

Coding dictionaries information: How to manage? How to use?

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ABSTRACT

This paper will present you the way we use the Medical Dictionary for Regulatory Activities (*MedDRA*) and the WHO Drug Dictionary (*WHODD*).

Three main steps can be identified:

- the load of the data
- the merge with the study datasets
- the reporting

INTRODUCTION

Coding information's is available in four different datasets:

- Two for MedDRA (SOC and SMQ datasets)
- Two for WHODD (ATC and ING datasets)

The SOC dataset displays full hierarchical information from LLT to SOC and all paths (primary and secondaries).

The SMQ dataset displays all SMQ information with related PTs and LLTs.

The ATC dataset displays full hierarchical information from recno to ATC code and all ATC hierarchies.

The ING dataset displays all drug names with their related ingredients.

More details with examples will be given in the presentation to explain the contents of these datasets.

LOAD OF DATA

The Clinical Data Management is in charge of load the 4 datasets in the CDM database.

The merge with the study datasets is done at this level.

But, due to some Issue of system performance, DB size or DB structure, it has been decided to do this merge at the very last moment.

The next paragraph will explain in details the merge.

MERGE WITH THE STUDY DATASETS

EXAMPLE OF STEPS FOR THE MERGE BETWEEN THE ATC DICTIONARY AND THE STUDY MEDICATIONS DATASET

1. Identified and Remove variables related to coding from the study dataset

```
proc contents data=dico_who out=contents noprint; run;
data _null_;
  attrib drop_items format=$200. label='Drop Items';
  retain drop_items '';
  set contents end=EOF;
  if substr(upcase(name),3) in ('DECOD','MED','DICTV') |
     substr(upcase(name),1) in
('ATCCHO','ATCLIST','ATCSEL','DRUGKEY','DRUGNAM','SATCNL1','SATCNL2','SATCNL3')
  then do;
    drop_items = compbl(drop_items||' '||name);
  end;
  if EOF then call symput('drop_items',drop_items);
run;
```

2. Retrieve ATC path from dictionary

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```
proc sort data= whodd.ATC(where=(seq2='001') rename=(recno=recno_d seq1=seq1_d))
out=ATC(drop=seq2);
by drugkey;
run;
```

3. Merge study data & ATC information

```
proc sql;
create table &data_out. (drop=recno_d seq1_d) as
select a.*
       ,b.*
from dico_who (drop=&drop_items) a left join atc b
on a.&v_merg1=b.recno_d and a.&v_merg2=b.seq1_d
order by line_no
;
quit;
```

THE REPORTING

The possible use is very important

Here is a classic example of the AE report but we will present you other approaches (screening, grouping ...)

Number (%) of patients experiencing TEAE(s) presented by Primary System Organ Class and Preferred Term

Primary System Organ Class Preferred Term n(%)	Trt A (N=XX)	Trt B (N=XX)
Any class	xxx (xx.x%)	xxx (xx.x%)
Infections and infestations	xxx (xx.x%)	xxx (xx.x%)
Influenza	xxx (xx.x%)	xxx (xx.x%)
Nasopharyngitis	xxx (xx.x%)	xxx (xx.x%)
Gastroenteritis	xxx (xx.x%)	xxx (xx.x%)
Bronchitis	xxx (xx.x%)	xxx (xx.x%)
Sinusitis	xxx (xx.x%)	xxx (xx.x%)
Upper respiratory tract infection	xxx (xx.x%)	xxx (xx.x%)
Cystitis	xxx (xx.x%)	xxx (xx.x%)
General disorders and administration site conditions	xxx (xx.x%)	xxx (xx.x%)
Asthenia	xxx (xx.x%)	xxx (xx.x%)
Fatigue	xxx (xx.x%)	xxx (xx.x%)
Pyrexia	xxx (xx.x%)	xxx (xx.x%)

CONCLUSION

The possible uses of the coding dictionaries are very important but it should be used very carefully if the user wants to extract the right information.

CONTACT INFORMATION

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