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

Reviewing medical literature

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

All records are kept in the Data Management Tracking Tool.

3. 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
Embase	Excerpta Medica Database, a biomedical database and pharmacological database of public literature
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

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Term	Definition
	administration of one or more medicinal products to an individual Patient at a particular point of time.
MLM	Medical Literature Monitoring

4. Instructions

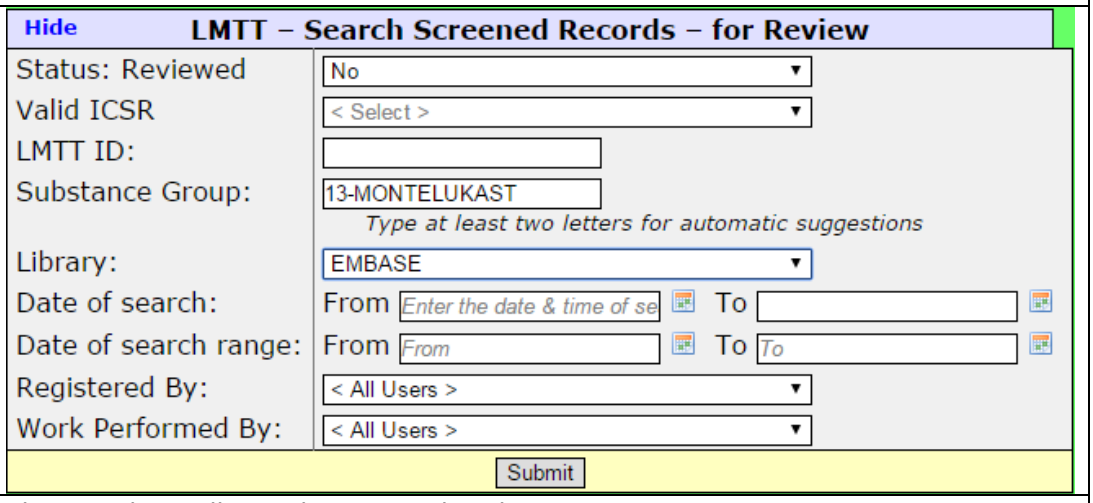
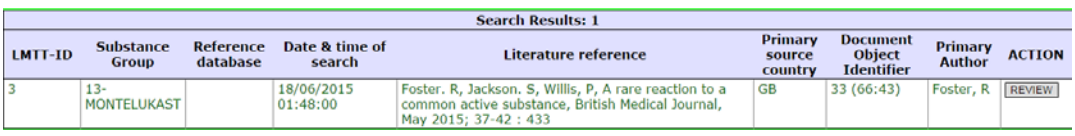
General principles

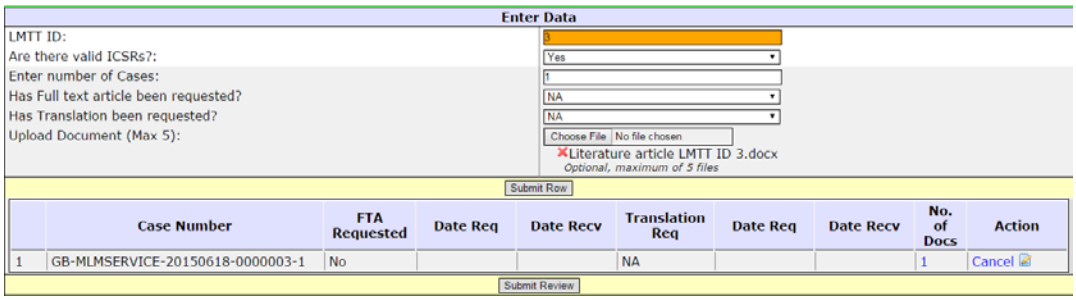
The search is performed using the approved search strings published on the EMA website.

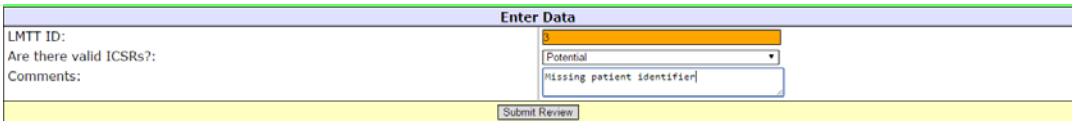
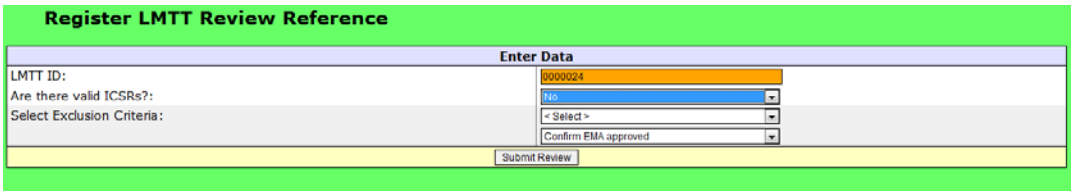
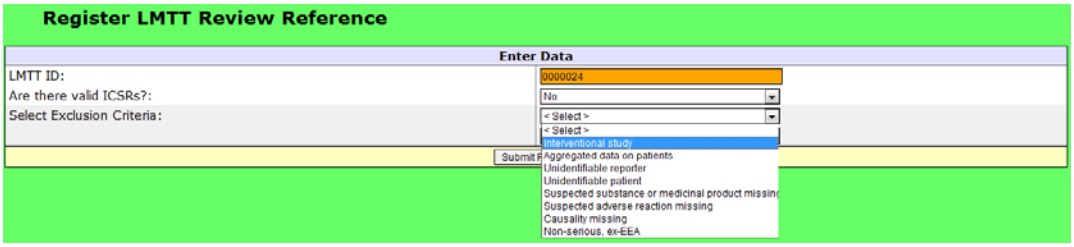
Review must be complete no later than one calendar day after screening.

The clock start date is the date all criteria are identified for a valid ICSR (i.e. date of search, or date of obtaining FTA if appropriate). This will typically be the date of the search, or the date a full text article was received to demonstrate an ICSR. In the instance where a follow-up is received, the receipt date of receipt of the information will be the clock start date.

4.1. Reviewing of records

Step	Action
1. Access records for review in DMTT	Enter Search Parameters to retrieve records pending review by substance groups, library and, if required, date of search. Click Submit
1a.	
1b.	The records pending review are retrieved. Reviewer should cross check the number of records in DMTT against citations for review in the literature database.  Click on review to begin review of record.

2. Review abstract / FTA against inclusion / exclusion criterion	Open the reference database against which the search was performed, including the dates of search. Review the information available from the abstract / full text article if available. Review against each exclusion criteria as per Inclusion / Exclusion criteria for MLM service. Reviewer should follow the exclusion criteria in the following order: 1. Interventional Trials 2. Aggregate analysis on patient data from publicly available database 3. Unidentifiable reporter 4. Unidentifiable patient 5. No suspect / interacting active substance 6. No suspected adverse reaction(S) 7. No causal relationship 8. Non-serious ex-EEA
2a. If Valid ICSR present	If a valid ADR is present, obtain Full Text Article – if available immediately, upload the article to the DMTT by choosing file from local drive. • Enter 'Yes' in 'valid ICSR'. • Enter the number of valid cases in 'Number of cases'. • Enter 'Yes' in 'Full text article requested', If Full text article is required. • Enter 'Yes' in 'translation required', if translation of any article is required. Upload the abstract / full text article (Max 5) • Select 'Submit row'.  Once the case Number appears and matches the number of valid ICSRs identified, select "Submit Review"
2b. If Potential ICSR present	If potential ICSR following full text article review: • Enter 'potential' in 'Are there valid ICSRs?' • Enter all the missing or possibly applicable exclusion criteria (e.g. Missing patient identifiers)

	• Initiate the follow-up process as per WIN/MLM/004.  Click “Submit Review”
2c. If no ICSR	If no ICSR: • Enter ‘No’ in ‘are there valid ICSRs?’ • Select exclusion criterion that applies • If the reason for exclusion is not defined by the criteria above, select one of the following options from the drop down o Toxicology / in vitro study o Animal study o Erroneous search result, article unrelated to active substance or Adverse event  • Select the appropriate exclusion criteria from the drop down menu.  • If the criteria matches the EMA approved list of exclusion criteria, select EMA approved = Yes Click “Submit Review”