

SCOPE Joint Action Stakeholder Event



Duplicate detection

Topic 1: Audit of national reporting
systems

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Learning objectives

- To understand the importance of duplicate detection and recognise key points of the process
- To provide examples of good practice related to duplicate detection process

SCOPE deliverables



- Document: *Good practice on duplicate detection (with case studies)*
- E-learning module: *Duplicate detection*

Guidance document on duplicate detection



- Good practice on duplicate detection (with case studies)
 - Describes the importance and key steps of the process
 - Identification of duplicate cases
 - Conformation of duplicates
 - Management of duplicates
 - Provides summary of applicable EU guidelines related to duplicate detection
 - Provides recommendations for good practice
 - Can be used to:
 - Raise awareness
 - Improve MSs' internal procedures
 - Education

E-learning module: Duplicate detection



- Provides an overview of the key steps of the duplicate detection process
 - Identification of duplicate cases
 - Conformation of duplicates
 - Management of duplicates

- Provides summary of applicable EU guidelines related to duplicate detection

- Provides examples of good practice with duplicate detection
 - Case study 1: MHRA, UK
 - Case study 2: Lareb, The Netherlands
 - Case study 3: SUKL, The Czech Republic
 - Case study 4: Uppsala Monitoring Centre (UMC)

- Can be used to:
 - Educate new assessors
 - Raise awareness
 - Improve MSs' internal procedures

Identification of duplicates in the ADR database



- Depending of the database set-up and number of ADR reports in the database

individual case review of all reports

or

computerised duplicate detection algorithm

Identification of duplicates in the ADR database



Duplicate detection algorithms

- Generally not published
- Usually rely on rules such as: if two reports match on the certain fields, then they are suspected duplicates.

Management of duplicates



- Tool used for merging the duplicate reports: UK example

The screenshot displays the SCOPE web application interface. At the top, the browser address bar shows "http://prdasm10.sentinel.m...". The application header includes "Case: ADR 23677972-001 Status: Pending" and navigation links for "Reports", "Documentum", "Case Documents", "Help", and "Close Window". Below the header, there are buttons for "Check Out", "Edit", "Check In", "Cancel Checkout", "View Index", "Remove Link", "Link Docs", "Import Docs", and "New Doc". The "Associated Documents" section shows a folder path "/Pharmacovigilance/ADR/ADR 23677972/Records" and a list of files: "169906.pdf" and "169906.xml".

The "Structured Data - Browse Mode" section is active, showing a table of duplicate ADRs. The table has columns for "ADR Case Folder" and "Status". Below this, there is a section for "Possible Duplicate ADRs" with columns for "ADR Case Folder", "Status", "Type", and "Suggested Master".

| ADR Case Folder | Status |
|-----------------|---------|
| ADR 23678005 | Pending |

| ADR Case Folder | Status | Type | Suggested Master |
|-----------------|---------|--------|------------------|
| ADR 23678005 | Pending | Manual | No |

A "Return to Top" button is located at the bottom of the "Possible Duplicate ADRs" section. The interface also includes a left-hand navigation menu with options like "Summary", "Workflow", "Lifecycle", "Related Cases", "Comments", "Case Attributes", "ADR Details", "ADR Admin", "Duplicates", "RFI", and "Communication". A video player control bar is visible at the bottom of the screenshot, indicating the video is at 00:03.

Take home messages

- Duplication of cases is important data quality problem and can pose significant problem for analysing signals arising from pharmacovigilance databases by misleading clinical assessment or distorting statistical screening, both artificially inflating and masking signals of disproportionate reporting
- There should be a swift and robust duplicate detection procedures at each organisation
- There are simple solutions applicable for all systems – just need to be aware of the issue

Questions?

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