Integrating the Healthcare Enterprise

IHE Quality, Research and Public Health (QRPH) Technical Framework Supplement 2009-2010

Drug Safety Content Profile

(DSC)

Trial Implementation Supplement

August 10, 2009

This is a supplement to the forthcoming IHE QRPH Technical Framework.

It is submitted for trial implementation at IHE Connectathons beginning in January 2010.

Comments on the profile should be submitted to http://forums.rsna.org/:

1. Select 2009-2010 Supplements for Trial Implementation
2. Select Drug Safety Content (DSC)
3. You will need to login or create an account before making your posting. Post brief comments by starting a new discussion thread in this subforum or replying to an existing one. Please use the Public Comment Template provided there for extensive comments and attach it to a new thread or reply posting.

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The IHE QRPH Technical Framework is not yet published as a consolidated volume. Previous supplements may be found at: http://www.ihe.net/technical_framework/index.cfm.

Editor's Note

This supplement describes the changes to the existing technical framework documents and where indicated amends text by addition (**bold underline**) or removal (~~**bold strikethrough**~~), as well as addition of large new sections introduced by editor's instructions to "add new text" or similar, which is not bolded or underlined for readability.

"Boxed" instructions like the sample below indicate to the volume editor how to integrate the relevant section(s) into the relevant Technical Framework volume:

Replace Section X.X by the following:

Contents

1.1 Profile Abstract

Drug Safety Content Profile (DSC)

The Drug Safety Content Profile (DSC) describes the content and format to be used within the Pre-population Data transaction described within the Retrieve Form for Data Capture (RFD) Integration Profile.[1] The purpose of this profile is to support a standard set of data in the Continuity of Care Document (CCD) format which the Form Filler provides for use in reporting adverse events as it relates to Drug Safety. In addition, as potential reference implementation this profile will reference the ability to convert this output into the ICH E2B M standard.

1.2 Open Issue Log

1.2.1.1.1 Queries on Multiple Patients

Outside the scope of this content profile but significant with respect to identification of all patients for which AE triggers exist. Such queries require capability for pseudonymization.

1.2.1.1.2 Support for Pseudonymization

Outside the scope of this content profile but significant with respect to maintaining patient privacy with submission of the individual case safety report.

1.3 Glossary

CCD: ASTM/HL7 Continuity of Care Document (CCD)

Drug Safety CCD: Refers to the CCD constrained within the Drug Safety Content (DSC) profile.

E2B(R3): Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports (Information available at: http://www.fda.gov/CBER/gdlns/iche2bmqa.htm)

Form Manager: The Form Manager actor provides the store of forms ready for use by a

Form Filler: The Form Filler actor retrieves forms from a Form Manager as and when required. When requesting a form, the Form Filler actor can optionally provide context information by providing pre-population xml data in the request for use by the Form Manager. The Form Filler may also specify a Form Archiver actor. The Form Archiver actor specified by the Form Filler is in addition to any Form Archiver actors specified by the Form Manager.

Form Receiver: The Form Receiver actor receives and processes completed or partially completed forms instance data from a Form Filler. Form Receiver processing is out of the scope of the profile.

Form Archiver: The Form Archiver actor receives completed or partially completed forms instance data and stores these for archival purposes.

1 Retrieve Form for Data Capture (RFD) Integration Profile, Integrating the Healthcare Enterprise (IHE) Technical Framework Supplement 2007-2008, Trial Implementation Version, available at: ftp.ihe.net/IT_Infrastructure/iheitiyr5-2007-2008/Technical_Cmte/Profile_Work/RFD/IHE_ITI_TF_Supplement_RFD_TI_080207_noTracking.doc.

ICH: The International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH) was established in 1990 as a joint regulatory/industry project to improve, through harmonisation, the efficiency of the process for developing and registering new medicinal products in Europe, Japan and the United States, in order to make these products available to patients with a minimum of delay. The six parties to ICH represent the regulatory bodies and research-based industry in the three regions, Europe, Japan and the USA, where the vast majority of new medicines are currently developed.

ICSR: Individual Case Safety Reports (Information is available at: http://www.fda.gov/CDER/guidance/6675fnl.htm)

Retrieve Form: The Retrieve Form transaction carries the form identifier from a Form Filler to a Form Manager. The transaction also allows a Form Filler to optionally specify a Form Archiver actor as well as optionally containing context information in the form of xml data to be used in the selection and pre-population of the requested form prior to the form being returned to the Form Filler.

RFD: Retrieve Form for Data Capture Profile (RFD)

Standard CRF: Refers to a Standard Case Report Form in an ODM format which is mapped to CDASH

Also refer to Glossary of ICH Terms at http://www.ich.org/cache/html/2791-272-1.html

Volume I

Drug Safety Content Profile (DSC)

1.4 Dependencies

Content Profile	Dependency	Dependency Type	Purpose
Drug Safety Content Profile (DSC)	RFD	Integration Profile	This is a content profile that will be used in the context of the RFD Integration profile.

1.4.1 Profile Name

Drug Safety Content Profile (DSC) - DSC describes the content and format to be used within the Pre-population Data transaction described within the RFD Integration Profile. The purpose of this profile is to support a standard set of data in CCD format which the Form Filler provides for use in reporting adverse events as it relates to Drug Safety. In addition this profile will reference the ability to convert this output into the ICH E2B M Standard.

1.4.2 Use Case

1.4.2.1 Adverse Event (AE) Reporting

1.4.2.1.1 Clinical Trial AE Reporting

A physician, Dr. Smith, is seeing his first clinical trial patient, Rita Jones, for her trial visit. As he talks to her he is reviewing her clinical data in the clinical trial management software used by his practice. After discussing her progress over the last two weeks on the trial, she describes a pain in her abdomen that wasn't present until she started the trial drug for her heart condition. Dr. Smith notices an unanticipated increase in her amylase level and decides this could be due to the trial drug, as this is the second case with similar symptoms he's seen in the last week.

He chooses a menu item from the software to 'Report AE" and a form appears in which he selects the information to include in the report. Ms. Jones' labs, medications, demographics, physical exam and current complaint information is added into the form automatically. Dr. Smith adds some additional information on his suspicions in a text box on the form and pushes 'Report this AE", and the form disappears from his screen.

Dr. Smith recalls the time prior to using the automated reporting process, and remembers how he would want to report an event like this, but after finishing seeing his patients, doing paperwork and getting lunch, he would only remember a few of the case details, and he never remembered where he could find a copy of the form to report the event. If he ran into his study nurse he would tell her the bare details of the case and ask her to report it, but that was as much as he was able to do given his schedule.

With this new system, he was confident that the case had the relevant clinical information, and he could add his interpretation of the case during the patient visit, while the impressions were

fresh in his mind. The entire process usually took him only a few minutes to complete and he knew that the report would be complete and of high quality. He also knew that he could call the report up whenever he wished to review it in light of new information or similar cases.

1.4.2.1.2 Post-Market Surveillance AE Reporting

In the afternoon, when he was seeing the ambulatory clinic patients, Dr. Smith discussed with Mr. Brown the muscle weakness and shooting pains in his legs that started a few days after being put on his high dose statin regimen following his angioplasty. Dr. Smith thought it was likely related to the statin and after counseling Mr. Brown, Dr. Smith pulled up his record in the EHR used by his practice, discontinued the statin, and marked reason for discontinuation as "AE". This brought up a pre-populated form with Mr. Brown's demographics, current labs, medical history, medications and a text box labeled "Adverse Event". Dr. Smith typed in 'myopathy' and noted that the generic and trade name of the statin was pre-populated in the form. He added a note that he had ordered tests to help confirm the diagnosis and they were pending. He then pressed the "Submit AE" button on the form and it disappeared, and Dr. Smith finished ordering tests and writing his notes on Mr. Brown in the EHR.

Dr. Smith remembered how he never previously considered reporting an AE from one of his patients since it involved finding a reporting form, filling out the information himself and usually being late to see his next patient. And if he would ask a nurse or pharmacist to file a report he knew the report would rarely, if ever, be submitted. With this new process he could complete the report himself and not have to pass along the burden to someone else.

1.4.2.2 Current State

Currently in the U.S. ,Europe, and Japan, adverse drug events (ADEs) and adverse drug reactions (ADRs), here generally referred to as adverse events (AEs), are collected on drugs (here meant to include both exogenous chemical and endogenous or 'biologics') through all phases of clinical trials and after the drug has been approved for marketing, through to the life of the drug on the market. There are some differences in regulations, practices and systems by geographic region, but certain commonalities remain:

Clinical Trial

- During clinical trial (CT) investigations, objectives include AEs as a safety component, one aspect of which is the reporting out of AEs during the trial. Certain types of AEs, classified as 'serious' by regulatory definition, must be reported according to a strict timeline and cannot wait until the completion of the trial. Data and information on these events must be collected, evaluated and sent to regulatory authorities by the principal investigator in a timely fashion. Currents methods of reporting range from a completion of a simple paper form by the principal investigator or a designee based on data captured in case record forms, visits and phone calls with medical personnel, to initial population of data directly from trial management systems and electronic health records (EHRs) used at the trial sites followed by assessment and refining of the information by designated personnel. A significant issue with all AE reporting from clinical trials involves the myriad number of clinical data storage systems, standards and data mappings and translations needed to get the data from the parent system to the regulators in a timely fashion.

Post-market Surveillance

- Once a drug is on the market, AEs are collected through various means, but in general the common state of affairs is through a paper-based system of reporting. In some cases reporting initiates from phone calls to a drug information center sponsored by a drug manufacturer from consumers taking the medication, doctors caring for patients or other healthcare personnel such as pharmacists. The information is transcribed by the call center personnel and forwarded on to the manufacturer. In other situations the consumer or healthcare practitioner may call the FDA directly or may send in a paper form through the postal service or by fax, to report the event. In the U.S. a MedWatch® form can be used for this purpose.[2] In all cases of post-marketed reporting, getting the data from the system in which it resides (e.g., EHR) into a form which is ready to be received by regulatory authorities is a laborious process and not part of any clinical routine. This 'burden of reporting' likely has a significant role in the number of difficulties seen in post marketing reporting of AEs which include a lack of quality in reports, a small number of reports, and a general difficulty in getting enough information in any one report to make a adequate assessment of the event(s) in question. In some countries this situation is improved through national systems and/or regulatory requirements for reporting, but in all cases the act of reporting can be made easier through a more direct flow of clinical information on the AE to the regulatory authorities and manufacturers.

Phase IV Trial

- One frequent source of post-marketing AEs comes from trials undertaken once the drug is on the market. These trials can range from Phase IV trials in which there is some type of case control or other means of control and a formal protocol to more loosely controlled trials (commonly referred to as 'marketing trials' in which there is a very general protocol). Phase IV trials are often performed to test the safety and effectiveness of new indications for drugs approved for more limited clinical use. The more well-controlled the trial, the more the data collection and reporting requirements resemble that of pre-marketing CTs. But in marketing trials, data may be collected from various means - through phone interviews, surveys, emails, and from a very large number of consumers/patients. In these trials the quality and amount of data collection can vary tremendously.
- A common thread in all AE reporting is the heterogeneity of the systems and stakeholders in the process. This creates a large number of possible forms, interfaces and data translation requirements which increase the friction between the participants - from the original reporter all the way through to the regulator.
- The current post marketing reporting process in the U.S. is largely paper-based and requires people to track down paper or .pdf forms which take anywhere from 30 to 45 minutes to complete. In Europe some countries have specialized reporting of AEs from, e.g., general practitioners, but there are common technological challenges with maintaining reporting forms and decreasing the burden of producing a report remains problematic. In other countries the process is similar to the U.S., with similar issues. Beyond the initial report, because of the number of handoffs in the process, the different requirements of the various

2 MedWatch® is a voluntary AE reporting form from the US Food and Drug Administration (FDA) that can be used for online data entry, or printing and submission via fax or postal service. Information is available at: http://www.fda.gov/medwatch.

data processing systems involved, and the various requirements for data privacy, a standardized means of defining and moving data through the process is also needed - a commonly recognized format and process can greatly improve how post marketing reports are created and received in the future. Such transmission, privacy and security concerns are not in the direct scope of this profile which specifically addresses the content of the message.

1.4.2.3 Desired State

Given the heterogeneous environment for AE collection and reporting, it is highly desirable to provide some more efficient way to move the data through the reporting system so that the act of reporting becomes easier as a routine output of usual clinical care processes, data fidelity can be maintained, reporting can be timely, and the number of translations of data that occur can be reduced to a minimum.

Clinical Trials and Phase IV

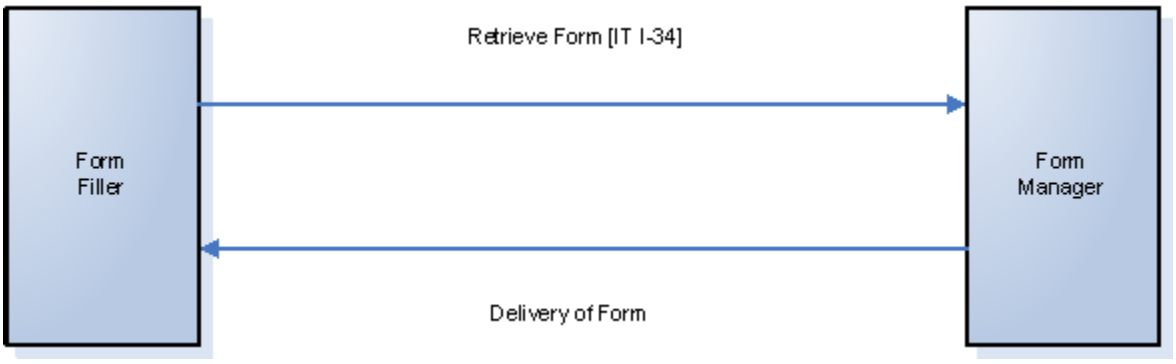
- In clinical trials, an investigator should be able to use a single process to report AEs across any CTs, and should not have to remember or transcribe data that already exists in the clinical systems. Additionally, to improve the reporting process, maintenance of data required for reporting should be accomplished without modification of each underlying data source system, especially given the large number of systems used in generating the data at the sites, in managing the trials, in processing the data at the manufacturers, and in receiving the data at the regulators Standardization of data collection instruments and avoidance of duplicate data entry and transcription is similarly a desire for post marketing trials.

Post-market Surveillance

- The desired state for post-marketing reporting is one in which the burden to submit an AE report is very low, and is part of the routine of the reporter - especially in the case of the physician or other healthcare practitioner. This same reasoning holds true if the reporter is a consumer or patient using a system to maintain their personal health information such as a Personal Health Record. In such post-marketing AE reporting, integrated reporting solutions should trigger and pre-populate essential information to the extent possible in standard formats. Such solutions should also enable behind the scene mapping of clinical care interface terminology through clinically interoperable formats directly to elements required for surveillance for medications and biologics in an integrated fashion.

1.4.2.4 Actors/Transaction

This content profile addresses the Retrieve Form [IT I-34] transaction with the Pre-population argument between the two actors, Form Filler and Form Manager. The Form Filler can request that the Form Filler context information be used by the Form Manager in the selection and/or creation of the returned form. The sharing of content from one actor to the other is addressed by the appropriate use of IHE profiles described below, and is out of scope of this profile. The Retrieve Form for Data Capture embodies the Form Filler Actor and Form Manager Actor. The sharing of content or updates from one actor to the other is addressed by the use of appropriate IHE profiles described by the 2007-2008 Trial Implementation Supplements to ITI-TF v. 4.0 specifically the Retrieve Form for Data Capture (RFD) supplement.



Drug Safety Content Actor Diagram

1.4.2.5 Grouping

1.4.2.6 Content Bindings with RFD

The Retrieve Form for Data Capture Profile (RFD) provides a method for gathering data within a user's current application to meet the requirements of an external system. RFD supports the retrieval of forms by a Form Filler from a Form Manager optionally using pre-population data sent from the Form Filler and then further describes display and completion of a form, and return of instance data from the Form Filler to the Form Receiver as well as optionally to a Form Archiver. This content profile will be bound to the pre-population data transaction described in RFD. [For more details on these profiles, see the IHE IT Infrastructure Technical Framework].

Content profiles may impose additional requirements on the transactions used when grouped with actors from other IHE Profiles.

Drug Safety Content	
Actor	Action
Form Filler	CCD
Form Manager	CCD

Drug safety content profile

1.4.2.6.1 CCD

The Form Filler can produce a valid CCD as content for the pre-population data transaction as defined in RFD. This valid CCD will be further constrained in volume 2 of this profile.

The Form Manager receive a valid CCD as content for the pre-population data transaction as defined in RFD. This valid CCD will be further constrained in volume 2 of this profile. Note the reference implementation that then supports conversion of this CCD into E2B M.

1.4.2.6.2 Process Flow

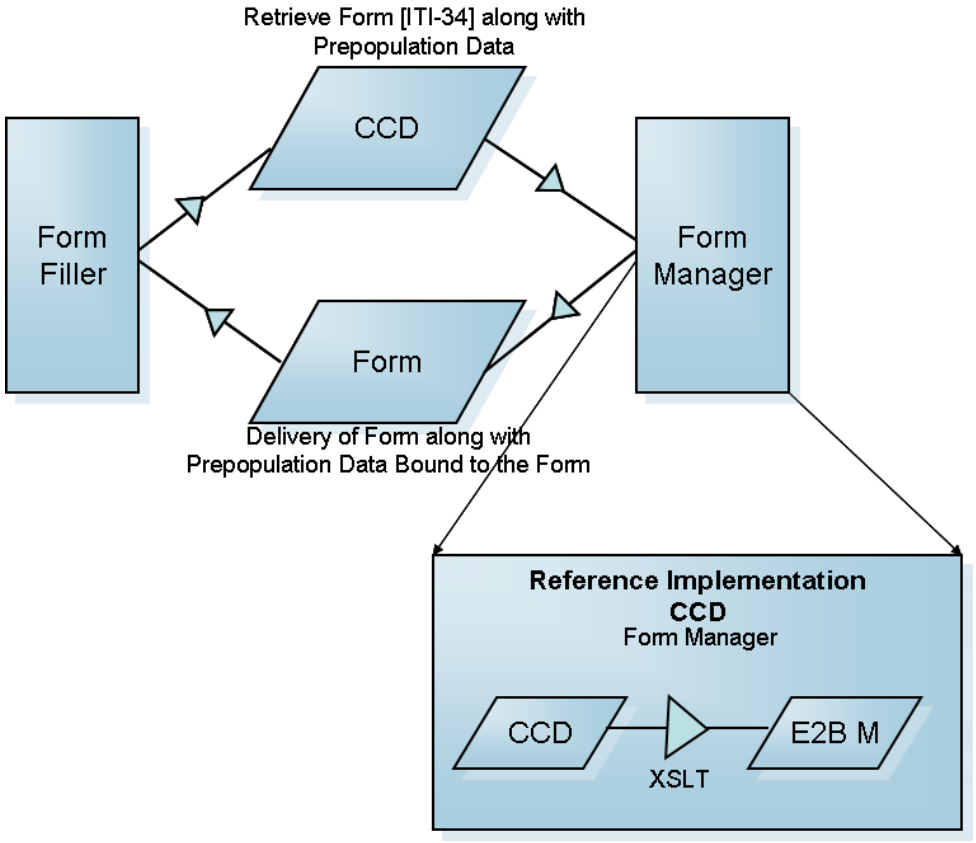


Figure 1.4.2.6.2-1: Drug Safety Content Process Flow for CCD

In this CCD process flow, the Form Filler knows which form it wants to retrieve from the Form Manager. In addition the Form Filler wants to send the pre-population data for this form. The Drug Safety Content (DSC) Profile in addition to this CCD process flow requires that this pre-population data conform to the DSC CCD. The CCD DSC requires the Form Manager to accept the DSC CCD format. Inside the Form Manager there is a reference implementation (see section below) that then describes how the Form Manager could transform this DSC CCD into Standard E2B M. The data that was sent to the Form Manager is then bound to the form and returned to the Form Filler.

1.4.3 Actor Definitions

Form Manager:The Form Manager actor provides the store of forms ready for use by a Form Filler.

Form Filler: The Form Filler actor retrieves forms from a Form Manager as and when required. When requesting a form, the Form Filler actor can optionally provide context information by providing pre-population xml data in the request for use by the Form Manager. The Form Filler may also specify a Form Archiver actor. The Form Archiver actor specified by the Form Filler is in addition to any Form Archiver actors specified by the Form Manager.

1.4.4 Transaction Definitions

Retrieve Form: The Retrieve Form transaction carries the form identifier from a Form Filler to a Form Manager. The transaction also allows a Form Filler to optionally specify a Form Archiver actor as well as optionally containing context information in the form of xml data to be used in the selection and pre-population of the requested form prior to the form being returned to the Form Filler. The trigger for initiating the Retrieve Form action is defined by the local business actor to generate the trigger for the Form Filler to request the Form from the Form Manager. See Appendix A for options regarding triggers that can be used with clinical decision support algorithms to generate the Retrieve Form request.

Appendix A: Triggers

Management of triggers for generating drug safety content

Triggers are generally managed within the EHR workflow to request from a clinician a determination as to whether or not an adverse event has occurred. Some triggers that have been used include:

- In the EHR used in the ASTER project, a question each time a medication is discontinued for the ordering physician to enter if the discontinuation is due to an adverse event
- Automated triggers based on specific medication orders or laboratory results or clinical events as listed in Minutes_Drugs_Safety_Content_Profile_June_5,_2008
- Regardless, triggers require clinician determination before a drug safety content report can be initiated and, therefore, triggers are the responsibility / expectation of the originating EHR.

Sources for triggers:

- Institute for Healthcare Improvement [(IHI) http://www.ihi.org/ihi/workspace/tools/trigger/ ADE Trigger Tools]
- Rozich JD, Haraden CR, Resar RK. Adverse drug event trigger tool: a practical methodology for measuring medication related harm, Qual Saf Health Care. 2003;12:194-200. - Lists 24 clinical triggers to identify potential adverse drug events. *** See Table Below for 24 Triggers
- Resar RK, Rozich JK, Classen D. Methodology and rationale for the measurement of harm with trigger tools, Qual Saf Health Care. 2003;12:ii30-ii45.
- Takata GS, Mason W, Taketomo C, Logsdon T and Sharek PJ. Development, Testing, and Findings of a Pediatric-Focused Trigger Tool to Identify Medication-Related Harm in US Children's Hospitals. Pediatrics 2008;121:927-935. Full Text of Article

Table A-1: Clinical Triggers

Rozich, Haraden, Resar - Clinical Triggers3			
Trigger #	**Trigger**	**Concern**	**EHR Trigger Type (added)**
T1	Diphenhydramine	Hypersensitivity reaction or drug effect	Order
T2	Vitamin K	Over-anticoagulation with warfarin	Order
T3	Flumazenil	Oversedation with benzodiazepine	Order
T4	Droperidol	Nausea/emesis related to drug use	Order
T5	Naloxone	Oversedation with narcotic	Order

3 Rozich JD, Haraden CR, Resar RK. Adverse drug event trigger tool: a practical methodology for measuring medication related harm, Qual Saf Health Care. 2003;12:194-200. - Lists 24 clinical triggers to identify potential adverse drug events.

Rozich, Haraden, Resar - Clinical Triggers3			
T6	Antidiarrheals	Adverse drug event	Order
T7	Sodium polystyrene	Hyperkalemia related to renal impairment or drug effect	Order
T8	PTT >100 seconds	Over-anticoagulation with heparin	Result occurrence
T9	INR >6	Over-anticoagulation with warfarin	Result occurrence
T10	WBC <3000 × 106/µl	Neutropenia related to drug or disease	Result occurrence
T11	Serum glucose <50 mg/dl	Hypoglycemia related to insulin use	Result occurrence
T12	Rising serum creatinine	Renal insufficiency related to drug use	Result occurrence (calculated delta)
T13	Clostridium difficile positive stool	Exposure to antibiotics	Result occurrence (perhaps order for stool C difficile)
T14	Digoxin level >2 ng/ml	Toxic digoxin level	Result occurrence
T15	Lidocaine level >5 ng/ml	Toxic lidocaine level	Result occurrence
T16	Gentamicin or tobramycin levels peak >10 µg/ml,trough >2 µg/ml	Toxic levels of antibiotics	Result occurrence
T17	Amikacin levels peak >30 µg/ml, trough >10 µg/ml	Toxic levels of antibiotics	Result occurrence
T18	Vancomycin level >26 µg/ml	Toxic levels of antibiotics	Result occurrence
T19	Theophylline level >20 µg/ml	Toxic levels of drug	Result occurrence
T20	Oversedation, lethargy, falls	Related to overuse of medication	Occurrence of finding/observation
T21	Rash	Drug related/adverse drug event	Occurrence of finding/observation
T22	Abrupt medication stop	Adverse drug event	Order to discontinue
T23	Transfer to higher level of care	Adverse event	Order
T24	Customized to individual institution	Adverse event	Local determinant Acronyms: PTT=prothrombin time; INR=international normalized ratio; WBC=white blood cells

Retrieved from "**http://wiki.ihe.net/index.php?title=Minutes_Drugs_Safety_Content_Profile_June_5%2C_2008**"

355

Volume II

1.5 Drug Safety Content

1.5.1 Standards

CDAR2: Clinical Document Architecture, Release 2, 2005 HL7

CRS: Implementation Guide for CDA Release 2 – Level 1 and 2 – Care Record Summary (US realm), 2006, HL7.

CCD: ASTM/HL7 Continuity of Care Document (Draft)

ICH E2B M: ICH (International Conference on Harmonisation) Harmonized Tripartite Guideline: Data Elements for Transmission of Individual Case Safety Reports and its associated companion guide: Electronic Transmission of Individual Case Safety Reports Message Specification (ICH ICSR DTD Version 2.1)

1.5.1.1 Data Element Index

A relevant data set for drug safety content reporting include those elements identified within the US efforts under the Healthcare Information Technology Standards Panel (HITSP).. The Drug Safety Content CCD described below overlays these data elements. This Data Element Index is an attempt to describe which sections are intended to cover which domains. The list includes data elements not currently represented in standards, most of which are optional. Where such standards do not exist, the Form Manager will enhance with non-standard fields

Optionality Key

Designation	Meaning
R	Required Section
R2	Required Section if data present
O	Optional section

1.5.1.2 Document Specification

Table 1.5.1.2-1: Document Specification

Data Element	Definition	CCD Description	CCD Code	Optionality
Facility/ Importer Name	The name of the facility that the health care provider diagnosed the subject of the Case Report.	Facility	Author.assignedAuthor.representedOrganization.Name	R
Facility Identifier	Unique facility identifier.	Facility	Author.assignedAuthor.representedOrganization.Id	O
Address	The address (Street, City, State, Zip Code) of the person or facility that diagnosed the subject of the Case Report	Facility	Author.assignedAuthor.representedOrganization.Addr	R
Telephone	The phone number of the person or facility that diagnosed the subject of the Case Report.	Facility	Author.assignedAuthor.representedOrganization.Name telecom	O
Contact Person	The name of the person to be contacted for further information We assume this is the organizations contact	Facility	Author.assignedAuthor.representedOrganization.associatedEntity[classCode='CON'].assignedPerson.name	O
Contact Phone Number	The telephone number fore the contact person We assume this is the organizations contact	Facility	Author.assignedAuthor.representedOrganization.associatedEntity[classCode='CON'].assignedPerson.telecom	O
Responsible physician/Health care provider name	The name of the person that diagnosed the subject	Author	Author.assignedAuthor.assignedPerson.name	o
User Facility / Importer Report Number	The number of the report assigned by the reporting facility	Author	Author.assignedAuthor.assignedPerson.Id	O
Type of Report	The type of report (e.g., Drug Event Report, Healthcare Associated Infection Report, etc.)	TypeId		O
Report Date	The date that the Case Report is being sent	effectiveTime		O
Reported Previously	Indication if the information is supplemental to update in event already reported	versionNumber		O
Report sent to	The organization to which the report is submitted	informationRecipient	intendedRecipient.receivedOrganization	O
Report sent to FDA	Indication if the report is submitted to the Food and Drug Administration	informationRecipient	intendedRecipient.receivedOrganization[id='*FDA*']	O

Data Element	Definition	CCD Description	CCD Code	Optionality
	(FDA) – US			
Date User Facility/Importer Became Aware of Event	The date the event was first recognized by an observer	Event	effectiveTime 1.3.6.1.4.1.19376.1.5.3.1.3.13 statusCode code='active'	O
Date report sent	The date the report is submitted	Not Known		O
Date sent to FDA	The date the report was submitted to the FDA – US	Not Known		O
Report Source	The originator of the report	Author	Author.assignedAuthor.representedOrganization.Name	O
Reporter Name	The name of the person or facility sending the Case Report	Author	Author.assignedAuthor.assignedPerson.name	R
Occupation of Reporter	The role of the reporter (e.g., physician, nurse, administrator, etc.)	no template		O
Telephone	The phone number of the person or facility sending the Case Report	no template		O
Reporter Email	The email contact information for the reporter	no template		O
Type of Reporter	The role of the reporter with respect to the patient (e.g., treating or consulting clinician, case manager, etc.)	no template		O
Reporter Address (street name, city, state, zip code)	The address of the reporter	Author	Author.assignedAuthor.assignedPerson.addr	O
Patient identifier	The identifier for the patient, may be a pseudonymized identifier	Patient	ClinicalDocument.recordTarget.patientRole.id	AE:R
Patient Name (first, MI, Last)	The name (preferably legal) of the subject of the case report.	Patient	ClinicalDocument.recordTarget.patientRole.patient.name	O
Date of Birth	Date of birth	Patient	ClinicalDocument.recordTarget.patientRole.patient.birthTime	O
Age	The age of the subject of the case report at time of diagnosis	no template		O
Gender	Patient sex	Patient	ClinicalDocument.recordTarget.patientRole.patient.administrativeGenderCode	O
Pregnancy	Whether the subject of the case report was pregnant	no template		O

Data Element	Definition	CCD Description	CCD Code	Optionality
Status	at time of diagnosis.			
Estimated Deliver Date	Estimated date of delivery (or est. date of confinement [EDC])	Patient	EDD Observation 1.3.6.1.4.1.19376.1.5.3.1.1.11.2.3.1	O
Weight	The weight of the patient at the time of the report	Patient	Vital Signs Observation 1.3.6.1.4.1.19376.1.5.3.1.4.13.2	O
Birth Weight	The weight of the patient at birth	Patient	Vital Signs Observation 1.3.6.1.4.1.19376.1.5.3.1.4.13.2	O
Number of Siblings	The number of siblings in a multiple birth	Patient	Pregnancy Observation 1.3.6.1.4.1.19376.1.5.3.1.4.13.5	O
Patient Address (street name, city, state, zip code)	The address of the subject of the case report.	Patient	ClinicalDocument.recordTarget.patientRole.addr	O
Patient Telephone	The telephone of the subject of the case report.	Patient	ClinicalDocument.recordTarget.patientRole.telecom	O
Patient County	The county of the address of the subject of the case report	no template		O
Patient Country	The country of the address of the subject of the case report.	no template		O
Race	The race(s) of the subject of the case report.	Patient	ClinicalDocument.recordTarget.patientRole.patient.raceCode	O
Ethnicity	The ethnicity of the subject of the case report	Patient	ClinicalDocument.recordTarget.patientRole.patient.ethnicGroupCode	O
Occupation	The occupation of subject of the case report. Enter as much detail as possible (e.g. Teacher in Pre-School facility)	no template		O
Date of Death	If patient has died, deceased date/time	no template		O
Date of Event	The date the event first occurred	no template		R
Description of Event	A textual description of the event	Event	originalText 1.3.6.1.4.1.19376.1.5.3.1.3.13 statusCode code='active'	O
Name of Condition	The name of the condition diagnosed for the subject of the Case Report	Event	displayName 1.3.6.1.4.1.19376.1.5.3.1.3.13 statusCode code='active'	R
Event Patient Problem Code	The locally determined code to identify the problem for subsequent follow up	no template		O
Event Device Problem	The locally determined code to identify the	no template		O

Data Element	Definition	CCD Description	CCD Code	Optionality
Code	problem for subsequent follow up			
Type of Reportable Event	Seriousness of the event	no template		O
Type of Event and/or Issue		no template		O
Approximate Age of Device	The length of time the device has been in use for the patient	no template		O
Outcome attributed to AE	Textual description of the outcome associated with the adverse event	no template		O
Patient Recovered Diagnosis	Final determination of reaction – diagnosis	no template		O
Location where Event Occurred	The location of the event – e.g., home, hospital, other facility, etc.	no template		O
Adverse Event Terms		no template		O
Event Abated after use stopped or dose reduced?	Indication that the event resolved / abated after usage stopped or dose reduced	no template		O
Event Reappeared after reintroduction	Indication if the reaction reoccurred after rechallenging the patient to the suspected substance	no template		O
Concomitant Medical Product Name	Other medical products in use for the patient to determine proximal relationships	Admission Medication	1.3.6.1.4.1.19376.1.5.3.1.3.20	O
Therapy Dates	Dates of treatment with the suspected agent	no template		O
Pre-existing physician diagnosed allergies, birth defects. Medical conditions	Allergies, conditions existing prior to the use of the suspected agent	no template		O
Current Medications (Medwatch concomitant meds)	Other medications in use	Allergies and Other Adverse Reactions	1.3.6.1.4.1.19376.1.5.3.1.3.13 statusCode code='active|suspended|aborted|completed'	O
Previous Vaccine Type	The type of vaccine	no template		O

Data Element	Definition	CCD Description	CCD Code	Optionality
Previous Vaccine Manufacturer	The manufacturere of the vaccine dose	substanceAdministration/text/reference/@value	1.3.6.1.4.1.19376.1.5.3.1.4.12	O
Previous Vaccine Lot #	The lot number of the vaccine dose	consumable/administerableMaterial/ administerableMaterial/ asMedicineManufacturer.manufacturer.id	1.3.6.1.4.1.19376.1.5.3.1.4.12	O
Previous Vaccine Route/Site	The route of administration of the vaccine dose	Immunization	manufacturedLabeledDrug 1.3.6.1.4.1.19376.1.5.3.1.3.23	O
Vaccine # Previous Doses	The number of previous doses of the vaccine type	Immunization	lotNumberText 1.3.6.1.4.1.19376.1.5.3.1.3.23	O
Previous Vaccine Date Given	The date the vaccination dose suspected was administered	Immunization	routeCode 1.3.6.1.4.1.19376.1.5.3.1.3.23	O
AE Following Prior Vaccination	Description of the adverse event	no template		O
Vaccine Purchased With	Indication of vaccination source (e.g., special program such as Vaccine for Children, state or provincial programs, etc)	Immunization	effectiveTime 1.3.6.1.4.1.19376.1.5.3.1.3.23	O
Suspect Product Name	Product name	no template		O
Product Dose	The dose of the product administered	no template		O
Product Frequency	The frequency with which the product was administered	Medications Administered	Product 1.3.6.1.4.1.19376.1.5.3.1.3.21	O
Product Route Used	The route of administration of the product (e.g., oral, intravenous, intramuscular, etc.)	Medications Administered	Dose 1.3.6.1.4.1.19376.1.5.3.1.3.21	O
Product Therapy Dates	Duration of therapy with the product	no template		O
Product Diagnosis for Use	The reason the product was initially used	Medications Administered	Route 1.3.6.1.4.1.19376.1.5.3.1.3.21	O
Product Lot #	The product lot number	no template		O
Expiration Date	The expiration date of the product	Medications Administered	Indication 1.3.6.1.4.1.19376.1.5.3.1.3.21	O

Data Element	Definition	CCD Description	CCD Code	Optionality
NDC# or Unique ID	The unique identifier for the product	Medications Administered	Lot #	O
Event Abated after use stopped or dose reduced?	Indication that the event resolved / abated after usage stopped or dose reduced	Medications Administered	expirationTime	O
Event Reappeared after reintroduction ?	Indication if the reaction reoccurred after rechallenging the patient to the suspected substance	Medications Administered	Code 1.3.6.1.4.1.19376.1.5.3.1.3.21	O
Suspect Medical Device Brand Name	Brand name of the suspect device	no template		O
Common Device Name	Common name of the device	no template		O
Manuf. name, City and State	Manufacturer of the device	no template		O
Medical Device Model #	Model number of the device	no template		O
Medical Device Catalog #	Catalog number of the device	no template		O
Medical Device Serial #	Serial number of the device	no template		O
Medical Device Lot #	Lot number of the device	no template		O
Medical Device Other #	Other identifiers for the device	no template		O
Operator of Device	The individual managing the device	no template		O
If implanted give date	Date of implantation of the device (if implanted)	no template		O
If explanted give date	Date device was removed (if removed)	no template		O
Is this a single use device that was reprocessed and reused on patient?	Indication if the device is a single-use device that was cleaned/reprocessed and is reused on the affected patient	no template		O
Name and Address of Reprocessor	Name and address of the individual / organization reprocessing the single use device	no template		O

Data Element	Definition	CCD Description	CCD Code	Optionality
Product available for evaluation?	Indication if the product is still available to be evaluated	no template		O
Date product returned to manuf .	If returned to the manufacturer, date of return	no template		O
Concomitant Medical Products & Therapy Dates	Other medical products and treatment used proximal to the event	no template		O
Signs and Symptoms	The signs and symptoms experienced by the patient	no template		O;
Symptom/ Illness Onset Date/Time	This is the range of time of which the problem was active for the patient; for PH: The date that the subject began having symptoms of condition being reported	Admission Medication	1.3.6.1.4.1.19376.1.5.3.1.3.20	O
Patient Class	General type of patient, e.g., Inpatient, Outpatient, Emergency			O
Reporting Laboratory Identifier	Identifier for laboratory that is sending the result. This laboratory may be sending results received back from reference laboratories			O
Performing Laboratory	Laboratory that produced the test result. This may be a reference laboratory identifier.			O
Report Date/Time	Date/time of report			O
Results Status	Status of report (preliminary, final, corrected)			O
Ordered Test Code	The identifier code for the requested observation/test/battery			O
Resulted Test	“The identifier code for the specific test component resulted			O
Result Unit	Unit for numeric result context			O
Test Interpretation	Interpretation of test result, including the susceptibility test interpretation			O
Test Status	Status of the test result			C

Data Element	Definition	CCD Description	CCD Code	Optionality
Date of Test	The date that the laboratory test was performed for the subject of the Case Report.			O
Test Method	Testing method used to arrive at the specific result :The name of the laboratory test.			O
Test Result	The test result of the laboratory test including any applicable result units of measure			O
Specimen Collection Date	The date that the specimen for the laboratory test was taken from the subject of the Case Report			O
Source of Specimen	The physical body location from where the specimen for the lab report was taken from the subject			O
Name of Organization Collecting Specimen	Name of organization collecting specimen which may be different from the organization performing the laboratory analysis			O
Diagnosis/Injury Code	Diagnosis or diagnoses assigned as a result of the encounter			O;
Diagnosis Type	Type of diagnosis being sent (admitting, working, final)			O;
Diagnosis Date/Time	The date that the subject of the Case Report was diagnosed with Condition above			O;
Previous Event Report Details	Definitions pending - see appendix for detail to be considered			O
Reason for Non-Evaluation	Definitions pending - see appendix for detail to be considered			O
Type of Follow-Up	Definitions pending - see appendix for detail to be considered			O
Type of Remedial Action	Definitions pending - see appendix for detail to be considered			O
Administration of	Was treatment administered?			R

Data Element	Definition	CCD Description	CCD Code	Optionality
Treatment				
Date of Admin of Treatment	The date treatment was administered. For HepB, Date HBV vaccine administered			R
Name of Treatment	Name of the treatment			R
Hospitalization	If the subject of the case report was hospitalized			R
Admission Date	Enter the date that the subject of the Case Report was Admitted to the hospital.			O
Discharge Date	Enter the date that the subject of the Case Report was Discharged from the hospital			R
Hospital Name	Name of hospital the case was admitted.			O
Recovered	Did the subject recover from the disease?			R
Death	Did the subject die as a result of the disease?			R

1.5.1.3 Header Sample

1.5.1.3.1 Immunizations Example

```
<component>
  <section>
    <templateId root='2.16.840.1.113883.10.20.1.6'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.23'/>
    <id root=' ' extension=' '/>
    <code code='11369-6' displayName='HISTORY OF IMMUNIZATIONS'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>
    <entry>
         :
      <!-- Required Immunization element -->
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.12'/>
         :
    </entry>

  </section>
</component>
```

1.5.1.3.2 Allergies and Other Adverse Reactions Examples

```
<component>
  <section>
```



```
    <templateId root='2.16.840.1.113883.10.20.1.2'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.13'/>
    <id root=' ' extension=' '/>
    <code code='48765-2' displayName='Allergies, adverse reactions, alerts'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>
    <entry>
        :
      <!-- Required Allergies and Intolerances Concern element -->
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.3'/>
        :
    </entry>

  </section>
</component>
```

1.5.1.3.3 Admission Medication History Example

```
<component>
  <section>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.20'/>
    <id root=' ' extension=' '/>
    <code code='42346-7' displayName='MEDICATIONS ON ADMISSION'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>
    <entry>
        :
      <!-- Required Medications element -->
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7'/>
        :
    </entry>

  </section>
</component>
```

1.5.1.3.4 ClinicalDocument Header Example

```
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
                  xmlns="urn:hl7-org:v3"
xmnls:lab="urn:oid:1.3.6.1.4.1.19376.1.3.2"
                  xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <realmCode code="US" codeSystem="2.16.1" codeSystemName="ISO3166-1"
displayName="US"/>
  <typeId extension="POCD_HD000040" root="2.16.840.1.113883.1.3"/>
  <templateId extension="Lab.Report.Clinical.Document"
root="1.3.6.1.4.1.19376.1.3.3"/>
  <id root="1.19.6.11.13.103000012000025132.1181266627192.1"/>
  <code code="18725-2" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC"
        displayName="Microbiology Studies"/>
```



```
  <title>Public Health Laboratory Report</title>
  <effectiveTime value="20070607183707.0222-0700"/>
  <confidentialityCode code="N" codeSystem="2.16.840.1.113883.5.25"
displayName="Normal"/>
  <languageCode code="en-US" codeSystem="2.16.840.1.113883.6.99"
codeSystemName="ISO639-1" displayName="en-US"/>
  <setId extension="07SR012345" root="2.16.840.1.113883.1.3"/>
<versionNumber value="1"/>
```

1.5.1.3.5 Medications Administered Example

```
<component>
  <section>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.21'/>
    <id root=' ' extension=' '/>
    <code code='18610-6' displayName='MEDICATION ADMINISTERED'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>
    <entry>
         :
      <!-- Required Medications element -->
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7'/>
         :
    </entry>

  </section>
</component>
```

1.5.1.3.6 Author Example

```
  <author>
    <time value="19990522"/>
    <assignedAuthor>
      <id extension="11111111" root="1.3.5.35.1.4436.7"/>
      <assignedPerson>
        <name>
          <prefix>Dr.</prefix>
          <given>Bernard</given>
          <family>Wiseman</family>
          <suffix>Sr.</suffix>
        </name>
      </assignedPerson>
      <representedOrganization>
     <id extension="aaaaabbbbb"root="1.3.5.35.1.4436.7"/>
     <name>Dr. Wiseman's Clinic</name>
      </representedOrganization>
    </assignedAuthor>
  </author>
```


1.5.1.3.7 Patient Example

```
  <recordTarget>
    <patientRole classCode="PAT">
      <id root="27143B24-E580-4F47-9405-3D0DC2BF1223" extension="1022"/>
      <addr>
        <streetAddressLine/>
        <city/>
        <state>FM</state>
        <postalCode/>
        <country>Canada</country>
      </addr>
      <telecom nullFlavor="UNK" use="HP"/>
      <patient classCode="PSN" determinerCode="INSTANCE">
        <name>
          <prefix/>
          <given>Christine</given>
          <family>Smith</family>
          <suffix/>
        </name>
        <ethnicGroupCode code="364699009" displayName="ethnic group"
          codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"/>
        <administrativeGenderCode code="F"
codeSystem="2.16.840.1.113883.5.1"/>
        <birthTime value="20040725"/>
        <raceCode code=”2106-3” codeSystem=”2.16.840.1.113883.5.104”/>
      </patient>
      <providerOrganization classCode="ORG" determinerCode="INSTANCE">
        <id root="2.16.840.1.113883.19.5"/>
      </providerOrganization>
    </patientRole>
  </recordTarget>
```

1.5.1.3.8 Vital Signs Observation Example

```
<observation classCode='OBS' moodCode='EVN'>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/>
 <templateId root='2.16.840.1.113883.10.20.1.31'/>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.2'/>
 <id root=' ' extension=' '/>
 <code code=' ' codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
 <text><reference value='#xxx'/></text>
 <statusCode code='completed'/>
 <effectiveTime value=' '/>
 <repeatNumber value=' '/>
 <value xsi:type='PQ' value=' ' unit=' '/>
 <interpretationCode code=' ' codeSystem=' ' codeSystemName=' '/>
 <methodCode code=' ' codeSystem=' ' codeSystemName=' '/>
 <targetSiteCode code=' ' codeSystem=' ' codeSystemName=' '/>
</observation>
```

1.5.1.3.9 Pregnancy Observation Example

```
<observation typeCode='OBS' moodCode='EVN'>
```



```
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.5'/>
 <id root=' ' extension=' '/>
 <code code=' ' displayName=' ' codeSystem='2.16.840.1.113883.6.1'
codeSystemName='LOINC'/>
 <text><reference value='#xxx'/></text>
 <statusCode code='completed'/>
 <effectiveTime value=' '/>
 <repeatNumber value=' '/>
 <value xsi:type=' ' .../>
 <interpretationCode code=' ' codeSystem=' ' codeSystemName=' '/>
 <methodCode code=' ' codeSystem=' ' codeSystemName=/>
 <targetSiteCode code=' ' codeSystem=' ' codeSystemName=' '/>
</observation>
```

1.5.1.3.10 EDD Observation Example

```
<observation classCode='OBS' moodCode='EVN'>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.11.2.3.1'>
 <statusCode code='completed'/>
 <effectiveTime value=' '/>
 <author typeCode='AUT'>
   <time value=' '/>
   <assignedAuthor>
     <id root=' ' extension=' '/>
   </assignedAuthor>
 </author>
 <id root=' ' extension=' '/>
 <code code='11778-8'
       displayName='DELIVERY DATE-TMSTP-PT-^PATIENT-QN-CLINICAL.ESTIMATED'
       codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
 <text><reference value='id-foo'/></text>
 <value xsi:type='TS' value=' '/>
 <entryRelationship typeCode='SPRT'>
   <observation classCode='OBS' moodCode='EVN'>
     <id root=' ' extension=' '/>
     <statusCode code='completed'/>
     <effectiveTime value=' '/>
     <author typeCode='AUT'>
        <time value=' '/>
        <assignedAuthor classCode=' '>
          <id root=' ' extension=' '/>
        </assignedAuthor>
     </author>
     <code code='[11779-6|(xx-EDD-by-PE)|11781-2|(xx-EDD-by-Qck)|(xx-EDD-by-
Fund)]'
           codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
     <value type='TS' value=' '>
     <entryRelationship typeCode='DRIV'>
       <observation  classCode='OBS' moodCode='EVN'>
         <id root=' ' extension=' '/>
         <statusCode code='completed'/>
         <effectiveTime value=' '/>
         <author typeCode='AUT'>
```



```
            <time value=' '/>
            <assignedAuthor>
              <id root=' ' extension=' '/>
            </assignedAuthor>
          </author>
          <informant typeCode='INF'>
            <relatedEntity classCode=' '>
              <id root=' ' extension=' '/>
            </relatedEntity>
          </informant>
          <code code='[8655-2|(xx-ga-by-pe)|11888-5|(xx-date-of-qck)|(xx-date-
of-fund-umb) ]'
                codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
          <value type='[PQ|TS]' value=' ' units='week'/>
        </observation>
      </entryRelationship>
    </observation>
  </entryRelationship>
</observation>
```

1.5.2 Reference Implementation

1.5.2.1 Drug Safety Content CCD to E2B M Crosswalk

This section is intended to be a guide as to how a Form Manager would crosswalk an individual case safety report CCD structure into a standard used for routine reporting by regulatory agencies such as the Food and Drug Administration (FDA) in the United States, the European Medicines Agency (EMEA), the Ministry of Health Labour and Welfare (MHLW) in Japan and HealthCanada. There is ongoing harmonization work by HL7, ISO and CEN and ICH to align reporting data elements within the E2B standard, moving from the existing E2B M to E2B R3. The harmonization work will also modify the messaging requirements as the Individual Case Safety Report (ICSR) R3. The roadmap is to align HL7, ISO and CEN beginning with a draft ballot for review September 2008 and finalize formal SDO balloting by December 2009. The E2B R3 content standard timeline is expected to be completed after ICSR R3 is finalized. In the interim, regulatory bodies will continue to receive electronic submissions from pharmaceutical companies using E2B M transmission standards. The benefit for EHR implementations and EHR vendors is alignment of all reporting to external agencies by use of CDA mapping and RFD infrastructure. The expected mid term goal is for the Form Manager to map to ICSR R3 and the related content, E2B R3. This reference implementation constrains the data element list to only those elements with E2B M tags. Some data elements are not represented within E2B M, even though there may be CCD elements that can capture them.

The adopted format for this transformation from one structure to the other is an XSLT. The intent is to have this XSLT not be presented here within the DSC profile and remain static, but to further develop and refine this XSLT as supplemental material. The goal is to allow additional Use Cases to drive different flavors of transformations all of which might be available to be referenced. IHE is developing processes which aren't ready at time of this publication to help maintain source control and facilitate sharing and updating of this as well as other reference

transformations. When the IHE process and procedures are determined this section will refer to those documents.

The list includes data elements not currently represented in standards, most of which are optional. Where such standards do not exist, the Form Manager will enhance with non-standard fields.

Table 1.5.2.1-1: Drug Safety Content CCD to E2B M Crosswalk

Data Element	Definition	Option-ality	E2B M Description	E2B M Code	CCD Description	CCD Code
Facility/ Importer Name	The name of the facility that the health care provider diagnosed the subject of the Case Report.	R	reporterorganization	A.2.1.2a	Facility	Author.assignedAuthor.representedOrganization.Name
Facility Identifier	Unique facility identifier.	O			Facility	Author.assignedAuthor.representedOrganization.Id
Address	The address (Street, City, State, Zip Code) of the person or facility that diagnosed the subject of the Case Report	R	reporteraddress, reporterstreet,reportercity,reporterpostalcode,reporterstate	A.2.1.2c, A.2.1.2d, A.2.1.2e, A.2.1.2f	Facility	Author.assignedAuthor.representedOrganization.Addr
Telephone	The phone number of the person or facility that diagnosed the subject of the Case Report.	O			Facility	Author.assignedAuthor.representedOrganization.Name telecom
Contact Person	The name of the person to be contacted for further information	O	sendergivename, senderfamilyname	A.3.1.3c, A.3.1.3e		
Contact Phone Number	The telephone number fore the contact person	O	sendertel	A.3.1.4f		
Responsible physician/Health care provider name	The name of the person that diagnosed the subject	O	reportergivename, reporterfamilyname	A.2.1.1b, A.2.1.1d	Author	Author.assignedAuthor.assignedPerson.name

Data Element	Definition	Option-ality	E2B M Description	E2B M Code	CCD Description	CCD Code
User Facility / Importer Report Number	The number of the report assigned by the reporting facility	O	patienthospitalrecordnumb	B.1.1.1c	Author	Author.assignedAuthor.assignedPerson.Id
Type of Report	The type of report (e.g., Drug Event Report, Healthcare Associated Infection Report, etc.)	O			no template	
Report Date	The date that the Case Report is being sent	O	transmissiondateformat, transmissiondate	A.1.3a, A.1.3b	no template	
Reported Previously	Indication if the information is supplemental to update in event already reported	O			no template	
Report sent to	The organization to which the report is submitted	O	receiver	A.3.2	no template	
Report sent to FDA	Indication if the report is submitted to the Food and Drug Administration (FDA) – US	O			no template	
Date User Facility/Importer Became Aware of Event	The date the event was first recognized by an observer	O	receivedate	A.1.6b	Event	effectiveTime 1.3.6.1.4.1.19376.1.5.3.1.3.13 statusCode code='active'
Date report sent	The date the report is submitted	O	transmissiondateformat, transmissiondate	A.1.3a, A.1.3b	no template	
Date sent to FDA	The date the report was submitted to the FDA – US	O			no template	

Data Element	Definition	Option-ality	E2B M Description	E2B M Code	CCD Description	CCD Code
Report Source	The originator of the report	O	?		no template	
Reporter Name	The name of the person or facility sending the Case Report	R	sendergivename, senderfamilyname	A.3.1.3c, A.3.1.3e	no template	
Occupation of Reporter	The role of the reporter (e.g., physician, nurse, administrator, etc.)	O			no template	
Telephone	The phone number of the person or facility sending the Case Report	O			no template	
Reporter Email	The email contact information for the reporter	O			no template	
Type of Reporter	The role of the reporter with respect to the patient (e.g., treating or consulting clinician, case manager, etc.)	O	qualification	A.2.1.4	no template	
Reporter Address (street name, city, state, zip code)	The address of the reporter	O	reporteraddress, reporterstreet,reportercity,reporterpostalcode,reporterstate	A.2.1.2c, A.2.1.2d, A.2.1.2e, A.2.1.2f	Author	Author.assignedAuthor.assignedPerson.addr
Patient identifier	The identifier for the patient, may be a pseudonymized identifier	AE:R	patientinital, patientgpmedicalrecordnumb	B.1.1, B.1.1.1a	Patient	ClinicalDocument.recordTarget.patientRole.id

Data Element	Definition	Option-ality	E2B M Description	E2B M Code	CCD Description	CCD Code
Patient Name (first, MI, Last)	The name (preferably legal) of the subject of the case report.	O			Patient	ClinicalDocument.recordTarget.patientRole.patient.name
Date of Birth	Date of birth	O	patientbirthdateformat, patientbirthdate	B.1.2.1a, B.1.2.1b	Patient	ClinicalDocument.recordTarget.patientRole.patient.birthTime
Age	The age of the subject of the case report at time of diagnosis	O	patientonsetage	B.1.2.2a	no template	
Gender	Patient sex	O	patientsex	B.1.5	Patient	ClinicalDocument.recordTarget.patientRole.patient.administrativeGenderCode
Pregnancy Status	Whether the subject of the case report was pregnant at time of diagnosis.	O			no template	
Estimated Deliver Date	Estimated date of delivery (or est. date of confinement [EDC])	O			Patient	EDD Observation 1.3.6.1.4.1.19376.1.5.3.1.1.11.2.3.1
Weight	The weight of the patient at the time of the report	O	patientweight	B.1.3	Patient	Vital Signs Observation 1.3.6.1.4.1.19376.1.5.3.1.4.13.2
Birth Weight	The weight of the patient at birth	O			Patient	Vital Signs Observation 1.3.6.1.4.1.19376.1.5.3.1.4.13.2
Number of Siblings	The number of siblings in a multiple birth	O			Patient	Pregnancy Observation 1.3.6.1.4.1.19376.1.5.3.1.4.13.5

Data Element	Definition	Option-ality	E2B M Description	E2B M Code	CCD Description	CCD Code
Patient Address (street name, city, state, zip code)	The address of the subject of the case report.	O			Patient	ClinicalDocument.recordTarget.patientRole.addr
Patient Telephone	The telephone of the subject of the case report.	O			Patient	ClinicalDocument.recordTarget.patientRole.telecom
Patient County	The county of the address of the subject of the case report	O			no template	
Patient Country	The country of the address of the subject of the case report.	O			no template	
Race	The race(s) of the subject of the case report.	O			Patient	ClinicalDocument.recordTarget.patientRole.patient.raceCode
Ethnicity	The ethnicity of the subject of the case report	O			Patient	ClinicalDocument.recordTarget.patientRole.patient.ethnicGroupCode
Occupation	The occupation of subject of the case report. Enter as much detail as possible (e.g. Teacher in Pre-School facility)	O			no template	
Date of Death	If patient has died, deceased date/time	O	patientdeathdateformat, patientdeathdate	B.1.9.1a, B.1.9.1b	no template	

Data Element	Definition	Option-ality	E2B M Description	E2B M Code	CCD Description	CCD Code
Date of Event	The date the event first occurred	R			no template	
Description of Event	A textual description of the event	O	reactionstartdateformat, reactionstartdate	B.2.i.4a, B.2.i.4b	Event	originalText 1.3.6.1.4.1.19376.1.5.3.1.3.13 statusCode code='active'
Name of Condition	The name of the condition diagnosed for the subject of the Case Report	R	primarysourcereaction	B.2.i.0	Event	displayName 1.3.6.1.4.1.19376.1.5.3.1.3.13 statusCode code='active'
Event Patient Problem Code	The locally determined code to identify the problem for subsequent follow up	O	reactionmeddrallt	B.2.i.1b	no template	
Event Device Problem Code	The locally determined code to identify the problem for subsequent follow up	O			no template	
Type of Reportable Event	Seriousness of the event	O			no template	

Data Element	Definition	Option-ality	E2B M Description	E2B M Code	CCD Description	CCD Code
Type of Event and/or Issue		O			no template	
Approximate Age of Device	The length of time the device has been in use for the patient	O			no template	
Outcome attributed to AE	Textual description of the outcome associated with the adverse event	O	reactionoutcome	B.2.i.8	no template	
Patient Recovered Diagnosis	Final determination of reaction – diagnosis	O	reactionoutcome	B.2.i.8	no template	
Location where Event Occurred	The location of the event – e.g., home, hospital, other facility, etc.	O			no template	
Adverse Event Terms		O	reactionmeddrallt	B.2.i.1b	no template	
Event Abated after use stopped or dose reduced?	Indication that the event resolved / abated after usage stopped or dose reduced	O	drugrecurreadministration	B.4.k.17.1	no template	

Data Element	Definition	Option-ality	E2B M Description	E2B M Code	CCD Description	CCD Code
Event Reappeared after reintroduction	Indication if the reaction reoccurred after rechallenging the patient to the suspected substance	O	drugrecurreadministration	B.4.k.17.1	no template	
Concomitant Medical Product Name	Other medical products in use for the patient to determine proximal relationships	O	medicinalproduct, drugcharacterization	B.4.k.2.1, B.4.k.1	Admission Medication	1.3.6.1.4.1.19376.1.5.3.1.3.20
Therapy Dates	Dates of treatment with the suspected agent	O			no template	
Pre-existing physician diagnosed allergies, birth defects. Medical conditions	Allergies, conditions existing prior to the use of the suspected agent	O	drugstartdateformat, drugstartdate, drugendateformat, drugendate	B.4.k.12a, B.4.k.12b, B.4.k.14a, B.4.k.14b	no template	
Current Medications (Medwatch concomitant meds)	Other medications in use	O	patientepisodename	B.1.7.1a.2	Allergies and Other Adverse Reactions	1.3.6.1.4.1.19376.1.5.3.1.3.13 statusCode code='active|suspended|aborted|completed'
Previous Vaccine Type	The type of vaccine	O	medicinalproduct, drugcharacterization	B.4.k.2.1, B.4.k.1	no template	
Previous Vaccine Manufacturer	The manufacturere of the vaccine dose	O			substanceAdministration/text/reference/@value	1.3.6.1.4.1.19376.1.5.3.1.4.12

Data Element	Definition	Option-ality	E2B M Description	E2B M Code	CCD Description	CCD Code
Previous Vaccine Lot #	The lot number of the vaccine dose	O			consumable/administerableMaterial/ administerableMaterial/ asMedicineManufacturer. manufacturer.id	1.3.6.1.4.1.19376.1.5.3.1.4.12
Previous Vaccine Route/Site	The route of administration of the vaccine dose	O			Immunization	manufacturedLabeledDrug 1.3.6.1.4.1.19376.1.5.3.1.3.23
Vaccine # Previous Doses	The number of previous doses of the vaccine type	O			Immunization	lotNumberText 1.3.6.1.4.1.19376.1.5.3.1.3.23
Previous Vaccine Date Given	The date the vaccination dose suspected was administered	O			Immunization	routeCode 1.3.6.1.4.1.19376.1.5.3.1.3.23
AE Following Prior Vaccination	Description of the adverse event	O			no template	
Vaccine Purchased With	Indication of vaccination source (e.g., special program such as Vaccine for Children, state or provincial programs, etc)	O			Immunization	effectiveTime 1.3.6.1.4.1.19376.1.5.3.1.3.23

Data Element	Definition	Option-ality	E2B M Description	E2B M Code	CCD Description	CCD Code
Suspect Product Name	Product name	O			no template	
Product Dose	The dose of the product administered	O			no template	
Product Frequency	The frequency with which the product was administered	O	medicinalproduct, drugcharacterization	B.4.k.2.1, B.4.k.1	Medications Administered	Product 1.3.6.1.4.1.19376.1.5.3.1.3.21
Product Route Used	The route of administration of the product (e.g., oral, intravenous, intramuscular, etc.)	O	drugdosagetext	B.4.k.6	Medications Administered	Dose 1.3.6.1.4.1.19376.1.5.3.1.3.21
Product Therapy Dates	Duration of therapy with the product	O	drugseparatedosagenumb	B.4.k.5.3	no template	
Product Diagnosis for Use	The reason the product was initially used	O	drugadministrationroute	B.4.k.8	Medications Administered	Route 1.3.6.1.4.1.19376.1.5.3.1.3.21

Data Element	Definition	Option-ality	E2B M Description	E2B M Code	CCD Description	CCD Code
Product Lot #	The product lot number	O	drugstartdateformat, drugstartdate, drugendateformat, drugendate	B.4.k.12a, B.4.k.12b, B.4.k.14a, B.4.k.14b	no template	
Expiration Date	The expiration date of the product	O	drugindication	B.4.k.11b	Medications Administered	Indication 1.3.6.1.4.1.19376.1.5.3.1.3.21
NDC# or Unique ID	The unique identifier for the product	O	drugbatchnumb	B.4.k.3	Medications Administered	Lot #
Event Abated after use stopped or dose reduced?	Indication that the event resolved / abated after usage stopped or dose reduced	O			Medications Administered	expirationTime
Event Reappeared after reintroduction?	Indication if the reaction reoccurred after rechallenging the patient to the suspected substance	O	drugauthorizationnumb	B.4.k.4.1	Medications Administered	Code 1.3.6.1.4.1.19376.1.5.3.1.3.21
Suspect Medical Device Brand Name	Brand name of the suspect device	O	drugrecurreadministration	B.4.k.17.1	no template	

Data Element	Definition	Option-ality	E2B M Description	E2B M Code	CCD Description	CCD Code
Common Device Name	Common name of the device	O	drugrecurreadministration	B.4.k.17.1	no template	
Manuf. name, City and State	Manufacturer of the device	O			no template	
Medical Device Model #	Model number of the device	O			no template	
Medical Device Catalog #	Catalog number of the device	O			no template	
Medical Device Serial #	Serial number of the device	O			no template	
Medical Device Lot #	Lot number of the device	O			no template	

Data Element	Definition	Option-ality	E2B M Description	E2B M Code	CCD Description	CCD Code
Medical Device Other #	Other identifiers for the device	O			no template	
Operator of Device	The individual managing the device	O			no template	
If implanted give date	Date of implantation of the device (if implanted)	O			no template	
If explanted give date	Date device was removed (if removed)	O			no template	
Is this a single use device that was reprocessed and reused on patient?	Indication if the device is a single-use device that was cleaned/reprocessed and is reused on the affected patient	O			no template	
Name and Address of Reprocessor	Name and address of the individual / organization reprocessing the single use device	O			no template	

Data Element	Definition	Option-ality	E2B M Description	E2B M Code	CCD Description	CCD Code
Product available for evaluation?	Indication if the product is still available to be evaluated	O			no template	
Date product returned to manuf .	If returned to the manufacturer, date of return	O			no template	
Concomitant Medical Products & Therapy Dates	Other medical products and treatment used proximal to the event	O			no template	
Signs and Symptoms	The signs and symptoms experienced by the patient	O;			no template	
Symptom/ Illness Onset Date/Time	This is the range of time of which the problem was active for the patient; for PH: The date that the subject began having symptoms of condition being reported	O			Admission Medication	1.3.6.1.4.1.19376.1.5.3.1.3.20
Patient Class	General type of patient, e.g., Inpatient, Outpatient, Emergency	O				

Data Element	Definition	Option-ality	E2B M Description	E2B M Code	CCD Description	CCD Code
Reporting Laboratory Identifier	Identifier for laboratory that is sending the result. This laboratory may be sending results received back from reference laboratories	O	reactionstartdateformat, reactionstartdate	B.2.i.4a, B.2.i.4b		
Performing Laboratory	Laboratory that produced the test result. This may be a reference laboratory identifier.	O				
Report Date/Time	Date/time of report	O				

Data Element	Definition	Option-ality	E2B M Description	E2B M Code	CCD Description	CCD Code
Results Status	Status of report (preliminary, final, corrected)	O				
Ordered Test Code	The identifier code for the requested observation/test/battery	O				
Resulted Test	"The identifier code for the specific test component resulted	O				
Result Unit	Unit for numeric result context	O				
Test Interpretation	Interpretation of test result, including the susceptibility test interpretation	O				
Test Status	Status of the test result	C				
Date of Test	The date that the laboratory test was performed for the subject of the Case Report.	O				

Data Element	Definition	Option-ality	E2B M Description	E2B M Code	CCD Description	CCD Code
Test Method	Testing method used to arrive at the specific result :The name of the laboratory test.	O				
Test Result	The test result of the laboratory test including any applicable result units of measure	O	testdateformat, testdate	B.3.1a, B.3.1b		
Specimen Collection Date	The date that the specimen for the laboratory test was taken from the subject of the Case Report	O				
Source of Specimen	The physical body location from where the specimen for the lab report was taken from the subject	O	testresult	B.3.1d		
Name of Organization Collecting Specimen	Name of organization collecting specimen which may be different from the organization performing the laboratory analysis	O				

Data Element	Definition	Option-ality	E2B M Description	E2B M Code	CCD Description	CCD Code
Diagnosis/Injury Code	Diagnosis or diagnoses assigned as a result of the encounter	O;				
Diagnosis Type	Type of diagnosis being sent (admitting, working, final)	O;				
Diagnosis Date/Time	The date that the subject of the Case Report was diagnosed with Condition above	O;				
Previous Event Report Details	Definitions pending - see appendix for detail to be considered	O				
Reason for Non-Evaluation	Definitions pending - see appendix for detail to be considered	O				

Data Element	Definition	Option-ality	E2B M Description	E2B M Code	CCD Description	CCD Code
Type of Follow-Up	Definitions pending - see appendix for detail to be considered	O				
Type of Remedial Action	Definitions pending - see appendix for detail to be considered	O				
Administration of Treatment	Was treatment administered?	R				
Date of Admin of Treatment	The date treatment was administered. For HepB, Date HBV vaccine administered	R				
Name of Treatment	Name of the treatment	R				
Hospitalization	If the subject of the case report was hospitalized	R				
Admission Date	Enter the date that the subject of the Case Report was Admitted to the hospital.	O				

Data Element	Definition	Option-ality	E2B M Description	E2B M Code	CCD Description	CCD Code
Discharge Date	Enter the date that the subject of the Case Report was Discharged from the hospital	R				
Hospital Name	Name of hospital the case was admitted.	O				
Recovered	Did the subject recover from the disease?	R				
Death	Did the subject die as a result of the disease?	R				
Data Element	Definition	O	reactionoutcome	B.2.i.8		
Facility/ Importer Name	The name of the facility that the health care provider diagnosed the subject of the Case Report.	O	seriousnessdeath	A.1.5.2a		

