

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

MLM Duplicate Management Process

Preamble

This WIN governs the activities of contractors working for the European Medicines Agency providing the Medical Literature Monitoring service. The WIN was created by the contractors and approved by the Agency.

1. Changes since last revision

New WIN.

2. Records

Not applicable.

3. Definitions

Term	Definition
DMTT	Data Management Tracking Tool
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 Safety Reports (ICSRs) and to support the EU pharmacovigilance activities at Community level.
EV	EudraVigilance
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.

Term	Definition
MLM	Medical Literature Monitoring
NCA	National Competent Authority

4. 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](#)" (Doc Ref. EMA/262834/2015); however not all steps are directly applicable because that document describes the work of the duplicate detection team, of the EMA & of the MLM team, giving a global perspective of the process. This WIN details the MLM contractors' steps.

4.1. 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 from the Agency in MLM@Kinapse.com that potential duplicates have been identified from the MLM service.
2	Open DMTT and retrieve information on both articles and ICSRs.
3	Review and cross reference ICSR information against 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).
5	Nullify Case B in EVWEB and enter nullification information in the DMTT
6	Process with standard QA processes in accordance with WINMLM003 – Processing and Reporting of ICSRs
7	Submit both updated case A and nullified case B in EVWEB to EudraVigilance and National Competent Authorities respectively.

4.2. Duplicate of non-MLM case found before data entry

Step	Action
1	Cross check article against EMA MLM literature article spreadsheet
2	Request duplicate case from EMA MLM co-ordinators
3	Receive case back as an XML from EMA via EVHUMANWT in EVWEB
4	Access EVWEB, WEB Trader and locate the safety ID
5	Remote import the case, and create follow-up
6	Change the Safety Report ID to MLMSERVICE ID From LMTT (DO NOT change the Case

	Number)
7	Change "Date" to today's date
8	Change receive and receipt date to day zero for MLM service (date of search or retrieval of full text article)
9	Update the case with any pertinent information, ensuring to redact any personal data.
10	Process with standard QA processes in accordance with WINMLM003 – Processing and Reporting of ICSRs
11	Submit case to EudraVigilance and NCAs

4.3. Duplicate of non-MLM case found after submission

Step	Action
1	Receive notification from the Agency that a duplicate case has been identified
2	EMA Send Master case XML through EV WEB and notify Contractor that it's been sent
3	Receive case back as an XML from EMA via EVHUMANWT in EVWEB
4	Open MLM case, hit follow-up and update with new information from master case
5	Copy Master Case number to Report Duplicate, and copy other non-MLM case numbers from Master Case Report Duplicates section into report duplicate section of MLM case
6	Check for differences in the case and update if necessary, redacting any personal information
7	Process with standard QA processes in accordance with WINMLM003 – Processing and Reporting of ICSRs
8	Enter duplicate reference number in DMTT
9	Submit Case via EVWEB