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

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OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY (OSE)

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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. ENTITY RELATIONSHIP DIAGRAM (ERD).

For every report, there is one row in the "demographic" table (file). Each row in the demographic table can be linked to none, one, or more than one row in the "Reaction", "Outcome" and "Report_Sources" tables. Also for every one row in the "demographic" table, you can have one or more rows in the "Drug" table. For every drug, you can have one or more rows in the "Therapy" table that shows when the drug was started and stopped. Also for every drug you can have none, one or more than one indication in the "Indication" table (see section F.2).

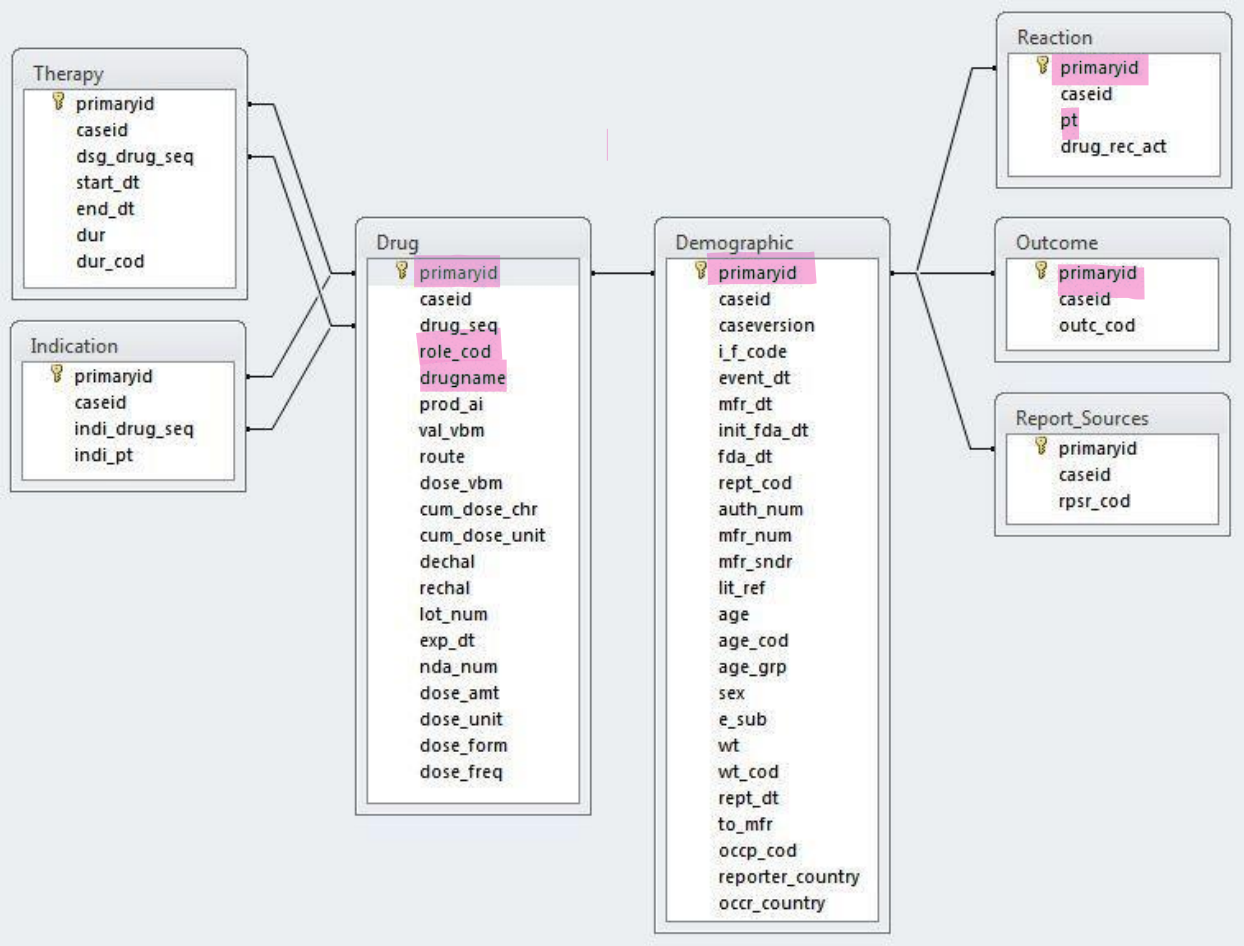

Figure 1 – ASCII Entity Relationship Diagram (ERD)

C. 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:
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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.)

D. 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.
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_DT	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).

1) DEMOGRAPHIC file (DEMOyyQq.TXT)	
Name	**Description**
REPT_COD	Code for the type of report submitted (See table below) Also, see Section F, End Notes below. CODE MEANING_TEXT ---- --------------- EXP Expedited (15-Day) PER Periodic (Non-Expedited) DIR Direct 5DAY 5-Day 30DAY 30-Day
AUTH_NUM	Regulatory Authority's case report number, when available. + New tag added in 2014Q3 extract.
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.
LIT_REF	Literature Reference information, when available; populated with last 500 characters if >500 characters are available. + New tag added in 2014Q3 extract.
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
AGE_GRP	Patient Age Group code as follows, when available: CODE MEANING_TEXT ----- ----------------- N Neonate I Infant C Child T Adolescent A Adult E Elderly + New tag added in 2014Q3 extract.
SEX	Code for patient's sex (See table below) CODE MEANING_TEXT ---- ------------ UNK Unknown M Male F Female

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

1) DEMOGRAPHIC file (DEMOyyQq.TXT)	
Name	**Description**
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. https://www.fda.gov/industry/structured-product-labeling-resources/geopolitical-entities-names-and-codes-genc
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 F, End Notes 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 DN Drug Not Administered
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.
PROD_AI	Product Active Ingredient, when available. + New tag added in 2014Q3 extract.
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

2) DRUG file (DRUGyyQq.TXT)	
Name	**Description**
CUM_DOSE_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 NOTE: The list below provides Dose codes which are commonly reported; however, dose codes are not limited to this list and other code values may be present.
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

2) DRUG file (DRUGyyQq.TXT)	
Name	**Description**
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 (as reported).
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 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 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.

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. It is the Identifier for the case sequence (version) number as reported by the 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.
DRUG_REC_ACT	Drug Recur Action data - populated with reaction/event information (PT) if/when the event reappears upon readministration of the drug. + New tag added in 2014Q3 extract.

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. It is the Identifier for the case sequence (version) number as reported by the 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 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.
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 F, End Notes 2, below.)
START_DT	Date the 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

6) THERAPY dates file (THERyyQq.TXT)	
Name	**Description**
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 F, End Notes 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)

E. DATA ELEMENT CONTENTS AND MAXIMUM LENGTHS

DATA ELEMENT	DATA CONTENT	MAX LENGTH
AGE	N (numeric)	12 (including 2 decimal places)
AGE_COD	A (Alpha)	7
AGE_GRP	AN (alphanumeric)	15
AUTH_NUM	AN (alphanumeric)	500

DATA ELEMENT	DATA CONTENT	MAX LENGTH
CASEID	N (numeric)	500
CASEVERSION	N (numeric)	10
CUM_DOS_UNIT	AN (alphanumeric)	50
CUM_DOSE_CHR	AN (alphanumeric)	15
DECHAL	A (Alpha)	20
DOSE_AMT	AN (alphanumeric)	15
DOSE_FORM	AN (alphanumeric)	50
DOSE_FREQ	AN (alphanumeric)	50
DOSE_UNIT	AN (alphanumeric)	50
DOSE_VBM	AN (alphanumeric)	300
DRUG_REC_ACT	AN (alphanumeric)	500
DRUG_SEQ	N (numeric)	10
DRUGNAME	AN (alphanumeric)	500
DSG_DRUG_SEQ	N (numeric)	10
DUR	N (numeric)	150
DUR_COD	A (Alpha)	500
E_SUB	AN (alphanumeric)	1
END_DT	N (or D, date)	8
EVENT_DT	N (or D, date)	8
EXP_DT	N (or D, date)	1000
FDA_DT	N (or D)	8
I_F_CODE	AN (alphanumeric)	1
INDI_DRUG_SEQ	N (numeric)	10
INDI_PT	AN (alphanumeric)	1000
INIT_FDA_DT	N (or D)	8
LIT_REF	AN (alphanumeric)	1000
LOT_NUM	AN (alphanumeric)	1000
MFR_DT	N (or D)	8
MFR_NUM	AN (alphanumeric)	500
MFR_SNDR	AN (alphanumeric)	300
NDA_NUM	N (numeric)	100
OCCP_COD	A (Alpha)	300
OCCR_COUNTRY	A (Alpha)	2
OUTC_COD	A (Alpha)	4000
PRIMARYID	N (numeric)	1000
PROD_AI	AN (alphanumeric)	500
PT	AN (alphanumeric)	500
RECHAL	A (Alpha)	20
REPORTER_COUNTRY	A (Alpha)	500

DATA ELEMENT	DATA CONTENT	MAX LENGTH
REPT_COD	A (Alpha)	9
REPT_DT	N (or D, date)	8
ROLE_COD	A (Alpha)	22
ROUTE	A (Alpha)	500
RPSR_COD	A (Alpha)	32
SEX	A (Alpha)	5
START_DT	N (or D, date)	8
TO_MFR	A (Alpha)	100
VAL_VBM	N (numeric)	22
WT	N (numeric)	14 (including 5 decimal places)
WT_COD	A (Alpha)	20

F. 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; “5day” and “30day” reports are combination product reports (combination products are considered both drug and device).

2 DRUG_SEQ (drug sequence number found in the Drug file, Therapy file, and Indications file) denotes the relationship between the drug(s) reported for a Case, the therapy date(s) reported for the drug(s), and the indications 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
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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 number 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 number is no longer a unique key as was the case in LAERS QDE. The Drug Seq number 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.

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 (*****). Tags added after the initial FAERS extract contain a plus (+) and the date add is noted in the tag description in Section C.

LAERS ASCII Field	FAERS ASCII Field	ASCII File Name
ISR	PRIMARYID*	DEMO
CASE	CASEID*	DEMO
FOLL_SEQ	N/A*	DEMO
N/A	CASEVERSION*	DEMO
I_F_COD	I_F_COD	DEMO
IMAGE	N/A*	DEMO
EVENT_DT	EVENT_DT	DEMO
MFR_DT	MFR_DT	DEMO
N/A	INIT_FDA_DATE*	DEMO
FDA_DT	FDA_DT	DEMO
REPT_COD	REPT_COD	DEMO
N/A	AUTH_NUM*+	DEMO
MFR_NUM	MFR_NUM	DEMO
MFR_SNDR	MFR_SNDR	DEMO
N/A	LIT_REF*+	DEMO
AGE	AGE	DEMO
AGE_COD	AGE_COD	DEMO
N/A	AGE_GRP*+	DEMO
GNDR_COD	GNDR_COD	DEMO
E_SUB	E_SUB	DEMO
WT	WT	DEMO
WT_COD	WT_COD	DEMO
REPT_DT	REPT_DT	DEMO

LAERS ASCII Field	FAERS ASCII Field	ASCII File Name
TO_MFR	TO_MFR	DEMO
OCCP_COD	OCCP_COD	DEMO
DEATH_DT	N/A*	DEMO
CONFID	N/A*	DEMO
REPORTER_COUNTRY	REPORTER_COUNTRY	DEMO
N/A	OCCR_COUNTRY*	DEMO
ISR	PRIMARYID*	DEMO
CASE	CASEID*	DEMO
FOLL_SEQ	N/A*	DEMO
N/A	CASEVERSION*	DEMO
I_F_COD	I_F_COD	DEMO
IMAGE	N/A*	DEMO
EVENT_DT	EVENT_DT	DEMO
MFR_DT	MFR_DT	DEMO
N/A	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	N/A*	DEMO
CONFID	N/A*	DEMO
REPORTER_COUNTRY	REPORTER_COUNTRY	DEMO
N/A	OCCR_COUNTRY*	DEMO
ISR	PRIMARYID*	DRUG
CASE	CASEID*	DRUG
DRUG_SEQ	DRUG_SEQ	DRUG
ROLE_COD	ROLE_COD	DRUG
DRUGNAME	DRUGNAME	DRUG
N/A	PROD_AI*+	DRUG
VAL_VBM	VAL_VBM	DRUG
ROUTE	ROUTE	DRUG

LAERS ASCII Field	FAERS ASCII Field	ASCII File Name
DOSE_VBM	DOSE_VBM	DRUG
N/A	CUM_DOSE_CHR*	DRUG
N/A	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
N/A	DOSE_AMT*	DRUG
N/A	DOSE_UNIT*	DRUG
N/A	DOSE_FORM*	DRUG
N/A	DOSE_FREQ*	DRUG
ISR	PRIMARYID*	REACTION
N/A	CASEID*	REACTION
PT	PT	REACTION
ISR	PRIMARYID*	OUTCOME
N/A	CASEID*	OUTCOME
OUTC_COD	OUTC_COD	OUTCOME
ISR	PRIMARYID*	REPORT SOURCE
N/A	CASEID*	REPORT SOURCE
RPSR_COD	RPSR_COD	REPORT SOURCE
ISR	PRIMARYID*	THERAPY
N/A	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
N/A	CASEID*	INDICATIONS
DRUG_SEQ	INDI_DRUG_SEQ*	INDICATIONS
INDI_PT	INDI_PT	INDICATIONS
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

LAERS ASCII Field	FAERS ASCII Field	ASCII File Name
N/A	CUM_DOSE_CHR*	DRUG
N/A	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
N/A	DOSE_AMT*	DRUG
N/A	DOSE_UNIT*	DRUG
N/A	DOSE_FORM*	DRUG
N/A	DOSE_FREQ*	DRUG
ISR	PRIMARYID*	REACTION
N/A	CASEID*	REACTION
PT	PT	REACTION
NA	DRUG_REC_ACT*+	REACTION
ISR	PRIMARYID*	OUTCOME
N/A	CASEID*	OUTCOME
OUTC_COD	OUTC_COD	OUTCOME
ISR	PRIMARYID*	REPORT SOURCE
N/A	CASEID*	REPORT SOURCE
RPSR_COD	RPSR_COD	REPORT SOURCE
ISR	PRIMARYID*	THERAPY
N/A	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
N/A	CASEID*	INDICATIONS
DRUG_SEQ	INDI_DRUG_SEQ*	INDICATIONS
INDI_PT	INDI_PT	INDICATIONS

H. REVISION HISTORY

August 2013 (QDE 2012Q4)

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.

For LAERS revision history details, refer to ASCII_NTS.doc files from previous extracts available at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm083765.htm.

August 2014 (QDE 2013Q4)

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).

October 2014 (QDE 2014Q1)

Correction was made in section C.2 to Cumulative dose to first reaction unit (CUM_DOS_UNIT) list.

April 2015 (QDE 2014Q3)

A number of changes have been implemented with this release:

- Added new field for Authority Number (AUTH_NUM) in Demographic file populated with Regulatory Authority's case report number, when available
- Added new field for Literature Reference (LIT_REF) in Demographic file populated with Literature Reference information, when available
- Added new field for Age Group (AGE_GRP) field in Demographic file populated with Age Group code as follows, when available:

CODE	MEANING_TEXT
N	Neonate
I	Infant
C	Child
T	Adolescent
A	Adult
E	Elderly

- Added new field for Product Active Ingredient (PROD_AI) in Drug file populated with Product Active Ingredient, when available

- Added new field for Drug Recur Action (DRUG_REC_ACT) in Reaction file populated with the Reaction/Event information if/when Rechallenge equals Y (Positive Rechallenge)
- Modified field header from GNDR_COD to SEX in Demographic file

March 2016 (QDE 2015Q4)

Added Section B to provide an Entity Relationship Diagram (ERD) depicting how the relationship between the seven ASCII files is structured

June 2016 (QDE 2016Q1)

Data Elements Max Lengths (Section E – "Data Element Contents And Maximum Lengths") were reviewed and updated.

February 2022 (QDE 2021Q4)

QDE will now uses GENC as the basis for country codes. See Section D, Demographic File, REPORTER_COUNTRY, OCCR_COUNTRY

October 2022 (QDE 2022Q3)

The values of 5DAY and 30DAY were added to the REPT_COD variable in Section D which are present in combination product reports.

January 2025 (QDE 2024Q4)

The value of Drug Not Administered (DN) has been added as a valid choice to the Drug Role Code (ROLE_COD) in the Drug File.