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

| Title: Medical Literature Monitoring Screening and Reviewing Process | | |
|---|---|---|
| Applies to: Staff members in EMA and its contractors | | |
| Document no.: SOP-02 | Effective date: 01-April 2024 | Supersedes: vs_4.0 |
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## 1. Purpose

The purpose of this SOP is to describe the process for processing of Medical Literature Monitoring ICSRs and to ensure that the activities are performed in an efficient and consistent way and thus, by doing so support pharmacovigilance at the EU level.

## 2. Scope

This SOP is applicable to Agency's contractor.

## 3. Responsibilities

It is the responsibility of the contractor to ensure that the procedure outlined is adhered within the MLM Service team. The responsibilities for the execution of a specific part of the procedures laid out in this SOP are identified in the right-hand column of 8. Procedure.

## 4. Changes since last revision

SOP formatted as per the agency's current template.

LMTT replaced with LiEMA throughout the document.

'Quality review' has been replaced with 'Quality Control' throughout the document.

Section 5: WIN-01 name updated.

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# 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 – Searching, Screening & Importing 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*

• *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*

• *Monitoring of medical literature and the entry of relevant information into the EudraVigilance database by the European Medicines Agency (Inclusion and exclusion criteria for processing of Individual Case Safety Reports). Published on the EMA's MLM web page https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/medical-literature-monitoring*

• *Medical Literature Monitoring: substance and herbal substance groups. Published on the EMA's MLM web page https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/medical-literature-monitoring*

•*Medical Literature Monitoring: Description of journals / reference databases used. Published on the EMA's MLM web page https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/medical-literature-monitoring*

•*Process description for managing duplicates in the context of the Medical Literature Monitoring (MLM) service. Published on the EMA's MLM web page https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/medical-literature-monitoring*

# 6. Related documents

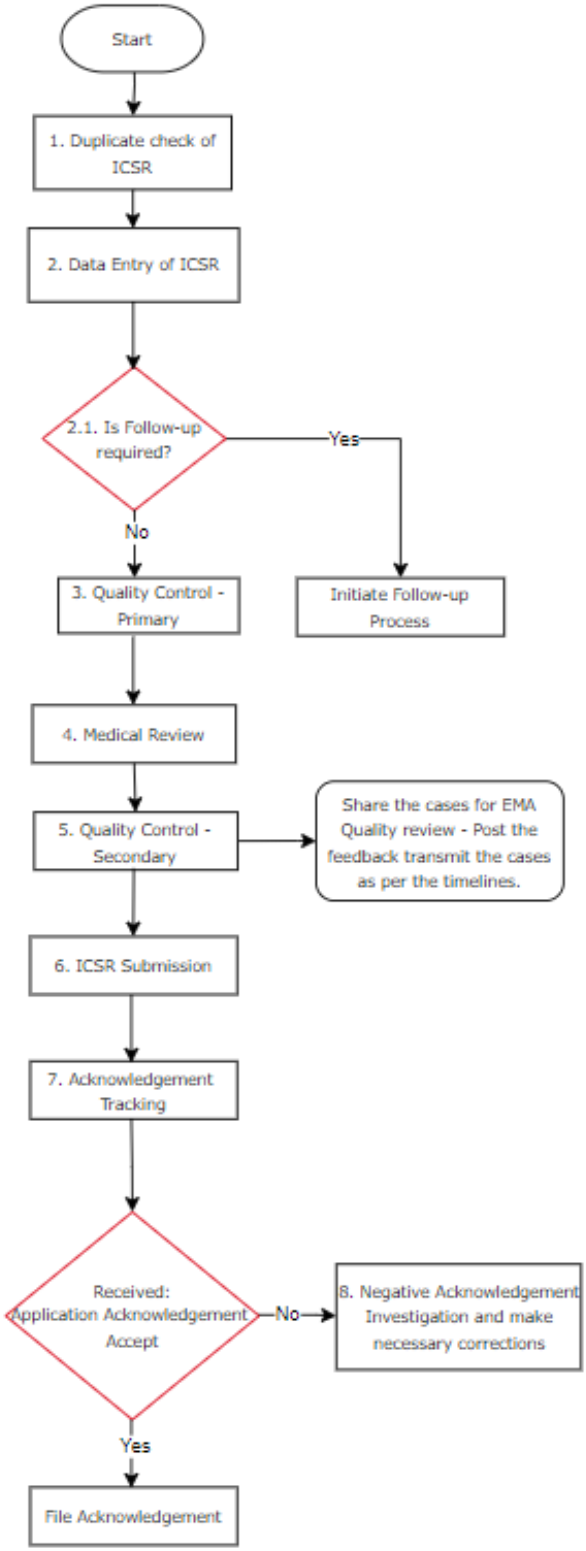
Not Applicable

# 7. Definitions

| Term | Definition |
|---|---|
| Business day | Monday – Friday, including Bank Holidays |
| 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 |

| Term | Definition |
|---|---|
| EVWEB | EVWEB is a tool which provides users 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. |
| MedDRA | Medical Dictionary for Regulatory Affairs |
| MLM | Medical Literature Monitoring |

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



# 9. Procedures

| Step | Action – initiation and waiver | Responsibility |
|---|---|---|
| 1. | **Duplicate check of ICSR**<br>Access LiEMA case processing and select record.<br><br>Perform a daily search in EudraVigilance literature spreadsheet for ICSR parameters to determine if Individual Case Safety Report (ICSR) is a duplicate.<br><br>Is ICSR a duplicate?<br><br>If yes, process the ICSR as per MLM Duplicate Management Process (MLM WIN-06)<br><br>If no, continue to step 2 | MLM Analyst |
| 2. | **Data Entry of ICSR**<br><br>Access LiEMA case processing area and find record.<br><br>In EVWEB, create an ICSR in accordance with EVWEB User Manual and MLM WIN-03.<br><br>Perform data entry against source documentation, update LiEMA post completion of Data Entry. | MLM Analyst |
| 2.1 | **Is follow-up required?**<br><br>If no, go to step 3.<br><br>If yes, follow MLM WIN-04 and using standardised follow-up e-mail template request missing information from the author. | MLM Analyst |
| 3. | **Quality Control - Primary**<br><br>Perform full Quality Control of ICSR against the source document. Ensure all fields in EVWEB are completed, including appropriate removal of personal data in all the fields*, MedDRA coding and case narrative.<br><br>Save the XML (by naming the file with the Case Id) and update LiEMA with completion of Quality Review.<br><br>Send the ICSR to the Medical Review workflow.<br><br>*If an ICSR is based on the follow-up information received from the author, then any information received in the follow-up which could be used to identify the patient (initials, date of birth) must not be included in the ICSR unless they were present in the article. | MLM Analyst |

| | | |
|---|---|---|
| 4. | **Medical Review**<br><br>Perform full Medical Review of the ICSR against the source document.<br><br>Access follow-up questions being asked to the author and insert pertinent questions for follow-up to be sent to the primary author.<br><br>Once medical review is complete, mark medical review as complete in LiEMA. | MLM Physician |
| 5. | **Quality Control - Secondary**<br><br>Check in LiEMA, if any changes are suggested by Medical Reviewer. Incorporate the changes, review and finalise the ICSR.<br><br>Update the LiEMA, post-secondary QC completion.<br><br>ICSRs are sent for EMA quality control and upon review, if any changes need to be made in ICSR, they are incorporated and the ICSR is submitted. If the submission timeline approaches, MLM Service will submit the case to meet the SLA timelines and upon EMA quality control, if any major changes are required, MLM Service will update and re-submit the ICSR as needed. | MLM Analyst<br><br>EMA QC |
| 6. | **ICSR Submission**<br><br>Validate and submit the ICSR in EVWEB, update LiEMA with submission information (including submission date). | MLM Analyst |
| 7. | **Acknowledgement tracking**<br><br>Review EVWEB to check if successful transmission Application Acknowledgment Accept (acknowledgement) has been received for all ICSRs transmitted to EV.<br><br>If 'Application Acknowledgment Accept' received, update LiEMA with the information. End of process.<br><br>If 'Application Acknowledgment Error'/'Application Acknowledgment Reject' received, continue to step 8. | MLM Analyst |
| 8. | **Negative acknowledgement investigation**<br><br>Investigate the reason(s) for 'Application Acknowledgment Error'/'Application Acknowledgment Reject' from EVWEB.<br><br>Make any necessary case corrections and submit the case again in accordance with step 6. | MLM Analyst |

# 10. Records

File location for electronic records: All relevant documents are stored on the contractors Document Management System.