Medical Literature Monitoring Service Contractor Standard Operating Procedure (MLM SOP-02)

Processing of Medical Literature Monitoring ICSRs

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 Monitoring ICSRs are processed. 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.

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 **8. Procedure**.

4. Changes since last revision

New SOP.

5. Documents needed for this SOP

- MLM Service Contractor MLM SOP-01 – Medical Literature Monitoring Screening and Reviewing Process
- 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

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- MLM Service Contractor MLM WIN-04 – Performing Follow-up for MLM ICSRs
- 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

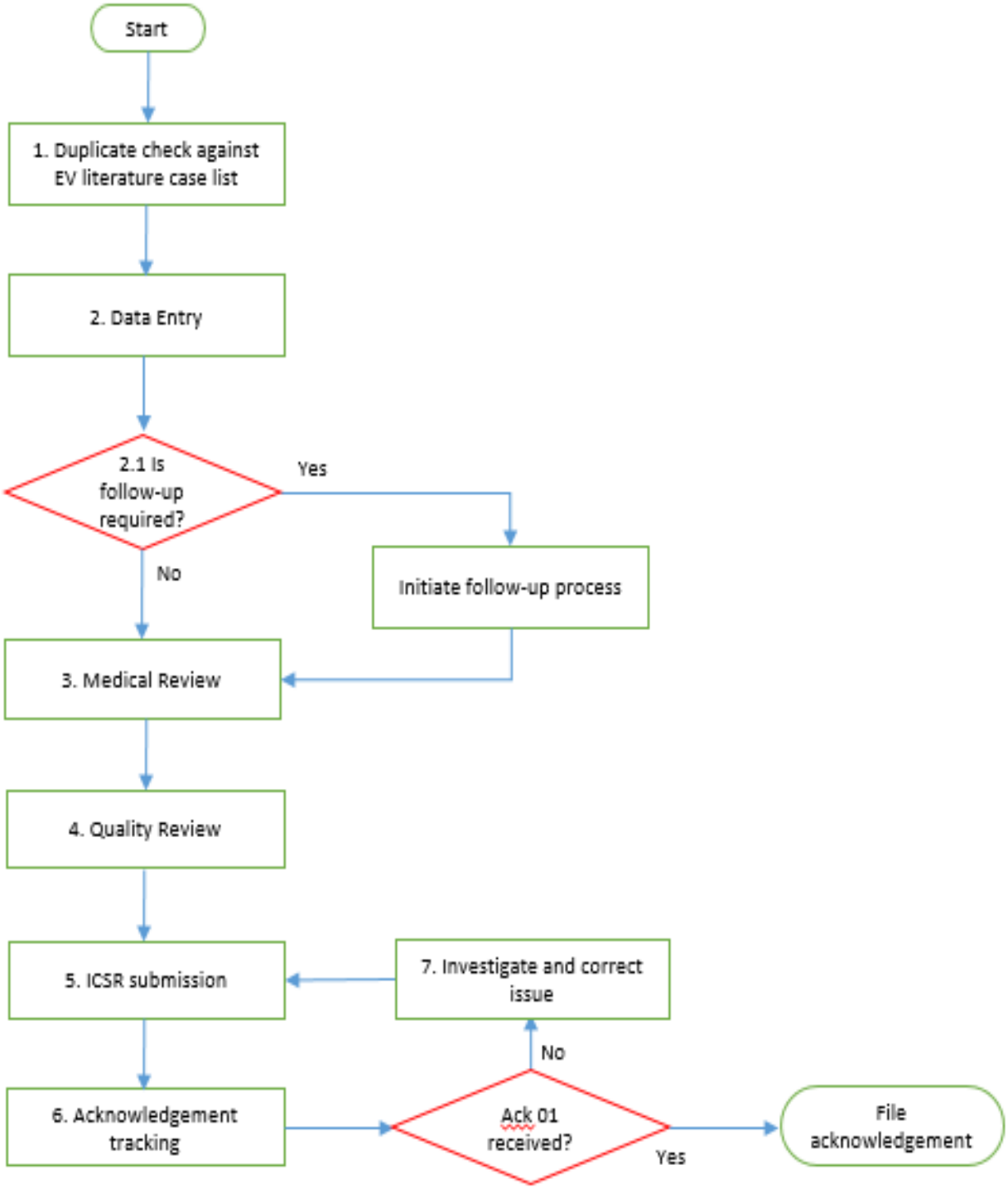
Detailed guide regarding the monitoring of medical literature and the entry of relevant information into EudraVigilance database.

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
DMTT	Literature Monitoring Tracking Tool – a subset of the Data Management Tracking Tool used by the contractor and the EMA to record & monitor work on EV data
EEA	European Economic Area
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.
MedDRA	Medical Dictionary for Regulatory Affairs
MLM	Medical Literature Monitoring
NCA	National Competent Authority

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



9. Procedure

Step	Action	Responsibility
1	**Duplicate Check** Access DMTT case processing and select record. Perform search in daily Eudravigilance literature spreadsheet for ICSR parameters to determine if ICSR is a duplicate. Is the ICSR a duplicate? If yes, process in entry of duplicate cases MLM WIN-06 If no, continue to step 2	MLM Senior Analyst
2	**Data Entry** Access DMTT case processing, and find record. In EVWEB, create an ICSR in accordance with the EVWEB User Manual and MLM WIN-03. Perform data entry against source information, and enter seriousness in DMTT.	MLM Analyst
2.1	**Is follow-up required?** If no, go to step 3. If yes, follow (MLM WIN-04) determine whether the follow-up requires special circumstances follow-up (against insert document title) and create standardised folow-up message in follow-up tracked to reflect important missing information.	MLM Senior Analyst
3	**Medical Review** Performs full medical review of ICSR against source information. Access follow-up tracker and insert pertinent questions for follow-up to be sent to primary author. Once medical review is complete, mark medical review as complete in DMTT.	MLM Physician
4	**Quality Review** Performs full quality review of ICSR against source information, ensuring all fields in EVWEB, including appropriate anonymisation of private data received in follow-up, MedDRA coding and case narrative are completed. Once completed, save the XML (by naming the file with the WWID) and update DMTT with completion of Quality Review.	MLM Senior Analyst
5	**ICSR Submission** Validate and submit ICSR in EVWEB, update DMTT with submission information, including date submitted.	MLM Analyst

Step	Action	Responsibility
6	**Acknowledgement tracking** Review EVWEB to determine if Ack 01 has been received for case transmission to EV and NCAs as appropriate. If Ack 01 has been received, update DMTT with information, end of process. If Ack 02 has been received, continue to step 7	MLM Analyst
7	**Negative acknowledgement investigation** Investigate reason for 02 acknowledgment from EVWEB or NCA. Make any necessary case corrections and submit case again in accordance with step 5.	MLM Senior Analyst

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.