Medical Literature Monitoring by EMA

Changes to the MLM Service

Training module EV-M7

An overview of the changes for stakeholders using the MLM Service that will arise as a result of the changes to EudraVigilance

Content Summary

Introduction

Changes to case format

Changes to accessing the cases

Converting MLM ICSRs to R2

Simplified reporting

What will NOT change

Summary

Version 1.0

Introduction

Changes to case format

Changes to accessing the cases

Converting MLM ICSRs to R2

Simplified reporting

What will NOT change

Summary

Introduction

- This session is intended for Marketing Authorisation Holders who use the EMA's MLM Service

- The session explains what will and will not change as a result of the upgrade to the EudraVigilance system

- To get the best out of this session, you should already be familiar with the MLM service and the data provided

  - Information on the MLM service is available from the MLM webpage, which contains this training video

Introduction: Learning Objectives

- At the end of this module participants will have an understanding of:

  - Changes to the case format

  - Changes to accessing the cases

  - Converting MLM ICSRs to R2

  - What will not change

Introduction

Changes to case format

Changes to accessing the cases

Converting MLM ICSRs to R2

Simplified reporting

What will NOT change

Summary

Changes to case format

- This section explains the changes to the format of the cases that are produced by the MLM Service:

  - What the current format is

  - What the new format will be

  - Why the format will change

  - How you will be affected

Changes to case format

- MLM Service cases are created using EVWEB

- The current (pre-November 2017) version of EVWEB is based on ICH E2B(R2)

- The new (post-November 2017) version of EVWEB will be based on ICH E2B(R3) in order to maintain compliance with the 2010 pharmacovigilance legislation

- Further details on the changes to the case format can be found in training module Implementing ISO ICSR/ICH E2B(R3): Impact on adverse reaction reporting (PhV-M2a)

  - Slides

  - Video

Changes to case format

- The MLM service ICSRs are created in EVWEB & because EVWEB will be based on the E2B(R3) format,

- therefore, all ICSRs created by the MLM Service after the new system goes live will be in ICH E2B(R3) format

- If you download MLM service ICSRs and save them in your own database, then you will need to either upgrade your database to R3 or convert the ICSRs to R2 format before loading them

  - Converting ICSRs from R3 to R2 is covered later in this presentation

Changes to case format – Take Away

- In this section we have covered:

  - What the current format is

  - What the new format will be

  - Why the format will change

  - How you will be affected

- Introduction
- Changes to case format
- **Changes to accessing the cases**
- Converting MLM ICSRs to R2
- Simplified reporting
- What will NOT change
- Summary

Changes to accessing the cases

- This section explains the changes to accessing the cases that are produced by the MLM Service:

  - What the current methods of accessing the cases are

  - What the new methods of accessing the cases will be

  - How the changes will affect you

Changes to accessing the cases

- The current methods of accessing MLM service cases are as follows:

  - ICSR Export Manager

  - EVWEB MLM export section

Changes to accessing the cases – current method

- ICSR Export Manager

Changes to accessing the cases – current method

- ICSR Export Manager

  - Optimised for downloading batches of cases

    - Cases can be immediately loaded into PV databases

  - Filters can be saved for repeated use

  - Limited number of searchable fields

    - Not including searching by case number

  - Cases available the day after transmission

Changes to accessing the cases – current method

- EVWEB MLM export section

Changes to accessing the cases – current method

- EVWEB MLM export section

  - Optimised for single case downloading

  - Cases immediately available

  - Large variety of searchable fields

    - Filters cannot be saved & need entering each time

  - Messages require amending before loading into PV database

Changes to accessing the cases

- With the change to the system, all MLM Service cases will be downloaded from EVWEB

- Either via

  - Single case downloading

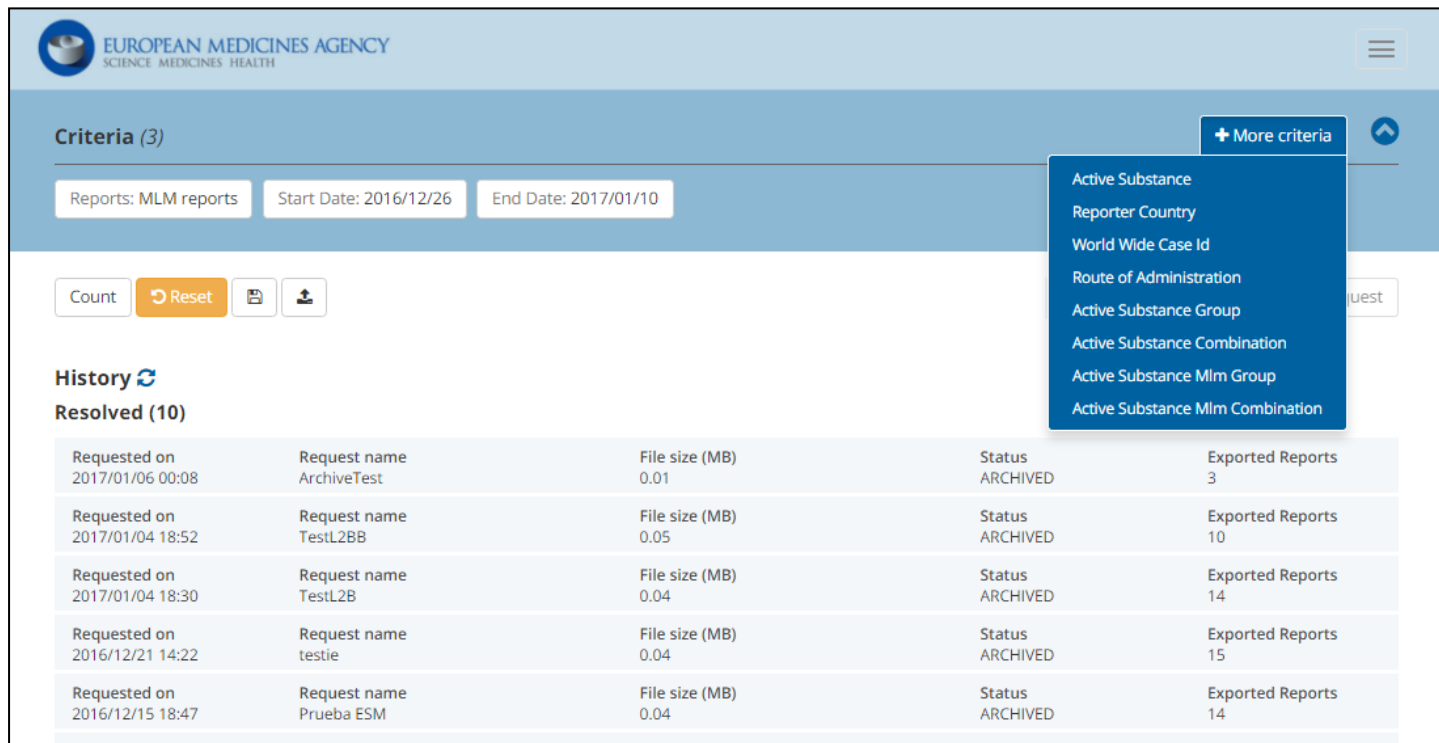 - General bulk downloading

  - MLM Bulk downloading

Changes to accessing the cases – future method

- EVWEB single case downloading

Changes to accessing the cases – future method

- EVWEB bulk downloading

Changes to accessing the cases – future method

- All the best features of each current method have been combined

  - All cases available immediately after transmission

  - Optimised for downloading batches of cases

  - Filters can be saved for repeated use

    - If you already have filters saved for the current ICSR export manager you will need to recreate these in the new system

  - Single case searching via case number available

  - Messages can be immediately loaded into a PV database without amendment

Changes to accessing the cases – future method

- To see the full changes to the downloading functionality, you will need to see session EV-M3c: EV Reporting process for users: Export functions in EVWEB (EV-M3c)

  - Slides

  - Video

Changes to accessing the cases – Take Away

- **In this section we have covered:**

  - What the current methods of accessing the cases are

  - What the new methods of accessing the cases will be

  - How the changes will affect you

Introduction

Changes to case format

Changes to accessing the cases

Converting MLM ICSRs to R2

Simplified reporting

What will NOT change

Summary
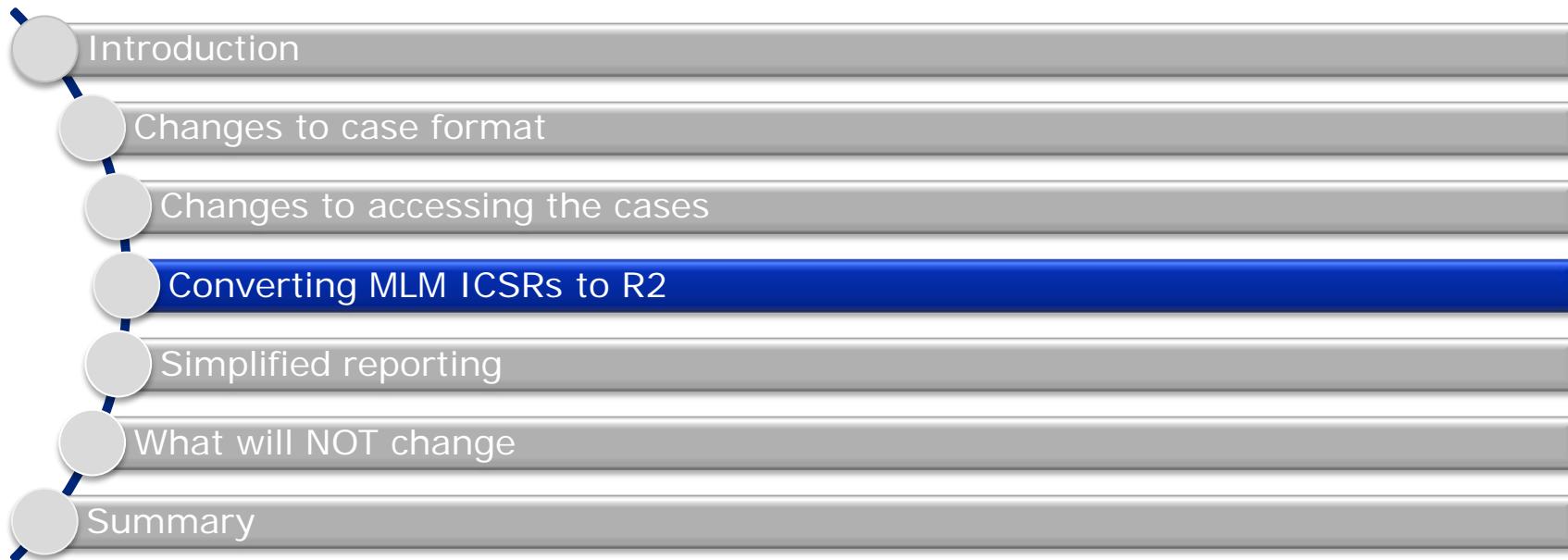
Converting MLM ICSRs to R2

- This section covers conversion of ICSRs from R3 format to R2:

  - Why you may need to perform this conversion

  - How to perform this conversion

  - More information on converting ICSR format

Converting MLM ICSRs to R2

- Cases created in R3 format cannot necessarily be loaded directly into an R2-specific database

- Many of the fields do not directly translate from one format to the other

  - In R2 seriousness and country of occurrence are at case level, whereas in R3 they are at reaction level

- This means that importing R3 files into an R2 database would both lose information from the R3 file & not have mandatory fields required for R2 cases

- Therefore, if you have an R2-based database, you will need to convert cases from R3 format to R2 in order to be able to load them into the database

Converting MLM ICSRs to R2

- To perform this conversion, you will need a backwards-forwards conversion tool that will ensure that the correct changes are made reliably and consistently

- You can either build your own tool or you can use the tool created by the EMA

- Further information on the principles of conversion & the EMA's backwards-forwards conversion tool is available from training module "Implementing ISO ICSR/ICH E2B(R3): Backwards and forwards conversion" (PhV-M2b)

  - Slides

  - Video

Converting MLM ICSRs to R2 – Take Away

- **In this section we have covered:**

  - Why you may need to perform this conversion

  - How to perform this conversion

  - More information on converting ICSR format

Introduction

Changes to case format

Changes to accessing the cases

Converting MLM ICSRs to R2

Simplified reporting

What will NOT change

Summary
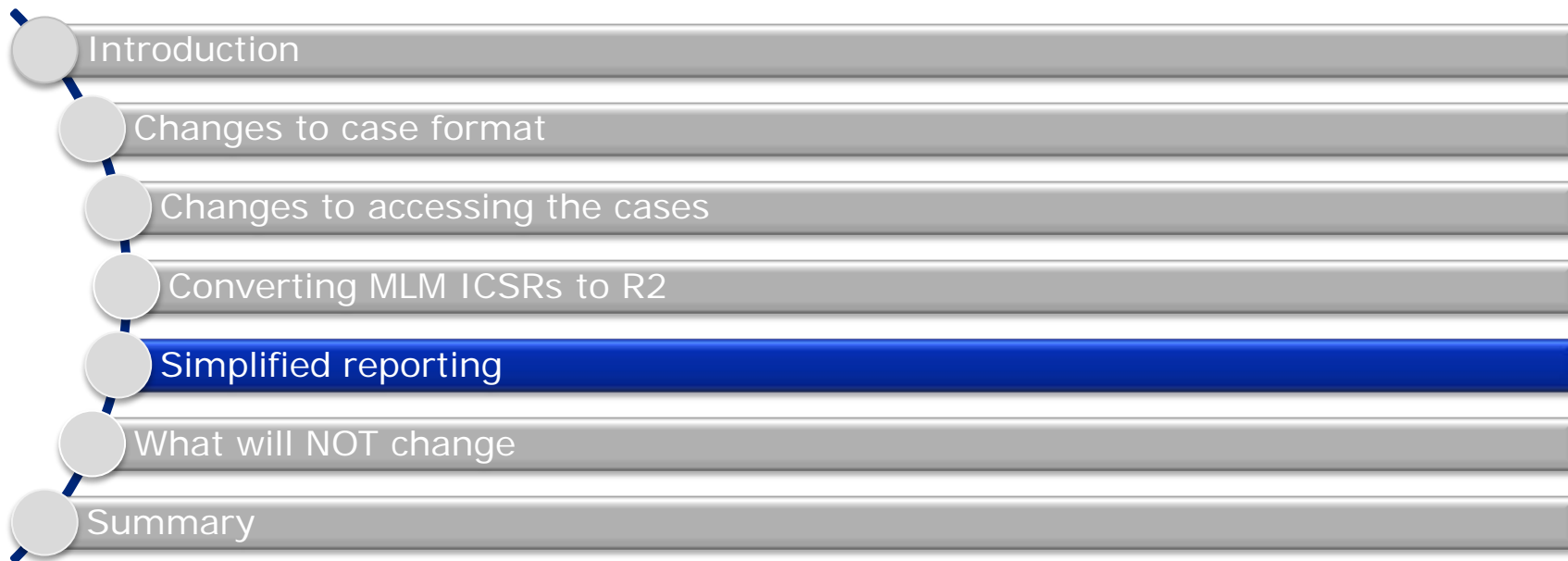
Simplified reporting

- This section explains how the move to simplified reporting will affect your literature reporting obligations and use of the cases produced by the MLM Service:

  - What are the current obligations

  - What the new obligations will be

Simplified reporting – Current obligations

- If an MAH is continuing to perform their own literature monitoring, they should not transmit to EudraVigilance cases identified from the literature if they are related to substances that the Agency is monitoring

- Concerned MAHs should not re-submit the ICSRs resulting from the medical literature monitoring service to EudraVigilance

- Unless otherwise specified by national legislation and guidance, concerned marketing authorisation holders should not submit the ICSRs resulting from the medical literature monitoring service to the concerned NCAs in the EEA

  - Until the move to simplified reporting is made, German legislation requires MAHs to continue to transmit all literature cases occurring in Germany to BfArM/PEI
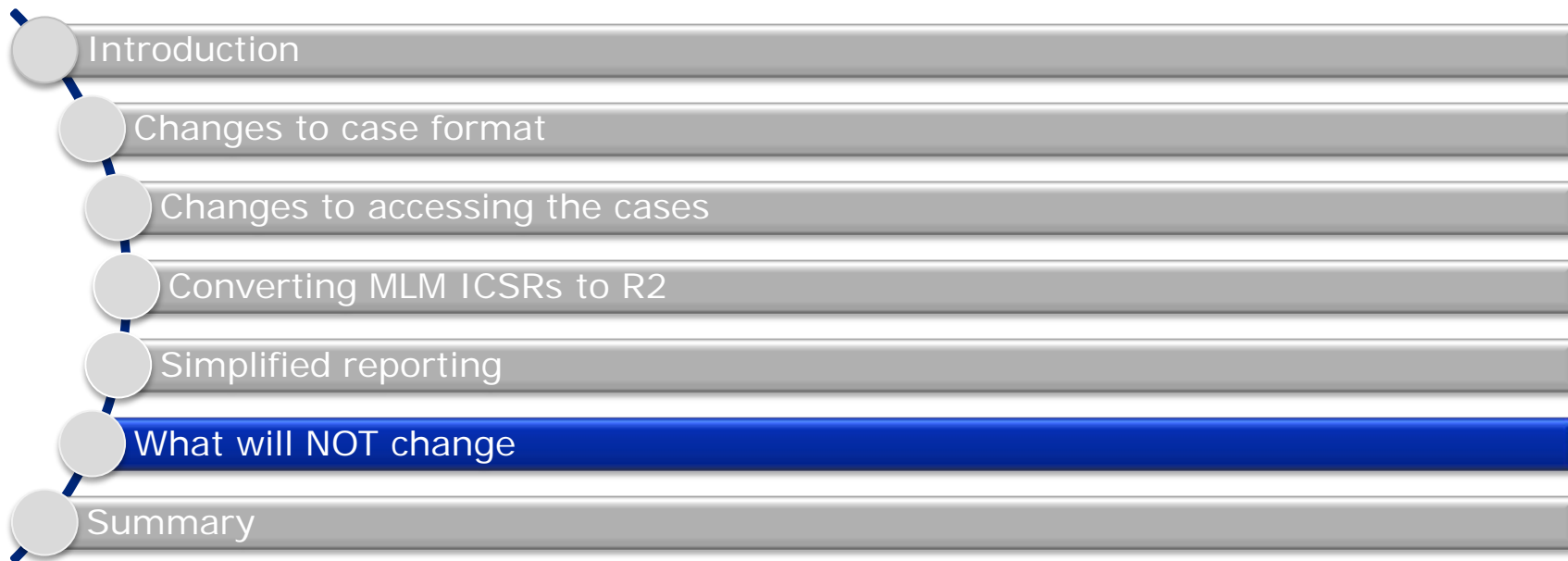
Simplified reporting – new obligations

- If an MAH is continuing to perform their own literature monitoring, they should not transmit to EudraVigilance cases identified from the literature if they are related to substances that the Agency is monitoring
  - Nor should such cases be transmitted to the concerned NCAs in the EEA
- Concerned MAHs should not re-submit the ICSRs resulting from the medical literature monitoring service to EudraVigilance
- Concerned MAHs should not re-submit the ICSRs resulting from the medical literature monitoring service to the concerned NCAs in the EEA

Simplified reporting – Take Away

- **In this section we have covered:**

  - How your literature reporting obligations & use of the cases created by the MLM Service will change with the move to simplified reporting

    - MAHs will no longer be required to forward MLM service cases to any EEA NCA

- Introduction
- Changes to case format
- Changes to accessing the cases
- Converting MLM ICSRs to R2
- Simplified reporting
- **What will NOT change**
- Summary

What will NOT change

- This section explains what will NOT change regarding the MLM service as a result of the changes to EudraVigilance
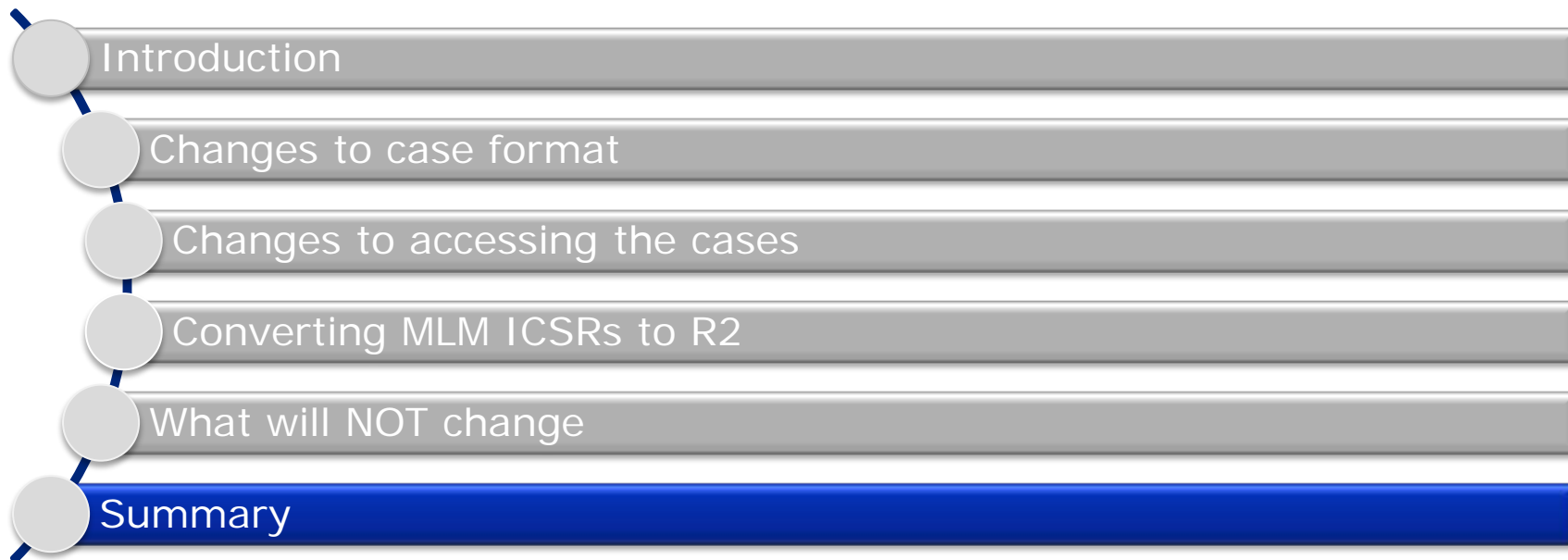
What will NOT change

- Whilst creating & accessing the ICSRs created by the MLM service will change, none of the other business processes will change as a result of the changes to EudraVigilance and the move to simplified reporting:

  - The list of substances will not change

  - The journals being monitored will not change

  - The screening, review and assessment process will not change

  - The follow-up process will not change

  - The duplicate management process will not change

  - The quality management & stakeholder interaction processes will not change

What will NOT change – Take Away

- **In this section we have covered the business processes that will not change:**

  - The substances being monitored

  - Journals being monitored

  - Screening, review & assessment processes

  - Follow-up processes

  - Duplicate management

  - Quality management & stakeholder interaction

Introduction

Changes to case format

Changes to accessing the cases

Converting MLM ICSRs to R2

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Summary

Summary

All cases will be created & transmitted in E2B(R3) format

Cases will be accessed via EVWEB

- Either individually or via bulk export

Cases will be available the same day

If you do not yet have an R3-compliant database, you will need to convert the cases to R2

MAHs will no longer have to submit cases to any EEA NCAs

No other business processes will change as a result of the changes to EV

Further guidance

- Training module PhV M2b – Backwards-Forwards Conversion (Video¦Slides)

- Training module EV-M3c – Export functions in EVWEB (Video¦Slides)

- MLM webpage

  - Detailed guide

  - Inclusion-exclusion criteria

  - Questions & Answers

  - Duplicate management process

  - Substances & herbal substance groups

  - Description of the journal/reference databases used

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.

Acronyms

- EV: EudraVigilance

- EVWEB: EudraVigilance Web application

- ICH: The **I**nternational **C**onference on **H**armonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

- ICSR: Individual Case Safety Report

- MLM: Medical Literature Monitoring

- NCA: National Competent Authority

Thank you for your attention

Further information

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