



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Implementing ISO ICSR/ICH E2B(R3)

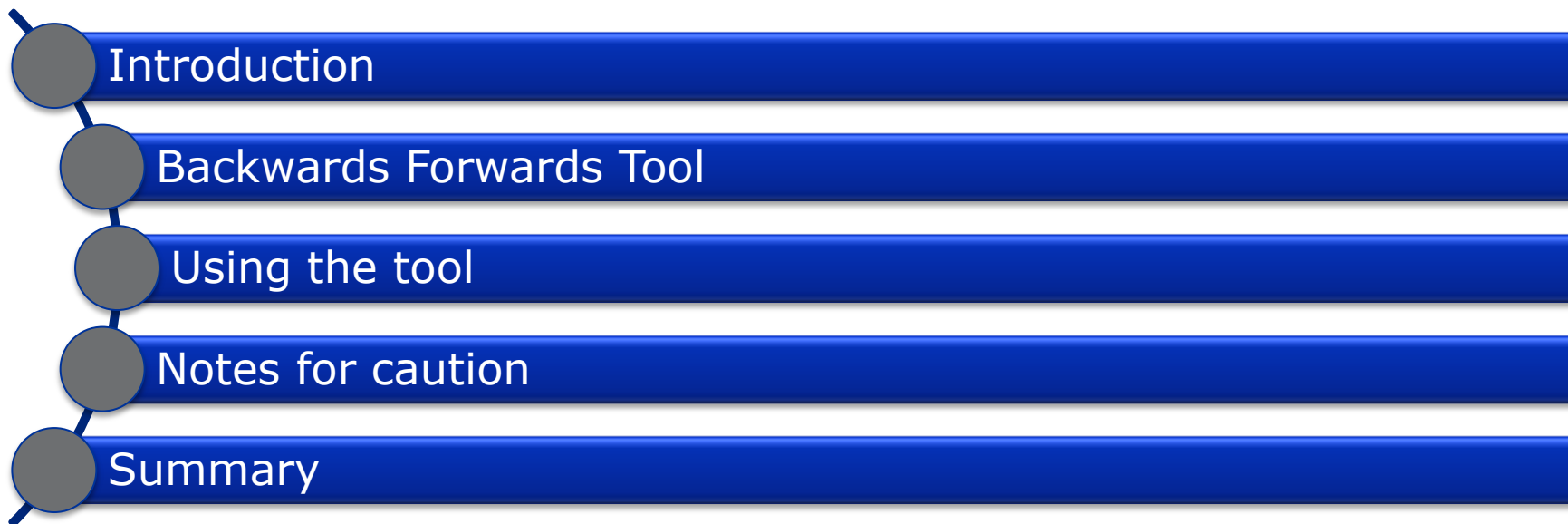
Training Module PhV-M2b

Submodule b: backwards and forwards conversion - impact on adverse reaction reporting





Summary





- Introduction
- Backwards Forwards Tool
- Using the tool
- Notes for caution
- Summary



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

- The ICH E2B(R3) Implementation Working Group developed guidance on how to convert between the E2B(R2) and E2B(R3) Individual Case Safety Report (ICSR) formats
- ICH has published two documents as part of the ICH E2B(R3) ICSR Implementation Guide
 - ICH ICSR Backwards and Forwards Compatibility Recommendations
 - Backwards and Forwards Element Mapping spreadsheet
- In addition, the above recommendations and mappings have been used to create the ICH Backwards and Forwards conversion tool (BFC)

Introduction: Learning objectives

Following the completion of PhV-M2b training module you should be able to understand:

- ✓ The background about the conversion tool
- ✓ How to perform a conversion
- ✓ The issues that may be experienced after converting files



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ICH Backwards Forwards Conversion Tool

- The ICH backwards and forwards conversion tool has been built using eXtensible Stylesheet Language Transformations (XSLTs)
- XSLT is a computer language used for transforming XML documents into other XML documents
- The BFC tool is not a computer application in itself and requires the use of a separate computer program that understands XSLT language to perform a conversion



EU Backwards Forwards Conversion Tool

- The EU ICSR Implementation Guide contains additional data fields and requirements in addition to the ICH ICSR Implementation Guide
- In support of EU stakeholders EMA has amended the ICH BFC tool to include the additional fields and requirements introduced in the EU Implementation guide
- The original ICH XSLTs have been amended and the updated EU version of the BFC tool published on the EMA website ([EudraVigilance Change Management page](#))



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Using the XSLT to perform a conversion

- The BFC XSLT package contains 31 files, of these files the following are the key files for performing the conversion
 - **ICSR Conversion**
 - **downgrade-icsr.xsl** – Converts an E2B(R3) file into an E2B(R2) file
 - **upgrade-icsr.xsl** – Converts an E2B(R2) file into an E2B(R3) file
 - **Acknowledgement Conversion**
 - **downgrade-ack.xsl** – Converts an E2B(R3) file into an E2B(R2) file
 - **upgrade-ack.xsl** – Converts an E2B(R2) file into an E2B(R3) file



Using the XSLT to perform a conversion

- Many programs exist that can use XSLTs to convert one XML format into another
- An example of a free to download program is MSXSL.exe, this program requires the use of a command line:

msxsl <file to be converted> <XSLT location> -o <file name of converted file>

Example:

msxsl "E2B(R3)_file.XML" downgrade-icsr.xsl -o "E2B(R2)_file_convert.xml"

Use of the BFC tool

When to use

- Creating test E2B(R3) files for development
- Interim process (survival) to convert E2B(R3) data obtained from EudraVigilance to load into an E2B(R2) system

When not to use

- Loading E2B(R2) data into an E2B(R3) system – Conversions may issues e.g. lab test units
- Long term
- Converting E2B(R2) files to E2B(R3) for sending to other receivers. Conversions must only be performed by the receiver of the file, not the sender.

Note: A system should not be called E2B(R3) compliant if it uses these XSLTs. It is advisable for your systems to continue to support receiving E2B(R2) ICSRs directly as this format will continue to be used for some time going forward.



Use of the BFC tool

- In accordance with ICH best practice the conversions must only be performed by the receiver of the file.
- In addition, it should be noted that
 - The receiver of E2B(R2) message is allowed to return an E2B(R3) acknowledgement
 - The receiver of E2B(R3) message is allowed to return an E2B(R2) acknowledgement
- In normal situations the EudraVigilance system will generate E2B(R2) acknowledgements for E2B(R2) ICSRs and E2B(R3) acknowledgements for E2B(R3) ICSRS.
 - Note: Invalid error XML/ICSRs submitted in either E2B(R2) or E2B(R3) format will receive E2B(R3) acknowledgments



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BFC R2 → R3 – Note for caution UCUM

- The BFC rule tries to map units from R2 lists to UCUM units, the list of UCUM units used is limited
- If it can not find a mapping the curly brackets will be used {..} to transfer the data
- This will cause an issue for converting lab test result units which do not have a published R2 list
- It may cause issue when migrating data in the future as the values might not be found in approved UCUM lists



BFC R3 → R2 – Note for caution case narrative

- When downgrading an ICSR many field lengths have changed leading to truncations. If a truncation occurs information is copied to the case narrative
- Case narrative length in R2 is smaller than R3, it is likely that converted files will have case narratives over 20,000 characters
- This means that a converted file might be rejected by your system's field length restrictions

Conversion impacts on the data in the ICSRs

- Changes can be categorized as follows (see ICH BFC document):
 - Date format
 - Code mapping: E2B(R2) and E2B(R3) provide sets of codes for several fields that may have changed or amended
 - Deletion: some fields of E2B(R2) have been deleted in E2B(R3).
 - Addition: some fields have been added in E2B(R3).
 - Field length: some fields have been extended (i.e. increased field length) in E2B(R3).
 - Masking: E2B(R3) provides another way to mask information, for privacy purposes, or because information is unknown.
 - Structure: E2B(R3) provides another way to structure the information that was available in E2B(R2).



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Summary

In this session we have reviewed the following

- ✓ The background about the conversion tool
- ✓ How to perform a conversion
- ✓ The issues that may be experienced after converting files



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.

Disclaimer

The European Commission is not responsible for the content of questionnaires created using the EUSurvey service - it remains the sole responsibility of the form creator and manager. The use of EUSurvey service does not imply a recommendation or endorsement, by the European Commission, of the views expressed within them.

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Acronyms

UCUM – Unified Code for Units of Measure

ICH - International Conference on Harmonisation

XSLT - eXtensible Stylesheet Language Transformations



Thank you for your attention

Further information

European Medicines Agency

30 Churchill Place • Canary Wharf • London E14 5EU •
United Kingdom

Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660
5555

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