



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# ISO ICSR standard implementation for IT system developers

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## **Training Module IT-M1**





# Content Summary

- Introduction
- Overview of changes to EudraVigilance
- Preparing for EudraVigilance system changes
- EU extensions to E2B (R3)
- Summary



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## Introduction: Target audience

- Target audience for this training module:
  - National Competent Authorities (NCAs) in the European Economic Area (EEA)
  - Marketing authorisation holders (MAHs)
  - Sponsors of clinical trials (Sponsors)
  - Research institutions/Academia
  - Other interested parties

## Introduction: Learning objectives

Following the completion of IT-M1 training module you should be able to understand:

- ✓ The background ICSR documentation
- ✓ EU specific requirements for implementing the ISO ICSR standard
- ✓ The potential issues that may be faced



- Introduction
- Overview of changes to EudraVigilance**
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## Why is EudraVigilance changing?

- Post authorisation legal requirement changes
  - In December 2010, the pharmacovigilance legislation was updated through amendments to Regulation (EC) No 726/2004 and Directive 2001/83/EC, followed by the addition of Commission Implementing Regulation (EU) No 520/2012 in June 2012.
- The main changes to electronic reporting requirements are:
  - Usage of ISO standards in the reporting of ICSRs, ISO ICSR standard 27953-2:2011
  - Usage of ISO IDMP terminologies, once available, in the submission of ISO ICSR messages
  - EMA Medical Literature monitoring service
  - The Audit of the EudraVigilance system
  - Centralisation of reporting of ICSRs in the EU and forwarding of national cases to the relevant NCA.

## How is EudraVigilance changing?

- Key milestones:
  - New EV system stakeholder testing: start End of Q2 2016
    - Scope: to provide opportunity to selected MAHs to test the new functionalities implemented in the EV system.
  - New XCOMP available to stakeholder for testing: Q2 2017
  - Training launch: Q1 2017
  - Go-live: November 2017





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## How to prepare for technical changes? (1/3)

- **Implementing ISO ICSR (E2B(R3)) support in MAH's PhV systems:**
  - MAHs need to consider implementing a fully ISO ICSR compliant system or to use a backwards/forwards conversion tool in order to support the processing of the E2B(R3) format ICSRs and acknowledgements from EV.
  - Understand and apply new E2B(R3) principles (e.g. seriousness at event level, amendment reports, additional drug role characterisation)
- **Electronic Gateway for ICSR transmission:**
  - Current software solution will remain the same, however configuration changes may be needed to support E2B(R3) messages including acknowledgments from EV.
  - As only submissions of ICSRs to the EV will be considered as fulfilling the MAH's legal obligations, MAHs should ensure that modifications to their submission systems are configured and tested well in advance of the planned implementation.

## How to prepare for technical changes? (2/3)

- **MAH Testing:**

- No testing with NCAs
- MAHs are required to test once they are ready to implement the new system supporting the submission of E2B(R3) ICSRs, using the new simplify testing process with EMA.
- MAHs should plan to complete any testing of their existing systems 6 to 3 months prior to the new EV system going live in order to give time for any issues to be addressed

- **EV-WEB:**

- a new version of this application will be released to support E2B(R3) format ICSRs data entry. MAHs should plan to start training of their staff 6 months in advance of the new system being implemented followed by regular refresher training at least 3 months and 2 weeks before implementation.

- **EV Downloading ICSRs concerning MAH's products:**

- a download tool will be made available in order for MAH to download ICSRs concerning their products.

## How to prepare for technical changes? (3/3)

- **The new EV system and ISO IDMP, xEVMPD/Article 57**
- The future use of the ISO IDMP standard in the context of the new ICH E2B(R3) format is further elaborated in the EU Individual Case Safety Report (ICSR) Implementation Guide (EMA/51938/2013 )
- Art.57/xEVMPD database, which contains core data elements from the ISO IDMP standard, serves as the dictionary for medicinal product information until the ISO IDMP standards implementation
- For the ISO IDMP standards and terminologies, an incremental introduction is planned over time taking into account the migration of the existing xEVMPD/Article 57 content as the starting point
- Please refer to dedicated webpage “Implementation of the ISO IDMP standards” on the EMA website for ongoing activities and next steps  
([http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general\\_content\\_000645.jsp&mid=WC0b01ac058078fbe2](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000645.jsp&mid=WC0b01ac058078fbe2))



## How to prepare for Business process changes? (1/2)

- **Centralised reporting of ICSRs to EudraVigilance:**
  - MAH will need to ensure that all reportable ICSRs are submitted to EudraVigilance only, including EEA non-serious within 90 days.
  - Planning should be put in place to ensure MAHs are ready to report directly to EudraVigilance prior to move to centralised reporting .
  - MAHs using EV-WEB will need to plan for an increase in resources for the manual data entry of non-serious EEA cases into EudraVigilance, taking into account that the number of non-serious cases received is generally higher than serious cases.

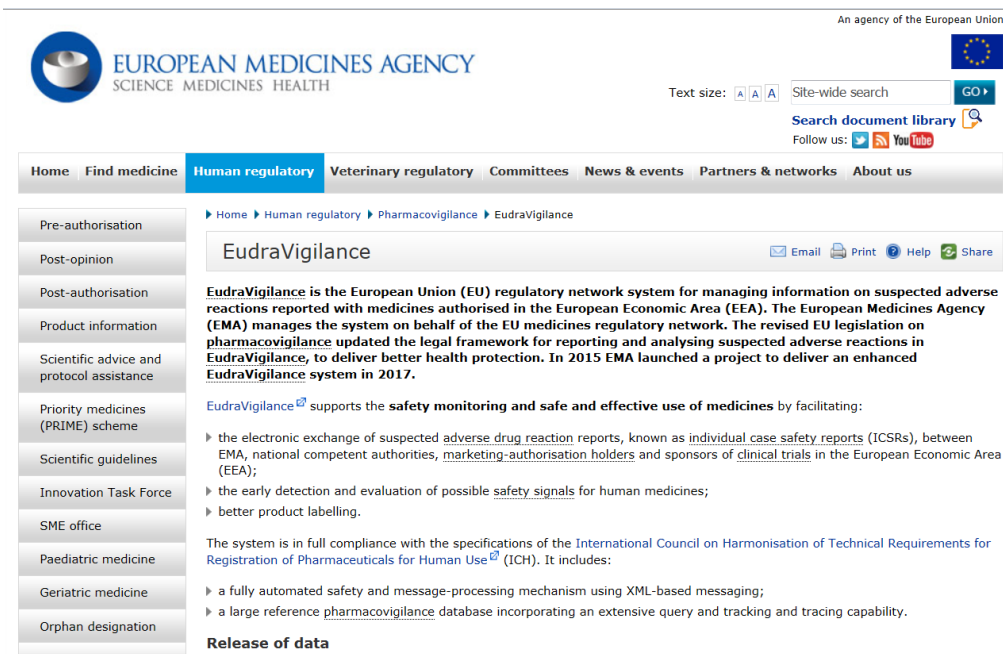


## How to prepare for Business process changes? (1/2)

- **Reporting of SUSARs to EudraVigilance:**
  - Until the Clinical Trials regulation is applicable, there is no change to the current process for the submission of SUSARs for clinical trials approved through the Clinical Trials directive 2001/20/EC.

# Where to find further guidance and detailed information?

- Dedicated EudraVigilance webpage at the Agency's corporate website



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Home > Human regulatory > Pharmacovigilance > EudraVigilance

## EudraVigilance

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**EudraVigilance is the European Union (EU) regulatory network system for managing information on suspected adverse reactions reported with medicines authorised in the European Economic Area (EEA). The European Medicines Agency (EMA) manages the system on behalf of the EU medicines regulatory network. The revised EU legislation on pharmacovigilance updated the legal framework for reporting and analysing suspected adverse reactions in EudraVigilance, to deliver better health protection. In 2015 EMA launched a project to deliver an enhanced EudraVigilance system in 2017.**

EudraVigilance<sup>27</sup> supports the **safety monitoring and safe and effective use of medicines** by facilitating:

- ▶ the electronic exchange of suspected adverse drug reaction reports, known as individual case safety reports (ICSRs), between EMA, national competent authorities, marketing-authorisation holders and sponsors of clinical trials in the European Economic Area (EEA);
- ▶ the early detection and evaluation of possible safety signals for human medicines;
- ▶ better product labelling.

The system is in full compliance with the specifications of the International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use<sup>27</sup> (ICH). It includes:

- ▶ a fully automated safety and message-processing mechanism using XML-based messaging;
- ▶ a large reference pharmacovigilance database incorporating an extensive query and tracking and tracing capability.

**Release of data**



# Change management plan



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26 October 2015  
EMA/797114/2014  
Information Management Division

EudraVigilance stakeholder change management plan

Consultation of Project Maintenance Group 1	15 July 2015
Consultation of Eudravigilance Expert Working Group	23 September 2015
Consultation of Signal Management Review Technical Working Group (SMART WG) – Work Stream 1	7-10 September 2015
Consultation of the Pharmacovigilance Risk Assessment Committee (PRAC)	7-10 September 2015
Implementation Group (IG) for information	14 September 2015
IT Directors for information	22 October 2015
EU Telematic Management Board (EUTMB) for information	15 September 2015
Endorsement by European Risk Management Facilitation Group (ERMS-FG)	12 October 2015
Heads of Medicines Agencies (HMA) for information	22 October 2015

[http://www.ema.europa.eu/ema/pages/includes/document/open\\_document.jsp?webContentId=WC500196029](http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500196029)












# Further guidance and detailed information

## ICH implementation guidance

Documentation	Description
<a href="#">ICH Implementation guide package</a>	A set of documents including the ICH ICSR implementation guide, backwards and forwards compatibility recommendations and element mapping.
<a href="#">ICH E2B(R3) Questions and answers</a>	A question-and-answer document relevant for technical E2B questions.

## EU implementation guidance

Documentation	Description
 <a href="#">EU ICSR Implementation Guide</a>	A guide describing the additional EU-specific requirements to generate a valid ICSR and message acknowledgment to implement EN ISO ICSR in accordance with ICH E2B(R3).
 <a href="#">EU ICSR implementation guide business rules spreadsheet</a>	This spreadsheet includes all the ICH E2B(R3) and EU specific business rules in a format to help system developers.
 <a href="#">EU backwards forwards conversion element mapping spreadsheet</a>	This document describes the relationship between EU specific data elements in E2B(R3) and E2B(R2). This document is an addition to the ICH backwards-forwards conversion rules. It covers additional EU-specific rules for the conversion back and forth between E2B(R2) and E2B(R3).
 <a href="#">Draft EU BFC conversion</a>	The ICH backwards-forwards conversion tool updated to include additional EU-specific data fields.
 <a href="#">EU E2B(R3) code lists</a>	The list of codes for EU-specific data fields.
 <a href="#">EU reference instances</a>	ICH reference instances amended to include EU-specific data fields.
 <a href="#">EU example instances</a>	Additional example instances to be used for testing E2B(R3) transmissions to the EudraVigilance system.

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q\\_and\\_a/q\\_and\\_a\\_detail\\_000149.jsp&mid=WC0b01ac05800250b5](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000149.jsp&mid=WC0b01ac05800250b5)



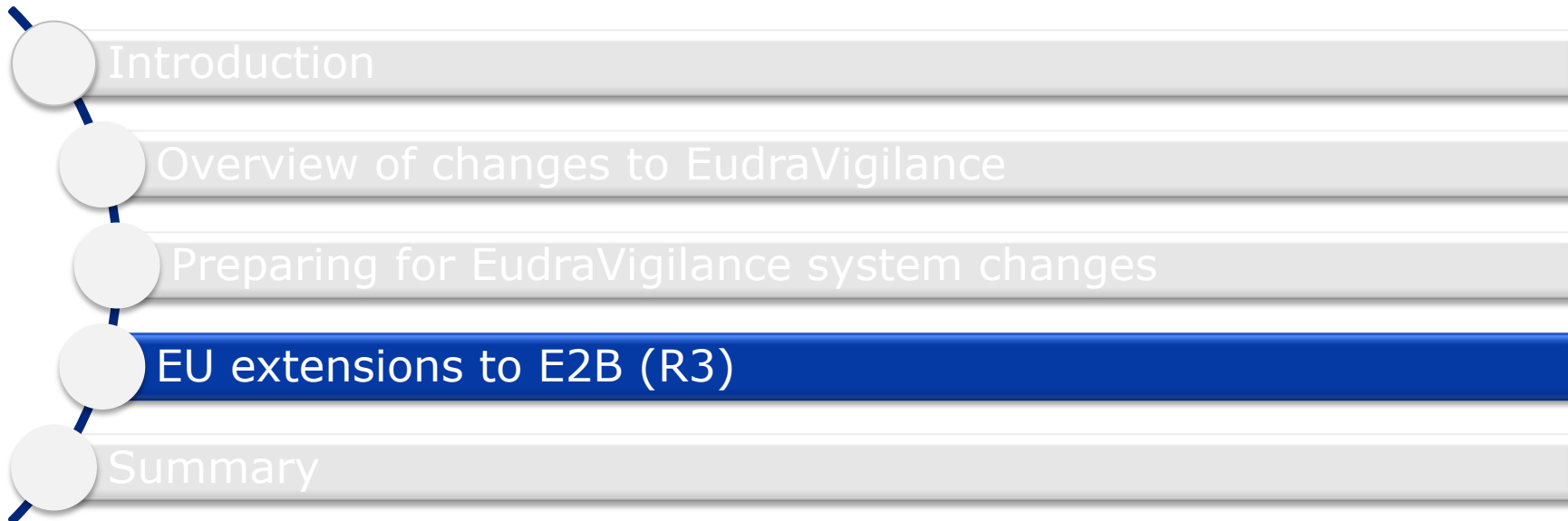
## Relationship between ISO ICSR standard, ICH E2B(R3) & the EU Implementation Guides

- The ISO standard provides the schema files (technical structure) to be used to create ICSR messages
- The ICH E2B(R3) implementation guide (IG) provides the core set of requirements for the contents of messages
- The EU Implementation Guide supplements the ICH E2B(R3) IG with additional EU specific requirements



# ICH & EU Documentation for ISO ICSR

- Published Technical documentation
  - ICH Documentation (<http://estri.ich.org>)
    - [ICH Implementation guide package](#)
    - [ICH E2B\(R3\) Questions & Answers \(Q&As\)](#)
  - EU Documentation (<http://www.ema.europa.eu>)
    - [EU Individual Case Safety Report \(ICSR\) Implementation Guide](#)
- These documents **should not** be read in isolation
- The EU implementation has additional requirements
  - Additional Data elements to the ICH IG
  - Controlled vocabularies specific to the EU
  - Business rules (some optional fields in ICH are mandatory in the EU)





## EU Causality Assessment Reporting in ICSRs

- EU Causality Assessment can be used for SUSAR (mandatory) and post-authorisation reporting (optional)
  - Source of Assessment – e.g. Investigator, Sponsor, MAH, Health Care professional
  - Result of Assessment - Reasonable possibility or No reasonable possibility
- Based on the CIOMS Working Group VI binary decision causality assessment
- The same assessment is used in E2B(R2) using free text fields. In E2B(R3) these fields are controlled vocabularies



## Biological Products Requiring Batch Number

- For suspected adverse reactions relating to biological medicinal products, the identification of the concerned product with regard to its manufacturing is important
- All appropriate measures should be taken to clearly identify the name of the product and the batch number
- The batch number field is mandatory in the EU for all suspect drugs
  - The nullflavor "ASKU" should be completed for biological products where the primary source has been contacted for this information but is unable to provide it
  - The nullflavor "UNK" should be used for all other situations when this information is missing



## Device Component and Device Batch number

- Advanced therapies or involve medicinal products that have device component(s) additional fields are available in the ISO ICSR to capture specific information about the device component(s)
  - Device ID – Will form part of ISO IDMP controlled vocabularies
  - Device name
  - Device batch/lot number
- This information can be important where the reporter has suspected that the device component may have led to the adverse reaction experienced by the patient or in cases of device failure.
- The batch/lot number is separate and specific to the device and is different to the medicinal product “box” level batch/lot number



## EU ICSR Implementation Guide Business rules Spreadsheet

- This Excel Spreadsheet contains all the business rules contained in the EU implementation guide along with additional technical information
- It can be used to easily identify ICH and EU data fields
- Differences between the ICH business rules and EU business rules are also highlighted
- [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Other/2015/10/WC500196023.xlsx](http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/10/WC500196023.xlsx)





# ICH/EU Reference Instances

```

<component typeCode="COMP">
  <causalityAssessment classCode="OBS" moodCode="EVN">
    <code code="39" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="causality"/>
    <value xsi:type="ST">G.k.9.i.2.r.3</value>
    <!--G.k.9.i.2.r.3: Result of Assessment Drug #1, Reaction #2, Assessment #1 -->
    <methodCode>
      <originalText>G.k.9.i.2.r.2</originalText>
      <!--G.k.9.i.2.r.2: Method of Assessment Drug #1, Reaction #2, Assessment #1 -->
    </methodCode>
    <author typeCode="AUT">
      <assignedEntity classCode="ASSIGNED">
        <code>
          <originalText>G.k.9.i.2.r.1</originalText>
          <!-- G.k.9.i.2.r.1: Source of Assessment Drug #1, Reaction #2, Assessment #1 -->
        </code>
      </assignedEntity>
    </author>
  </causalityAssessment>
</component>

```

```

<component typeCode="COMP">
  <causalityAssessment classCode="OBS" moodCode="EVN">
    <code code="39" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="causality"/>
    <!-- EU Reference instance - EU Causality assessment -->
    <value xsi:type="CE" code="1" codeSystem="2.16.840.1.113883.3.989.5.1.1.5.3" codeSystemVersion="G.k.9.i.2.r.3.EU.1.CSV" displayName="Reasonable possibility"/>
    <!-- G.k.9.i.2.r.3.EU.1: Result of Assessment - captured in the code field -->
    <methodCode code="1" codeSystem="2.16.840.1.113883.3.989.5.1.1.5.2" codeSystemVersion="G.k.9.i.2.r.2.EU.1.CSV" displayName="EU Method of Assessment"/>
    <!-- G.k.9.i.2.r.2.EU.1: EU Method of assessment - captured in the code field -->
    <author typeCode="AUT">
      <assignedEntity classCode="ASSIGNED">
        <code code="1" codeSystem="2.16.840.1.113883.3.989.5.1.1.5.4" codeSystemVersion="G.k.9.i.2.r.1.EU.1.CSV" displayName="Investigator"/>
        <!-- G.k.9.i.2.r.1.EU.1: EU Source of assessment - captured in the code field -->
      </assignedEntity>
    </author>
  </causalityAssessment>
</component>

```

[http://www.ema.europa.eu/ema/pages/includes/document/open\\_document.jsp?webContentId=WC500196027](http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500196027)

## ICH/EU Code lists

- The EU Implementation includes 4 additional code lists to the existing 27 ICH
- 1 Code list for additional Message types e.g. backlog
- 3 Code lists for SUSAR drug reaction assessments
  - Note – These can also be used for post-authorisation ICSRs (Optional)

[http://www.ema.europa.eu/ema/pages/includes/document/open\\_document.jsp?webContentId=WC500196025](http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500196025)



## EU Example Instances

- Example instances can be used for testing E2B(R3) and for testing transmissions to the EudraVigilance system.
- The file 05\_Standard EV QA test cases-R3.xml is intended for final testing with the EMA before moving a new system into production with EudraVigilance
- [http://www.ema.europa.eu/ema/pages/includes/document/open\\_document.jsp?webContentId=WC500196026](http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500196026)



## Access policy

- The access policy details which E2B(R3) data fields MAHs will have access to in EudraVigilance and what conditions are placed on that access.
- [http://www.ema.europa.eu/ema/pages/includes/document/open\\_document.jsp?webContentId=WC500199048](http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500199048)



# ISO ICSR Standard



INTERNATIONAL STANDARD ISO/HL7 27953-2:2011(E)

First edition 2011-12-01

**Health informatics — Individual case safety reports (ICSRs) in pharmacovigilance —  
Part 2:  
Human pharmaceutical reporting requirements for ICSR**

*Informatique de santé — Rapports de sécurité de cas individuel (ICSRs) en pharmacovigilance —  
Partie 2: Exigences pharmaceutiques humaines à rapporter pour un rapport de sécurité de cas individuel (ICSR)*

[ISO/HL7 27953-2:2011\(E\)](#)

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## Suggested Reading

- ISO/HL7 27953-2:2011 Standard  
[http://www.iso.org/iso/iso\\_catalogue/catalogue\\_tc/catalogue\\_detail.htm?csnumber=53825](http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=53825)
- HL7 books
  - HL7 Version 3 Primer Normative Edition version ISBN 3-933819-21-0
  - Principles of Health Interoperability HL7 and SNOMED ISBN: 978-1-44712-800-7
  - <http://www.hl7.org.uk/marketing/publications.asp>



## ISO ICSR Schema Location

<http://eudravigilance.ema.europa.eu/xsd/>

E2B(R3) XSD Reference:

[http://eudravigilance.ema.europa.eu/xsd/multicacheschemas/MCCI\\_IN200100UV01.xsd](http://eudravigilance.ema.europa.eu/xsd/multicacheschemas/MCCI_IN200100UV01.xsd)





## ICH Technical info document

- Contains useful information examples for structuring Time intervals, Lab test results and dosage information
- **Warning** – Some of the XPATHs in the document are incorrect/incomplete. The ICH Reference message instance is the source of truth for ICH not this document.



## GVP module VI & IX and Clinical Trials updates

- These Good Pharmacovigilance Practice business level documents are being updated. During this update changes to the business rules might occur, therefore the EU Implementation Guide and supporting documents may also be revised to reflect the change in requirements
- In addition the guidance for the Clinical Trials regulation is also under discussion which can also lead to new requirements that would need to be reflected in the EU Implementation Guide and supporting documents.



## ISO IDMP implementation

- Not planned for release as part of the new EudraVigilance system in 2017.
- ISO IDMP once established will be implemented in EudraVigilance and its use is likely to become mandatory for use by all organisations at some point after that. E2B(R2) would no longer be support for submission as part of this implementation



## Usage of nullflavor flags

- The HL7/ISO ICSR schema requires that mandatory data elements must always be part of the ICSR message. In some situations mandatory data elements might be empty of content for specific reasons for an ICSR that is still considered valid.
- In HL7 messaging the issue of empty elements is handled through the use of a nullFlavor flags. These flags prevent a field being empty and provides the receiver of the ICSR with a reason for the lack of data.
- Valid messages can be created containing mandatory elements without transmitting content. The reason for a blank element is referred to as the 'flavor' of the null value.

## Nullflavor Types

- 15 Types of null found in the HL7 V3 specifications
  - 8 are used in the E2B(R3) Implementation

<b>NI</b>	No Information
<b>NA</b>	Not Applicable
<b>UNK</b>	Unknown
<b>NINF</b>	Negative Infinity
<b>PINF</b>	Positive Infinity
<b>MSK</b>	Masked
<b>ASKU</b>	Asked but unknown
<b>NASK</b>	Not asked



## Usage of nullflavor flags

- Nullflavors give a reason why a specific field in an ICSR is empty/blank
- The HL7/ISO ICSR schema requires that some data elements must always be part of the ICSR message even if ICH/EU IGs classifies those fields as optional. In such situations a nulflavor will be permitted
- The EU implementation has some difference to the ICH IG. The ICH IG allows some fields to be null however these fields are mandatory in the EU e.g Reporter Qualification, Literature Reference(s) & Study Registration Country
- Nullflavors represent some technical challenges for implementing in IT systems and for displaying in data entry tools



## UUIDs - Universally Unique Identifier

- Used in the ICSR message for cross-referencing, this allows many to many relationships within the XML such as drug-reaction assessments
  - xxxxxxxx-xxxx-4xxx-xxxx-xxxxxxxxxxxx
- There are 5 versions of the standard
  - Which version should you implement?
    - The ICH documentation does not specify a version or a preferred version
    - Version 4 - Random numbers will be implemented for EudraVigilance



# UUIDs - Universally Unique Identifier

- **Questions**
  - Should you store the UUID used in received or sent messages?
  - Should you re-use the same UUID in follow-ups?
  - What will other organisations you exchange data with do?
- There is no specific ICH guidance on this
- EudraVigilance will generate UUIDs at the time of XML file creation





# UCUM

- For physical quantities and units of time HL7 Messaging uses UCUM

<http://unitsofmeasure.org/ucum.html>

<http://unitsofmeasure.org/graphics/ucum-state-automaton.gif>

## UCUM - PQ data type

- The Unified Code for Units of Measure is a code system intended to include all units of measures
- The single units of UCUM can be combined in many ways as long as they follow the correct syntax rules

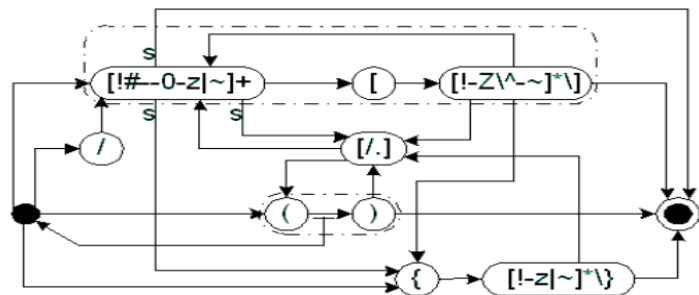


Figure 1: Pushdown-state automaton describing the syntax.



## UCUM challenges

- Kilograms can be expressed as **1000.g** or **10\*3.g** or **kg**
- Coding Test result units may require regular expressions in order to validate that correct UCUM values have been provided.
- Biological units expressed within `{}` brackets may require additional agreement between organisations
- `{}` brackets also used for BFC rules to transfer non-UCUM codes from E2B(R2) XML file into an E2B(R3) file



- Introduction
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## Summary

In this training module the following topics have been covered:

- The background ICSR documentation
- EU specific requirements for implementing the ISO ICSR standard
- The potential issues that may be faced



# Feedback

- Please provide us with feedback on this E-learning module and any attendant guidance documents you have viewed by taking the EMA training survey.
- The survey is accessible via [this link](#).

Save a backup on your local computer (disable if you are using a public/shared computer)

## EudraVigilance training feedback survey

Fields marked with \* are mandatory.

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## Acronyms (1/3)

<b>Acronym</b>	<b>Description</b>
CIOMS	Council for International Organizations of Medical Sciences
EV	EudraVigilance
xEVMPD	EudraVigilance Medicinal Product Dictionary
EEA	European Economic Area
EU	European Union
HL7	Health Level 7
IDMP	Identification of Medicinal Products

## Acronyms (2/3)

<b>Acronym</b>	<b>Description</b>
IG	Implementation Guide
ICSR	Individual Case Safety Reports
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ISO	International Organization for Standardization
MAH	Marketing authorisation holder
NCA	National competent authority
SUSAR	Suspected Unexpected Serious Adverse Reaction





## Acronyms (3/3)

<b>Acronym</b>	<b>Description</b>
UCUM	Unified Code for Units of Measure
UUID	Universally Unique Identifier



Thank you for your attention

## Further information/ **Contact information**

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