



Innovative Clinical Development Solutions

Migration of Rave Coder

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PROMETRIKA Sandbox

- Test Synonyms in PROMETRIKA sandbox prior to implementing on production study
 - Created synonym lists from the terms coded in DsNavigator
 - Set up coder according to the PROMETRIKA coder implementation process
 - Created a test study
 - Downloaded the production study ALS and uploaded to the test study
 - Configured Rave fields for coding
 - Created test subjects with data for coding/UAT Synonym lists

Synonym Lists - Adverse Events, Concomitant Medications, and Medical History

- Created Synonym list specifications
 - Report Logic for synonym lists
 - Mapping specifications
 - Synonym lists to contain a list of unique coded terms
 - Create synonym lists of coded terms so that the terms will automatically code when the terms are uploaded from Rave into Coder.
- Programmatically mapped specific DsNavigator fields to the Coder Synonym list template
 - Verbatim|Code|Level|Path|Primary Flag|Supplemental Info|Status**

Mapping of DsNavigator Fields to the Coder Synonym List

Column Name and order for Text file	Column Name from DSNavigator
Verbatim	Verbatim
Code	Key Value
Level	Term Type
Path	Concatenate the fields as below: Object Code; Level 4 Type:Level 4 Code; Level 3 Type:Level 3 Code;Level 2 Type:Level 2 Code; Level 1 Type:Level 1 Code
Primary Flag	NA
Supplemental Info	AVFYN: Reference #4 (eg;-AVFYN:Yes or AVFYN: No)
Status	NA

Synonym List Concomitant Medication

- Special Considerations for this synonym list
- The format of **Code** in the synonym list is '**XXXXXX XX XXX**'.
 - Eg:-In DSNavigator file, the value is '00139501007'. This value needs to be formatted to 001395 01 007 in the synonym list.
 - e.g. Trade = PRODUCTSYNONYM = 001395 01 007 = formatted for synonym list
 - e.g. Preferred = PRODUCT = 001395 01 001 for all products add 001 to the end after the number has been formatted

Synonym List UAT

- Synonym Lists Review
 - QC of Programming
 - Visual verification of synonym lists according to the specifications
 - QC only unique terms present
- Synonym Lists test upload in PROMETRIKA Sandbox

Synonym List Upload UAT

- Errors noted during upload tests for AE, MH and CMED
- Verbatim terms were not altered, so these terms were removed from the synonym lists and were manually coded after the migration
 - Synonym exists with a different path
 - Verbatim column value cannot contain ;, :, | or invalid escape values

Synonym List Upload UAT

- Supplemental Info contains invalid format
 - Can not have ";" in the CMREAS therefore will not upload per specification requirements
- Invalid synonym upload path
 - Invalid path error acceptable as these medications do not code to the ATC4 Code level
- Synonym exists with a different path
 - This error indicates a medication that has same verbatim and route and indication but different ATC4 Code and text.

Study Migration

- Provided Final Synonym Lists to be uploaded
- Set up Coder on Study segment per our Coder Implementation process; included creating blank Synonym lists and then uploading synonyms
- UAT coded fields/Coder integration
 - Reviewed/Coded Production terms that did not autocode per the Synonym List Upload reports
 - Compared Rave and DsNavigator coded files

Other Items Updated

- Upgrading the Study URL
 - (a) have the Coding Hierarchy automatically applied to the CVs, so no script/CMP would be required to get the proper WhoDRUG columns added to the CVs
 - (b) have the terms requiring coding automatically sent to Coder as part of the Rave study migration, rather than needing Medidata to requeue all of the verbatims
- In configuring the Coder application, we discovered that there was no existing “Site from Coder” marking group on the Study URL. Marking group was added.