

# Medical Literature Monitoring Service Contractor Work Instruction (MLM WIN-01)

## Screening 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

Not applicable.

### 3. Definitions

Term	Definition
Calendar Day	Monday – Friday, including Bank Holidays
DOI	Document Object Identifier
DMTT	Data Management Tracking Tool
EBSCO	Broad range of full text and bibliographic databases designed for research
EMA	European Medicines Agency
Embase	Excerpta Medica Database, a biomedical database and pharmacological database of public literature
FTA	Full text article

Term	Definition
<b>Individual Case Safety Report (ICSR)</b>	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.
<b>MLM</b>	Medical Literature Monitoring

## 4. Instructions

### General principles

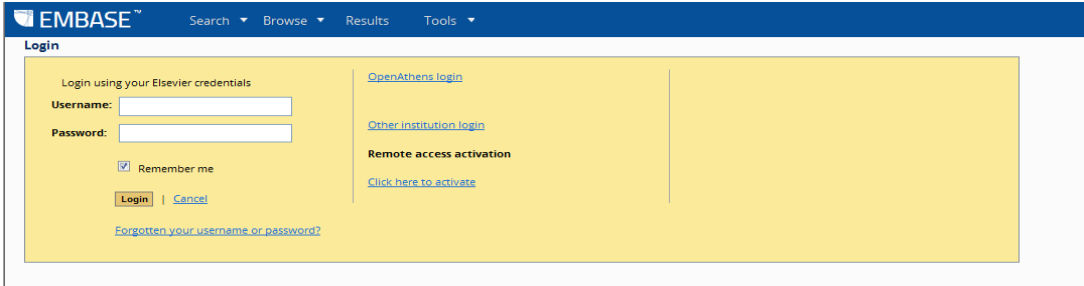
Medical Literature is to be screened and logged in the DMTT each working day for Embase and the first working day each month for searches in EBSCO.

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

Screening must take place each calendar day and reviewed no later than one calendar day later.

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 confirm an ADR. In the instance where a follow-up is received, the date of receipt of the information will be the clock start date.

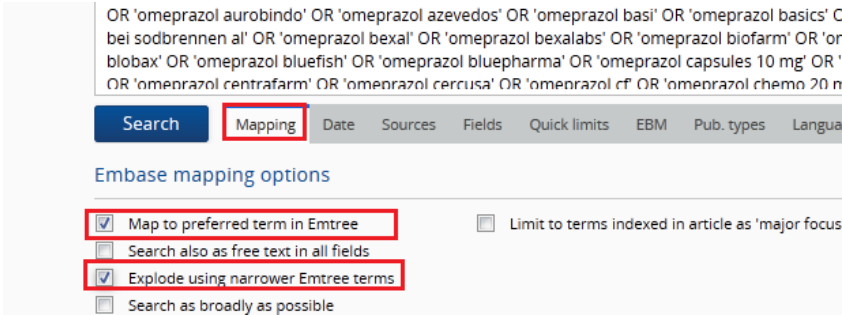
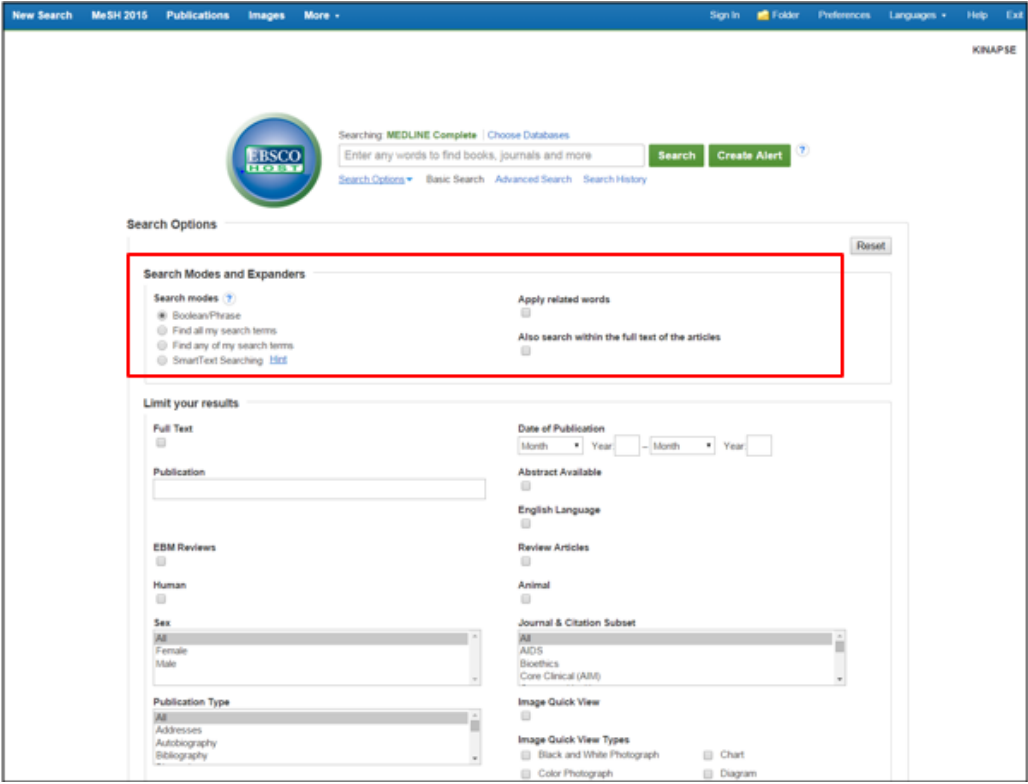
#### 4.1. Screening of literature database

Step	Action
1. Login to reference database	Daily searches are performed in Embase each working day  Monthly searches are performed in EBSCO, the first working day of each month
1A.	For daily searches in Embase, access Embase.com/login and enter the username and password.  

1B.

For monthly searches in EBSCO, access <http://search.ebscohost.com> and enter username and password.

Select databases to be used for search

2. Load search	Check that there has been no updates to the active substance search strings published on EMA MLM website.
2A. Embase	<p>For Embase Click on the Advance search and enter the product specific Search Strategy into Advanced Search Box and select mapping options and appropriate filters (human, dates only).</p> <p>Enter the dates from previous day and the search day (eg. 01 Jul 2015 to 02 Jul 2015, if the search day is 02 Jul 2015) and click on 'Search' button</p> 
2B EBSCO.	<p>For EBSCO, under search options ensure 'BooleanPhrase' is selected and paste the search strategy into the search box.</p> <p>Ensure the complete month is entered e.g. 01 Aug 2015 – 31 Aug 2015 in the search date range.</p> 

3.  
Execute  
search

Press search, and the search results are retrieved.

For Embase the following is seen.

The screenshot shows the Embase search results interface. At the top, there are tabs for 'Results', 'View', 'Print', 'Export', 'Email', 'Order', and 'Add to Clipboard'. Below these, there's a 'Sort by' section with options: Relevance, Publication Year, and Entry Date (selected). A 'Selected: 0 (clear)' and 'Select number of items' dropdown are also present. The results list three articles:

- Effectiveness of Montelukast on asthma control in infants: Methodology of a French claims data study**  
Belhassen M., de Pouvoirville G., Laforest L., Brouard J., de Blic J., Fauroux B., Laigle V., Chanut-Vogel C., Lameze L., Van Ganse E.  
*BMC Pulmonary Medicine* 2015 **15**:1 Article Number 51  
Embase [Abstract](#) [Index Terms](#) [View Full Text](#)
- Acute cocaine administration decreases advantageous decision-making but does not affect impulsive action as measured by a rodent gambling task**  
Ferland J.M., Tremblay M., Adams W.K., Winstanley C.A.  
*International Journal of Neuropsychopharmacology* 2014 **17** SUPPL. 1(48-)  
Embase [Abstract](#) [Index Terms](#) [View Full Text](#)
- Chronic vagal stimulation rewire brain hedonic network**  
Malbert C.-H.  
*Brain Stimulation* 2015 **8**:2(436-)  
Embase [Abstract](#) [Index Terms](#) [View Full Text](#)

For EBSCO, the results are seen as follows;

The screenshot shows the EBSCO Search History/Alerts interface. At the top, there are tabs for 'Print Search History', 'Retrieve Searches', 'Retrieve Alerts', and 'Save Searches / Alerts'. Below these, there's a 'Select / deselect all' checkbox and buttons for 'Search with AND', 'Search with OR', and 'Delete Searches'. A 'Refresh Search Results' button is also present. The results table has four columns: Search ID#, Search Terms, Search Options, and Actions. It lists four searches:

Search ID#	Search Terms	Search Options	Actions
S1	"omeprazole" OR "omeprazol (als magnesium) muf" OR "omeprazol (als magnesium) dte" OR "omeprazol bei sodbrennen" OR "omeprazol chemol" OR "omeprazol infusa" OR "omeprazol muf" OR "omeprazol protect" OR "omeprazol s" OR "omeprazol t" OR "omeprazol tartet" OR "uniprax" OR "omeprazole magnesium" OR "omeprazole sodium" OR "omeprazols" OR "omeprazolas" OR "omeprazolo" OR "omepreasol" OR "omeprazole" OR "omeprazol" OR "omeprasool" OR "omeprasool" OR "acidcare" in OR "omeprazole" OR "omeprezol"	Search modes - BooleanPhrase	<a href="#">View Results (10,186)</a> <a href="#">View Details</a> <a href="#">Edit</a>
S2	(MH "adverse drug reaction" OR "adverse drug reaction" OR MH "drug overdose" OR "drug overdose" OR MH "drug misuse" OR "drug misuse" OR "drug abuse" OR MH "substance abuse" OR "substance abuse" OR MH "pregnancy" OR "pregnancy" OR MH "drug efficacy" OR "drug efficacy" OR MH "drug withdrawal" OR "drug withdrawal" OR MH "drug tolerance" OR "drug tolerance" OR MH "medication error" OR "medication error" OR MH "death" OR "death" OR MH "drug interaction" OR "drug interaction" OR MH "cancer"	Search modes - BooleanPhrase	<a href="#">View Results (1,991,013)</a> <a href="#">View Details</a> <a href="#">Edit</a>
S3	S1 AND S2	Search modes - BooleanPhrase	<a href="#">View Results (489)</a> <a href="#">View Details</a> <a href="#">Edit</a>
S4	S1 AND S2	Limiters - Human Search modes - BooleanPhrase	<a href="#">View Results (405)</a> <a href="#">View Details</a> <a href="#">Edit</a>

Each search result will be entered into DMTT.

<b>4.</b> Entry of screening results into DMTT.	<p>Ensure the date and time of search are entered. Date as 'search day' and time as 'time of search'.</p> <p>Enter the dates from previous day and search day (eg. 01 Jul 2015 to 02 Jul 2015, if the search day is 02 Jul 2015), also accounting for weekends if necessary.</p> <p>Select the substance group from the drop down menu, the prefixed number matches the active substance group list (i.e. 1 – Paracetamol).</p> <p>Select the Library from the drop down menu in which the search was conducted, Embase or EBSCO.</p> <p>Select the Primary Source Country using the two letter ISO country code from the drop down menu.</p> <p>Enter Author details using Vancouver style.</p> <p>A comma (,) will separate each author. The last author must have a full stop (.) after their name. (e.g. Soto M.E, Hernandez-Becerril N, Perez-Chiney A.C.)</p> <p>A maximum of 6 authors will be captured. If more authors are present state 'et al.' (e.g. Soto ME, Hernandez-Becerril N, Perez-Chiney AC, Hernandez-Rizo A, Telich-Tarriba JE, Juarez-Orozco LE et al.)</p> <p>Enter the primary author (first listed author) remembering to remove any full stops (.) or commas (,)</p> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 45%;"><b>Primary Source Country:</b></td> <td><div style="border: 1px solid black; padding: 2px;">--Select--</div></td> </tr> <tr> <td><b>Authors:</b></td> <td><div style="border: 1px solid black; padding: 2px;">Soto ME, Hernandez-Becerril N, Perez-Chiney A.C.</div></td> </tr> <tr> <td><b>Primary Author:</b></td> <td><div style="border: 1px solid black; padding: 2px;"></div></td> </tr> <tr> <td><b>Issue/Vol No.:</b></td> <td><div style="border: 1px solid black; padding: 2px;"></div></td> </tr> </table> </div> <p>Enter volume number, page numbers and date of publication:</p> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 45%;"><b>Authors:</b></td> <td><div style="border: 1px solid black; padding: 2px;">Soto M.E, Hernandez-Becerril N, Perez-Chiney A.C</div></td> </tr> <tr> <td><b>Primary Author:</b></td> <td><div style="border: 1px solid black; padding: 2px;">Soto M.E</div></td> </tr> <tr> <td><b>Issue/Vol No.:</b></td> <td><div style="border: 1px solid black; padding: 2px;">2015: 5</div></td> </tr> <tr> <td><b>Page No.:</b></td> <td><div style="border: 1px solid black; padding: 2px;">(13-22)</div></td> </tr> <tr> <td><b>Date of Publication:</b></td> <td><div style="border: 1px solid black; padding: 2px;">01-Jan-2015</div></td> </tr> </table> </div> <p>NOTE: for Vancouver style, ensure no punctuation marks (i.e. full stops or commas) are added into DMTT as the system is programmed to configure this.</p> <p>If the article has previously been registered, the information will begin to autocomplete on entry of author / primary author information. If it does, verify that it is a duplicate entry for that substance group and complete all fields and mark as a duplicate entry – search DMTT to find duplicate DMTT ID to cross reference.</p> <p>Source the DOI or URL from the publisher website, and paste into the DMTT.</p>	<b>Primary Source Country:</b>	<div style="border: 1px solid black; padding: 2px;">--Select--</div>	<b>Authors:</b>	<div style="border: 1px solid black; padding: 2px;">Soto ME, Hernandez-Becerril N, Perez-Chiney A.C.</div>	<b>Primary Author:</b>	<div style="border: 1px solid black; padding: 2px;"></div>	<b>Issue/Vol No.:</b>	<div style="border: 1px solid black; padding: 2px;"></div>	<b>Authors:</b>	<div style="border: 1px solid black; padding: 2px;">Soto M.E, Hernandez-Becerril N, Perez-Chiney A.C</div>	<b>Primary Author:</b>	<div style="border: 1px solid black; padding: 2px;">Soto M.E</div>	<b>Issue/Vol No.:</b>	<div style="border: 1px solid black; padding: 2px;">2015: 5</div>	<b>Page No.:</b>	<div style="border: 1px solid black; padding: 2px;">(13-22)</div>	<b>Date of Publication:</b>	<div style="border: 1px solid black; padding: 2px;">01-Jan-2015</div>
<b>Primary Source Country:</b>	<div style="border: 1px solid black; padding: 2px;">--Select--</div>																		
<b>Authors:</b>	<div style="border: 1px solid black; padding: 2px;">Soto ME, Hernandez-Becerril N, Perez-Chiney A.C.</div>																		
<b>Primary Author:</b>	<div style="border: 1px solid black; padding: 2px;"></div>																		
<b>Issue/Vol No.:</b>	<div style="border: 1px solid black; padding: 2px;"></div>																		
<b>Authors:</b>	<div style="border: 1px solid black; padding: 2px;">Soto M.E, Hernandez-Becerril N, Perez-Chiney A.C</div>																		
<b>Primary Author:</b>	<div style="border: 1px solid black; padding: 2px;">Soto M.E</div>																		
<b>Issue/Vol No.:</b>	<div style="border: 1px solid black; padding: 2px;">2015: 5</div>																		
<b>Page No.:</b>	<div style="border: 1px solid black; padding: 2px;">(13-22)</div>																		
<b>Date of Publication:</b>	<div style="border: 1px solid black; padding: 2px;">01-Jan-2015</div>																		

www.sciencedirect.com/science/article/pii/S2211283913000178

ScienceDirect Journals Books

Download PDF Export

Article outline ☐ Show full outline

Abstract  
Keywords  
1. Introduction  
2. Methods  
3. Results  
4. Discussion  
5. Conclusion  
References

Figures and tables

Table 1  
Table 2  
Table 3  
Table 4  
Table 5  
Table 6  
Table 7  
Table 8

Predictive value of anti diseases classified by specialized health insti

María Elena Soto<sup>a</sup>, Nidia Alfredo Hernández-Rizo<sup>a</sup>, José Gabriela Melendez<sup>d</sup>, Rafael Bo

Under a Creative Commons license

Show more

doi: 10.1016/j.rnim.2013.10.003

If the DOI is not available, enter the DMTT ID into the DOI field.

Once all information is completed, press submit.

Article Identifier(DOI):	10.1016/j.rnim.2013.10.003
	www.sciencedirect.com/science/article/pii/S2211283913000178
	<input type="checkbox"/> Duplicate Entry
MTT ID:	
<input type="button" value="Submit"/> <input type="button" value="Complete"/>	

Repeat for all entries retrieved from the literature database for each active substance.

In case no literature found in the search results for an active substance, check the 'no article returned' and submit press submit.

Enter Data	
Enter the date & time of search:	25-Jun-2015 14:54
Enter the search date range:	From 24-Jun-2015 To 25-Jun-2015
Substance Group:	7-DICLOFENAC <i>Type at least two letters for automatic suggestions</i>
Library:	EMBASE
Journal:	<input checked="" type="checkbox"/> No Articles returned
Article Title:	
Primary Source Country:	--Select--
Authors:	
Primary Author:	
Issue/Vol No.:	
Page No.:	
Date of Publication:	
Document Object Identifier(DOI):	
URL:	
Duplicate LMTT ID:	<input type="checkbox"/> Duplicate Entry
<input type="button" value="Submit"/> <input type="button" value="Complete"/>	

5. Edit screening record

To edit an entered record that has been screened, click on edit screened record at the bottom of the page.

### Search Records

#### LMTT – Search Screened Records – for Editing

Enter at least one search parameter to locate the entered record to retrieve the record(s).

Search Results: 1								
LMTT-ID	Substance Group	Reference database	Date & time of search	Literature reference	Primary source country	Document Object Identifier	Primary Author	ACTION
1	MONTELUKAST	EMBASE	17-06-2015 13:11:00	Foster. R, Jackson. S, Willis, P,A rare reaction to a common active substance,British Medical Journal,May 2015;433	GB	(433:807)	Foster, R	

Click on edit under action, and the record is available to update.