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

Title: WIN on Searching, Screening & Importing Medical Literature		
Applies to: Staff members in EMA and its contractors		
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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 importing literature references from external alerts, creating literature references manually and importing literature references from Ad Hoc search.

4. Definitions

Term	Definition
Allied & Complementary Medicine Database (AMED)	Allied & Complementary Medicine covers the fields of complementary or alternative medicine and allied health. Information is geared toward medical professionals and health practitioners and care-givers, as well as the pharmaceutical

Term	Definition
	industry. Journal articles, newspapers and books are indexed and coverage is international.
Business day	Monday – Friday, including Bank Holidays
Dialog	Dialog is an automated search tool which provides access to over 1.7 billion records across more than 140 databases of peer-reviewed literature.
DOI	Document Object Identifier
EEA	European Economic Area
EMBASE	Comprehensive bibliographic coverage of the literature on drugs and pharmacology and of all other aspects of human medicine and related disciplines. Embase® is a key resource for biomedical evidence, from published, peer-reviewed literature, in-press publications and conference abstracts. Use Embase® to review clinical trials, to generate systematic reviews, to monitor products for pharmacovigilance and much more. Embase comprehensive indexing - of drugs, devices, manufacturers and disease names - ensures maximum search ability.
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.
International Pharmaceutical Abstracts (IPA)	The International Pharmaceutical Abstracts database provides comprehensive coverage of worldwide pharmaceutical and related healthcare literature. Topics range from drug use, adverse reactions and drug interactions to pharmacy practice and drug research and technology. The scope of the file covers the clinical, practical and theoretical to the economic and scientific aspects of the literature.
LiEMA	LiEMA is a reference management system that provides literature safety surveillance and reference management capabilities.
MEDLINE	MEDLINE is a bibliographic database produced by the U.S. National Library of Medicine. It covers the whole field of medicine including dentistry, veterinary medicine, and medical psychology. Clinical and preclinical medicine, anatomy, pharmacology, toxicology, genetics, microbiology, pathology, environmental health, occupational medicine, psychology, biomedical technology, health planning and administration, space life science, and many other related subject areas are included.
MLM	Medical Literature Monitoring

Term	Definition
PMID	PubMed Unique Identifier is a 1- to 8-digit accession number with no leading zeros. It is present on all records and is the accession number for managing and disseminating records. PMIDs are not reused after records are deleted.
Vancouver Style	As per Vancouver style of referencing, Journal article references contain the following elements in order: Author(s), Article title, Journal Title Abbreviation, Date of Publication/Publication Year, Volume and Issue number, Pagination

5. Instructions

General Principles

Medical Literature is imported and tracked in LiEMA each business day for Embase, Medline, IPA and AMED.

The literature references are imported using predefined search strategies. Each time the search strategies are updated, mandatory training will take place. Automated import will take place each business day and the literature references will be reviewed within 1 business day of import. The clock start date is the date, all criteria is identified for a valid Individual Case Safety Report (ICSR) (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).

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's 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.

The MLM team will use a 24-hour clock format.

5.1. Literature References Import

Literature references will be automatically imported into LiEMA.

A new literature reference will be created in LiEMA for each newly identified alert (i.e., not previously sent as this would be categorised as a duplicate).

If the literature reference already exists in LiEMA, a duplicate reference will not be created.

5.2. Literature References Import – Manual Creation

New literature references can be created manually by users with the appropriate permissions.

Steps to follow in LiEMA for adding literature reference manually.

Step	**Action**
1. Login to LiEMA	Login to LiEMA use Single Sign On (SSO) by entering your work e-mail address, click 'Sign In'. Select 'LitRev' role associated with your email address, click 'Continue'.
2. Add a new literature reference in LiEMA	Click 'References' tab and click on 'Add Reference'. The user will be directed to a new window.
3. Selection of active substance	Select one or more active substance from 'Select Specific Drugs'. A new window will open for 'Drug Code Selector'. Search for the appropriate active substance by typing the active substance name in the search bar. After getting the desired active substance name displayed, click 'Add Selected Drugs'.
4. Search Literature reference	Search a Literature Reference using either of the available options in LiEMA by completing 'Step 2 Search for a Reference'. a) Title Contains: Type the literature reference that needs to be added. b) First Author's Name: Type the author's name that needs to be added. While performing search with first author's name, the last name of the first author should be used. c) DOI - Use alone or with other criteria: Type the DOI that needs to be added. Click 'Search'.
5. Review possible existing literature references	If a duplicate literature reference is present, it will be displayed at the bottom of the screen. Possible duplicate references should be checked to confirm that the new literature reference is a true duplicate. If the literature citation is a duplicate, a new record should not be created. If needed, the existing record can be updated to add new substances. To do this, follow the steps in 5.5. If the literature citation is not a duplicate, then the literature reference can be added by creating a new literature reference.

Step	Action
6. Create a new literature reference	If the literature reference doesn't exist, enter the below mentioned details into step 4 to create a new literature reference- a) Day Zero Date: Select the appropriate day zero in by clicking on the calendar icon. b) PMID (Optional): Enter the PubMed ID, if available. c) Select a reviewer: Select the appropriate reviewer from the drop-down menu. **Note:** The reviewer will be auto populated to themselves. Click 'Create Reference' and a new reference ID will be generated. The reviewer should complete all the information below 'Edit Reference Details'. a) Article Title: Enter the article title as provided in the source document. b) Authors: Enter the author's name(s) as provided in the source document. If more than one author is present in the source document, click 'Add' to add more authors. c) Source Information: Under source information, enter 'Source Name', 'Volume', 'Issue', 'Page', 'Supplement', 'ISSN', 'ISBN', 'Publication Date (YYYY-MM-DD)' and 'Commercial Source' as provided in the source document. **Note:** Under Source Information, it is required to enter the publishing date in the format YYYY-MM-DD (mandatory field). d) Author Abstract: Enter abstract information from the source document, if available. e) DOI: Enter the DOI as provided in the source document. f) Indexing: Enter the indexing information from the source document, if available. g) Notes: Update the reason for manual creation of literature reference. Click 'Update' to update the information entered. **Note:** By clicking 'Update and Return to ref' the information will be updated, and the user will be redirected to the 'References' tab. By clicking 'Cancel' any changes a reviewer may have made will not be saved and only the original information (that was present on the page when the reviewer was directed to it) will be saved and the user will be redirected to the new literature reference created under 'References' tab.

5.3. Literature References Import – Ad Hoc Search

An authorised user (Admin) can import XML format records from an ad hoc search.

Steps to follow in LiEMA for importing records from Ad Hoc search (Dialog)

Step	Action
1. Login to LiEMA	Login to LiEMA use Single Sign On (SSO) by entering your work e-mail address, click 'Sign In'. Select 'Admin' role associated with your email address, click 'Continue'.
2. Import of records	Click 'Imports' tab. Under 'Dialog Ad Hoc Import', select the appropriate active substance by clicking on 'Select Drug Code' for which the literature references need to be imported. **Note:** Only one substance code can be applied to incoming references during an import. If more than one drug is required, the user must re-import the file with the different substance name. To import, click 'Choose File' and upload the XML file, click 'Import References' Note: It may take up to 30 minutes to complete the import. An acknowledgement will be displayed to indicate the import has started. Upon completion of the import, an e-mail containing the import log will be sent to the recipients listed in the 'Import Notifications' setup, confirming the number of records had successfully been imported. The import (import log) e-mail will be saved in Document Management System.

5.4. Edit an existing Literature References

Steps to follow in LiEMA for editing an existing literature reference.

Step	Action
1. Login to LiEMA	Login to LiEMA use Single Sign On (SSO) by entering your work e-mail address, click 'Sign In'. Select 'LitRev' role associated with your email address, click 'Continue'.
2. Access record to edit in LiEMA	Search the literature reference by entering 'DocID' in the available search options, click 'Search'. The appropriate 'DocID' will open up. Click on 'Edit Reference' and a new window will open 'Edit Reference Details > DocID'. Update the below mentioned fields as appropriate- • Article Title • Authors • Source Information • Author Abstract • DOI • Indexing • Notes **Note:** Under Source Information, a publication date is required to save the record and must be in the format YYYY-MM-DD. Click 'Save' or 'Save & Return to Ref' to add the new/edited details to the reference. Furthermore, if 'Save & Return to Ref' is selected, the Add/Edit Reference Details browser tab will refresh to show the Reference Assessment page but will remain open in addition to the original browser tab. **Note:** By clicking 'Cancel' any changes a reviewer may have made will not be saved and only the original information (that was present on the page when the reviewer was directed to it) will be saved and the user will be redirected to the new literature reference created under 'References' tab. Once the editing step is completed, the action will be recorded in 'Reference History' section of References.

5.5. Add a new active substance to an existing Literature Reference

Steps to follow in LiEMA for adding a new active substance to an existing Literature Reference

Step	Action
1. Login to LiEMA	Login to LiEMA use Single Sign On (SSO) by entering your work e-mail address, click 'Sign In'. Select 'LitRev' role associated with your email address, click 'Continue'.
2. Access record to add active substance in LiEMA	Search the literature reference by entering 'DocID' in the available search options. Click 'Search'. The appropriate 'DocID' will open up. Click 'Add Drugs' to add more active substances for which literature reference was not indexed. A new window opens for 'Drug Code Selector'. Search for the appropriate active substance by typing the active substance name in the search bar. Click 'Add Selected Drugs'. A notification will appear to confirm 'Adding drugs to a reference cannot be undone. Are you sure you want to continue with this action?'. Click 'Yes, add drugs' to add a new active substance to the existing literature reference and click 'No, I am not ready' to cancel adding the active substance. Under 'References' tab, 'Associated Drugs' table will be updated with the added active substances as unreviewed in the workflow. **Note:** The original Day Zero date will be retained.

6. Reference documents

Not Applicable

7. Annexes

Not Applicable