement to the dietRadio-pharmaceutical Blood-based product A diagnostic tool Homeopathic treatment for the liver Almost every herbal entry that has been put into the WHO Drug Dictionary over the years is included in the WHO Herbal Dictionary. All herbals will be listed exclusively in the WHO Herbal Dictionary starting in 2005. The Herbal Anatomical Therapeutic Chemical (HATC) classification is used to classify the WHO Herbal Dictionary. Information about medicinal products can be found in the WHO Drug Dictionaries. This data isutilized to find a phrase (medicinal product) that is quite similar to the term reported on DCI. The dictionary includes the ATC categorization. This is used to categorise the pharmaceuticalproduct according to the active ingredient (sprincipal)'s therapeutic application.[10]

LEVEL 1: The primary anatomical group SUBDIVISION 2: THERAPEUTIC SUBGROUPS

PHARMACEUTICAL SUBGROUPS (LEVEL 3) CHEMICAL SUBGROUPS (LEVEL 4) CHEMICAL SUBSTANCE, LEVEL 5

The ATC categorization for the medical substance Metformin will be as follows, according to theabove system:

A stomach and intestines, as well as metabolism (1st level, anatomical main group)

A10 Diabetes Medications

(therapeutic subgroups at the second level)

A10B Insulins, blood glucose-lowering medicines pharmacological

subgrous (3rd level) Biguanides A10BA

(chemical subgroup, 4th level)Metformin (A10BA02)

Chemical compound (5th level)

Common problems faced by medical coding expert while coding medicinal products:

spelling errors

- use of abbreviations
- indication prescribed for the medicinal product is not an approved indication mentioned onprescribing information
- local brand available in market and generic/active ingre-dient is not known.
- multiple medications recorded together. To code we need to split the terms.[11]

CONCLUSION

The conversion of procedures, healthcare diagnoses, medical services, and equipment into medical alphanumeric codes is known as medical coding. Reducing and managing medical coding and billing errors has a significant impact on the organization's accuracy and revenue. The majority of errors were due to insufficient documentation, incorrect coding and modifiers, service unbundling, a lack of knowledge on coding guidelines, anatomy, and medical terminology. Proper training on coding guidelines, auditing and monitoring, and imparting knowledge on - medical terminology, anatomy and physiology, medical abbreviations, and diagnosis are all ways to reduce errors among medical coders. Coding and billing errors are avoidable, but they can be reduced and managed by understanding the cause of the error.[12]

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