



## Medical Literature Monitoring Service Contractor Work Instruction (MLM WIN-06)

Title: WIN on MLM Duplicate Management Process		
Applies to: Staff members in EMA and its contractors		
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### 1. Changes since last revision

WIN formatted as per the agency's current template.

LMTT replaced with LiEMA throughout the document.

### 2. Records

Electronic copy of this WIN will be stored in Document Management System (DMS).

No paper copies are archived.

### 3. Scope

The aim of this WIN is to outline the process for managing duplicate ICSRs in accordance with the published 'Process description for managing duplicates'.

### 4. Definitions

Term	Definition
EMA	European Medicines Agency
EudraVigilance	The European data-processing network and management system, which has been developed according to internationally agreed standards and which allows the EMEA to manage the electronic data exchange of Individual Case



Term	Definition
	Safety Reports (ICSRs) and to support the EU pharmacovigilance activities at Community level.
EV	EudraVigilance
EVDAS	EudraVigilance Data Analysis System
EVWEB	EVWEB is a tool that provides user's direct, and secure access to EudraVigilance over the internet.
Individual Case Safety Report (ICSR)	An ICSR is an electronic report, which provides the most complete information related to an individual case at a certain point of time. An individual case is the information provided by a primary source to describe suspected adverse reaction(s) related to the administration of one or more medicinal products to an individual Patient at a particular point of time.
LiEMA	LiEMA is a reference management system that provides literature safety surveillance and reference management capabilities.
MLM	Medical Literature Monitoring
XML	eXtensible Markup Language

## 5. Instructions

### General Principles

The management of duplicate ICSRs is managed in accordance with the "[Process description for managing duplicates in the context of the medical literature monitoring \(MLM\) service](#)", which can be found on the EMA website; however not all steps are directly applicable as that document describes the work of the EMA duplicate detection team and the MLM team giving a global perspective of the process.

### **5.1. MLM individual case identified as a duplicate of another MLM individual case (originating from a different article but referring to the same individual case)**

Step	Action
1.	Receive notification via e-mail from the EMA that potential duplicates have been identified from the Medical Literature Monitoring (MLM) service.
2.	Open LiEMA & EVWEB and retrieve information for both the articles and Individual Case Safety Reports (ICSRs).
3.	Review and cross reference ICSR information against the source information and determine the existence of duplicate cases.
4.	If duplicate cases are confirmed, update case A in EVWEB with any missing information from case B (at a minimum enter case number and literature reference).

Step	Action
5.	Nullify case B in EVWEB and enter nullification information in LiEMA.
6.	Process the case in accordance with WIN MLM-03 – Processing and submitting ICSRs in EVWEB.
7.	Submit both the updated case A and nullified case B to EudraVigilance.

### **5.2. Duplicate of non-MLM case found before data entry**

Step	Action
1.	The designated MLM team member appends daily EVDAS reported literature reference data received from EMA to the cumulative spreadsheet in the DMS and then runs the search on the cumulative spreadsheet to check the duplicates.
2.	If a duplicate ICSR is identified, locate the MAH XML and safety ID in EVHUMANWT (EudraVigilance Web Trader).
3.	Export the MAH XML to computer system from EVHUMANWT (EudraVigilance Web Trader).
4.	Import the MAH case XML to EVWEB (MLMSERVICE) and update the case as per the available information. Note: Once the MAH case XML has been imported, the XML of the MAH case should be deleted from the computer system. This is to comply with EMA and EUDPR guidelines.
5.	Change the Safety Report ID to MLMSERVICE ID from LiEMA (DO NOT change the Case Number).
6.	Change first received date and last received date to day zero for MLM service (date of search or retrieval of full text article or date of follow-up received from the author or translation received date in case of non-European language)
7.	Update the case with any pertinent information, ensuring redaction of any personal data.
8.	Process the case in accordance with WIN MLM-03 – Processing and submitting ICSRs in EVWEB.
9.	Submit the case to EudraVigilance.

### **5.3. Duplicate of non-MLM case found after submission**

Step	Action
1.	Receive notification via e-mail from the EMA that a duplicate case has been identified.
2.	EMA send Master case XML through EVWEB and notify contractor that it has been sent.
3.	Receive case back as an XML from EMA via EVHUMANWT in EVWEB.
4.	Open MLM case, select follow-up and update the case with the new information from Master case.

Step	Action
5.	Copy Master case number and other non-MLM case numbers from Other Case Identifiers section of Master case into Other Case Identifiers section of MLM case.
6.	Check for differences in the case and update if necessary, redacting any personal information.
7.	Process the case in accordance with WIN MLM-03 – Processing and submitting ICSRs in EVWEB.
8.	Submit the case to EudraVigilance.

## 6. Reference documents

Not Applicable

## 7. Annexes

Not Applicable