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

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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.

TABLE OF CONTENTS

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:
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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: Northrop Grumman, MedDRA MSSO, 15010 Conference Center Drive, Chantilly, VA 20151, USA. The website is www.meddramsso.com.

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.)

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
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
001	kg or kilogram(s)
002	G or gram(s)
003	Mg or milligram(s)
004	µg or microgram(s)*

* Additional codes for this field are located in the ICH document:
http://estri.ich.org/e2br22/ICH_ICSR_Specification_V2-3.pdf

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. (See table below.)

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 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:

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PRIMARYID
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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 # 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

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
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
EVENT_DT	EVENT_DT	Demo
MFR_DT	MFR_DT	Demo
None	INIT_FDA_DATE*	Demo
FDA_DT	FDA_DT	Demo

LAERS ASCII Field	FAERS ASCII Field	ASCII File Name
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
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

LAERS ASCII Field	FAERS ASCII Field	ASCII File Name
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
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

LAERS ASCII Field	FAERS ASCII Field	ASCII File Name
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