

SafeRx: FAERS Data Element Definitions and Data Interpretation

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This document describes the data elements and data relationships for reported adverse drug event information imported from the FDA Adverse Event Reporting System (FAERS) website <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm082193.htm>. FAERS data files contain information on adverse drug events (ADEs) which have been reported to the FDA.

The FDA assigns each incoming report a unique primary identifier (primary ID), and information corresponding to a report is divided among several data categories which are stored as separate files at the FAERS website: demographics, drugs, reactions, indications, outcomes, report sources, and therapy. Report information stored across data categories (i.e., in separate files) is linked by the reported event's unique primary ID.

In this document, we will describe:

- FAERS data elements. Data corresponding to a reported adverse event is uniquely identified by a primary ID and includes:
 - Demographic information
 - List of one or more drugs
 - Role for each drug listed
 - Zero or more indications for each drug listed
 - Zero or more therapies for each drug listed
 - List of one or more reactions
 - List of zero or more outcomes
- How data elements are related, in particular which data elements are directly linked to the report primary ID only and which data elements are directly linked to the report primary ID and to a specific drug listed in the reported event. We also explore inferences we can make based on interpretation of data relationships
- Algorithm for counting ADE reports for specified criteria

The information is presented in six sections:

1. FAERS data categories (FDA files) and their SafeRx dataviews
2. Key FAERS data elements by category and uniqueness information
3. More information about the Primary ID, Case ID and Case version number
4. Interpretation of FAERS data for SafeRx reports
5. Algorithm for ADE report counting
6. FDA definitions and notes

1. FAERS data categories (FDA files) and their SafeRx dataviews

There are seven types of files provided by the FDA FAERS system: demographics, drugs, reactions, indications, outcomes, report sources, and therapy. The files and their content are described in this section.

Each file (data category) has a SafeRx dataview that shows all data elements provided by the FDA for that category. Some of the dataviews are long-running (e.g., demographics, data), but these dataviews are very useful because

- All available data elements provided by the FDA are displayed. Therefore, these views can be used by the SafeRx researchers to identify any new data elements they would like to incorporate into investigative dataviews (the new dataviews are then fine-tuned for performance.)
- Researchers can check the completeness of the FDA data by filtering on blanks or dashes in the column searchboxes above any column. Much of the FDA data is sparse and these dataviews allow you to see where and how often there is missing data.

- (1) Demographics file: Contains patient demographic and administrative information. For each reported event, the demographic and administrative information data element is uniquely associated with the primary ID assigned to that report. The dataview <https://ccheb.org/dataviewer/view/saferx:db/demographics/> shows all data elements in the demographic file. Country development status and Year/Quarter have been added to the dataview.

Primary ID	Case ID	Case Version	I F Code	Event Date	Mfr Date	Init Fda Date	Fda Date	Rept Code	Auth Num	Mfr Num	Mfr Sndr	Literature References	Age	Age Code
122103651	12210365	1	Initial	-	2016-03-23	2016-03-25	2016-03-25	Expedited (15-Day)	-	US-ROCHE-1731227	ROCHE	-	-	-
122171071	12217107	1	Initial	-	2016-03-21	2016-03-29	2016-03-29	Expedited (15-Day)	GB-MHRA-EYC-00136701	GB-WATSON-2016-06364	WATSON	-	31.0	YEAR
122023191	12202319	1	Initial	-	2016-03-17	2016-03-23	2016-03-23	Periodic (Non-Expedited)	-	US-AMGEN-USASP2016035250	AMGEN	-	50.0	YEAR
122137641	12213764	1	Initial	-	2016-03-16	2016-03-28	2016-03-28	Expedited (15-Day)	-	US-GLAXOSMITHKLINE-US2016037753	GLAXOSMITHKLINE	-	-	-

- (2) Drug file: Contains drug/biologic information. For each reported event, all drugs reported for that event are listed and associated with the primary ID assigned to that report (1 or more drug per reported event). The dataview <https://ccheb.org/dataviewer/view/saferx:db/drugs/> shows all data elements in the drug file. Year/Quarter has been added to the dataview.

Primary ID	Case ID	Drug Seq	Role Cod	Drug Name	Product Active Ingredient	Val Vbm	Route	Dose Vbm	Cum Dose Chr
1180383812	11803838	2	Secondary Suspect Drug	SIGNIFOR	PASIREOTIDE	Validated trade name used	Subcutaneous	0.6 MG, BID	-
1180383812	11803838	3	Primary Suspect Drug	METOPROLOL	METOPROLOL	Validated trade name used	Unknown	25 MG, BID	-
1183308410	11833084	1	Secondary Suspect Drug	XARELTO	RIVAROXABAN	Validated trade name used	Oral	-	-
1183308410	11833084	2	Secondary Suspect Drug	XARELTO	RIVAROXABAN	Validated trade name used	Oral	-	-
1183308410	11833084	3	Secondary Suspect Drug	XARELTO	RIVAROXABAN	Validated trade name used	Oral	-	-
1183308410	11833084	4	Primary Suspect Drug	XARELTO	RIVAROXABAN	Validated trade name used	Oral	-	-

- (3) **Reaction file:** Contains reaction information using MedDRA–like terminology codes. For each reported event, all reactions reported for that event are listed and associated with the primary ID assigned to that event. None of the reactions in the list are directly linked to any particular drug reported for the event, all reactions correspond to the primary ID event only. (1 or more reaction per reported event, NOT directly associated with any particular drug listed for the reported event) The dataview <https://ccehub.org/dataviewer/view/saferx:db/reactions/> shows all data elements in the reactions file. Year/Quarter has been added to the dataview.

Reactions				
Download Fullscreen Clear Filters No-Wrap				
Show 50 entries				
Primary ID	Case ID	PT	Drug Recur Action	Year/Qua
Primary ID	Case ID	Pt	Drug Recur Action	16Q
33538582	3353858	Escherichia sepsis	-	16Q1
33568652	3356865	Cardiac failure	-	16Q1
33612122	3361212	Leukopenia	-	16Q1
34795972	3479597	Bone marrow failure	-	16Q1
34835022	3483502	Bone marrow failure	-	16Q1
34839842	3483984	Neutropenia	-	16Q1
36427022	3642702	Gastrointestinal ulcer	-	16Q1
36427022	3642702	Oesophageal stenosis	-	16Q1
36427022	3642702	Oesophageal ulcer	-	16Q1
37216792	3721679	Alanine aminotransferase increased	-	16Q1

- (4) **Outcome file:** Contains patient outcome of the reported event. All outcomes correspond to the reported event primary ID only. None of the outcomes in the list are directly linked to any particular drug or reaction reported for the event, (0 or more outcomes per reported event, NOT directly associated with any particular drug or reaction listed for the reported event). The dataview <https://ccehub.org/dataviewer/view/saferx:db/outcomes/> shows all data elements in the outcomes file. Year/Quarter has been added to the dataview.

Outcomes				
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Show 50 entries				
Primary ID	Case ID	Outc Cod	Year/Quar	
Primary ID	Case ID	Outc Cod	16Q	
33538582	3353858	Life-Threatening	16Q1	
33568652	3356865	Hospitalization - Initial or Prolonged	16Q1	
33612122	3361212	Other Serious (Important Medical Event)	16Q1	
34795972	3479597	Other Serious (Important Medical Event)	16Q1	
34835022	3483502	Other Serious (Important Medical Event)	16Q1	
34839842	3483984	Other Serious (Important Medical Event)	16Q1	
36427022	3642702	Other Serious (Important Medical Event)	16Q1	
37216792	3721679	Hospitalization - Initial or Prolonged	16Q1	
37536492	3753649	Other Serious (Important Medical Event)	16Q1	

- (5) **Report Source File:** Contains sources listed for the reported event. More than one source can be listed for a reported event. This file provides source information in addition to the single source listed in the demographic file for each reported event. The sources in this file can take on values such as foreign, study, company representative, distributor and Literature, in addition to sources like consumer and health professional which are found in the demographics file. (0 or more sources per reported event, NOT directly associated with any particular drug listed for the reported event).The dataview

https://ccehub.org/dataviewer/view/saferx:db/report_sources/ shows all data elements in the report source file. Year/ Quarter has been added to the dataview.

Report Sources			
Primary ID	Case ID	Rpsr Cod	Year/Quar
118886451	11888645	Health Professional	16Q1
118886491	11888649	Consumer	16Q1
118886691	11888669	Health Professional	16Q1
118886851	11888685	Health Professional	16Q1
118886901	11888690	Health Professional	16Q1
118887131	11888713	Health Professional	16Q1
118887311	11888731	Health Professional	16Q1

- (6) **Therapy File:** Contains the start and end dates of therapy for the drugs listed in the reported event. Each therapy entry is directly associated with both the primary ID and the reported drug (using the drug sequence number). (0 or more therapies per drug listed in the reported event, directly associated with each reported drug using the drug sequence number). The dataview <https://ccehub.org/dataviewer/view/saferx:db/therapy/> shows all data elements in the therapy file. Year/ Quarter has been added to the dataview.

Therapy						
Primary ID	Case ID	Dsg Drug Seq	Start Dt	End Dt	Dur	Dur Cod
69834743	6983474	5	2014-00-00	-	-	-
73497452	7349745	8	2014-00-00	-	-	-
74079546	7407954	6	2014-02-24	2014-03-16	-	-
74865913	7486591	2	2014-12-00	-	-	-
77207562	7720756	2	2014-00-00	-	-	-
77370402	7737040	2	2014-00-00	-	-	-
77636844	7763684	21	2014-00-00	-	-	-
77636844	7763684	22	2014-00-00	-	-	-

- (7) **Indications File:** Contains indications for drugs listed for a reported event and identified by primary ID. Indications for a reported event are directly associated with a drug listed for the event. Indications information is specified with MedDRA-like terminology codes. (0 or more indications per drug listed in the reported event, directly associated with a reported drug using the drug sequence number). The dataview <https://ccehub.org/dataviewer/view/saferx:db/indications/> shows all data elements in the indications file. Year/ Quarter has been added to the dataview.

Primary ID	Case ID	Indications	Year
40318462	4031846	HIV infection	16Q
40318462	4031846	HIV infection	16Q
40438332	4043833	Asthma	16Q
40465893	4046589	Sickle cell anaemia	16Q
40465893	4046589	Contraception	16Q
40465893	4046589	Prophylaxis	16Q
40465893	4046589	Prophylaxis	16Q
40838072	4083807	Heart transplant	16Q

2. Key FAERS data elements by category with uniqueness information

The table in this section lists key data elements from each data category (FDA file), including the data elements available as selection criteria in the SafeRx data explorer. For each data element, the association of the data to the reported event primary ID is indicated. For data elements that can also be directly linked to a particular drug listed for the reported event, an explanation of the linkage is given.

Category (file)	Data element	How many listed in a single ADE reported event	Comment
Demographics	Patient age	1	Units for age: Decade, Year, Month, Week, Day, Hour
	Patient gender	1	Values: Unknown, Male, Female, Not specified
	Patient weight	1	Units for weight: Kilograms, pounds, grams
	ADE report date	1	Date of initial case report to FDA
	Event date	1	Date of adverse event
	Occurring country	1	Country code for where the adverse event occurred
	Reporting manufacturer	1	Manufacturer sending the report for the adverse event. The manufacturer is not directly linked to any listed drug for the reported event.
Drug	Occupation of the reporting source in most recent version of case	1	Values: consumer, physician, pharmacist, other health professional, lawyer
	Drug	1 or more in a reported event. (On average, 4 drugs are reported for each event)	Reported for the adverse event. Each drug in a report is given a unique sequence number (1, 2 ...).
	Role	1 for each drug listed in a reported event. A unique role is specified for each drug listed in the reported event.	Each drug reported for an ADE event has its own unique role assigned to it. Values: primary suspect, secondary suspect, concomitant, interacting.

	Drug sequence number	1 for each drug listed in a reported event. A unique drug sequence number is specified for each drug listed in a reported event.	Each drug reported for an event has its own unique sequence number assigned to it. (1,2,3, ...) The combination of primary ID and drug sequence number is used to identify drug role, drug indication(s), and drug therapy.
	Active ingredient	Associated directly with a listed drug in the reported event.	
	Verbatim or validated trade name used	Associated directly with a listed drug in the reported event.	
	Route of drug administration	Associated directly with a listed drug in the reported event.	
	Dose information (multiple data elements)	Associated directly with a listed drug in the reported event.	Amount, unit, form, and frequency: these are identified per drug reported for the reported event.
Reaction	Reaction(s) are listed with preferred MedDRA-like terminology and assigned to a reported event	1 or more in each reported event. (On average, about 6 reactions are reported for each event)	Reported for the adverse event and NOT for any particular drug in the list of drugs for the event. There is no direct link between a reaction and any of the drugs listed for a reported event. Reactions are not ordered by priority.
Outcome	Outcome(s) assignment to a reported event	0 or more for each reported event. (On average, 1.5 outcomes are reported for each event)	Reported for the adverse event and NOT for any particular drug in the list of drugs for the event. There is no direct link between an outcome and any of the drugs listed for a reported event. Outcomes are not ordered by significance.
Report Sources	Additional details for the source of the reported event	0 or more in each reported event.	Reported for the adverse event and NOT for any particular drug in the list of drugs for the event. There is no direct link between a source and any drug for a reported event.
Therapy	Start and end dates for <u>a specific drug</u> listed in a reported event	0 or more for a drug listed in the reported event.	Drugs reported for an event have their own unique therapy information assigned. Dates are sparse and can show only year (not month or day)
Indications	Indication(s) are MedDRA-like terminology assigned to <u>each drug</u> listed in a reported event	0 or more for each drug listed in a reported event.	Each drug reported for an event has its own unique indication(s) assigned to it based on the drug sequence number.

3. More information about the Primary ID, Case ID and Case Version Number

The FDA definitions for the primary ID and case ID with version number are listed in the table below, along with the relationships of the identifiers.

Data element	Description	Relationship to Primary ID
PRIMARYID	Unique number for identifying a FAERS report. This is the link between report data that is separated into different files. It concatenates Case ID and Case Version Number.	
CASEID	Number identifying a FAERS case. A case consists of one or more versions. A follow-up version (i.e., the newest or most recent version received by FDA) will have the same CASE number as the initial or oldest version.	PRIMARYID encompasses one or more cases. The PRIMARYID contains the CASEID and is followed by the CASEVERSION
CASEVERSION	Version number of the report case. The initial case report is version 1; follow-ups to the case are incremented sequentially.	PRIMARYID encompasses one or more cases. The PRIMARYID contains the CASEID and is followed by the CASEVERSION

4. Interpretation of the FAERS data for SafeRx Reports

To better understand the results of SafeRx reports, some facts and inferences about the data are given here.

Fact: Each reported event (with unique primary ID) has one or more drugs listed for that event.

Fact: Each drug listed in a reported event has a unique drug sequence number to identify it within the event. This sequence number is used to uniquely assign a role, indication and therapy to a drug reported for the event.

About reactions and drugs ...

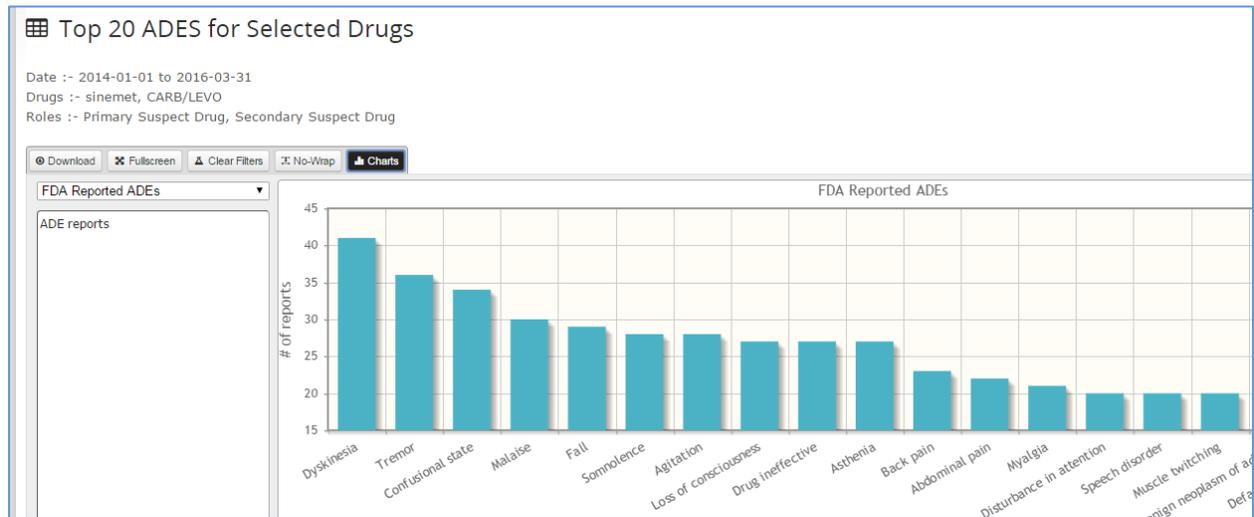
Fact: The primary and secondary suspect roles are assigned to each drug individually. The purpose of assigning a primary or secondary suspect role is to identify the most likely of the listed drugs to have caused the adverse event.

Fact: **Reactions** are listed by reported event and are not directly associated with any particular drug listed for the reported event.

Inference: Any drug listed as a primary or secondary suspect for a reported event is more likely than the other drugs in the list to have caused reported reactions, in particular those reactions that are significant.

Inference: In presenting ADE report counts to link a drug to a reaction (or reaction to a drug), the association of primary or secondary suspect drug to a reaction is more likely when the number of reported cases in which they appear together is large.

Confirmation: When the top 20 ADEs for a selected primary or secondary suspect drug are consistent with side-effects identified for that drug.



Side effects listed by <http://www.webmd.com/> and <http://www.parkinson.org/> for sinemet: dyskinesia (writting, muscle twitching), confusion, sleepiness, sudden onset sleep, compulsive behaviors, impulse control disorder, disorientation, lightheadedness, dizziness. Tremors and speech disorders are symptoms of Parkinson’s Disease. The expected side-effects for sinemet are reflected in the SafeRx-processed Top 20 reactions for that drug.

About outcomes and drugs ...

Fact: **Outcomes** are listed by reported event and are not directly associated with any particular drug listed for the reported event.

Inference: Any drug listed as a primary or secondary suspect for a reported event is more likely than the other drugs in the list to have caused the listed outcomes.

Inference: In presenting the ADE report counts to link a drug to an outcome, the association of primary or secondary suspect drugs to a serious outcome such as “life threatening” or death is more likely when the count is high, e.g., in the thousands.

SafeRx processing of Top 20 drugs and reaction reports is based on nearly 20 million data records provided by the FDA.

5. Algorithm for SafeRx Report Counting

This section documents our report counting algorithms for the SafeRx data explorer and the information is presented in the table below. The details for how our queries operate can be used for comparison against reported event results from other sources such as ResearchAE <http://www.researchae.com/drugevent> and the Institute for Safe Medical Practices (ISMP). Some notes about the selection criteria available at ResearchAE are included in the table.

Quick notes about ResearchAE and SafeRx:

ResearchAE does not give users a list of choices for drugs, reactions, indications and manufacturers that are available in the FAERS data. This makes it challenging to know what to enter for those criteria when using the tool at ResearchAE. The SafeRx data explorer provides a “magnifying glass” where researchers can click to see and search all possible FAERS names for drugs, reactions, indications and manufactures. This SafeRx feature is a useful aid for selecting criteria because it lets users see all possible FAERS data values – and users can make their choices for drugs, reactions, etc. from the listing.

ResearchAE has selection by pharmacological class and classifications by generic and brand, which are not currently available in the SafeRx data explorer. We will be adding classifications to the data explorer in the coming year.

This table describes how data explorer selection criteria are used to query FAERS data for SafeRx report counting.

No.	Field	SafeRx Values	Comment
1	Date	Date and date range queries use the demographics value for Report Date, the initial date the case was reported to the FDA	The FDA initial report date is available for 100% of the report. The Event Date is missing for 46% of the reported events. (*)
2	Age	Users can specify age in years, but can also choose specifically to look at ages that were reported in days, months or not specified.	The query for age searches demographic age data for the user’s selected criteria. If no criteria is specified, all reported events are used without regard to age, and includes those events where age is not specified. ResearchAE does not support searches on events where age is specified in days or months.
3	Gender	Gender choices are M, F, NS, or blank. Age queries allow selection for all choices or any subset of the choices	The query for gender uses exact match for each selection. If no criteria is specified, all reported events are considered without regard to the gender value, and includes events where gender is not specified. Research AE does not distinguish between NS and blank, and doesn’t allow those to be specifically selected.
4	County	All countries or selected countries (up to 4) using demographic “occurring” country. Users can include or not include reports where the country is not specified.	The country query uses exact match on selected countries. If no criteria is specified, all reported events are considered without regard to country, and includes events where country is not specified.
5	Drug	The query for drug names can be specified as “exact match” or as “similar match”. There are 20 entry boxes for the selection of drug names.	When drugs are submitted with “exact match”, the query matches the entered name exactly against FAERS drug names listed in the reported event. When drug are submitted with “similar match”, the query currently matches ANY drug name that BEGINS with the entered drug name and is followed by any other characters. We will enhance this match to include any drug name that CONTAINS the entered drug (i.e. will match if the entered drug appears anywhere WITHIN the FAERS drug name) (**)

			<p>Note that the full list of ALL MATCHING DRUGS from the query can be seen on the drop down menu in the column selection box above the drug column of the generated report dataview.</p> <p>ResearchAE does not specify how entered drug names are matched for their query.</p>
6	Manufacturer	Reporting manufacturer. Up to 4 reporting manufacturers can be entered, and users can include or not include reported events where the reporting manufacturer is not specified.	<p>The query does an exact match on the selected reporting manufacturer. If no are criteria specified, all reported events are considered without regard to reporting manufacturer, including those where it is not specified.</p> <p>Note that the reporting manufacturer is not necessarily the manufacture of any of the listed drugs in the reported event.</p>
7	Role	0 or more roles can be chosen from the 4 choices (primary suspect, secondary suspect, concomitant, interacting). The chosen roles <u>are applied to each drug entered in the selected criteria.</u>	Since roles are directly linked to drugs, the query ensures that the selected drugs for all reported events returned have the identified roles. If no roles are chosen, then the drugs are not restricted by role for the generated report dataview.
8	Indication	Up to 4 indications can be entered. Indications <u>are applied to each of the selected drugs.</u> Since indications are directly associated with drugs – if entering an indication, the user should ensure that the indication does apply to all selected drugs, otherwise the query will return an empty report.	<p>The query applies all indications entered to all selected drugs.</p> <p>Indications for each drug in a reported event are stored as separate comma-separated items (identified by primary ID and by drug). If the user chooses “exact match”, the query will do an “exact match” on the chosen indications for each item in the comma-separated list for each drug.</p> <p>Otherwise the query will search for the selected indication anywhere in the FAERS indication list. For example, for a similar match for “pain”, the query will find indications such as the following: “pain”, “abdominal pain”, “pain in extremity”, and “back pain, injury”.</p> <p>ResearchAE does not specify how entered indications are matched for their query.</p>
9	Reaction	Up to 4 reactions can be entered. The chosen reactions <u>are applied to the reported events</u> by primary ID, since reactions are linked to reported events only (and not to specific drugs in a reported event)	Reactions are stored as comma-separated items for each reported event (primary ID). The query will always do a “similar match” search on the FAERS reaction list for each reported event.

			<p>More precisely, the reaction query will search the comma-separated list to see if the entered reactions appear ANYWHERE WITHIN any reaction listed for each reported event. Thus the entered reaction can be any part of the reaction: it can appear at the beginning, end, or within.</p> <p>ResearchAE does not specify how entered reactions are matched for their query.</p>
10	Outcome	<p>0 or more outcomes can be chosen from the 8 choices. The chosen outcomes <u>are applied to the reported events</u>, since outcomes are linked to reported events and not to drugs listed for an event.</p> <p>Users can include or not include reported events where the outcome is not specified.</p>	<p>The query does an exact match on the outcomes chosen by the user. Since outcomes are a comma separated list associated with a reported event, the query searches for the exact match within the list of outcomes.</p> <p>If no criteria is selected, then the outcome values are ignored in selecting reported events, and include those outcomes which are not specified.</p>
11	Source	<p>0 or more sources can be chosen from the 8 choices. The source selections are from the demographics data and the query searches the demographic source value for the user's selections.</p> <p>Users can include or not include reported events where the source is not specified.</p>	<p>The query does an exact match on the sources chosen by the user against the demographic source value associated uniquely with a reported event primary ID.</p> <p>If no criteria is selected, then the source values are ignored in selecting reported events, and include those sources which are not specified.</p>

(*) Why we chose the FDA report date for our date and date range queries:

table	attribute	total	is null	is not null	% is null	% is not null
demographics	event_dt	3641813	1670213	1971600	45.86%	54.14%
demographics	mfr_dt	3641813	127616	3514197	3.50%	96.50%
demographics	init_fda_dt	3641813	0	3641813	0.00%	100.00%
demographics	fda_dt	3641813	0	3641813	0.00%	100.00%
demographics	rept_dt	3641813	5718	3636095	0.16%	99.84%

(**) Drug names in the FAERS data must be cleaned and curated so that the matching does not require handling of corner cases, for example where drug names have random characters inserted. The cleaning and curation of drug names is a proposed task for the coming year.

6. FDA definitions and notes

"ASC_NTS.DOC" FILE FOR THE
QUARTERLY DATA EXTRACT (QDE) FROM THE
FDA ADVERSE EVENT REPORTING SYSTEM (FAERS)

U.S. FOOD AND DRUG ADMINISTRATION (FDA)
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY (OSE)

REVISED January 2015

IMPORTANT:

This document describes significant changes resulting from the FDA's transition from Legacy AERS (LAERS) to the new FDA AERS (FAERS) database. We have added fields to the FAERS database structure and have made minor changes to existing field contents. Users of the QDE ASCII extract file should review all of these database changes before loading the file into their systems.

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A. INTRODUCTION

The ASCII data files are '\$' delimited; that is, a '\$' separates the data fields. You can import these files into SAS, MS Access or other database programs. (Some data files, such as DRUGyyQq and REACyyQq, will exceed the maximum number of records that can be imported into spreadsheet programs such as MS Excel.)

In the ASCII format, file names have the format <file-descriptor>yyQq, where <file-descriptor> is a 4-letter abbreviation for the data source, 'yy' is a 2-digit identifier for the year, 'Q' is the letter Q, and 'q' is a 1-digit identifier for the quarter. As an example, DEMO12Q4 represents demographic file for the 4th quarter of 2012.

The set of seven ASCII data files in each extract contains data for the full quarter covered by the extract.

B. FILE DESCRIPTIONS

ASCII Data Files:

1. DEMOyyQq.TXT contains patient demographic and administrative information, a single record for each event report.
2. DRUGyyQq.TXT contains drug/biologic information for as many medications as were reported for the event (1 or more per event).
3. REACyyQq.TXT contains all "Medical Dictionary for Regulatory Activities" (MedDRA) terms coded for the adverse event (1 or more). For more information on MedDRA, please contact the MSSO Help Desk at mssohelp@meddra.org. The website is www.meddra.org.
4. OUTCyyQq.TXT contains patient outcomes for the event (0 or more).
5. RPSRyyQq.TXT contains report sources for the event (0 or more).
6. THERyyQq.TXT contains drug therapy start dates and end dates for the reported drugs (0 or more per drug per event).
7. INDIyyQq.TXT contains all "Medical Dictionary for Regulatory Activities" (MedDRA) terms coded for the indications for use (diagnoses) for the reported drugs (0 or more per drug per event).

ASCII Informational Files:

-
1. ASC_NTS.DOC, which you are reading, shows in some detail the organization and content of the ASCII data files.
 2. STATyyQq.TXT gives null (that is, no data) counts and frequency counts for selected fields in the ASCII data sets. (The frequency counts also include the number of null values; however, the percentages shown are for non-null values only.)

C. DATA ELEMENT DESCRIPTIONS

1) DEMOGRAPHIC file (DEMOyyQq.TXT)

NAME DESCRIPTION

PRIMARYID Unique number for identifying a FAERS report. This is the primary link field (primary key) between data files (example: 31234561). This is a concatenated key of Case ID and Case Version Number. It is the Identifier for the case sequence (version) number as reported by the manufacturer.

CASEID Number for identifying a FAERS case (example. 3123456). A case consists of one or more versions. A follow-up version (that is, the newest/latest version received by FDA) will have the same CASE number as the initial/oldest version.

CASEVERSION Safety Report Version Number. The Initial Case will be version 1; follow-ups to the case will have sequentially incremented version numbers (for example, 2, 3, 4, etc.).

I_F_COD Code for initial or follow-up status of report, as reported by manufacturer.

CODE MEANING_TEXT

---- -----

I Initial
 F Follow-up

EVENT_DT Date the adverse event occurred or began. (YYYYMMDD format) – If a complete date is not available, a partial date is provided. See the NOTE on dates at the end of this section.

MFR_DT Date manufacturer first received initial information. In subsequent versions of a case, the latest manufacturer received date will be provided (YYYYMMDD format). If a complete date is not available, a partial date will be provided. See the NOTE on dates at the end of this section.

INIT_FDA_DATE Date FDA received first version (Initial) of Case (YYYYMMDD format)

FDA_DT Date FDA received Case. In subsequent versions of a case, the latest manufacturer received date will be provided (YYYYMMDD format).

REPT_COD Code for the type of report submitted. (See table below.)
 Also, see Section E, End Note 1, below.

CODE	MEANING_TEXT
---	-----
EXP	Expedited (15-Day)
PER	Periodic (Non-Expedited)
DIR	Direct

MFR_NUM Manufacturer's unique report identifier.

MFR_SNDR Coded name of manufacturer sending report; if not found, then verbatim name of organization sending report.

AGE Numeric value of patient's age at event.

AGE_COD Unit abbreviation for patient's age. (See table below.)

CODE	MEANING_TEXT
---	-----
DEC	DECADE
YR	YEAR
MON	MONTH
WK	WEEK
DY	DAY
HR	HOUR

GNDR_COD Code for patient's sex. (See table below.)

CODE	MEANING_TEXT
---	-----
UNK	Unknown
M	Male
F	Female
NS	Not Specified

E_SUB Whether (Y/N) this report was submitted under the electronic submissions procedure for manufacturers.

WT Numeric value of patient's weight.

WT_COD Unit abbreviation for patient's weight. (See table below.)

CODE	MEANING_TEXT
----	-----
KG	Kilograms
LBS	Pounds
GMS	Grams

REPT_DT Date report was sent (YYYYMMDD format). If a complete date is not available, a partial date is provided. See the NOTE on dates at the end of this section.

TO_MFR Whether (Y/N) voluntary reporter also notified manufacturer (blank for manufacturer reports).

OCCP_COD Abbreviation for the reporter's type of occupation in the latest version of a case.

CODE	MEANING_TEXT
----	-----
MD	Physician
PH	Pharmacist
OT	Other health-professional
LW	Lawyer
CN	Consumer

REPORTER_COUNTRY The country of the reporter in the latest version of a case:

NOTE: Country codes are available per the links below.

http://estri.ich.org/icsr/ICH_ICSR_Specification_V2-3.pdf

http://www.iso.org/iso/home/standards/country_codes/iso-3166-1_decoding_table.htm

OCCR_COUNTRY The country where the event occurred.

2) DRUG file (DRUGyyQq.TXT)

NAME DESCRIPTION

PRIMARYID Unique number for identifying a FAERS report. This is the primary link field (primary key) between data files (example: 31234561). This is a concatenated key of Case ID and Case Version Number. It is the Identifier for the case sequence (version) number as reported by the manufacturer.

CASEID Number for identifying a FAERS case.

DRUG_SEQ Unique number for identifying a drug for a Case. To link to the THERyyQq.TXT data file, both the Case number (primary key) and the DRUG_SEQ number (secondary key) are needed. (For an explanation of the DRUG_SEQ number, including an example, please see Section E, End Note 2, below.)

ROLE_COD Code for drug's reported role in event.(See table below.)

CODE	MEANING_TEXT
PS	Primary Suspect Drug
SS	Secondary Suspect Drug
C	Concomitant
I	Interacting

DRUGNAME Name of medicinal product. If a "Valid Trade Name" is populated for this Case, then DRUGNAME = Valid Trade Name; if not, then DRUGNAME = "Verbatim" name, exactly as entered on the report. For the great majority of reports, there is a "Valid Trade Name."

VAL_VBM Code for source of DRUGNAME.(See table below.)

CODE	MEANING_TEXT
1	Validated trade name used
2	Verbatim name used

ROUTE The route of drug administration.

DOSE_VBM Verbatim text for dose, frequency, and route, exactly as entered on report.

CUM_DOSE_CHR Cumulative dose to first reaction

CUM_DOS_UNIT Cumulative dose to first reaction unit

CODE	Meaning_Text
KG	Kilogram(s)
GM	Gram(s)
MG	Milligram(s)
UG	Microgram(s) (µg)
NG	Nanogram(s)
PG	Picogram(s)
MG/KG	Milligram(s)/Kilogram
UG/KG	Microgram(s)/Kilogram (µG/KG)
MG/M**2	Milligram(s)/Sq. Meter
UG/M**2	Microgram(s)/Sq. Meter (µG/M**2)
L	Litre(s)
ML	Millilitre(s)
UL	Microlitre(s) (µL)
BQ	Becquerel(s)
GBQ	Gigabecquerel(s)
MBQ	Megabecquerel(s)
KBQ	Kilobecquerel(s)
CI	Curie(s)
MCI	Millicurie(s)
UCI	Microcurie(s) (µCi)

NCI	Nanocurie(s)
MOL	Mole(s)
MMOL	Millimole(s)
UMOL	Micromole(s)
IU	International Unit(s)
KIU	International Unit*(1000s)
MIU	International Unit*(1,000,000s)
IU/KG	IU/Kilogram
MEQ	Milliequivalent(s)
PCT	Percent (%)
GTT	Drop(s)
DF	Dosage Form

DECHAL Dechallenge code, indicating if reaction abated when drug therapy was stopped. (See table below.)

CODE	MEANING_TEXT
----	-----
Y	Positive dechallenge
N	Negative dechallenge
U	Unknown
D	Does not apply

RECHAL Rechallenge code, indicating if reaction recurred when drug therapy was restarted. (See table below.)

CODE	MEANING_TEXT
----	-----
Y	Positive rechallenge
N	Negative rechallenge
U	Unknown
D	Does not apply

LOT_NUM Lot number of the drug.

EXP_DT Expiration date of the drug. (YYYYMMDD format) - If a complete date is not available, a partial date is provided, See the NOTE on dates at the end of this section.

NDA_NUM NDA number (numeric only)

DOSE_AMT Amount of drug reported

DOSE_UNIT Unit of drug dose

DOSE_FORM Form of dose reported

DOSE_FREQ Code for Frequency.

NOTE: The list below provides frequency codes which are commonly reported; however, dose frequency codes are not limited to this list and other code values may be present.

CODE	Meaning_Text
----	-----
1X	Once or one time

BID	Twice a day
BIW	Twice a week
HS	At bedtime
PRN	As needed
Q12H	Every 12 hours
Q2H	Every 2 hours
Q3H	Every 3 hours
Q3W	Every 3 weeks
Q4H	Every 4 hours
Q5H	Every 5 hours
Q6H	Every 6 hours
Q8H	Every 8 hours
QD	Daily
QH	Every hour
QID	4 times a day
QM	Monthly
QOD	Every other day
QOW	Every other week
QW	Every week
TID	3 times a day
TIW	3 times a week
UNK	Unknown

3) REACTION file (REACyyQq.TXT)

NAME DESCRIPTION

PRIMARYID Unique number for identifying a FAERS report. This is the primary link field (primary key) between data files (example: 31234561). This is a concatenated key of Case ID and Case Version Number – Identifier to be used as the case sequence (version) number as reported by manufacturer.

CASEID Number for identifying a FAERS case.

PT "Preferred Term"-level medical terminology describing the event, using the Medical Dictionary for Regulatory Activities (MedDRA). The order of the terms for a given event does not imply priority. In other words, the first term listed is not necessarily considered more significant than the last one listed.

4) OUTCOME file (OUTCyyQq.TXT)

NAME DESCRIPTION

PRIMARYID Unique number for identifying a FAERS report. This is the primary link field (primary key) between data files (example: 31234561). This is a concatenated key of Case ID and Case Version Number. It is the Identifier for the case sequence (version) number as reported by the manufacturer.

CASEID Number for identifying a FAERS case.

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 Serious (Important Medical Event)

NOTE: The outcome from the latest version of a case is provided. If there is more than one outcome, the codes will be line listed.

5) REPORT SOURCE file (RPSRyyQq.TXT)

NAME DESCRIPTION

PRIMARYID Unique number for identifying a FAERS report. This is the primary link field (primary key) between data files (example: 31234561). This is a concatenated key of Case ID and Case Version Number – Identifier to be used as the case sequence (version) number as reported by manufacturer.

CASEID Number for identifying a FAERS case.

RPSR_COD Code for the source of the report. (See table below.)

CODE	MEANING_TEXT
----	-----
FGN	Foreign
SDY	Study
LIT	Literature
CSM	Consumer
HP	Health Professional
UF	User Facility
CR	Company Representative
DT	Distributor
OTH	Other

NOTE: The source from the latest version of a case is provided. If there is more than one source, the codes will be line listed.

6) THERAPY dates file (THERyyQq.TXT)

NAME DESCRIPTION

PRIMARYID Unique number for identifying an FAERS report. This is the primary link field (primary key) between data files (example: 31234561). This is a concatenated key of Case ID and Case Version Number. It is the Identifier for the case sequence (version) number as reported by the manufacturer.

CASEID Number for identifying a FAERS case.

DSG_DRUG_SEQ Drug sequence number for identifying a drug for a Case. To link to the DRUGyyQq.TXT data file, both the Case number primary key and the DRUG_SEQ number (secondary key) are needed. (For an explanation of the DRUG_SEQ number, including an example, see Section E, End Note 2, below.)

START_DT A date therapy was started (or re-started) for this drug. (YYYYMMDD) – If a complete date not available, a partial date is provided. See the NOTE on dates at the end of this section.

END_DT A date therapy was stopped for this drug. (YYYYMMDD) – If a complete date not available, a partial date will be provided. See the NOTE on dates at the end of this section.

DUR Numeric value of the duration (length) of therapy

DUR_COD Unit abbreviation for duration of therapy (see table below)

CODE	MEANING TEXT
----	-----
YR	Years
MON	Months
WK	Weeks
DAY	Days
HR	Hours
MIN	Minutes
SEC	Seconds

7) INDICATIONS for use file (INDIyyQq.TXT)

NAME DESCRIPTION

PRIMARYID Unique number for identifying a FAERS report. This is the primary link field (primary key) between data files (example: 31234561). This is a concatenated key of Case ID and Case Version Number. It is the Identifier for the case sequence (version) number as reported by the manufacturer.

CASEID Number for identifying a FAERS case.

INDI_DRUG_SEQ Drug sequence number for identifying a drug for a Case. To link to the DRUGyyQq.TXT data file, both the Case number (primary key) and the DRUG_SEQ number (secondary key) are needed. (For an explanation of the DRUG_SEQ number, including an example, see Section E, End Note 2, below.)

INDI_PT "Preferred Term"-level medical terminology describing the Indication for use, using the Medical Dictionary for Regulatory Activities (MedDRA).

NOTE: Date fields will be coded as follows based upon data available in FAERS:

- year month day (YYYYMMDD)
- year month (YYYYMM)
- year (YYYY)

D. DATA ELEMENT CONTENTS AND MAXIMUM LENGTHS

DATA ELEMENT	DATA CONTENT	MAX LENGTH
PRIMARYID	N	1000
CASEID	N (numeric)	500
CASEVERSION	N	22
I_F_CODE	AN (alphanumeric)	1
EVENT_DT	N (or D, date)	8
MFR_DT	N (or D)	8
INIT_FDA_DT	N (or D)	8
FDA_DT	N (or D)	8
REPT_COD	A	9
MFR_NUM	AN	500
MFR_SNDR	AN	300
AGE	N	12 (including 2 decimal places)
AGE_COD	A	7
GNDR_COD	A	5
E_SUB	AN	1
WT	N	14 (including 5 decimal places)
WT_COD	A	20
REPT_DT	N (or D)	8
Contd...		

DATA ELEMENT	DATA CONTENT	MAX LENGTH
OCCP_COD	A	300
TO_MFR	A	100
REPORTER_COUNTRY	A	500
OCCR_COUNTRY	A	2
OUTC_COD	A	4000
RPSR_COD	A	32
PT	AN	500
DRUG_SEQ	N	22
ROLE_COD	A	22
DRUGNAME	AN	500
VAL_VBM	N	22
ROUTE	A	25
DOSE_VBM	AN	300
DOSE_AMT	AN	15
DOSE_UNIT	AN	50
DOSE_FORM	AN	50
DOSE_FREQ	AN	50
CUM_DOSE_CHR	AN	15
CUM_DOS_UNIT	AN	50
DECHAL	A	20
RECHAL	A	20
LOT_NUM	AN	1000
EXP_DT	N (or D)	1000

NDA_NUM	N	100	
DSG_DRUG_SEQ	N		22
START_DT	N (or D)	8	
END_DT	N (or D)	8	
DUR	N	150	
DUR_COD	A	500	
INDI_DRUG_SEQ	N		22
INDI_PT	AN	1000	

E. END NOTES

1 REPT_COD (Demographic file). Expedited (15-day) and Periodic (Non-Expedited) reports are from manufacturers; "Direct" reports are voluntarily submitted to the FDA by non-manufacturers.

2 DRUG_SEQ (Drug file, Therapy file, and Indications file). The best way to explain the DRUG_SEQ (drug sequence number) is with an example. This will also clarify the relationship between a Case, the drug(s) reported for that Case, and the therapy date(s) reported for the drug(s). Consider Case 3078140 version 1, received by the FDA on 12/31/97. The PRIMARYID for this case is 30781401. Like any Case, it appears once (and only once) in the Demographic file:

```
PRIMARYID
---
30781401
```

Four drugs were reported for this Case: Aricept was reported as suspect, and Estrogens, Prozac, and Synthroid as concomitant. Primaryid 30781401 appears four times in the Drug file, with a different DRUG_SEQ for each drug:

PRIMARYID	DRUG_SEQ	DRUGNAME
---	-----	-----
30781401	1	Aricept
30781401	2	Estrogens
30781401	3	Prozac(Fluoxetine Hydrochloride
30781401	4	Synthroid (Levothyroxine Sodium)

Dates of therapy for Aricept were reported as "4/97 to 6/13/97", and "6/20/97 (ongoing)." Since the drug was started, stopped, then restarted, there are two entries in the Drug Therapy file. In such a circumstance, the two entries will have the same PRIMARYID and the same DRUG_SEQ # (or DSG_DRUG_SEQ # as it is called in the Therapy file - see below). No therapy dates were reported for the concomitants; therefore, they do not appear in the Drug Therapy file, which is excerpted as follows:

PRIMARYID	DSG_DRUG_SEQ #	START_DT	END_DT
---	-----	-----	-----
30781401	1	199704	19970613
30781401	1	19970620	

NOTE: The Drug Seq # is no longer a unique key as was the case in LAERS QDE. The Drug Seq # simply shows the order of the DRUGNAME within a unique case. Additionally, the fields labeled DRUG_SEQ, INDI_DRUG_SEQ, and DSG_DRUG_SEQ in the Drug, Indication, and Therapy files, respectively, all serve the same purpose of linking the data elements in each individual file together with the appropriate drug listed in the case using the PRIMARYID.

F. REVISION HISTORY

Sep – Dec (Q4), 2012

FDA converted from Legacy AERS to the new FDA Adverse Event Reporting System (FAERS) in September 2012.

Due to the timing of the commissioning of FAERS and work to ensure the new extract provides the necessary data, this extract will include data for September 2012 and the 4th Quarter (timeframe from August 28 - December 31, 2012).

The FAERS database introduces various changes to the data and tables due to the switch from an ISR-based system to a Case/Version-based system. We have added new data elements to the FAERS QDE, which we will provide in the files associated with this document. See the ASCII Tag Comparison Table below for more details.

For LAERS revision history details, refer to ASCII_NTS.doc files from previous extracts available at www.fda.gov/cder/aers.

Jan - Mar (Q1), 2013

No Changes

Apr - Jun (Q2), 2013

No Changes

Jul - Sep (Q3), 2013

No Changes

Oct - Dec (Q4), 2013

Medical Dictionary for Regulatory Activities (MedDRA) Contact information was updated (Section B.3). Additionally, clarification was added in Section C.2 for Code for Frequency (DOSE_FREQ).

Jan - Mar (Q1), 2014

Correction was made in section C.2 to Cumulative dose to first reaction unit (CUM_DOS_UNIT) list. No other changes.

Apr - Jun (Q2), 2014

No Changes

G. Legacy AERS (LAERS) vs. FDA AERS (FAERS) ASCII Tag Comparison Tables

Note: The changes to the FAERS ASCII Tags are highlighted in yellow and also contain an asterisk (*).

LAERS ASCII Field	FAERS ASCII Field	ASCII File Name
ISR	PRIMARYID*	Demo
CASE	CASEID*	Demo

LAERS ASCII Field	FAERS ASCII Field	ASCII File Name
FOLL_SEQ	NA*	Demo
None	CASEVERSION*	Demo
I_F_COD	I_F_COD	Demo
IMAGE	NA*	Demo
EVENT_DT	EVENT_DT	Demo
MFR_DT	MFR_DT	Demo
None	INIT_FDA_DATE*	Demo
FDA_DT	FDA_DT	Demo
REPT_COD	REPT_COD	Demo
MFR_NUM	MFR_NUM	Demo
MFR_SNDR	MFR_SNDR	Demo
AGE	AGE	Demo
AGE_COD	AGE_COD	Demo
GNDR_COD	GNDR_COD	Demo
E_SUB	E_SUB	Demo
WT	WT	Demo
WT_COD	WT_COD	Demo
REPT_DT	REPT_DT	Demo
TO_MFR	TO_MFR	Demo
OCCP_COD	OCCP_COD	Demo
DEATH_DT	NA*	Demo
CONFID	NA*	Demo
REPORTER_COUNTRY	REPORTER_COUNTRY	Demo
None	OCCR_COUNTRY*	Demo
ISR	PRIMARYID*	Demo
CASE	CASEID*	Demo
FOLL_SEQ	NA*	Demo
None	CASEVERSION*	Demo
I_F_COD	I_F_COD	Demo
IMAGE	NA*	Demo

LAERS ASCII Field	FAERS ASCII Field	ASCII File Name
EVENT_DT	EVENT_DT	Demo
MFR_DT	MFR_DT	Demo
None	INIT_FDA_DATE*	Demo
FDA_DT	FDA_DT	Demo
REPT_COD	REPT_COD	Demo
MFR_NUM	MFR_NUM	Demo
MFR_SNDR	MFR_SNDR	Demo
AGE	AGE	Demo
AGE_COD	AGE_COD	Demo
GNDR_COD	GNDR_COD	Demo
E_SUB	E_SUB	Demo
WT	WT	Demo
WT_COD	WT_COD	Demo
REPT_DT	REPT_DT	Demo
TO_MFR	TO_MFR	Demo
OCCP_COD	OCCP_COD	Demo
DEATH_DT	NA*	Demo
CONFID	NA*	Demo
REPORTER_COUNTRY	REPORTER_COUNTRY	Demo
None	OCCR_COUNTRY*	Demo
ISR	PRIMARYID*	Drug
CASE	CASEID*	Drug
DRUG_SEQ	DRUG_SEQ	Drug
ROLE_COD	ROLE_COD	Drug
DRUGNAME	DRUGNAME	Drug
VAL_VBM	VAL_VBM	Drug
ROUTE	ROUTE	Drug
DOSE_VBM	DOSE_VBM	Drug
None	CUM_DOSE_CHR*	Drug
None	CUM_DOS_UNIT*	Drug

LAERS ASCII Field	FAERS ASCII Field	ASCII File Name
DECHAL	DECHAL	Drug
RECHAL	RECHAL	Drug
LOT_NUM	LOT_NUM	Drug
EXP_DT	EXP_DT	Drug
NDA_NUM	NDA_NUM	Drug
None	DOSE_AMT*	Drug
None	DOSE_UNIT*	Drug
None	DOSE_FORM*	Drug
None	DOSE_FREQ*	Drug
ISR	PRIMARYID*	Reaction
None	CASEID*	Reaction
PT	PT	Reaction
ISR	PRIMARYID*	Outcome
None	CASEID*	Outcome
OUTC_COD	OUTC_COD	Outcome
ISR	PRIMARYID*	Report Source
None	CASEID*	Report Source
RPSR_COD	RPSR_COD	Report Source
ISR	PRIMARYID*	Therapy
None	CASEID*	Therapy
DRUG_SEQ	DSG_DRUG_SEQ*	Therapy
START_DT	START_DT	Therapy
END_DT	END_DT	Therapy
DUR	DUR	Therapy
DUR_COD	DUR_COD	Therapy
ISR	PRIMARYID*	Indications
None	CASEID*	Indications
DRUG_SEQ	INDI_DRUG_SEQ*	Indications
INDI_PT	INDI_PT	Indications
ISR	PRIMARYID*	Drug

LAERS ASCII Field	FAERS ASCII Field	ASCII File Name
CASE	CASEID*	Drug
DRUG_SEQ	DRUG_SEQ	Drug
ROLE_COD	ROLE_COD	Drug
DRUGNAME	DRUGNAME	Drug
VAL_VBM	VAL_VBM	Drug
ROUTE	ROUTE	Drug
DOSE_VBM	DOSE_VBM	Drug
None	CUM_DOSE_CHR*	Drug
None	CUM_DOS_UNIT*	Drug
DECHAL	DECHAL	Drug
RECHAL	RECHAL	Drug
LOT_NUM	LOT_NUM	Drug
EXP_DT	EXP_DT	Drug
NDA_NUM	NDA_NUM	Drug
None	DOSE_AMT*	Drug
None	DOSE_UNIT*	Drug
None	DOSE_FORM*	Drug
None	DOSE_FREQ*	Drug
ISR	PRIMARYID*	Reaction
None	CASEID*	Reaction
PT	PT	Reaction
ISR	PRIMARYID*	Outcome
None	CASEID*	Outcome
OUTC_COD	OUTC_COD	Outcome
ISR	PRIMARYID*	Report Source
None	CASEID*	Report Source
RPSR_COD	RPSR_COD	Report Source
ISR	PRIMARYID*	Therapy
None	CASEID*	Therapy
DRUG_SEQ	DSG_DRUG_SEQ*	Therapy

LAERS ASCII Field	FAERS ASCII Field	ASCII File Name
START_DT	START_DT	Therapy
END_DT	END_DT	Therapy
DUR	DUR	Therapy
DUR_COD	DUR_COD	Therapy
ISR	PRIMARYID*	Indications
None	CASEID*	Indications
DRUG_SEQ	INDI_DRUG_SEQ*	Indications
INDI_PT	INDI_PT	Indications