HL7 Individual Case Safety Report Release 1:

Implementation Guide for FDA Medical Device Reporting

HL7 Informative Document

Sponsored by:
Patient Safety Special Interest Group
Regulated Clinical Research Information Management Technical Committee

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Introduction

The HL7 Individual Case Safety Report (ICSR) is a Health Level Seven (HL7) standard for the exchange of adverse event or product problem reports to public health, patient safety, healthcare quality improvement organizations or regulatory authorities. Release 1 of the standard supports reporting for drugs, therapeutic biologics, blood derivatives, devices and vaccines. Release 2 of the standard is being balloted to support other product types such as foods, food additives, dietary supplements, cosmetics and veterinary drugs. As the ICSR standard continues to evolve, the implementation manual will be amended to include new requirements and guidance on how to implement the revisions to the message standard, and FDA will publish separate guidance concerning the use of the ICSR for regulatory reporting purposes. The standard is specifically designed to support individual case safety reports and not support population-based case reporting for disease surveillance or outbreak events. Additionally, the standard supports international safety reporting requirements as defined by the International Conference on Harmonisation's (ICH) E2B(M) ICSR message specification.

Scope of This Document

This ICSR Implementation Guide was created by the HL7 Patient Safety Special Interest Group (PSSIG) as a companion document for early adopters of the standard. The guide provides an overview of the standard data attributes, and includes a more detailed appendix oriented toward submission of device adverse event and product problem reports to the FDA Center for Devices and Radiological Health (CDRH). The ICSR being piloted in CDRH uses only a subset of the information described in the HL7 ICSR standard. Detailed information about CDRH's submission requirements are provided in **Appendix H**. Because the ICSR can be used to support a broad spectrum of reporters, it is important to discuss how the HL7 ICSR can be used to support existing or emerging public health surveillance messaging requirements, and therefore a discussion of the United States (US) National Information Infrastructure, Canadian Public Health Surveillance Program, and ICH reporting are included in this guide.

A. HL7 ICSR Relationship to the US National Health Infrastructure Initiative

[1]The National Health Information Infrastructure (NHII) is an initiative set forth to improve the effectiveness, efficiency and overall quality of health and health care in the US. The NHII will support a comprehensive knowledge-based network of interoperable systems of clinical, public health, and personal health information that would improve decision-making by making health information available when and where it is needed. It encompasses the the set of technologies, standards, applications, systems, values, and laws that support all facets of individual health, health care, and public health. FDA's role in NHII covers:

- Regulation of health-related products
- Monitoring and reporting on safety and adverse effects
- Coordination of a clinically useful drug code

[2]Achieving the vision of a national health information infrastructure first requires interoperability to link previously disparate health care information systems. The Office of the National Coordinator for Health Information Technology (ONCHIT) provides leadership for the development and nationwide implementation of an interoperable health information technology infrastructure to improve the quality and efficiency of health care and the ability of consumers to manage their care and safety.

[3]The Consolidated Health Informatics (CHI) initiative is one of the Office of Management and Budget's (OMB) eGov initiatives. CHI is a collaborative effort to adopt health information interoperability standards, particularly health vocabulary and messaging standards, for implementation in federal government systems. CHI adopted 20 uniform standards for electronic exchange of clinical information to be used across the federal health enterprise. At the time of this ballot, it is understood that that CHI group will be absorbed the broader framework ONCHIT. Therefore, the ICSR will support CHI recommendations that have been approved for use through July 1, 2006.

FDA's support in these initiatives is to participate in the creation of the messaging and vocabulary standards that support regulatory submissions for adverse event reporting and product labeling. An increase in the development of combination

[1] Excerpt from NHII website: http://www.aspe.hhs.gov/sp/nhii/
[2] Excerpt from ONCHIT website: http://www.hhs.gov/healthit/mission.html
[3] Consolidated Health Informatics website: http://www.hhs.gov/healthit/chi.html

products (drug-device, biologic-device), and consumer concerns about drug-dietary supplement interactions are driving the need to implement a common adverse event reporting format and repository at FDA. The HL7 ICSR supports NHII and FDA goals to adopt open consensus standards that support patient safety messaging and interoperability requirements for the new federal health enterprise.

B. HL7 ICSR Relationship to the Canadian Public Health Surveillance Program

The Canadian Public Health Surveillance (PHS) Program will accelerate the implementation of health surveillance systems in each of Canada's public health jurisdictions. These systems track communicable disease cases to allow public health monitoring of the treatment patients receive, manage information related to immunization, and support the detection of suspected outbreaks as early and accurately as possible. Timely and accurate detection of individual cases and emerging outbreaks is crucial to mounting an effective response, to safeguard public health and safety. The project will deliver stable HL7 V3 messaging standards to support exchange between PHS solution components, and between the PHS solution and jurisdiction-specific components, which include terminologies to support integrated operation among Solution components. PHS solution components include:

- Functional Components:
    1. Communicable Disease Case Management
    2. Outbreak Management
    3. Alerts Management
    4. Immunization Management
        - Service Delivery
        - Immunization Registry
    5. Inventory Management (Materials & Vaccine)
    6. Work Management (Scheduling & allocation)
    7. Terminology Registry
        - based on HL7 Common Terminology Services standards
    8. Disease Registry

The Canadian PHS project has a requirement for messages for reporting a suspected vaccine failure and intends to adapt the HL7 ICSR Product Defect Interaction for this purpose.

C. HL7 ICSR Relationship to ICH E2B Message Specification

The ICH E2B message specification supports clinical trial and postmarketing adverse event reporting between pharmaceutical companies and regulatory authorities in the United States, European Union, Japan, and Canada. Additionally, The World Health Organization (WHO) uses E2B to exchange safety data with regulatory authorities and serves the role as an Observer in the ICH standards process. The E2B message specification currently supports drugs, therapeutic biologics, and is currently under revision to support vaccines. The ICH E2B message specification was used to build the base requirements for the HL7 ICSR. Additionally, other US and UK data collection forms were used to design the HL7 ICSR to ensure that the message can be leveraged to support other non-regulated reporting requirements. ICH E2B uses the Medical Dictionary for Regulatory Activities (MedDRA) to code adverse event terms, laboratory tests and other medical concepts used in regulated adverse event reporting. E2B supports primary business requirements for pharmacovigilence activities, whereas the HL7 ICSR supports broader requirements for patient safety analysis.

ONCHIT requires the use of open consensus standards organizations that are willing to collaborate and support efforts to build open standards to achieve the goal of interoperability between disparate health information systems. ICH membership is limited to the pharmaceutical industry and regional regulatory authorities, and excludes participation from the healthcare provider community, contract research organizations, academia, patient safety and other health services industry partners that could potentially benefit from ICH activity. The scope and use of E2B is limited and does not offer the flexibility needed to support US NHII initiatives, which require the use of SNOMED and other terminologies defined by CHI for use in the federal health enterprise. Therefore, the HL7 ICSR was created to support the vision and mission of the NHII and provide a consistent, standardized adverse event reporting format that supports a variety of product types and reporting partners.

D. FDA CRDH ICSR IMPLEMENTATION

FDA is organized as a collection of Centers that often act independently, and therefore it is possible for the different Centers to vary their implementations of the ICSR. CDRH has developed an implementation pilot for the ICSR that meets the specific requirements to support their Electronic Medical Device Reporting Program (e-MDR). For the purposes of the device eMDR program, the FDA schema supports only those features of the ICSR that were needed to meet the needs of the program, and other features were added that were identified as omissions from the standard, and these changes were forwarded to HL7 for inclusion in the next release of ICSR. The following list describes the different ways in which the initial device reporting implementation pilot differs from the published ICSR standard:

1) In the ballot package, the discussion of the ICSR assumes that any report is related either to an adverse event, or to a product problem, and a separate trigger event is assigned to each case. However, in reality, a report can also cite both an adverse event and a product problem. Therefore, only a single trigger event and associated interaction is being supported, the Event Report. However, the design of the message payload allows both adverse events and/or product problems to be reported.

2) The ICSR will be implemented to support batch transport. Therefore, the batch structure documented in the December 2005 Ballot package is being used. Within that structure, information for batch sender and receiver is captured as associations of the batch class. Conversely, the associations carrying information regarding the sender and receiver of individual messages are not used.

3) Attachments that are passed along with an ICSR report are supported using the attachmentText attribute within the Message class.

4) FDA's MedWatch form includes several attributes which collect information related to the types of reports being submitted. These attributes will be supported using the Detected Issues structure within the Control Act Wrapper.

5) The CDRH implementation pilot does not support information related to documents considered pertinent to the investigation.

6) Since the CDHR implementation pilot only refers to device reporting, no structures for drugs or substance administrations are included.

7) The CDRH implementation pilot will not collect information related to other related investigations.

8) The CDRH implementation pilot will capture information on Secondary Case Notifications. However, the negation indicator has been added to the receiver participation in order to allow the indication of whether or not reports had been sent to FDA or to manufacturers.

9) The CDRH implementation pilot does not support the collection of Reaction Emphasis, Outcome, or Concurrent Observations associated directly with the reaction. All observations associated with the reaction or with the patient are collected as observations associated with the investigative subject.

10) The CDRH implementation pilot does not collect information for the location of a reaction.

11) The CDRH implementation pilot does not collect any information related to clinical trials in which the investigative subject may be enrolled.

12) The CDRH implementation pilot does not collect information about other persons who are related to the investigative subject. No identifiers for the investigative subject are collected.

13) Clinical information associated with the investigative subject is limited to observations. Procedure, substance administration, and other act types are not collected as such. For the most part, all information on relevant tests and other relevant history is collected as text blocks that correspond to the structure of the MedWatch form.

14) The CDRH implementation pilot will capture information on Primary Case Notifications. However, the negation indicator has been added to the receiver participation in order to allow the indication of whether or not reports had been sent to FDA or to manufacturers.

15) When persons and organizations are captured as authors of reports, or as contacts, for example the manufacturer contact within the R_Device model, the multiplicity of the telecom attribute has been relaxed to support multiple telecommunication addresses. This allows the collection of fax numbers and email addresses as well as telephone numbers. When an organization is captured as the author of a report, a contact role has been added to make it possible to indicate a person acting as a contact for that organization.

16) The only information collected about the performer of a device related procedure is the professional role played by the performer.

17) No location information is collected for the location where the device related procedure took place.

18) The CDRH implementation pilot does not support the collection of Intervention Characterization Observations associated directly with the device related procedure.

19) Clinical information associated with the device related procedure is limited to observations. Procedure, substance administration, and other act types are not collected as such. For the most part, all information on relevant tests and other relevant history is collected as text blocks that correspond to the structure of the MedWatch form.

20) A device observation structure has been added to allow the capture of observations associated directly with the device.

21) The CDRH implementation pilot does not support approval information associated with the identified device role. Now, however, that IDs assigned by a regulatory authority, e.g., IND #, are captured as regulated product information associated with the device model.

22) No location information is collected for the location where the device is or was located.

23) The CDRH implementation pilot does not capture agency relationships for manufacturers of devices. These are relationships that indicate when one manufacturer is producing a device as an agent for another one.

Perspectives for ICSR Reporting

The ICSR supports adverse event reporting between a variety of public health and patient safety organizations, and different parties may be involved in the reporting process. Since these parties can exchange information with each other, or send reports directly to the public health or regulatory agency, it is important to grasp the relationships between senders, and the manner in which these relationships appear in the ICSR specification. The diagram provides an example of the ways in which different reporting parties are involved in the ICSR submission process:

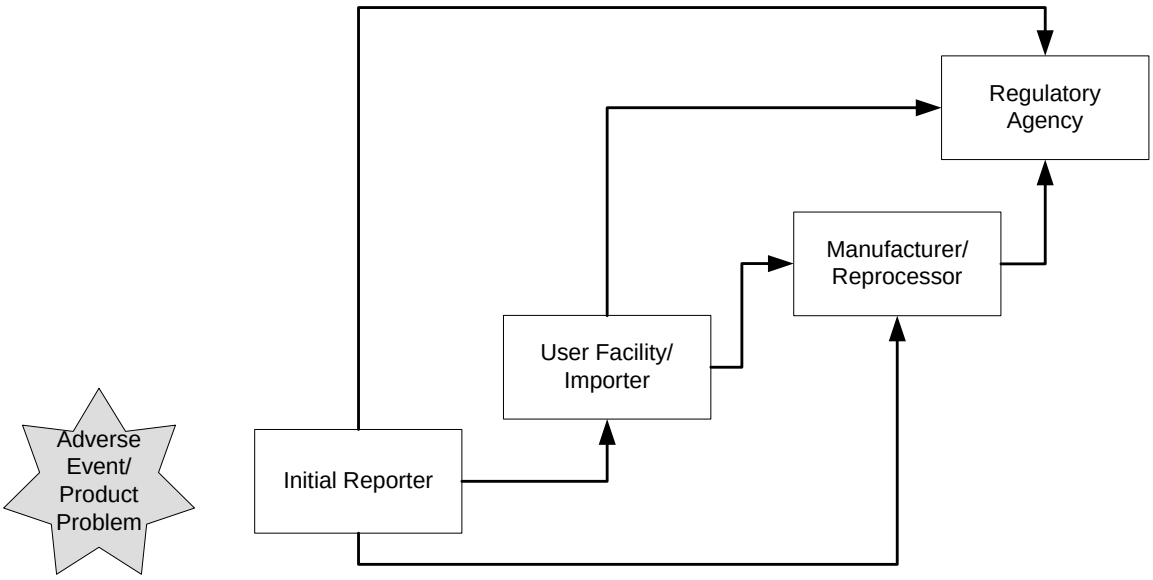


Figure 1. Reporting Parties and Reporting Flows

Within in the ICSR, four different roles are recognized as senders and receivers of information about an adverse event or product problem:

- **Initial Reporter**: the person who first recognizes an event as an adverse event or a product problem. This is most typically a heath professional working in the context of a user facility. However the initial reporter could also be the affected person, a relative of that person, or another associated party such as a lawyer. There is always an initial reporter involved with an adverse event or product problem report, even if no information about that party is collected. The initial reporter may:

    - Report directly to the regulatory agency or other public health agency
    - Provide information to a user facility or to a reporter
    - Provide information to the manufacturer of the suspect medical product

  When the initial reporter uses the ICSR to provide information directly to a regulatory agency, the initial reporter is captured as the author of the investigation, and information such as contact information is captured within that section of the specification.

- **User Facility/Importer**: The organization which provides a context for the work of the initial reporter, e.g., the user facility, and/or which the initial reporter sees as the immediately responsible party to receive information relating to the adverse event or product problem.

  The user facility or importer may:

    - Receive a report from the initial reporter.
    - Report directly to the regulatory agency.
    - Provide information to the manufacturer or the product in question.

  When the user facility uses the ICSR to provide information directly to the regulatory agency, the user facility is captured as the author of the investigation, and information such as contact information is captured within that section of the specification. Information related to the initial reporter is captured in the context of the primary case notification.

- **Manufacturer/Reprocessor**: the organization responsible for producing the product in question.

  The manufacturer or reprocessor may:

    - Receive a report from the initial reporter.
    - Receive a report from the user facility or importer.
    - Report directly to the regulatory agency

  When the manufacturer or reprocessor uses the ICSR to provide information directly to the regulatory agency, the manufacturer or reprocessor is captured as the author of the investigation, and information such as contact information is captured within that section of the specification. Information related to the initial reporter is captured in the context of the primary case notification. Information related to the user facility or importer is captured in the context of the secondary case notification.

- Regulatory Agency: the organization responsible for authorizing the production, distribution and marketing of products, and monitoring compliance and safety for their use

  The regulatory agency may:

  - Receive a report from an initial reporter (Consumers, healthcare providers)
  - Receive a report from the user facility or importer (Hospitals, Distributors)
  - Receive a report from medical product manufacturers or reprocessors

When the ICSR is used to provide information to a regulatory agency, information about the party sending the notification is captured as the author of the investigation. This is the case irrespective of whether the sender is an initial reporter, a user facility or importer, manufacturer or reprocessor. If the sender is not an initial reporter, then information relating to the initial report is captured in the context of the primary case notification. If the sender of the report has received information from other parties – except for the initial reporter – information about those other parties and their reports are captured in the context of the secondary case notification.

What is the ICSR?

A significant aspect to describing the ICSR is to describe the data types (drawn from the HL7 specification) that are used within the FDA's implementation of the message:

1. Storyboards

HL7 has documented storyboards in order to illustrate the requirements for each interaction specified within the standard. The storyboard offers an example of a concrete situation in which data as specified by the ICSR standard would flow from sender to receiver. The scope of this implementation guide covers the storyboard interactions that can be used for medical device reporting. Appendix H provides the ICSR storyboard used to support CDRH's Electronic Medical Device (eMDR) reporting program.

2. Application Roles

Only a very simple notion of application behavior has been defined within the context of the ICSR, and of adverse event reporting. There are systems that send notifications and those that receive them:

ICSR Notification Sender: Indicates the party that provides notification of the adverse event or product problem.

ICSR Notification Receiver: Indicates the party that receives notification of the adverse event or product problem.

3. Trigger Events

This section lists the trigger events that have been defined to support ICSR messaging. Note each trigger event is associated with an interaction in which the application roles of ICSR Sender and ICSR Receiver are involved:

ICSR Notification (PORR_TE040001UV01) : Indicates that notification of an eligible case e.g. report of à drug reaction, is ready for transmission to an eligible receiver. Note that this trigger event is used to support reports that include both an adverse event and product problem.

ICSR Revise Notification (PORR_TE040002UV01) : Indicates that the creating institution has made changes to the material covered in a previous individual case safety report, and is transmitting a revised version.

ICSR Withdraw Notification (PORR_TE040003UV01): Indicates that notification of an eligible case, e.g., individual report of an adverse drug reaction/event, is ready for transmission to an eligible receiver.

Product Defect Report Notification (PORR_TE040004UV01): Indicates that notification of a product defect report is ready for transmission to an eligible receiver. This trigger event is used for product defect reports that do not include adverse events.

Product Defect Report Revise Notification (PORR_TE040005UV01): Indicates that the creating institution has made changes to the material covered in a previous product defect report, and is transmitting a revised version.

Product Defect Report Withdraw Notification (PORR_TE040006UV01): Indicates that the creating institution has cancelled a previously issued product defect report.

4. Refined Message Information Models

Like any HL7 Version 3 specification, an ICSR instance is drawn from multiple message models. However, the ICSR is unusual in having a payload that draws from multiple payload Refined Message Information Models (RMIM); usually there is just one. This complexity in the specification is based – not surprisingly – on the complexity in the underlying domain. The diagram below provides an indication of the sources from which the data used in an ICSR are drawn:

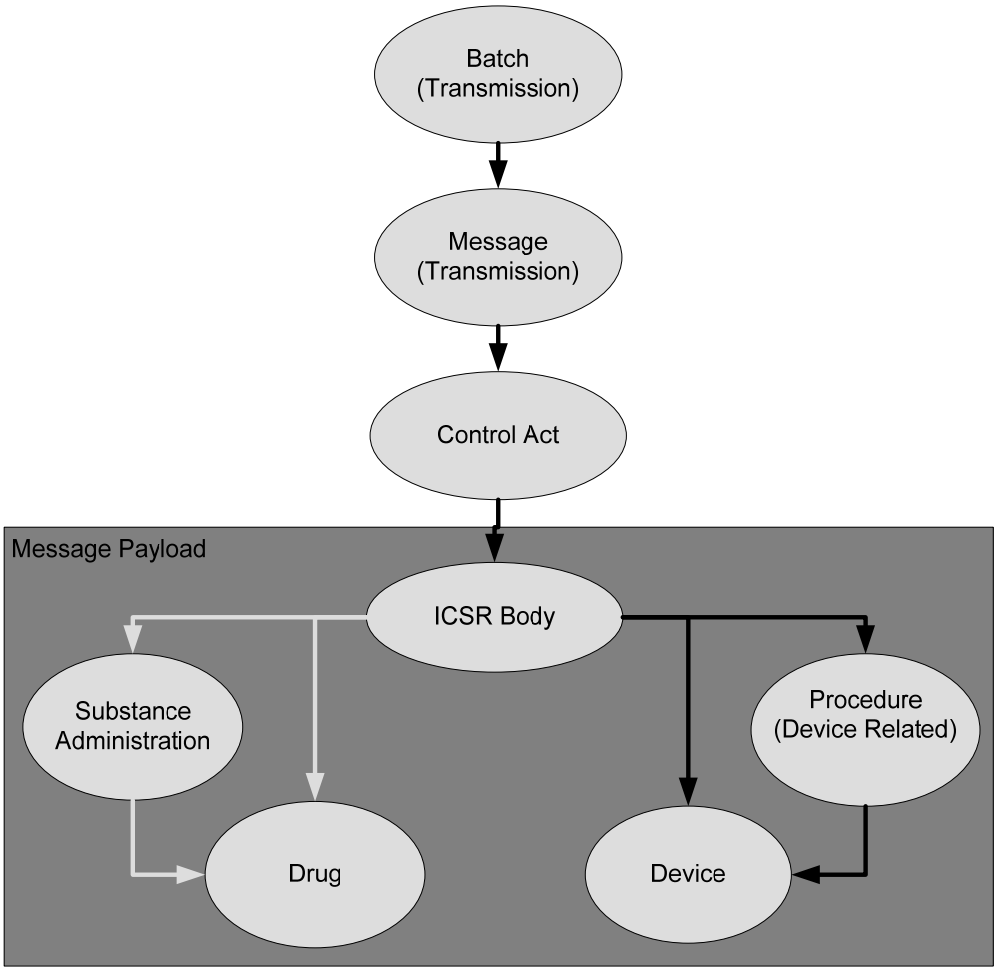


Figure 2: RMIMs for an ICSR Instance

4.1. Transmission

This RMIM carries information related to the actual transaction. The message class serves as the entry point to the model, and to the message as a whole. The attributes of the class carry information, e.g., message id, effective time, that is relevant for the entire transaction:

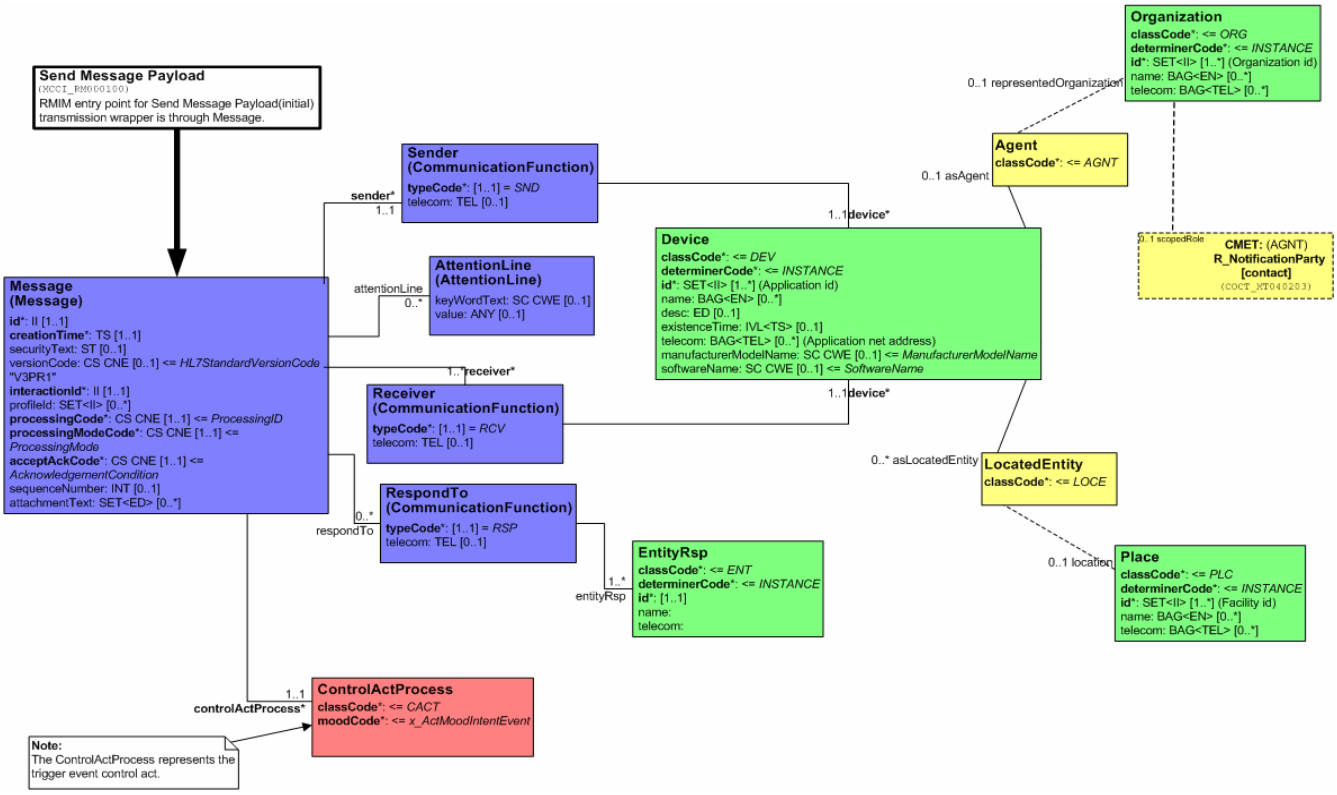


Figure 3: Transaction Diagram

The following associations are defined for the message class:

- Sender (Communication Function): Captures information relating to the organization sending the message, and the specific device responsible for the transmission. Information for the organization includes a contact person for that organization.

- Attention Line: This class is included to allow parameters for a technology specific transport to be represented in the V3 message outer wrapper.

- Receiver (Communication Function): Captures information relating to the organization receiving the message, and for the specific device expected to receive the message. Note that the class structure for this information is the same as for the sender.

- Respond To (Communication Function): Captures information relating to the device which is expected to receive an application level response to the transmission.

- Control Act Process: this association carries a link to the control act and to the message payload.

4.2. Control Act

The control act model carries information related to the trigger event that initiated transmission of the information contained in the message. For the ICSR, the control act process class provides an anchor for relevant information about the message source and the type of information being provided:

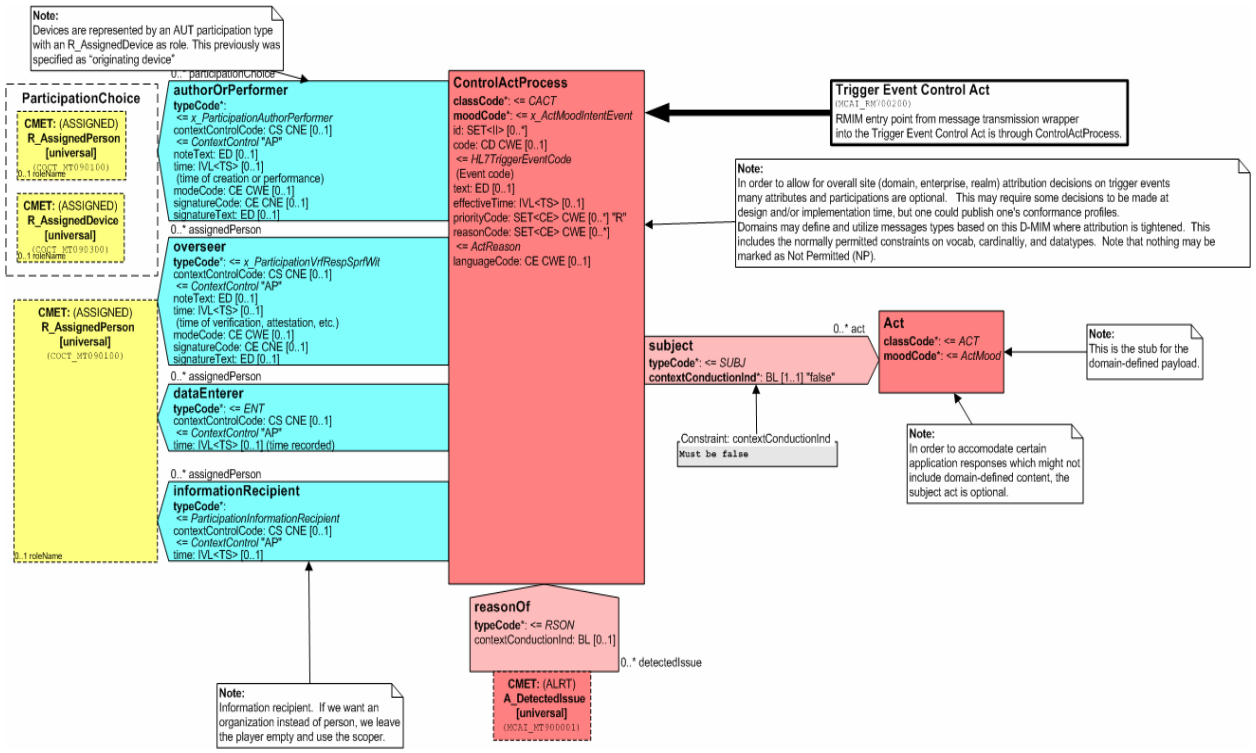


Figure 4: Control Act Diagram

The following associations - act relationships and participations - are defined for the investigation event itself. Each association captures the relationship between the investigation and an entity or another type of act that plays a significant part in the investigation. (Note, the discussion of the associations has been ordered by "walking" around the central class in a clockwise direction, and that the association role text is recorded for each. Also, as in the ultimate XML schema, the association text is used as the tag for referring to the individual association.). Not all of these associations will be used in implemented ICSR transmissions.

- Subject Act: this association carries a link to the message payload.
- Reason Of Detected Issue Event: captures information related to business rules or processes that are related to processing the message. Within the ICSR, this class is currently used to carry information such as message type and follow-up number that is required for managing the message content.
- Information Recipient: information related to parties who are expected to receive the information contained within the message contents.
- Data Enterer: information related to the party responsible for data entry related to the message contents.
- Overseer: information related to a party responsible for overseeing the work of the party responsible for creating the message contents.
- Author or Performer: information related to a party or parties responsible for authoring the message, or for performing an activity or activities specified within the message.

4.3. ICSR Payload

The Individual Case Safety Report (ICSR) Refined Message Information Model (RMIM) is oriented around the concepts listed below. Appendix A provides the HL7 ICSR base payload diagram that illustrates the concepts described in this section.

- **Adverse events/experiences**: Any adverse event associated with the use of a product in humans, whether or not considered product related, including the following: An adverse event occurring in the course of the use of a product in professional practice, an adverse event occurring from over- dose of the product whether accidental or intentional, an adverse event occurring from withdrawal of the product, and any failure of expected pharmacological action. Note that these events result in unintended harm to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient.

- **Suspected Adverse Drug Reaction**: A noxious and unintended response to any dose of a drug product for which there is a reasonable possibility that the product caused the response. In this definition, the phrase "a reasonable possibility means that the relationship cannot be ruled out.

- **Suspected medical product problems or defects**: A problem that is detected before a substance is given to a patient, or a device is used for treatment.

- **An affected person**, e.g., patient.

- **Substance administrations**: drugs, therapeutic biologics, vaccines.

- **Medical devices or procedures related to devices**.

- **Supporting clinical information**: The notion of supporting clinical information includes additional detail such as relevant observations, procedures, substance administrations and encounters. These are included if the reporting party thinks them relevant, whether referring to the same point in time as the suspect event or as part of the patient history.

This RMIM is designed to support two kinds of messages. The first type of message consists of a report on the investigation into the adverse event(s) or reaction(s) suffered by an affected person who has experienced an intervention or interventions in a therapeutic context. The suspect event may or may not have a causal relationship with the administration of one or more pharmaceutical products, or it could be associated with a device. The second type of message consists of a report on the investigation into a reported problem associated with a drug, biologic, vaccine or a device.

4.3.1. InvestigationEvent

The InvestigationEvent serves as the entry point for the messaging model (as noted above, this entry point links back to the control act). The investigation class captures information directly related to the investigation, and pulls together the rest of the relevant information. Depending on the situation, the investigation will be associated either with information possibly related to a device or drug related reaction suffered by a subject, or with information related to a product (drug or device) problem.

Note; the attributes associated with an investigation are captured within the InvestigationEvent class in the RMIM. In particular, activityTime is used to record the time that the report is completed, while availabilityTime is used to record the time on which the most recent information included within the investigation report was received. For the sake of completeness, it is worth mentioning that the date on which the report is transmitted is captured within the Control Act structure.

4.3.1.1. InvestigationEvent Associations

The following associations - act relationships and participations - are defined for the investigation event itself. Each association captures the relationship between the investigation and an entity or another type of act that plays a significant part in the investigation.

4.3.1.1.1. **Document**: This act relationship provides a way of capturing primary source documents and literature references that the report sender feels are relevant to the investigation, and considered part of the report.

4.3.1.1.2. **CaseSeriousness**: The act relationship provides a way to capture information regarding the seriousness of the suspected reaction - that is to say the extent to which the patient was injured.

4.3.1.1.3. **Product**: The participation captures information related to a drug or device that is the subject of a product problem report. (Note that this association will not exist in an adverse event ICSR) The detailed product report is captured in the R_Drug and R_Device message element types that are defined within the PORR domain.

4.3.1.1.4. **Intervention**: The act relationship provides information for those interventions that are most significantly related to the suspected reaction(s) covered by the report. This includes suspect, concomitant and interacting interventions, and interventions performed to mitigate the effect of a suspected reaction. This association also makes it possible to record the priority of each intervention for those reports in which multiple interventions are included within a single report. This includes mitigating interventions as well as suspect ones.

4.3.1.1.5. **Reaction**: This act relationship relates the investigation to the reaction or reactions that are the subject of an individual case safety report. (Note that this act relationship will not exist in a product problem report.) See below for a more detailed discussion of reactions and the items of information related to a reaction.

4.3.1.1.6. **SecondaryCaseNotification**: A secondary case notification is a report created by another party - such as another regulatory agency or a manufacturer - that conveys information about the event, suspected event, or possible product problem that is the subject of this report. The report is labeled a "secondary" report to distinguish it from the initial report of the event or problem.

4.3.1.1.7. **Investigation Event**: The act relationship records information, most notably the assigned identifier, for individual case safety investigations that are related to this one.

4.3.1.1.8. **AssignedEntity**: As is usual within HL7 messaging, there may be information that captures the author and/or performers of an act. In this case, the participation is linked to the Assigned Role. The author or performer (whichever is being specified) is captured as the player of this role. Information about the controlling jurisdiction, is captured as the scoper of the role

4.3.2. Reaction

A reaction is the consequence, perhaps strongly indicated, perhaps only possibly related, of the substance administration or device procedure. It constitutes the core of the individual case safety report since, without a reaction or event, there would be no perception of an adverse reaction, and no report at all.

4.3.2.1. Reaction Associations

The following associations - act relationships and participations - are defined for the reaction. Each association captures the relationship between the reaction and an entity or another type of act that plays a significant part in the individual case safety report. (Note, the discussion of the associations has been ordered by "walking" around the central case in a clockwise direction.)

4.3.2.1.1. **InterventionStub**: The act relationship makes it possible to record the time interval between an intervention (adverse drug or device event) and the reaction. It can also be used to identify the list of different interventions that are associated with the individual reaction. The intervention stub choice box includes stub classes - containing just an id - that allow linkage to substance administration(s) or procedure(s) that have already been referenced. Note that identifiers should be assigned which are only relevant within the context of a single ICSR in order to support cases in which patient confidentiality must be maintained.

4.3.2.1.2. **ReactionRelatedness**: The act relationship captures the assessment or assessments of the relatedness between an intervention and the reaction. That is to say, it records judgments - made by the party indicated by the author or performer participation - about the extent to which the intervention caused a particular reaction.

4.3.2.1.3. **ReactionEmphasis**: The act relationship records the emphasis, e.g., Highlighted that the reporter placed on the reaction.

4.3.2.1.4. **Outcome:** The act relationship records the outcome of the reaction.

4.3.2.1.5. **ConcurrentObservation:** The act relationship captures clinical observations about the patient suffering the reaction that are directly tied to the reaction itself. For example, age at the time of exposure.

4.3.2.1.6. **ServiceDeliveryLocation:** The participation captures the location at which the patient received care related to the reaction.

4.3.2.1.7. **InvestigativeSubject:** The participation captures information about the person who, by virtue of the suspected reaction, is the subject of the report. This is person plays the role of investigated subject. All of the clinical statements related to an investigation are associated with the investigation subject, or with a person - typically mother or sibling associated with the investigated subject. The identifier in the investigated subject role is intended for disambiguating the subject of clinical statements, and for keeping track of the clinical statements linked to a particular investigation. It should not be used to carry information that could identify the subject in any context external to the investigation.

4.3.2.1.8. **PrimarySourceReport:** The primary source report captures information about the original report of the reaction. This report could be from a health care provider, the patient or relative of the patient, or from another party such as a lawyer. You should note that the primary source report could also be associated to the secondary case notifications.

4.3.3. Affected Person

This is the person directly affected by the event(s) or reaction(s). Other parties who are directly related to the substance administration or device procedure may also be included. In the case of safety reports that involve drug administrations, it is possible for the patient to be a nursing infant or a fetus who is harmed by drugs administered to the patient's mother. Similarly, information may be captured for siblings (this is done in the case of vaccine reactions) or other persons related to the affected person.

4.3.3.1. Affected Person Roles

The following associations are defined for the person or persons affected by the possible adverse event. (Note, the discussion of the roles has been ordered by "walking" around the central affected person class in a clockwise direction.

4.3.3.1.1. **AsResearchSubject**: This association is relevant when the person suffering the reaction is also part of a clinical trial. In that case, the cluster of classes related to ResearchSubject and Clinical Trial serves to identify the clinical trial and to provide the patient's id within that trial. The person may be the research subject of either a pre-market or post-market clinical trial.

4.3.3.1.2. **SubjectAffectedPerson**: This association provides the linkage - mentioned above - to the reaction suffered by the investigated person. It is also important to note that a wide range of information may be recorded about the patient. This information is managed through the Clinical Statement Choice data structure, which is modeled on the emerging HL7 consensus for supporting clinical statements.

4.3.3.1.3. **RelationshipHolder**: In those cases in which information is collected about persons other than the person suffering the reaction, that person plays the role of the associated person scoped by the patient. Today, these cases include mothers who ingested drugs that affected a fetus or nursing child, and siblings of persons suffering vaccine reactions. The relationship between the associated person and the patient is indicated by AssociatedPerson.code.

4.3.3.1.4. **AssociatedPerson**: In the situation discussed above, the patient, scopes the role of AssociatedPerson.

4.3.3.1.5. **AsIdentifiedEntity:** This association makes it possible to record identifiers the patient or associated person is known by. The party issuing the identifier is indicated as the scoping entity for the IdentifiedEntity role.

4.3.3.1.6. **AsPersonalRelationship**: This association makes it possible to record the relationship between the investigative subject and the reporter of the reaction in cases where this is relevant.

4.3.4. Drug/Device

The interventions that led to (perhaps) patient reactions or adverse events currently fall into two categories: substance administrations (drugs, biologics or vaccines), and the use of devices or device procedures. The specific information for each suspect intervention is captured in the A_DrugIntervention and A_DeviceIntervention message element types that are associated with the InvestigationEvent through the intervention association. These message element types are defined elsewhere within the PORR domain. Note interventions deemed concomitant or historical are captured directly within the ICSR RMIM as supporting clinical information, as discussed below.

4.3.5. Supporting Clinical Information

The ClinicalStatementChoice structure and all its associations capture a range of relevant clinical or contextual facts that are captured for the report. Among other items, this includes observations from the patient's medical history, and other observations that are entered in order to provide context to the suspect event. The attribute, ActCode, plays a key role for the observations and other acts recorded within this structure. It identifies the type of act that is being recorded or requested. As with interventions, the subject of the observation may not be the patient, but could be a person related to the patient. Supporting clinical information could include substance administrations, procedures, encounters and supply acts as well as observations. Within this structure it is worth noting that observations can be supported by reference ranges - as indicated by the related Observation Criterion act, that the consumable substance for a substance administration is captured as a Medication entity playing the role of administered drug, and that the product distributed in a supply act is captured in a similar fashion. Also, the sourceOf act relationship can be used to link multiple instances of any of the acts within the choice structure.

The reader should note that the committee expects the use of supporting clinical information within the ICSR (as shown by the ClinicalStatementChoice structure) to follow the pattern supported by the general HL7 consensus for modeling clinical statements. If that consensus is manifested in the creation of a Common Message Element Type (CMET), the CMET will be used if possible. However, the requirements of ICSR reporting have led the committee to make additions to the current clinical statement draft model. These additions are represented by two sets of acts related to the clinical statement choice:

4.3.5.1. **InterventionCharacterization**: This act makes it possible to for a reporter to indicate the role that the primary reporter felt that the suspect intervention - either a substance administration or a device related procedure - played in the incident being reported

4.3.5.2. **Indication**: This act allows the reporter to identify the indication - the reason - for an act that was performed on the subject of the act.

4.4. Substance Administration

Appendix B provides the A_DrugIntervention (substance administration) diagram that illustrates the concepts described in this section. The A_DrugIntervention message element type captures the substance administration related information that is relevant for drug administrations possibly related to an adverse reaction. The relevant information includes items related to the substance administration itself, to component parts of a more general administration act, as well as to ancillary information related to the substance administration. This message element type is being used to capture substance administrations for drugs, therapeutic biologics, and vaccines. In the basic ICSR model, this information is associated with the InvestigationEvent class through the Intervention association.

The SubstanceAdministrationEvent class captures information directly related to the administration of the drug that is possibly related to a reaction/event. If it is necessary to introduce component substance administrations, this initial administration will provide the overall context for the adverse event.

The following list goes through the different participations and act relationships that are specified for the substance administration. These associations are ordered by taking a clockwise walk around the base class within this model.

4.4.1. **Drug:** This participation indicates which drug has been administered, and provides a link to other relevant information regarding that drug. That information is discussed in the description of the R_Drug message element type.

4.4.2. **AssignedEntity:** The participation provides relevant information about parties responsible for authoring and/or performing the substance administration.

4.4.3. **ServiceDeliveryLocation:** The participation provides relevant information about the location at which the drug was administered.

4.4.4. **InterventionCharacterization:** This act relationship makes it possible to characterize the substance administration as either suspect, concomitant, interacting, or historical. This characterization offers a judgment of how the intervention was related to the reaction suffered by the patient.

4.4.5. **ActionTaken:** This act relationship makes it possible to characterize the action taken with regard to the substance administration as drug withdrawn, dose reduced, dose increased, etc. This characterization offers a judgment of practitioner's response to the patient's problem.

4.4.6. **(Pertinent)substanceAdministrationEvent:** This recursive act relationship makes it possible to provide information about other substance administrations that are related to the original one. This makes it possible, for example, to capture information about drugs given to mitigate the effects of the suspect drug.

4.4.7. **(Component)substanceAdministrationEvent:** This act relationship makes it possible to identify components of a more general substance administration. The creation of multiple components is needed to record, for example, multiple routes of administration used for a single drug within the context of a more general administration regime.

4.4.8. **ClinicalStatementChoice:** This act relationship makes it possible to refer to clinical statements that are relevant to the substance administration. Please refer to the description of the base ICSR model for a brief discussion of the clinical statement choice structure.

4.4.9. **SubjectChoice:** This participation indicates the subject of the substance administration. That subject is either an investigated or associated person for which information was captured in the base ICSR model. The reference to the investigated person or investigated person roles contains an ID which should only be valid within the context of this ICSR in order to preserve patient confidentiality. This ID is not used for or intended to reference an organization's unique patient identifier.

4.5. Procedure (Device related)

Appendix C provides the A_DeviceIntervention (procedure) diagram that illustrates the concepts described in this section. The A_DeviceIntervention message element type captures the procedure related information that is relevant to medical device adverse event reporting. The relevant information includes items related to the procedure itself, to component parts of a more general procedure act, as well as to ancillary information related to the procedure.

The following list goes through the different aspects of the message element type.

4.5.1. **Device:** A device related adverse event has to be related to a procedure - the purpose that the device is supposed to serve. This class collects the information directly related to the procedure. If it is necessary to introduce component procedures, this procedure will provide the overall context for the adverse event. Note it is assumed that the person identified as the patient for the overall ICSR is the person using the device.

4.5.2. **AssignedEntity:** The association provides relevant information about parties responsible for authoring and/or performing the device intervention procedure.

4.5.3. **ServiceDeliveryLocation:** The association provides relevant information about the location at which the device was used for patient care.

4.5.4. **InterventionCharacterization:** This association makes it possible to characterize the procedure (device related) as either suspect, concomitant, interacting, or historical. This characterization offers a judgment of how the device intervention was related to the reaction suffered by the patient.

4.5.5. **ActionTaken:** This association makes it possible to characterize the action taken with regard to the device related procedure. This characterization offers a judgment of practitioner's response to the patient's problem.

4.5.6. **(Component)procedureEvent:** This association makes it possible to identify components of a more general procedure. The creation of multiple components is needed to record, for example, information about device implantation and explantation.

4.5.7. **ClinicalStatementChoice:** This association makes it possible to identify clinical statements that are associated with the device procedure or other relevant medical history. Please refer to the description of the base ICSR model for a brief discussion of the clinical statement choice structure.

4.5.8. **SubjectChoice:** This association makes it possible to identify the person on whom the procedure was performed. That person will be an investigated person or an associated person for whom information was collected in the base ICSR model. The identifier used for the person should only be valid within the context of a single ICSR in order to preserve patient confidentiality.

4.6. Medication

Appendix D provides the R_Drug (medication) information diagram that illustrates the concepts described in this section. The R_Drug message element type captures the drug information that is relevant for drug related* adverse event and product reporting. The relevant information includes items related to the drug itself, and to its manufacture and sale.
***Note:** This message element type is being used to capture information for drugs, therapeutic biologics and vaccines. The model also captures financial information for mass immunization programs, such as military, school, or state/local immunization programs.

The following list summarizes the different aspects of the message element type. The reader should note that, while expressing the requirements of public health reporting, the model follows, as much as possible, the structure used in the pharmacy/medication related domain model and CMETs.

The central class in this model - Medication - captures information about the substance that was administered to the subject of the substance administration, either an investigated person or a person related to the investigated person. The information associated with the medication is described by walking, as usual, clockwise around this central class.

4.6.1. **AsRetailedProduct:** It is relevant, for drug related adverse events, to collect information about the location where the drug was sold, in particular to identify the country of sale.

4.6.2. **Ingredient:** This association makes it possible to identify the ingredients contained within a drug. This is particularly important for multi-ingredient formulations.

4.6.3. **AsEntityWithGeneric:** In some cases it is relevant to identify the generic name that is used for a drug.

4.6.4. **AsManufacturedProduct:** The model captures the site at which the drug is manufactured - at the most detailed level known to the reporter (if at all). If, in addition to the manufacturing site, it is important to be able to identify the drug manufacturer (the corporate entity that organizes and carries out drug development, production, and distribution); this information is captured as an organization scoping the agent role played by the manufacturing site. This agency role can be traversed as many times as necessary to capture the organization responsibility for manufacturing the product.

There are associations of the manufacturer that should be noted.

4.6.5. **ContactParty:** In some cases, it is important to be able to contact a manufacturer representative in order to follow up on a report of a drug adverse event.

4.6.6. **RepresentedManufacturer:** This association is valued to indicate the organization that scopes the Agent role played by the direct manufacturer of the product.

4.6.7. **AsAgent:** It is possible for the organization manufacturing the product to do so as an agent of another party. In that case, the manufacture plays the role of agent - which is scoped by another instance of the manufacturer class

4.6.8. **PartMedication:** This association captures the fact that the medication is relevant for the ICSR as an AdministeredDrug (a substance that either was administered or was going to be administered to a subject). The AdministeredDrug role also provides the entry point to the message element type.

There is an association of the AdministeredDrug that deserves attention.

4.6.9. **Approval:** The approval association captures information about the process of approving a substance for therapeutic use. The relevant items include the identifier (often known as NDA number in the US) that is assigned to the approval, the country in which this approval was issued - shown as the Country that plays the role of Territorial Authority for the regulatory Agency issuing the approval, and the date the approval was granted.

4.7. Device

Appendix E provides the R_Device (device) information diagram that illustrates the concepts described in this section. The R_Device message element type captures the device information that is relevant for device related adverse event and product reporting. The relevant information includes items related to the device itself, and to its manufacture and sale.

A device, in this context, refers to a manufactured item that is used directly in treating and/or caring for the patient. The model captures information about devices by using one class - Device - to capture descriptive information directly related to the particular device, and another - DeviceModel to capture information related to the kind of device.

4.7.1. Device

The following list provides a review of various roles and act relationships associated with the Device entity. Note, the descriptions are ordered by taking a clockwise walk through the data structure.

4.7.1.1. **IdentifiedDevice**: This association makes it possible to record identifiers for the device, along with the role played by the identifier (Role.code), and the organization responsible for the identifier.

4.7.1.2. Associated with the **IdentifiedDevice** role is the Approval act. This act captures information about the process of approving a device for therapeutic use. The relevant items include the identifier (often known as PMA or 510(K) number in the US) that is assigned to the approval, the country in which this approval was issued - shown as the Country that plays the role of Territorial Authority for the regulatory Agency issuing the approval and the date approval was granted.

4.7.1.3. **AsLocationLocatedEntity**: The association between the device and the location role CMET captures the location at which the device was located.

4.7.1.4. **AsManufacturedProduct:** The scoper for this role (ManufacturerOrReprocessor) captures the site at which the device is manufactured and/or reprocessed - at the most detailed level known to the reporter (if at all). If, in addition to the device manufacturing site, it is important to be able to identify the device manufacturer (the corporate entity that organizes and carries out the medical device development, production, and distribution); this information is captured as a representedManufacturerOrReprocessor scoping the agent role played by the manufacturing or reprocessing site. This agent role can be traversed as many times as necessary to capture the organization responsibility for manufacturing or reprocessing of the product. The scoper for the ManufacturedProduct may also be the site at which the drug is manufactured - at the most detailed level known to the reporter (if at all). If, in addition to the drug manufacturing site, it is important to be able to identify the drug manufacturer (the corporate entity that organizes and carries out drug development, production, and distribution); this information is captured as a representedManufacturerOrReprocessor scoping the agent role played by the manufacturing site. This agent role can be traversed as many times as necessary to capture the organization responsibility for manufacturing the product. In the situation where the device is a single use device that has been reprocessed, it is relevant to identify the re-processor instead of the original manufacturer.

The associations related to the manufacturing entity (ManufacturerOrReprocessor) are sufficiently rich to deserve their own discussion:

4.7.1.5. **ContactParty**: It is important to be able to contact a manufacturer representative in order to follow up on a report of a device adverse event.

4.7.1.6. **AsRole:** In some cases, a device will be returned to the manufacturer or re-processor for evaluation. This evaluation is captured as an act in its own right. The items of information collected as a result of this evaluation, Evaluation Method, Evaluation Result, and Evaluation Conclusion, are collected as acts related to an Investigation Event. This structure makes it possible to record information about the evaluation, about observations recorded during the evaluation, and about the final conclusions of the evaluation process.

4.7.1.7. **AsIdentifiedOrganization:** In some cases the report on the device includes identifiers for the manufacturing organization.

4.7.1.8. **AsAgent:** The Agent role was described above, and makes it possible to specify the organization that is ultimately responsible for manufacture of the medical device (the manufacturer as opposed to the manufacturing site). This makes it possible to identify the country and other relevant information about that responsible party.

4.7.1.9. **RepresentedManufacturerOrReprocessor:** The reader should note that the entity ManufacturerOrReprocessor both plays and scopes the agent role. That is to say, the same class in the model is used to capture information about the manufacturer and the manufacturing site. When the party fabricating the device (aka manufacturer) is captured as the Agent for another organization, that organization scopes the Agent role as shown by the association that as labeled as "representedManufacturerOrReprocessor".

4.7.1.10. **InventoryItem:** This association indicates the device type related to this device instance.

4.7.2. Device Model

The following list provides a review of various roles and act relationships associated with the Device Model. The descriptions are ordered by taking a clockwise walk through the data structure:

4.7.2.1. **ManufacturedDeviceModel:** As noted, above, the DeviceModel class represents the device instance related to this device type.

4.7.2.2. **AsRegulatedProduct**: Provides a link to the regulatory authority that is relevant when we need to record identifiers assigned by the authority which is used to identify the device as it moves through the stages of development, testing, and production.

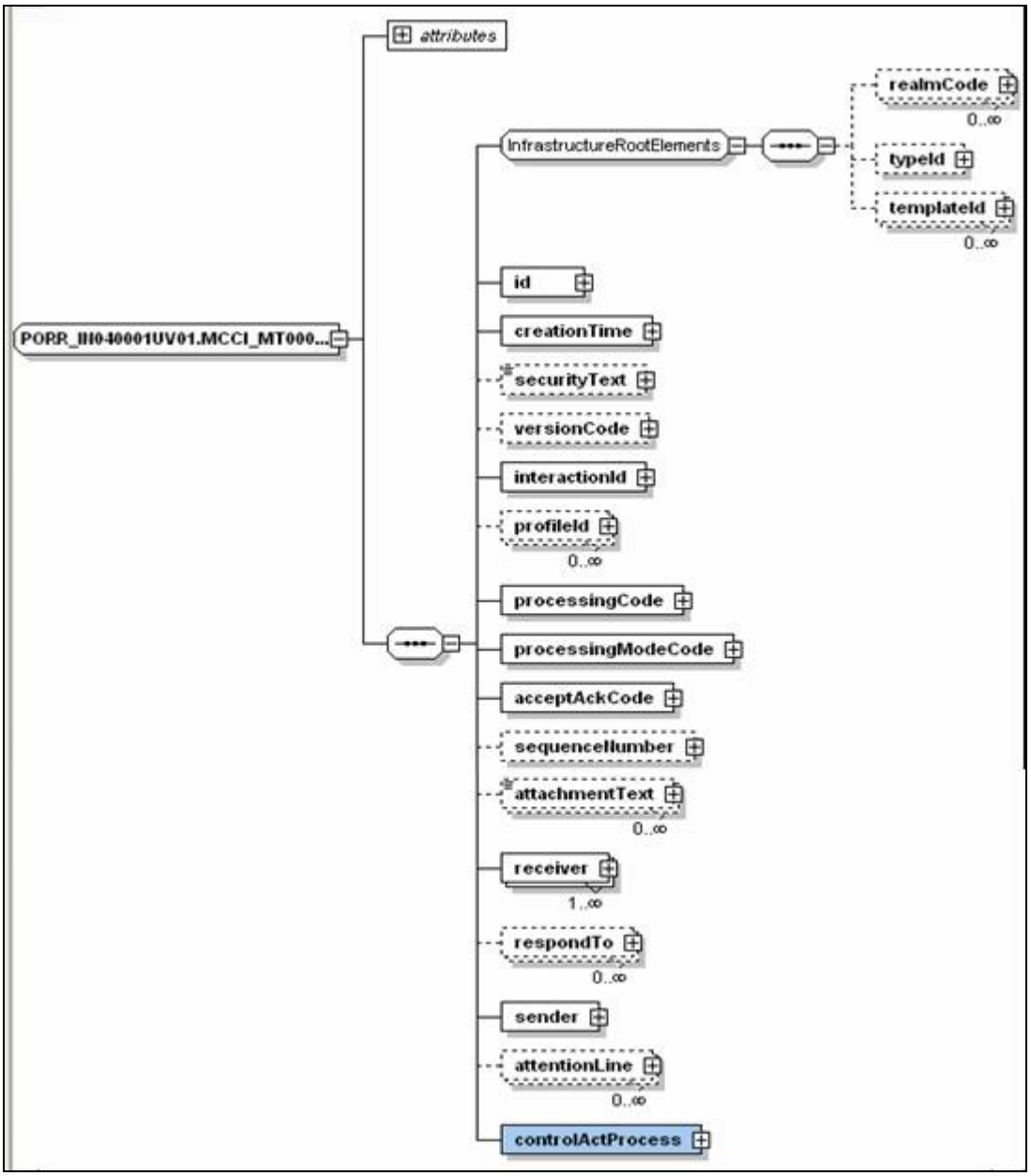
ICSR Schemas

1. ICSR Model Review

This section provides a more detailed walk though of the content of the ICSR Hierarchical Message Descriptions (HMDs) which represent the actual message specifications. It uses the XML schema as published by HL7 as the point of reference. For additional perspective, it is best to review the text overview of the ICSR in advance of reviewing this section. HL7 provides a set of schemas to support the creation and management of Version 3 messages. This includes schemas to support the messaging wrappers, each of the ICSR component models, all included CMETs, and common structures such as data types and vocabulary. All of these schemas are organized within the context of a schema that models each of the interactions, and the XML “include” construct allows the content of one schema to be addressed from another. This discussion is based on the content of the schema: PORR_IN04001UV01. However, virtually the same pattern emerges from the others. Note, due to the size and complexity of the ICSR data structure, it is not possible to discuss every single (XML) element within the specification. As always, the HL7 Normative Edition document should be consulted for more information.

2. Message

The diagram shows the contents of the message element, which includes, directly or indirectly, all the others.

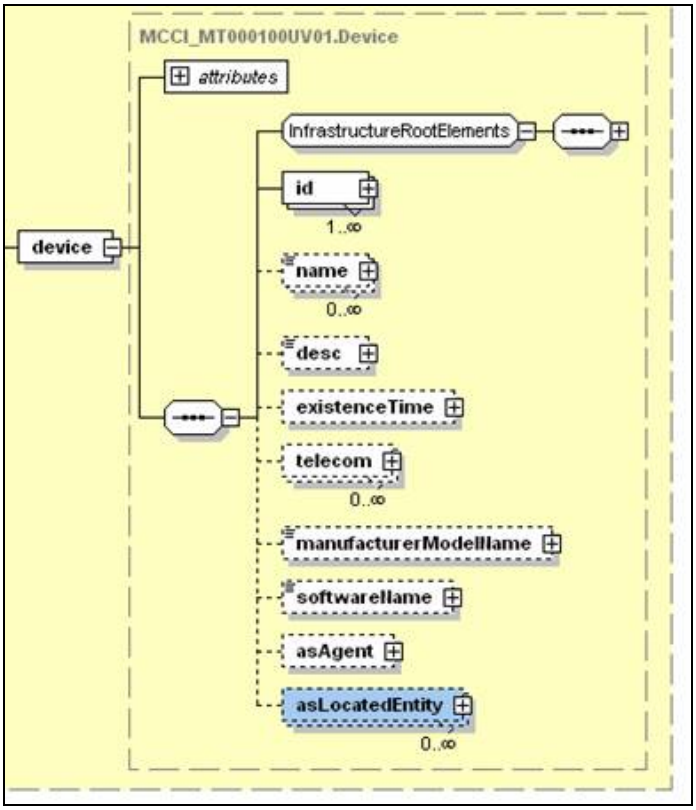


Message Element Contents	
Element	Discussion
attributes	**The one attribute common to all elements in a V3 message is the null Flavor. It is used to indicate the reason for an element not being valued. It should be ignored in the message element.**
Infrastructure Root Elements	**These elements, which are common to all elements drawn from classes in an HL7 model, contain values which are used to localize the V3 message implementation.**
id	**Provides an identifier for the message instance. Note, as with all ids, that an OID to indicate the id namespace is**

	required.
creationTime	**Date time for creation of the message.**
securityText	**Allows a text block to support security processing.**
profiled	**TBD**
processingCode	**Defines whether the message is part of a production, training, or debugging system.**
processingModeCode	**Defines whether the message is being sent in current processing (the usual mode), archive mode, initial load mode, restore from archive mode, etc**
acceptAckCode	**Defines whether or not an application acknowledgement is expected. For ICSR it is not.**
sequenceNumber	**Allows the sender to indicate the sequence number for a message where relevant..**
attachmentText	**Contains arbitrary attachments of data blocks to which can be referred to from the interior of the message**
receiver	**Associates the message with a device that will receive the transaction, and with the organization that the device is associated with. Note, address and phone information is supported, both for the information and for a contact. See the discussion of the device element below.**
respondTo	**Allows the identification of a device that will receive responses to the message. This element is not used within the ICSR.**
sender	**Associates the message with a device that will send the transaction, and with the organization that the device is associated with. Note, address and phone information is supported, both for the information and for a contact. See the discussion of the device element below.**
attentionLine	**This class allows parameters for a technology specific transport to be represented in the V3 message transmission wrapper.**
controlActProcess	**This association indicates the information for the control act, and, within the control act, for the rest of the ICSR contents. This element is further explained elsewhere in the document.**

3. Device (Transmission)

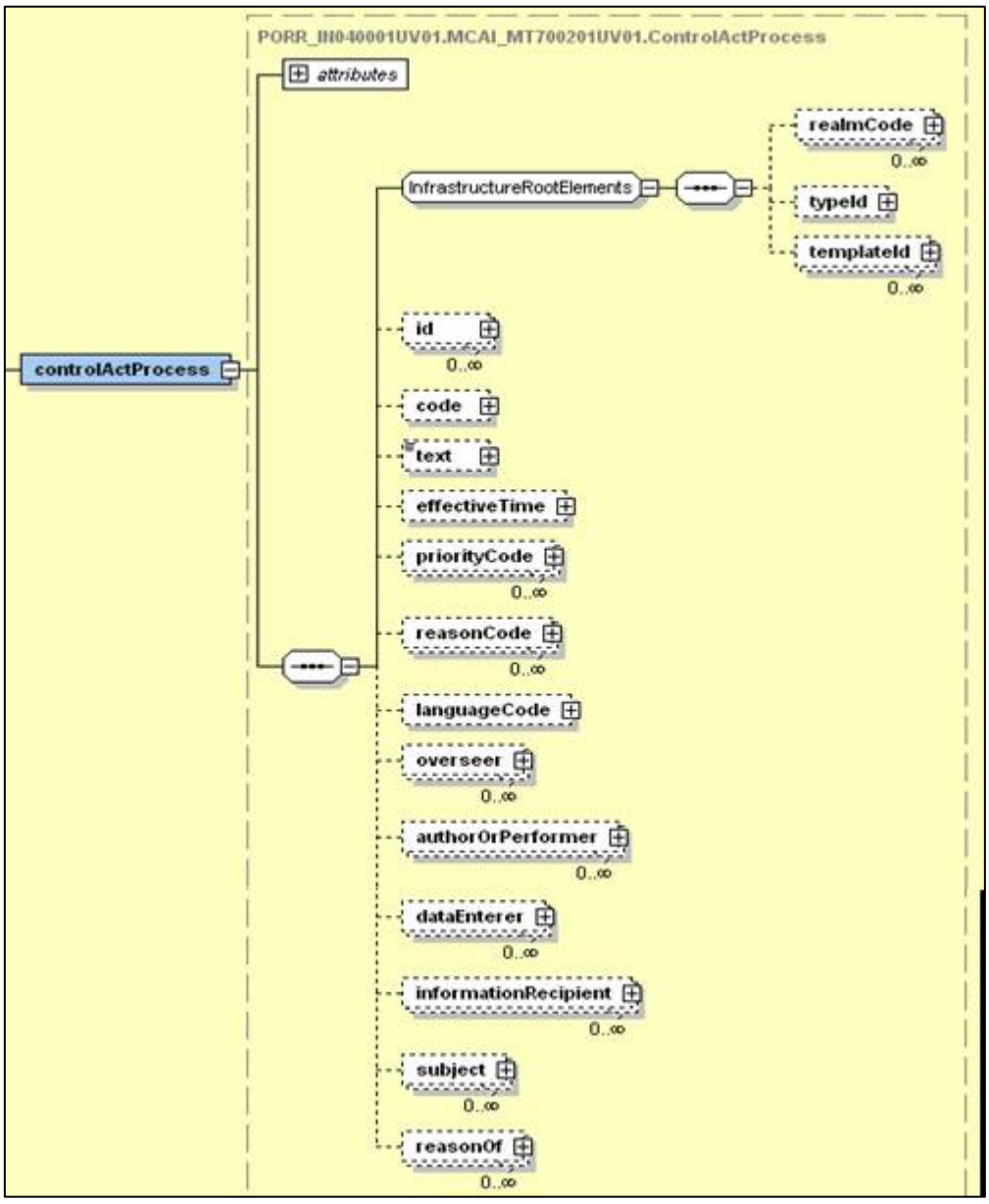
The diagram shows the contents of the device element that captures information for both message senders and receivers.



Device (Transmission) Element Contents	
Element	Discussion
Id	**An identifier assigned to the device used for transmitting or receiving the message.**
name, desc, existenceTime, telecom, manufacturer ModelName, softwareName	**None of these elements, all of which are optional ways of passing information about the sender or receiver device, will be supported for ICSR messaging.**
as Agent	**An association that includes information on the organization for which the device is acting as an agent. It is possible to collect name, phone number and address for the organization. It is also possible to collect information for a person who acts as a contact for the organization. This information is represented within the R_NotificationParty CMET.**
asLocatedEntity	**The association makes it possible to indicate data regarding the place where the device is located. It will not be used for ICSR messaging.**

4. Control Act

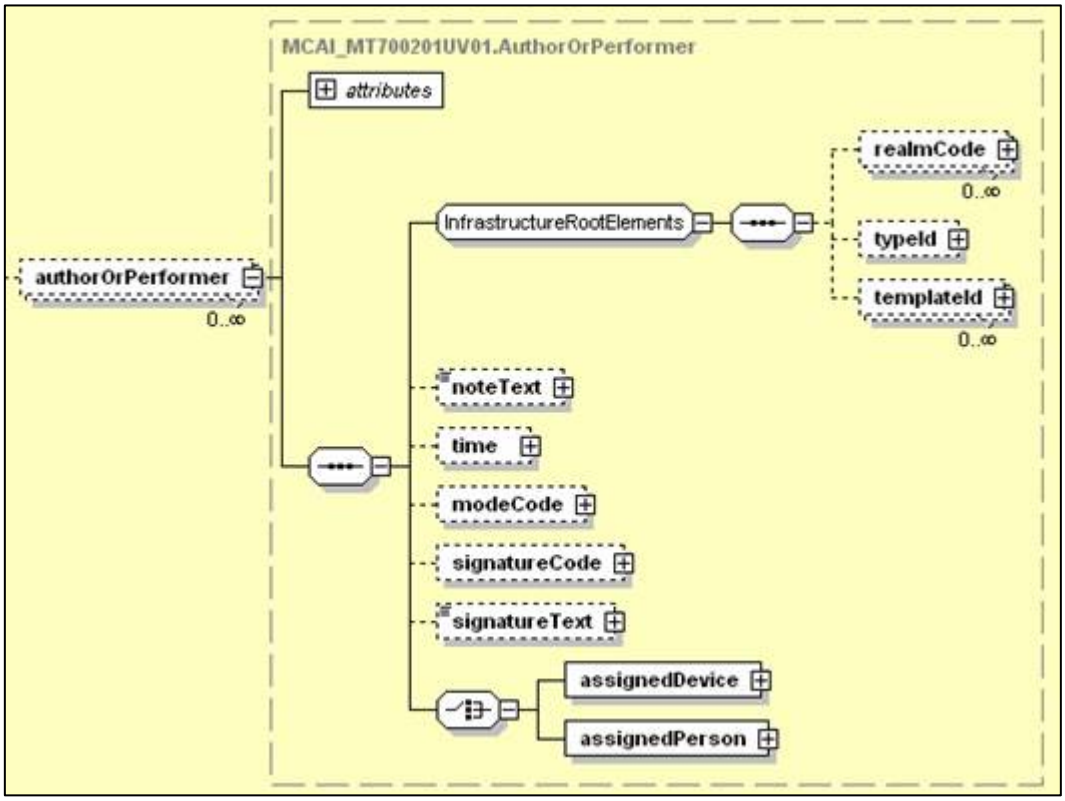
The diagram shows the elements directly associated with the control act.



Control Act Element Contents	
Element	Discussion
attributes	**The values of these attributes, except for the null value indicator are fixed within the schema. Since there can be no message without a control act, the null value indicator should be ignored.**
Infrastructure Root Elements	**ICSR messaging does not use these elements.**
id	**An identifier for the trigger event, or action that initiated the message. This required elements should be populated with nullFlavor = "NI" since it is not currently used by ICSR messaging.**
code	**Identifies the HL7 trigger event that is used. Note, whenever a coded element appears, the code system used is identified using a code system identifying OID.**
text	**ICSR messaging does not use this element.**
effectiveTime	**Indicates the date of the report.**
priorityCode	**ICSR messaging does not use this element.**
reasonCode	**ICSR messaging does not use this element.**
languageCode	**ICSR messaging does not use this element. It is assumed the language is English. However, this could be used for senders/receivers that want to use other languages.**
overseer	**Allows the sender to indicate a party who supervises the generation of the report. Note, this element supports the passing of contact information for an overseeing person or organization. It expands into a complex structure that is identical to that for authorOrPerformer which is explored below.**
authorOrPerformer	**Indicates the party taking responsibility for authoring the report. This element is further explained elsewhere in the document.**
dataEnterer	**ICSR messaging does not use this element.**
informationRecipient	**ICSR messaging does not use this element.**
subject	**This element links to the InvestigationEvent, and through it to the entire ICSR payload. This element is further explained elsewhere in the document.**
reasonOf	**The element links to the "detectedIssueEvent". The specifications note that this structure "can be used to convey observations made by a system as part of it's processing of a message". Within the ICSR, it is used to carry key information related to the report such as report type and follow-up number. {See the section on Medwatch mapping for more details.} This element is further explained elsewhere in the document.**

5. Control Act Author Or Performer

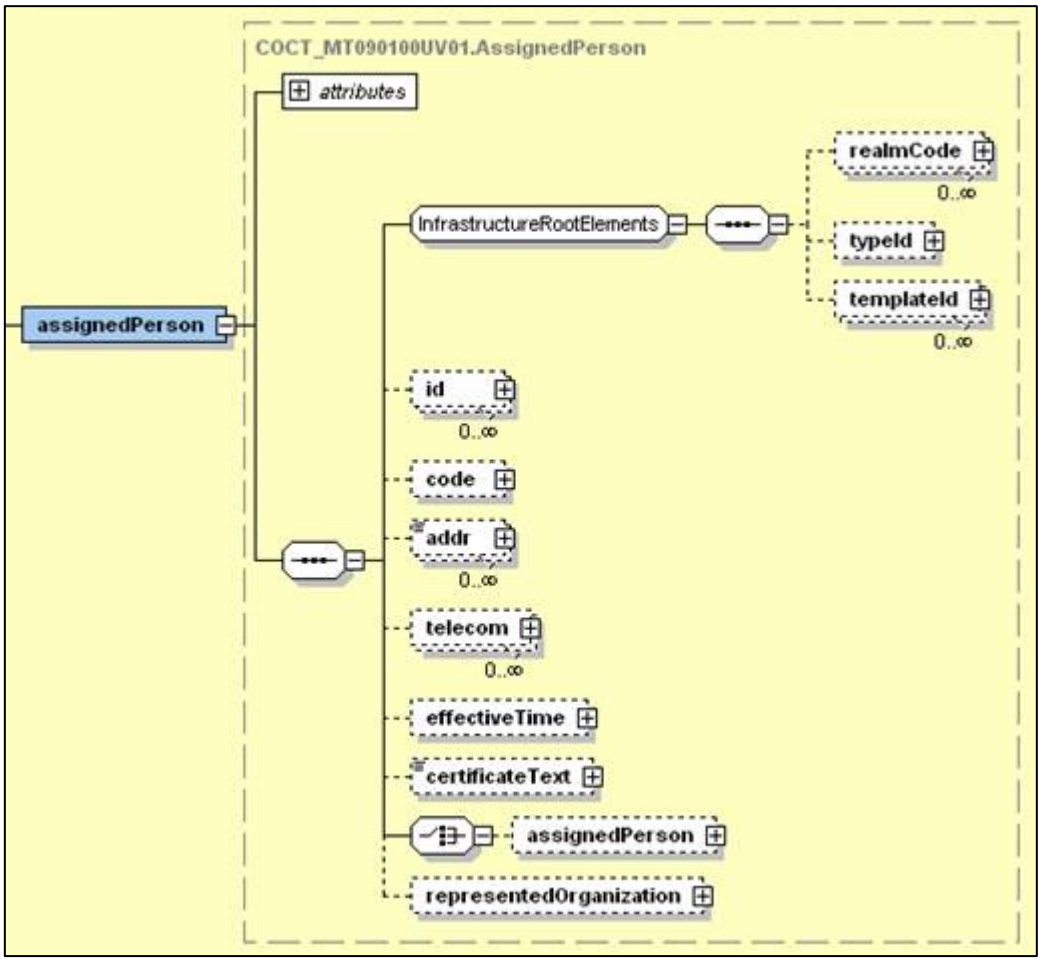
The diagram shows the content of this structure. The pattern used here also applies to the overseer element if that needs to be implemented.



AuthorOrPerformer Element Contents	
Element	Discussion
attributes	**Null value indicator will be set to "NI" for implementations that do not include authorOrPerformer information.**
Infrastructure Root Elements	**ICSR messaging does not use these elements.**
noteText	**ICSR messaging does not use this element.**
Time	**ICSR messaging does not use this element.**
modeCode	**ICSR messaging does not use this element.**
signatureCode	**ICSR messaging does not use this element.**
signatureText	**ICSR messaging does not use this element.**
assignedDevice	**ICSR messaging does not use this element.**
assignedPerson	**This element includes contact information for the party who actually transmits the report. This element is further explained elsewhere in the document.**

6. Assigned Person

The diagram shows the contents of this element. The Assigned Person role is repeated several times within the ICSR, as with any HL7 Version 3 implementation. (The actual schema information is drawn from a CMET, as can be seen by the label at the top of the diagram.)

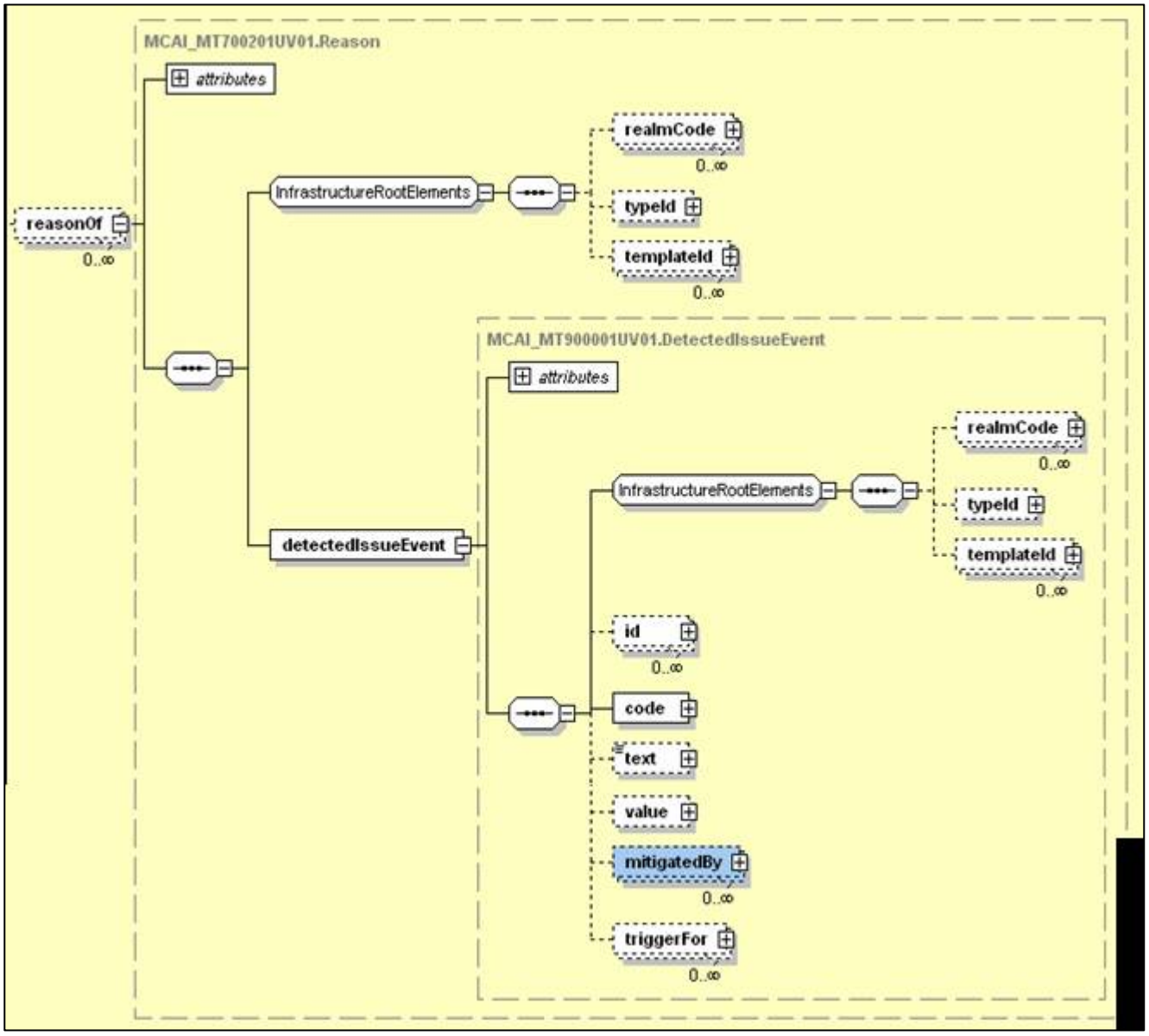


Assigned Person Element Contents	
Element	Discussion
Attributes	**The null value indicator will not be used here.**
Infrastructure Root Elements	**ICSR messaging does not use these elements.**
id	**ICSR messaging does not use this element.**
code	**Indicates the role played by the sender of the report. For ICSR, it is used to indicate different types of report sender, e.g., manufacturer.**
addr	**If needed, the postal address for the sender.**
telecom	**If needed, a telecommunications address for the sender. This includes phone numbers, fax numbers, and email addresses.**
effectiveTime	**ICSR messaging does not use these elements.**
certificateText	**ICSR messaging does not use these elements.**
assignedPerson	**Includes demographic information for the person responsible for sending the report.**

represented Organization	**Provides information related to the organization that is sponsoring the report.**

7. Detected Issue

The diagram captures the data structure used to carry relevant information related to the creation of the report. Refer to the mapping sections of this guide for more information.

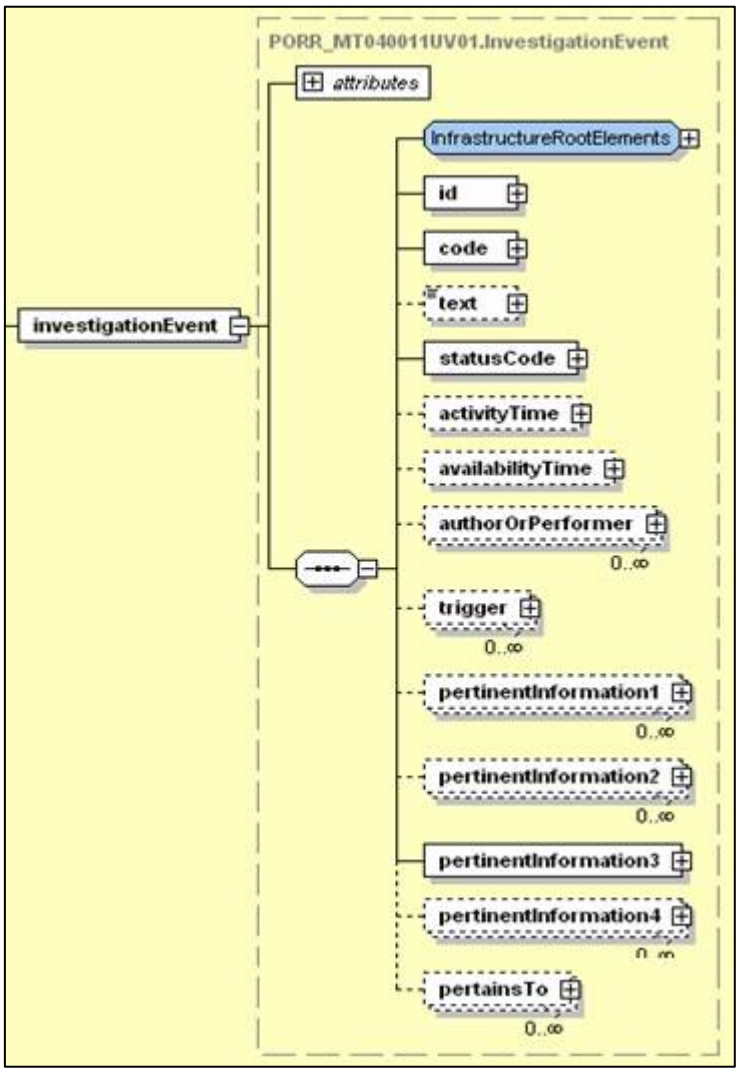


Detected Issue Element Contents	
Element	Discussion
reasonOf attributes	**The null value indicator will not be used here.**
reason of Infrastructure Root Elements	**ICSR messaging does not use these elements.**
detectedIssue	**ICSR messaging does not use these elements.**

Infrastructue Root Elements	
id	ICSR messaging does not use this element.
code	Indicates the type of information that is passed in the value. . The attribute here works exactly the same way that it does within an observation or other type of act.
text	ICSR messaging does not use this element.
value	Carries the information whose type is indicated by the content of the code element.
mitigatedBy	ICSR messaging does not use this element.

8. ICSR Adverse Event Report Base Payload

The diagram shows the core structures for the ICSR adverse event report.

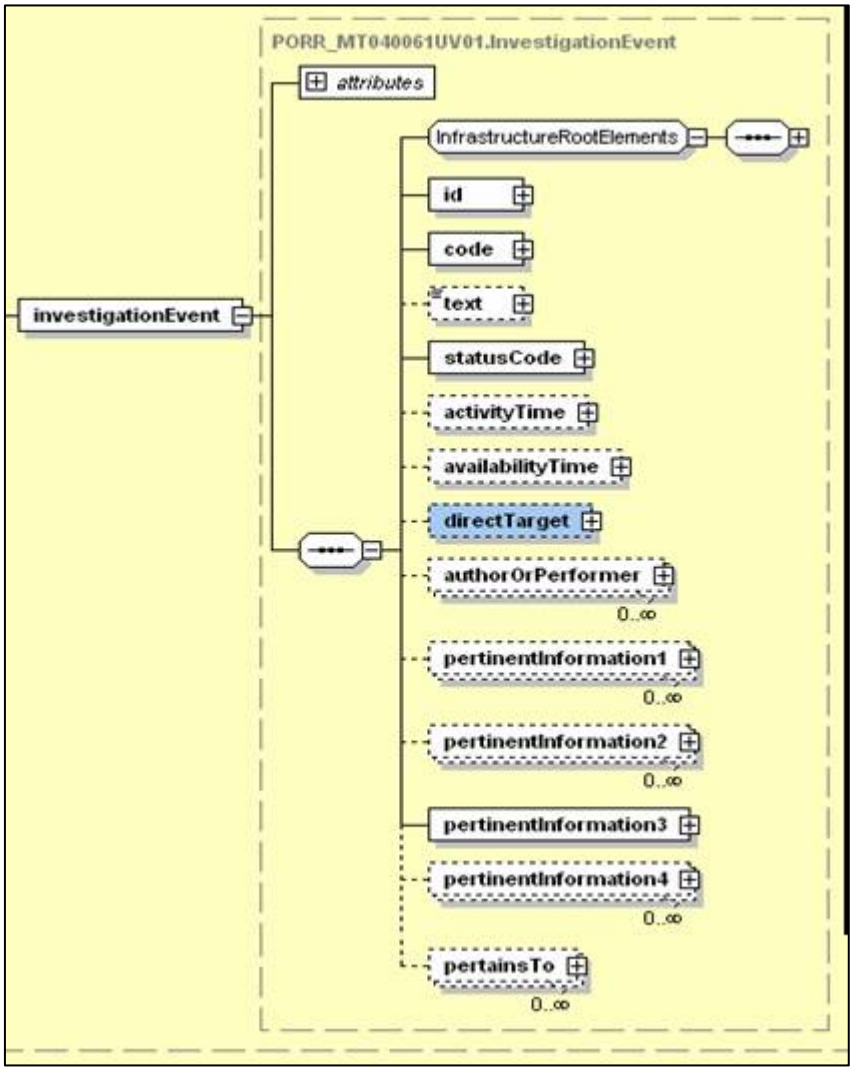


ICSR Adverse Event Report Element Contents	
Element	Discussion
attributes	**The null value indicator will not be used here.**
Infrastructure Root Elements	**ICSR messaging does not use these elements.**
id	**Provides an identifier for the report.**
code	**Provides a single typing attribute to indicate the report type. It is used to indicate whether the report addresses a product problem, an adverse event, or both.**
text	**Supports a text description of the adverse event or product problem.**
statusCode	**If used, provides information on the status of the report.**
activityTime	**If used, provides information on the start and or stop date of the investigation being reported.**
availabilityTime	**ICSR messaging does not use this element.**
authorOrPerformer	**This element expands to include information on the party responsible for the investigation as well as, if needed, parties responsible for carrying it out. The structure is very similar to that of the Control Act authorOrPerformer described**

	above.
trigger	**This element expands to capture information related to the reaction or reactions suffered by the case subject. This element is further explained elsewhere in the document.**
pertinent Information1	**This element expands to capture information for Secondary Case Notifications – that is about other reports that the organization carrying out the investigation has received with regard to this adverse event or product problem. This element is further explained elsewhere in the document.**
pertinent Information2	**This element expands to capture information for other Investigation Events – that is about reports that the organization carrying out the investigation has received with regard to other adverse events or patient problems that are relevant to this investigation. Data collected include the identifier and type code of the other investigation.**
pertinent Information3	**This element expands to capture information about the patient outcome or outcomes of the case that is being reported. The associated information, which HL7 labels "case seriousness" is structured as an observation.**
pertinent Information4	**This element expands to capture information on documents that are relevant to the adverse event or product problem. Document type, title, and bibliographic designation are captured. In addition, the document text can be passed if that is desired.**
pertainsTo	**This element indicates the act that is implicated in an adverse event report. Currently that act is either a medication oriented substance administration, or a medical device related procedure. However, over time, additional types of acts may be included. This element makes it possible for the priority number associated with an implicated act to be assigned. It also expands to include other information about implicated acts and their associated product. This element is further explained elsewhere in the document.**

9. ICSR Product Defect Report Base Payload

The diagram shows the core structures for the ICSR product defect report.

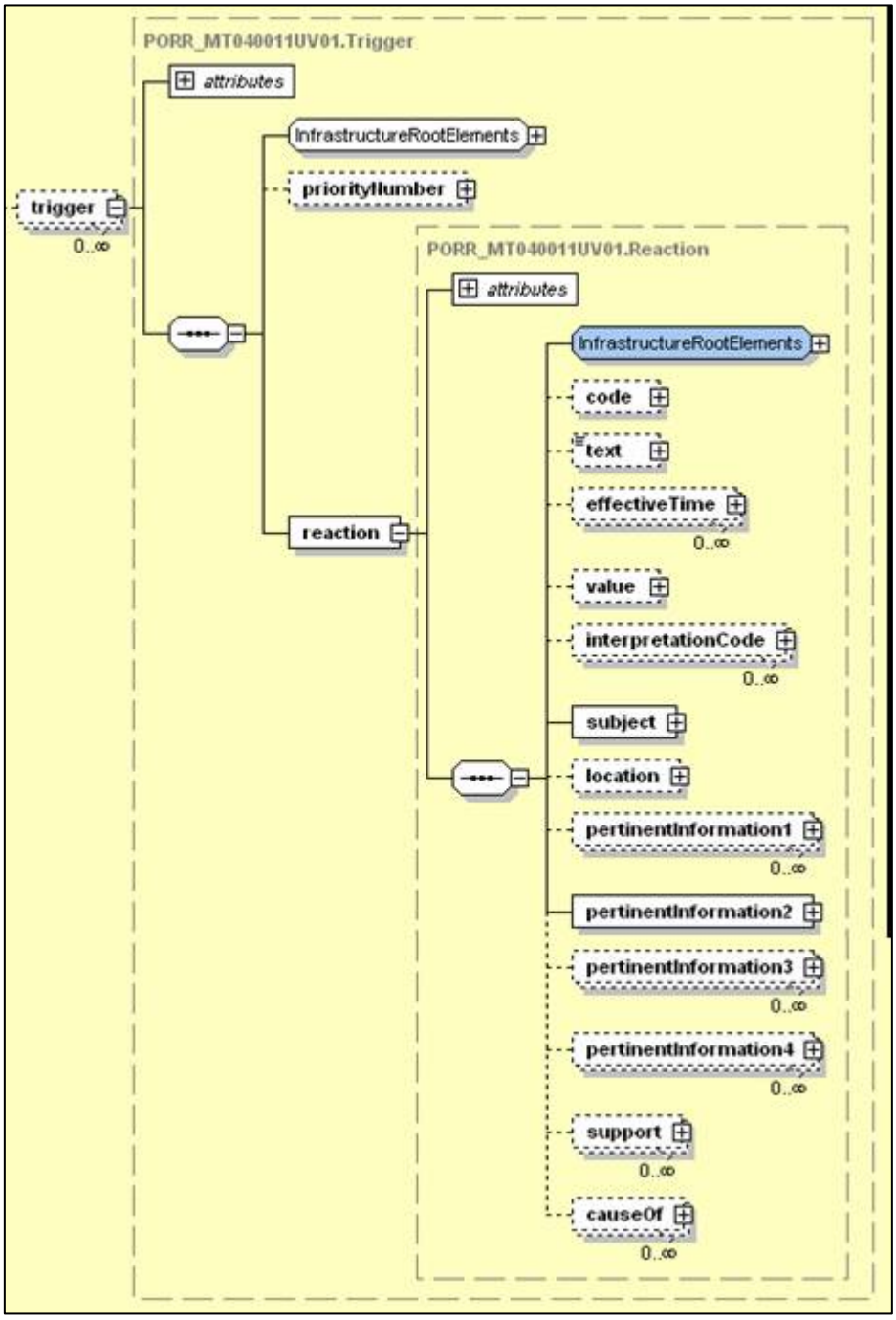


ICSR Product Defect Report Element Contents	
Element	Discussion
attributes	**The null value indicator will not be used here.**
Infrastructure Root Elements	**ICSR messaging does not use these elements.**
id	**Provides an identifier for the report.**
code	**Provides a single typing attribute to indicate the report type. It is used to indicate whether the report addresses a product problem, an adverse event, or both.**
text	**Supports a text description of the adverse event or product problem.**
statusCode	**If used, provides information on the status of the report.**
activityTime	**If used, provides information on the start and or stop date of the investigation being reported.**
availabilityTime	**ICSR messaging does not use this element.**
directTarget	**This element expands to provide information on the particular product that is being reported on as a product problem. Currently, drugs and medical devices are the only product types that are supported by the ICSR. Over time, as**

	the scope of the ICSR implementation is expanded, additional product types will be added. This element is further explained elsewhere in the document.
authorOrPerformer	**This element expands to include information on the party responsible for the investigation as well as, if needed, parties responsible for carrying it out. The structure is very similar to that of the Control Act authorOrPerformer described above.**
pertinent Information1	**This element expands to capture information for Secondary Case Notifications – that is about other reports that the organization carrying out the investigation has received with regard to this adverse event or product problem. This element is further explained elsewhere in the document.**
pertinent Information2	**This element expands to capture information for other Investigation Events – that is about reports that the organization carrying out the investigation has received with regard to other adverse events or patient problems that are relevant to this investigation. Data collected include the identifier and type code of the other investigation.**
pertinent Information3	**This element expands to capture information about the patient outcome or outcomes of the case that is being reported. The associated information, which HL7 labels "caseSeriousness" is structured as an observation.**
pertinent Information4	**This element expands to capture information on documents that are relevant to the adverse event or product problem. Document type, title, and bibliographic designation are captured. In addition, the document text can be passed if that is desired.**
pertainsTo	**This element is only used when the ICSR is an adverse event related report, as opposed to a product defect report.**

10. Reaction

The diagram shows the information that is collected directly for the reaction or reactions that trigger an adverse event related ICSR.

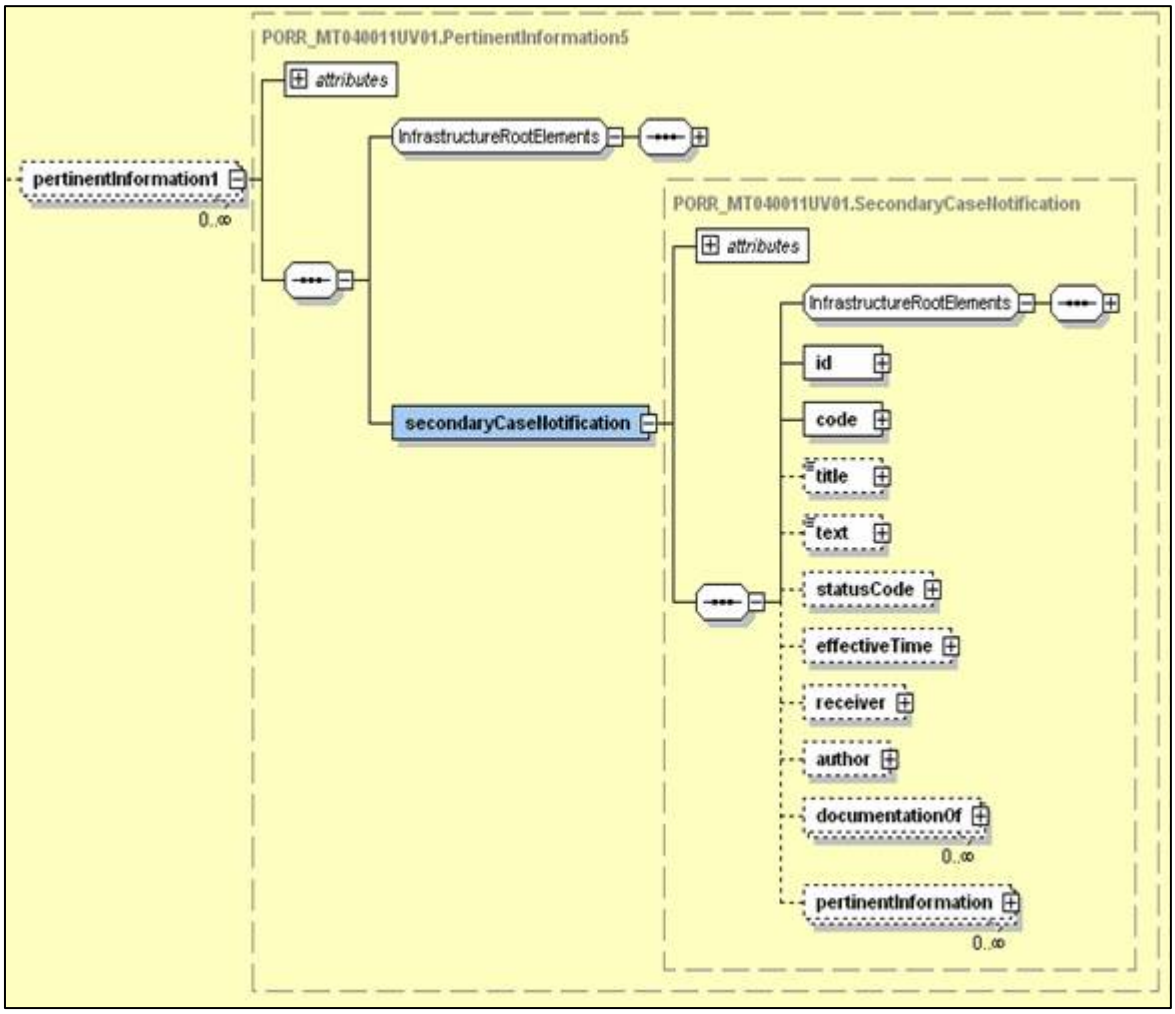


Trigger and Reaction Element Contents	
Element	Discussion
trigger attributes	**The mood code and class code values will be supplied by the schema.**
trigger Infrastructure Root Elements	**These elements are not supported within the ICSR.**
priorityNumber	**Makes it possible to provide the desired priority ordering for**

	the reactions in cases in which multiple reactions are reported.
reaction attributes	**The mood code and class code values will be supplied by the schema.**
Reaction Infrastructure Root Elements	**These elements are not supported within the ICSR.**
code	**Identifies this observation as a reaction.**
text	**Provides a text description of the reaction.**
effectiveTime	**Captures the effective date and time for the reaction.**
value	**Allows the designation of the reaction type. Ideally this would be a MedDRA code.**
interpretation Code	**Enables the reporter to provide a rough qualitative interpretation of the reaction.**
subject	**This element expands to provide information about the person who is the subject of the reaction. This element is further explained elsewhere in the document.**
location	**This element captures information for the service delivery location associated with the reaction. Id and type code for the location are captured.**
pertinent information1	**This element expands to support concurrent observations related to the reaction. Note, this is to be distinguished from relevant clinical information related to the case subject which is captured elsewhere.**
pertinent information2	**This element expands to support observations that provide information on the emphasis which the reporter placed on the reaction.**
pertinent information3	**This element expands to support observations that provide information on the extent to which a particular reaction is related to a suspect act (substance administration or device related procedure). Note that the observation is associated with "act stub" which only indicates the id for the procedure or substance administration. It is important to also note that information about the author of the relatedness act can be collected as well.**
pertinent information4	**This element expands to provide information related to the first report of the adverse event and the patient's reaction to it. The information captured for the primary source report has a similar structure to the secondary source report which is expanded elsewhere in the document.**
support	**This element expands to support information on the delay in time – the "pause quantity" between the suspect act and the reaction. Note that the observation is associated with "act stub" which only indicates the id for the procedure or substance administration**
causeOf	**This element expands to provide observations related to outcomes associated with the reaction.**

11. ICSR Secondary Case Report

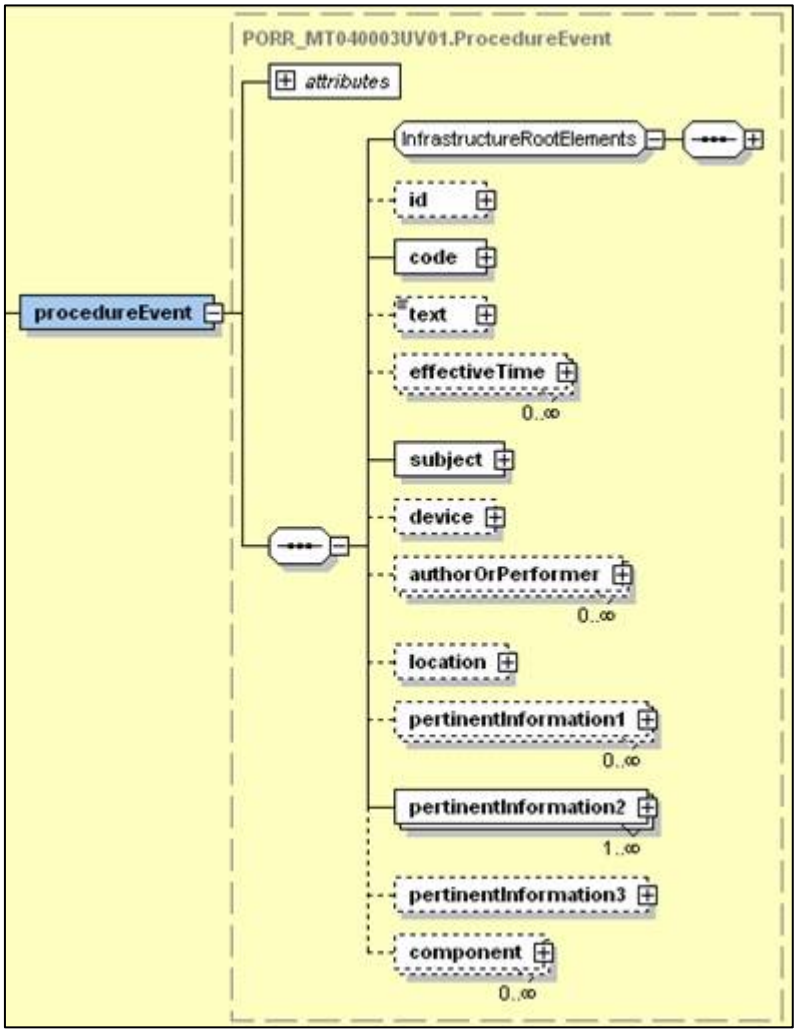
The diagram shows the information that is captured for other reports of the adverse event or product problem. The reader should note that the initial report of the event or problem is not included in this category, but is supported by its own data structure.



Secondary Case Report Element Contents	
Element	Discussion
SecondaryCase Notification attributes	**Values of the structural attributes are provided in the schema.**
SCN Infrastructure Root Elements	**These elements are not used in the ICSR.**
id	**An identifier for the secondary notification.**
code	**Indicates the report type for the secondary notification.**
title	**Allows passage of a title for the report**
text	**Allows passage of the text contents of the notification**
statusCode	**Information on the status of the report at the time it was sent.**
effectiveTime	**Information about the date and time of report creation.**
receiver	**This element expands to include information regarding the party to whom the report was sent. The format for that information follows that documented above for controlAct author.**
author	**This element expands to include information regarding the party responsible for creating the report. The format for that information follows that documented above for controlAct author.**
documentationOf	**This element expands to provide a linkage to the primary (initial) report of the adverse event or product problem.**
pertinentInformation	**This element expands to provide a linkage to other secondary case notifications.**

12. Procedure Event

The diagram depicts the information captured for the device related procedure related to an adverse event associated with a device.

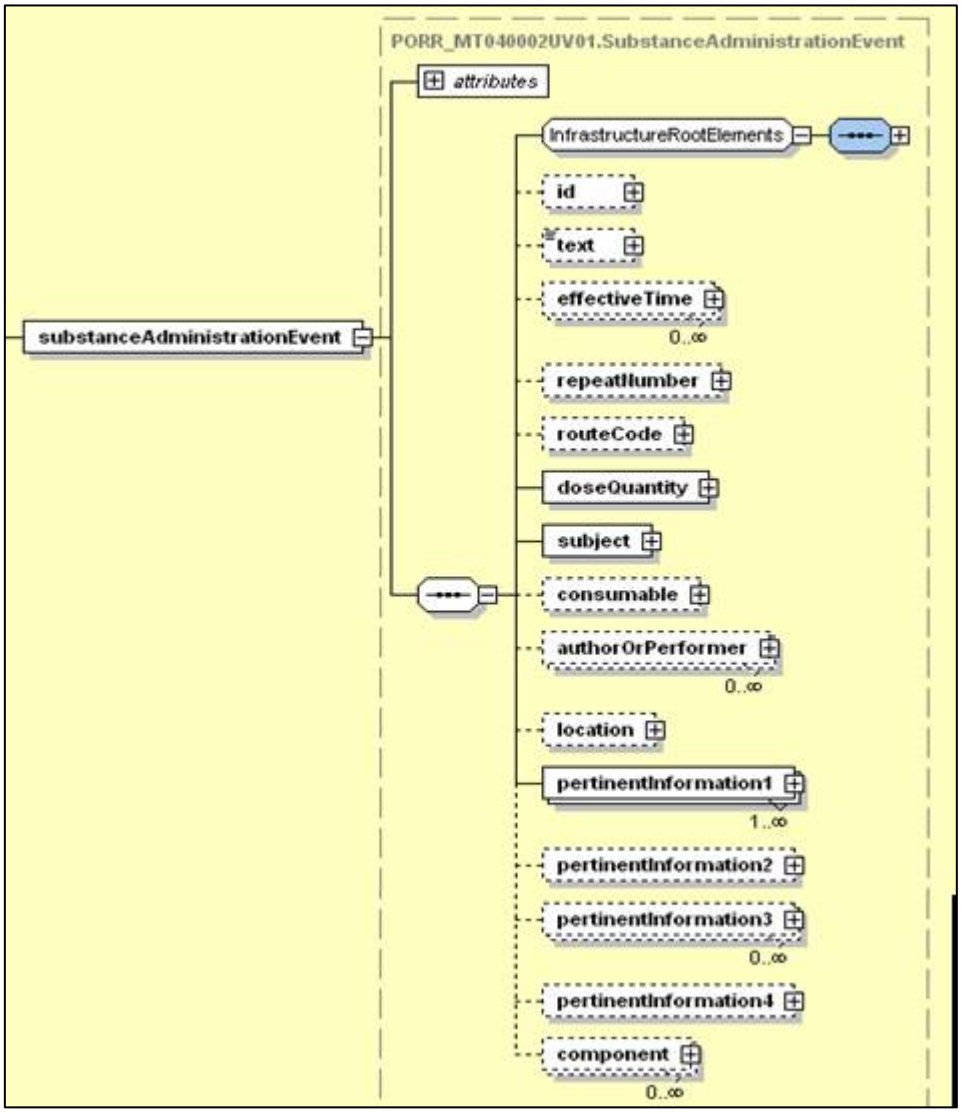


Procedure Event Element Contents	
Element	Discussion
Attributes	**Values of the structural attributes are provided in the schema.**
Infrastructure Root Elements	**These elements are not used in the ICSR.**
id	**An identifier for the procedure. Note, a value is needed for this attribute is associations to procedure stubs are used.**
code	**An indication of the type of procedure. Note, when device information is collected, both implantation and explantation procedures are treated as components of a higher level procedure**
text	**Allows capturing a text description of the procedure.**
effectiveTime	**The date and time of the procedure.**
subject	**Expands to provide information on the entity which is the subject of the procedure. This information must be provided if a) there is more than one case subject, or b) the procedure is done on a person other then the one suffering the interaction.**

device	**Expands to provide information for the medical device that is involved in the procedure. This element is further explained elsewhere in the document.**
authorOrPerformer	**Expands to allow entry of information related to the party ordering and/or performing the procedure. Note, the pattern for this information follows that of the ControlAct author or Performer**
location	**Expands to provide information on the place of service where the procedure took place.**
pertinentInformation1	**Expands to include observations that capture information for the actions taken to mitigate procedure related interactions.**
pertinentInformation2	**Expands to allow information on a wide range of different types of acts (what HL7 calls clinical statements) associated with the procedure. It is expected that initial FDA implementations will focus on associated observations. This element is further explained elsewhere in the document.**
pertinentInformation3	**Expands to include observations that capture information to characterize the intervention – that is the procedure.**
component	**Provides a recursive reference to allow the inclusion of information about additional acts that are considered to be components of the device related procedure. Currently, this construct is expected to be used for implantation and explantation acts.**

13. Substance Administration Event

The diagram depicts the information captured for the medication related substance administration related to an adverse event associated with a drug.

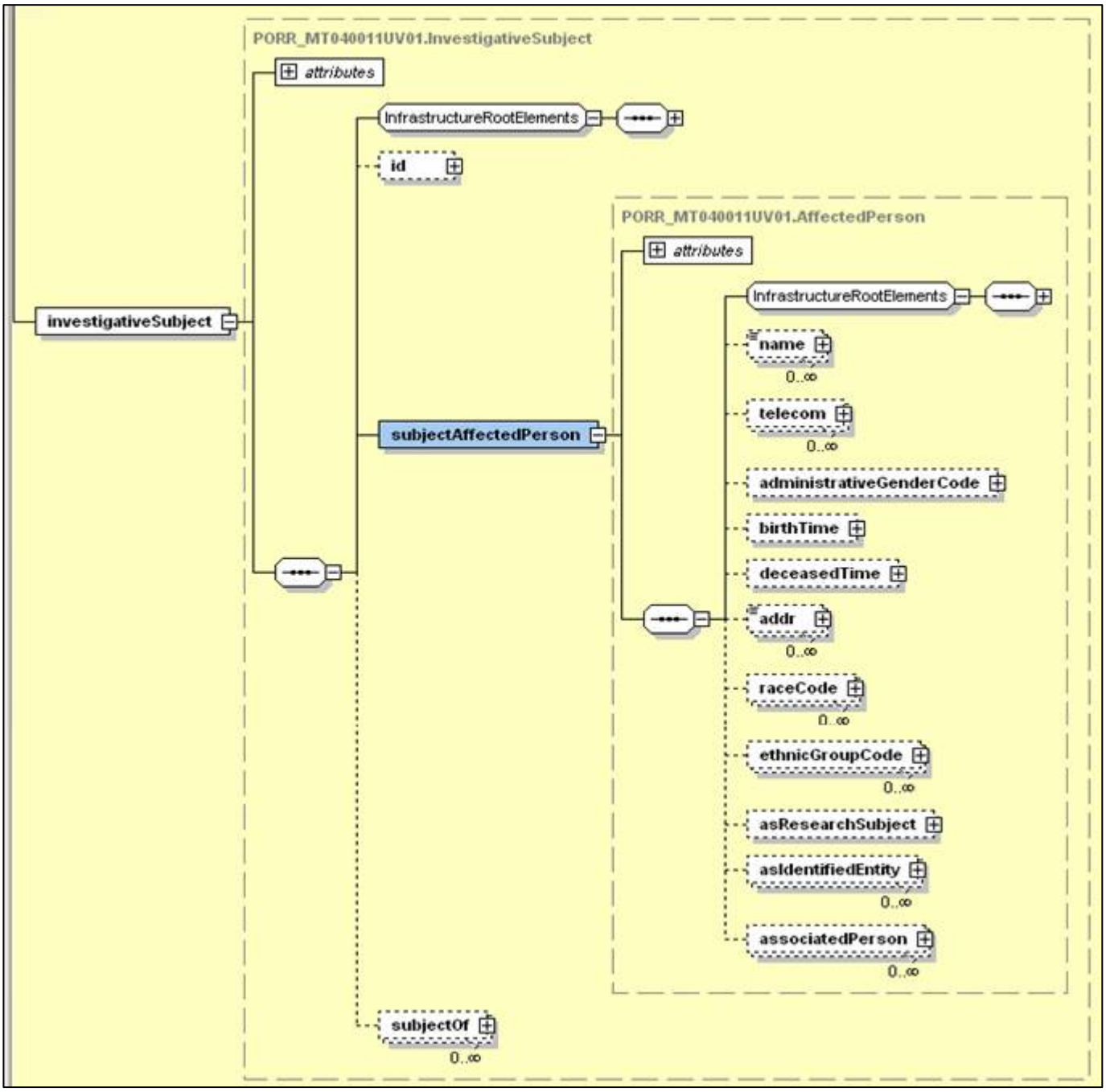


Substance Administration Event Element Contents	
Element	Discussion
Attributes	**Values of the structural attributes are provided in the schema.**
Infrastructure Root Elements	**These elements are not used in the ICSR.**
id	**An identifier for the substance administration. Note, a value is needed for this attribute is associations to substance administration stubs are used.**
text	**Allows capturing a text description of the substance administration.**
effectiveTime	**The date and time of the substance administration. This can be expressed as a date, a range of dates or as a frequency (which may be simple or complex.)**
repeatNumber	**Indicates the number of times that the act was repeated.**
routeCode	**Indicates the route of administration for the medication.**

doseQuantity	**Indicates the amount of medication contained in a single dose.**
subject	**Expands to provide information on the entity which is the subject of the substance administration. This information must be provided if a) there is more than one case subject, or b) the substance administration is administered to a person other then the one suffering the interaction.**
consumable	**Expands to provide information for the medication that is involved in the substance administration. This element is further explained elsewhere in the document.**
authorOrPerformer	**Expands to allow entry of information related to the party ordering and/or performing the substance administration. Note, the pattern for this information follows that of the ControlAct author or Performer**
location	**Expands to provide information on the place of service where the substance administration took place.**
pertinentInformation1	**Expands to include observations that capture information for the actions taken to mitigate substance administration related interactions.**
pertinentInformation2	**Expands to allow information on a wide range of different types of acts (what HL7 calls clinical statements) associated with the substance administration. It is expected that initial FDA implementations will focus on associated observations. This element is further explained elsewhere in the document.**
pertinentInformation3	**Expands to include observations that capture information to characterize the intervention – that is the substance administration e.**
component	**Provides a recursive reference to allow the inclusion of information about additional acts that are considered to be components of the substance administration.**

14. Investigative Subject

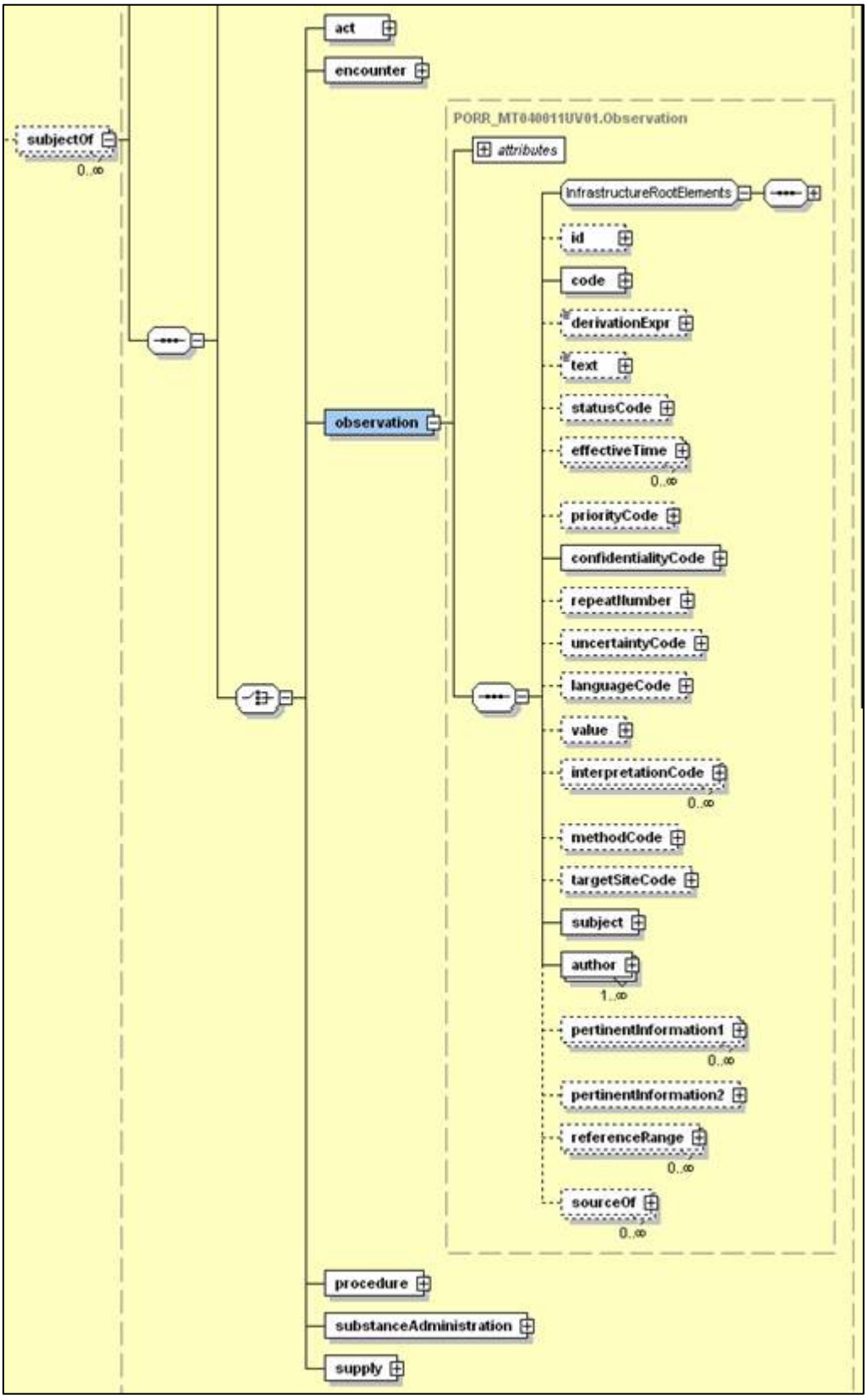
The diagram provides information related to the person playing the role of investigative subject who is the subject of the reaction or reactions being reported as an adverse event.



Case Subject Element Contents	
Element	Discussion
Investigative Subject attributes	**Values of the structural attributes are provided in the schema.**
Investigative Subject infrastructure root elements	**These elements are not used in the ICSR.**
Affected Person Subject attributes	**Values of the structural attributes are provided in the schema.**
Affected person infrastructure root elements	**These elements are not used in the ICSR.**
name	**Allows entry of the name of the person associated with the adverse event report. Note, this is not a required field, so patient name is not required.**
telecom	**Allows entry of one or more telecommunications addresses, e.g., phone number, email address, fax number, for the person.**
administrative GenderCode	**Allows entry of a gender or sex code for the person.**
birthTime	**Allows entry of the birth dateTime for the person.**
deceasedTime	**Allows entry of the death dateTime for the person.**
addr	**Allows entry of one or more postal addresses for the person.**
raceCode	**Allows entry of one or more race codes for the person.**
ethnicGroupcode	**Allows entry of one or more ethnic group codes for the person.**
asResearchSubject	**Expands to capture information for a clinical trial in which the affected person is involved.**
asIdentifiedEntity	**Expands to capture information for one or more identifiers which have been assigned to the affected person.**
associatedPerson	**Expands to capture information for other persons that are associated with the investigative subject. Since the association is recursive, any information items for the additional persons, are the same as those described for the investigative subject. The relationship between the two persons is captured as well.**
subjectOf	**This association of the investigative subject role expands to show information about a range of possible acts (usually known as clinical statements) that carry relevant information about the affected person and their medical history. This element is further explained elsewhere in the document.**

15. Associated Acts

The diagram captures the range of act types that support additional information related to the investigative subject. Since, this information is most usually represented as an observation, that class is expanded to show its component attributes and associations.



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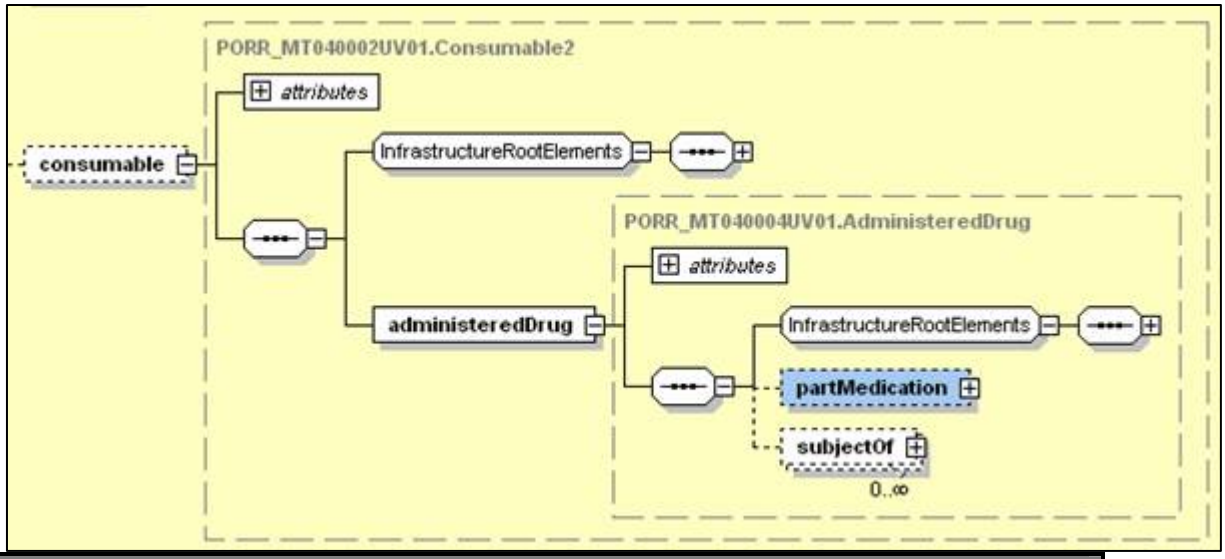
Associated Acts Element Contents	
Element	Discussion
subjectOf act	**Expands to provide information about a generic act containing relevant information for the investigative subject.**
subjectOf encounter	**Expands to provide information about an encounter containing relevant information for the investigative subject.**
observation attributes	**Values of the structural attributes except for the mood code are provided in the schema. The value provided for the mood code indicates whether the observation has been performed (EVN), has been ordered (REQ), or is conceived of in some other way. Currently, ICSR messaging focuses on observations in the Event mood, that is to say, those observations that have already taken place.**
observation Infrastructure Root Elements	**These elements are not used in the ICSR.**
observation id	**A value that uniquely identifies the act.**
observation code	**A coded value that identifies which particular type of observation this is. The observation code provides the context for all the other aspects of the observation, and makes them meaningful.**
observation derivationExpr	**This element is not currently used in the ICSR.**
observation text	**Allows entry of text that describes the observation.**
observation statusCode	**Indicates the state of the observation, e.g., final, preliminary.**
observation priorityCode	**Indicates the urgency with which the observation was performed or is to be performed.**
observation confidentialityCode	**Controls the disclosure of information about the observation.**
observation repeatNumber	**Indicates the maximum and minimum number of repetitions of the observation.**
observation uncertaintyCode	**Indicates the level of uncertainty of the information contained.**
observation languageCode	**This element is not currently used in the ICSR. It is assumed that English is used.**
observation value	**The information carried within the observation. It is the observation value in particular which is only meaningful in the context of the value of observation code. For instance, the value 45 kilos has little relevance unless one knows it is a person's weight.**
observation interpretationCode	**Provides a rough qualitative interpretation of the observation value. E.g., normal, below normal.**
observation methodCode	**Provides additional detail regarding the method with which the observation was carried out.**
observation targetSitecode	**Indicates the relevant anatomical site or system on which the observation was carried out, if that is not already specified by observation code.**
observation subject	**Expands to provide information about the party who is the direct subject of the observation. This is normally**

	the investigative subject, but could be instead a person related to the investigative subject. Note, within this association, the awareness code provides an indication of whether or not the subject is aware of the observation.
observation author	**Expands to provide information about the person, usually a clinician, who is the author of the observation.**
observation pertinentInformation1	**Expands to provide information about indications for an affected act. This element is not currently used by ICSR messaging.**
observation pertinentInformation2	**Expands to provide information that characterizes an intervention that has been modeled as an affected act. This element is not currently used by ICSR messaging.**
observation referenceRange	**Expands to provide information on the reference range or normal values that are relevant for interpretation of the observation. This element is not currently used by ICSR messaging.**
observation sourceOf	**Expands to provide a recursive link back to the affected acts collection. That is, it allows information about observations or other act types related to this observation. This element is not currently used by ICSR messaging.**
subjectOf procedure	**Expands to provide information about a procedure containing relevant information for the investigative subject.**
subjectOf substance Administration	**Expands to provide information about a substance administration containing relevant information for the investigative subject.**
subjectOf supply	**Expands to provide information about a supply act containing relevant information for the investigative subject.**

16. Administered Drug

The diagram depicts the directly related to an administered drug item associated with an adverse event.

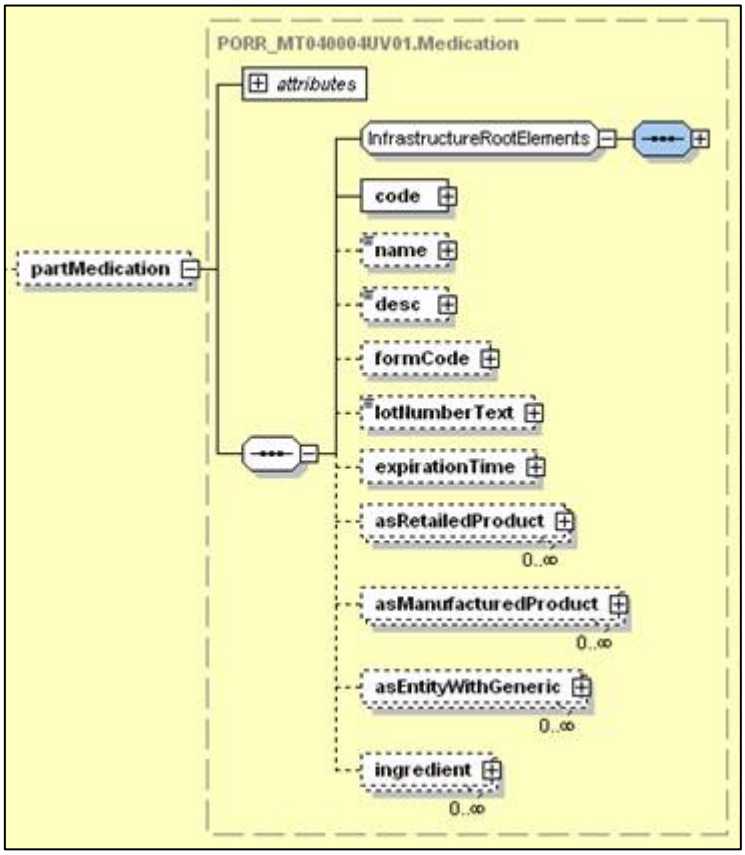


Administered Drug Element Contents	
Element	Discussion

consumable Attributes	**Values of the structural attributes are provided in the schema.**
consumable Infrastructure Root Elements	**These elements are not used in the ICSR.**
administeredDrug Attributes	**Values of the structural attributes are provided in the schema.**
administeredDrug Infrastructure Root Elements	**These elements are not used in the ICSR.**
partMedication	**This element expands to provide information related to the medication that is being consumed. This element is further explained elsewhere in the document.**
subjectOf	**This element expands to provide information on the regulatory approval that has been received to market the drug. Currently, the only item used from this structure is the approval id, e.g., NDA number, assigned by the regulatory authority.**

17. Medication

The diagram shows the information directly captured for a medication item.

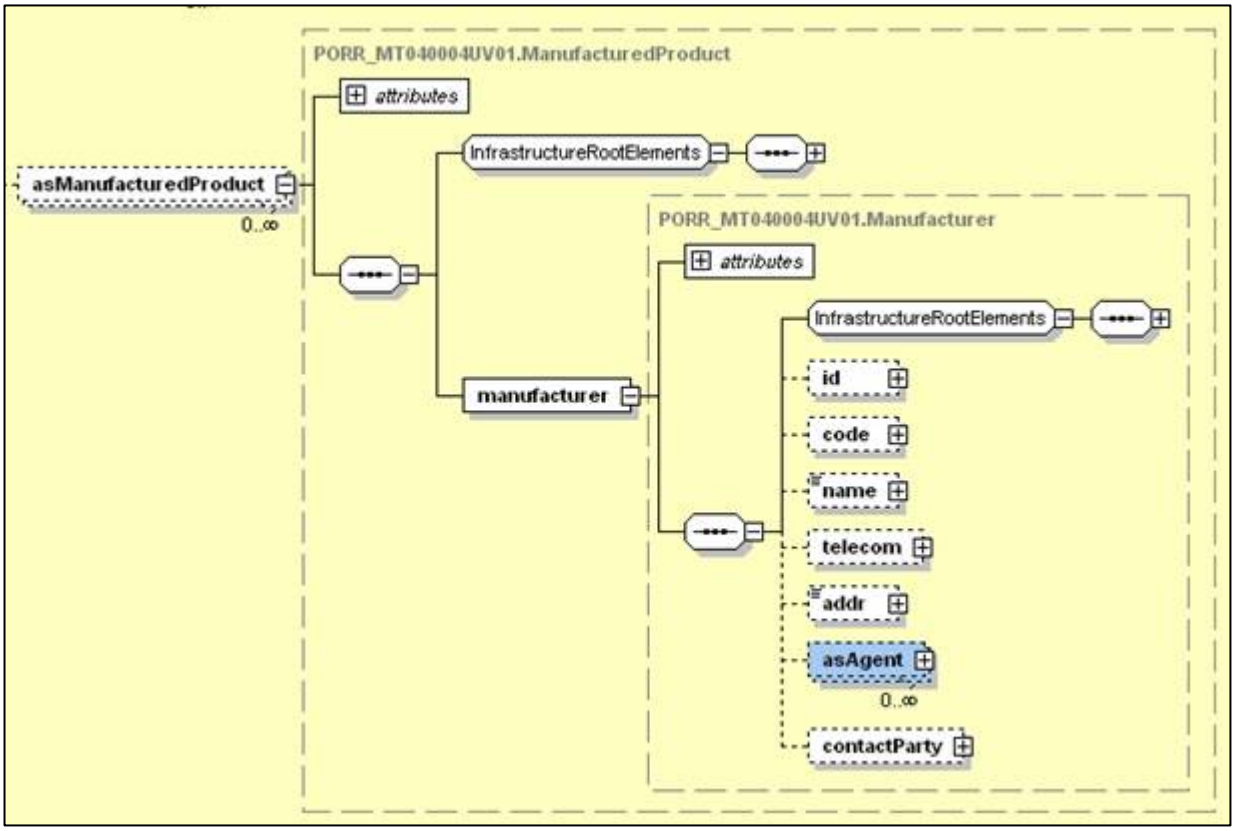


Medication Element Contents	
Element	Discussion
Attributes	**Values of the structural attributes are provided in the schema.**
Infrastructure Root Elements	**These elements are not used in the ICSR.**

code	**A coded indication of the type of medication that has been provided.**
name	**The name of the product, if there is a name different from the text associated with the actual medication code.**
desc	**A text description of the medication.**
formCode	**A coded indication of the dose form.**
lotNumberText	**The lot number assigned to the lot in which the medication item was distributed.**
expirationTime	**The date time after which the product is no longer considered effective.**
asRetailedProduct	**Expands to provide information about the retailer which sold the medication and the funding source used to pay for it.**
asManufacturedProduct	**Expands to provide information about and related to the manufacturer of the drug. This element is further explained elsewhere in the document.**
asEntityWithGeneric	**Expands to provide information about the generic name for the medication.**
ingredient	**Expands to provide information for active and inactive ingredients within the medication.**

18. Manufactured Product

The diagram shows the information collected for medication manufacturers.

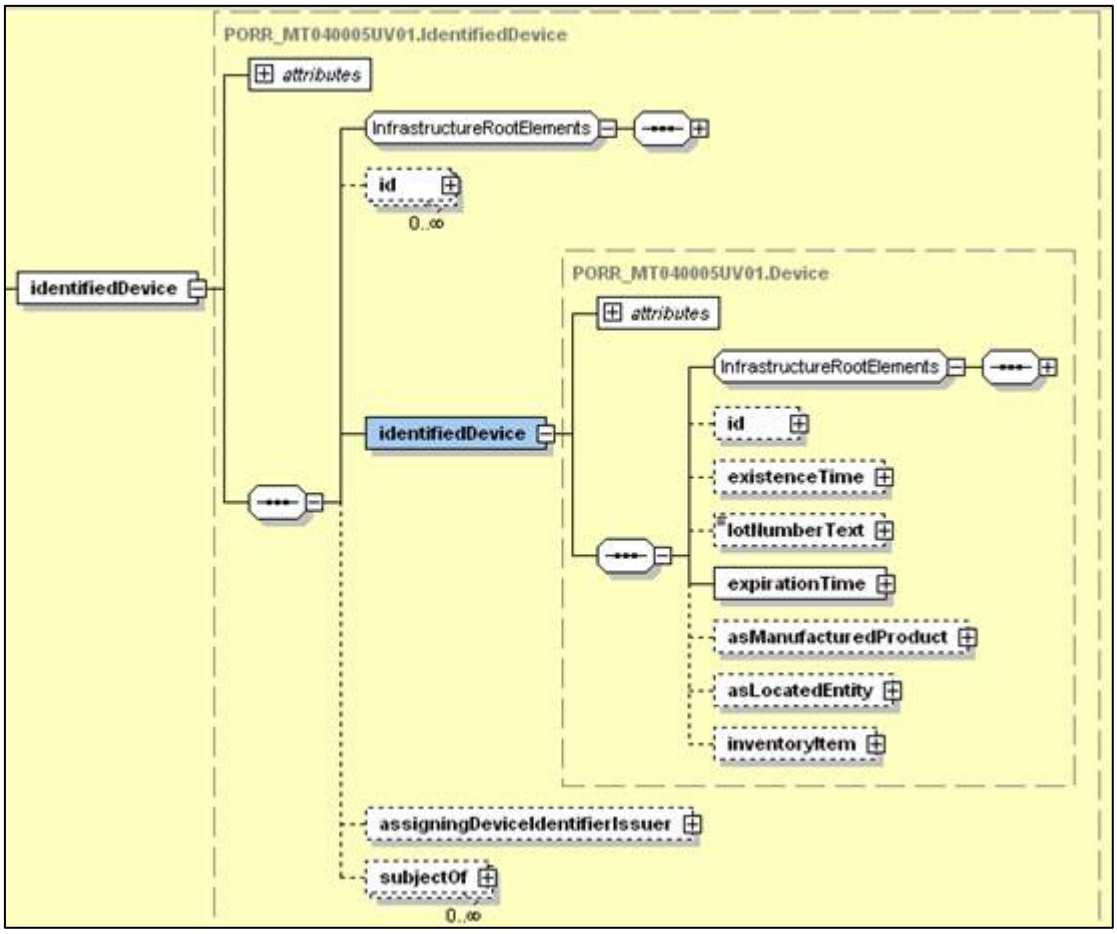


Manufactured Product Event Element Contents	
Element	Discussion
Manufactured Product Attributes	**Values of the structural attributes are provided in the schema.**
Manufactured Product Infrastructure Root Elements	**These elements are not used in the ICSR.**
Manufacturer Attributes	**Values of the structural attributes are provided in the schema.**
Manufacturer Infrastructure Root Elements	**These elements are not used in the ICSR.**
id	**Allows the sender to provide an identifier for the manufacturer.**
code	**Allows the inclusion of a code that indicates the organizational classification assigned to the manufacturer.**
name	**Provides the name of the manufacturer.**
telecom	**Provides a telephone number of the manufacturer.**
addr	**Provides a postal address for the manufacturer**
asAgent	**Expands to provide information about the sponsoring**

	organization in those cases in which the manufacturer produced the medication as an agent for another organization. Note, multiple layers of agency can be represented.
contactParty	**Expands to provide information – name, address, and phone number for a person who serves as a contact for the organization.**

19. Identified Device

The diagram provides the immediate information for a device which has been identified as involved in an adverse event related procedure, or in a product problem report.

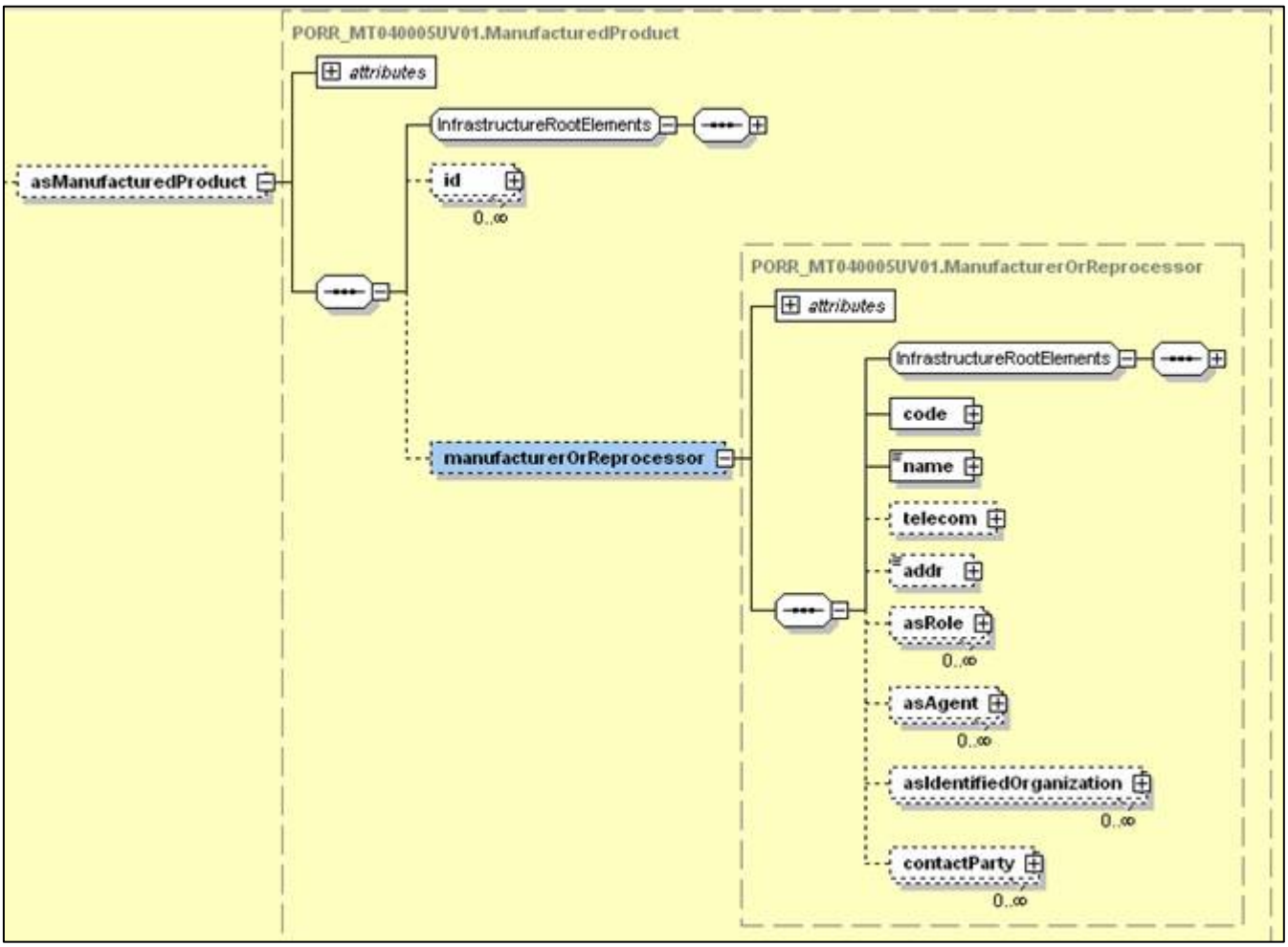


Identified Device Element Contents	
Element	Discussion
Identified Device Attributes	**Values of the structural attributes are provided in the schema.**
Identified Device Infrastructure Root Elements	**These elements are not used in the ICSR.**
Identified Device id	**Provides one or more identifiers that have been assigned to the device. When the ICSR is used to support FDA's MedWatch form, the "other identifiers" are mapped here.**
Device Attributes	**Values of the structural attributes are provided in the schema.**
Device Infrastructure Root Elements	**These elements are not used in the ICSR.**
Device id	**Provides an identifier for the material time as it plays the role of an identified device for medical uses. For the ICSR, this attribute is used to**

	capture the serial number attached to the device.
existenceTime	**The date time on which the device was manufactured.**
lotNumberText	**The lot number assigned to the lot that the device was distributed in.**
expirationTime	**The date time on which the device is considered too old for further use.**
asManufacturedProduct	**Expands to capture information about the manufacturer and/or reprocessor of the device. This element is further explained elsewhere in the document.**
asLocatedEntity	**Expands to capture information about a place at which the device is located.**
inventoryItem	**Expands to provide information about the device model. That is to say, information about the class of which this device is a particular instance. This element is further explained elsewhere in the document.**
Identified Device assigning Device Identifier Issuer	**Expands to provide information on the party assigning the identified Device id. This element is not currently used in ICSR messaging.**
Identified Device subjectOf	**This element expands to provide information on the regulatory approval that has been received to market the drug. Currently, the only item used from this structure is the approval id, e.g., NDA number, assigned by the regulatory authority.**

20. Manufactured Product

The diagram depicts the relevant information for the device manufacturer.

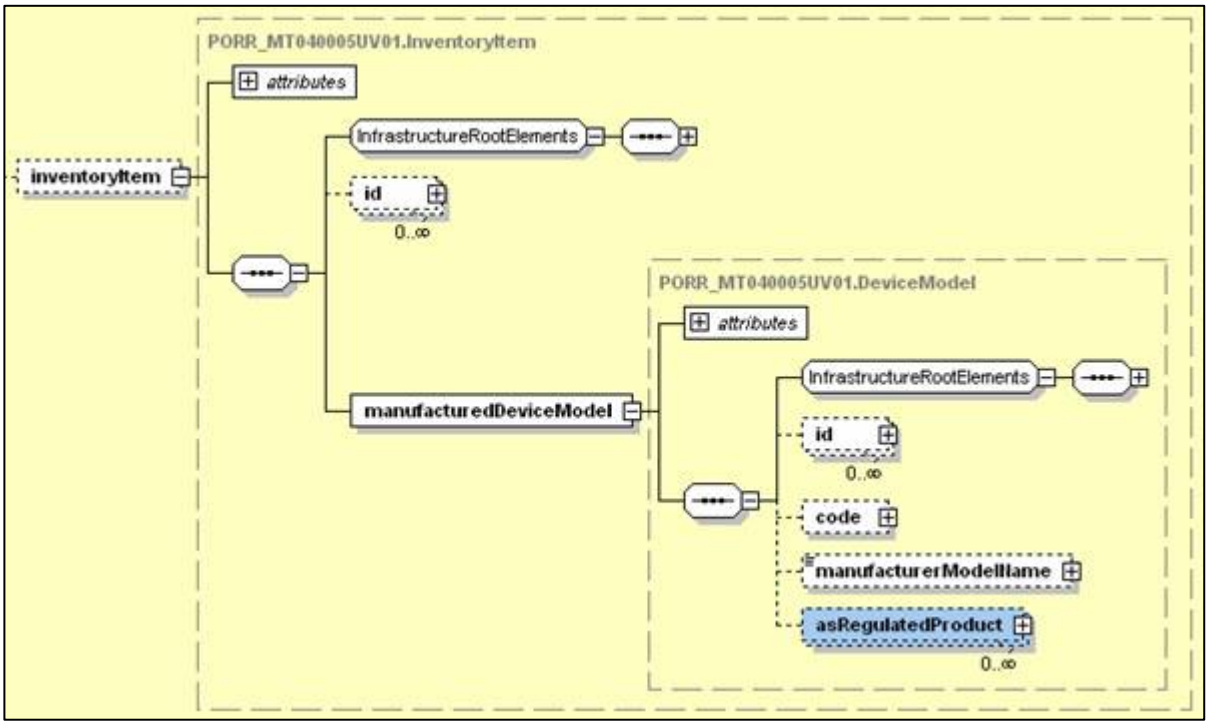


Manufactured Product Element Contents	
Element	Discussion
Manufactured Product Attributes	**Values of the structural attributes are provided in the schema.**
Manufactured Product Infrastructure Root Elements	**These elements are not used in the ICSR.**
Manufactured Product id	**Provides the identifier that the manufacturer assigns to the product. That is to say, the device catalog number.**
Manufacturer Attributes	**Values of the structural attributes are provided in the schema.**
Manufacturer Infrastructure Root Elements	**These elements are not used in the ICSR.**
code	**Allows the inclusion of a code that indicates the organizational classification assigned to the manufacturer. In the current ICSR, it is used to indicate whether the organization is acting as a manufacturer or as a reprocessor.**
name	**Provides the name of the manufacturer.**

	telecom	**Provides a telephone number of the manufacturer.**
	addr	**Provides a postal address for the manufacturer**
	asRole	**Expands to provide information about any investigation which the manufacturer or reprocessor performed on the suspect device. The structure supports observations to capture evaluation result, method, and conclusion codes.**
	asAgent	**Expands to provide information about the sponsoring organization in those cases in which the manufacturer produced the medication as an agent for another organization. Note, multiple layers of agency can be represented.**
	asIdentifiedOrganization	**Expands to allow the assignment of identifiers to the organization.**
	contactParty	**Expands to provide information – name, address, and phone number for a person who serves as a contact for the organization.**

21. Inventory Item

The diagram provides information about the device model – of which this device is an instance.



Inventory item Element Contents	
Element	Discussion
Inventory Item Attributes	**Values of the structural attributes are provided in the schema.**
Inventory Item Infrastructure Root Elements	**These elements are not used in the ICSR.**
Inventory Item id	**This element is not currently used in the ICSR.**
Device Model Attributes	**Values of the structural attributes are provided in the schema.**
Device Model Infrastructure Root Elements	**These elements are not used in the ICSR.**
Device Model id	**An identifier for the device model that identifies what kind of device it is. That is to say, the device model number**
code	**A coded indication of what kind of product this is, the product code.**
manfacturerModel Name	**The name assigned to the device model by the manufacturer.**
asRegulatedProduct	**Expands to provide information about the device type's approval by the regulatory authority.**

ICSR Data types

Data Type	Discussion
AD – Postal Address	Mailing and home or office addresses. A sequence of address parts, such as street or post office Box, city, postal code, country, etc. The AD data type is primarily used to communicate data that will allow printing mail labels, or that will allow a person to physically visit that address. Structurally, the postal address data type is a sequence of address part values with an added "use" code and a valid time range for information about if and when the address can be used for a given purpose.
ANY - Any	The ANY datatype serves as the base type for all the rest. Within a message, it appears directly as the datatype assigned to Observation.value. The following datatypes are supported in place of ANY: CE, INT, PQ, ST, TS. That is to say, the only types of observation value that are supported within ICSR messaging at this time, and that should be transmitted using the Notification Message, are , coded values, text, dates, date ranges, physical quantities, or integers. Note, null flavor is a property of the ANY datatype that is inherited by all the rest.
BL – Boolean	The Boolean type stands for the values of two-valued logic. A Boolean value can be either true or false, or, as any other value may be NULL.
CD – Concept Descriptor	A concept descriptor represents any kind of concept usually by giving a code defined in a code system. A concept descriptor can contain the original text or phrase that served as the basis of the coding and one or more translations into different coding systems. A concept descriptor can also contain modifiers to describe, e.g., the concept of a "left foot" as a post-coordinated term built from the primary code "FOOT" and the modifier "LEFT". In exceptional cases, the concept descriptor need not contain a code but only the original text describing that concept.
CE – Coded Element	Coded data consists of a coded value (CV) and, optionally, coded value(s) from other coding systems that identify the same concept. This datatype is used when alternative codes may exist.
CS – Coded Simple	Coded data in its simplest form consists of a code and display name. The code system and code system version is fixed by the context in which the CS value occurs. CS is used for coded attributes that have a single HL7-defined value set.
ED – Encapsulated Data	Data that is primarily intended for human interpretation or for further machine processing outside the scope of HL7. This includes unformatted or formatted written language, multimedia data, or structured information in as defined by a different standard (e.g., XML-signatures.) Instead of the data itself, an ED may contain only a reference Note that ST is a specialization of the ED where the mediaType is fixed to text/plain.
EN – Entity Name	A name for a person, organization, place or thing. A sequence of name parts, such as first name or family name, prefix, suffix, etc. Structurally, the entity name data type is a sequence of entity name part values with an added "use" code and a valid time range for information about if and when the name can be used for a given purpose.
II – Instance Identifie	An instance identifier is an identifier that uniquely identifies a thing or object. Examples are object identifier for HL7 RIM objects, medical record number, order id, service catalog item id, Vehicle Identification Number (VIN), etc. Instance identifiers are

r	defined based on ISO object identifiers. Some identifier schemes define certain style options to their code values. For example, the U.S. Social Security Number (SSN) is normally written with dashes that group the digits into a pattern "123-12-1234". However, the dashes are not meaningful and a SSN can just as well be represented as "123121234" without the dashes.
INT - Integer	Positive and negative whole numbers typically the results of counting and enumerating. The standard imposes no bounds on the size of integer numbers.
IVL<INT> Interval of Integers	HL7 has defined interval (IVL) as a generic datatype that can apply to any ordered datatype. An interval of integers makes it possible to provide both a lower and upper bound for an integer value.
IVL<TS> - Interval of Time Stamps	HL7 has defined interval (IVL) as a generic datatype that can apply to any ordered datatype. The notion of time stamp intervals includes open intervals, that is, where only start or stop dates are valued. It also includes duration periods of time without either start or stop date valued.
ON – Organization Name	A specialization of the EN datatype to only support organization names. It is a sequence of name parts. An organization name consists only of untyped name parts, prefixes, suffixes, and delimiters.
PN – Person Name	A specialization of the EN datatype to only support person names. A name part is a restriction of entity name part that only allows those entity name parts qualifiers applicable to person names. Since the structure of entity name is mostly determined by the requirements of person name, the restriction is very minor.
PQ – Physical Quantity	A dimensioned quantity expressing the result of measuring. As a result, both the quantity and the unit of measure are captured.
SC – Character String with Code	A character string that optionally may have a code attached. The text must always be present if a code is present. The code is often a local code. SC is used in cases where coding is exceptional (e.g., user text messages are essentially text messages, and a printable message is the important content. Yet, sometimes messages come from a catalog of canned messages, which SC allows to reference.
ST - String	The character string data type stands for text data, primarily intended for machine processing (e.g., sorting, querying, indexing, etc.) Used for names, symbols, and formal expressions. ST is a restricted ED whose data must be inlined and not compressed. Thus, the properties compression, reference, integrity check, algorithm, and thumbnail are not applicable. The character string data type is used when the appearance of text does not bear meaning, which is true for formalized text and all kinds of names.
SXCM_TS Set Component of Time Stamps	The timing specification suite of data types is used to specify the complex timing of events and actions such as those that occur in order management and scheduling systems. It also supports the cyclical validity patterns that may exist for certain kinds of information, such as phone numbers (evening, daytime), addresses (so called "snowbirds," residing closer to the equator during winter and farther from the equator during summer) and office hours.

	The timing specification data types include point in time (TS) and the interval of time (IVL_TS) and add types that are specifically suited to repeated schedules. These additional types include periodic interval, event-related periodic interval, and finally the general timing specification types itself. All these timing types describe the time distribution of repeating states or events.
TEL – Telecommunications Address	**A telephone number (voice or fax), e-mail address, or other locator for a resource mediated by telecommunication equipment. The address is specified as a Universal Resource Locator (URL) qualified by time specification and use codes that help in deciding which address to use for a given time and purpose.**
TS – Time Stamp	**A quantity specifying a point on the axis of natural time. A point in time is most often represented as a calendar expression. HL7 found it necessary to take special measures with this datatype since, for W3C, the timestamp data does not allow the expression of dates and date/times with variable levels of precision. Such an expression is a requirement for HL7. Essentially, the TS datatype contains a single component that can either express a date/time, a date, a year and month, or a year.**

HL7 Vocabulary Principles

The ability to rigorously specify the valid contents for a coded attribute is a key feature of the Version 3 specification. Within the RIM, and within each RMIM, the valid content for each coded attribute is specified through definition of a vocabulary domain. The vocabulary domain is a description of the set of all the concepts that can be taken as valid values for the attribute in question. When a specification is implemented, its implementation guide must define the value set which is used to support each vocabulary domain. A value set is a collection of codes, as defined within one or more coding systems, that serves to support the vocabulary domain in a particular concept. It is important to note that when a code is passed in an HL7 message, it is necessary to define the coding system it is drawn from. This is done in order to ensure unique identification of the concept that the code represents. HL7 defines a code system as "a scheme for representing concepts using short (usually) concept identifiers to denote the concepts that are members of the system. Examples of coding systems are ICD-9, LOINC and SNOMED. Code systems are often managed by third parties, especially when the systems capture complex and evolving clinical vocabularies.

A. Object Identifiers and Globally Unique Identifiers

An Object Identifier (OID) is a way to uniquely identify an object. It is a managed hierarchy supported by the International Standards Organization (ISO) and the International Telecommunications Union (ITU). ISO and ITU delegate OID management to other organizations by assigning them OID numbers. OIDs are intended to be globally unique, and are formed by taking a unique string and adding additional digits in a unique fashion. There is no limit to the length of an OID, and the computational burden to having a long OID is minimal. OIDs exist to provide a unique number, recognizing that in a decentralized world, organizations may pick the same identical names for objects that they manage. The Global Unique Identifier (GUID) is a unique 128- bit number that is produced by the Windows operating system or by some Windows applications to identify a particular component, application, database entry, file, and/or user. Acquiring and managing OIDs or GUIDs are outside the scope of this guide. The HL7 Object Identifier Registry should be referenced for further information on this topic at: http://www.hl7.org/oid/.

The HL7 ICSR will require the use of unique report numbers generated by senders. For example, manufacturers or user facilities may generate their own unique report identifiers that are consistently referenced in follow up reports. In order to retain the use of these unique IDs and support the ability to link initial and follow up reports in the safety database, the use of unique identifiers are required for the InvestigationEvent.id attribute. The InvestigationEvent.id can be created by using the root or arc OID that identifies a company, and then extended to include the Manufacturer Control Number (company's report ID), and additional extensions if required to reference follow up reports. Senders and receivers of the ICSR will need to negotiate the best methods for generating unique IDs between systems. FDA has not standardized a solution for representing unique report IDs at this time. However, CDRH eMDR Appendix

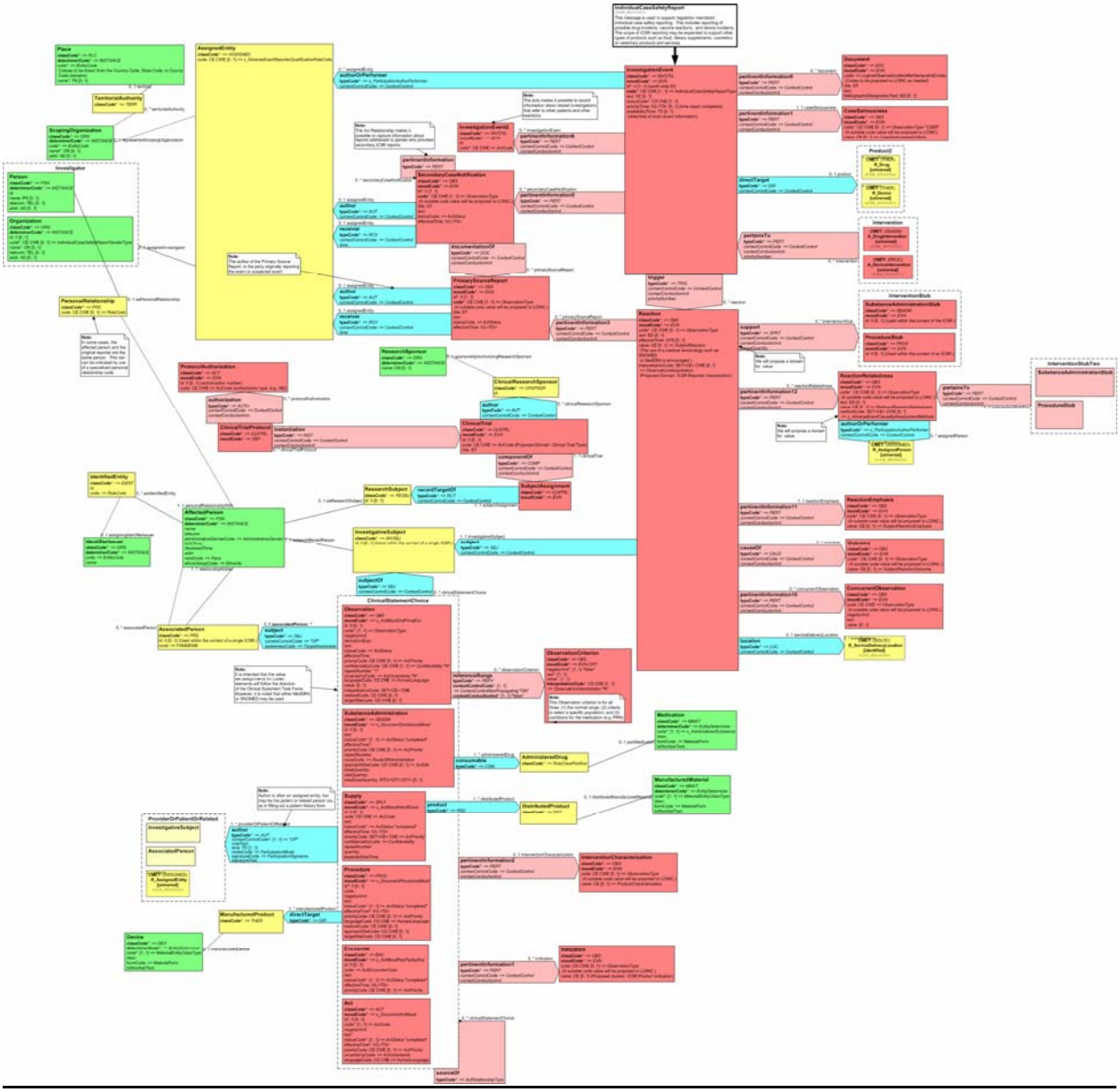
offers guidance on the generation of the report ID for testing purposes. As FDA gains more experience with implementation and pilot testing, FDA will issue guidance on how this ID should be generated for regulatory reporting.

B. HL7 ICSR Vocabulary

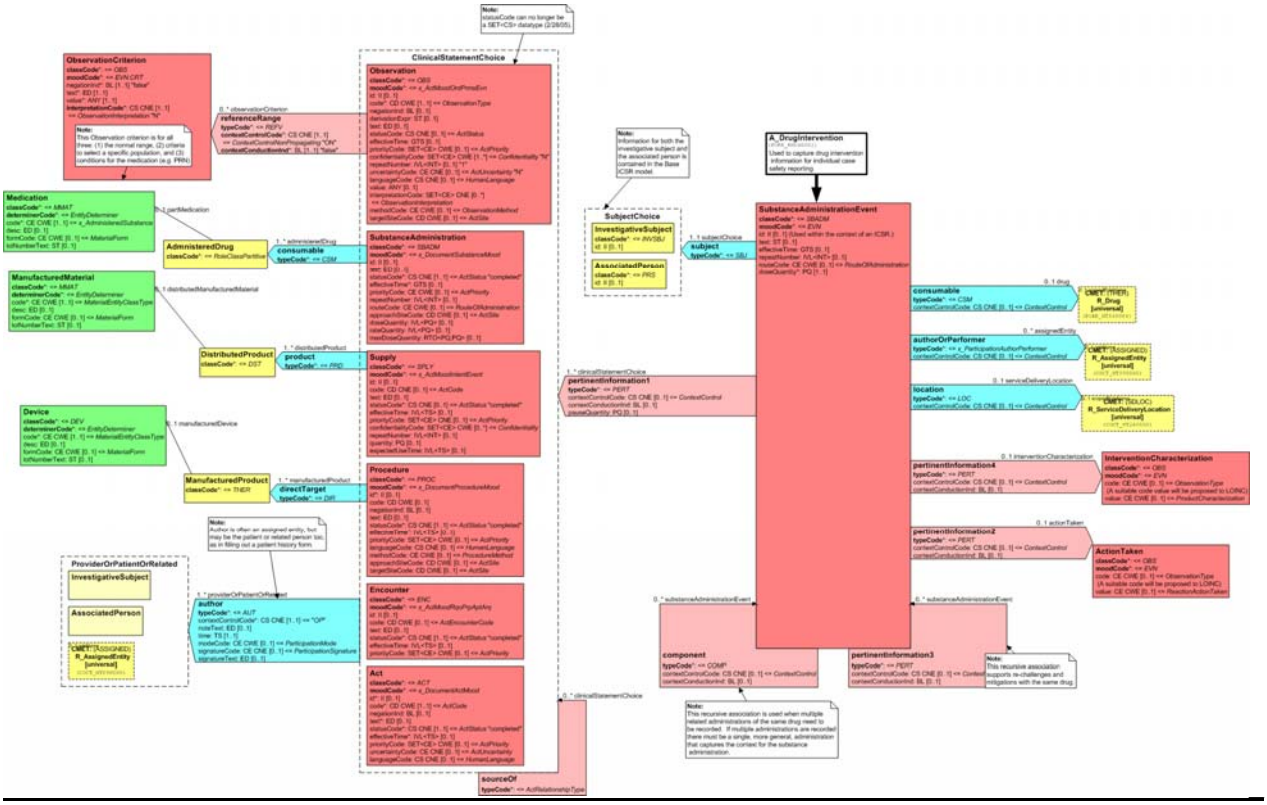
FDA has partnered with the National Cancer Institute (NCI) to develop and maintain clinical research terminology. NCI's Enterprise Vocabulary Service (EVS) will be used to support many of the ICSR terminology requirements. These terms are stored in the NCI Thesaurus, and access to the needed vocabularies (value sets) is maintained by NCI. The NCI EVS supports a download utility that can be used to access the collection of ICSR value sets, and other mandated FDA vocabulary, such as Manufacturer and User Facility Report ID numbers, will be available from the FDA website. Information about the NCI EVS and download utility can be found at: http://evs.nci.nih.gov/terminologies/. FDA supports and use of HL7 or ISO standardized terms for certain coded elements, such as race/ethnicity and country codes. This guideline provides the procedures for accessing FDA terms identified to support FDA reporting in Appendix F.

Organizations that are interested in using the HL7 ICSR for their internal reporting requirements are encouraged to use American National Standard Institute (ANSI), HL7, or International Standards Organization (ISO) approved vocabularies wherever possible. Since the HL7 ICSR was created to support a broad spectrum of reporters, it is expected that terms and/or codes for similar concepts may be captured using different code sets that meet the unique requirements of senders and receivers.

APPENDIX A: HL7 ICSR BASE REFINED MESSAGE INFORMATION MODEL (RMIM)

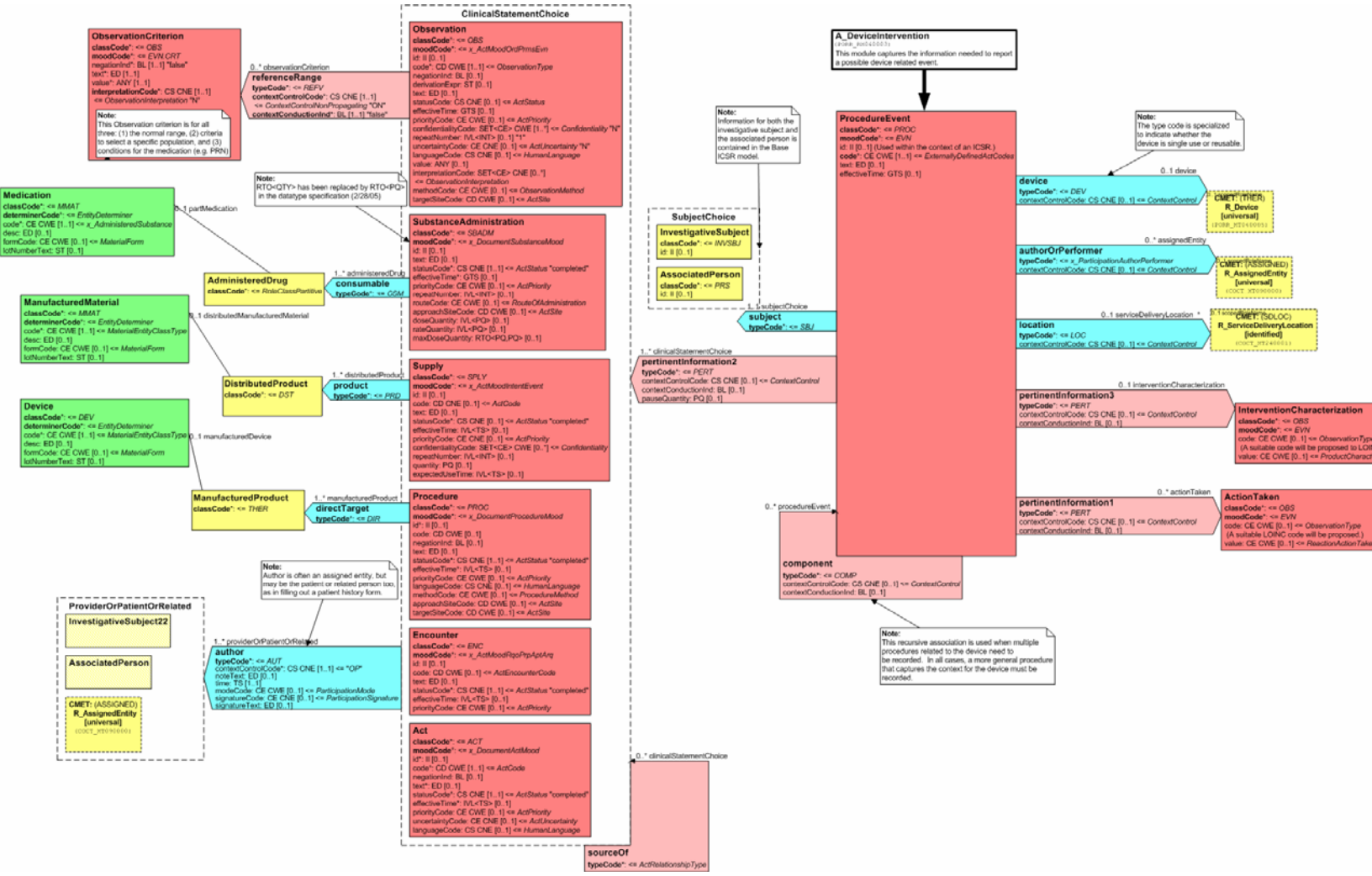


APPENDIX B: HL7 ICSR SUBSTANCE ADMINISTRATION RMIM
A_DrugIntervention

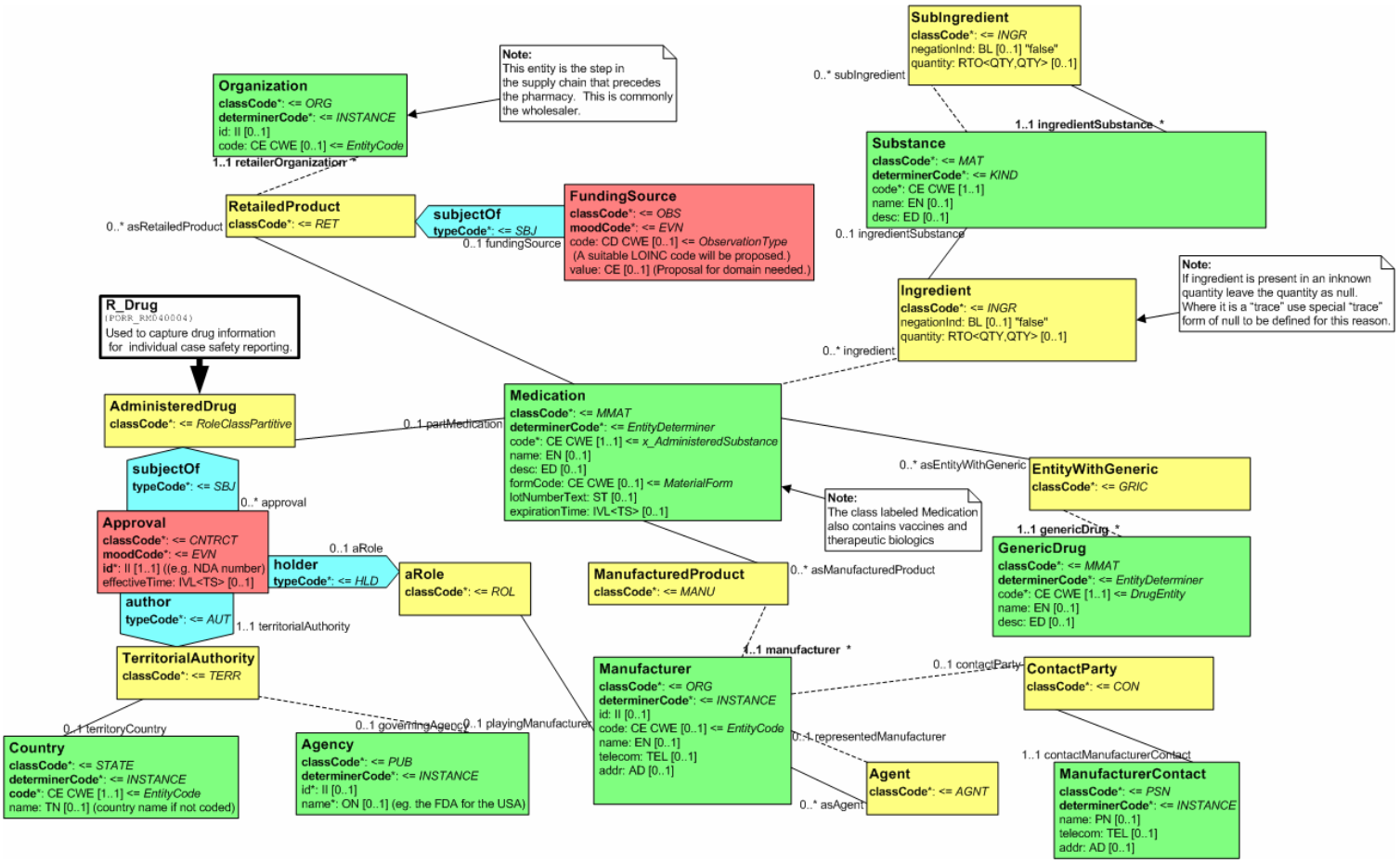


APPENDIX C: DEVICE PROCEDURE RMIM

A_DeviceIntervention

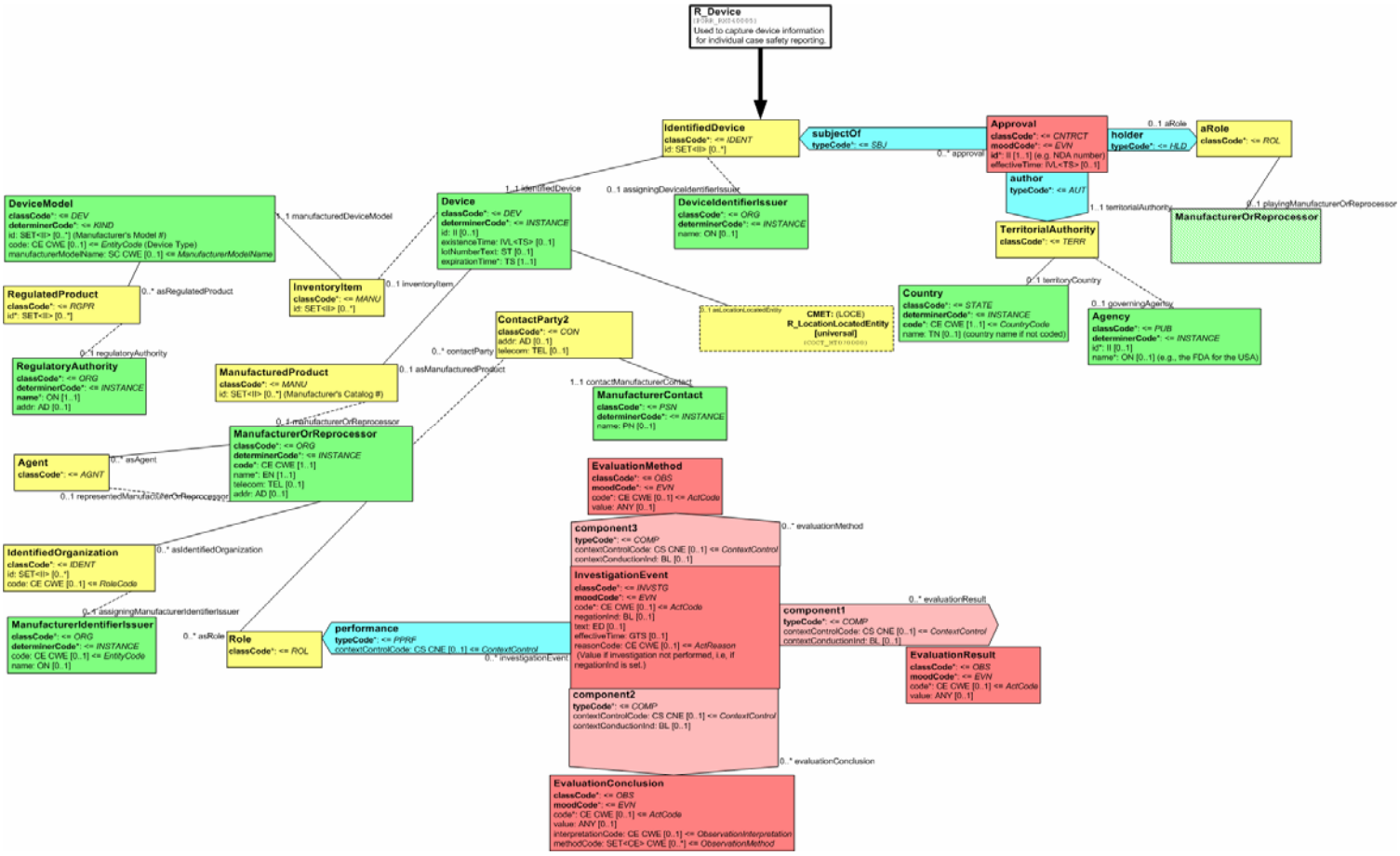


APPENDIX D: MEDICATION INFORMATION RMIM:
R_Drug



APPENDIX E: DEVICE INFORMATION RMIM:

R_Device



APPENDIX F: NCI ENTERPRISE VOCABULARY SERVICE

(May 23, 2006 version, on ways to access FDA and other subsets that are in NCI Thesaurus)

Table of Contents

The NCI Thesaurus contains a growing number of terminology subsets from the FDA, CDISC and other groups including:

- Patient codes
- Medical device components and accessories
- Routes of administration
- Package type
- Dosage form
- Individual Case Safety Report (ICSR)
- Unit of potency
- Structured Product Labeling Color
- Structured Product Labeling Shape
- Structured Product Labeling DEA Schedule

There are several ways of accessing the subset terminologies which include:

- Using the Report Writer
- Using the Application Programming Interfaces (APIs)
- Using the NCI Terminology Browser

Using the Report Writer

The Report Writer is a desktop java application that retrieves concept data from the production version of the NCI Thesaurus terminology. It is run from a console (i.e. DOS window), as opposed to a GUI (Graphical User Interface), and accepts input parameters from the command line.

The application file, named **ReportWriter.zip**, is available from the anonymous FTP site here:
ftp://ftp1.nci.nih.gov/pub/cacore/EVS/fda/

The application will:

- Retrieve all concepts in any **Subset**
    - Concepts in every Subset will be identified by the **Concept_In_Subset** association.
    - The Report Writer application will retrieve a **complete list of the available Subsets** from the terminology server and display them.
    - From this list the user will **choose the desired Subset**
    - The Report Writer application will **retrieve all of the concepts in the selected Subset** and display them.
- The Report Writer application will generate a concept report for each of the concepts selected above, including:
    - Preferred Name
    - NCI Concept Code
    - Definition

    - Comment
- The detailed concept report will contain comma separated text, which is easily loaded into Excel and databases.

Additional details on how to install and run the Report Writer can be found in the **ReadMe.txt** file that is contained in the **ReportWriter.zip** download.

See **Appendix I** below for a list of current subsets (as of May 17, 2006).

Using the Application Programming Interfaces (APIs)

The most flexible way for software developers to access the FDA terms in the NCI Thesaurus is to use the application programming interfaces (APIs).

Programmers will find the required information in the:

- **caCORE Technical Guide**:
  ftp://ftp1.nci.nih.gov/pub/cacore/caCORE2.0_Tech_Guide.pdf

- **caCORE Technical Supplement**:
  ftp://ftp1.nci.nih.gov/pub/cacore/caCORE3.0.1_Tech_Supp.pdf

- **Release notes**: http://ncicb.nci.nih.gov/core/caCORE3.0.1_notes.txt

The **client side APIs** and **JavaDocs** are available for download here:
http://ncicb.nci.nih.gov/download/downloadcabio.jsp

Technical support is also provided at: http://ncicbsupport.nci.nih.gov/sw/

Using the NCI Terminology Browser

The **NCI Terminology Browser** can also be used to access a subset terminology. However, there is a ***maximum display limit of 250*** concepts. Therefore, this method is best used for subsets smaller than 250, or searching for specific, individual concepts.

The NCI Terminology Browser is located on the Web:

http://nciterms.nci.nih.gov/NCIBrowser/Dictionary.do

The NCI Thesaurus is already selected as the default on this page. To enter the search area:

- Click the **Connect** button at the bottom of the screen.

Current Retrieval Methods

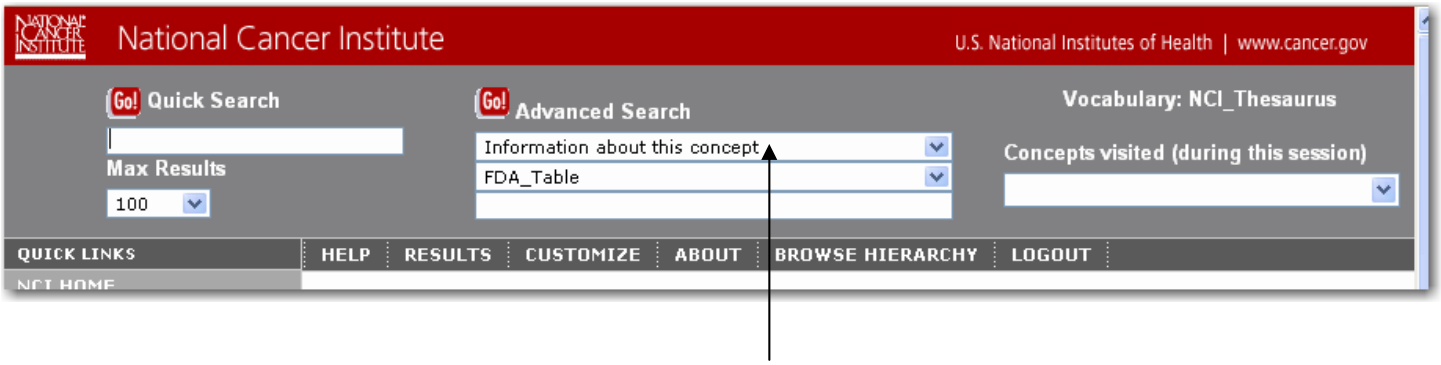
There are currently two main ways to access subset terms within the Terminology Browser:

1. Advanced Search
2. Browse the Tree Hierarchy

Advanced Search

Using one of the following properties:

- **FDA_Table**
- **FULL_SYN**
- **Concept_In_Subset**



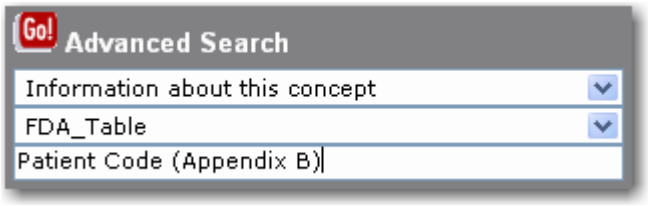
As you can see above there are three drop-down lists under **Advanced Search**:

- In the **first box** is the selection "Information about this concept". Leave that as the selection.
- In the **second box** select **FDA_Table** or **FULL_SYN** from the drop-down list.
- In the **third box**, enter the text or number you wish to retrieve.
- When your search terms are entered, click the **Go!** button next to Advanced Search.

Searching the FDA_Table property:

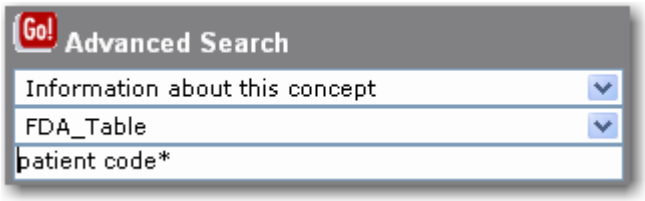
- In the second drop-down box, choose **FDA_Table**
- In the third box, enter the full name of the concept you wish to retrieve.

For example: Patient Code (Appendix B)



You can also use the wildcard character * along with part of the name of the concept you wish to retrieve.

For example: patient code*



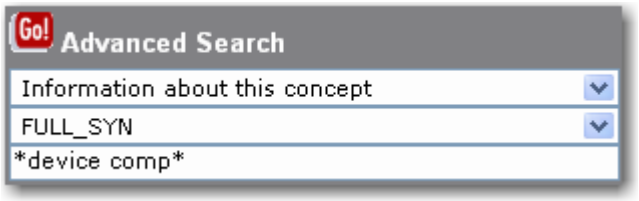
- After entering your search term(s), Click the **Go!** button.

NOTE: A maximum of 250 search results can be retrieved by using the **Max Results** drop-down list on the left-hand side of the page.

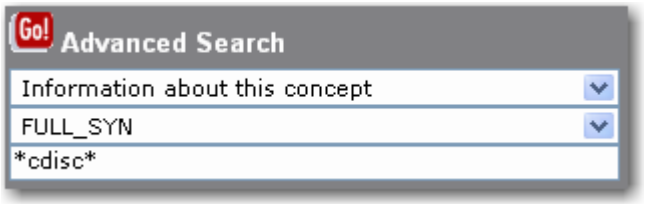
Searching the FULL_SYN property:

- In the second box, choose **FULL_SYN**
- In the third box, enter the search term or partial term with wildcard * that you wish to retrieve. You can use the wildcard on both the left and right of the partial search terms.

  For example, to retrieve device component terms, enter: *device comp*



Or, to retrieve CDISC terms, enter: *cdisc*



- After entering your search term(s), Click the **Go!** button.

NOTE: A maximum of 250 search results can be retrieved by using the **Max Results** drop-down list on the left-hand side of the page.

Searching the Concept_In_Subset association:

The **Concept_In_Subset** association will establish a semantic relation between the concept defining a particular subset and all concepts that are supposed to belong to this subset. This can be used by terminology subset owners and users to retrieve the list of the concepts that belong to a particular subset of terminology.

For example, the following subset exists as a concept in the NCI Thesaurus:

Medical_Device_Component_or_Accessory_Terminology

The full list of medical device components could then be retrieved by specifying the Medical_Device_Component_or_Accessory_Terminology_CDRH concept using the Concept_In_Subset association via the existing **API** or the **Report Writer** program.

The **Advanced Search** in the NCI Terminology Browser can also be used to retrieve this information:

- In the first drop-down box, choose **Associations**
- In the second drop-down box, choose **Concept_In_Subset**; and
- In the third box, enter all or part of the subset name you wish to retrieve.
  For example: medical device component*

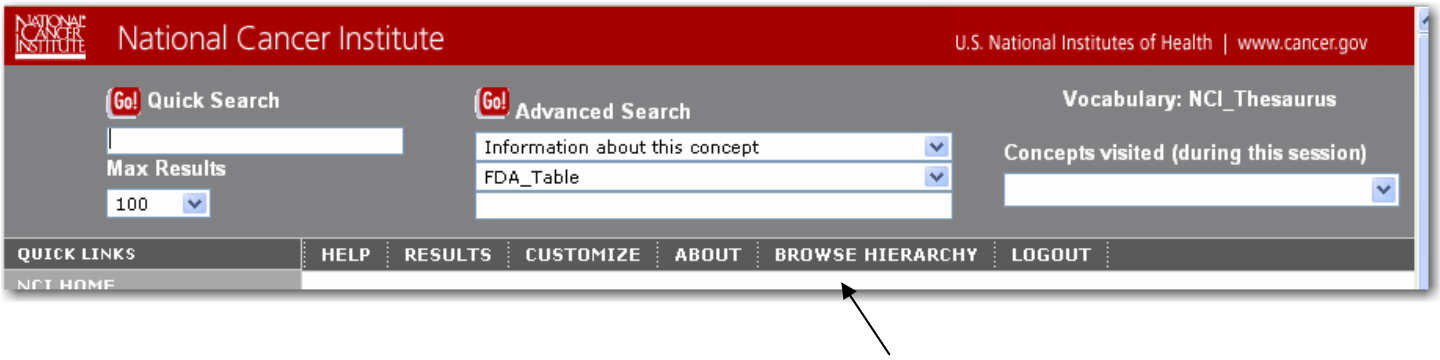
- After entering your search term(s), Click the **Go!** button.

The list of results shows the concepts that are in the Medical_Device_Component_or_Accessory_Terminology_CDRH subset.

Availability: The Concept_In_Subset association is available starting with the 06.04d version of the NCI Thesaurus.

NOTE: A maximum of 250 search results can be retrieved by using the **Max Results** drop-down list on the left-hand side of the page.

Browse the Tree Hierarchy



Another way to view specific terms within the vocabulary is to use the **Browse Hierarchy** option. This is a hierarchical display of all the concepts in the vocabulary.

To access the tree display:

- Click on the **Browse Hierarchy** button in the display (located underneath the Advanced Search area.)
- A separate window will open, showing the top-most concepts in each of the vocabulary's main subdivisions.
- If you wanted to browse for certain types of equipment, for example, you would click on the plus sign next to the term **Diagnostic, Therapeutic, and Research Equipment**.

  The tree would expand, and you would see a display that starts liked this:

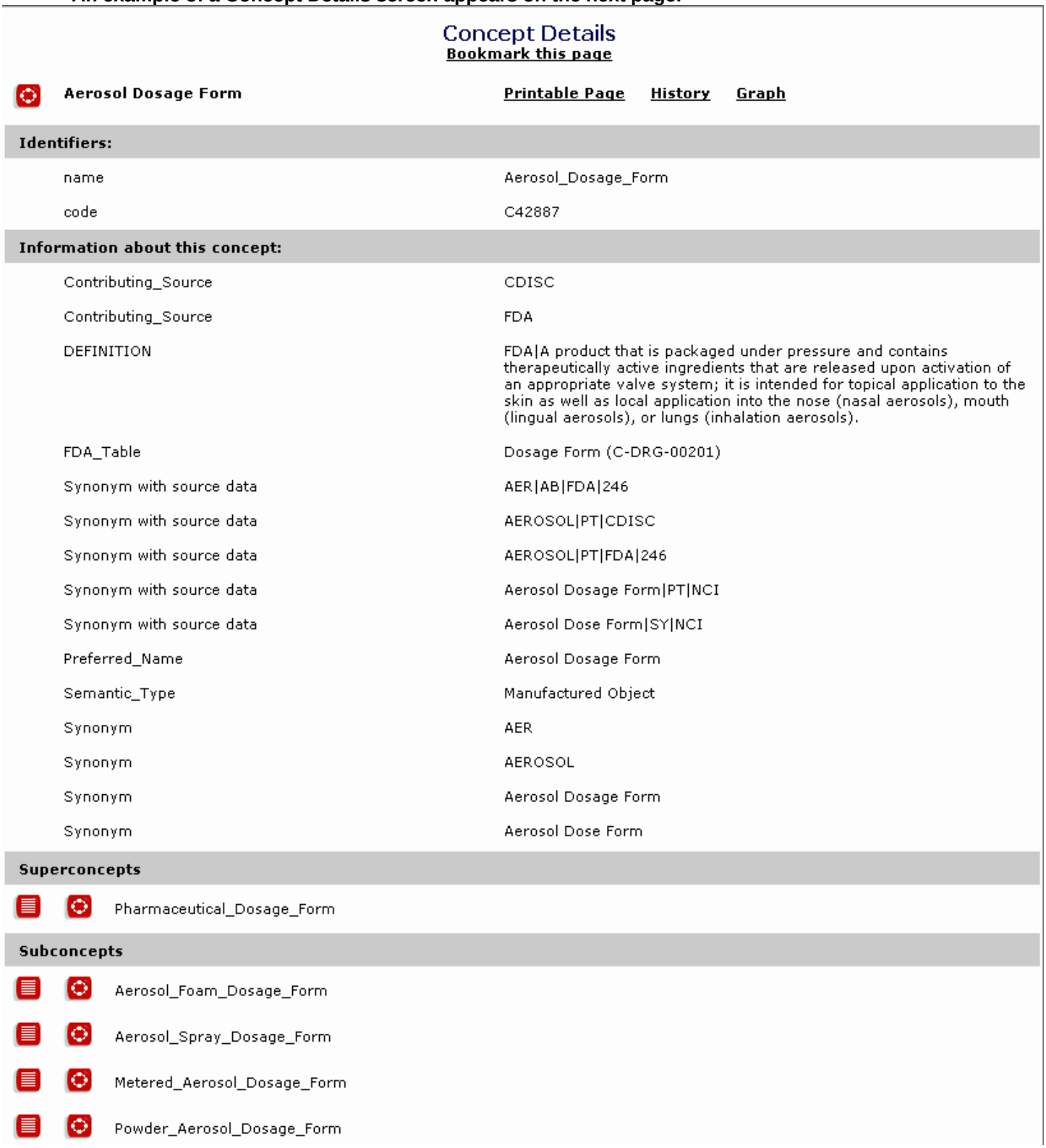
- To open up a full concept record in the main window, click on the **red Concept Details icon** to the left of the concept.
- Or, click on a plus sign in the hierarchy window to view terms further down in the hierarchy.

In the main window, the full concept record shows all of the details about a given concept including:

- Definition
- Synonyms
- Subconcepts
  - This section lists all of the concepts contained under the concept you are viewing. This is an alternate way to view what terms are contained in a given subset.

- Keep in mind that a subconcept may have other concepts underneath it in the hierarchy that are not shown here. To view them, click on the concept details record next to a given subconcept, or browse the tree hierarchy to open up the terminology list further.

An example of a Concept Details screen appears on the next page.



Concept Details

Bookmark this page

Aerosol Dosage Form Printable Page History Graph

Identifiers:	
name	Aerosol_Dosage_Form
code	C42887
Information about this concept:	
Contributing_Source	CDISC
Contributing_Source	FDA
DEFINITION	FDA|A product that is packaged under pressure and contains therapeutically active ingredients that are released upon activation of an appropriate valve system; it is intended for topical application to the skin as well as local application into the nose (nasal aerosols), mouth (lingual aerosols), or lungs (inhalation aerosols).
FDA_Table	Dosage Form (C-DRG-00201)
Synonym with source data	AER|AB|FDA|246
Synonym with source data	AEROSOL|PT|CDISC
Synonym with source data	AEROSOL|PT|FDA|246
Synonym with source data	Aerosol Dosage Form|PT|NCI
Synonym with source data	Aerosol Dose Form|SY|NCI
Preferred_Name	Aerosol Dosage Form
Semantic_Type	Manufactured Object
Synonym	AER
Synonym	AEROSOL
Synonym	Aerosol Dosage Form
Synonym	Aerosol Dose Form

Superconcepts

Pharmaceutical_Dosage_Form

Subconcepts

Aerosol_Foam_Dosage_Form

Aerosol_Spray_Dosage_Form

Metered_Aerosol_Dosage_Form

Powder_Aerosol_Dosage_Form

Terminology_Subset Concepts

The following is a listing of the concepts under the **Terminology_Subset** concept of the NCI Thesaurus. The numeric prefix is an indication of their tree placement. This listing was generated on May 17, 2006; the number of concepts in this branch of the NCI Thesaurus is expected to change/grow in future releases.

1 Individual_Case_Safety_Report_Terminology
1.1 Adverse_Event_Outcome_ICSR_Terminology
1.2 Device_Usage_ICSR_Terminology
1.3 Location_Of_Event_Occurrence_ICSR_Terminology
1.4 Occupation_ICSR_Terminology
1.5 Operator_of_Medical_Device_ICSR_Terminology
1.6 Reason_For_Non-Evaluation_ICSR_Terminology
1.7 Report_Source_ICSR_Terminology
1.8 Type_Of_Follow-Up_ICSR_Terminology
1.9 Type_Of_Manufacturer_ICSR_Terminology
1.10 Type_Of_Remedial_Action_ICSR_Terminology
1.11 Type_Of_Report_ICSR_Terminology
1.12 Type_Of_Reporter_ICSR_Terminology
1.13 Type_of_Event_ICSR_Terminology
1.14 Type_of_Reportable_Event_ICSR_Terminology
2 Medical_Device_Component_Or_Accessory_Terminology_CDRH
3 Medical_Device_Problem_Codes_FDA_CDRH
4 Patient_Problem_Codes_FDA_CDRH
5 Structured_Product_Labeling_Terminology
5.1 Limitation_Of_Use_Structured_Product_Labeling_Terminology
5.2 Pharmacokinetic_Effect_Consequences_Structured_Product_Labeling_Terminology
5.3 Structured_Product_Labeling_Color_Terminology
5.4 Structured_Product_Labeling_DEA_Schedule_Terminology
5.5 Structured_Product_Labeling_Drug_Route_of_Administration_Terminology
5.6 Structured_Product_Labeling_Medical_Product_Intent_Of_Use_Terminology
5.7 Structured_Product_Labeling_Package_Type_Terminology
5.8 Structured_Product_Labeling_Pharmaceutical_Dosage_Form_Terminology
5.9 Structured_Product_Labeling_Potency_Terminology
5.10 Structured_Product_Labeling_Shape_Terminology
5.11 Structured_Product_Labeling_Type_Of_Drug_Interaction_Consequence_Terminology

HL7 Version 3

Introduction HL7 Version 3

This section provides an introduction to HL7 Version 3. It addresses the role of HL7 in providing a means for FDA to improve data transfer with its customers, and includes brief discussions of key HL7 concepts.

Health Level Seven: Standards Development Organization

HL7's mission is to provide standards for the exchange, management and integration of data that supports clinical patient care and the management, delivery and evaluation of healthcare services. Specifically, to create flexible, cost effective approaches, standards, guidelines, methodologies, and related services for interoperability between healthcare information systems.

HL7 is one of several ANSI-accredited Standards Developing Organizations (SDOs) operating in the healthcare arena. Most SDOs produce standards (sometimes called specifications or protocols) for a particular healthcare domain such as clinical data, pharmacy, medical devices, imaging or insurance (claims processing) transactions. Health Level Seven's domain is clinical and administrative data.

HL7 is a not-for-profit volunteer organization. Its members - providers, vendors, payers, consultants, government groups, pharmaceutical and others who have an interest in the development and advancement of clinical and administrative standards for healthcare - develop the standards. Like all ANSI-accredited SDOs, HL7 adheres to a strict and well-defined set of operating procedures that ensure consensus, openness and balance of interest. A frequent misconception about HL7 (and presumably about the other SDOs) is that it develops software. In reality, Health Level Seven develops specifications; the most widely used being a messaging standard that enables disparate healthcare applications to exchange key sets of clinical and administrative data.

Health Level Seven Version 3

The development of HL7 Version 3 is based on experience with its predecessor – HL7 Version 2. Like the different editions of Version 2, Version 3 is a standard for exchanging messages among information systems that implement healthcare applications. However, V3 strives to improve the V2 process and its outcomes. The original process for defining HL7 messages was established in 1987, and has served well since. However, as HL7 membership grew and its standards became more widely used, HL7 has become aware of opportunities to revolutionize healthcare interface computing. The need for a more robust expression of the standard became more important as HL7 expanded its scope to include areas such as adverse event reporting that go beyond the scope of traditional healthcare applications.

The experience with HL7 Version 2, led implementers to voice a wide range of criticisms, which centered on Version 2's lack of a clear design methodology, its use of HL7 custom encoding rules for messaging, and its lack of attention to vocabulary issues.

By contrast, Version 3 is characterized by:

- The use of a formal design methodology that aims to minimize ambiguity within the contents of the standard
- Development of procedures for specifying messages and implantation guides that minimize the use of optional elements within messages.
- The use of rigorous modeling during the development of specifications to ensure consistency across the standard, and to enable mapping to and convergence with other healthcare standards.
- The rigorous definition of vocabularies to assure clear communication.
- The use of industry standard encoding – XML (extended Markup Language) - for representing message instances.

The Message Specification and its Contents

In order to use HL7 specifications, it is necessary to understand the varied array of components (HL7's documentation calls these "artifacts"), that make up the standard. All of these are based on HL7's fundamental paradigm – which is expressed in the diagram below:

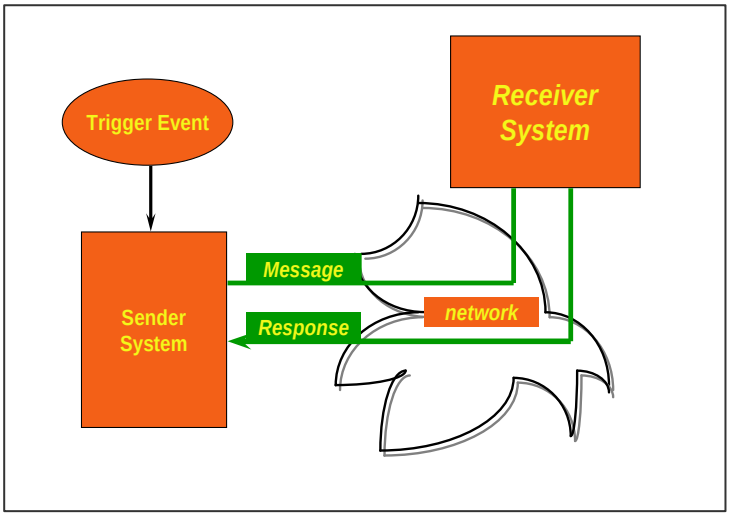


Figure 1. Fundamental Paradigm of HL7

In HL7 messaging, a system detects a trigger event, and, based on the trigger event sends a message to a receiver system over a network (whose behavior is specified externally to the standard) the receiver may – based on the requirements of the given situation – provide a response which is then transmitted to the sender.

In HL7 Version 3, the components of this fundamental paradigm are formally expressed, (The ins and outs of the methodology for developing the components is documented in the HL7 Development Framework). The HL7 ballot packages and Normative Editions document the particular components needed to express the requirements of the individual messaging domains.

Documenting Requirements

Within the Version 3 specifications, the requirements for messaging are documented in the form of storyboards. A storyboard is a concrete description of a situation in which data exchange through messaging is required.

HL7 Dynamic Model

Within HL7 Version 3, the "dynamic model" provides information about the types of systems that exchange information, and the events that trigger message transmission. Within the standard the contents of this model are defined through the creation of "interactions". An interaction defines the movement of information between sender and receiver application roles that take place after detection of a trigger event, and that may imply a receiver responsibility. These notions are defined as follows:

- Application Role: A way of describing message sender and/or receiver so as to only focus on message related behavior.
- Trigger Event: According to the HL7 Glossary: "An event which, when recorded or recognized by an application, indicates the need for an information flow to one or more other applications." The trigger event initiates the process of message exchange.
- Receiver Responsibility: According to the HL7 Glossary: "An obligation on an application role that receives an interaction". Receiver responsibilities are optional; the need for a receiver responsibility is based on the storyboard behind the interaction being supported.
- Interaction: The notion of interaction ties together the concepts expressed above. According to the HL7 Glossary: "A single, one-way information flow that supports a communication requirement" as defined by a storyboard. An interaction is also associated with a payload – a particular static information structure as described below.

HL7 Message Contents

As noted above, each interaction is associated with a specific message structure. There are three critical aspects to that structure.

Derivation from a Central Source

All HL7 Version 3 messages draw their content from a common model – the Reference Information Model. Having a single model that provides the starting point for data definition ensures consistency across the body of HL7 models. When the specification for a particular purpose, e.g., the Individual Case Safety Report, is developed, it is constructed in such a way that the resulting model is fully consistent with and derived from the Reference Information Model. The model that is developed, known as a Refined Message Information Model (RMIM) uses the base classes from the RIM: Act, Act Relationship, Entity, Role, and draws on the attributes that have been defined for those classes.

Common structures for Messaging

All HL7 Version 3 messages include data content that is specific to that message – its "payload", as well as two common structures known as "wrappers". The diagram below illustrates this notion. You should note that, in an XML instance, the content of the wrappers appears exactly that way. Given the hierarchical nature of an XML instance the wrapper comes both before and after the contents of the payload.

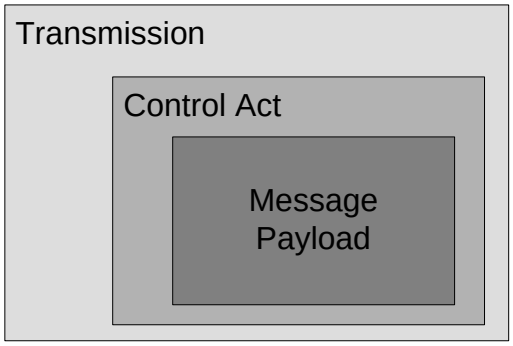


Figure 2: Transaction Components

We can describe these transaction components as follows:

- Transmission Wrapper: contains information that relates directly to the transmission from sender to receiver. E.g., date of message transmission, message id. This is information that would traditionally be captured in a "message header".

- Control Act Wrapper: contains information that directly relates to the trigger event. According to the discussion in the HL7 standard: "the 'Trigger Event Control Act' contains administrative information related to the 'controlled act' which is being communicated as a messaging interaction. A Trigger Event Control Act describes the 'action' that is happening to the subject of the message (the payload). ..(It) contains details about the trigger event for the message such as who, when, where and why. In general, the Trigger Event Control Act Infrastructure is intended to promote the reuse of similar structures that are used for the same type of interactions across the domains that contribute content to the HL7 Version 3 messaging standard."

- Message Payload: contains the material specific to a transaction, i.e., to a given functional requirement. The discussion of the ICSR model provides details on the contents of the message payload for adverse event reporting.

Common modules within the message structures

HL7 Version 3 goes to great lengths to prevent independent descriptions of the same concept in different HL7 models (or message specifications). The chief tool to achieve this goal is the use of Common Message Element Types (CMETs). CMETs are created to model data structures, e.g., patient, service location, organization, that appears over and over again in the requirements for messaging. A CMET is best though of as a model fragment that is inserted into another model in a similar manner to the way those subroutines are used in computer programming. CMETs are used in all three types of HL7 transaction component. When implementers work with the schemas that implement the HL7 specifications, it is necessary to keep track of the CMETs that appear within the message model, since that content must be taken into account as well as that of the base model.

Vocabulary

The ability to rigorously specify the valid contents for a coded attribute is a key feature of the Version 3 specification. Within the RIM, and within each RMIM, the valid content for each coded attributes is specified through definition of a vocabulary domain. The vocabulary domain is a description of the set of all the concepts that can be taken as valid values for the attribute in question. When a specification is implemented, its implementation guide must define the value set which is used to support each vocabulary domain. A value set is a collection of codes, as defined within one or more coding systems, that serves to support the vocabulary domain in a particular concept. It is important to note, that, when a code is passed in an HL7 message, it is necessary to define the coding system it is drawn from. This is done in order to ensure unique identification of the concept that the code represents.

Data Types

Each attribute within the RIM and within each model derived from it is assigned a data type which defines the meaning or semantics of the values that can be assigned to the attribute. The data types that are used, also serve to encapsulate complexity and, as a result, allow the HL7 models appear less complicated then they really are. In particular, it is essential to realize that the data types used within HL7 are not the atomic data types familiar to database developers. Instead, HL7 data types can encompass complex notions such as postal address, clinical concept, and order frequency. The HL7 Normative edition notes:

> “According to ISO 11404, a data type is "a set of distinct values, characterized by properties of those values and by operations on those values." A data type has intension and extension. Intentionally, the data type defines the properties exposed by every data value of that type. [That is to say, it is defined by describing the kinds of characteristics that are allowed] Extensionally, data types have a set of data values that are of that type (the type's "value set"). [That is to say, it is defined by listing possible values.]
>
> Semantic properties of data types are what ISO 11404 calls "properties of those values and [...] operations on those values." A semantic property of a data type is referred to by a name and has a value for each data value. The value of a data value's property must itself be a value defined by a data type - no data value exists that would not be defined by a data type.
> Data types are thus the basic building blocks used to construct any higher order meaning: messages, computerized patient record documents, or business objects and their transactions.”

APPENDIX H: FDA CDRH eMDR IMPLEMENTATION GUIDE

Center for Devices and Radiological Health

eMDR – electronic Medical Device Reporting
Health Level 7 (HL7) Individual Case Safety Report (ICSR)
Implementation Guide for Medical Devices
DRAFT
v1.1

June 27, 2006

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Contents

Section I – Introduction

This appendix is a companion guide to the HL7 ICSR Implementation Guide that provides unique guidance for implementing the ICSR for medical device reporting via CDRH's electronic Medical Device Reporting (eMDR) project.

The document below is divided into two sections. The business section is geared for business and non-technical audiences. It provides a brief overview of the various concepts without going into the technical details. The technical section is geared for technical and information technology audience and provides technical details of the implementation.

Section II – Business Section

The purpose of this section is to provide an overview of HL7, the ICSR and explain the electronic reporting initiative in CDRH, eMDR. This section also briefly explains the advantages of reporting using a standard electronic message.

A. Health Level Seven: Standards Development Organization

HL7 is a not-for-profit volunteer organization. Its members all assist in standards development and include: providers, vendors, payers, consultants, government groups, pharmaceutical and others who have an interest in the development and advancement of clinical and administrative standards for healthcare. Like all ANSI-accredited SDOs, HL7 adheres to a strict and well-defined set of operating procedures that ensure consensus, openness and balance of interest. A frequent misconception about HL7 is that it develops software. In reality, Health Level Seven develops specifications; the most widely used being a messaging standard that enables disparate healthcare applications to exchange key sets of clinical and administrative data.

HL7's mission is to provide messaging standards for the exchange, management and integration of data that supports clinical patient care and the management, delivery and evaluation of healthcare services. Specifically, the organization works to create flexible, cost effective approaches, standards, guidelines, methodologies, and related services for interoperability between healthcare information systems.

HL7 is one of several ANSI-accredited Standards Developing Organizations (SDOs) operating in the healthcare arena. Most SDOs produce standards (sometimes called specifications or protocols) for a particular healthcare domain such as clinical data, pharmacy, medical devices, imaging or insurance (claims processing) transactions. Health Level Seven's is clinical and administrative data.

B. ICSR – Individual Case Safety Report

The general HL7 ICSR message supports the exchange of data and other safety reporting requirement between various public health and patient safety organizations. The message supports the reporting of adverse events or product problems associated with the use of drugs, therapeutic biologics, vaccines, and devices. This appendix provides information required to report a device adverse event to CDRH. Over time, CDRH files will include more components of the ICSR message and the scope of the message may be expanded to support other types of products such as food, dietary supplements, cosmetics or veterinary products and services. While the message is specifically designed to support individual case safety reports, it does not support population-based case reporting for disease surveillance or outbreak events.

C. Electronic Medical Device Reporting (eMDR)

Independent of the development of the HL7 ICSR, the CDRH initiated the eMDR project to receive medical device adverse event reports (MDRs) electronically. Phase I of the eMDR implementation will accept electronic medical device reports via two options, targeting both small and large volume reporters. Small volume reporters can submit MDRs to CDRH by downloading the CDRH eSubmitter (CeSub) software via an on-line application available for download at http://www.fda.gov/cdrh/cesub/. Large volume reporters can submit MDRs as a batch or individually as xml files, using the HL7 ICSR standard. Over time FDA will streamline its safety data collection systems and provide additional guidance concerning consumer, healthcare provider and manufacturer reporting methods. Section III offers technical guidance for

implementing the ICSR standard.

D. FDA Electronic Submissions Gateway (ESG)

eMDR will use the FDA Electronic Submissions Gateway (ESG), an agency-wide entry point for all electronic submissions, to receive electronic MDRs. The FDA ESG enables the secure submission of regulatory information for review. The FDA ESG will enable the FDA to process regulatory information automatically while it functions as a single point of entry for the receipt and processing of all electronic submissions in a highly secure environment that complies with secure messaging standards. The FDA ESG is a conduit, or "highway", along which submissions travel to reach their final destination. It does not open or review submissions; it automatically routes them to the proper FDA Center or Office. The electronic submission process encompasses the receipt, acknowledgment of receipt (to the sender), routing, and notification (to a receiving Center or Office) of the delivery of an electronic submission.

Electronic MDR reporters need to register as trading partners with the ESG to submit via the Gateway. For further information, visit http://www.fda.gov/esg/. The site contains a contact email address for questions related to the gateway. Inquiries are answered within 1-2 days of receipt.

E. ICSR and eMDR

Implementation of the ICSR message via the eMDR project supports Federal government goals to adopt open consensus standards for patient safety messaging and interoperability requirements of the new federal health infrastructure. Adopting a standard message specification for adverse events helps ease the difficulties of exchanging safety information between disparate health systems and aids in risk assessment and risk communication efforts. In addition, it provides CDRH an opportunity to improve data quality and provides a means for FDA to improve data transfer with its reporters.

For reporters of adverse event information, submitting MDRs using the HL7 ICSR standard has several benefits. The current regulatory framework for device reporting necessitates exchange of safety information between several entities. The ICSR will permit an easier exchange of information and overcomes interoperability issues between various systems, and can be used to report electronically to all the necessary parties.

Additionally, globalization of manufacturered products introduces new safety concerns as they are manufactured in one part of the world and used in another. The ability to share critical safety information across disparate systems is facilitated by the implementation of international standards such as the ICSR.

Portions of the HL7 V3 ICSR used for CDRH were used to map device reporting requirements described on the MedWatch 3500A released November 1, 2005. The CDRH files include a ‘schema’ or ‘file format’ to utilize for submission of MDR data as an ICSR message. Reporters can use the specified format to submit MDR data and fulfill their MDR reporting obligation.

One of the key features of HL7 version 3 is the use of a standard vocabulary as part of the message. Members of the CDRH ICSR team worked with terminology experts from the National Cancer Institute Enterprise Vocabulary Service (NCI EVS) to identify the majority of vocabulary for MDRs. These vocabulary terms will be stored in the NCI Thesaurus. Concepts such as event type have an alphanumeric code that corresponds to Death, Serious Injury and Malfunction. The receiving system can access the NCI EVS to translate the concept code to the corresponding event type.

F. Device Reporting Storyboard and Refined Message Information Models

HL7 has documented storyboards in order to illustrate the requirements for each interaction specified within the standard. The storyboard offers an example of a concrete situation in which data as specified by the ICSR standard would flow from sender to receiver. The storyboard provided in this appendix provides an example of the submission of an MDR or a device-related procedure. It was created by FDA CDRH to illustrate the reporting of device-related events using a fully implemented ICSR process. Some capabilities are not currently available. The name, device, and adverse event are fictitious:

The Event

On December 12, 2005, J. Doe, a 54 year old female was admitted to the Outpatient Surgery Center for the placement of a Medical Corporation X, Model LS 4700, implantable pain pump. In surgery, the pain pump was implanted without difficulty and was determined to be functional. After the procedure the patient was transferred to the recovery area for stabilization. In the recovery room, the anesthesiologist, Dr. Zoe, initiated the programming of Ms. Doe's implanted pump. During this set-up procedure the pump stopped functioning and the pump's visual display went blank. The anesthesiologist was unable to troubleshoot the cause of the device failure, nor restore its function. The patient was informed of the device failure and opted to return to the O.R. the next day for the removal of the defective device and placement of a new pain pump. The patient was scheduled to return to the O. R. for the repeated procedure. The second Model LS 4700 implantable pain pump was implanted and completed its programming process without difficulty.

Creation of Initial Report

Dr. Zoe decided to complete an electronic Individual Case Safety Report (ICSR), using the hospital's incident reporting system because he felt his patient had suffered a serious injury. He logged into the incident reporting system and completed the necessary fields required to populate a device adverse event. The form appeared on the computer screen with a great deal of Ms. Doe's patient demographics, medical history and many details of her surgical case already populated because the incident reporting system is linked to the electronic medical record. The event information was obtained from the surgeon's and the anesthesiologist's progress notes and automatically populated into those fields on the form. Once the report of the incident was completed, Dr. Zoe clicked the submit key. This sent the information to the risk manager, Patient Safety Committee, the device manufacturer and the regulatory authority. The risk manager reviewed the incident, made some edits and gave approval that this was a reportable event and could be sent to FDA. She clicked a 'Submit SMDA Event' button that sent the information to the Manufacturer using the ICSR standard message. Additionally, the hospital's risk manager returned the pain pump to the manufacturer for their analysis three days after the event.

Manufacturer Response to Reported Event

Two weeks after the implantable pain pump was returned to the manufacturer for failure analysis, the manufacturer sent an ICSR update to the hospital and to the FDA. The manufacturer was able to store the hospital's report and create a new report on their internal Adverse Event Reporting System using the User Facility Report as a base document.

FDA Request for Additional Information

FDA electronically returns the ICSR report with an attached document. This correspondence is in response to information received at the Center for Devices and Radiological Health (CDRH) involving the Medical Corporation X, Model LS 4700 implantable pain pump implanted on December 12, 2005. The FDA requested additional information about the software issue described in the medical device report, including the steps taken to address the stated problem. The manufacturer will be given 30 days to respond to the centers request for additional information.

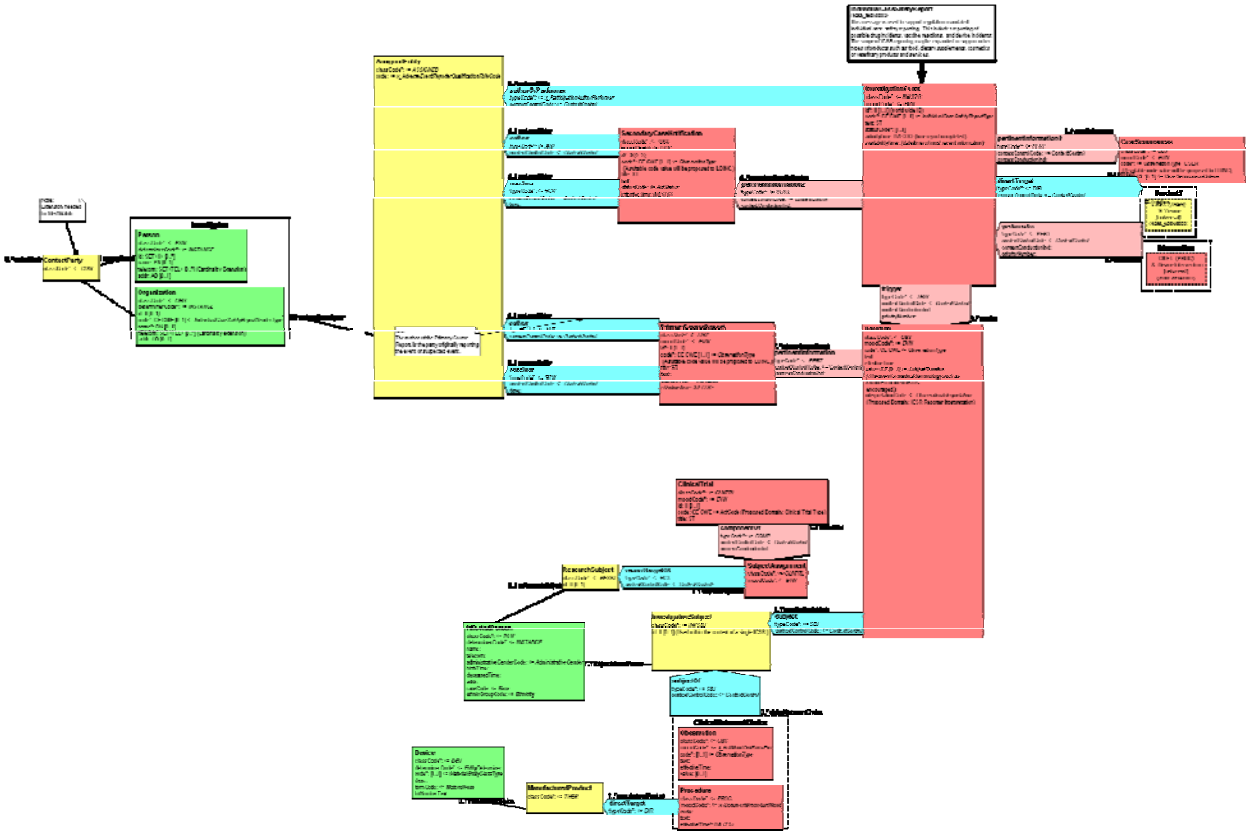
Manufacturer Response to Request for Additonal Information

Manufacturer sends new, changed or updated information via ICSR. This follow up serves to respond to the CDRH's request for additional information about the software issue described in a report involving a Medical Corporation X, Model LS 4700 implantable pain pump, implanted on December 12, 2005. The center requested information as to the software issue described as part of the root cause analysis of the implanted pain pump's failure. Our responses to the issues posed are as follows: The software issue described in this report was a result of an event that would take place only in the rare instances of high resistance of the motor, causing an excessive back EMF (Electromotive Force). This would ultimately lead to an inadvertent timeout of the internal watchdog times of the microprocessor, causing the pump to turn off prematurely. A revision to the software of the Model LS 4700 implantable pain pump has completed Medical Corporation X's Engineering Design Change Process. Additionally, testing has been conducted on the software revision and no further instances of this failure have been detected. It is felt no further risk can be associated with this release of the software. Once approved, new pumps being built will contain the new software revision. FDA stores all of the information related to this event and completes appropriate review of the event.

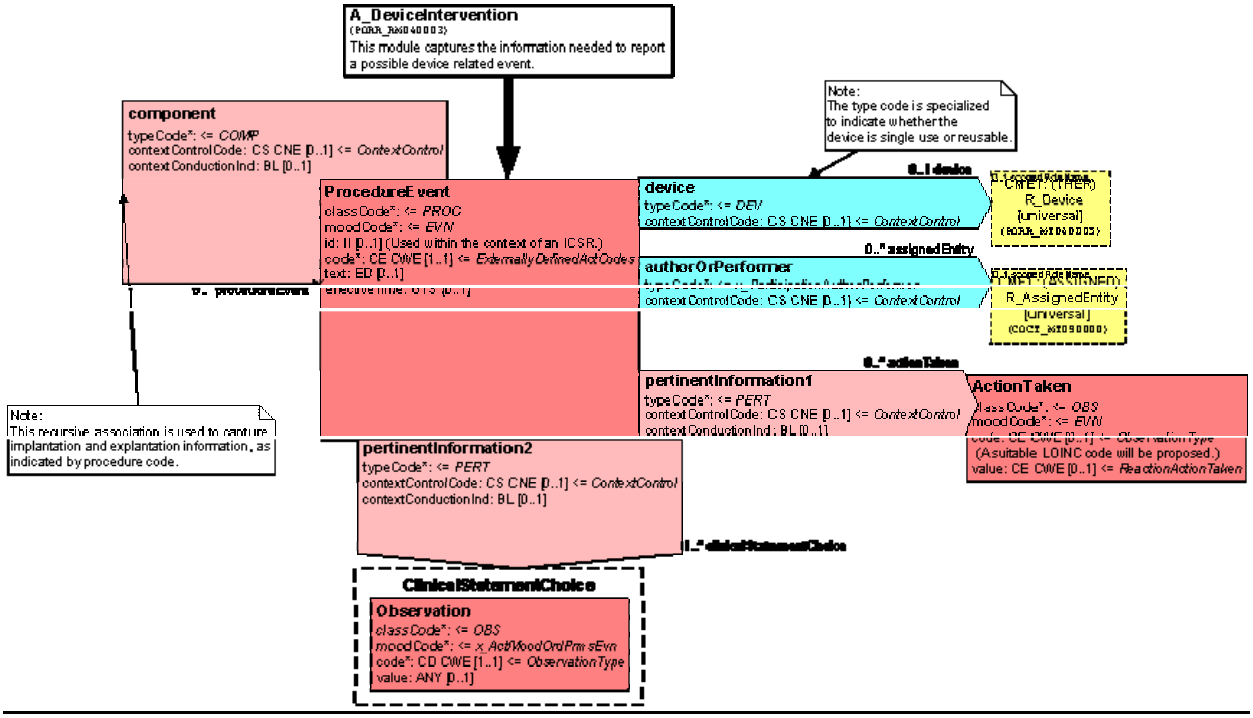
G. eMDR Refined Message Information Models

CDRH has constrained the ICSR schemas to support only those requirements identified to support eMDR. RMIMs have been created to show the model attributes that are used for eMDR:

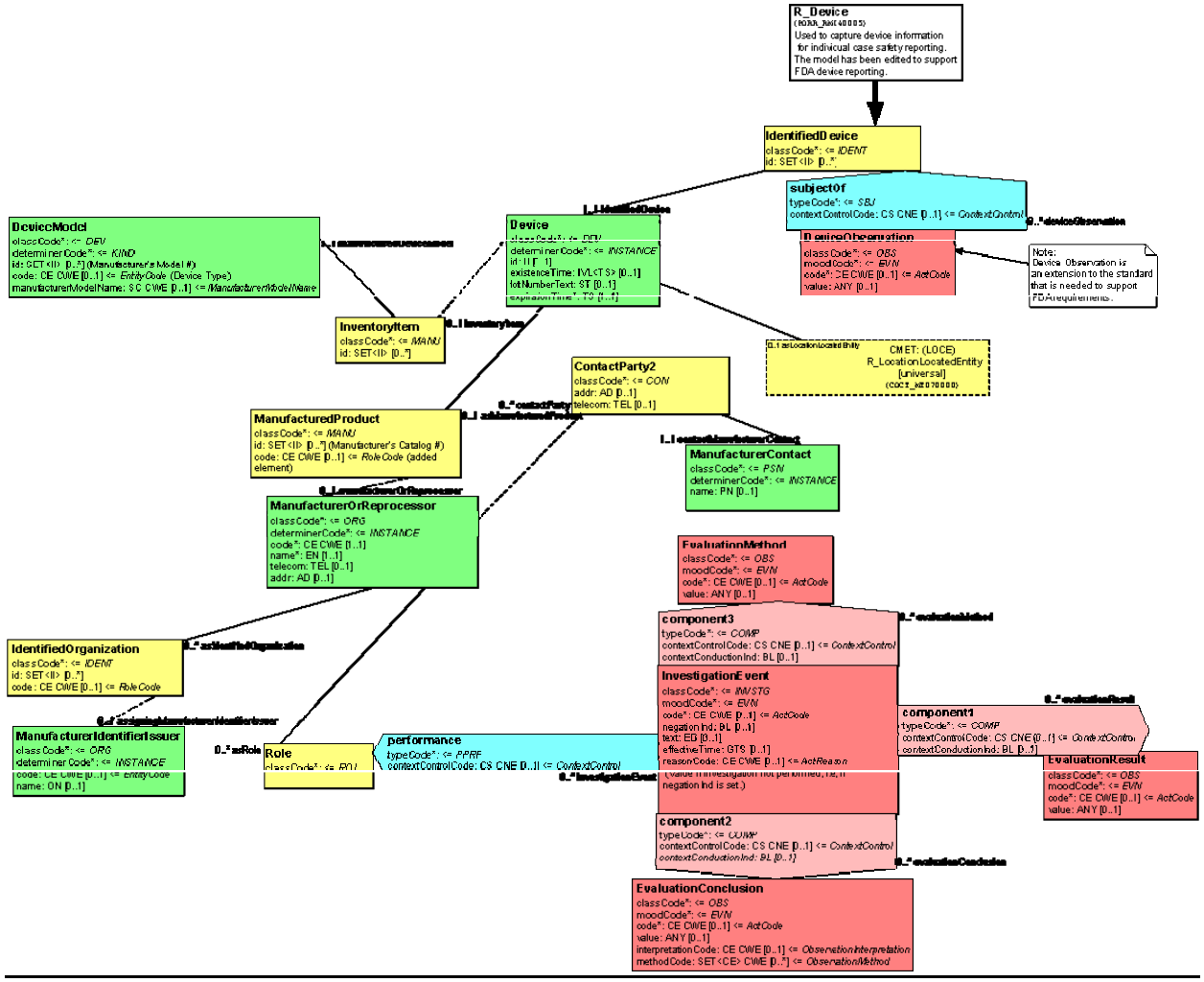
eMDR ICSR BASE RMIM



eMDR DEVICE PROCEDURE RMIM



eMDR DEVICE MODEL RMIM



Section III – ICSR Technical Section for CDRH Implementation

For the purposes of the device eMDR pilot program, the implemented schema supports only those features of the ICSR that were needed to meet the specific needs of device reporting. Additionally, other features were added that were identified as omissions from the standard, and these changes will be forwarded to HL7 for inclusion in the next release of ICSR. Future plans also include integrating the information required for different FDA regulated products into the message received through eMDR. Pilot participants can obtain a zip file containing the files necessary to generate the current device ICSR message from the FDA website at: http://www.fda.gov/oc/datacouncil/ . A list of the files and descriptions of their function are provided in this appendix.

The diagram below provides a representation of the ICSR Model. This ICSR has five RMIMs (refer to section III.1) – the base ICSR, A_Procedure_Intervention, R_Device, A_Substance_Administration, R_Drug. The CDRH implementation traverses down the device path ONLY. A_Procedure_Intervention captures information about the procedure that associates a patient with a device; R_Device captures information about the device itself.

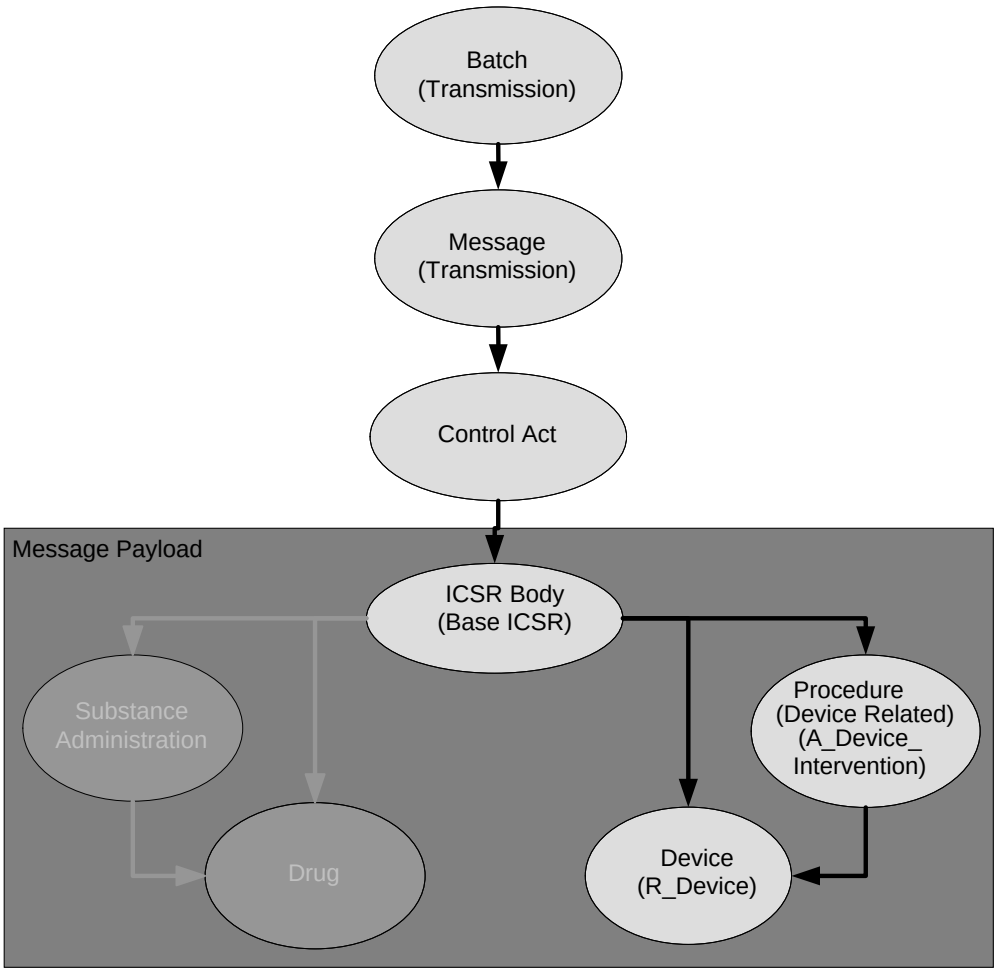


Figure 1: CDRH Representation of the ICSR Model

In HL7, trigger events are identified which initiate the process of information exchange. For the ICSR, three trigger events are supported – send, update and delete. At this time, the CDRH implementation will only be using the ICSR 'send' notification PORR_TE040001UV01, i.e. report of a device adverse event and/or product problem, is ready for transmission to an eligible receiver. Other trigger events may be used with further development of the model.

A. CDRH ICSR MESSAGE CONTENTS

A.1 Transaction Wrapper

For the CDRH ICSR implementation, the transmission wrapper contains everything in the schema from the beginning of the file until the tag <controlActProcess>.

A.2 Control Act Wrapper

The control act wrapper contains administrative type information that directly relates to the trigger event. The trigger event for the CDRH implementation at this time would only include the send event. The control act wrapper contains details for the message such as who, when, where and why, i.e., date of the report (Medwatch 3500A B4), U/F or Importer (Medwatch 3500A F1) etc. For the CDRH, the Control Act wrapper would comprise of everything in the schema until the tag **<investigationEvent>**.

A.4 Message Instance Example

To demonstrate an eMDR message instance, the following example can be should be to prepare a submission:

```
<?xml version="1.0" encoding="UTF-8" ?>
<!-- filename - mappingInstance.xml, 7/20/2006 -->
<!-- this example has a manufacturer report as the primary source, user
facility report as secondary source -->

  -<PORR_IN040001UV01 xmlns="urn:hl7-
    org:v3" xmlns:mif="urn:hl7-org:v3/mif"
    xmlns:xsi="http://www.w3.org/2001/X
    MLSchema-instance"
    xsi:schemaLocation="urn:hl7-org:v3
    Impl_Files\Con060221.xsd"
    ITSVersion="XML_1.0"> <!-- populate
    reporter name (such as manufacturer
    or User Facility name under
    assigningAuthorityName --> <!--
    populate batchID under 'extension' -->
    <id root="1.1" extension="batchID here"
    assigningAuthorityName="MessageSender
    " /> <creationTime value="20050101" />
    <!--batch creation -->
    <responseModeCode /> <interactionId /> -
    <receiver> <!-- batch receiver
    information --> <!-- refer to the
    Vocabulary sheet in HL7Medwatch.xls
    file on how to address null values -->
    <!-- Two allowable null values are
    'Unknown' and 'Not applicable' (NA) --
    > <!-- 'NA' has been added in the
    example below --> <telecom /> -<device>
    <id nullFlavor="NA" /> -<asAgent> -
    <representedOrganization> <id
    nullFlavor="NA" /> <name>CDRH</name>
    </representedOrganization> </asAgent>
    </device> </receiver> -<sender> <!--
    batch sender information --> <telecom
    /> -<device> <id nullFlavor="NA" /> -
    <asAgent> -<representedOrganization>
    <id nullFlavor="NA" /> <name>USA
```

```
        Device Manufacturer</name>
        </representedOrganization> </asAgent>
        </device> </sender> -<message> <!--
        header information --> <id
        nullFlavor="NA" /> <creationTime
        nullFlavor="NA" />
<interactionId root="2.16.840.1.113883.1.6" extension="PORR_IN04001"
  assigningAuthorityName="HL7" />
<processingCode nullFlavor="NA" />
<processingModeCode nullFlavor="NA" />
<acceptAckCode nullFlavor="NA" />

 -<receiver> <telecom /> -
     <device> <id
     nullFlavor="NA" />
     </device> </receiver>
     -<sender> <telecom />
     -<device> <id
     nullFlavor="NA" />
     </device> </sender> -
     <attachment
     nullFlavor="NA"> <id
     xsi:type="II"
     root="12345"
     displayable="true" /> -
     <text
     mediaType="text/plain
     "
     representation="B64">

    JVBERi0xLjQNJeLjz9MNCjYgMCBvYmo8PC9IWzQ3NiAxMzNdL0xpbmVhcmI6ZWQg
    TCA1Njg5L04gMS9PIDkvVCA1NTIzPj4NZW5kb2JqDSAgICAgICAgICAgICAgICAgI
    DQp4cmVmDQo2IDkNCjAwMDAwMDAwMTYgMDAwMDAgbg0KMDAwMDAwMDYw
    MDAwNDc2IDAwMDAwIG4NCjAwMDAwMDA2ODUgMDAwMDAgbg0KMDAwMDAw
    MDAwMDAwODk2IDAwMDAwIG4NCjAwMDAwMDEyNjEgMDAwMDAgbg0KMDAwM
    DQowMDAwMDAxNzE0IDAwMDAwIG4NCnRyYWlsZXINCjw8L1NpemUgMTUvUHJl
    NyAwIFIvSW5mbyA1IDAgUi9JRFs8YmYyNWQwY2RjZWVjMTUzM2ZmODBmMWE
    MzA4ZWYxYWY5YWJhNGRiYmM4ZmU0OTZiZDUyYTYzPl0+Pg0Kc3RhcnR4cmVmD
    ICAgICAgICAgICAgICAgICAgICAgICAgICAgICAgICAgICAgICAgICAgDQo4IDAgb2JqPDwvTGVuZ3RoIDU2L0ZpbHRlci9Gb
    ZS9MIDcwL1MgMzg+PnN0cmVhbQ0KeNpiYGBgY2Bg0mAAApZABlTACBJk4GhAFm
    jaUSMLVslUCaCYgtAAIMAHWNA9INCmVuZHN0cmVhbQ1lbmRvYmoNNyAwIG9iaj
    MCBSL1R5cGUvQ2F0YWxvZy9QYWdlTGFiZWxzIDEgMCBSL01ldGFkYXRhIDQgMCB
    DTkgMCBvYmo8PC9Db250ZW50cyAxMiAwIFIvVHlwZS9QYWdlL1BhcmVudCAzIDA
    MC9NZWRpYUJveFswIDAgNjEyIDc5Ml0vQ3JvcEJveFswIDAgNjEyIDc5Ml0vUmVzb
    IDAgUj4+DWVuZG9iag0xMCAwIG9iajw8L0ZvbnQ8PC9UVDIgMTEgMCBSPj4vUHJv
    L1RleHRdL0V4dEdTdGF0ZTw8L0dTMSAxNCAwIFI+Pj4+DWVuZG9iag0xMSAwIG9
    Rm9udC9FbmNvZGluZy9XaW5BbnNpRW5jb2RpbmcvQmFzZUZvbnQvVGltZXNOZX
    Rmlyc3RDaGFyIDMyL0xhc3RDaGFyIDExNi9TdWJ0eXBlL1RydWVUeXBlL0ZvbnREZ
    IDEzIDAgUi9XaWR0aHNbMjUwIDAgMCAwIDAgMCAwIDAgMCAwIDAgMCAwIDAg
    MCA1MDAgMCA1MDAgMCAwIDAgMCAwIDAgMCAwIDAgMCAwIDAgMCAwIDAgMC
    IDAgMCAwIDAgMCAwIDYxMSAwIDAgMCAwIDAgMCAwIDAgMCAwIDAgMCA0NDQ
    NDQ0IDMzMyA1MDAgNTAwIDI3OCAwIDAgMCA3NzggNTAwIDUwMCAwIDAgMzM
    ZW5kb2JqDTEyIDAgb2JqPDwvTGVuZ3RoIDE0NS9GaWx0ZXIvRmxhdGVEZWNvZG
    SIk0is0KwjAQhO/7FHNMhKSbYGt7FUXw6t7EQ639UWgKNtDXN0VlmJmPYbLTxaG
    g5NSVYwdI7YqICMx+mRp1hIQcsroXHW5ZDDb5ANsWVmvx7NHxe6KmnniDrGuh
```

ca9nbXJbfMdiizY00+MZegt9kzMdhT4CDABYuyfnCg0KZW5kc3RyZWFtDWVuZG9ia
ajw8L1R5cGUvRm9udERlc2NyaXB0b3IvRm9udEJCb3hbLTU2OCAtMzA3IDIwMDA
dE5hbWUvVGltZXNOZXdSb21hblBTTVQvRmxhZ3MgMzQvU3RlbVYgODIvQ2FwSGV
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cCBmYWxzZS9PUE0gMT4+DWVuZG9iag0xIDAgb2JqPDwvTnVtc1swIDIgMCBSXT
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UGFnZXM+Pg1lbmRvYmoNNCAwIG9iajw8L0xlbmd0aCAzMzI1L1R5cGUvTWV0YWR
ZS9YTUw+PnN0cmVhbQ0KPD94cGFja2V0IGJlZ2luPSfvu78nIGlkPSdXNU0wTXBD
TlRjemtjOWQnPz4KPD9hZG9iZS14YXAtZmlsdGVycyBlc2M9IkNSTEYiPz4NCjx4On
eG1sbnM6eD0nYWRvYmU6bnM6bWV0YS8nIHg6eG1wdGs9J1hNUCB0b29sa2l0ID
cmFtZXdvcmsgMS42Jz4NCjxyZGY6UkRGIHhtbG5zOnJkZj0naHR0cDovL3d3dy53M
OS8wMi8yMi1yZGYtc3ludGF4LW5zIycgeG1sbnM6aVg9J2h0dHA6Ly9ucy5hZG9iZS
MS4wLyc+DQo8cmRmOkRlc2NyaXB0aW9uIHJkZjphYm91dD0ndXVpZDozYTlkNGY
MzgtYjM0Zi03YTFlOWFjY2ViOTMnIHhtbG5zOnBkZj0naHR0cDovL25zLmFkb2JlLm
MS4zLycgcGRmOlByb2R1Y2VyPSdBY3JvYmF0IERpc3RpbGxlciA2LjAgKFdpbmRvd
ZjpEZXNjcmlwdGlvbj4NCjxyZGY6RGVzY3JpcHRpb24gcmRmOmFib3V0PSd1dWlkO
LWE4N2YtNDAzOC1iMzRmLTdhMWU5YWNjZWI5MycgeG1sbnM6eGFwPSdodHRw
Y29tL3hhcC8xLjAvJyB4YXA6Q3JlYXRlRGF0ZT0nMjAwNi0wNy0xOVQyMjowMDozM
eGFwOkNyZWF0b3JUb29sPSdQU2NyaXB0NS5kbGwgVmVyc2lvbiA1LjIuMicgeGFw
dGU9JzIwMDYtMDctMTlUMjI6MDA6MzAtMDQ6MDAnPjwvcmRmOkRlc2NyaXB0aW
ZXNjcmlwdGlvbiByZGY6YWJvdXQ9J3V1aWQ6M2E5ZDRmNTctYTg3Zi00MDM4LWI
Y2NlYjkzJyB4bWxuczp4YXBNTT0naHR0cDovL25zLmFkb2JlLmNvbS94YXAvMS4w
TU06RG9jdW1lbnRJRD0ndXVpZDpkNDkwNDMxZi0wZGExLTQyNjMtYmE4Ny01YTQ
Lz4NCjxyZGY6RGVzY3JpcHRpb24gcmRmOmFib3V0PSd1dWlkOjNhOWQ0ZjU3LWE
MzRmLTdhMWU5YWNjZWI5MycgeG1sbnM6ZGM9J2h0dHA6Ly9wdXJsLm9yZy9kY
LjEvJyBkYzpmb3JtYXQ9J2FwcGxpY2F0aW9uL3BkZic+PGRjOnRpdGxlPjxyZGY6QW
bGkgeG1sOmxhbmc9J3gtZGVmYXVsdCc+TWljcm9zb2Z0IFdvcmQgLSBEb2N1bWV
aT48L3JkZjpBbHQ+PC9kYzp0aXRsZT48ZGM6Y3JlYXRvcj48cmRmOlNlcT48cmRmO
cmRmOmxpPjwvcmRmOlNlcT48L2RjOmNyZWF0b3I+PC9yZGY6RGVzY3JpcHRpb2
REY+DQo8L3g6eG1wbWV0YT4NCiAgICAgICAgICAgICAgICAgICAgICAgICAgICAgICAg
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    b2JqPDwvTW9kRGF0ZShEOjIwMDYwNzE5MjIwMDMwLTA0JzAwJykvQ3JlYXRpb2
    NjA3MTkyMjAwMzAtMDQnMDAnKS9UaXRsZShNaWNyb3NvZnQgV29yZCAtIERvY3
    YXRvcihQU2NyaXB0NS5kbGwgVmVyc2lvbiA1LjIuMikvUHJvZHVjZXIoQWNyb2Jhd
    ZXIgNi4wIFwoV2luZG93c1wpKS9BdXRob3IoTGVuKT4+DWVuZG9iag14cmVmDQ
    MDAwMDAgNjU1MzUgZg0KMDAwMDAwMTc5MCAwMDAwMCBuDQowMDAwMDAx
    MDAwMDE4NDYgMDAwMDAgbg0KMDAwMDAwMTg5NiAwMDAwMCBuDQowMDAw
    CnRyYWlsZXINCjw8L1NpemUgNj4+DQpzdGFydHhyZWYNCjExNg0KJSVFT0YNCg==
    <reference value="sample_attachment.pdf" />
  </text> </attachment> -
<controlActProcess
moodCode="EVN"> <code
code="PORR_TE040001UV01
" codeSystem="HL7"
    codeSystemName="HL7 Trigger Event Id" />
  <effectiveTime value="20050101" />
  <!-- Date of this Report, BOX B4 -->

-<authorOrPerformer typeCode="AUT">
  -<assignedPerson>
      <!-- Type of Reporter, indicate Manufacturer or User Facility
      or Distributor or Voluntary. Use vocabulary -->
      <!-- Code is populated with value for manufacturer -->
      <code code="C53616" codeSystem="2.16.840.1.113883.3.26.1.1"

      codeSystemName="Type_of_Report
  er" />
  </assignedPerson>
  </authorOrPerformer>
  -<subject>

  -<investigationEvent>
      <!-- Manufacturer Report Number, BOX G9 -->
      <id root="2.16.840.1.113883.3.24" extension="5555555-2005
55555" assigningAuthorityName="FDA" />
<!-- Adverse Event Or Product Problem, BOX B1 -->
<!-- Code is populated with Value for Adverse Event -->

      <code code="C41331" codeSystem="2.16.840.1.113883.3.26.1.1"
        codeSystemName="Adverse_Event_Or_Product_Problem_Report
      " /> <!-- Additional Manufacturer Narrative, BOX H10 --> <text
      mediaType="text/plain">Our evaluation revealed that at this
        moment we need to evaluate more</text>
      <statusCode />
```

```
      <activityTime />
      <availabilityTime />

      -<authorOrPerformer
         typeCode="AUT">
         <assignedEntity />
         </authorOrPerformer>
         -<trigger>

      -<reaction>
         <!-- Describe Event or Problem, BOX B5 -->
         <text mediaType="text/plain">During procedure the


            patient seemed to be doing well. Then, things
            went a little down-hill</text> <!-- Date of
            Event, BOX B3 -->
  <effectiveTime value="20050101" /> -<subject> -
<investigativeSubject>
   -<subjectAffectedPerson>
      <!-- Patient Identifier, BOX A1 -->
      <name>XYZ12345</name>
      <!-- Sex, BOX A3, Code is populated with
      Male -->
      <administrativeGenderCode code="C20197"


                        codeSystem="2.16.840.1.113883.3.26.1.1"
        codeSystemName="Sex" /> <!-- Date of Birth, BOX A2 --> <birthTime value="20000101"
      /> <!-- Outcomes Attributed to Adverse Event\Death Date, BOX B2  --> <deceasedTime
      value="20040101" /> <!-- Other Relevant History, Including Preexisting Medical
      Conditions\Race, BOX B7 --> <!-- Code is populated with Value for Native
      Hawaiian/Other Pacific Islander  --> <raceCode code="C41219"
     codeSystem="2.16.840.1.113883.3.26.1.1"
     codeSystemName="Race" />
     </subjectAffectedPerson>
     -<subjectOf>

    -<observation moodCode="EVN"> <!-- Age at Time of Event, BOX A2 --> <!-- Code is
       populated with Concept ID for age --> <code code="C25150"

                        codeSystem="2.16.840.1.113883.3.26.1.1"
         codeSystemName="Age" /> <!-- PQ = Phyical Quantity --> <value xsi:type="PQ"
       value="4" unit="YR" />
     </observation>
   </subjectOf>
   -<subjectOf>

    -<observation moodCode="EVN"> <!--Weight, A4 --> <!-- Code is populated with Concept
       ID for weight --> <code code="C25208"
      codeSystem="2.16.840.1.113883.3.26.1.1"
```

```
    codeSystemName="Weight" /> <value xsi:type="PQ" value="20"
    unit="lbs" /> </observation> </subjectOf> -<subjectOf>
  -<observation moodCode="EVN"> <!-- Relevant Tests/Labratory Data, Including
     Dates, BOX B6 --> <!-- Code is populated with Concept ID
    for Test_Result -->
     <code code="C36292" codeSystem="NCI"
     codeSystemName="Test_Result" />

    <value xsi:type="ED"
     mediaType="text/plain">CT of lumbar
     spine</value>

  </observation>
</subjectOf>
-<subjectOf>

 -<observation moodCode="EVN">
    <!-- Other Relevant History, Including
    Preexisting Medical Conditions\Race, BOX B7 -->
    <!-- Code is populated with Concept ID
    for Other_Personal_Medical_History -->
    <code code="C53263"


     codeSystem="2.16.840.1.113883.3.26.1.1"
     codeSystemName="Other_Personal_Medical_History" />
    <value xsi:type="ED"
     mediaType="text/plain">Patient was in
     good health before
     hospitalization</value>

  </observation>
</subjectOf>
-<subjectOf>

 -<observation moodCode="EVN"> <!-- Event Problem Codes\Patient Problem Codes, BOX F10
    --> <!-- for multiple values, repeat observation block --> <!-- First Code is
    Populated with Temporary FDA ID, Value is populated with valid MAUDE Patient Pr

    <code code="C53983"
     codeSystem="2.16.840.1.113883.3.26.1.1"
     codeSystemName="Patient_Problem_Code" />

  <value xsi:type="CE" code="1708"
   codeSystem="2.16.840.1.113883.3.26.1.1" />
    </observation>
    </subjectOf>
    -<subjectOf>

 -<observation moodCode="EVN"> <!-- Event Problem Codes\Patient Problem Codes, BOX F10
    --> <!-- First Code is Populated with Temporary FDA ID, Value is populated with
    valide MAUDE Patient p
```

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      <code code="C53983"
        codeSystem="2.16.840.1.113883.3.26.1.1"
        codeSystemName="Patient_Problem_Code" />

    <value xsi:type="CE" code="2229"
      codeSystem="2.16.840.1.113883.3.26.1.1" />
      </observation> </subjectOf>
      </investigativeSubject> </subject>
-<location>
  -<locatedEntity> <!-- Location where Event Occurred, BOX F12 -> <!-- Code is Populated with
     Concept ID for Hospital -->
    -<location>
      -<code code="C16696" codeSystem="2.16.840.1.113883.3.26.1.1"
        codeSystemName="Location"> <originalText>On the road</originalText>
                                              </code>
                                            </location>
                                          </locatedEntity>

  </location> -<pertinentInformation>
  -<primarySourceReport> <id nullFlavor="UNK" /> <code nullFlavor="UNK" /> <!-- Initial
     Reporter Also Sent Report To FDA? BOX E.4 --> <!-- populate 'false' if E4 is YES -->
     <!-- populate 'true' if E4 is NO or Unk -->
      -<receiver negationInd="false"> -<assignedEntity> -
        <assignedOrganization> <name>FDA</name>
        </assignedOrganization> </assignedEntity> </receiver> -
        <author> -<assignedEntity> <!-- Initial Reporter
        Occupation, BOX E3
          --> <!-- Code is populated with value for Audiologist --> <code code="C51804"

          codeSystem="2.16.840.1.113883.3.26.1.1"
          codeSystemName="Occupation" /> <!-- The value of BOX.E.2 will be inferred from
        the choice offered for E.3 -->
      -<assignedPerson>
        -<name> <!-- Initial Reporter First Name, BOX E1 --> <given>Jane</given> <!--
           Initial Reporter Middle Name, BOX E1 --> <given>Adams</given> <!-- Initial
           Reporter Last Name, BOX E1 --> <family>Doe</family>
          </name>
          <!-- Initial Reporter Phone Number,
          BOX E1 -->
          <telecom value="tel:+1(555)555

            5555" /> <!-- Initial Reporter Email Address, BOX E1 -->
          <telecom
            value="mailto:nowhere@nowhere.com" /> <!--Fax Number, BOX E1 --> <telecom
          value="fax:+1(555)555
            5555" />
        -<addr> <!-- Initial Reporter Address\Line 1, BOX E1 --> <streetAddressLine>888
           No
            Street1</streetAddressLine> <!-- Initial Reporter Address\Line 2,
           BOX E1 -->
           <streetAddressLine>No Street2)
            </streetAddressLine> <!--Initial ReporterAddress\City, BOX E1 --> <city>No
           City</city> <!--Initial ReporterAddress\State, BOX E1 --> <state>XY</state>
```

```
            <!-- Initial Reporter Address\Zip Code, BOX E1 --> <postalCode>55555
             5555</postalCode>
           </addr>
           </assignedPerson>

         -<representedOrganization> <!-- Initial Reporter Facility Name, BOX E1 -->
            <name>Get Better Hospital</name>
       </representedOrganization>
     </assignedEntity>
     </author>
     </primarySourceReport>
     </pertinentInformation>
     </reaction>
     </trigger>

   -<pertinentInformation1> <!-- Follow-up Number if Follow-up is
      selected in BOX F7 --> <sequenceNumber value="1" /> -
      <secondaryCaseNotification> <!-- UF/Importer Report Number,
      BOX F2 FDA OID is used here temporarily --> <id
      root="2.16.840.1.113883.3.24" extension="555555555
2005-0001" assigningAuthorityName="FDA" /> <!-- Type of Report, BOX F7 Populated with
 Initial Report of An Adverse Event -->
 <code code="C53620"
  codeSystem="2.16.840.1.113883.3.26.1.1"
  codeSystemName="Type_of_Report" />

 <!-- Date User Facility or Importer Became Aware of
 Event, BOX F6 -->
 <effectiveTime value="20050101" />
 <!-- Report Sent to FDA?, BOX F11 -->
 <!-- populate 'false' if answer is YES -->
 <!-- populate 'true' if answer is NO -->

   -<receiver negationInd="false"> <!-- Date Report Sent to FDA, if
      answer is YES to BOX F11, BOX F11 --> <time value="20050101"
      /> <!-- Code below supports BOX F11. Who was thereport sent to?
      Populated with FDA --> <!-- Code is populated with value for
      FDA --> -<assignedEntity> -<assignedOrganization> <code
      code="C17237" codeSystem="2.16.840.1.113883.3.26.1.1"
      codeSystemName="Report_Receiver" />
  </assignedOrganization> </assignedEntity> </receiver> -
 <author>
 -<assignedEntity>
    <!-- Report from User Facility or Importer, BOX
    F1 -->
    <!-- Code is populated with value for User
    Facility -->
    <code code="C53567"

     codeSystem="2.16.840.1.113883.3.26.1.1"
     codeSystemName="Type_of_Reporter" />
     -<assignedOrganization>
     <name nullFlavor="NA" />
```

```
    -<addr>
       <!-- User Facility or Importer
       Name/Address\Facility, BOX F3 -->
       <additionalLocator>Get Better

         Hospital</additionalLocator> <!-- User Facility or Importer
       Name/Address\Line 1, BOX F3 -->
       <streetAddressLine>888
         Nostreet1</streetAddressLine> <!-- User Facility or Importer
       Name/Address\Line 2, BOX F3 -->

         <streetAddressLine>Nostreet2</streetAddressLine> <!-- User Facility or Importer
       Name/Address\City, BOX F3 -->
          <city>No City</city>
          <!-- User Facility or Importer
          Name/Address\State, BOX F3 -->
          <state>XY</state>
          <!-- User Facility or Importer
          Name/Address\Zip Code, BOX F3 -->
          <postalCode>55555-5555</postalCode>
          <!-- User Facility or Importer
          Name/Address\Country, BOX F3 -->
          <country>World</country>

         </addr>
       -<contactParty>
       -<contactPerson>

          -<name> <!-- Contact Person\First Name, BOX F4 --> <given>Adam</given> <!--
             Contact Person\Middle Name, BOX F4 --> <given>M</given> <!-- Contact
             Person\Last Name, BOX F4 --> <family>John</family> <!-- Contact
             Person\Suffix, BOX F4
               -->
             <suffix>III</suffix> </name> <!--Phone Number, BOX F5 --> <telecom
           value="tel:+1(555)555
       5555" /> <!-- Email Address, BOX F5 --> <telecom
      value="mailto:noone@noone.com" /> </contactPerson>
      </contactParty> </assignedOrganization> </assignedEntity>
      </author> </secondaryCaseNotification>
      </pertinentInformation1> -<pertinentInformation1>
-<secondaryCaseNotification>
   <id nullFlavor="UNK" />
   <code nullFlavor="UNK" />
   <!-- Report Sent to Manufacturer? BOX F13 -->
   <!-- populate 'false' if E4 is YES -->
   <!-- populate 'true' if E4 is NO or Unk -->

 -<receiver negationInd="false">
   -<time> <!-- Report sent to Manufacturer\YES, populate date below, BOX F13 --> <!--
      The beginning of the time interval captures
     when the report was sent to manufacturer, BOX F13 --> <low value="20050110" /> <!--
      Date Received by Manufacturer, BOX G4 --> <!-- The end of the time interval
```

```
        captures when the report was received by manufacturer, BOX G4 --> <high
        value="20050114" />
      </time>
    -<assignedEntity>

      -<assignedOrganization> <!-- Code below supports BOX F13. Who was the report sent to?
         --> <!-- Code is populated with value for MANUFACTURER --> <code code="C53616"

                          codeSystem="2.16.840.1.113883.3.26.1.1"
          codeSystemName="Report_Receiver" /> <!-- Manufacturer Name and Address\Name,
         BOX F14 --> <name>American Reprocessor Choice</name> <!--Fax Number, BOX F14 -
         -> <telecom value="fax:+1(888)888-8888" /> <!-- Email Address, BOX F14 -->
         <telecom value="mailto:repr@noone.com" />
        -<addr> <!-- Manufacturer Name and Address\Address Line 1, BOX F14 -->
           <streetAddressLine>41 New
             Street</streetAddressLine> <!-- Manufacturer Name and
           Address\Address Line 2, BOX F14 -->
           <streetAddressLine />
           <!-- Manufacturer Name and Address\City,
           BOX F14 -->
           <city>New City</city>
           <!-- Manufacturer Name and Address\State,
           BOX F14 -->
           <state>ZC</state>
           <!-- Manufacturer Name and Address\Zip
           Code, BOX F14 -->
           <postalCode>88887-7272</postalCode>
           <!-- Manufacturer Name and
           Address\Country, BOX F14 -->
           <country>USA</country>

      </addr>
    </assignedOrganization>
    </assignedEntity>
    </receiver>
    </secondaryCaseNotification>
    </pertinentInformation1>

-<pertinentInformation2> <!-- Outcomes Attributed to Adverse Event, BOX B2 --> <!-- First
   code is Populated with Concept ID for Adverse_Event_Outcome, Value code populated with
   value for Hospitalization
  -<caseSeriousness moodCode="EVN">
    <code code="C49489"
     codeSystem="2.16.840.1.113883.3.26.1.1"
     codeSystemName="Adverse_Event_Outcome" />

   <value xsi:type="CE" code="C25179"
    codeSystem="2.16.840.1.113883.3.26.1.1" />
    </caseSeriousness>
    </pertinentInformation2>

-<pertinentInformation3> <!-- Attachments to the MDR can be embedded below. Please refer to
   the implementation guide materials for information on how to emb
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```
-<document>
  -<text mediaType="text/plain">

   attached is more information
   <reference value="URL or other
   reference for the attachment" />
   </text> </document>
   </pertinentInformation3> -
   <pertainsTo> -<procedureEvent>
   <code nullFlavor="UNK" /> -<device>
    -<identifiedDevice>
       <!-- Device Other Number, BOX D4 -->
       <id extension="1234567891011" />

     -<identifiedDevice>
        <!-- Device Serial Number, BOX D4  -->
        <id extension="XYZ45678" />
        <!-- Device Manufacture Date, BOX H4 -->
        <existenceTime value="20000101" />
        <!-- Device Lot Number, BOX D4 -->
        <lotNumberText

         mediaType="text/plain">ABCD123</lotNumberText> <!--
       Device Expiration Date, BOX D4 --> <expirationTime
       value="20060101" /> -<asManufacturedProduct>
         <!-- Device Catalog Number, BOX D4 -->
         <id extension="SMTFY999" />
         <code code="CXXXXX"

            codeSystem="2.16.840.1.113883.3.26.1.1" />
        -<manufacturerOrReprocessor>
        -<!-

                                    The manufacturer
                                 or Reprocessor
                                 element can appear
                                 twice. The first
                                 in

          -->

          <code code="C53616"
            codeSystem="2.16.840.1.113883.3.26.1.1"
            codeSystemName="Type_of_Manufacturer" />
          <!-- Manufacturer Name, City and
          State\Name, BOX D3 -->


<name>USA Device
  Manufacturer</name>
<!--Fax Number, BOX D3 -->
<telecom value="fax:+1(666)666

   6666" />
 <!-- Email Address, BOX D3 -->
```

```
<telecom
value="mailto:mfr@noone.com" />

 -<addr> <!-- Manufacturer Name, City and
    State\Address Line 1, BOX D3 -->
    <streetAddressLine>555 Manufacturer
    Drive</streetAddressLine> <!-- Manufacturer Name,
    City and State\City Line 2, BOX D3 -->
    <streetAddressLine>Manufacturer
    Drive2</streetAddressLine> <!-- Manufacturer Name,
    City and State\City, BOX D3 -->
    <city>Manufacturer City</city> <!-- Manufacturer
    Name, City and State\State, BOX D3 -->
    <state>XZ</state> <!-- Manufacturer Name, City and
    State\Zip Code, BOX D3 -->
    <postalCode>123451234</postalCode> <!--
    Manufacturer Name, City and State\Country, BOX D3
    -->
 <country>USA</country> </addr> -
<asRole> -<performance> -
<investigationEvent>
   -<component1> <!--Evaluation Codes\Results, BOX H6 --> <!--First code populated with
      temporary FDA ID, Value populated with va
     -<evaluationResult>
        <code code="C53985" codeSystem="2.16.840.1.113883.3.26.1.1"
         codeSystemName="Evaluation_Result_Code" />
        <value xsi:type="CE" code="704" codeSystem="2.16.840.1.113883.3.26.1.1" />
      </evaluationResult> </component1> <!--Evaluation Codes\Conclusions, BOX H6 --> <!--
     First code populatedwith temporary FDA ID, Value populated with valid MAUDE Co
   -<component2> -<evaluationConclusion>
        <code code="C53986" codeSystem="2.16.840.1.113883.3.26.1.1"
         codeSystemName="Evaluation_Conclusion_Code" />
        <value xsi:type="CE" code="41" codeSystem="2.16.840.1.113883.3.26.1.1" />
      </evaluationConclusion>
     </component2>

   -<component3> <!--Evaluation Codes\Method, BOX H6 --> <!--First code populated with
      temporary FDA ID, Value populated with va
     -<evaluationMethod>
        <code code="C53984" codeSystem="2.16.840.1.113883.3.26.1.1"
         codeSystemName="Evaluation_Method_Code" />
        <value xsi:type="CE" code="12" codeSystem="2.16.840.1.113883.3.26.1.1" />
   </evaluationMethod> </component3>
 </investigationEvent> </performance>
 </asRole> -<contactParty>
-<addr> <!-- Contact Office - Name/Address(and Manufacturing Site for Devices)\Facility,
   <additionalLocator>USA Device
     Manufacturer - MDR
     Contact</additionalLocator>

   <!-- Contact Office - Name/Address(and Manufacturing Site for Devices)\Address Li
   <streetAddressLine>999 Lala
     Lane</streetAddressLine> <!-- Contact Office - Name/Address(and Manufacturing Site
   for Devices)\Address Li
```

```
    <streetAddressLine>Lala Lane Line
      2</streetAddressLine> <!-- Contact Office - Name/Address(and Manufacturing Site for
    Devices)\City, BOX
    <city>Bam Bam</city>
    <!-- Contact Office -
    Name/Address(and Manufacturing Site for Devices)\State, BOX

    <state>VIRGINIA</state>
    <!-- Contact Office -
    Name/Address(and Manufacturing Site for Devices)\Zip Code,

    <postalCode>12345
      8888</postalCode> <!-- Contact Office - Name/Address(and Manufacturing Site for
    Devices)\Country, B
        <country>USA</country>
      </addr>
      <!--Fax Number, BOX G1 -->
      <telecom value="fax:+1(777)777

        7777" />
      <!-- Email Address, BOX G1 -->
      <telecom

        value="mailto:mdrContact@noone.com" />
      <!-- Manufacturer Phone Number,
      BOX G2 -->

      <telecom value="tel:+1(111)666
        7777" />
        -<contactManufacturerContact>

      -<name> <!-- Contact Office - Name/Address(and Manufacturing Site for
          Devices)\Title, BO
          <prefix>Mr.</prefix> <!-- Contact Office - Name/Address(and Manufacturing Site
          for Devices)\First Nam
          <given>John</given> <!-- Contact Office - Name/Address(and Manufacturing Site
          for Devices)\Middle Na
          <given>Quincy</given> <!-- Contact Office - Name/Address(and Manufacturing Site
          for Devices)\Last Name
     <family>Adams</family> </name>
    </contactManufacturerContact> </contactParty>
    </manufacturerOrReprocessor>
    </asManufacturedProduct> -
    <asManufacturedProduct> -<!-
                              The manufacturer or
                            Reprocessor element can
                            appear twice. The second
                            instanc
  -->
-<manufacturerOrReprocessor>

    <code code="C53614"
      codeSystem="1.10.9"
      codeSystemName="Type_of_Manufacturer" />
```

```
<!--Name and Address of
Reprocessor\Name, BOX D9 -->
<name>American Reprocessor

  Choice</name>
<!--Fax Number, BOX D9 -->
<telecom value="fax:+1(888)888
8888" />
<!-- Email Address, BOX D9 -->
<telecom
value="mailto:repr@noone.com" />
-<addr>
<!--Name and Address of

 Reprocessor\Address Line 1, BOX D9 --> <streetAddressLine>41 New
    Street</streetAddressLine> <!--Name and Address of Reprocessor\Address Line 2, BOX
  D9 --> <streetAddressLine>New Street Line
    2</streetAddressLine> <!--Name and Address of Reprocessor\City, BOX D9 -
    ->
    <city>New City</city>
    <!--Name and Address of
    Reprocessor\State, BOX D9 -->
    <state>ZC</state>
    <!--Name and Address of
    Reprocessor\Zip Code, BOX D9 -->
    <postalCode>88887
    7272</postalCode> <!--Name and Address of Reprocessor\Country, BOX D9 -->
 <country />
</addr>
</manufacturerOrReprocessor>
</asManufacturedProduct>
-<inventoryItem>
<!-- Device Model Number, BOX D4 -->

-<manufacturedDeviceModel> <id extension="ABCDE" /> <!-- Common Device Name\Product
   Code, BOX D2 Populate with MAUDE Code FRN -->
 -<code code="FRN" codeSystem="2.16.840.1.113883.3.26.1.1"
    codeSystemName="Type_of_Device"> <originalText
                        mediaType="text/plain">All in one
    pump</originalText> </code> <!--Brand Name, BOX D1 --> <manufacturerModelName

                        mediaType="text/plain">THE ONE
                        DEVICE</manufacturerModelName>
 -<asRegulatedProduct> <!-- Premarket Number, BOX G5 --> <id extension="PMA00001" />
</asRegulatedProduct> </manufacturedDeviceModel>
</inventoryItem> </identifiedDevice> -<subjectOf>
-<deviceObservation>
<!-- Device Available for Evaluation?,
BOX D10 -->
<!-- Code is populated with Concept ID
for question -->
```

```
      <!-- populate true for YES and a date if
      available -->
      <!-- populate false for NO -->
      <code code="C53449"

       codeSystem="2.16.840.1.113883.3.26.1.1"
       codeSystemName="Device_available_for_evaluation" />
       <!-- Returned to Manufacturer on, BOX D10

        -->
      <effectiveTime value="20050101" />
      <value xsi:type="BL" value="true" />

  </deviceObservation> </subjectOf> -
<subjectOf>
  -<deviceObservation>
      <!-- Approximate Age of Device, BOX F9
      Code is concept id for approximate_age_of_device -->
      <code code="C53451"

     codeSystem="2.16.840.1.113883.3.26.1.1"
     codeSystemName="Approximate_Age_of_Device" />
     <value xsi:type="PQ" value="4" unit="YR" />
     </deviceObservation>
     </subjectOf>

-<subjectOf> <!-- Event Problem Codes\Device Code, BOX F10 --> <!-- First code is populated
    with NCI concept code, Value populated with valid MAUDE Device Problem Code
  -<deviceObservation>
      <code code="C53982"
        codeSystem="2.16.840.1.113883.3.26.1.1"
        codeSystemName="Device_Problem_Code" />

    <value xsi:type="CE" code="1450"
      codeSystem="2.16.840.1.113883.3.26.1.1" />
      </deviceObservation> </subjectOf> -
      <subjectOf> -<deviceObservation>
      <code code="C53982"
        codeSystem="2.16.840.1.113883.3.26.1.1"
        codeSystemName="Device_Problem_Code" />

    <value xsi:type="CE" code="1449"
      codeSystem="2.16.840.1.113883.3.26.1.1" />
      </deviceObservation> </subjectOf> -<subjectOf>
  -<deviceObservation>
      <!-- Device Evaluated by Manufacturer?,
      BOX H3 -->
      <!-- Code is populated with Concept ID
      for question -->
      <!-- populate true for YES -->
      <!-- populate false for NO -->
      <code code="C53629"

     codeSystem="2.16.840.1.113883.3.26.1.1"
```

```
      codeSystemName="Device_Evaluated_By_Manufactur
      er" /> <value xsi:type="BL" value="false" />
      </deviceObservation> </subjectOf> -<subjectOf>
-<deviceObservation>
    <!--Device Evaluated by
    Manufacturer\Evaluation Summary Attached, BOX H3 -->
    <!-- Code is populated with Concept ID
    for question -->
    <!-- populate true for YES -->
    <!-- populate false for NO -->
    <code code="C53592"

  codeSystem="2.16.840.1.113883.3.26.1.1"
  codeSystemName="Evaluation_Summary_Status" />
  <value xsi:type="BL" value="false" />
  </deviceObservation> </subjectOf> -<subjectOf>
-<deviceObservation> <!--Device Evaluated byManufacturer\Explain why not evaluated or
    provide code, BOX H3
  -<!-
                              Code is populated with
                            Concept ID for Reason for non-
                            evaluation, Value is MAUDE cod
    -->
    <code code="C53593"
      codeSystem="2.16.840.1.113883.3.26.1.1"
      codeSystemName="Reason_for_Non-
      Evaluation" />

  -<value xsi:type="CE" code="81"
      codeSystem="2.16.840.1.113883.3.26.1.1">
      <originalText>Very very good

     reason</originalText> </value>
 </deviceObservation> </subjectOf> -
 <subjectOf> -<deviceObservation>
    <!-- Labeled for Single Use?, BOX H5 -
    >
    <!-- Code is populated with Concept ID
    for question -->
    <!-- populate true for YES -->
    <!-- populate false for NO -->
    <code code="C53602"

   codeSystem="2.16.840.1.113883.3.26.1.1"
   codeSystemName="Device_Labeled_for_single_use" />
   <value xsi:type="BL" value="true" />
   </deviceObservation>
   </subjectOf>

  -<subjectOf>
    -<deviceObservation> <!-- If Remedial Action Initiated, Check Type, BOX H7 --> <!--
       Code is populated with Concept ID for Type_of_Remedial_Action, Value is code for
       Other --> <code code="C53603"
```

```
        codeSystem="2.16.840.1.113883.3.26.1.1"
        codeSystemName="Type_of_Remedial_Action" />
      -<value xsi:type="CE" code="C17649"
        codeSystem="2.16.840.1.113883.3.26.1.1">
        <!-- populate below if OTHER was
        chosen for H7, text to explain OTHER -->
        <originalText>Something else entirely

       different happened</originalText>
     </value>
     </deviceObservation>
     </subjectOf>
     -<subjectOf>

    -<deviceObservation> <!-- Usage of Device, BOX H8 --> <!-- First code is populated with
       concept ID for Initial Usage, Value is code for Initial Usage --> <code
       code="C53645"
      codeSystem="2.16.840.1.113883.3.26.1.1"
      codeSystemName="Usage_of_Device" />
      <value xsi:type="CE" code="C53612"
      codeSystem="2.16.840.1.113883.3.26.1.1" />
      </deviceObservation>
      </subjectOf>
      -<subjectOf>
      -<deviceObservation>
      <!-- If action reported under 21 USC 360i

       (f) list correction/removal reporting number, BOX H9 --> <!-- First code is
       populated with concept ID for Corrective_Action_Number, Value is id number -->
       <code code="C53619"
     codeSystem="2.16.840.1.113883.3.26.1.1"
     codeSystemName="Corrective_Action_Number" />
     <value xsi:type="ED"
     mediaType="text/plain">7778877</value>
     </deviceObservation> </subjectOf> </identifiedDevice>
     </device> -<authorOrPerformer typeCode="AUT">
-<assignedEntity>
    <!-- Operator of Device, BOX D5 Code is Value
    for Other -->

  -<code code="C17649"
      codeSystem="2.16.840.1.113883.3.26.1.1"
      codeSystemName="Operator_of_Medical_Device">
      <!--text for OTHER -->

        <originalText mediaType="text/plain">Hospital
          Worker Bee</originalText>
          </code>

                                        </assignedEntity>
                                      </authorOrPerformer>
                                    -<pertinentInformation1>

    -<observation moodCode="EVN">
```

```
    <!-- Box D8 Is this a single use device that was
    reprocessed and reused on a patient? -->
    <!-- Code is populated with Concept ID for
    question -->
    <!-- populate true for YES -->
    <!-- populate false for NO -->
    <code code="C53563"

      codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="Single-
      Use_Device_Reprocessed_and_Reused_on_Patient" />
  <value xsi:type="BL" value="true" />
</observation>
</pertinentInformation1>
-<pertinentInformation1>

-<observation moodCode="EVN"> <!-- Concomitant Medical Products and TherapyDates, BOX
    D11 --> <!-- First code is populated with concept ID for Concomitant_Therapy,
    Populate date of therapy if available, populate
```

```
        <code codeSystem="C53630"
          code="2.16.840.1.113883.3.26.1.1"
          codeSystemName="Concomitant_Therapy" />

        <!-- Concomitant Medical Products and Therapy
        Dates\Date, BOX D11 -->
        <effectiveTime value="20030303" />
        <value xsi:type="ED"

      mediaType="text/plain">Special
      treatment was
      given to the patient as
      necessary</value>
      </observation>
      </pertinentInformation1>
      -<component1>

     -<implantation>
        <!-- If Implanted, Give Date, BOX D6 -->
        <effectiveTime value="20030101" />

      </implantation>
    </component1>
    -<component2>

     -<explantation>
        <!-- If Explanted, Give Date, BOX D7 -->
        <effectiveTime value="20030110" />

    </explantation>
  </component2>
  </procedureEvent>
  </pertainsTo>
  </investigationEvent
  >
    </subject> -<reasonOf> -
  <detectedIssueEvent> <!--
  Report Source, BOX G3 --> -
  <!-
                  First code is populated
                 with concept ID for Report
                 Source,
                 Value is code for User
                 Facility
    --> <code code="C53566"
    codeSystem="2.16.840.1.113883.3.26.1.1
    " codeSystemName="Report_Source" />
    <value xsi:type="CE" code="C53567"
    codeSystem="2.16.840.1.113883.3.26.1.1
```

```
    " /> </detectedIssueEvent> </reasonOf> -
    <reasonOf>
  -<detectedIssueEvent>
     <!-- Type of Report, BOX G7 -->
     <!-- First code is populated with concept ID for Type of
     Report, Value is code for Follow Up -->
     <code code="C53571" codeSystem="2.16.840.1.113883.3.26.1.1"

       codeSystemName="Type_of_Report" />
     <text mediaType="text/plain">Follow-up#8</text>
     <value xsi:type="CE" code="C53579"

     codeSystem="2.16.840.1.113883.3.
  26.1.1" /> </detectedIssueEvent>
  </reasonOf> -<reasonOf>
  -<detectedIssueEvent>
     <!-- Type of Reportable Event, BOX H1 -->
     <!-- First code is populated with concept ID for Type of
     Reportable Event, Value is code for Death -->
     <code code="C53570" codeSystem="2.16.840.1.113883.3.26.1.1"

codeSystemName="Type_of_Reportable_Event" />
    -<value xsi:type="CE" code="C28554"
       codeSystem="2.16.840.1.113883.3.26.1.1">
       <!-- Text to explain Other, BOX H1 -->
       <originalText>If you had to explain other, you would do it

      here</originalText>
   </value>
   </detectedIssueEvent>
   </reasonOf> -<reasonOf>
  -<detectedIssueEvent> <!-- If Follow-up, What type?, BOX H2 --> <!-- First code
     is populated with concept ID for Type of Follow up, Value is code for
     Additional Information Report --> <code code="C53584"
     codeSystem="2.16.840.1.113883.3.26.1.1"
      codeSystemName="Type_of_Follow-up" />
    <value xsi:type="CE" code="C53586"
    codeSystem="2.16.840.1.113883.3.26.1.1" />
    </detectedIssueEvent>
    </reasonOf>

</controlActProcess> </message> </PORR_IN040001UV01>
```

A.4 Vocabulary

The HL7 Version3 specification requires the use of vocabularies to ensure clear communication across disparate systems. In each HL7 model, including the ICSR, a vocabulary domain specifies the set of all the concepts that can be taken as valid values in an instance of a particular field or attribute. The coded values must be identified in the HL7 message by an alphanumeric code and an object identifier coding system (OID). An OID is a way to uniquely identify an object and is a managed hierarchy that starts with the International Standards Organization (ISO) and International Telecommunications Union (ITU). ISO and ITU delegate OID management to organizations such as NCI and FDA by assigning them OID numbers. OIDs are intended to be globally unique. They are formed by taking a unique string and adding additional digits in a unique fashion. These vocabulary requirements ensure unique identification of the concept that the code represents. In addition, they provide capability for the receiving system to convert those codes into meaningful terms to be stored in the receiving database or IT system.

A..4.1 CDRH eMDR ICSR Vocabulary

The CDRH eMDR ICSR implementation uses two HL7 compliant vocabulary domains -- the NCI open source Thesaurus and an FDA vocabulary domain. The appropriate domains are determined by their corresponding OIDs:

Vocabulary Domain	**OID**
NCI Thesaurus	2.16.840.1.113883.3.26.1.1
FDA	2.16.840.1.113883.3.24

Detailed Information concerning the attribute values used to populate the eMDR message instance can be found at: http://www.fda.gov/oc/datacouncil/. The table below provides a summary of the coded elements for eMDR:

TABLE 1: eMDR VOCABULARY VALUES

NCI Concept Code	NCI Concept Preferred Term (PT)
	Type_of_Reporter
C53567	User Facility
C53616	Manufacturer
C53617	Importer
C53618	Original_Equipment_Manufacturer
C53614	Reprocessor

C25150	Age
C28421	Sex
C20197	Male
C16576	Female
C17998	Unknown
C25208	Weight
No Code Required	Adverse_Event_and_Product_Problem_Report
C41331	Adverse_Event
C53054	Product_Problem
C49489	Adverse_Event_Outcome
C41337	Life_Threatening_Adverse_Event
C25179	Hospitalization
C21007	Disablity
C2849	Congenital_Abnormality
C52668	Intervention_Required
C17649	Other
C17998	Unknown
C28554	Death
C36292	Test_Result
C17049	Race
C41219	Native Hawaiian/Other Pacific Islander
C16310	Asian American
C41259	American Indian or Alaska Native

C16352	African American
C41261	White
C53263	Other_Personal_Medical_History
C53265	Type_of_Device
C53272	Operator_of_Medical_Device
C51959	Attorney
C51804	Audiologist
C51960	Biomedical_Engineer
C53428	Dental_Assistant
C53293	Dental_Hygienist
C52654	Dentist
C53274	Device_Unattended
C28248	Dietician
C53417	Emergency_Medical_Technician
C53287	Health_Care_Professional
C53287	Health_Care_Professional
C53429	Home_Health_Aid
C53433	Hospital_Service_Technician
C16960	Patient
C53430	Medical_Assistant
C53442	Medical_Equipment_Company_Technician_or_Representative
C53418	Medical_Technologist
C48660	Not_Applicable

C53419	Nuclear_Medicine_Technologist
C20821	Nurse
C53431	Nursing_Assistant
C28174	Occupational_Therapist
C17649	Other
C53427	Other_Caregiver
C53289	Other_Health_Care_Professional
C53420	Paramedic
C16960	Patient
C53432	Patient Family Member Or Friend Patient_Family_Member_or_Friend
C53431	Nursing_Assistant
C51840	Pharmacist
C53421	Phlebotomist
C53422	Physical Therapist
C25741	Physician
C53423	Physician_Assistant
C53446	Physicist
C53424	Radiologic_Technologist
C53425	Respiratory_Therapist
C53448	Risk_Manager
C53441	Service_and_Testing_Personnel

C53273	Service_Personnel
C28247	Speech_Therapist
C17998	Unknown
C53563	Single-Use_Device_Reprocessed_and_Reused_on_Patient
C53449	Device_Available_for_Evaluation
C53481	Date_of_Device_Return_to_Manufacturer
C53630	Concomitant_Therapy
C53486	Date_of_Concomitant_Therapy
	Occupation
C53571	Type_of_Report
C53620	Initial_Adverse_Event_and_Product_Problem_Report
C53579	Follow-Up_Report
C53451	Approximate_Age_of_Device
FDA001	Device_Problem_Code
FDA002	Patient_Problem_Code
	Report_Receiver
C17237	Food_and_Drug_Administration
	Location_Where_Event_Occurred
C16281	Ambulatory_Care_Facility
C51957	Ambulatory_Surgical_Center
C51945	Ambulatory_Surgical_Facility
C51963	Blood_Bank
C51964	Bloodmobile

C51966	Free-Standing_Cardiac_Catheterization_Laboratory
C53510	Cardiac_Catheterization_Suite
C51967	Chemotherapy_Center
C51282	Clinic
C53511	Intensive_Care_Unit
C53518	Dialysis_Center
C53512	Dialysis_Unit
C53519	Drug_Rehabilitation_Clinic
C53513	Emergency_Room
C53514	Examination_Room
C18002	Home
C53532	Hospice
C16696	Hospital
C16696	Hospital
C53521	Mobile_Imaging_Center
C53522	Stationary_Imaging_Center
C53538	In_Transit_to_Medical_Facility
C37984	Laboratory
C53551	Laboratory_or_Pathology_Department
C53530	Long-Term_Care_Facility
C53515	Maternity_Ward_or_Nursery
C53523	Mobile_Health_Unit
C53524	MRI_Center
C48660	Not_Applicable
C53533	Nursing_Home

C53516	Operating_Room
C17649	Other
C53541	Outdoors
C51945	Ambulatory_Surgical_Facility
C53548	Outpatient Diagnostic Facility
C53549	Outpatient_Treatment_Facility
C53542	Park
C18002	Home
C53552	Ward_or_Patient_Room
C53545	Playground
C53564	Psychiatric_Center
C53536	Psychiatric_Facility
C53546	Public_Building
C53540	Public_Venue
C53517	Radiology Department
C53535	Rehabilitation_Center
C53537	Retirement_Home
C17118	School
C25690	Street_Address
C53525	Tuberculosis_Clinic
C17998	Unknown

C53528 Urgent_Care_Center

	Report_Receiver
C53616	Manufacturer
C53566	Report_Source
C51968	Company_Representative
C53568	
C48289	Distributor
C25512	Foreign

C53287	Health_Care_Professional
C50913	Invalid_Data
C48471	Publication
C17649	Other
C15206	Clinical_Study
C17998	Unknown
C53567	User_Facility
	Type_of_Report
C53573	Five-Day_Report
C53574	Seven-Day_Report
C53575	Ten-Day_Report
C53576	Fifteen-Day_Report
C53577	Thirty-Day_Report
C53578	Periodic_Report
C53579	Follow-up_Report
C53580	FDA_Requested_Report
C53581	Manufacturer_Response_to_Voluntary_Report
C53570	Type_of_Reportable_Event
C28554	Death
C53569	Serious_Injury
C25745	Failure
C53584	Type_of_Follow-Up_Report
C53585	Correction_Report
C53586	Additional_Information_Report
C53587	Response_to_FDA_Request
C53588	Device_Evaluation_Report
C53629	Device_Evaluated_by_Manufacturer

C53592	Evaluation_Summary_Status
C53593	Reason_for_Non-Evaluation
C53598	Device_Received_in_Condition_Which_Made_Analysis_Impossible
C53601	Device_Evaluation_Anticipated_But_Not_Yet_Begun
C53599	Device_Not_Made_by_Company
C53600	Device_Problem_Already_Known_No_Evaluation_Necessary
C17649	Other
C53591	Device_Returned_to_Manufacturer_for_Evaluation
C53602	Device_Labeled_for_Single_Use
FDA003	Evaluation_Code_Result
FDA004	Evalutaion_Code_Conclusion
FDA005	Evaluation_Code_Method
C53603	Type_of_Remedial_Action
C53604	Inspection
C53606	Modification_or_Adjustment
C25297	Notification
C17649	Other
C53607	Patient_Monitoring
C53608	Relabeling
C53609	Recall
C53610	Replacement
C53611	Repair
C53645	Usage_of_Device
C53612	Initial Usage
C53613	Reuse

C17998	Unknown
C53619	Corrective_Action_Number

The majority of the concepts for the CDRH eMDR ICSR vocabulary come from the NCI Thesaurus. NCI Thesaurus assigns a unique concept ID to every item it stores.

The message examples below illustrate how codes are used in the CDRH eMDR xml message:

Patient Weight Observation

```
<code code="C25208" codeSystem="2.16.840.1.113883.3.26.1.1"
    codeSystemName="Weight" />
<value xsi:type="PQ" value="100" unit="lb" />
```

code – the actual alphanumeric value that is used to specify the concept or attribute, i.e., in this case, weight
codeSystem – specifies the vocabulary domain. Note the NCI OID indicates that this is the NCI domain.
codeSystemName – descriptive name of the actual attribute or concept being defined in this example
value – the actual value that is associated with the attribute weight

The value attribute is optional. In some cases the message contains a standard name for an attribute (e.g. administrativeGenderCode is the standard attribute for gender or sex). Since there is no requirement for a special code to indicate sex, the code C20197 specifies the value for sex (in this case 'male') and there is no need for a value attribute.

Patient Gender

```
<administrativeGenderCode code="C20197"
codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="Sex" />
```

There are 2 code sets that will not use the NCI Thesaurus OID because they are maintained by FDA. These are the Manufacturer and User Facility Report ID numbers. Temporarily, we have assigned the FDA OID, to these numbers. The example below illustrates how to value report number in the ICSR:

```
<id root="2.16.840.1.113883.3.24" extension="555555555-2005-0001"
assigningAuthorityName="FDA" />
```

id root – FDA OID
extension –manufacturer and/or user facility report number based on your current processes or system
assigningAuthorityName – specify FDA

The CDRH ICSR instance example provides a variety of coding examples. Comments have been inserted into the instance to assist you in code assignment. In general, codes are used to indicate a particular concept (e.g. C53272 is the code for Operator of Device). Codes identify values associated with those concepts (e.g. C51804 – Audiologist is an allowable value for operator of the device). Certain concepts do not need a code because HL7 has already identified the concept and accommodations for them are inherent in the schema, therefore, no codes need to be assigned.

FDA has created a detailed Excel spreadsheet (**HL7 Medwatch.07.21.06.xls)** file that contains a list of all value sets for the CDRH eMDR ICSR implementation and for all the information needed to populate the ICSR mapping instance. The columns in the spreadsheet contain the current 3500A location and label for

the term, the allowable field lengths, the assigned NCI Code, NCI definition and FDA definition (if available). This file can be downloaded from the FDA website at: http://www.fda.gov/oc/datacouncil/.

Terms stored in the NCI Thesaurus will be accessible from the National Cancer Institute Thesaurus website via a browser or Application Programming Interface (API) application. http://nciterms.nci.nih.gov/NCIBrowser/Dictionary.do. The most flexible way for developers of ICSR-related software to access the FDA CDRH eMDR ICSR terms in the NCI Thesaurus is to use the application programming interfaces. For future reference, programmers will find information about accessing these terms at:

caCORE Technical Guide:
ftp://ftp1.nci.nih.gov/pub/cacore/caCORE2.0_Tech_Guide.pdf
caCORE Technical Supplement:
ftp://ftp1.nci.nih.gov/pub/cacore/caCORE3.0.1_Tech_Supp.pdf
Release notes:
http://ncicb.nci.nih.gov/core/caCORE3.0.1_notes.txt.
Technical support is available at: http://ncicbsupport.nci.nih.gov/sw/
The client side APIs and JavaDocs are available for download at
http://ncicb.nci.nih.gov/download/downloadcabio.jsp

ftp://ftp1.nci.nih.gov/pub/cacore/EVS/FDA/
Information about FDA terminology

A..5 Data Types

In HL7 version 3, data types define the meaning or semantics of the values that can be assigned to the attribute. They are not the atomic data types familiar to database developers. Instead, HL7 data types can encompass complex notions such as postal address, clinical concept, and order frequency. For more information about data types refer to Appendix H: HL7 Version 3 Reference Information.

A.6 How to create an MDR as an HL7 ICSR xml file

There are several possible ways to create an MDR as an HL7 ICSR xml message. The below lists some suggestions, which do not include an exhaustive list:

XSLT (eXtensible Stylesheet Language Transformation)

XSLT uses XSL (eXtensible Stylesheet Language) and Xpath. Xpath is a query language for finding information in an XML document. Path expressions are used to navigate XML documents.
Create an XML file based on your database tables.
Use XSLT to transform it to an XML - HL7 message.
Validate it against the schema.

Inject Data into Template

Start with a “blank” instanceMapping.xml file by removing the data (not the meta-data) from the file. This will leave you with an XML-HL7 message with place holders for your data.
Create a program that opens your blank instance
Run SQL statements against your database to retrieve data
Use XPath to figure out where in the instance the data should be inserted.
Insert this data into your blank instance

Create the Message from Scratch

Programmatically create a new XML file to walk the message structure, query the background database and create and XML instance.
Create a program that opens your new XML file
Run SQL statements against your database to retrieve data
Use XPath to figure out where in the instance the data should be inserted.
Insert your data into the instance

A.7 CDRH ICSR Files

FDA CDRH have created a packet of files to assist in implementation of the ICSR message that can be downloaded from the FDA website at: http://www.fda.gov/oc/datacouncil/. The following provides a description of each of these files.

File Name	Contents
HL7Medwatch.xls	3500A_HL7 Sheet - lists each medwatch element, current instructions, HL7 pointers and field lengths; Vocabulary Sheet - lists all of the vocabulary items required by the ICSR message x_path' Sheet - used to find the particular nodes in the XML document that are used in the 3500A form
ICSRDiagrams022006.xls	ICSR diagrams for CDRH implementation
voc.xsd	Schema file used for vocabulary validation
Con060221.xsd	Unpopulated ICSR schema for implementation; consolidated XML schema file to which the HL7 message will be validated; includes InfrastructureRoot.xsd
mappingInstance.xml	Example MDR instance using our xml schema. Your MDR submission should look similar to this. This file is a sample HL7 message validated against the Con060221.xsd schema file. When creating your own messages, the data may change from one message to the next but, the structure and meta data should stay the same.
datatypes.xsd, datatypes-base.xsd	Common files used to support datatype structures; schema file that defines the representation of HL7 V3 data types in XML; includes Datatypes-base.xsd. Note that there are some sections of these files that are not used by the ICSR and are commented out.
Infrastructureroot.xsd,	For future use only; this schema file includes datatypes.xsd and voc.xsd and is also used to validate the HL7 message;
narrativeblock.xsd	For future use only; this schema is for use with HL7 Clinical Document Architecture (CDA) standard for electronic forms.