1. Drug-ADE Table.

NAME DESCRIPTION

----------- -----------------------------------------------------------------

ISR Number that uniquely identifies an AERS report. Primary link field between data files.

DRUG\_SEQ Unique number for identifying a drug for an ISR. To link to the THERyyQq.TXT data file in AERS, both the ISR number (primary key) and the DRUG\_SEQ number (secondary key) are needed.

DRUG\_NAME “DRUGNAME”, “ROUTE”, “DOSE\_VBM” fields in “DRUG” file of AERS are concatenated into this “DRUG\_NAME” field, ending with space and dot.

RxCUI Normalized RxNorm CUI for DRUG\_NAME.

SOC CODE System Organ Class code in MedDRA.

PT CODE Preferred Term code in MedDRA.

PT Preferred Term in MedDRA.

1. Drug Normalization Table.

NAME DESCRIPTION

----------- -----------------------------------------------------------------

Pattern The pattern of mapping between AERS drug and NDF-RT classes, including “exact mapping” and “one-many mapping”.For more details see the note.

RxCUI1 RxCUI of NDF-RT classes

Drug\_Class\_type   Class types in NDF-RT, for example “VA Class”. See Table 1

for detail.

RxCUI2 RxCUI Mapping to NDF-RT from RxCUI3.

RxCUI3 Normalized RxCUI for DRUG\_NAME in AERS.

TTY1 Term types of RxCUI3 in RxNorm.

Path Traversal path in NDF-RT from RxCUI2 (if any).

REL RxNorm relationship(s) of RxCUI3 to RxCUI2 (if any).

TTY2 Term type of RxCUI2 in RxNorm (if any).  

1. Drug-ADE-Outcome Table

NAME DESCRIPTION

----------- -----------------------------------------------------------------

OUTC\_COD Code for a patient outcome

ISR Number that uniquely identifies an AERS report. Primary link field between data files.

DRUG\_SEQ Unique number for identifying a drug for an ISR. To link to the THERyyQq.TXT data file in AERS, both the ISR number (primary key) and the DRUG\_SEQ number (secondary key) are needed.

DRUG\_NAME “DRUGNAME”, “ROUTE”, “DOSE\_VBM” fields in “DRUG” file of AERS are concatenated into this “DRUG\_NAME” field, ending with space and dot.

RxCUI Normalized RxNorm CUI for DRUG\_NAME.

SOC CODE System Organ Class code in MedDRA.

PT CODE Preferred Term code in MedDRA.

PT Preferred Term in MedDRA.

OUTC\_COD Code for a patient outcome. (See table below.)

CODE MEANING\_TEXT

----------- -----------------------------------------------------------------

DE Death

LT Life-Threatening

HO Hospitalization - Initial or Prolonged

DS Disability

CA Congenital Anomaly

RI Required Intervention to Prevent Permanent Impairment/Damage

OT Other

1. Table for Coverage of AERS drugs by NDF-RT classes. “Drug\_class\_type” represents various classes provided by NDF-RT as shown, and “Drug\_Class (No.)” is the number of the direct subordinate classes of each Drug\_class\_type. “Total No. of RxNorm concepts in AERS” shows the total number of RxNorm concepts in AERS for each drug class type.

|  |  |  |
| --- | --- | --- |
| **Drug\_class\_type** | **Drug\_class (No.)** | **Total No. of RxCUI in AERS** |
| Generic Ingredient Combinations | 26 | 9813 |
| VA class | 29 | 5823 |
| FDA\_Established\_Pharmacologic\_Class (EPC) | 66 | 3049 |
| Chemical Ingredients Class | 16 | 9331 |
| Therapeutic Category | 7 | 2880 |
| Therapeutic Intent  induces may\_diagnose may\_prevent may\_treat | 7 | 8069 |
| Mechanism\_of\_Action  has\_mechanism\_of\_action has\_contraindicating\_mechanism\_of\_action | 7 | 8061 |
| Physiologic\_Effect  has\_physiologic\_effect has\_contraindicating\_physiologic\_effect | 16 | 7989 |
| Pharmacokinetics  has\_pharmacokinetics site\_of\_metabolism | 1 | 730 |

Note: **Exact mapping** means one AERS drug is mapped to one or more NDF-RT classes through only one NDF-RT term, for example “103 (mercaptopurine)” itself can be mapped to NDF-RT, and has two Physiologic Effects of “990547 (Decreased DNA Integrity)” and “988443 (Decreased RNA Integrity)”; or one AERS drug is mapped to the same NDF-RT classes through multiple NDF-RT terms, for example “496585 (Clindesse)” was mapped to both clinical product “Clindamycin 100 MG Vaginal Suppository” and precise ingredient “clindamycin phosphate” in NDF-RT, which belong to the same Therapeutic Category of “884 (Anti-infective Agent)”. **One-many mapping** means one AERS drug is mapped to different NDF-RT classes through multiple NDF-RT terms, for example “317461 (Phenobarbital 32 MG)” was mapped to three clinical products “315172 (PHENOBARBITAL 32MG CAP)”, “308847 (CA GLUCONATE 130MG/NIACINAMIDE 3MG/PHENOBARB 32MG TAB)” and “312364 (PHENOBARBITAL 32MG TAB,EC)” in NDF-RT, which belong to two VA classes “4703 (GASTROINTESTINAL MEDICATIONS)” and “2225 (CENTRAL NERVOUS SYSTEM MEDICATIONS)”.