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

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LAST REVISED: April 2015

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A. INTRODUCTION

This public-use data distribution uses the recommended XML file structure and is compliant with the DTD DCL files that are published as part of the ICH E2b/M2 version **2.1** standard. You can find more extensive and detailed information on this topic, including documents describing the standard content, fields, and attributes as well as the DTD and DCL file at these web addresses:

http://estri.ich.org/e2br22/ICH_ICSR_Specification_V2-3.pdf
http://www.accessdata.fda.gov/xml/icsr-xml-v2.1.dtd

Use of the XML file adheres to the original standards documents for E2b and the M2 implementation specifications. The *.XML file in this distribution can be parsed by the M2 version **2.1** DTD. Our distribution is tested with the **2.1** version of the DTD.

Since the FDA also receives cases from non-E2B sources (e.g., Direct MedWatch Reports), best effort is made to bring the case data into E2B standards.

B. PUBLIC USE DATA FIELD DESCRIPTIONS:

E2B Field	DTD Descriptor	Description
M2 specified Message Header fields...		
	messagetype	Holds the value 'ICSR'
	messageformatversion	Holds the value **'2.1'**.
	messageformatrelease	Holds the value '1.0'.
	messagenumb	Arbitrary message identifier. We have used an alpha-numeric string of the form yyyy-mm to identify the year and month of the data contained in the message.
	messagesenderidentifier	Sender identification (FDA CDER)
	messagereceiveridentifier	Receiver identification (Public Use)
	messagedateformat	Date format code; 204 means CCYYMMDDHHMMSS, where CCYY is the 4 digit year,etc..
	messagedate	Holds date/time 'stamp' assigned on creation of the message.
M2 specified Data Processing field...		
	safetyreportversion	Safety Report Version Number
E2b Step 4 specified data fields...		
A.1.0.1	safetyreportid	Unique report identifier used by the FDA AERS system. This number is used to link any additional information.
A.1.1	primarysourcecountry	Country of the primary reporter 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
A.1.10.1	authoritynumb	Regulatory Authority's case report number, when available. + New tag added in 2014Q3 extract.
A.1.10.2	companynumb	The value in this field, iF any, is the identification number supplied to FDA by the manufacturer submitting the report. This number will have differences in structure between manufacturers, but is required to be unique for a given event.

E2B Field	DTD Descriptor	Description
A.1.11	duplicate	Other case identifiers in previous transmissions - if case priority =Direct then duplicate = Null; if case priority is from 15-day or Periodic(Non-Expedited), then duplicate = 1
	reportduplicate	Report Duplicate details
A.1.11.1	duplicatesource	Source(s) of the case identifier (i.e., Coded name of manufacturer sending report; if not found, then verbatim name of organization sending report.) NOTE: This field may repeat for each source identifier where i=1,2,3…
A.1.11.2	duplicatenumb	Case identifiers (i.e., Manufacturer Control Number from the latest version of a Case.) NOTE: This field may repeat for each case identifier where i=1,2,3…
A.1.2	occurcountry	Country where reaction/event occurred 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
A.1.3a	transmissiondateformat	Date format code; 102 means CCYYMMDD, where CCYY is the 4-digit year.
A.1.3b	transmissiondate	System date in '102' format recorded when data file is created.
A.1.4	reporttype	Type of report; Code List: 1= Spontaneous 2= Report from Study 3= Other 4= Not available to sender (unknown)
A.1.5.1	serious	Value is 1 (1=yes) if any of the criteria (A.1.5.2a-A.1.5.2f) are indicated (2=no).
A.1.5.2a	seriousnessdeath	Results in death
A.1.5.2b	seriousnesslifethreatening	Life threatening
A.1.5.2c	seriousnesshospitalization	Caused/prolonged hospitalization
A.1.5.2d	seriousnessdisabling	Disabling/Incapacitating
A.1.5.2e	seriousnesscongenitalanomali	Congenital anomaly/birth defect
A.1.5.2f	seriousnessother	Other medically important condition
A.1.6a	receivedateformat	Date format code - see NOTE below.

E2B Field	DTD Descriptor	Description
A.1.6b	receivedate	Date report was first received by (Initial FDA Received Date)
A.1.7a	receiptdateformat	Date format code – see NOTE below.
A.1.7b	receiptdate	Date of most recent report received by FDA (Individual Case FDA Received Date)
A.1.9	fulfillexpeditecriteria	Value is: 1 (1=yes) for identified expedited reports (15-day) 2 for all others.
A.2.1.3	reportercountry	Country of the reporter in the latest case version 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
A.2.1.4	qualification	Possible codes are: 1= Physician 2= Pharmacist 3= Other Health Professional 4= Lawyer 5= Consumer or non-health professional
A.2.2	literaturereference	Literature Reference information, when available; populated with last 500 characters if >500 characters are available. + New tag added in 2014Q3 extract.
A.3.1.1	sendertype	Holds the value 2 (2=Regulatory Authority)
A.3.1.2	senderorganization	“FDA-Public Use”
A.3.2.1	receivertype	Holds the value 6 (6=Other)
A.3.2.2a	receiverorganization	Holds the value “FDA”
B.1.2.2a	patientonsetage	Value for patient age at onset of adverse event.
B.1.2.2b	patientonsetageunit	Units for the age value. Possible codes are: 800= Decade 801= Year 802= Month 803= Week 804= Day 805= Hour

E2B Field	DTD Descriptor	Description
B.1.2.3	patientagegroup	Patient Age Group code as follows, when available: 1= Neonate 2= Infant 3= Child 4= Adolescent 5= Adult 6= Elderly + New tag added in 2014Q3 extract.
B.1.3	patientweight	Weight in kilograms. NOTE: Value will display with up to 5 numeric digits with a max of 2 decimal points.
B.1.5	patientsex	Gender indicator Possible codes are: 0= unknown 1= male 2= female
B.2.i.2.a	reactionmeddraversionpt	MedDRA version for reaction/event term PT
B.2.i.2.b	reactionmeddrapt	MedDRA Preferred Term (text string) is used to characterize the event(s). Multiple reactions may be reported by using an additional block (B.2.1.2b, B.2.2.2b,... etc.). NOTE: This field may repeat for each reaction where i=1,2,3...
B.2.i.8	reactionoutcome	Outcome of reaction/event at the time of last observation Possible codes are: 1= recovered/resolved 2= recovering/resolving 3= not recovered/not resolved 4= recovered/resolved with sequelae 5= fatal 6= unknown
B.4.k.1	drugcharacterization	Reported role of drug in adverse event. Possible Codes are: 1= suspect 2=concomitant 3= interacting NOTE: This set of fields may repeat for each drug where k=1,2,3...
B.4.k.2.1	medicinalproduct	Valid Trade Name if populated; otherwise, verbatim name used by reporter.
B.4.k.2.2	activesubstancename	Product Active Ingredient, when available. + New tag added in 2014Q3 extract.

E2B Field	DTD Descriptor	Description
B.4.k.3	drugbatchnumb	Lot number, if provided.
B.4.k.4.1	drugauthorizationnumb	NDA number, if provided.
B.4.k.5.1	drugstructuredosagenumb	Dose (number)
B.4.k.5.2	drugstructuredosageunit	Dose (unit) Possible* codes are: 001= kg kilogram(s) 002= G gram(s) 003= Mg milligram(s) 004= µg microgram(s) *Additional codes for this tag are located in the ICH document: http://estri.ich.org/e2br22/ICH_ICSR_Specification_V2-3.pdf
B.4.k.5.3	drugseparatedosagenumb	Number of separate dosages
B.4.k.5.4	drugintervaldosageunitnumb	Number of units in the interval
B.4.k.5.5	drugintervaldosagedefinition	Definition of the interval Possible codes are: 801= Year 802= Month 803= Week 804= Day 805= Hour 806= Minute 807= Second 810= Cyclical 811= Trimester 812= As Necessary 813= Total
B.4.k.5.6	drugcumulativedosagenumb	Cumulative dose to first reaction
B.4.k.5.7	drugcumulativedosageunit	Cumulative dose to first reaction Unit Possible* codes are: 001= kg kilogram(s) 002= G gram(s) 003= Mg milligram(s) 004= µg microgram(s)* Additional codes for this tag are located in the ICH document: http://estri.ich.org/e2br22/ICH_ICSR_Specification_V2-3.pdf
B.4.k.6	drugdosagetext	Text describing drug dosage and frequency. (from box C.1 of the Medwatch form for paper submissions)
B.4.k.7	drugdosageform	Pharmaceutical form

E2B Field	DTD Descriptor	Description
B.4.k.8	drugadministrationroute	Route of administration code*. For example: 048=Oral 061=Topical *Additional codes for this tag are located in the ICH document: http://estri.ich.org/e2br22/ICH_ICSR_Specification_V2-3.pdf
B.4.k.11b	drugindication	MedDRA Preferred Term (text string) is used to characterize indication for use.
B.4.k.12a	drugstartdateformat	Date format code - see NOTE below.
B.4.k.12b	drugstartdate	Date when patient started taking the kth drug.
B.4.k.14a	drugenddateformat	Date format code – see NOTE below
B.4.k.14b	drugenddate	Date when patient stopped taking the kth drug.
B.4.k.15a	drugtreatmentduration	Duration of drug administration
B.4.k.15b	drugtreatmentdurationunit	Duration of drug administration Possible codes are: 801= Year 802= Month 803= Week 804= Day 805= Hour 806= Minute
B.4.k.16	actiondrug	Actions taken with drug Possible codes are: 1= Drug Withdrawn 2= Dose reduced 3= Dose Increased 4= Dose not changed 5= Unknown 6= Not applicable
B.4.k.17.1	drugrecurreadministration	Did Reaction recur on Readministration? Possible codes are: 1= Yes 2= No 3= Unknown
B.4.k.17.2b	drugrecuraction	Populated with the Reaction/Event information (PT) if/when <drugrecurreadministration> equals 1. + New tag added in 2014Q3 extract.

E2B Field	DTD Descriptor	Description
B.4.k.19	drugadditional	Dechallenge outcome information (event Abated after product use stopped or dose reduced) Possible codes are: 1= Yes 2= No 3= Doesn't Apply
B.5.1	narrativeincludeclinical	Case Event Date, when available; Displayed as follows: "CASE EVENT DATE: Event Date" Date Format YYYYMMDD or YYYYMM or YYYY NOTE: This tag does NOT include Case Narrative. + New tag added in 2014Q3 extract.
NOTE: Date fields will be coded as follows based upon data available in FAERS: 102 – year month day (YYYYMMDD) 610 – year month (YYYYMM) 602 – year (YYYY)		

USAGE NOTES:
The field lengths adhere to those specified in the M2 specification documents. These can be found at
http://estri.ich.org/e2br22/ICH_ICSR_Specification_V2-3.pdf

A table listing the old Legacy AERS (LAERS) tags and the new FDA AERS (FAERS) tags is provided below in section D as a reference to help quickly identify what new fields were added during the transition to the FAERS QDE.

C. LEGACY AERS (LAERS) VS. FDA AERS (FAERS) TAG COMPARISON TABLES

Note: There are 38 Legacy AERS tags and 67 FAERS XML tags that 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 B.

Legacy AERS Extract SGML Tags	FAERS Extract XML Tags
N/A	SAFETYREPORTVERSION*
SAFETYREPORTID	SAFETYREPORTID
N/A	PRIMARYSOURCECOUNTRY*
N/A	AUTHORITYNUMB*+
TRANSMISSIONDATEFORMAT	TRANSMISSIONDATEFORMAT
TRANSMISSIONDATE	TRANSMISSIONDATE
N/A	REPORTTYPE*
SERIOUS	SERIOUS
SERIOUSNESSDEATH	SERIOUSNESSDEATH
SERIOUSNESSLIFETHREATENING	SERIOUSNESSLIFETHREATENING
SERIOUSNESSHOSPITALIZATION	SERIOUSNESSHOSPITALIZATION
SERIOUSNESSDISABLING	SERIOUSNESSDISABLING
SERIOUSNESSCONGENITALANOMALI	SERIOUSNESSCONGENITALANOMALI
SERIOUSNESSOTHER	SERIOUSNESSOTHER
RECEIVEDATEFORMAT	RECEIVEDATEFORMAT
RECEIVEDATE	RECEIVEDATE
RECEIPTDATEFORMAT	RECEIPTDATEFORMAT
RECEIPTDATE	RECEIPTDATE
FULFILLEXPEDITECRITERIA	FULFILLEXPEDITECRITERIA
COMPANYNUMB	COMPANYNUMB
REPORTERCOUNTRY	REPORTERCOUNTRY
N/A	OCCURCOUNTRY*
N/A	DUPLICATE*
N/A	REPORTDUPLICATE*
N/A	DUPLICATESOURCE*
N/A	DUPLICATENUMB*
QUALIFICATION	QUALIFICATION
N/A	LITERATUREREFERENCE*+
N/A	SENDERTYPE*
SENDERORGANIZATION	SENDERORGANIZATION
N/A	RECEIVERTYPE*
N/A	RECEIVERORGANIZATION*
PATIENTONSETAGE	PATIENTONSETAGE
PATIENTONSETAGEUNIT	PATIENTONSETAGEUNIT
N/A	PATIENTAGEGROUP*+
PATIENTWEIGHT	PATIENTWEIGHT
PATIENTSEX	PATIENTSEX
REACTIONMEDDRAPT	REACTIONMEDDRAPT
N/A	REACTIONMEDDRAVERSIONPT*
N/A	REACTIONOUTCOME*

DRUG CHARACTERIZATION	DRUG CHARACTERIZATION
MEDICINALPRODUCT	MEDICINALPRODUCT
N/A	ACTIVESUBSTANCENAME*+
DRUGBATCHNUMB	DRUGBATCHNUMB
DRUGAUTHORIZATIONNUMB	DRUGAUTHORIZATIONNUMB
DRUGADMINISTRATIONROUTE	DRUGADMINISTRATIONROUTE
N/A	DRUGSTRUCTUREDOSAGENUMB*
N/A	DRUGSTRUCTUREDOSAGEUNIT*
N/A	DRUGSEPARATEDOSAGENUMB*
N/A	DRUGINTERVALDOSAGEUNITNUMB*
N/A	DRUGINTERVALDOSAGEDEFINITION*
N/A	DRUGCUMULATIVEDOSAGENUMB*
N/A	DRUGCUMULATIVEDOSAGEUNIT*
DRUGDOSAGETEXT	DRUGDOSAGETEXT
N/A	DRUGDOSAGEFORM*
DRUGINDICATION	DRUGINDICATION
DRUGSTARTDATEFORMAT	DRUGSTARTDATEFORMAT
DRUGSTARTDATE	DRUGSTARTDATE
DRUGENDDATEFORMAT	DRUGENDDATEFORMAT
DRUGENDDATE	DRUGENDDATE
DRUGTREATMENTDURATION	DRUGTREATMENTDURATION
DRUGTREATMENTDURATIONUNIT	DRUGTREATMENTDURATIONUNIT
N/A	ACTIONDRUG*
N/A	DRUGRECURREADMINISTRATION*
N/A	DRUGRECURACTION*+
DRUGADDITIONAL	DRUGADDITIONAL
N/A	NARRATIVEINCLUDECLINICAL*+

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

D. 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 added new data elements to the FAERS QDE.

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

April 2015 (QDE 2014Q3)

A Revision history section (Section C.) was added to this document (XML_NTS.doc) to enable the tracking of changes made to this extract format.

Additionally, new tags are added to the extract with this quarterly release in order to provide QDE users with a more robust dataset to perform analysis. The new tags are as follows:

Authority Number <authoritynumb>
Literature Reference <literaturereference>
Drug Recur Action <drugrecuraction>
Patient Age Group <patientagegroup>
Active Substance Name <activesubstancename>
Narrative Include Clinical <narrativeincludeclinical> in order to provide “Case Event Date” data, if available.

NOTE: Tag specific details are provided in the section B above.

The Patient Sex <patientsex> LOV was modified by removing the value of 9 (Not Specified) which is not an E2B approved value.