Health informatics — Pharmacovigilance — Individual case safety report —

Part 1:
The framework for adverse event reporting

Informatique de santé — Pharmacovigilance — Rapport de sécurité de cas individuel —

Partie 1: Cadre pour rapporter un événement défavorable

ISO/HL7 DIS 27953-1

ISO/TC 215
Secretariat: ANSI

Voting begins on: 2009-04-30
Voting terminates on: 2009-09-30

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the ISO-lead mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

In accordance with the provisions of Council Resolution 7/2002, this document is circulated in the English language only.

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Published in Ann Arbor, Michigan USA & Geneva, Switzerland
ISO/HL7 27953-1

Foreword

This standard is published as ISO 27953. It was prepared by Technical Committee ISO/TC 215, Health Informatics, CEN TC 251 Health Informatics and the HL7 Patient Safety Workgroup.

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75% of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 27953 was prepared by Technical Committee ISO/TC 215, *Health Informatics*, jointly working with CEN TC 251 *Health Informatics* and HL7 WG *Patient Safety*.

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0 Introduction

To enhance patient safety, it is noted that many countries have strong needs to exchange product safety information between varieties of stakeholders in the healthcare domain. Currently many regulatory agencies collect individual case safety reports of adverse events, infections and incidents from consumers, pharmaceutical companies and healthcare professionals. This standard consolidates content and messaging requirements based upon: 1) ISO New Work Item Proposal N545: Health Informatics - Pharmacovigilance - Structure and Data Elements of Individual Case Safety Report (reclassified as ISO 27953), 2) HL7 ICSR Release 1 Normative Standard, and 3) HL7 ICSR Release 2 Draft Standard for Trial Use (DSTU).

Readers should note that because of the significant differences in use cases and content requirements across these work items, this standard is published as a multi-part standard. Part one of the standard (ISO 27953-1) has been specifically produced to address all the areas of overlap, and to form a messaging framework reference that can be applied to the many different storyboards described in the standard. This is to allow for future development work to be carried out, so that the additional use cases that are not currently addressed in this release can be added in the future as new parts to this standard.

International vocabulary harmonization for ISO 27953-1 is out of scope for this release. However, implementers of other use cases (storyboards) described in this standard may use existing terminologies unique to their organization or region. It is recommended that organizations develop and publish implementation guides to inform and assist others in applying the standard to other use cases, and to facilitate vocabulary harmonization across SDOs. The sponsoring committees will continue to address vocabulary harmonization in subsequent releases of this standard. The initial release of this standard is to establish a common international framework to build upon and should be used to facilitate future SDO harmonization efforts for other product reporting such as medical devices or food safety.

Part 2 of this standard (ISO 27953-2) has been created for implementers interested in regulatory reporting for human pharmaceuticals, and the initial work has been based upon the International Conference on Harmonisation's (ICH) Revised Guideline E2B(R3): Data Elements for Transmission of Individual Case Safety Reports (version 3.96), November 2008. These initial requirements have been extended to take into account additional international requirements. This part of the standard is dependent upon the related ISO vocabulary harmonization work items: Data Elements and Structures for the Exchange of Regulated Product Information for Drug Dictionaries (see ISO 11615, 11616, 11238, 11239 and 11240) and Structures and Controlled Vocabularies for Laboratory Test Units for the Reporting of Laboratory Results (see ISO 11595).

Ballot Considerations

This draft standard document is a harmonized draft between ISO, CEN and HL7. It is jointly balloted in all three organizations. In ISO/TC 215 and CEN/TC 251, this is currently a committee level draft. At the HL7 level, the draft is formatted somewhat differently from other HL7 V3 specifications, because it is a harmonized draft with ISO/TC 215 and CEN/TC 251. Ballot comments should focus on the content rather than the presentation format. Ballot participants are encouraged to submit technical, general and editorial comments in accordance with the ballot governing rules, i.e., through ISO National Member Body (NMB) representative, CEN National Member Body (NMB) representative, or through appropriate HL7 membership voting. To help reduce duplication or conflicts in ballot responses among SDOs, HL7 International Affiliates are encouraged to coordinate with their ISO/CEN NMB representatives for submitting comments to this document. The
sponsoring ISO, CEN and HL7 committees (ISO/TC 215 WG 6: Pharmacy and Health Informatics and HL7 Patient Safety) will jointly consolidate and reconcile all comments per ISO/CEN Vienna Agreement and the ISO/HL7 pilot agreement requirements.

**HL7 Version 3 Contents**

The format of the document follows the standards used by ISO, as well as the model presentation and publication format used by the HL7 Version 3 balloting and standards presentation process. This makes it possible to present both the ICSR models and schemas in a seamless way, and to produce material that can be balloted in the CEN, ISO, and HL7 environments for Part 1. It should be noted that the HL7 V3 Messaging Infrastructure (Transmission and Control Act) are included as separate sections for this ballot to help demonstrate support for ISO requirements related to message attachments, batch submissions and acknowledgements. However, the representation of this content does not include the Hierarchical Message Definition (HMD) files and some hyperlinks to additional HL7 V3 content may not work properly. Technical and copyright issues related to ISO/CEN balloting of this content will continue to be addressed and the sponsoring committees expect resolution for final international standard publication. Note that this material is provided as reference only and is not subject to changes or comment as part of the ICSR ballot. Any comments received for this content will be forwarded to HL7 for consideration.

**SDO Harmonization**

The Joint Initiative on SDO Global Health Informatics Standardization has been formed to enable common, timely health informatics standards by addressing and resolving issues of gaps, overlaps, and counterproductive standardization efforts. The Joint Initiative Charter provides the basis, purpose and structure of the Joint Initiative on SDO Global Health Informatics Standardization. The Individual Case Safety Report (ICSR) Standard was approved as a Joint Initiative project February 2008. The ICSR standard is a candidate for SDO harmonization because of the global interest to improve patient safety by the electronic exchange of high quality, unambiguous, structured data that will support regulatory and patient safety requirements and efficient safety signal detection for patient protection. This standard is generally referred to as the Individual Case Safety Report (ICSR).

The standard's message specification is based upon the current release of HL7's Reference Information Model, including its data types. The sponsoring committees are aware of the current Joint Initiative Project, ISO/HL7 Data Types, and the standard will be updated in future releases to incorporate these data types once appropriate technical tools are available to facilitate conversion.

**Annexes**

The annexes are provided to facilitate ISO/CEN review of the HL7 content. Readers should note that this content is provided and fully accessible as part of HL7's normal ballot process. The annex is provided as background reference material and is not subject to ballot comments within this topic. Note, the HL7 RIM, Data Type, and Vocabulary specifications are listed as annexes for Part 2. Within Part 1, this content is available via hyperlinks within the HMD sections.

Annex A (Normative) Transmission Infrastructure - This annex includes information about message headers, acknowledgements and attachments.

Annex B (Normative) Control Act Infrastructure Topic. This annex includes information about the Control Act and its relationship to the ICSR payload.

Annex C (Informative) contains the HL7 Version 3 Guide
1 Scope: Individual Case Safety Report (ICSR)

Scope of Part 1

Part 1 of this standard seeks to establish an international framework for data exchange and information sharing by providing a common messaging format for transmission of ICSRs for adverse drug reactions (ADR), adverse events (AE), product problems and consumer complaints that may occur upon the administration or use of one or more products. Part 1 is based upon the HL7 Reference Information Model and can be extended or constrained to accommodate a variety of reporting requirements based upon ISO 27953-2 and other regional and international requirements summarized in the storyboard section of this ballot. It should be noted that Part 1 will be harmonized over time with other HL7 public health and patient safety incident reporting standards to help ensure messaging constructs and vocabulary are harmonized across the PORR domain. Furthermore, Part 1 of this standard does not govern or dictate reporting requirements for any product. The use cases (storyboards) described in this standard are for demonstration purposes only and are provided to help demonstrate the standard's scalability and interoperability across multiple stakeholders and product types. Future releases of this standard may be developed to include conformance profiles and vocabulary for all or a limited subset of the use cases.

Note that the data elements that were found to be consistent across all use cases are summarized as Generic Transmission Use Case Data Elements in this part. These data elements should be considered as a generic set of data elements that can be applied to any reporting scenario. Specific reporting requirements within organizations or regions may use all or only a subset of these data elements. Note this standard does not specify a vocabulary subset for these data elements in this release.

Scope of Part 2

Part 2 of this standard is based upon ISO 27953-2 requirements for regulatory reporting for human pharmaceutical products. Part 2 seeks to create a framework for international regulatory reporting and information sharing by providing a common set of data elements and messaging format for transmission of ICSRs for adverse drug reactions (ADR), adverse events (AE), infections and incidents that may occur upon the administration of one or more human pharmaceutical products to a patient, regardless of source and destination. The standard provides a structure where reports can be exchanged in a clear and unambiguous manner such that the nature of the case, the circumstances in which it arose, and particularly the identity of the medicinal product(s) in question, can be communicated with certainty. Requirements for this use case were initially based upon ICH and conformance includes parallel adoption of ISO vocabulary work items: Data Elements and Structures for the Exchange of Regulated Product Information for Drug Dictionaries (See ISO 11615, 11616, 11238, 11239, and 11240) and Structures and Controlled Vocabularies for Laboratory Test Units for the Reporting of Laboratory Results (See ISO 11595).

Topics outside of ISO 27953-2

Part 2 does not govern the reporting of ADRs or AE in animals, human exposure to products intended for veterinary use, safety reports related to blood transfusion, medical devices or combination products. However, in some regions combination products with device or tissue components are regulated as human pharmaceuticals. Implementers should consult specific regional
guidance for reporting these products using this standard. Additionally, these products are also out of scope for Part 2: foods, dietary supplements, in-vitro diagnostics, homeopathic products, minerals, cosmetics, photo-therapy, radiotherapy and other therapies without products classified as medicinal products. For these and other use cases please refer to Part 1 of the standard (ISO 27953-1).

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2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

HL7/ANSI Approved Individual Case Safety Report Release 1 Normative Standard 2005


ISO/HL7 21731:2006, Health informatics - HL7 Version 3 - Reference Information Model release 1


HL7 2008 Datatype Specification Abstract Data Types R1

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3 Terms and Definitions

Note that there are many different terms used to describe basic concepts in healthcare for different purposes available from ISO, CEN, HL7, and from various national and international organizations. Therefore, this standard does not attempt to force adoption of the terms and definitions described in this document. It is intended to be used in combination with any national/regional requirements, and, in case of conflict, national/regional requirements will prevail. This being said, for the purposes of this document, terms and definitions have been documented to facilitate conformance and interoperability testing for ICSR reporting. Terms and definitions specific to ICSR reporting have been moved into the HL7 glossary in order to provide a single source for definitional material. That glossary, can be accessed using the link below.

Detailed terms and definitions relevant to the HL7 messaging specification are provided in the Hierarchical Message Definition (HMD) file and other related sections in HL7's V3 Message Specifications.

Glossary Items
Individual Case Safety Report Topic

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5.4 Refined Message Information

5.2 Application

ICSR Basic Pattern

Introduction

Removal of ICSR Release 1 Content within the HL7 Public Health Reporting Domain

The Individual Case Safety Report Release 2 Draft Standard for Trial Use (DSTU) formally announced the deprecation of all ICSR Release 1 Normative Standard material and constructs from subsequent releases of ICSR. The committee received no negative comments or feedback about this decision, and all ICSR Release 1 content was carried over and supported in ICSR Release 2 DSTU. ICSR Release 3 supports all ICSR Release 1 content, and therefore this content will be removed from the 2009 Normative Edition and be replaced with ICSR Release 3 content.

Revocation of Safety Reporting Management Topic Content within the HL7 Public Health Reporting Domain

The Safety Reporting Management Topic introduced in the HL7 2007/2008 Normative Edition is being deprecated and removed with ICSR Release 3. The Safety Reporting Topic was created in the PWR domain to facilitate balloting for ICSR Release 2 and the Generic Incident Notification (GIN) Message. GIN will be retained in the publishing domain as a separate topic and Safety Reporting will be removed to eliminate redundancy with the ICSR Topic.

Generic Transmission Use Cases

The concept of a Generic Transmission Use Case is provided in this standard as a framework to better understand how requirements were combined and generalized to create a common international electronic exchange format to support reporting. Generally, under this concept, generic transmission use cases involve at least one (1) reporter, one (1) sender and one (1) receiver of an ICSR. The process for creating and transmitting an ICSR may be a manual (internet, web-based tool) or automated (EDI transfer) process. The sponsoring committees have identified a core set of common data elements that are consistent across all uses. Due to significant differences in national and international requirements that govern the release and exchange of safety data, this standard does not enforce adoption of these data set categories, nor does this standard support both coded attributes and free text entries for many of these data categories, and that readers should refer to the contents of the individual ICSR Refined Message Information Models (RMIMs) for detailed information about the attribute level descriptions for these data elements and categories.

1. Administrative Information: Information about senders, receivers, reporters, associated cases, report types, case identifiers, attachments and case seriousness.
   ○ Reporter Information:
     ● Reporter Name
     ● Reporter Address
     ● Reporter Telephone Number
     ● Reporter Title/Qualification
   ○ Sender Information:
     ● Organization Identifier
     ● Organization Name
     ● Organization Address
     ● Organization Telephone Number
     ● Organization Contact Party
     ● Contact Party Name
     ● Contact Party Address
     ● Contact Party Telephone Number
     ● Contact Party Title/Qualification
   ○ ICSR Receiver Organizations: Types of Organizations and Date of Receipt
   ○ Associated Cases (Related Reports)
     ● Related Report ID
     ● Related Report Sender (Organization or Reporter)
   ○ Report Types
   ○ Case Identifiers, including organization that assigns the identifier
   ○ Attachments (Documents associated with the case)
     ● Document Type
     ● Document Title
     ● Document Text
   ○ Clinical Trial Enrollment
     ● Study Name
     ● Study Type
     ● Study ID
   ○ Case Seriousness Indicator

2. Investigative Subjects: Information about patients (or other subjects) and associated persons to support specialized reports such as parent/child reports and includes relevant clinical and laboratory information, reactions, treatment, and any association with clinical trials
   ○ Investigative Subject Information: Human Patient Demographic Information:
     ● Patient Name or ID
     ● Patient Age
     ● Patient Sex
   ○ Patient Medical History, including relevant clinical observations and dates:
     ● Patient Height and weight
     ● Diseases/pre-existing conditions/allergies
     ● Social History/Risk Factors
     ● Clinical Procedures/Labs, including dates and results
   ○ Patient Medications History, including dates of use and previous reactions
   ○ Parent/Associated Person Information:
     ● Demographic Information (see patient demographics)
     ● Medical History, including relevant clinical observations and dates
     ● Height/Weight
     ● Diseases/pre-existing conditions/allergies
     ● Social History/Risk Factors
   ○ Medications History, including dates of use and previous reactions

3. Product Information: Information about the products used by investigative subjects, Includes product name, ingredients, production information (lot ID, expiration date), manufacturer and related product supply information such as distributors and importers
   ○ Product Code (ID)
   ○ Product Class
   ○ Product Name
   ○ Lot ID
   ○ Expiration Date
   ○ Dosage Form
   ○ Packaging Information
   ○ Manufacturer, distributor, or importer Information

4. Product Use Information: Includes information about how the product was used by the investigative subject and covers substance administrations, procedures, supply, and actions taken
   ○ Indication/reason for use
   ○ Dates of Use (Start/End Dates)
   ○ Route of Administration or Approach Site
   ○ Dosing Frequency
   ○ Product Supply Information (How/where product was obtained)
   ○ Service delivery location
   ○ Actions Taken
   ○ Associated or Component Procedures:
     ● Procedure Name
     ● Procedure Date

5. Case Narrative and Comments: Text summary of the pertinent information about the case
   ○ Overall case narrative
   ○ Comments by authors (Senders and Primary Sources)

ICSR Basic Pattern
The diagram below provides a summary view of the the salient features of the ICSR.

The following points should be noted:

- An adverse event is modeled as an investigation into one or more reactions (adverse events) suffered by one or more persons or animals (investigated entity) after using an implicated product. Product problem reports are treated similarly, except that the investigated entity is the type of product involved, and there is no reaction involved.
- When it is necessary to collect information about other parties who are directly involved in the event, e.g., the mother in cases where a nursing infant is harmed, or siblings in vaccine related events, the relevant data is organized within the related entity construct.
- The construct, "Product Reporting Relevant Information", supports information about how the product was used, as well as relevant background information, e.g., medical history, for the investigated entity, or for a related entity.
- The Product Model captures information about products that are implicated in adverse events or that were used around the same time. This model captures information about the product chain of custody (import, distribution and retail) and product testing and disposition of contaminated products are covered in this use case. Pet owners and caregivers may be captured in this use case. Reporting from consumers, healthcare providers and food establishments.

High-level Description of ICSR Content

The ICSR is comprised of two core models and two CMETs that are used to capture the use case content:

- **ICSR Base Model**: This model captures information about the investigation, related investigations and source reports, ICSR senders, receivers and reporters, subjective subjects, associated persons, subject reactions and medical history. Note that two CMETs are included in the base model: A_ProductReportRelatedInformation and A_ResearchStudyEnrollment. For detailed information about this model refer to the ICSR Refined Message Information Model (PORR_RM049006UV01).
- **Product Reporting Related Related Information CMET**: This CMET model replaces the A_SupportingClinicalInformation and A_ProductUse CMETs used in ICSR Release 2. The new CMET combines artifacts from the previous CMETs and includes only the relevant clinical, product use and product defect discovery information needed to support the various use cases. For detailed information about this model refer to the ICSR Related Information CMET Model (PORR_RM0490013UV01).

**CMET** combines artifacts from the previous CMETs and includes only the relevant clinical, product use and product defect discovery information needed to support the various use cases. This CMET model is used to capture information about the clinical trial that the investigative subject is enrolled in. The HL7 committee expects to continue harmonization with the HL7 Regulated Clinical Research Information Management Workgroup on clinical trial messaging and will update this CMET upon completion of the CDISC HL7 Messages Project. For detailed information about this model refer to the HL7 ballot package.
- **R_Product**: This model is used to capture information about a product referenced in the investigation. Information about the product class, product instance (lot ID, creation and expiration dates), packaging, product characteristics (intended use, size shape, color, etc.) and manufacturing are captured in this model. For detailed information about this model refer to the R_Product Refined Message Information Model (PORR_RM_049011UV01).

### 5.1 Storyboards

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- **Storyboards (Sorted by Title)**
  - Individual Case Safety Reporting (PORR_ST040001UV)
  - Storyboards (Sorted by Structured Sort Name)
  - Safetyreport (PORR_ST04001UV)
  - Storyboards (Sorted by Display Order)
  - Individual Case Safety Reporting (PORR_ST040001UV)

Reference

For details on the interpretation of this section, see the storyboard discussion in the Version 3 Guide.

### 5.1.1 Individual Case Safety Reporting (PORR_ST040001UV)

**Purpose**

The storyboards provide examples of situations in which the Public Health Individual Case Safety Report message would be used.

Several of the use cases referenced in the standard were provided by ISO prEN ISO 27953 which focuses on international human pharmaceutical reporting for the International Conference on Harmonisation (ICH). The use case also supports human exposure to drugs intended for veterinary use upon US requirements for the Food and Drug Administration (FDA) Center for Veterinary Medicine (CVM) which supports international regulatory reporting as described in GL 42 of the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH).

Additional use cases referenced in this standard were provided by FDA, US Agency for Healthcare Research and Quality, HL7 Patient Safety Special Interest Workgroup, and the European Medicines Agency (EMEA). The use cases supported by these groups include:

- **International regulatory reporting**: Regulatory reporting requirements were modeled based upon the current draft or final release of guidelines from ICH, VICH, and the Global Harmonization Task Force (GHTF). Reporting for human pharmaceuticals will be aligned with the ISO use cases. It should be noted that ICH and VICH are considering the adoption of ICSR Release 3 to support their reporting requirements. Readers should consult their website sites for future information. GHTF has made no decision at this time to adopt the ICSR for their purposes. The HL7 committee encourages an objective review of this standard by GHTF for future adoption to help better align drug and medical device reporting, especially in support of international combination product reporting.
- **Reporting from consumers, healthcare providers and food establishments**: The US Congress has mandated new FDA reporting mandates under the FDA Amendment Act (FDAMA) sections 1102 and 1002. These sections describe reporting requirements for cases involving the adulteration of human food, animal food/feed and pet treats. Information about product chain of custody (import, distribution and retail) and product testing and disposition of contaminated products are covered in this use case. Pet owners and veterinarians are encouraged to report problems to FDA, and healthcare providers are mandated to report serious adverse events and injuries under the National...
Vaccine Injury Act. Data elements needed to support consumer reporting are also included in this use case to facilitate the FDA (implementation of a web-based reporting portal).

- Reporting for Combination Products: Combination product reporting is supported by ICSR Release 3 using high-level requirements provided by the EU and US. The committee recognizes that there are no harmonized reporting criteria for combination products at this time and anticipates a new work proposal to be introduced in ISO for further collaboration.

- Patient Safety Reporting: Requirements for patient safety reporting were provided by the HL7 Patient Safety Special Interest Workgroup and the Agency for Healthcare Research and Quality (AHRQ). This use case considered reporting of certain types of patient safety incidents among healthcare organizations such as hospitals, outpatient clinics, and skilled nursing facilities. It should be noted that reporting requirements for medical devices (based upon the US Center for Devices and Radiological Health) are also supported in this use case. This use case includes no harm and potential harm incidents (i.e., medication errors). The HL7 committee reviewed preliminary output from AHRQ's Common Format work, emphasizing data elements needed to report patient safety incidents involving adverse events associated with medications, medical devices, tissues, blood, blood products and organs. Note that AHRQ has made no decisions to adopt their ICSR Release 3 to support their Patient Safety Organ (PSO) regulation. However, the HL7 committee wishes to continue its collaboration with AHRQ and other groups to better harmonize the ICSR and other public health reporting formats to specifically address vocabulary harmonization to facilitate national and international patient safety and public health initiatives. The committee expects that upon completion of the Public Health Reporting Domain Analysis Model, changes will be required to align and/or consolidate messaging in this domain and will assess impacts to ICSR and other existing message standards at that time.

### Diagram

#### ICSR Event Report
- Individual Case Safety Report
- Individual Case Safety Report Revision
- Individual Case Safety Report Prevention

#### ICSR Notification Schema
- Trigger and Notification
- Event
- Summary
- Description
- Risk
- Impact
- Follow-Up

### 5.1.1.1 ICSR Event Report (PORR_SN040001UV)

Mrs. Mary Jones visited her General Practitioner/Family Physician, Dr. Greta Greene last week because she was suffering from a severe urinary tract infection (UTI). Dr. Greene prescribed a course of Ciprofloxacin 250mg tablets to be orally taken twice a day for 5 days. Mrs. Jones' only other regular medication is hormone replacement therapy, for which she takes Prempro C 625micrograms.

After three days, Mrs. Jones' UTI is resolving well, but she is experiencing increasing soreness of her left ankle. She has no recollection of injuring her ankle in any way. On the fourth day, her ankle is so sore that she makes another appointment to see Dr. Greene later that day. Dr. Greene examines Mrs. Jones and observes that her left ankle is red, stiff, hot and swollen. Mrs. Jones' comments that she had some swelling in the last week of her ankle which improved. Dr. Greene wonders what other causes there might be for these symptoms. Remembering that she prescribed an antibiotic for a urinary tract infection on Monday for Mrs. Jones, she checks her clinical software for Mrs. Jones' medication record and sees the prescription for Ciprofloxacin. She then checks the electronic drug formulary for information on Ciprofloxacin and Quinolone antibiotics as a family, and it reminds her that Quinolones are known to have an adverse effect of tendonitis, especially the Achilles tendon. The formulary advises that the medicine should be stopped immediately and the affected joint rested.

Dr. Greene's clinical judgment leads her to be confident that Mrs. Jones is experiencing an adverse drug reaction to her treatment for her UTI. She explains this to Mrs. Jones, and that she must stop the Ciprofloxacin (she feels that the UTI has resolved well), and rest her ankle, and that the ankle soreness will resolve. She may take some painkiller medication (paracetamol/acetaminophen) if she would like to. However, she would like to see her again in a week just to be sure all is well. One week later, Mrs. Jones sees Dr. Greene again. Her ankle is improving nicely and she feels that in a couple of days she will be back to normal. After she has left, Dr. Greene thinks through this incident, and decides that, due to the severity of the event, she should report it to the patient safety/quality improvement organization, the relevant drug manufacturer, and regulatory authority. She logs into her clinical support system to complete an electronic Individual Case Safety Report form. The electronic form already includes many of the details of Mrs. Jones' adverse drug event. The form includes her demographic information, relevant medical history, lab tests and results and current medications. The form includes Dr. Greene's progress notes and other sections ready for her input. When Dr. Greene is satisfied that the form is complete, she then authorizes her clinical support system to send the electronic report to the appropriate organization(s).

Interaction: Individual Case Safety Report Create(PORR_SN040006)

### 5.1.1.2 ICSR Product Defect Report (PORR_SN04002UV)

Pharmacist Rebecca Rogers is preparing a solution to be used in chemotherapy for patients in General Hospital's outpatient cancer clinic. She notices, as she holds up a bottle from storage, that the solution appears cloudy and has particles floating in it. This physical property is not according to specification, and she sets the bottle aside. At the end of the day, a more thorough inspection reveals that half the bottles in a case of Solution X contain contaminated or defective solution. She reports the problem to the medical supply department, and the hospital files a product problem report with the regulatory authority and the manufacturer.

Interaction: Individual Case Safety Report Create(PORR_SN040006)

### 5.1.1.3 Follow Up (Revise) ICSR Event Report (PORR_SN04003UV)

Last week, Dr. Greta Greene submitted an Individual Case Safety Report that referred to Mrs. Mary Jones' adverse drug experience with Ciprofloxacin as a treatment for UTI. As she reviewed the records of the case, it seems to her that perhaps the fact that Mrs. Jones was an ardent runner could be a relevant factor in evaluating the cause of her recent tendonitis. Dr. Greene decides to send a follow-up ICSR so that this additional information will be considered when Mrs. Jones' case is evaluated by the appropriate organization(s).

Interaction: Individual Case Safety Report Create(PORR_SN040006)

### 5.1.1.4 Withdraw ICSR Event Report (PORR_SN04004UV)

Withdraw ICSR Event Report

[Note: this storyboard is not based on any real world event.] Regional Withenspoon, JD is an attorney specializing in private injury work. He has recently been putting together a class action suit seeking damages for patients who had been taking the drug, CureAll, as a treatment for lower back pain. However, in a fraction of cases, while the back pain had improved, patients had experienced severe headaches. Mr. Withenspoon, and his clients, believe that CureAll is responsible and they are seeking damages.

As Mr. Withenspoon's office signs up users of CureAll as parties to this lawsuit, they also file an ICSR for each new client. This report includes the relevant information regarding the individual case. Such a report was filed when the office agreed to represent George Gould, who stated that he was a long time CureAll user and headache sufferer.

After further discussions with Mr. Gould, it emerges that had started experiencing headaches long before his use of CureAll, and may be related to trauma he experienced as a child when he was kicked by a horse. Once it becomes clear that CureAll cannot reasonably be involved, Mr. Gould is informed that he is being dropped from the suit. Mr. Withenspoon's office also sends an ICSR retraction to the local regulatory agency.

Interaction: Individual Case Safety Report Withdraw(PORR_SN040007)

### 5.1.1.5 Follow Up (Revise) ICSR Product Defect Report (PORR_SN04005UV)

Shortly after the submission of the ICSR product problem report for Solution X, General Care Hospital receives a call from the Acme Supply Company, whom also received a copy of the ICSR product problem report. The Acme representative informs the hospital that based upon the lot number reported in the ICSR, this product could not be one of theirs because the product lot number in the report violates Acme's lot number convention for assigning lot identifiers. The hospital representative reviews the paperwork for deliveries from Acme Supply, and locates the correct bill of lading for the product delivery in question. With the proper lot information in hand, the hospital sends a follow up ICSR product problem report to the regulatory authority and the manufacturer.

Interaction: Individual Case Safety Report Create(PORR_SN040007)

### 5.1.1.6 Withdraw ICSR Product Defect Report (PORR_SN04006UV)

The RealFixit Corporation, a medical device manufacturer, reports a serious injury to the FDA for a patient who underwent major abdominal surgery. This manufacturer learned later that their product did not cause or contribute to the patient's injury; however another company's product caused the patient's injury. The RealFixit Corporation forwards a request to retract their original device problem report since their product did not contribute to the injury. The manufacturer of the other suspected problem device submitted a serious injury report also.

5.1.1.7 Cosmetic as Face Paint (PORR_SN040008UV)

Cosmetics Adverse Event Reporting: Multiple Suspected Cases

The following two adverse events involved the same cosmetic face paint product. They occurred within a few days of each other, from different areas of the country.

Wallace Waskyford, a Fun Store employee, submitted an adverse event report to the FDA to report an incident after being contacted by the principal of the Central Z Middle School. A black color face paint (Kern S), produced by Coverings Corporation, as listed on the label, was applied to the students as part of a special theme day. Approximately 300 students received an application of face paint with different brushes. The following day, approximately 70 - 80 students reported having a rash on their face. Later the number of rashes had accumulated to approximately 175. A dozen or so students sought medical treatment. Medical information was not included in the report from Mr. Waskyford. The report was sent electronically using a web-based form. The web-based form translates the information into an HL7 ICSR and routes the report to the appropriate FDA safety evaluator for analysis.

Interaction: Individual Case Safety Report Create (PORR_IN049006UV)

A counselor of a boy's organization called the state FDA Field Office to report an incident that occurred at their annual banquet. The counselor reported that several colors of face paint from Company Z were used to mark the cheek of each boy. A total of about 40 boys were marked in this manner using one of three colors: blue, red, and green. Of the 18 boys which received the blue face paint, a total of 16 experienced a skin reaction. This reaction ranged from a red, "burnt" appearance which lasted about 46 hours to a raised, bright red rash which still remained 5 days later when the incident was reported to the counselor. To the knowledge of the reporter, no boy received care from a medical doctor for the problem. The FDA Field Office employees entered the report into the Consumer Complaint System and the report was sent electronically to the FDA headquarters office for further analysis and follow up.

Interaction: Individual Case Safety Report Create (PORR_IN049006UV)

5.1.1.8 Dietary Supplement (PORR_SN040003UV)

Dietary Supplement Adverse Event Storyboard

Mrs. Nuclear, an 86 year old female consumed 400 IU of vitamin D made by Supplement Company 10P. Four hours later she fell to the floor and had a seizure. When she stopped seizing, she was able to note that she did not awake, and called the 911-Emergency Dispatcher. When the paramedics arrived, Mrs. Nuclear was still unconscious and she was taken to the hospital. When she arrived at the hospital, Mrs. Nuclear regained consciousness in the examination room, and the emergency room attending physician, Dr. Attend ordered a series of tests to help obtain a more precise diagnosis of Mrs. Nuclear condition. Mr. Nuclear informed the attending physician that they were taking a new vitamin D supplement, and that he suspects that Mrs. Nuclear is having an adverse reaction to the supplement. Dr. Attend responded to Mr. Nuclear that he does not suspect this to be the case, but informs Mr. Nuclear that he can report the incident to the dietary supplement company or FDA to help alter the distribution. Mrs. Nuclear called the FDA Consumer Complaint hotline to report the problem, and provided a contact number for Dr. Attend for follow up once the laboratory results are final. The FDA Consumer Complaint hotline technician entered the complaint into the system, and sent the case electronically to the FDA Center for Food and Applied Nutrition (CFSAN) for further analysis and follow up.

Interaction: Individual Case Safety Report Create (PORR_IN049006UV)

The following two adverse events involved the same dietary supplement product. They occurred within a few days of each other, from different areas of the country.

On December 12, 2005 Eve Eyswomon, a 54 year old female was admitted to the Outpatient Surgery Center for the placement of a Portman Medical Corporation, 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 referred to the recovery room, the anesthesiologist Dr. Sally Sleeper initiated the programming of Ms. Everywoman's implanted pump. During this set-up procedure the implantable pain pump stopped functioning and the pump's visual display went blank. The anesthesiologist was unable to troubleshoot the pump's 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. Sleeper decided to complete an electronic ICSR, Individual Case Safety Report, using the hospital's Incident Reporting System because he felt his patient had suffered a serious injury. She 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 pertinent information. The patient demographics, patient's medical history and many details of her surgery were already stored in the patient's electronic medical record. The event information was obtained from the surgeon's and the anesthesiologist's progress notes and automatically populated into the form. The pump's data were entered in this form. Once the pump's data were entered, the system displayed the following: the pump's condition was normal, the pump's current status was normal, and the pump's device failure was not restored. The patient was informed of the incident and was discharged, and Dr. Sleeper clicked the submit button. This sent the incident report to the risk manager. Patient Safety Committee, the device manufacturer and the regulatory authority. Mr. Randy Risers, the hospital risk manager, reviewed the incident report, made some edits and gave approval that this was a reportable event that could be sent to FDA. He clicked a 'Submit SPDA Event' button that electronically forwarded the ICSR report to the manufacturer.

Additionally, the hospital returned the pain pump to the manufacturer for evaluation three days after the event.

Interaction: Individual Case Safety Report Create (PORR_IN049006UV)

Manufacturer Response to Reported Event

Two weeks after the implantable pain pump was returned to Portman Medical 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 source report and create a new report in their internal Adverse Event Reporting System using the User Facility (hospital) Report as a source document.

Interaction: Individual Case Safety Report Create (PORR_IN049006UV)

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 Portman Medical Corporation, Model LS 4700 implantable pain pump implanted on December 12, 2005. The Center 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 Center's request for additional information.

Interaction: Individual Case Safety Report Create (PORR_IN049006UV)

Manufacturer Response to Request for Additional Information

The manufacturer sends new, changed or updated information via ICSR. This follow up serves to respond to CDRH's request for additional information about the software issue described in a report to the Center for Devices and Radiological Health (CDRH) involving the Portman Medical Corporation, Model LS 4700 implantable pain pump implanted on December 12, 2005. The Center requested additional information about the software issue described as part of the root cause analysis of the implantable pain pump’s failure. The 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...
nullification report (PORR_SN040012UV)

5.1.1.12 Parent Child Report (PORR_SN040011UV)

Event

On 4th of May, 2003, Mr A. Smith, a 92 year old male was admitted to Berlin General Hospital with Jaundice and elevated aminotransferase levels (ALT=125 i.u/l). The patient subsequently went into a coma and died on the 12th May 2003 due to acute hepatic failure.

The patient had been on treatment of oral Cimetidine 200mg Tablets twice a day for two days (02/05/2003 - 03/05/2003), for the indication of Acute gastric ulcer with perforation. The patient had also received Digoxin and Ranitidine as concomitant medication, no additional information was known at the time for these medications. The patient had previously been admitted to hospital in December 2002 due to a hip fracture.

Creation of Initial Report

The reporting physician Dr Garcia on the 14th May 2003 contacted the marketing authorisation holder (Nobel Company) of the Cimetidine as the doctor believes the acute hepatic failure was related to the Cimetidine. The manufacture collected all the details of the event within their own records system. An assessor from the pharmacovigilance group within the company reviewed the data and made the following comments:

1. Suspect medication: First case we have received. Two dubious cases found in the literature.
2. Hepatic failure: We lack in information to determine whether the patient had normal liver function test before treatment. Acute hepatic failure can also be caused by viruses, cardiac failure or septic shock, drugs and toxins.
3. Concomitant medication: Hepatic failures sometimes with fatal outcome have been associated with the use of RANITIDINE. Several cases have been recorded in our database.

Assessment: More details on clinical evolution of illness are being sought.

With current information (17 May 2003): the case is considered unlikely related to CIMETIDINE. In the expert's opinion there would be a more likely cause either an acute cardiac failure or the concomitant medication RANITIDINE.

As required by German Drug Law the company completed an electronic Individual Case Safety Report (ICSR), using their own IT system and submitted the report electronically to the German Medicines Agency (BfArM) on the 17th May 2003. The company assigned the following unique case identifier to the case report DE-Nobel-Testcase01.

German Medicines Agency response

The electronic report is received by the agency from Nobel company and it was checked against their requirements for a valid report. The report is found to be valid and a positive acknowledgement is returned to Nobel Company to confirm receipt and acceptance of the report.

Marketing Authorisation Holder Response to Reported Event

The company requested further information from the reporting physician and they received the following new information on 25th May 2003: Autopsy results confirmed patient died from extensive hepatic necrosis. The DIGOXIN was confirmed to have been given for the indication of heart failure and Medicinal Product Name of the drug containing RANITIDINE was found to be Avidol. The company's assessment of the case remains unchanged.

As required by German Drug Law the company completed an updated electronic Individual Case Safety Report (ICSR), using their own IT system and submitted the follow-up report electronically to the German Medicines Agency (BfArM). The company's unique case identifier for the case was kept as DE-Nobel-Testcase1.

German Medicines Agency response

The electronic follow-up report is received by the agency and it was checked against their requirements for a valid report. The report is found to be valid and a positive acknowledgement is returned to Nobel Company to confirm receipt and acceptance of the report. In the Agency's system the report is linked to the initial submission of the report. The follow-up report is used for an scientific evaluation of the case and the previous version are kept for audit purposes.

Marketing Authorisation Holder finds an error in the follow-up report

Whilst conducting an internal review of the case information the company finds out that there has been a mistake in the entry of the case notes into the company database as the patient age is actually 72 and not 92 as previously reported. There has not been any new communication with the reporting physician so the report can not have an updated receipt date of the latest information however a new version of the case needs to be submitted by the company to correct the information previously submitted as a follow-up. The company completed an updated electronic Individual Case Safety Report (ICSR), using their own IT system and submitted the report electronically flagged as an amendment report to the German Medicines Agency (BfArM). The company's unique case identifier for the case was kept as DE-Nobel-Testcase1.

German Medicines Agency response

The electronic amendment report is received by the agency and it was checked against their requirements for a valid report. The report is found to be valid and a positive acknowledgement is returned to Nobel Company to confirm receipt and acceptance of the report. In the Agency's system the report is linked to the initial submission of the report. The amended report is used for an scientific evaluation of the case and the previous versions are kept for audit purposes.

5.1.1.1 Nullification Report (PORR_SN040011UV)

The Event

On 4th June, 2007, Dr A. Jones, contacted Nobel company by telephone to see if the company’s product Abrovim and antihypertensive drug could of caused syncope in a 53 year old male patient. The drug information officer at the company confirmed that Syncope was listed in the company’s product information as a possible side effect of the medicine. The doctor provided no further information about the case at the time

Creation of Initial Report

The drug information officer at Nobel Company records the details of the telephone conversation into the company's pharmacovigilance system and details of the adverse drug event are sent to drug regulatory authority. Nobel Company also writes to Dr A Jones including a questionnaire to find out further details about the event.

Nullification of the Report

Dr A Jones, writes back to Noble Company on the 7th of July and informs the company that his patient did not in fact receive Abrovim and the syncope was not related to any medication taken by the patient.

A Nobel Company representative updates the case report on the company database and marks the report as deleted. A nullification report is created by Nobel giving the nullification reason that "Further information received from the reporting physician states that the patient did not receive the suspected drug and the event was unrelated to any medication taken by the patient". The nullification report is then sent to the regulatory authority. The regulatory authority on receipt of the nullification report the report within their system as "Nullified" and no longer uses the case for scientific evaluation but the case is kept for audit purposes.

5.1.1.12 Parent Child Report (PORR_SN040011UV)
The Event

On 12th of July, 2003, male child was born at full term (40 weeks gestation) with polydactyl feet (1 extra toe each foot). The mother of the child had been taking oral Propylthiouracil 200 mg once a day for Hyperthyroidism before and during early pregnancy (therapy dates 20th April 2003 to 28th June 2006). However the 30 year old mother stopped taking the drug at 12 weeks gestation as she experienced a severe skin eruption that was attributed due to the propylthiouracil. The mother’s event was reported to the authorities at that time and was assigned the case identifier US-Nobel-MT99101.

The obstetrician contacted the marketing authorisation holder of the medicinal product (Nobel Company) and informed them of the congenital anomaly due to exposure in-utero as he believed the child had receiving the drug transplacentally.

Creation of Initial Report

Nobel Company of the Cimetidine as the doctor believes the acute hepatic failure was related to the Cimetidine. The company collected all the details of the event within their own records system. An assessor from the pharmacovigilance group within the company reviewed the data and made the following comments:

Company comment: Propylthiouracil is known to cross the placental barrier in low quantities and has been used for sometime in pregnancy. Studies have shown that the frequency of congenital malformations is higher in patients not treated for hyperthyroidism than those treated for it. The alternatives treatments for hyperthyroidism of radioactive iodine and surgery are not recommended for pregnant patients.

The company completed an electronic Individual Case Safety Report (ICSR), using their own IT system and submitted the report electronically to the regulatory agency on the 20th July 2003.

Regulatory agency response

The electronic report is received by the agency from Nobel company and it was checked against their requirements for a valid report. The report is found to be valid and a positive acknowledgement is returned to Nobel Company to confirm receipt and acceptance of the report.

Lab Test Results:

Date Test Name - Result Test Units Normal Range
12/05/2003 Neutrophil Count - 4.0 x10^9 cells/l 2.0 - 7.5
12/05/2003 WBC - 6.8 x10^9 cells/l 4.0 - 11.0
19/05/2003 Neutrophil Count - 0.8 x10^9 cells/l 2.0 - 7.5
19/05/2003 WBC - 4.5 x10^9 cells/l 4.0 - 11.0
26/05/2003 Neutrophil Count - 3.8 x10^9 cells/l 2.0 - 7.5
26/05/2003 WBC - 6.3 x10^9 cells/l 4.0 - 11.0

The patient was treated with G-CSF and recovered a week later. The patient is a smoker and has a family history of breast cancer. The patient was also concomitantly taking oral domedrone for Nausea.

Creation of Initial Report

The investigator responsible for the patient (Dr A Davis at Cardiff University hospital, Cardiff, Wales) informed the sponsor (Big Company) of the event and the sponsor in turn created an electronic report to submit to the concerned regulatory authorities using their own IT system.

The company provides the following assessment of the case: It is likely that the investigational medicinal product caused this reaction.

Regulatory Authority response

The electronic report is received by the agency from Nobel company and it was checked against their requirements for a valid report. The report is found to be correct and a positive acknowledgement is returned to Nobel Company to confirm receipt and acceptance of the report.
The electronic report is received by an agency from Big Company and it is checked against their requirements for a valid report. The report is found to be valid and a positive acknowledgement is returned to Big Company to confirm receipt and acceptance of the report.

5.1.1.15Observational Study Report (PORR_SN040016UV)

The Event
A patient was enrolled in a UK based multi-centre observational study (Protocol No 12413/01) looking at the prevention of Osteoporosis using Hormone Replacement Therapy in post-menopausal women.

The patient has been taking unopposed oral Oestrogen 625 ug since June 1999 as she had a full hysterectomy in November 1998 due to endometriosis. The patient was enrolled in the study in April 2000 and was being monitored every 6 months at the Manchester general hospital.

In May 2004 the patient was diagnosed with breast cancer during a routine mammogram screening. The patient has been booked for surgery and has since stopped taking Oestrogen.

The patient is also taking Bendrofluazide Oral for Hypertension and medical history of smoking and being overweight.

Creation of Initial Report
The physician responsible for the patient (Dr J Jones at the Manchester general hospital, Manchester UK) informed SME Company of the event in their study and they in turn created an electronic report to submit to the concerned regulatory authority using their own IT system.

The company provides the following assessment of the case: It is possible that the investigational product caused this reaction.

Regulatory Authority response
The electronic report is received by an agency from SME company and it is checked against their requirements for a valid study report. The report is found to be valid and a positive acknowledgement is returned to SME Company to confirm receipt and acceptance of the report.

5.1.1.16Non Expedited Report (PORR_SN040017UV)

The Event
On 4th of February 2007, Mr A. Davis, a 42 year old male patient was seen by his physician after experiencing an extensive rash and cough. The patient had just started taking oral ramipril 75mg tablets for hypertension 3 days before (2nd February 2007). The treating physician attributed the rash and cough to the ramipril and instructed the patient to discontinue taking the ramipril and prescribed the patient an antihistamine. The physician informed the marketing authorisation holder of the ramipril (Big company) of this event but did not consider the event as serious. No other details are available about the case at this time.

Creation of a Report
Big Company entered the details of the event into their pharmacovigilance IT system. As the report is non-serious it is not reportable as a normal expedited ICSR report. However, the report needs to be submitted as part of a periodic safety update report. The Big company creates a non-expedited individual case safety report (PSUR) with the message transmission type selected to indicate a periodic submission rather than an expedited message transmission. The company then submits the case to a regulatory authority before the time of submission of it’s PSUR in accordance with regional requirements.

Authority response
The electronic report is received by the agency from Big company and it is checked against their requirements for a valid non-expedited report. The report is found to be valid and a positive acknowledgement is returned to Big Company to confirm receipt and acceptance of the non-expedited report.

5.1.1.17Clinical Trial Annual Safety Report (PORR_SN040018UV)

The Event
In the UK a multi-centre clinical trial with the EU Clinical trial authorisation number (EUDRACT No. 2004-00102-03) is being conducted to evaluate the efficacy and tolerability of Danthium, a new substance, in post-menopausal women with breast cancer hormone receptor positive tumours. The sponsor of the trial assigned the protocol No 0105798/01.

A 53 year-old female patient was enrolled in this trial with the patient ID 125-0872 and one week after the third cycle of chemotherapy treatment with intravenous danthium 20 mg/kg once a week, the patient developed nausea and raised liver function tests. Both nausea and raised liver function tests are mentioned in the investigators brochure as possible side effects.

Creation of a Report
Big company the sponsor of the clinical trial entered the details of the event into their pharmacovigilance IT system. Even though the reactions were considered serious they are known possible side effects and therefore the report is not reportable to the local authorities on an expeditable basis according to regional requirements. However, the reports are required to be reported by the time of the submission of the annual safety report. Big company creates an electronic report to submit to the concerned regulatory authorities using their own IT system. The message transmission type is selected to show that the report is a non-expedited clinical trial report and the case is submitted the case to the relevant authorities.

Authority response
The electronic report is received by the agency from Big company and it is checked against their requirements for a valid non-expedited report. The report is found to be valid and a positive acknowledgement is returned to Big Company to confirm receipt and acceptance of the non-expedited report.

5.1.1.18Backlog Report (PORR_SN040019UV)

It was created to illustrate the reporting of medicine-related event using a fully implemented ICSR process.

The Event
On 4th of June, 1996, Mr A. Smith, a 62 year old male was admitted to Berlin General Hospital with anaemia. The patient subsequently recovered by 6th August 1996.

The patient had been taking oral Ibuprofen 400mg Tablets twice a day, for arthritic pain of the hands. The patient had not been taking any concomitant medications at the time.

Creation of Initial Report
The reporting physician Dr Hughes contacted the marketing authorisation holder (Big Company) initially on the 17th June 1996 to inform them of this case. The physician then subsequently contacted the company again on the 7th August 1996 to inform them about the recover of the patient.

The company collected all the details of the event within their own records system. The report was then submitted to the local regulatory agency at that time on paper as was required in 1996. In 2006 the company was requested by the regulatory agency to resubmit this case in electronic format as required in regional requirements. The report is created by the company in electronic format with the message transmission type selected as backlog so that the report is clearly identifiable.

Regulatory Agency response
The electronic report is received by the agency from Big company and it was checked against their requirements for a valid backlog report. The report is found to be valid and a positive acknowledgement is returned to Big Company to confirm receipt and acceptance of the backlog report.
5.1.1.19 Medical confirmation at event level (PORR_SN040020UV)

The Event

On 4th of February 2007, Mr A. Davis, a 42 year old male patient experienced dizziness and heavy chest pain after taking two oral ramapril 75mg tablets. Feeling better after 20 minutes, he phoned the marketing authorization holder Big Pharma to report his experience, stating that he might have had a heart attack.

Creation of an initial report

Big Pharma collected all the details of the report in their pharmacovigilance IT system, with dizziness, chest pain and heart attack as reported events. These events were flagged as 'not confirmed by health care professional'. As the report originated from a consumer, the report did not qualify for submission in every jurisdiction and Big Pharma submitted the report as an expedited case only to the drug regulatory authorities requiring consumer reports.

Authority response

The electronic report is received by the agencies from Big Pharma and it is checked against their requirements for a valid expedited report. The report is found to be valid and a positive acknowledgement is returned to Big Pharma to confirm receipt and acceptance of the expedited report.

Marketing Authorisation Holder receives follow-up information from physician

Big Pharma requested permission from Mr A. Davis to consult his physician, Dr. Brown. The physician informs Big Pharma that Mr A. Davis had come to see him and states that Mr A. Davis did not experience a heart attack, but that he had been diagnosed with angina.

Creation of updated report

Big Pharma completed an updated Individual Case Safety Report, using their own IT system. Reported events were ‘angina’ (flagged as ‘confirmed by health care professional’), ‘dizziness’ (flagged as ‘not confirmed by health care professional’), ‘chest pain’ (flagged as ‘not confirmed by health care professional’) and ‘heart attack’ (flagged as ‘not confirmed by health care professional’). Big Pharma submitted the updated report electronically to the drug regulatory authorities that had received the initial version. As the report now contained information that had been confirmed by a health care professional, it qualified for submission to other drug regulatory authorities as well. Big Pharma submitted the report electronically to the drug regulatory authorities requiring medically confirmed reports.

Authority response

The electronic individual case safety report is received by the drug regulatory agencies and it is checked against their requirements for a valid expedited report. The report is found to be valid and a positive acknowledgement is returned to Big Pharma to confirm receipt and acceptance of the report.

5.1.1.20 Counterfeit medications (PORR_SN040021UV)

The event

A 22 year old woman ordered zolpidem (indicated for short-term treatment of insomnia), via an internet pharmacist. After taking two tablets she experienced difficulty in breathing, muscle spasms and muscle stiffness and emergency medical treatment in the General Hospital in Manchester was necessary. The patient brought the medication to the hospital and the treating physician Dr Brown informed the marketing authorisation holder shown on the package (Big Pharma) of these events. On request of Big Pharma Dr. Brown sent the package with the remaining zolpidem tablets to Big Pharma.

Creation of Initial Report

The drug information officer at Big Pharma records the details of the telephone conversation with Dr. Brown into the company’s pharmacovigilance system and details of the adverse drug event (with zolpidem stated as suspected medication) are sent to drug regulatory authority.

Authority response

The electronic report is received by the agency from Big Pharma and it was checked against their requirements for a valid report. The report is found to be valid and a positive acknowledgement is returned to Big Pharma to confirm receipt and acceptance of the report.

Marketing authorisation holder receives results of analysis

Laboratory analysis conducted by Big Pharma confirmed that the tablets contained haloperidol (an antipsychotic drug known to cause symptoms as difficulty in breathing, muscle spasms and muscle stiffness) instead of the intended drug zolpidem.

Creation of a Follow-up Report

Big Pharma updated the Individual Case Safety Report (ICSR) with this new information and submitted the follow-up report electronically to the drug regulatory authority. The suspected medication was kept as zolpidem, but this was flagged as ‘counterfeit’.

Authority response

The electronic report is received by the drug regulatory authority and it was checked against their requirements for a valid report. The report is found to be valid and a positive acknowledgement is returned to Big Pharma to confirm receipt and acceptance of the report. In view of the public health importance the drug regulatory authority decides to further investigate this issue.

5.1.1.21 Adulterated Food Reporting (PORR_SN040022UV)

The Event

On 4th of February 2007, Mr A. Davis, a 42 year old male patient experienced dizziness and heavy chest pain after taking two oral ramapril 75mg tablets. Feeling better after 20 minutes, he phoned the marketing authorization holder Big Pharma to report his experience, stating that he might have had a heart attack.

Creation of an initial report

Big Pharma collected all the details of the report in their pharmacovigilance IT system, with dizziness, chest pain and heart attack as reported events. These events were flagged as ‘not confirmed by health care professional’. As the report originated from a consumer, the report did not qualify for submission in every jurisdiction and Big Pharma submitted the report as an expedited case only to the drug regulatory authorities requiring consumer reports.

Authority response

The electronic report is received by the agencies from Big Pharma and it is checked against their requirements for a valid expedited report. The report is found to be valid and a positive acknowledgement is returned to Big Pharma to confirm receipt and acceptance of the expedited report.

Marketing Authorisation Holder receives follow-up information from physician

Big Pharma requested permission from Mr A. Davis to consult his physician, Dr. Brown. The physician informs Big Pharma that Mr A. Davis had come to see him and states that Mr A. Davis did not experience a heart attack, but that he had been diagnosed with angina.

Creation of updated report

Big Pharma completed an updated Individual Case Safety Report, using their own IT system. Reported events were ‘angina’ (flagged as ‘confirmed by health care professional’), ‘dizziness’ (flagged as ‘not confirmed by health care professional’), ‘chest pain’ (flagged as ‘not confirmed by health care professional’) and ‘heart attack’ (flagged as ‘not confirmed by health care professional’). Big Pharma submitted the updated report electronically to the drug regulatory authorities that had received the initial version. As the report now contained information that had been confirmed by a health care professional, it qualified for submission to other drug regulatory authorities as well. Big Pharma submitted the report electronically to the drug regulatory authorities requiring medically confirmed reports.

Authority response

The electronic individual case safety report is received by the drug regulatory agencies and it is checked against their requirements for a valid expedited report. The report is found to be valid and a positive acknowledgement is returned to Big Pharma to confirm receipt and acceptance of the report.

Before the problem was discovered, 6,000 of the 12-ounce (5,000 from lot # 2008-0701-200 and 1,000 from the other lot) and 6,000 of the 18-ounce Boxes were shipped to a local grocery warehouse in St Paul and 1,000 of the 18-ounce boxes were shipped to another local grocery warehouse in Richmond, VA. It was determined that the adulteration was unintentional and happened at the St Cloud facility and was not due to adulterated raw materials from suppliers.

The two retail warehouses were notified on 3 July in time for the warehouses to quarantine the reportable food products.

The remaining Great Crackers were disposed of on 3 July at the St Cloud plant.

The company’s risk manager and (the person who is in the FDA food facility registration database for the plant) logs into a Federal AE Portal and enters this report the evening of 3 July in compliance with 1005 legislation. His report includes the following information:

- The event occurred on 3 July 2007.
- The lot numbers involved were: Lot # 2008-0701-201 and Lot # 2008-0702-201.
- The amount of the 12 ounce adulterated product—both lots—was reported as the lot amount of the 12 ounce product.
- The adulteration discovery code is ‘self-discovery’.
- Both destinations of the shipments were identified and the amount shipped, by lot, to each location was reported.

The company’s risk manager reports that he has informed both ‘down’ locations of the adulteration on 3 July.

There is no requirement for the company or the risk manager to report the origin of the raw materials, since the adulteration only took place in St Cloud.

There is no requirement for either destination warehouse to report since they did not further distribute the reportable food prior to the notification and it was quarantined on site.
The Event

In the EU a multi-state clinical trial with the EU Clinical trial authorization number (EUDRACT No. 2004-09102-03) is being conducted in Germany and Netherlands to evaluate the efficacy and tolerability of Danthium, a new substance, in post-menopausal women with breast cancer hormone receptor positive tumors. The sponsor of the trial assigned the protocol number 016576/01. The clinical trial authorization number assigned by the German authorities is '12345678' and the authorization number assigned by the Dutch authorities is 'NL12345.001.07'.

A 50 year-old female patient with the patient ID 125-0871 was enrolled in this trial in a German centre and one week after the third cycle of chemotherapy treatment with intravenous Danthium 20 mg/kg once a week, the patient developed a fever (38°C) and diarrhea (11th May 2003). The patient was hospitalized. Blood tests were performed and the patient was discovered to have neutropenia. This adverse event was considered as serious and unexpected.

**Lab Test Results:**

<table>
<thead>
<tr>
<th>Date</th>
<th>Test Name</th>
<th>Test Result</th>
<th>Test Units</th>
<th>Normal Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/05/2003</td>
<td>Neutrophil Count</td>
<td>4.0 x 10^9</td>
<td>cells/l</td>
<td>2.0 - 7.5</td>
</tr>
<tr>
<td>12/05/2003</td>
<td>WBC</td>
<td>6.8 x 10^9</td>
<td>cells/l</td>
<td>4.0 - 11.0</td>
</tr>
<tr>
<td>19/05/2003</td>
<td>Neutrophil Count</td>
<td>0.8 x 10^9</td>
<td>cells/l</td>
<td>2.0 - 7.5</td>
</tr>
<tr>
<td>19/05/2003</td>
<td>WBC</td>
<td>4.5 x 10^9</td>
<td>cells/l</td>
<td>4.0 - 11.0</td>
</tr>
<tr>
<td>26/05/2003</td>
<td>Neutrophil Count</td>
<td>3.8 x 10^9</td>
<td>cells/l</td>
<td>2.0 - 7.5</td>
</tr>
<tr>
<td>26/05/2003</td>
<td>WBC</td>
<td>6.3 x 10^9</td>
<td>cells/l</td>
<td>4.0 - 11.0</td>
</tr>
</tbody>
</table>

The patient was treated with G-CSF and recovered a week later. The patient is a smoker and has a family history of breast cancer. The patient was also concomitantly taking oral domesdone for nausea.

**Creation of Initial Report**

The investigator responsible for the patient (Dr B. Bernard at Berlin University hospital, Berlin) informed the sponsor (Big Company) of the event and the sponsor in turn created an electronic report to submit to the concerned regulatory authorities using their own IT system. The company provides the following assessment of the case: It is likely that the investigational medicinal product caused this reaction.

**Regulatory Authority response**

The electronic report is received by an agency from Big Company and it is checked against their requirements for a valid report. The report is found to be valid and a positive acknowledgement is returned to Big Company to confirm receipt and acceptance of the report.

**5.2 Application Roles**

- Application Roles (Sorted by Artifact Code)
- ICSR Notification Sender (PORR_AR0400001UV)
- ICSR Notification Receiver (PORR_AR040002UV)
- Application Roles (Sorted by Structured Sort Name)
- Safetyreport Event Comprehensive Informer (PORR_AR0400001UV)
- Safetyreport Event Comprehensive Receiver (PORR_AR040002UV)
- Application Roles (Sorted by Display Order)
- ICSR Notification Receiver (PORR_AR040002UV [Elemental])
- ICSR Notification Sender (PORR_AR040001UV [Elemental])

**Reference**

For details on the interpretation of this section, see the discussion of application roles and their relationships in the Version 3 Guide.

**5.3 Trigger Events**

- Trigger Events (Sorted by Title)
- ICSR Create Notification (PORR_TE040002UV)
- ICSR Review Notification (PORR_TE040003UV)
- ICSR Withdraw Notification (PORR_TE040004UV)
- Trigger Events (Sorted by Structured Sort Name)
- Safetyreport Event Eventual Notification (PORR_TE040028UV)
- Safetyreport Event Create Notification (PORR_TE040029UV)
- Safetyreport Event Review Notification (PORR_TE040030UV)
- Trigger Events (Sorted by Display Order)
- ICSR Create Notification (PORR_TE040002UV)
- ICSR Withdraw Notification (PORR_TE040004UV)
- ICSR Review Notification (PORR_TE040003UV)

**Reference**
For details on the interpretation of this section, see the discussion of trigger events in the Version 3 Guide.

### 5.3.1.1 ICSR Create Notification (PORR_TE049006UV)

**Description**

- **Structured Name**: Safetyreport Event Create Notification
- **Type**: State-transition based

Indicates that a report containing notification of an eligible case associated with a regulated or suspect product, is ready for transmission to an eligible receiver. The notification may include the report of an adverse reaction, of a product problem, or include information related to both adverse events and product problems.

### 5.3.2.1 ICSR Withdraw Notification (PORR_TE049008UV)

**Description**

- **Structured Name**: Safetyreport Event Cancel Notification
- **Type**: State-transition based

Indicates that a prior report containing notification of an eligible case associated with a regulated or suspect product, is being withdrawn.

### 5.3.3.1 ICSR Revise Notification (PORR_TE049007UV)

**Description**

- **Structured Name**: Safetyreport Event Revise Notification
- **Type**: State-transition based

Indicates that a prior report containing notification of an eligible case associated with a regulated or suspect product, is being revised. The revision may include the communication of attachments including additional information related to the case.

### 5.4 Refined Message Information Models

**Refined Message Information Models (Sorted by Title)**

- ICSR_A_ProductReportingRelevantInformation(PORR_RM049013UV)
- ICSR_R_Product(PORR_RM049011UV)
- ICSR_Refined Message Information Model(PORR_RM049006UV)
- Refined Message Information Models(Sorted by Structured Sort Name)
- Safetyreport Event New(PORR_RM049006UV)
- Safetyreport Event New(PORR_RM049011UV)
- Safetyreport Event New(PORR_RM049013UV)
- Refined Message Information Models(Sorted by Display Order)
- ICSR_Refined Message Information Model(PORR_RM049006UV)
- ICSR_R_Product(PORR_RM049011UV)
- ICSR_A_ProductReportingRelevantInformation(PORR_RM049013UV)

**Reference**

For details on the interpretation of this section, see the description of RMIMs in the Version 3 Guide.

### 5.4.1.1 ICSR Refined Message Information Model (PORR_RM049006UV)

**Diagram**

[Diagram of ICSR Refined Message Information Model]

**Description**

- **Parent**: None Specified

**Model Overview**

The RMIMs are oriented around the following concepts:

1. **Adverse experiences**: Any adverse event associated with the use of a product in humans or animals, 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 overdose of the product whether accidental or intentional; an adverse event occurring from abuse of the product; an adverse event occurring from withdrawal of the product; and any failure of expected pharmacological action. Note these events may 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.

2. **Suspected adverse reaction**: A noxious and unintended response to a 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. The range of product types for which reports may be generated is set by regulatory and/or organizational administrative practice within the jurisdiction controlling the reporting between parties.

3. **Suspected product problems or defects**: Any problem or defect observed or detected before or after a product is used. This includes the use of drugs, biologics or medical devices used for treatment, or other consumer products such as food, cosmetics or dietary supplements. Some examples of product problems include faulty packaging or labeling, receipt of an expired therapeutic drug product, or suspected contamination based upon inappropriate or unauthorized preparations or mixtures.

4. **An affected person or animal**: If applicable to the report, this includes the investigative subject (patient) that experienced an adverse event.

5. **Substance administrations**: Includes information about how the product was given or used, or intended to be given or used by the investigative subject.

6. **Medical procedures related to devices**: Includes information about how a medical device was used or intended to be used by a patient or investigative subject. For example, device implant or removal procedures.

7. **Supporting clinical information**: Includes additional clinical detail such as relevant observations, procedures, substance administrations, supply acts or patient encounters. These observations are included if the reporter considers them relevant to the investigation, whether referring to the same point in time as the suspect event or as part of the patient's medical history.

The ICSR RMIM is designed to support within a single structure two aspects of product reporting. These include:

1. **A report about the investigation into the adverse event(s) or reaction(s) suffered by an affected person or animal that experienced an intervention or interventions in a therapeutic context. The suspect event may or may not have a causal relationship with the administration or use of one or more products; and**

2. **A report about the investigation into a product problem. Note that the key common factor is the involvement of an implicated product such as a medication, device, dietary supplement or cosmetic.**

This message, as with all HL7 V3 specifications, includes a Control Act structure which contains information about the actual report transmission. (The reader should refer to the HL7 V3 Infrastructure Management Domain for more details on this structure.)

Please refer to the MHD documentation for more detailed information on classes and attributes.
5.4.2 ICSR R_Product (PORR_RM049011UV)

Model Overview

The R_Product RMIM captures product information relevant for a wide range of adverse event and product problem reporting requirements. This information includes items related to the product itself, its packaging, manufacture and potential post-event evaluation by manufacturers or reprocessors.

A product in this context refers to a manufactured or home fabricated item that is used directly by an investigative subject - whether person or animal. This model serves three purposes:

- It provides a generic view of a product that supports the FDA’s (and presumably other reporting authorities') need for capturing product problems and adverse events associated with the use of other products such as foods, food additives, cosmetics, dietary supplements and veterinary drug products. The new structure provides all the attributes and functionality of the more specific product models.
- It addresses the need for reporting related to combination products. This category includes products which combine drugs, biologics and/or medical devices into one product for therapeutic use. It also includes situations in which two or more separately licensed products are used together to achieve a specific purpose as documented in the relevant labeling information.
- It provides a consolidated structure that can be used to replace the more specific product models for medicines and medical devices. This new structure supports migration for unification of the messaging specifications that support a wider variety of product types.

Please refer to the HMD documentation for more detailed information on classes and attributes.

5.4.3 ICSR A_ProductReportingRelevantInformation (PORR_RM049013UV)

Model Overview

The A_RelevantInformationForProductReporting RMIM captures information about the acts that describe how a product was used by an investigative subject or related to a product defect discovery. The information includes use of the product (substance administration and device procedures) and any associated clinical or laboratory information directly related to the product’s use at a particular point in time, e.g., related to an adverse event, or as part of a subject’s medical history. The model also supports other patient care or healthcare process related actions taken to mitigate or reduce harm. A choice box structure is used (similar to HL7’s A_SupportingClinicalInformation CMET) to capture the relevant information needed to evaluate the case.

This information includes:

- Drug Dosing and Device Procedure Information: date, time, quantity, and route of administration (or target site). Note dosage form is captured as product information in R_Product.
- Component acts or concomitant therapies.
- Authors and/or performers of healthcare acts or services.
- Product defect discovery information.
- Specimen collection and lab testing.
- Organizer class to facilitate grouping of related acts relevant to a point in time, e.g., vaccines given within the last 4 weeks prior to an adverse event.

Please refer to the HMD documentation for more detailed information on classes and attributes.
5.5 Hierarchical Message Descriptions

- Hierarchical Message Descriptions (Sorted by Title)
  - ICSR A_ProductReportingRelevantInformation HMD (PORR_HD049013UV)
  - ICSR_HMD (PORR_HD049006UV)
  - ICSR_R_Product HMD (PORR_HD049011UV)

- Hierarchical Message Descriptions (Sorted by Structured Sort Name)
  - Safetyreport Event (PORR_HD049013UV)
  - Safetyreport Event New (PORR_HD049006UV)
  - Safetyreport Event R_product Hmd (PORR_HD049011UV)

- Hierarchical Message Descriptions (Sorted by Display Order)
  - ICSR_HMD (PORR_HD049006UV)
  - ICSR A_ProductReportingRelevantInformation HMD (PORR_HD049013UV)
  - ICSR_R_Product HMD (PORR_HD049011UV)

Reference

For details on the interpretation of this section, see the description of HMDs in the Version 3 Guide.

5.5.1 ICSR HMD (PORR_HD049006UV)

Description

This HMD includes the data that may be needed to file an ICSR report on an adverse event or reaction to a drug, biologic, vaccine, or device that has been implanted or is otherwise providing services to a patient. This also includes the data that may be needed to file an ICSR report on a drug, device, or other product type that has not been involved in a patient related reaction.

At this time there is no content for this section.

Base Hierarchical Message Description

Message Type List

Safetyreport Event New

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5.5.2 ICSR A_ProductReportingRelevantInformation HMD (PORR_HD049013UV)

Description

The A_ProductReportingRelevantInformation HMD contains the serialized elements from the corresponding RMIM.

At this time there is no content for this section.

Base Hierarchical Message Description

Message Type List

Safetyreport Event

 PORR_MT049013UV

5.5.3 ICSR R_Product HMD (PORR_HD049011UV)

Description

The R_Product HMD contains the serialized elements from the corresponding RMIM.

At this time there is no content for this section.

Base Hierarchical Message Description

Message Type List

Safetyreport Event R_product Hmd

 PORR_MT049011UV

5.6 Interactions

- List of Interactions (Sorted by Title)
  - Individual Case Safety Report Create (PORR_IN049006UV)
  - Individual Case Safety Report Report (PORR_IN049006UV)
  - Individual Case Safety Report Review (PORR_IN049006UV)

- List of Interactions (Sorted by Structured Sort Name)
  - Safetyreport Event Cancel Notification (PORR_IN049008UV)
  - Safetyreport Event Create Notification (PORR_IN049006UV)
  - Safetyreport Event Revise Notification (PORR_IN049007UV)

- List of Interactions (Sorted by Display Order)
  - Individual Case Safety Report Create (PORR_IN049006UV)
  - Individual Case Safety Report Report (PORR_IN049006UV)
  - Individual Case Safety Report Revise (PORR_IN049007UV)

Reference

For details on the interpretation of this section, see the definition of Interactions in the Version 3 Guide.

5.6.1 Individual Case Safety Report Create (PORR_IN049006UV)

Description

Structured Name: Safetyreport Event Create Notification

The interaction supports the communication of a new individual case safety report.

Sender

ICSR Notification Sender

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5.6.2 Individual Case Safety Report Retraction (PORR_IN049008UV)

**Description**
The interaction supports the cancellation of a previously sent individual case safety report.

<table>
<thead>
<tr>
<th>Trigger Event</th>
<th>ICSR Withdraw Notification</th>
<th>PORR_TE049008UV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transmission Wrapper</td>
<td>Send Message Payload</td>
<td>MCCI_MT000100UV01</td>
</tr>
<tr>
<td>Control Act Wrapper</td>
<td>Trigger Event Control Act</td>
<td>MCAI_MT700201UV01</td>
</tr>
<tr>
<td>Message Type</td>
<td>ICSR</td>
<td>PORR_MT049006UV</td>
</tr>
</tbody>
</table>

**Sending and Receiving Roles**
- **Sender**: ICSR Notification Sender (PORR_AR040001UV)
- **Receiver**: ICSR Notification Receiver (PORR_AR040002UV)

5.6.3 Individual Case Safety Report Revision (PORR_IN049007UV)

**Description**
The interaction supports revisions to previously sent individual case safety report messages.

<table>
<thead>
<tr>
<th>Trigger Event</th>
<th>ICSR Revise Notification</th>
<th>PORR_TE049007UV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transmission Wrapper</td>
<td>Send Message Payload</td>
<td>MCCI_MT000100UV01</td>
</tr>
<tr>
<td>Control Act Wrapper</td>
<td>Trigger Event Control Act</td>
<td>MCAI_MT700201UV01</td>
</tr>
<tr>
<td>Message Type</td>
<td>ICSR</td>
<td>PORR_MT049006UV</td>
</tr>
</tbody>
</table>

**Sending and Receiving Roles**
- **Sender**: ICSR Notification Sender (PORR_AR040001UV)
- **Receiver**: ICSR Notification Receiver (PORR_AR040002UV)
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