Medical Literature Monitoring Service Contractor Standard Operating Procedure (MLM SOP-01)

Medical Literature Monitoring Screening and Reviewing Process

Preamble

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

1. Purpose

To describe the process by which Medical Literature is screened and reviewed. The Purpose of this SOP is to ensure these activities are performed in an efficient and consistent way and by doing so support pharmacovigilance at the EU level.

2. Scope

This SOP applies to the Agency's contractor providing the MLM Service.

3. Responsibilities

It is the responsibility of Contractor to ensure that this procedure is adhered to within the MLM Service team. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of **9. Procedure**.

4. Changes since last revision

New SOP.

5. Documents needed for this SOP

- MLM Service Contractor MLM SOP-02 – Processing of Medical Literature Monitoring ICSRs
- MLM Service Contractor MLM WIN-01 – Screening Medical Literature
- MLM Service Contractor MLM WIN-02 – Reviewing Medical Literature
- MLM Service Contractor MLM WIN-03 – Processing and submitting ICSRs in EVWEB
- MLM Service Contractor MLM WIN-04 – Performing Follow-up for MLM ICSRs

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- MLM Service Contractor MLM WIN-05 – MLM Service Desk Management
- MLM Service Contractor MLM WIN-06 – MLM Duplicate Management Process
- MLM Service Contractor MLM WIN-07 – MLM Quality Assurance
- Inclusion / Exclusion criteria for processing individual case safety reports
- Medical Literature Monitoring: substance and herbal substance groups
- Medical Literature Monitoring: Description of journals / reference databases used

6. Related documents

Detailed guide regarding the monitoring of medical literature and the entry of relevant information into EudraVigilance database.

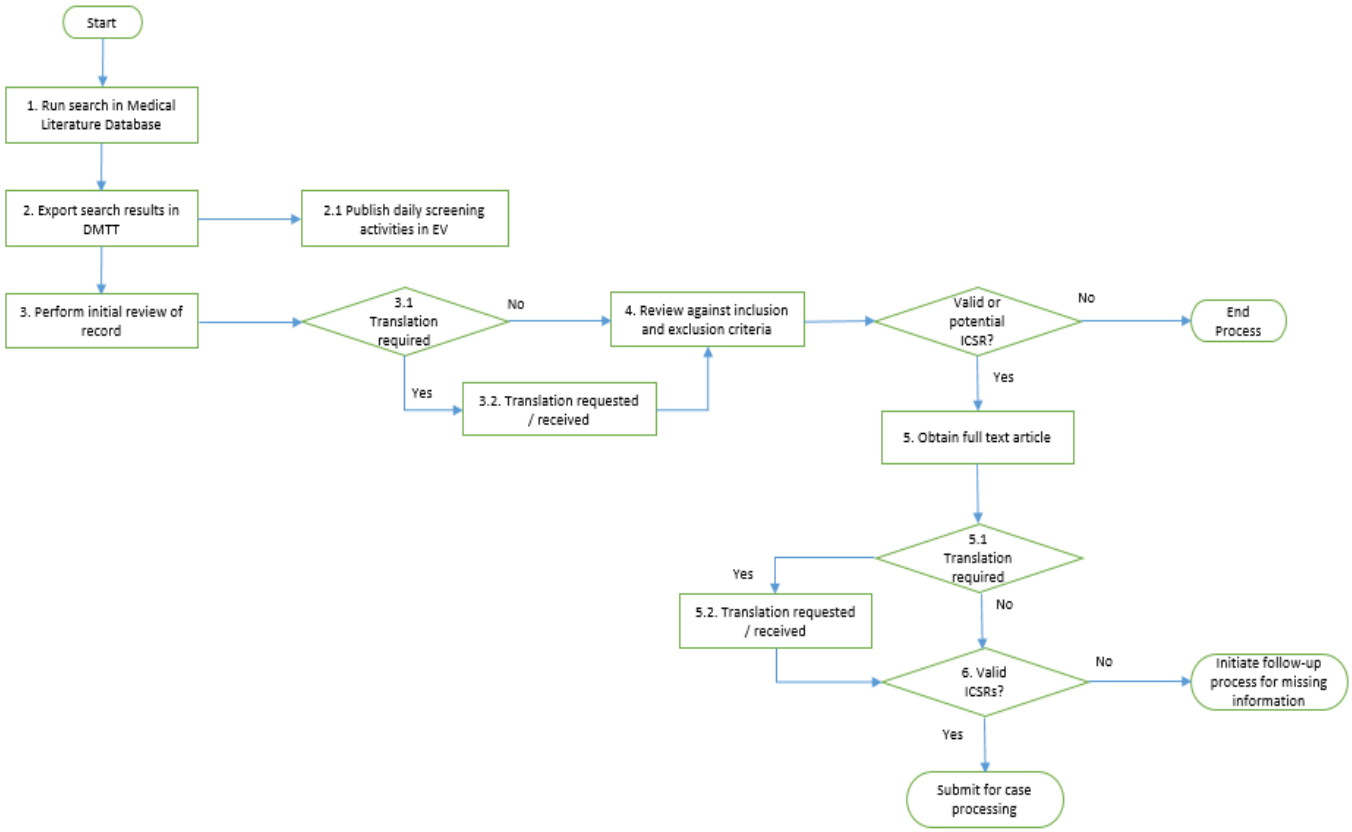
Process description for managing duplicates in the context of the medical literature monitoring service.

7. Definitions

Term	Definition
Calendar Day	Monday – Friday, including Bank Holidays
DOI	Document Object Identifier
DMTT	Data Management Tracking Tool used by the contractor and the EMA to record & monitor work on EV data, including all Medical Literature Monitoring work
EBSCO	Broad range of full text and bibliographic databases designed for research
EEA	European Economic Area
EMA	European Medicines Agency
Embase	Excerpta Medica Database, a biomedical database and pharmacological database of public literature
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
FTA	Full text article
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
URL	Uniform Resource Locator

8. Process map(s)/ flow chart(s)



9. Procedure

Step	Action	Responsibility
1.	**Run Search in Medical Literature Database** Every week day, a member the MLM literature team performs the daily screen of ICSRs in the Medical Literature Database for each substance group in scope in Embase using the current approved and published search string. If the first week day of the month, perform the monthly screen in EBSCO for each substance group in scope. Both searches will be performed in accordance with MLM WIN-01	MLM Analyst
2.	**Export Search Results In DMTT** All records retrieved from the daily search are logged in the DMTT,	MLM Analyst

Step	Action	Responsibility
	with the following parameters. • Date and Time of search • Search Date Range • Substance Group • Library (Literature Database searched) • Journal • Article Title • Primary Source Country • Authors • Primary Author • Issue / Vol No. • Page No. • Date of Publication • Document Object Identifier (DOI) • URL Once literature record is created in DMTT, submit to next workflow step for review. If the article is identified as a duplicate in logging the article in DMTT, mark as a duplicate and enter duplicate DMTT ID and end process. If no, literature is retrieved in the substance group search, track that no literature was returned from the search for screening. End of process.	
2.1	**Publish Daily Report on Literature Screening** Once all literature has been screened and logged in the DMTT, generate outcome of daily screening report. Review to ensure all data fields are completed and upload on the EudraVigilance restricted area website using MLM WIN-05.	MLM Senior Analyst
3.	**Perform Initial Review of record** Review title, abstract, citation and key words to determine the existence of a possible adverse reaction. Is abstract text in English? If yes, go to step 4. If no, go to step 3.1	MLM Senior Analyst

Step	Action	Responsibility
3.1	**Abstract text is not in English** If abstract text is not in English, send translaton request and log request in DMTT.	MLM Analyst
3.2	**Translation received** Log information in DMTT and return to step 3.	MLM Analyst
4.	**Perform Review of record against inclusion and exclusion criteria.** Review against the inclusion and exclusion criteria (See EMA/119265/2015), and MLM WIN-01. • Report Type • Identifiable Reporter • Identifiable Patient • One or more suspected subtance / medicinal product • One or more suspected adverse reaction(s) • Causality • Seriousness What is the outcome of the review? 1) Clearly meets exclusion criteria. Go to step (log exclusion critera in DMTT, end process) 2) Potential ICSRs, log all missing information from inclusion / exclusion criteria in comments box and go to step 5. 3) Valid ICSRs that meet the inclusion criteria, tick valid ICSR and select appropriate inclusion criteria. Document number of ICSRs if known. Go to step 5.	MLM Senior Analyst
5.	**Obtain full text article** Obtain or request full text article and enter dates in DMTT. When retrieved, upload article into DMTT. Submit record in DMTT for case processing.	MLM Analyst
5.1	**Full text article is not in English** Request translaton and log request in DMTT.	MLM Analyst
5.2	**Translation received** Request translaton and log request in DMTT.	MLM Analyst
6.	**Review full text article** Perform full triage of full text article to determine number of ICSRs.	MLM Senior Analyst

Step	Action	Responsibility
	Update DMTT with number of ICSRs if necessary, and submit for case processing. End of Process. If potential ICSR only, initiate follow-up process in MLM WIN-03, log in DMTT. End of process.	

10. Records

All records of literature reviews and ICSRs are stored within the DMTT

All other records are stored on the contractors local secure SharePoint Folder.

The ICSR screening output spreadsheet is stored in the secure area of EudraVigilance.