Medical Literature Monitoring Service Contractor Work Instruction (MLM WIN-02)

Title: WIN on Reviewing Medical Literature		
Applies to: Staff members in EMA and its contractors		
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Lead author	Reviewer	Approver
Name: Manu Rewari	Name: Rakesh Santhuram	Name: Tom Paternoster-Howe
Signature: Date:	Signature: Date:	Signature: Date:

1. Changes since last revision

WIN formatted as per the agency's current template.

LMTT replaced with LiEMA throughout the document.

Complete WIN updated as per the new technology system.

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 review of literature references.

4. Definitions

Term	Definition
Business day	Monday – Friday, including Bank Holidays
Case ID	Case Id is the ID generated by the system for the confirmed ICSR which contains 6 segments separated by a

Term	Definition
	dash/hyphen: 'Country Code-MLMSERVICE-YYYYMMDD-Doc ID-Drug ID-Number of cases'
CP	Case Processor
DMS	Document Management System
DOC ID	DocID is the unique ID generated by LiEMA for each literature reference(s) in the tracking tool.
EEA	European Economic Area
EMA	European Medicines Agency
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.
LiEMA	LiEMA is a reference management system that provides literature safety surveillance and reference management capabilities.
LitRev	LitRev refers to reviewer reviewing references for ICSR assessments
MLM	Medical Literature Monitoring
T/A/I	Title/Abstract/Indexing
WWID	ICH E2B(R3) C.1.8.1 – Worldwide Unique Case Identification

5. Instructions

General Principles

The search is performed using the approved search strings published on the MLM page of the EMA website.

Review must be completed no later than one business day after the literature references have been imported in LiEMA.

Day Zero for a Full Text Article (FTA) and Translations

The clock start date is the date where the four minimum criteria for a valid Individual Case Safety Report (ICSR) are available to the MLM Service (i.e. date of import, date of obtaining Full Text Article (FTA), date of obtaining the translation or date of obtaining confirmation from the author, as appropriate).

FTAs/abstracts which are not in English will need translating into English before reviewing and processing. The initial translation will be performed using translation tool. If a case is confirmed from an FTA/abstract which has gone through initial translation, then the FTA/abstract will be sent for full translation by human translators.

If a valid ICSR is identified from an initial translation of an abstract and is in an EEA language, the day zero will be the day when the literature reference has been imported.

If a valid ICSR is identified from an initial translation of an FTA and is in an EEA language, the day zero will be the receipt date of the FTA.

If a valid ICSR is identified from an initial translation of an FTA/abstract and is in a non-EEA language, the day zero will be the day the initial translation was performed.

If a valid ICSR can only be identified from a full translation of an FTA/abstract and is in a non-EEA language, the day zero will be the day the full translation was received.

If there is a delay in receiving the full translation for any language, the case will be submitted within timelines based on the initial translation. Once the full translation is received, the ICSR will be reconciled to ensure all information within the case is correct.

If the full translation is reviewed and the need for a correction is identified, the following days zero will be implemented:

- Abstract in EEA language, day zero will be the when the literature reference has been imported
- FTAs in EEA language, day zero will be the receipt date of the FTA
- Abstracts and FTAs in non-EEA language, day zero will be when the full translation was received

Note: In the instance where a follow-up is received, the receipt date of the follow-up information will be the clock start date for that version of the case or confirmation of valid ICSR.

5.1. Reviewing of Records

Step	**Action**
1. Login to LiEMA	Login LiEMA using SSO (Single Sign On) by entering your work e-mail address. Click 'Sign In'. Select 'LitRev' role associated with your e-mail address. Click 'Continue'.
2. Access records for review in LiEMA	Click 'References' tab and a list of literature references in LiEMA by review status will be displayed. The assigned literature references records pending for review are displayed. Click 'DocID' to start with the review of the assigned literature reference.
3. Review abstract/FTA against inclusion/exclusion criterion	Review the literature reference against the information present either in abstract or FTA (whichever is available). Select the country of reporter/author from the drop-down menu. **Note:** If correspondence author is already available under 'Abstract & Index' tab, country of reporter/author will be auto populated.

Step	Action
	Select the appropriate ICSR Source from the list below: • T/A/I • Conference Abstract • Full Text Article - Open Access • Full Text Article – Procured • Full Text Article – Rented • Translation – Initial • Translation – Full • Follow-up (LitRev) • Follow-up (CP)
4. If no Valid ICSR is present	Review the literature reference against Inclusion/Exclusion criterion for MLM service. Click the check box to record the most appropriate exclusion criteria in the following order: 1. 1.4.1- Animal Study 2. 1.4.2 - Toxicology / Invitro study 3. 1.4.3 - Interventional Trials 4. 1.4.5/1.5.1/1.5.3 - Aggregated data on patients 5. 2.4.2 - Unidentifiable reporter 6. 3.9 - Unidentifiable patient 7. 4.5 - Suspected substance or medicinal product missing 8. 5.10 - Suspected adverse reaction missing 9. 6.6.1- Causality missing 10. Erroneous search result, article unrelated to either active substance or adverse event 11. 5.3.2 - Termination of pregnancy with no ADR 12. 5.3.3 – Pregnancy/breastfeeding – no outcome 13. 5.3.4 - Pregnancy/breastfeeding – normal outcome 14. 5.4.2 – Paediatric population - no ADR 15. 5.4.2 – Elderly population - no ADR 16. 5.5.2 - Overdose – no ADR 17. 5.5.2 - Drug abuse – no ADR 18. 5.5.2 - Off-label use – no ADR 19. 5.5.2 - Drug misuse – no ADR 20. 5.5.2 - Medication error – no ADR 21. 5.5.2 - Occupational exposure – no ADR 22. 5.6.3 - Lack of efficacy (non-life-threatening): no ADR 23. 5.8.2 - Quality defects- no ADR 24. 6.6.1 - Falsified medicinal products–no ADR 25. Duplicate Citation 26. Bulk Exclusion **Note:** 'Bulk Exclusion' not to be used. Click 'Save' to submit the assessment.

Step	Action
5. If Valid ICSR is present	If a valid ICSR is present either from T/A/I or conference abstract or Full Text Article - Open Access, Click the check box to select the appropriate inclusion criterion from the options mentioned under 'ICSR Identified' as listed below: • 5.2.1 - Valid ADR • 5.3.1 - ADR+Pregnancy • 5.3.5 - Pregnancy RMP • 5.4.1 - ADR+Paedeatric/Elderly • 5.5.1 - ADR+Overdose etc • 5.6.1 – ADR+Lack of efficacy • 5.6.2 – Critical/Life threatening LoE • 5.7.1 – Infectious transmission • 5.8.1 – ADR+Quality defect/Falsified Click 'Save' to record the assessment. A notification will appear 'A positive ICSR was identified, and a case needs to be created and sent. If a case has already been created and changes occurred, it may need to be submitted'. Click 'Continue' to confirm valid ICSR. Click 'Cases' Tab and then 'Add Case' to create ICSR identified. A new set of options will be displayed under 'Case Processing' window to enter data for the ICSR identified. **Case Information** a) Case Description: Enter information related to Master or Duplicate case (example: master case needs to be entered as PT1-01-Master i.e. 1 Master case (01) created for Patient 1 (PT1)). b) First source of minimum information for ICSR*: Check the radio button appropriately as it's a mandatory field (*). c) Initial Day Zero*: Update initial day zero as appropriate by selecting the date from the calendar icon as it's a mandatory field (*). d) Latest Day Zero*: Update initial day zero as appropriate by selecting the date from calendar icon as it's a mandatory field (*). e) Country of Reporter: Select the country of the reporter as appropriate from the drop-down menu option. f) Type of Report*: Check the appropriate report type from the listed options as it's a mandatory field (*) - ☐ Spontaneous Report ☐ Report from study ☐ Other ☐ Not available to sender (unknown)

Step	Action
	g) Expedited Report: Select the appropriate radio button based on the seriousness of the adverse drug reaction identified in literature reference. ☐ Yes - Serious ☐ No - Non-Serious **Patient Characteristics** a) Patient Name: It will be auto populated as 'Unknown'. b) Age: Enter the age of the patient at the time of the occurrence of adverse drug reaction c) Age Unit: Select the appropriate age unit from the drop-down menu option. ☐ Hours ☐ Days ☐ Weeks ☐ Months ☐ Years d) Age group: Select the appropriate age unit from the drop-down menu option. ☐ Foetus ☐ Neonate (Preterm and Term newborns) ☐ Infant ☐ Child ☐ Adolescent ☐ Adult ☐ Elderly **Note:** Either age along with age unit or age group should be selected as LiEMA will not allow the user to save the case. e) Sex: Select the gender by selecting the appropriate radio button. ☐ Male ☐ Female ☐ Unknown **Reaction(s)/Events(s)** a) Reaction/Event*: Enter the adverse drug reaction identified as per the source document as it's a mandatory field (*). b) Seriousness*: Select the appropriate seriousness criterion from the drop-down menu option as per the source document as it's a mandatory field (*). ☐ Results in Death ☐ Life Threatening ☐ Caused/Prolonged Hospitalisation ☐ Disabling/Incapacitating ☐ Congenital anomaly/Birth defect ☐ Other Medically Important Condition ☐ Non-serious **Note:** Click 'Add Reaction' to add any other associated adverse drug reaction(s) as per the source document.

Step	Action
	c) Country of Incidence: Select the appropriate country where the adverse drug reaction has occurred. **Drug(s) Information** a) Drug Code*: Select the active substance from the drop-down menu option for which ICSR needs to be created. b) Characterisation of Drug Role*: Select the appropriate drug role from the drop-down menu options- ☐ Suspect ☐ Concomitant ☐ Interacting ☐ Drug Not Administered c) Indication: Enter the indication of the active substance as per the source document. **Case Narrative*** Enter whether the case is a Master or a Duplicate case (similar to what entered in Case Description). Once all the information has been entered, click 'Save'. WWID will be generated for ICSR under 'Cases' tab. Select the check box for WWID and click 'Send Selected to Case Processing' to forward it to case processing workflow. A notification will appear. Click 'Okay' to confirm. The status of WWID will change to 'Sent' and 'Last Sent' date will be auto populated. If more than one ICSR is identified for a given literature reference, click 'Add Case' to create additional ICSR(s) and repeat the above-mentioned steps accordingly.
6. If Potential ICSR is present	**Potential Pending Full Text:** Review the literature reference against the information present in abstract. Select the country of reporter/author from the drop-down menu. **Note:** If correspondence author is already available under 'Abstract & Index' tab, country of reporter/author will be auto populated. Select the appropriate ICSR Source as T/A/I. Click the check box under 'No ICSR Identified' as 'Potential Pending Full Text' to mark the literature reference as potential requiring either renting or procuring of full text article. Click 'Save' to record the assessment.

Step	Action
	Under 'Documents' tab, click 'Get Full Text' to request full text article. A notification will appear, click 'OK' to confirm Full Text Article. A status will appear as 'This article has a pending request for Full Text. To upload or close, use the Documents tab.' **Potential Pending Translation:** Review the literature reference against the information present either in abstract or FTA (whichever is available). If a translation is required to assess the literature reference, the abstract/FTA will be initially translated through LiEMA as per the steps mentioned below- Select the country of reporter/author from the drop-down menu. **Note:** If correspondence author is already available under 'Abstract & Index' tab, country of reporter/author will be auto populated. Select the appropriate ICSR Source from the list below: • T/A/I • Conference Abstract • Full Text Article - Open Access • Full Text Article – Procured Click the check box under 'No ICSR Identified' as 'Potential Pending Translation' to mark the literature reference as potential requiring translation of the source document. Click 'Save' to record the assessment. Under 'Documents' tab, click 'Request Translation' to perform the initial translation of the literature reference. A status will appear as 'This article has a pending request for Translation. To upload or close, use the Documents tab'. **Note:** The user will be redirected to the translation portal and will access the portal using Single Sign on Access (SSO) to perform the initial translation. Once navigated to translation portal, translation dashboard screen will be displayed. Click 'Document' tab, upload file that needs to be translated from the system. Once uploaded, select 'Source language' form the drop-down menu options (as appropriate) and 'Target Language' as 'English'. Click 'Translate' and translation window will be displayed.

Step	Action
	Once translated, 'Status' will appear as 'Translated' and download the translated document for further review. To upload initial translation, under 'Upload a document', select 'Translation' from the drop-down menu and click radio button 'Upload an attachment' to attach the initial translation. Click 'Choose File' to upload the initial translation and enter the 'Day Zero Date' by clicking on calendar icon. Select 'Upload' to confirm. **Note:** If a valid ICSR is identified from an initial translation of an abstract and is in an EEA language, the day zero will be the day when the literature reference has been imported. If a valid ICSR is identified from an initial translation of procured FTA and is in an EEA language, the day zero will be the receipt date of the FTA. If a valid ICSR is identified from an initial translation of an FTA/abstract and is in a non-EEA language, the day zero will be the day the initial translation was performed. If a valid ICSR is identified from the initial translation, send the untranslated abstract/FTA for full translation and under **'**Documents' tab, click 'Request Translation' to request full translation. A status will appear as 'This article has a pending request for Translation. To upload or close, use the Documents tab.' **Steps to follow in LiEMA if valid ICSR needs to be created from initial translation.** Click on the active substance for which ICSR was identified. Update 'ICSR Source' as 'Translation - Initial' by checking the radio button and uncheck the exclusion criterion under 'No ICSR identified'. Under 'ICSR Identified', select the most appropriate criterion for creation of a valid ICSR by selecting the check box. Click 'Save' to update the assessment. A notification will appear 'A positive ICSR was identified, and a case needs to be created and sent. If a case has already been created and changes occurred, it may need to be submitted' Click 'Continue' to confirm valid ICSR. Click 'Cases' Tab and then 'Add Case' to create ICSR identified. A new set of options will be displayed under 'Case Processing' window to enter data for the ICSR identified.

Step	Action
	Follow the steps mentioned above under Step 5 of section 5.1 Reviewing of Records to enter Case Information, Patient Characteristics, Reaction(s)/Event(s), Drug(s) Information and Case Narrative. **Note:** Under Case Information, first source of minimum information for ICSR* will be selected as Translation. Once all the information has been entered, click 'Save'. WWID will be generated for ICSR under 'Cases' tab. Select the check box for WWID and click 'Send Selected to Case Processing' to forward it to case processing workflow. A notification will appear. Click 'Okay' to confirm. The status of CaseID/WWID will change to 'Sent' and 'Last Sent' date will be auto populated. If more than one ICSR is identified for a given literature reference, click 'Add Case' to create additional ICSR(s) and repeat the above-mentioned steps accordingly. If no ICSR is identified from the initial translation, exclude the abstract/FTA and save all documentation in the DMS. **Steps to follow in LiEMA if literature reference is to be excluded.** Click on the active substance for which ICSR was identified. Update 'ICSR Source' as 'Translation - Initial' by checking the radio button and update the most appropriate exclusion criterion under 'No ICSR identified' to exclude the literature reference. Click 'Save' to update the assessment. **Potential Pending Follow-up with author (LitRev):** Review the literature reference against the information present either in abstract or FTA (whichever is available) and assess the literature reference for all the possible information require to create a valid ICSR. Select the country of reporter/author from the drop-down menu. **Note:** If correspondence author is already available under 'Abstract & Index' tab, country of reporter/author will be auto populated. Select the appropriate ICSR Source from the list below: • T/A/I • Conference Abstract • Full Text Article - Open Access

Step	Action
	• Full Text Article – Procured Click the check box under 'No ICSR Identified' as 'Potential Pending Follow-up with author (LitRev)'. Initiate the follow-up process as per WIN MLM-04. Enter the missing information for which follow up has been initiated with author under 'ICSR Negative Comment'. Click 'Save' to record the assessment. Under 'Documents' tab, click 'Author Follow Up'. A notification will appear 'Are you sure you want to record an author follow up request for this reference?'. Click 'OK' to record an author follow up request for the literature reference. A status will appear as 'This article has a pending request for Author Follow-up. To upload or close, use the Documents tab.'

5.2. Renting/Procuring Full Text Articles

Once the Quality Control of potential ICSRs has been completed, the FTA procuring team must work on the Ad Hoc Report pulled from LiEMA and obtain FTA(s) by either renting, procuring or downloading those which are freely available.

All the necessary details must be documented in the FTA tracker in the DMS.

For those literature references, where an order cannot be completed due to any technical or vendor related issue, a detailed reason must be documented in the FTA tracker.

In an event, where the FTA cannot be ordered, the FTA procuring team will follow-up via e-mail with the author or publisher to try and obtain the FTA. If this is not successful, the FTA procuring team will continue to search for the FTA on a monthly basis. After three months, the follow-up will be closed, and the citation will be excluded based on the lack of available information.

In LIEMA, under 'Documents' tab, from the drop-down menu options in 'Upload a document', select 'Full Text' and click the radio button for 'Close the request without an attachment'.

In 'Reason' box update the reason for not procuring the FTA. Click 'Close Request'

Note: On weekly basis, the MLM team will provide the EMA potential status that includes how many FTAs are outstanding and how many purchases could not be performed.

Please refer to the Process and Quality Control Plan for timeliness on ordering an FTA for potential and confirmed ICSRs.

5.3. Review of Full Text Articles

Once the FTA has been obtained and documented in the FTA tracker, the reviewer must close the review activity based on the FTA in LiEMA.

5.3.1. Full Text Articles - Rented

The review must be completed within 1 working day post renting the FTA.

The rented article should be reviewed thoroughly, and LiEMA should be updated for the respective Doc ID.

If the article is to be excluded based on the rented FTA, the reviewer should follow the process as per the steps mentioned below.

If there is a valid ICSR(s) in the rented full text article, the reviewer should inform the FTA procuring team and the FTA will be procured prior to case processing.

Steps to follow in LiEMA if full text article is rented

Step	**Action**
1. Login into LiEMA	Go to LiEMA main page and click 'Search' tab.
2. Access record for review in LiEMA	Search the literature reference by entering DocID in the available search options. Click 'Search'. Doc ID which has been marked as potential pending full text will appear in search results. Click on 'Literature Reference'.
3. Review rented FTA	Click on the active substance for which the literature reference was marked as potential pending full text. Update ICSR Source as 'Full Text Article – Rented' by checking the radio button. If no valid ICSR(s) was identified from the rented full text article, the reviewer should update the appropriate exclusion criterion under 'No ICSR Identified' by selecting the check box. Click 'Save' to update the assessment post review of rented full text article. Under 'Documents' tab, from the drop-down menu options in 'Upload a document', select 'Full Text' and click the radio button for 'Upload an attachment'. Click 'Choose File' to upload a blank PDF (with justification as due to copyright issue, full text rented could not be uploaded) and enter the 'Day Zero Date' by clicking on calendar icon. Select 'Upload' to confirm. **Note:** Day Zero Date will be the date when the full text article was rented.

5.3.2. Full Text Articles - Procured

If the renting option is not available for a full text article, the FTA procuring team will procure the FTA and document this in the FTA tracker. The reviewer must close the review activity based on the FTA in LiEMA.

This activity must be completed within 1 working day post procuring the FTA. The procuring article should be reviewed thoroughly, and LiEMA should be updated for the respective DocID.

Steps to follow in LiEMA if full text article is procured and literature reference is to be excluded

Step	Action
1. Login into LiEMA	Go to LiEMA main page and click 'Search' tab.
2. Access record for review in LiEMA	Search the literature reference by entering DocID in the available search options. Click 'Search'. Doc ID which has been marked as potential pending full text will appear in search results. Click on 'Literature Reference'.
3. Review procured FTA	Click on the active substance for which the literature reference was marked as potential pending full text. Update ICSR Source as 'Full Text Article – Procured' by checking the radio button. If no valid ICSR(s) was identified from the procured full text article, the reviewer should update the appropriate exclusion criterion under 'No ICSR Identified' by selecting the check box. Click 'Save' to update the assessment post review of procured full text article. Under 'Documents' tab, from the drop-down menu options in 'Upload a document', select 'Full Text' and click the radio button for 'Upload an attachment'. Click 'Choose File' to upload the procured full text article and enter the 'Day Zero Date' by clicking on calendar icon. Select 'Upload' to confirm. **Note:** Day Zero Date will be the date when the full text article was procured.

Steps to follow in LiEMA if full text article is procured and valid ICSR(s) needs to be created

Step	Action
1. Log in to LiEMA	Go to LiEMA main page and click 'Search' tab.
2. Access record for review in LiEMA	Search the literature reference by entering DocID in the available search options. Click 'Search'. Doc ID which has been marked as potential pending full text will appear in search results. Click on 'Literature Reference'.
3. Review procured FTA	Click on the active substance for which the literature reference was marked as potential pending full text. Update ICSR Source as 'Full Text Article – Procured' by checking the radio button. Under 'ICSR Identified', select the most appropriate criterion for creation of a valid ICSR by selecting the check box. Click 'Save' to update the assessment post review of procured full text article. A notification will appear 'A positive ICSR was identified, and a case needs to be created and sent. If a case has already been created and changes occurred, it may need to be submitted' Click 'Continue' to confirm valid ICSR. Click 'Cases' Tab and then 'Add Case' to create ICSR identified. A new set of options will be displayed under 'Case Processing' window to enter data for the ICSR identified. Follow the steps mentioned above under Step 5 of section 5.1 Reviewing of Records to enter Case Information, Patient Characteristics, Reaction(s)/Event(s), Drug(s) Information and Case Narrative. Once all the information has been entered, click 'Save'. WWID will be generated for ICSR under 'Cases' tab. Select the check box for WWID and click 'Send Selected to Case Processing' to forward it to case processing workflow. A notification will appear. Click 'Okay' to confirm. The status of CaseID/WWID will change to 'Sent' and 'Last Sent' date will be auto populated.

Step	Action
	If more than one ICSR is identified for a given literature reference, click 'Add Case' to create additional ICSR(s) and repeat the above-mentioned steps accordingly. Under 'Documents' tab, from the drop-down menu options in 'Upload a document', select 'Full Text' and click the radio button for 'Upload an attachment'. Click 'Choose File' to upload the procured full text article and enter the 'Day Zero Date' by clicking on calendar icon. Select 'Upload' to confirm. **Note:** Day Zero Date will be the date when the full text article was procured.

5.4. Review of Full Translations

Extract the Ad Hoc Report from LiEMA and filter the literature references marked as 'Potential Pending Translation'. This pertains to the literature references that have neither been excluded nor included as per exclusion/inclusion criteria.

Once the full translation has been obtained, the reviewer must action the pending DocID in LIEMA within 1 business day of receipt of full translation.

Steps to follow in LiEMA if full translation is received and literature reference is to be excluded

Step	Action
1. Login into LiEMA	Go to LiEMA main page and click 'Search' tab.
2. Access record for review in LiEMA	Search the literature reference by entering DocID in the available search options. Click 'Search'. Doc ID which has been marked as potential pending translation will appear in search results. Click on 'Literature Reference'.
3. Review full translation	Click on the active substance for which the literature reference was marked as 'Translation – Initial'. Update ICSR Source as' Translation – Full' by checking the radio button. If no valid ICSR(s) was identified from the full translation, the reviewer will uncheck 'Potential Pending Translation' and update the appropriate exclusion criterion under 'No ICSR Identified' by selecting the check box accordingly.

Step	Action
	Click 'Save' to update the assessment post review of full translation. Under 'Documents' tab, from the drop-down menu options in 'Upload a document', select 'Translation' and click the radio button for 'Upload an attachment'. Click 'Choose File' to upload full translation and enter the 'Day Zero Date' by clicking on calendar icon. Select 'Upload' to confirm. **Note:** Day Zero Date will be the date when the full translation is received.

Steps to follow in LIEMA if full translation is received and valid ICSR(s) needs to be created

Step	Action
1. Login into LIEMA	Go to LiEMA main page and click 'Search' tab.
2. Access record for review in LIEMA	Search the literature reference by entering DocID in the available search options. Click 'Search'. Doc ID which has been marked as potential pending translation will appear in search results. Click on the Literature Reference.
3. Review full translation	Click on the active substance for which the literature reference was marked as 'Translation – Initial'. Update ICSR Source as 'Translation – Full' by checking the radio button. If valid ICSR(s) is identified from the full translation, the reviewer will uncheck 'Potential Pending Translation' and update the appropriate criterion under 'ICSR Identified' by selecting the check box accordingly. Click 'Save' to update the assessment post review of full translation. A notification will appear 'A positive ICSR was identified, and a case needs to be created and sent. If a case has already been created and changes occurred, it may need to be submitted' Click 'Continue' to confirm valid ICSR. Click 'Cases' Tab and then 'Add Case' to create ICSR identified. A new set of options will be displayed under 'Case Processing' window to enter data for the ICSR identified.

Step	Action
	Follow the steps mentioned above under Step 5 of section 5.1 Reviewing of Records to enter Case Information, Patient Characteristics, Reaction(s)/Event(s), Drug(s) Information and Case Narrative. **Note:** Under Case Information, first source of minimum information for ICSR* will be selected as Translation. Once all the information has been entered, click 'Save'. WWID will be generated for ICSR under 'Cases' tab. Select the check box for WWID and click 'Send Selected to Case Processing' to forward it to case processing workflow. A notification will appear. Click 'Okay' to confirm. The status of CaseID/WWID will change to 'Sent' and 'Last Sent' date will be auto populated. If more than one ICSR is identified for a given literature reference, click 'Add Case' to create additional ICSR(s) and repeat the above-mentioned steps accordingly. Under 'Documents' tab, from the drop-down menu options in 'Upload a document', select 'Translation' and click the radio button for 'Upload an attachment'. Click 'Choose File' to upload the full translation and enter the 'Day Zero Date' by clicking on calendar icon. Select 'Upload' to confirm. **Note:** Day Zero Date will be the date when the full translation is received.

Note: For the initial version of a case that has already been processed and transmitted to EudraVigilance based on the available information, if any additional non-English language information is received, the translated source should be routed to the case processor for assessment and potential processing.

For any articles requiring translation that are not received within the agreed timelines, the EMA is informed in the weekly quality meeting, and is followed-up with the translation vendor for the reason in delay of translating the article.

A full Root Cause Analysis and Corrective Action, Preventive Action (RCA CAPA) will be requested from the translation vendor for any translation not received within the agreed timelines (refer to the Process and Quality Control document, appendix 3).

6. Reference documents

MLM WIN-04 - Performing follow-up for MLM ICSRs

Process and Quality Control document, appendix 3

7. Annexes

Not Applicable