EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

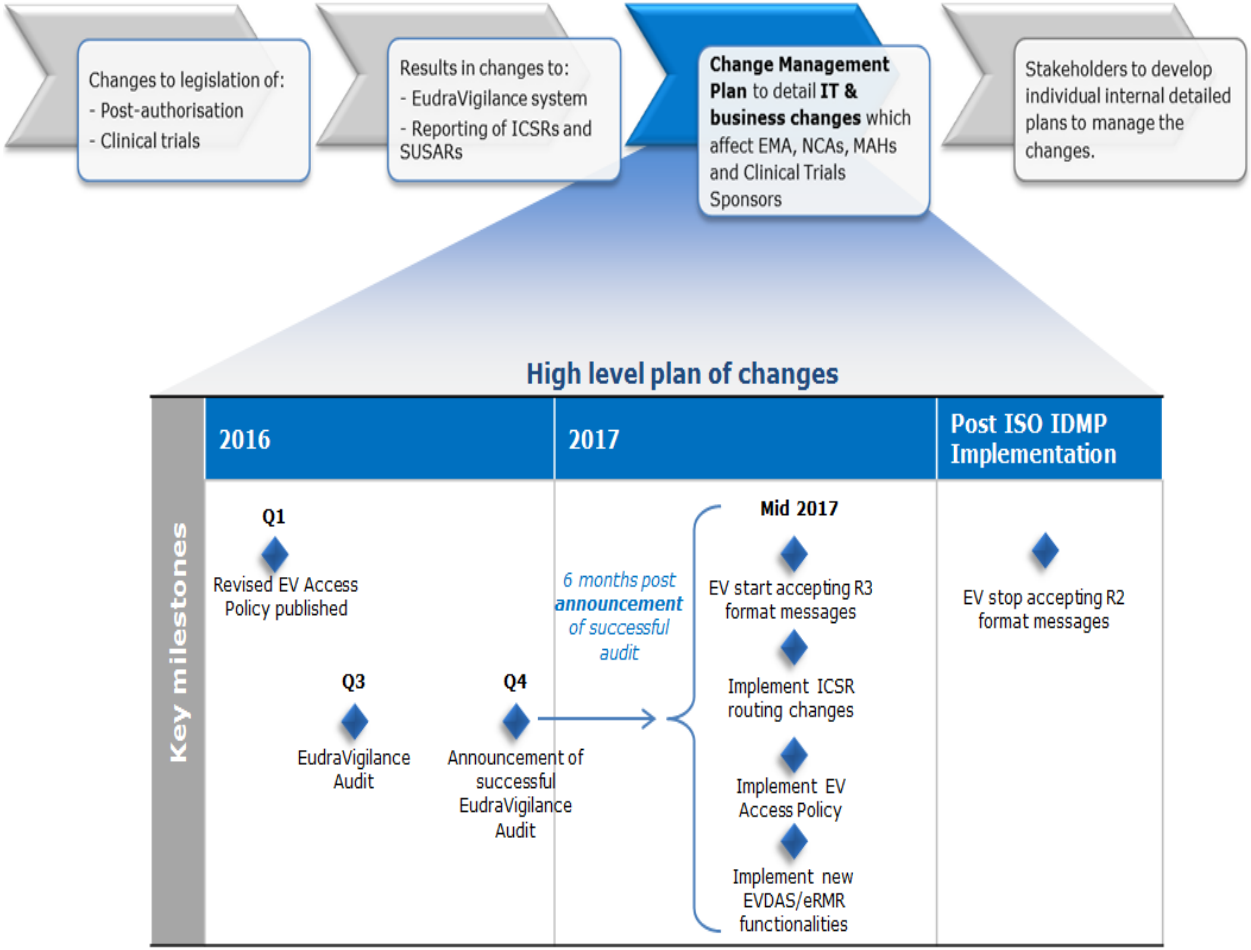
Session 1 – Documentation, Resources & Implementation Milestones

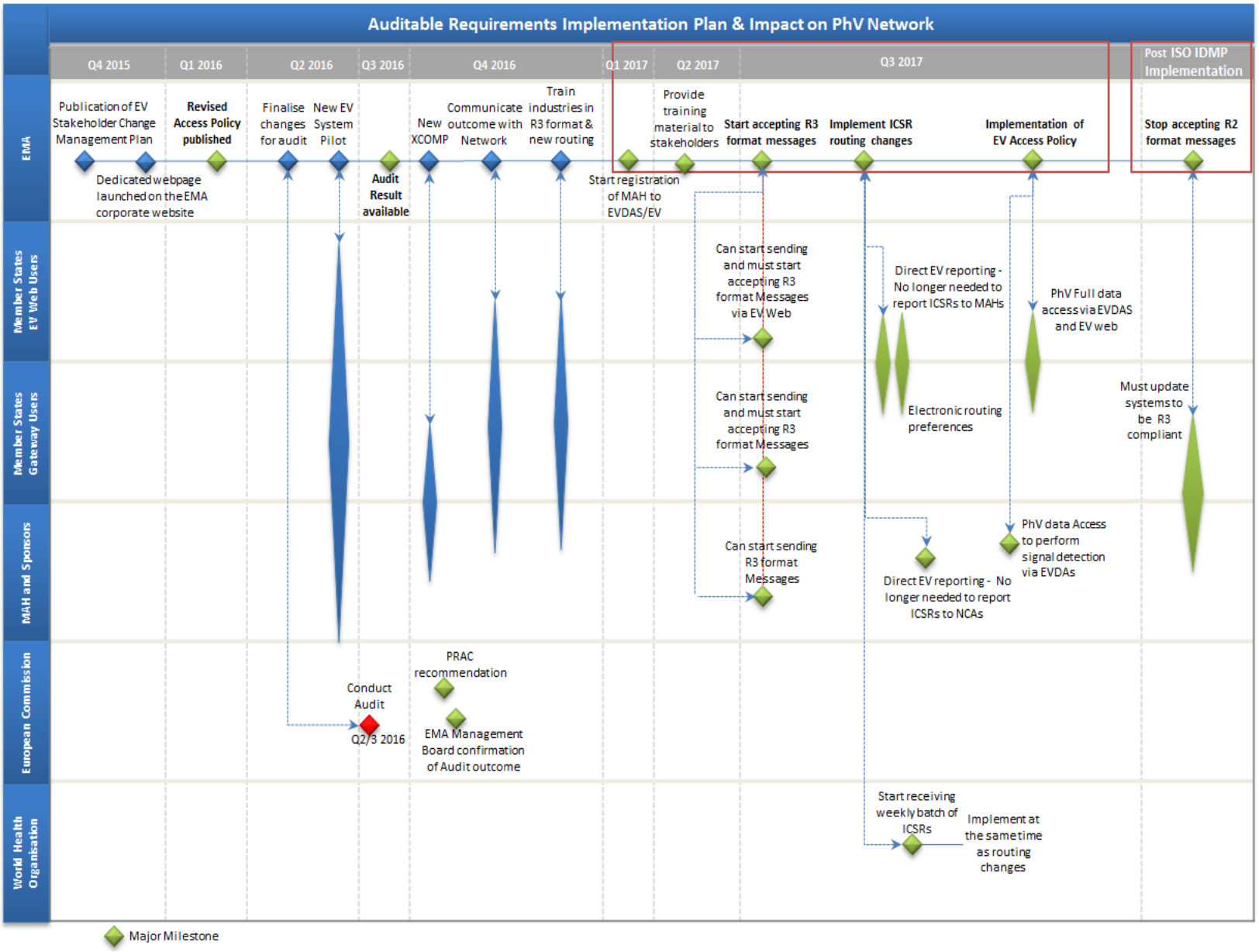
Presented by: Nick Halsey
Data Standardisation and Analytics

Agenda

- Why is EudraVigilance changing?
- How is EudraVigilance changing?
- How to prepare for technical changes?
- Technical Support, & available Documentation

Project Milestones




Auditable Requirements Implementation Plan & Impact on PhV Network
Q4 2015
Q1 2016
Q2 2016
Q3 2016
Q4 2016
Q1 2017
Q2 2017
Q3 2017
Post ISO IDMP Implementation
EMA
Member States EV Web Users
Member States Gateway Users
MAH and Sponsors
European Commission
World Health Organisation
Publication of EV Stakeholder Change Management Plan
Dedicated webpage launched on the EMA corporate website
Revised Access Policy published
Finalise changes for audit
New EV System Pilot
Audit Result available
New XCOMP
Communicate outcome with Network
Train industries in R3 format & new routing
Start registration of MAH to EVDAS/EV
Provide training material to stakeholders
Start accepting R3 format messages
Implement ICSR routing changes
Implementation of EV Access Policy
Stop accepting R2 format messages
Can start sending and must start accepting R3 format Messages via EV Web
Can start sending and must start accepting R3 format Messages
Can start sending R3 format Messages
Direct EV reporting - No longer needed to report ICSRs to MAHs
Electronic routing preferences
PhV Full data access via EVDAS and EV web
Must update systems to be R3 compliant
PhV data Access to perform signal detection via EVDAs
Direct EV reporting - No longer needed to report ICSRs to NCAs
Conduct Audit
Q2/3 2016
PRAC recommendation
EMA Management Board confirmation of Audit outcome
Start receiving weekly batch of ICSRs
Implement at the same time as routing changes
Major Milestone

Why is EudraVigilance changing? (1/4)

- 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.

Why is EudraVigilance changing? (2/4)

- Clinical Trials legal requirement changes
  - The new Clinical Trials Regulation (Regulation (EU) No 536/2014) will apply as from six months after the publication of the Commission notice about the full functionality of the EU portal and database, and no earlier than 28th May 2016.
  - According to the Regulation, the Agency shall set up and maintain an electronic database for the reporting of SUSARs and annual safety reports. The database shall be a module of the EudraVigilance database.

Why is EudraVigilance changing? (3/4)

- The main planned changes to electronic reporting requirements are:
  - Usage of ISO standards in the reporting of SUSARs, ISO ICSR standard 27953-2:2011
  - Usage of ISO IDMP set of standards and terminologies, once available, in the submission of ISO ICSR messages
  - Centralisation of reporting SUSARs in the EU
  - Development of a standard web-based structured form for the SUSARs reporting by sponsors to EudraVigilance; This form would be ISO ICSR 27953-2:2011 (E2B(R3)) compliant.

Why is EudraVigilance changing? (3/4)

- Revision of the EudraVigilance Access Policy
  - **Article 24(2) of the Regulation defines the level of EudraVigilance access as follows:**
    - EudraVigilance shall be fully accessible to the competent authorities of the Member States and to the Agency and the European Commission.
    - It shall also be accessible to MAHs to the extent necessary for them to comply with their pharmacovigilance obligations.
    - The Agency shall ensure that healthcare professionals and the public have appropriate levels of access to the EudraVigilance database, while guaranteeing personal data protection.
  - **Article 28(c) of Regulation (EC) No 726/2004 further states that:**
    - The Agency shall make available promptly all suspected adverse reaction reports occurring in the Union to the WHO.

How is EudraVigilance changing? (1/4)

- In December 2013, the EMA Management Board endorsed the "EudraVigilance Auditable requirements" :
  - Simplified reporting of side effect reports for MAHs with re-routing to NCAs
  - Provision of reports to WHO (respecting EU data protection legislation)
  - EV access for MAHs to conduct product monitoring including signal detection (respecting EU data protection legislation)
  - Publication of data and search availability for healthcare professionals and the public for all medicines authorised in the EU

How is EudraVigilance changing? (2/4)

- Continued:
  - Compliance with international ICSR standards (and compatibility with IDMP standards based on Article 57 data) by 1 July 2016 including backwards and forwards conversion tools for E2B(R2)/(R3) messages
  - Conversion of legacy data (> 7 mill. ICSRs currently held in EV)
  - System performance and scalability based on increased number of users and volume of data
  - Security (authentication, authorisation and data transaction to limit the risks of unauthorised access)

How is EudraVigilance changing? (3/4)

- EudraVigilance Audit:
  - Functional specifications were prepared by the Agency in collaboration with Member States and the Commission to address required changes
  - Functional specifications were endorsed by EMA Management Board in December 2013 and are subject to an independent audit ("auditable requirements")
  - EMA Management Board is to announce when Eudravigilance database has achieved full functionality and the system meets the functional specifications based on
    - Independent audit report
    - Recommendation of the Pharmacovigilance Risk Assessment Committee
  - Simplification of adverse reaction reporting will apply six months following the announcement by the Board

How is EudraVigilance changing? (4/4)

- 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 EVTEST system available to stakeholder for testing: Q4 2016
  - Training launch: Q1 2017
  - Go-live: July 2017

How to prepare for technical changes?

- **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)

How to prepare for technical changes?

- 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?

- **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

How to prepare for technical changes?

- **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?

- **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

How to prepare for technical changes?

- 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)

How to prepare for Business process changes?

- **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?

- **MAH Signal validation and management process**:
  - MAHs will have the legal obligation to monitor data available in EV and to inform the Agency and NCAs about any validated signals they identify.
  - The new process for signals validated by MAHs will be designed, discussed and consulted during the 1st revision of the GVP Module IX on signal management (Public consultation planned for 2nd quarter of 2016).
  - Other guidance documents, including training materials, will be created and provided as relevant. MAHs should put in place training for their staff concerning this new process.

How to prepare for Business process changes?

- **MAH Signal validation and management process**
  - MAHs will be granted access to the EudraVigilance Data Analysis system in order to comply with their pharmacovigilance obligations and use the signal detection and analytical reporting functions (e.g. electronic reaction monitoring report and ICSR line listings).
  - MAHs should put in place training for their staff concerning this new tool and register their staff to have access to it.

How to prepare for Business process changes?

- **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.
  - Clinical Trials approved through the Clinical Trials directive 2001/20/EC will continue to have the same SUSAR reporting requirements as specified in the directive for a transition period of 3 years after the Clinical Trials regulation is applicable.
  - Note: Option will remain for small organisations to report SUSARs directly to the NCA that has approved the trial through establishing an agreement between the sponsor and the NCA concerned. The NCA will then forward these SUSARs to EV.

What training will be available? (1/2)

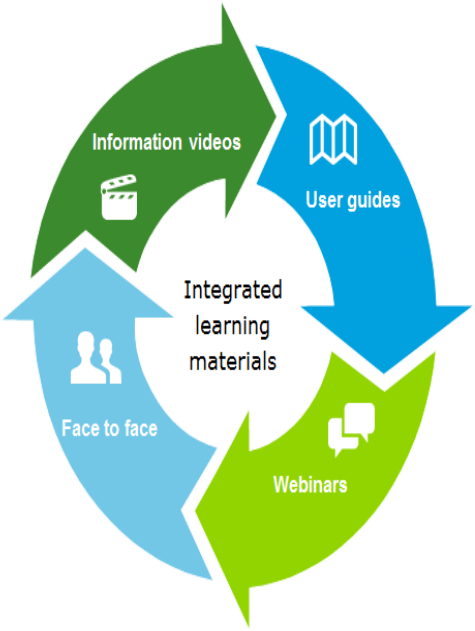
- Training should be planned for MAH staff on the new business process and new IT systems at least 6 months prior to implementation in order to be ready once the new EudraVigilance system is implemented.

- Module based online training approach for all users accessible through the EMA website

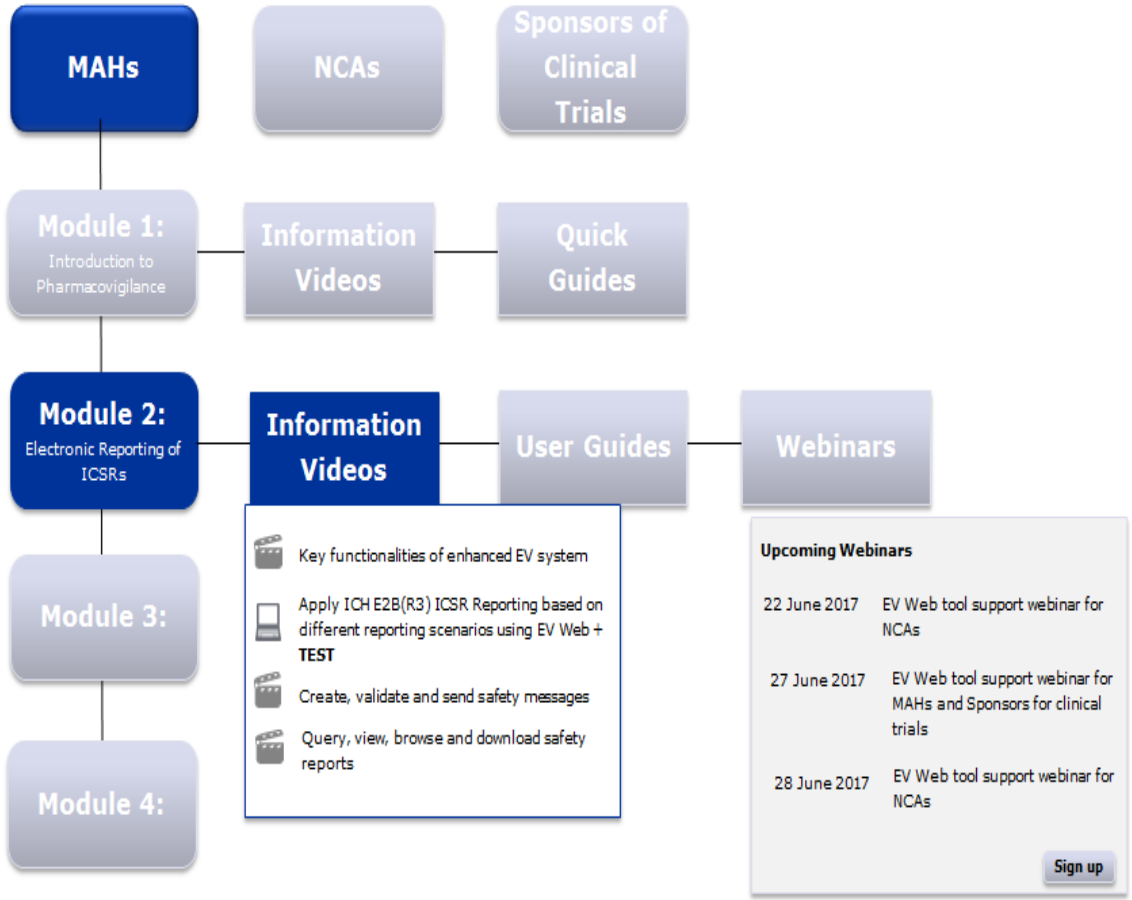
- The online learning comprises the use of:
  - Information videos,
  - Contextual help in EV Web
  - User Manuals,
  - Demo videos,
  - Competency assessments.

- Limited face to face trainings based on a train the trainer approach might be offered.

Flexible training paths



What training will be available? (2/2)

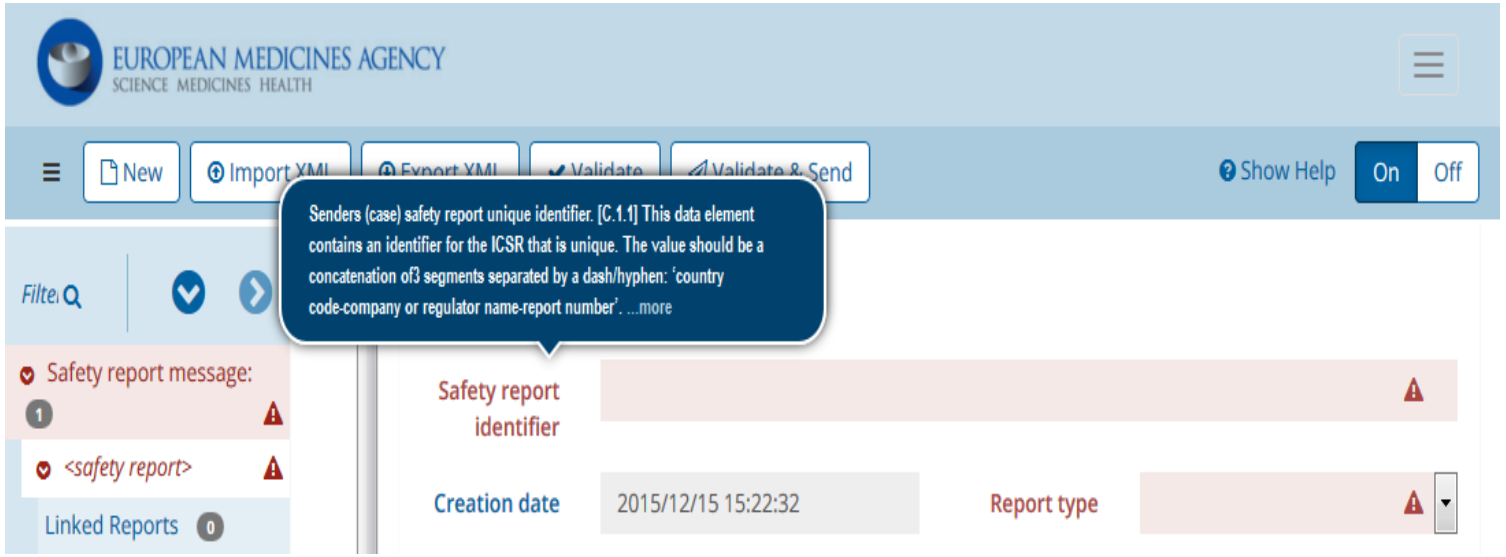


MAH Learning Path (under finalisation)

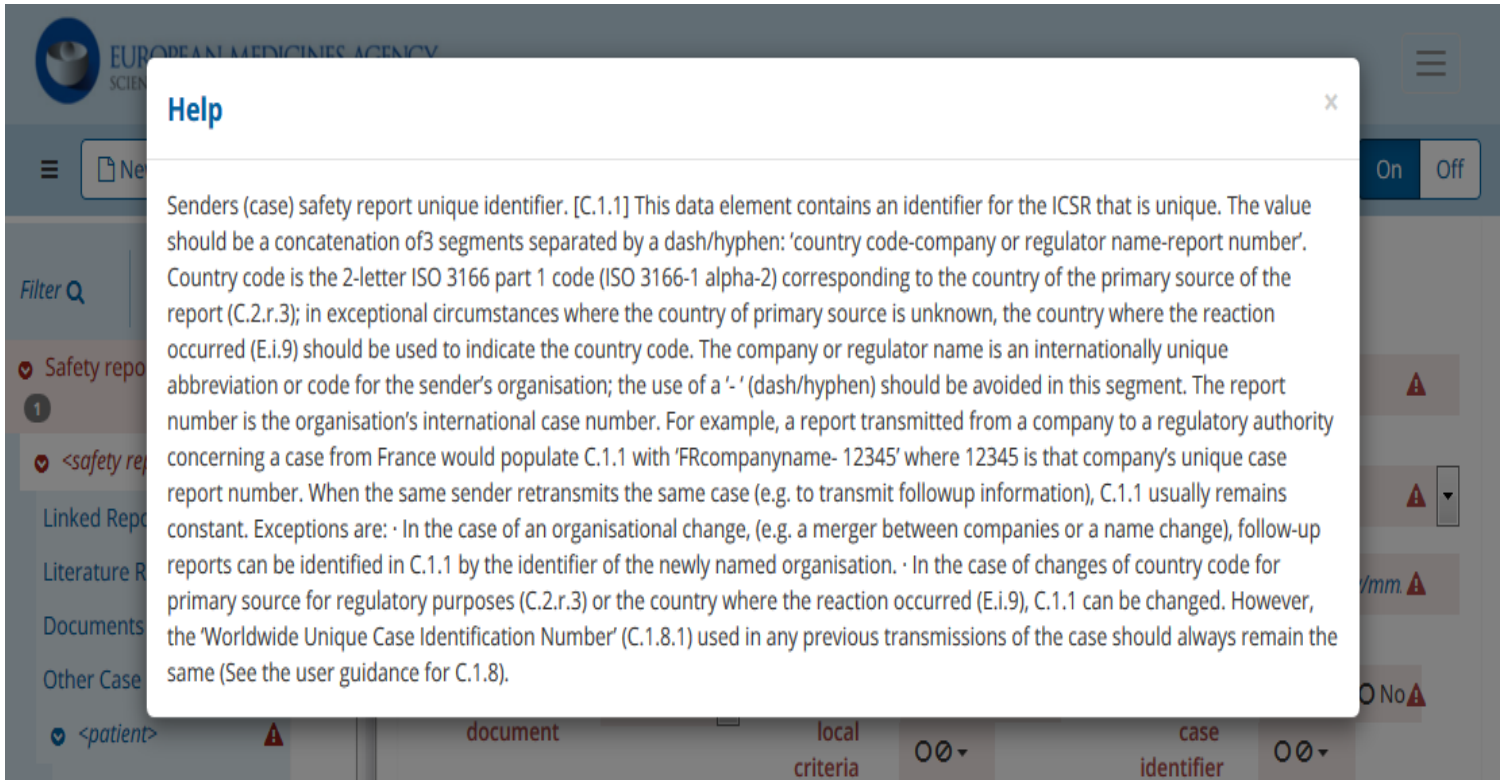
	Pharmacovigilance Operations	New EudraVigilance Functionalities	New EudraVigilance Functionalities - IT
E-learning	Introduction to training offering by the EMA	How to register with EudraVigilance and EVDAS	ISO ICSR standard implementation for IT system developers
	New EV functionalities and 2010 pharmacovigilance legislation	Introduction to EV system components and system functionalities	Gateway adaptations for ISO ISCR/ACK message exchange with Eudravigilance
	Implementing ISO ICSR/ICH E2B R3	Overview of reporting process for EV users	Instructions on how to test ICSR submissions to EV
	How to prepare for simplified adverse reaction reporting in the EU	EudraVigilance export manager and ICSR download	
	Revised EV Access policy – how does it impact on MAHs and NCAs	EVDAS training for MAHs	
	Revised GVP guidelines – updates and impact	Medical Literature Monitoring service	
	Medical Literature Monitoring by EMA – what's new		
Guidance	Revised Signal Detection Guideline	MAH's level 1 access via EVDAS	
	Revised GVP Module VI	EVDAS Report Manual	
	Revised GVP Module IX	Webport user guide for ADR website	
Webinars	Pharmacovigilance Operations Support webinar	EV/EVDAS Functionalities webinar	

All MAH users will have access to all training course. The learning path aims to indicate course best suited for each stakeholder group

Built-in help in EV web (1/2)

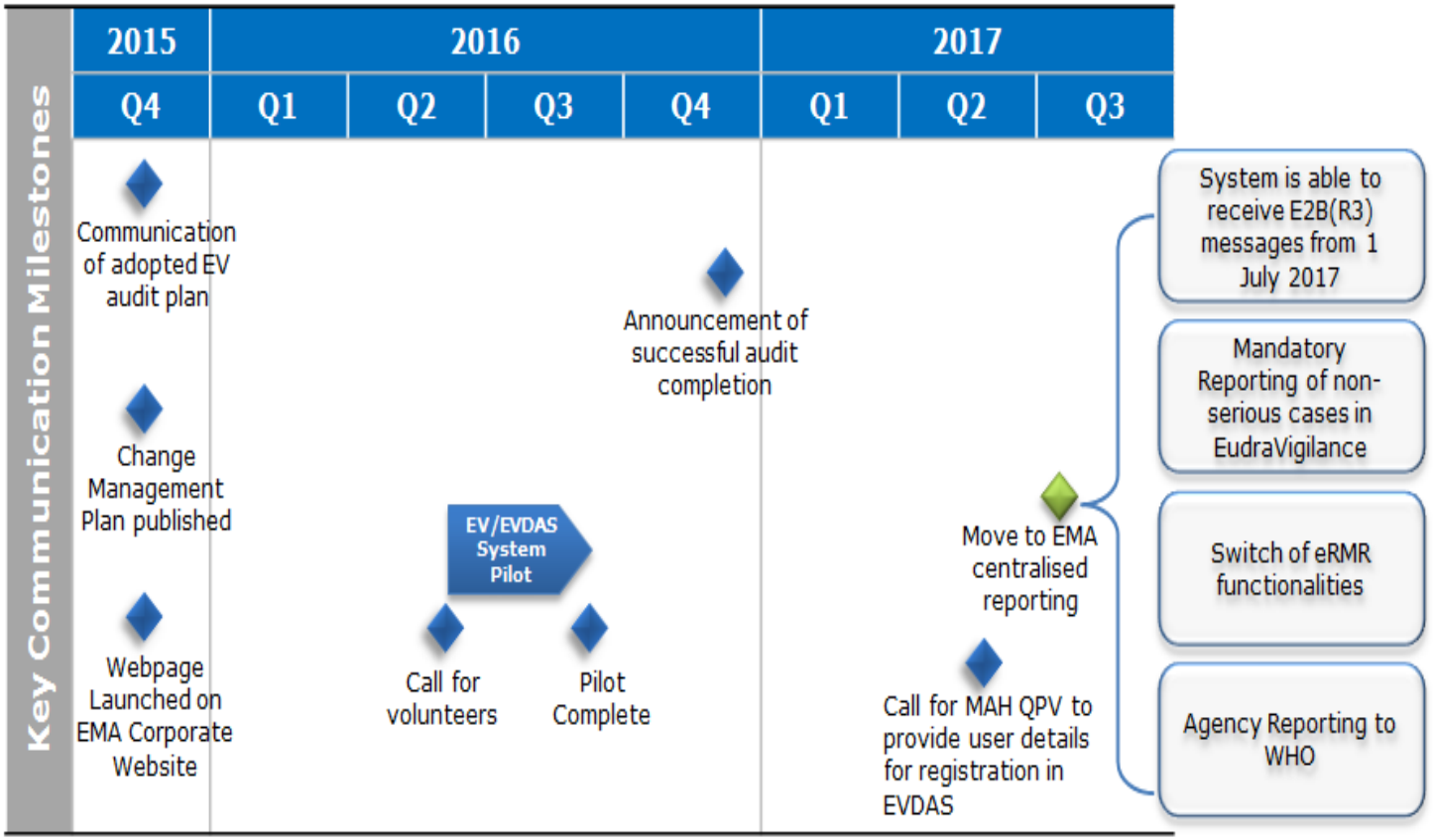


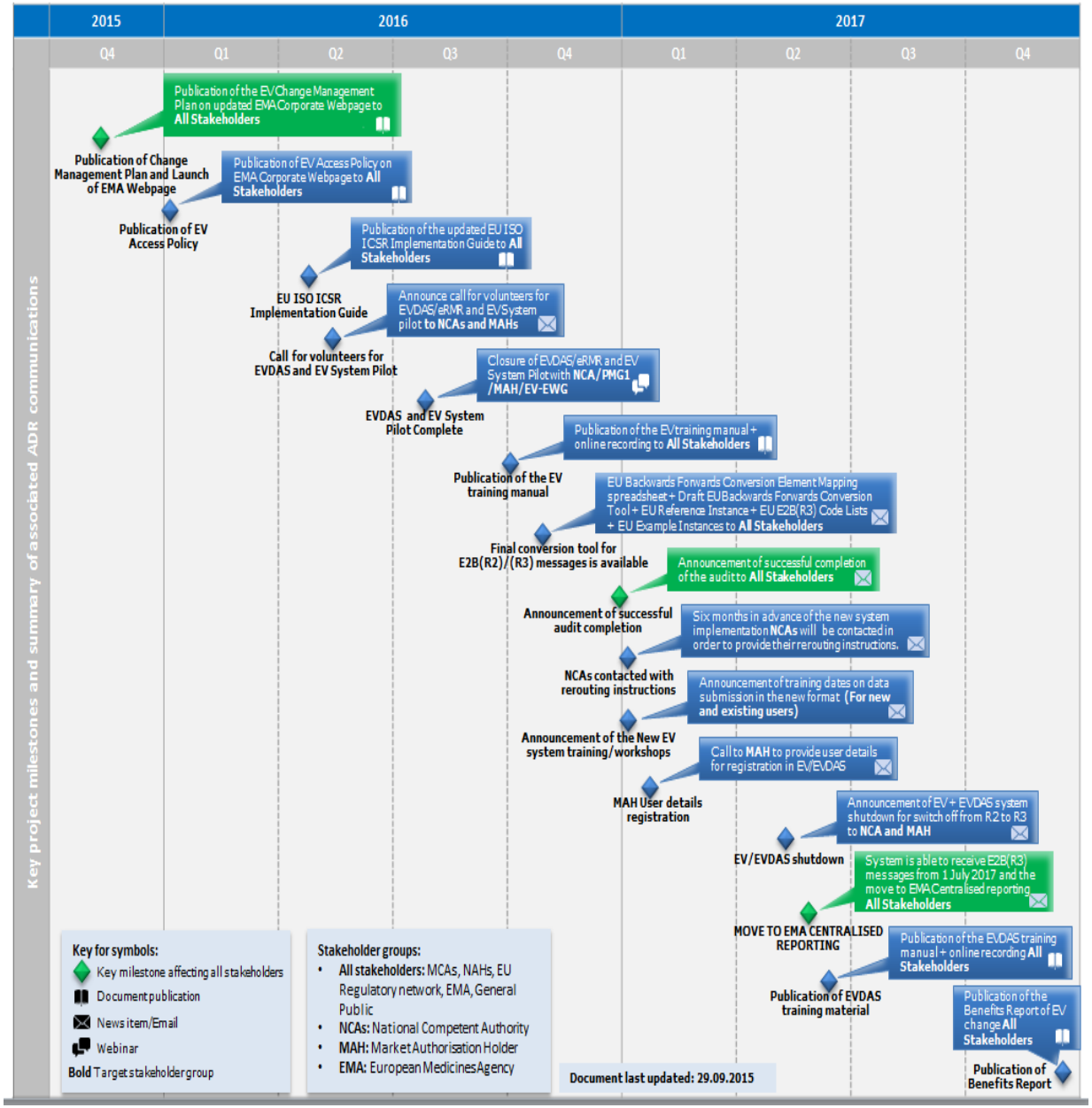
Built-in help in EV web (2/2)



What communication will be available?

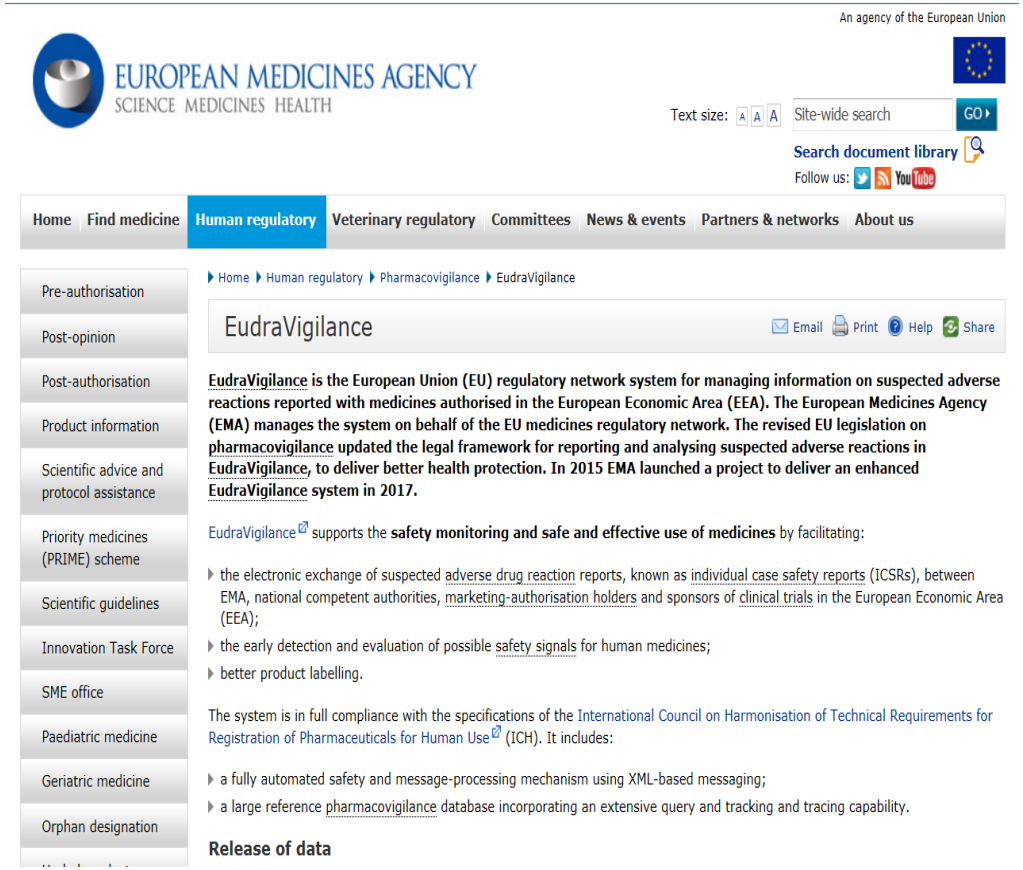
MAHs should consider developing a communication plan to ensure that the necessary information is circulated within their own organisation and with other organisations that they work with.



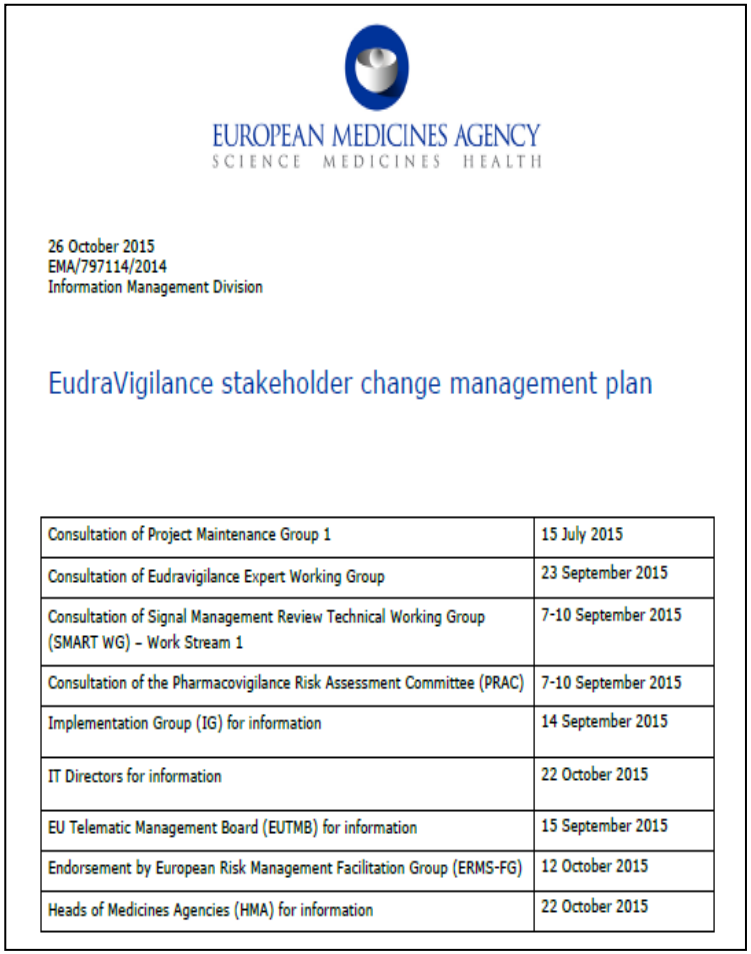

2015
2016
2017
Q4
Q1
Q2
Q3
Q4
Q1
Q2
Q3
Q4
Key project milestones and summary of associated ADR communications
Publication of the EV Change Management Plan on updated EMA Corporate Webpage to All Stakeholders
Publication of Change Management Plan and Launch of EMA Webpage
Publication of EV Access Policy on EMA Corporate Webpage to All Stakeholders
Publication of EV Access Policy
Publication of the updated EU ISO ICSR Implementation Guide to All Stakeholders
EU ISO ICSR Implementation Guide
Announce call for volunteers for EVDAS/eRMR and EV System pilot to NCAs and MAHs
Call for volunteers for EVDAS and EV System Pilot
Closure of EVDAS/eRMR and EV System Pilot with NCA/PMG1 /MAH/EV-EWG
EVDAS and EV System Pilot Complete
Publication of the EV training manual + online recording to All Stakeholders
Publication of the EV training manual
EU Backwards Forwards Conversion Element Mapping spreadsheet + Draft EU Backwards Forwards Conversion Tool + EU Reference Instance + EU E2B(R3) Code Lists + EU Example Instances to All Stakeholders
Final conversion tool for E2B(R2)/(R3) messages is available
Announcement of successful completion of the audit to All Stakeholders
Announcement of successful audit completion
Six months in advance of the new system implementation NCAs will be contacted in order to provide their rerouting instructions.
NCAs contacted with rerouting instructions
Announcement of training dates on data submission in the new format (For new and existing users)
Announcement of the New EV system training/workshops
Call to MAH to provide user details for registration in EV/EVDAS
MAH User details registration
Announcement of EV + EVDAS system shutdown for switch off from R2 to R3 to NCA and MAH
EV/EVDAS shutdown
System is able to receive E2B(R3) messages from 1 July 2017 and the move to EMA Centralised reporting All Stakeholders
MOVE TO EMA CENTRALISED REPORTING
Publication of the EVDAS training manual + online recording All Stakeholders
Publication of EVDAS training material
Publication of the Benefits Report of EV change All Stakeholders
Publication of Benefits Report
Key for symbols:
Key milestone affecting all stakeholders
Document publication
News item/Email
Webinar
Bold Target stakeholder group
Stakeholder groups:
All stakeholders: MCAs, NAHs, EU Regulatory network, EMA, General Public
NCAs: National Competent Authority
MAH: Market Authorisation Holder
EMA: European Medicines Agency
Document last updated: 29.09.2015

Where to find further guidance and detailed information?

- Dedicated EudraVigilance webpage at the Agency's corporate website



Change management plan



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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

Further guidance and detailed information

ICH implementation guidance

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

EU implementation guidance

Documentation	Description
EU ICSR Implementation Guide	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).
EU ICSR implementation guide business rules spreadsheet	This spreadsheet includes all the ICH E2B(R3) and EU specific business rules in a format to help system developers.
EU backwards forwards conversion element mapping spreadsheet	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).
Draft EU BFC conversion	The ICH backwards-forwards conversion tool updated to include additional EU-specific data fields.
EU E2B(R3) code lists	The list of codes for EU-specific data fields.
EU reference instances	ICH reference instances amended to include EU-specific data fields.
EU example instances	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

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 Extensions to E2B(R3)

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

Usage of nullflavor flags

- Nulflavors 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
- Nulflavors represent some technical challenges for implementing in IT systems and for displaying in data entry tools

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

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>
```

```
<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">
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    </assignedEntity>
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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 ones
- 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

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

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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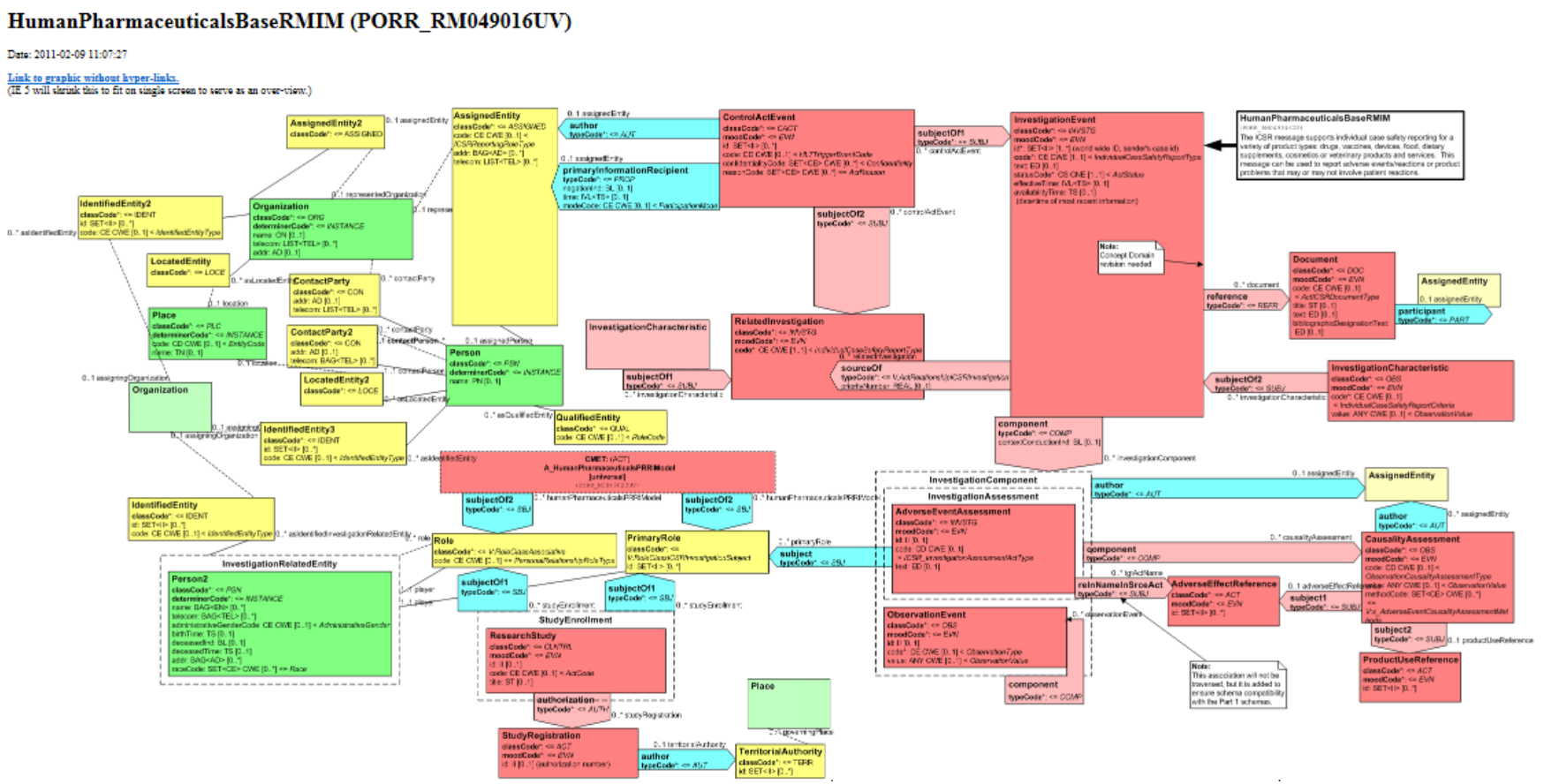
ISO ICSR Standard



ISO ICSR Schema Location

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

E2B(R3) XSD Reference:

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.

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

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

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 mid 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