

# Medical Literature Monitoring Service Contractor Work Instruction (MLM WIN-07)

MLM Quality Assurance

## 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
DMTT	Data Management Tracking Tool
EMA	European Medicines Agency
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.
MLM	Medical Literature Monitoring

## 4. Instructions

### General principles

Quality Assurance activities will be undertaken for the following workstream activities:

- Screening of reference articles
- Review of articles
- Management of follow-up activities
- Processing of ICSRs
- Submission of ICSRs

100% quality assurance for all records will be undertaken for:

- Management of follow-up activities (weekly basis)
- Processing of ICSRs (per case)
- Submission of ICSRs (weekly basis)

For the remaining workstreams, the quality assurance activities will commence at 100% for the first two weeks of production and will reduce to 75% in the last two weeks of production subject to satisfactory performance.

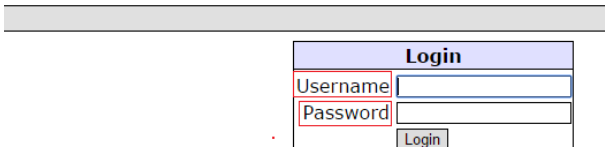
From month 2 quality assurance activities will be undertaken for 50% of all outputs and subject to satisfactory performance this will be reduced to 25% in month 3.

Weekly meetings with the EMA will be scheduled to discuss quality findings and inconsistencies.

From month 4 onwards quality assurance activities for all workstreams described above will be maintained at 5% until the duration of the programme, unless performance issues are deemed unsatisfactory.

#### 4.1. Quality Assurance for screening of literature

The initial Screening which is being quality assured should have been performed in accordance with MLM SOP-01 – Medical Literature Monitoring Screening and Reviewing Process and MLM WIN-01 – Screening Medical Literature

Step	Action
1. Login to DMTT	Access DMTT and enter the username and password.
	<div><b>Data Management Tracking Tool</b> </div>

1a.	<p>Upon successful login, select the Quality Assurance- DMTT Screening link from the left-hand side of the screen</p> <div><div>Quality Assurance</div><div><div>Quality Assurance - Duplicate Detection</div><div>Quality Assurance - Manual Recoding</div><div>Quality Assurance - ICSR Quality Review</div><div>Quality Assurance - xEVMPD Review (Art 57)</div><div>Quality Assurance - xEVMPD Review (Non EU products)</div><div>Quality Assurance - LMTT Screening</div><div>Quality Assurance - LMTT Review Reference</div><div>Quality Assurance - LMTT Case Processing</div></div></div>																																																
2. Load search	<p>Enter the appropriate substance group</p> <p>Enter the dates from previous day and the search day in the date of search field (eg. 01Jul 2015 to 02 Jul 2015, if the search day is -1 July 2015)</p> <div><div>Hide</div><div>QA Search LMTT Screening Records</div><div><div>Search QR checked articles:</div><div>&lt; Select &gt;</div></div><div><div>Search entry by Articles returned</div><div>&lt; Select &gt;</div></div><div><div>Search for a specific LMTT ID:</div><div></div></div><div><div>Search by Substance Group:</div><div></div><div>Type at least two letters for automatic suggestions</div></div><div><div>Search by Error Type</div><div><div>Major</div><div>Minor</div><div>To discuss</div><div>No Error</div></div></div><div><div>Search for entry 'searched' between a given time frame:</div><div>From</div><div></div><div>To</div><div></div></div><div><div>Search for entry by 'date of search' range:</div><div>From</div><div></div><div>To</div><div></div></div><div><div>Search by Library:</div><div>&lt; Select &gt;</div></div><div><div>Search by Article Title:</div><div></div></div><div><div>Search for entry registered by a given user :</div><div>&lt; All Users &gt;</div></div><div><div>Search for entry quality reviewed within a given time frame</div><div>From</div><div></div><div>To</div><div></div></div><div><div>Search for entry quality reviewed by a specific user :</div><div>&lt; All Users &gt;</div></div><div><div>Where a random selection of articles is required for a given number, enter desired number of randomly selected articles within a given search criteria. Where all articles are required - leave blank and all articles will be retrieved</div><div></div></div><div><div>Submit</div></div></div>																																																
3. Submit search	<p>Press submit, and the search results are retrieved.</p> <div><div>Show</div><div>QA Search LMTT Screening Records</div><div><div>Search Results: 15</div><table><thead><tr><th>LMTT ID</th><th>Final QA Status</th><th>ACTION</th></tr></thead><tbody><tr><td>0005216</td><td></td><td></td></tr><tr><td>0005220</td><td></td><td></td></tr><tr><td>0005226</td><td></td><td></td></tr><tr><td>0005233</td><td></td><td></td></tr><tr><td>0005243</td><td></td><td></td></tr><tr><td>0005247</td><td></td><td></td></tr><tr><td>0005257</td><td></td><td></td></tr><tr><td>0005280</td><td></td><td></td></tr><tr><td>0005290</td><td></td><td></td></tr><tr><td>0005297</td><td></td><td></td></tr><tr><td>0005305</td><td></td><td></td></tr><tr><td>0005312</td><td></td><td></td></tr><tr><td>0005322</td><td></td><td></td></tr><tr><td>0005327</td><td></td><td></td></tr><tr><td>0005332</td><td></td><td></td></tr></tbody></table></div></div>	LMTT ID	Final QA Status	ACTION	0005216			0005220			0005226			0005233			0005243			0005247			0005257			0005280			0005290			0005297			0005305			0005312			0005322			0005327			0005332		
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4.  
Review of records.

Review the results from the execution of the associated search string for the substance being reviewed by selecting 'Action'.

Confirm number of records retrieved within the DMTT matches with number of records retrieved within the search output.

Select a record from the display for review and assess entry within screening against the reference details in the search output. Where updates are required capture within Kinapse QA field.

Enter Data		Kinapse QA
LMTT ID:	0005216	
Enter the date & time of search:	09-Jul-2015 11:01	Enter your comment here....
Enter the search date range:	From 08-Jul-2015 To 09-Jul-2015	Enter your comment here....
Substance Group:	1-PARACETAMOL	Enter your comment here....
Library:	EMBASE	Enter your comment here....
No Articles returned	No	Enter your comment here....
Journal:	International Orthopaedics	Enter your comment here....
Article Title:	The effect of intra-articular Tenoxicam on knee effusion after arthroscopy.	Enter your comment here....
Primary Source Country:	FR	Enter your comment here....

Once all fields have been reviewed, select appropriate 'Error Type' assessment.

If the work was acceptable, with no errors, mark the Kinapse QA status as 'Accepted'

If it was not acceptable, do not mark the Kinapse QA status as 'Accepted'.

Repeat for agreed percentage of entries retrieved from the DMTT Screening QA module for each active substance.

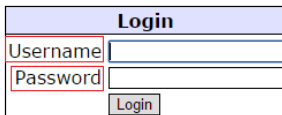
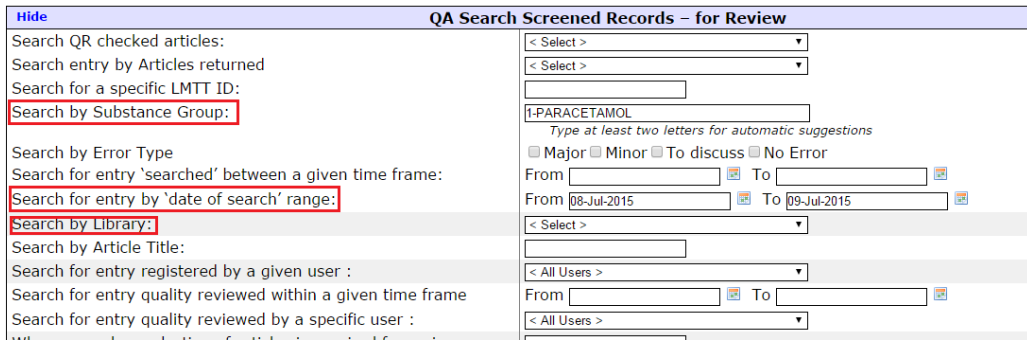
Duplicate LMTT ID:	
Error Type:	<input type="checkbox"/> Major <input type="checkbox"/> To discuss <input type="checkbox"/> Resolved <input type="checkbox"/> Accepted <input type="checkbox"/> Accepted by EMA
Kinapse QA Status:	<input type="checkbox"/> Minor <input checked="" type="checkbox"/> No Error
Final QA Status:	
Submit	

















Major is defined as either a missing article, more than 3 incorrectly populated fields in the same record or a consistent error by the same user for over 3 records. Where a Major error has been identified the QA lead is responsible for discussing the identified errors with the responsible screener and supporting in refresher training.

100% of the users records will then be reviewed for a 1 day period to ensure the refresher training was impactful.

## 4.2. Quality Assurance for reviewing of literature references

The literature reviewing which is being quality assured should have been performed in accordance with MLM SOP-01 – Medical Literature Monitoring Screening and Reviewing Process and MLM WIN-02 – Reviewing MLM Literature

Step	Action
5. Login to DMTT	Access DMTT and enter the username and password.
	<p><b>Data Management Tracking Tool</b></p> 
5a.	<p>Upon successful login, select the Quality Assurance- DMTT Review Reference link from the left-hand side of the screen</p> <p><b>Report Viewing</b> Create and View Reports</p> <p><b>Quality Assurance</b>  <a href="#">Quality Assurance - Duplicate Detection</a>  <a href="#">Quality Review - Manual Recoding</a>  <a href="#">Quality Assurance - ICSR Quality Review</a>  <a href="#">Quality Assurance - xEVMPD Review (Art 57)</a>  <a href="#">Quality Assurance - xEVMPD Review (Non EU products)</a>  <a href="#">Quality Assurance - LMTT Screening</a>  <a href="#">Quality Assurance – LMTT Review Reference</a>  <a href="#">Quality Assurance – LMTT Case Processing</a>  <a href="#">Quality Assurance – LMTT Case Submission</a> </p>
6. Load search	<p>Enter the appropriate substance group and library</p> <p>Enter the dates from previous day and the search day in the date of search field (eg. 08Jul 2015 to 09 Jul 2015, if the search day is -9 July 2015)</p> 
7. Submit search	Press submit, and the search results are retrieved.

		<a href="#">Show</a> <b>QA Search Screened Records – for Review</b>																								
		<b>Search Results: 32</b>																								
LMTT ID	Case No	Valid ICSR	Final QA Status	<b>ACTION</b>																						
0004660		No																								
0004673		No																								
0004680		No																								
0004685		No																								
0004693	CO-MLMSERVICE-20150709-0004693-1	Yes																								
0004698		No																								
0004707	FR-MLMSERVICE-20150709-0004707-1	Yes																								
0004713		No																								
0004767		No																								
0004775		No																								
0004781		No																								
0004789		No																								
0004797		No																								
0004807		No																								
0004815		No																								
0004824		No																								
8.	<p>Review of records.</p> <p>Review the results from the execution of the associated search string for the substance being reviewed by selecting 'Action'.</p> <p>Select a record from the display for review and assess entry within review against the reference details in the search output. Where updates are required capture within Kinapse QA field.</p>																									
<p>Logged in: <b>Humaira Qureshi</b> - <a href="#">HQureshi</a> [<a href="#">Log off</a>]   <a href="#">Home</a> » <a href="#">Quality Assurance – LMTT Review Reference</a></p> <p align="center"><b>Quality Assurance - LMTT Review Reference</b></p> <table border="1"> <thead> <tr> <th colspan="2">Enter Data</th> <th><b>Kinapse QA</b></th> </tr> </thead> <tbody> <tr> <td>LMTT ID:</td> <td><input type="text" value="4660"/></td> <td><div>Enter your comment here....</div></td> </tr> <tr> <td>Case No:</td> <td><input type="text"/></td> <td><div>Enter your comment here....</div></td> </tr> <tr> <td>Are there valid ICSRs?</td> <td><input type="text" value="No"/></td> <td><div>Enter your comment here....</div></td> </tr> <tr> <td>Comments:</td> <td><div><input type="text"/></div></td> <td><div>Enter your comment here....</div></td> </tr> <tr> <td>Exclusion Criteria:</td> <td><input type="text" value="Aggregated data on patients"/></td> <td><div>Enter your comment here....</div></td> </tr> <tr> <td>Confirm EMA approved:</td> <td><input type="text" value="No"/></td> <td><div>Enter your comment here....</div></td> </tr> </tbody> </table> <p>Once all fields have been reviewed, select appropriate 'Error Type' assessment.</p> <p>If the work was acceptable, with no errors, mark the Kinapse QA status as 'Accepted'</p> <p>If it was not acceptable, do not mark the Kinapse QA status as 'Accepted'</p> <p>Repeat for agreed percentage of entries retrieved from the DMTT Literature reviewing QA module for each active substance.</p>						Enter Data		<b>Kinapse QA</b>	LMTT ID:	<input type="text" value="4660"/>	<div>Enter your comment here....</div>	Case No:	<input type="text"/>	<div>Enter your comment here....</div>	Are there valid ICSRs?	<input type="text" value="No"/>	<div>Enter your comment here....</div>	Comments:	<div><input type="text"/></div>	<div>Enter your comment here....</div>	Exclusion Criteria:	<input type="text" value="Aggregated data on patients"/>	<div>Enter your comment here....</div>	Confirm EMA approved:	<input type="text" value="No"/>	<div>Enter your comment here....</div>
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Confirm EMA approved:	<input type="text" value="No"/>	<div>Enter your comment here....</div>																								

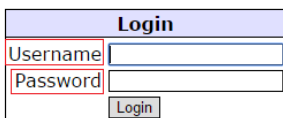
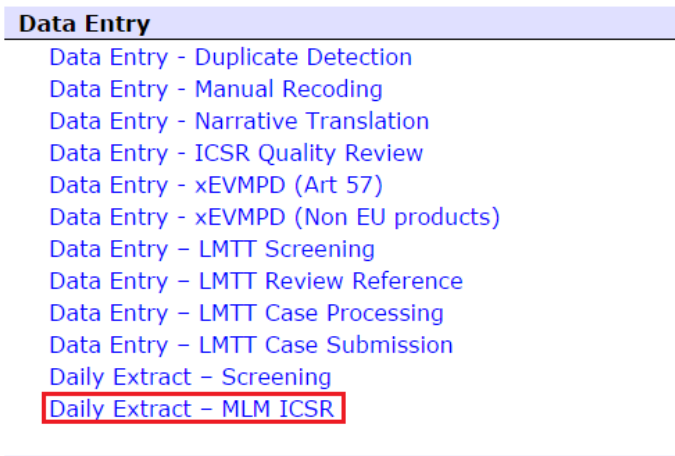
Duplicate LMTT ID: <input type="text"/> Error Type: <input type="text"/> Kinapse QA Status: <input type="text"/> Final QA Status: <input type="text"/>	<input type="checkbox"/> Major <input type="checkbox"/> To discuss <input type="checkbox"/> Resolved <input type="checkbox"/> Accepted <input type="checkbox"/> Accepted by EMA	<input type="checkbox"/> Minor <input checked="" type="checkbox"/> No Error <input type="text"/>
<input type="button" value="Submit"/>		

Major is defined as a clearly incorrect decision (deciding that an article contains a confirmed or potential case when it does not, or vice versa) or a consistent error by the same user for over 3 records. Where a Major error has been identified the QA lead is responsible for discussing the identified errors with the responsible reviewer and supporting in refresher training.

100% of the users records will then be reviewed for a 1 day period to ensure the refresher training was impactful.

### 4.3. Quality Assurance for the Management of follow-up activities

The follow-up activities which are being quality assured should have been performed in accordance with MLM SOP-01 – Medical Literature Monitoring Screening and Reviewing Process, MLM SOP-02 - Processing of Medical Literature Monitoring ICSRs, MLM WIN-02 – Reviewing MLM Literature, MLM WIN-03 – Processing and reporting of MLM ICSRs and MLM WIN-04 - Follow-up MLM Literature

Step	Action
9. Login to DMTT	Access DMTT and enter the username and password.
	<b>Data Management Tracking Tool</b> 
9a.	Upon successful login, select the Data Entry- DMTT Daily Extract- MLM ICSR link from the left-hand side of the screen  

10.  
Load search

Select the Extract Excel button and the daily screening report will download

### Daily Extract – Screening

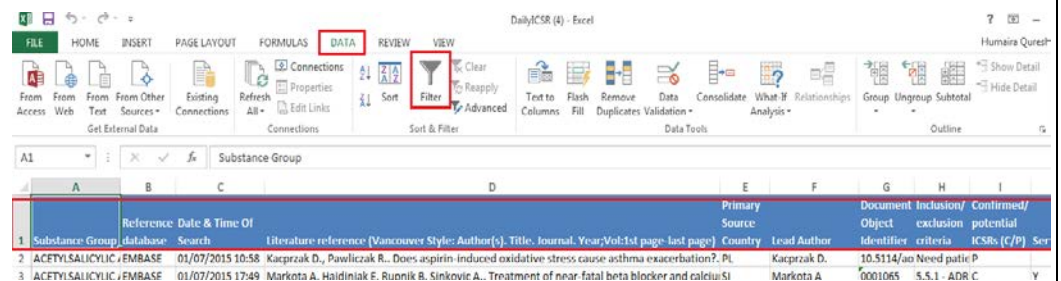
Activity	
Date	User
10-Jul-2015 04:38	Lavanya Kakileti (Lavanya)
09-Jul-2015 16:59	Humaira Qureshi (HQureshi)
09-Jul-2015 16:59	Humaira Qureshi (HQureshi)
09-Jul-2015 11:38	nethravathi krishnamurthy (nethravathi)
09-Jul-2015 10:00	Jahnavi Tallamyella (Jahnavi)
09-Jul-2015 09:58	Neha Sharma (neha)
09-Jul-2015 09:42	Kruthi Gurudev (KruthiG)
09-Jul-2015 09:37	Kruthi Gurudev (KruthiG)
09-Jul-2015 09:27	Nazia Syed (Nazias)
09-Jul-2015 08:50	Pareek Priyanka (priyankaP)

Records created on: From 10-Jul-2015

**Extract Excel**

2015

Select row 1 with the column headers and apply filters to the spreadsheet, using the data tab in excel as below.



11.  
Review of Follow-up status

Filter in column H to review all Full text Article requests. Ensure that Column K has a date or NA entered. Ensure Column L has a full text receive date entered. Where column L is blank and a date has been entered in column K, ensure a follow up email is sent to receive latest expected receipt date. Additionally review the follow up requested date (if required) and ensure that the date of follow up was not historic. If it has passed, then this must be passed to the review team to ensure the reference is updated to reflect closure to follow-up.

Primary Source		Document Object		Confirmed/ potential		Full text request date		Full text receive date	
Country	Lead Author	Identifiers	Inclusion/ exclusion criteria	CSRs (C/	Serious	request date	receive date	Tr	re
7 US	Cavaguti RF	10.1007/s0	Full text requested	P		N/A	01/07/2015		
8 JP	Nakazato S	10.1684/ej	Full text requested	P		N/A	01/07/2015		
9 IT	Pagliarello C	10.1684/ej	Full text requested	P		N/A	01/07/2015		
10 CN	Liang Y	DOI: 10.111	Full text requested	P		N/A	01/07/2015		
13 US	Holliman J	http://www	Full text requested	P		N/A	01/07/2015		
14 CA	Raphael MJ	10.1503/cn	Full text requested	P		N/A	01/07/2015		
15 US	Binder A	10.1111/ha	Full text requested	P		N/A	01/07/2015		
16 ES	Aguilar C	10.1111/ha	Full text requested	P		N/A	01/07/2015		
18 US	Daniell HW	10.71007/?	Full text requested	P		N/A	01/07/2015		
19 US	Ali FI	10.1016/j.j	Full text requested	P		N/A	01/07/2015		
20 US	Thawabi M	10.1016/j.j	Full text requested	P		N/A	01/07/2015		
27 US	Dudzinski DM	10.1056/NE	Full text requested	P		N/A	01/07/2015		
28 IN	Abhinav C	10.1111/ij	Full text requested	P		N/A	01/07/2015		
40 US	Ryan NM	10.3109/15	Full text requested	P		N/A	01/07/2015		
42 SV	Brvar M	10.1007/s0	Full text requested	P		N/A	01/07/2015		

Filter in column H for all unidentifiable patients and then for no suspect drug. Ensure



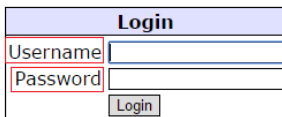
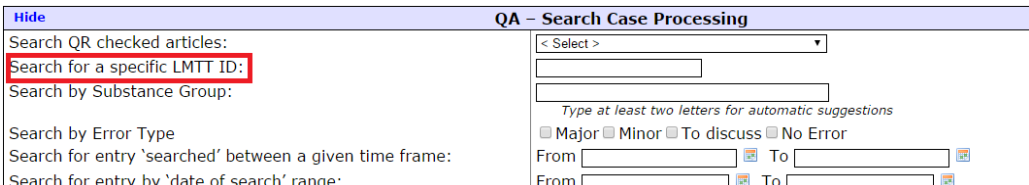
	<p>that Column K has a date or NA entered. Ensure Column L has a full text receive date entered. Where column L is blank and a date has been entered in column K, ensure a follow up email is sent to receive latest expected receipt date. Additionally review the follow up requested date (if required) and ensure that the date of follow up was not historic. If it has passed, then this must be passed to the review team to ensure the reference is updated to reflect closure to follow-up.</p> <p>Undertake the same process for the screening spreadsheet and ensure that where articles have been assessed with exclusion criteria- unidentifiable patient, no suspect drug or no reporter, that the case has follow-up requested and that the date the follow up was required has not surpassed.</p>
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#### 4.4. Quality Assurance for the Processing of ICSRs

Quality Assurance for ICSRs within the Medical Literature Processing must occur by day 6 at the very latest. The purpose of this review is to assess the quality of the data entry.

The ICSR processing activities which are being quality assured should have been performed in accordance with MLM SOP-02 - Processing of Medical Literature Monitoring ICSRs, MLM WIN-03 – Processing and reporting of MLM ICSRs and MLM WIN-06 - MLM Duplicate Management Process

Upon completion of case processing the following steps will be undertaken

Step	Action
12. Login to DMTT	Access DMTT and enter the username and password.
	<p>Data Management Tracking Tool</p> 
12a.	<p>Upon successful login, select the Quality Assurance- DMTT Case processing link from the left-hand side of the screen</p> <p><b>Quality Assurance</b></p> <ul style="list-style-type: none"> <li>Quality Assurance - Duplicate Detection</li> <li>Quality Assurance - Manual Recoding</li> <li>Quality Assurance - ICSR Quality Review</li> <li>Quality Assurance - xEVMPD Review (Art 57)</li> <li>Quality Assurance - xEVMPD Review (Non EU products)</li> <li>Quality Assurance - LMTT Screening</li> <li>Quality Assurance - LMTT Review Reference</li> <li><b>Quality Assurance - LMTT Case Processing</b></li> <li>Quality Assurance - LMTT Case Submission</li> </ul>
Retrieval of cases	<p>Enter Appropriate DMTT IDD in search field and hit submit:</p> 

	<p>Select case from search results</p> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <div style="display: flex; justify-content: space-between; border-bottom: 1px solid black; padding-bottom: 5px;"> <span>Show</span> <span>QA – Search Case Process</span> </div> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <thead> <tr style="background-color: #e6f2ff;"> <th colspan="3">Search Results: 8</th> </tr> <tr style="background-color: #e6f2ff;"> <th style="width: 40%;">LMTT ID</th> <th style="width: 40%;">Final QA Status</th> <th style="width: 20%;">ACTION</th> </tr> </thead> <tbody> <tr> <td>US-MLMSERVICE-20150703-0002605-1</td> <td></td> <td style="text-align: center;"></td> </tr> </tbody> </table> </div>	Search Results: 8			LMTT ID	Final QA Status	ACTION	US-MLMSERVICE-20150703-0002605-1																									
Search Results: 8																																	
LMTT ID	Final QA Status	ACTION																															
US-MLMSERVICE-20150703-0002605-1																																	
Review of record	<p>Select a record from the display for review and assess entry within review against the source. Where updates are required capture within Kinapse QA field.</p> <div style="border: 1px solid black; padding: 10px; margin-top: 10px;"> <h3 style="text-align: center; margin: 0;">Quality Assurance - LMTT Case Processing</h3> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #e6f2ff;"> <th colspan="2">Enter Data</th> <th style="width: 15%; text-align: center;">Kinapse QA</th> </tr> </thead> <tbody> <tr> <td style="width: 40%;">CASE NUMBER:</td> <td style="width: 30%;">US-MLMSERVICE-20150703-0002605-1</td> <td style="width: 25%;">Enter your comment here...</td> </tr> <tr> <td>Literature reference (Vancouver style):</td> <td>Case Reports in Medicine</td> <td>Enter your comment here...</td> </tr> <tr> <td>Author:</td> <td>Al Danaf J, Madara J, Dietsche C.</td> <td>Enter your comment here...</td> </tr> <tr> <td>Country:</td> <td>US</td> <td>Enter your comment here...</td> </tr> <tr> <td>Valid ICSR:</td> <td>Yes</td> <td>Enter your comment here...</td> </tr> <tr> <td>Has Full text article been requested?</td> <td>No</td> <td>Enter your comment here...</td> </tr> <tr> <td>Date Requested:</td> <td></td> <td>Enter your comment here...</td> </tr> </tbody> </table> <p style="margin-top: 10px;">Once all fields have been reviewed, select appropriate 'Error Type' assessment, if applicable.</p> <p>A Major error is defined as one which would affect timelines (a serious case entered as non-serious), signal detection (missing or otherwise erroneous reactions or drugs), significantly poor quality in a case: e.g. test data completely omitted, narrative not containing relevant salient facts about the case, multiple small errors in the case, or a consistent error by the same user for over 3 records. Where a Major error has been identified the QA lead is responsible for discussing the identified errors with the responsible reviewer and supporting in refresher training.</p> <p>If the work was acceptable, with no errors, mark the Kinapse QA status as 'Accepted'</p> <p>If it was not acceptable, do not mark the Kinapse QA status as 'Accepted'</p> <div style="border: 1px solid black; padding: 10px; margin-top: 10px;"> <table style="width: 100%;"> <tr> <td style="width: 50%;">Duplicate LMTT ID:</td> <td><input style="width: 100%;" type="text"/></td> </tr> <tr> <td>Error Type:</td> <td> <input type="checkbox"/> Major      <input type="checkbox"/> Minor  <input type="checkbox"/> To discuss      <input checked="" type="checkbox"/> No Error  <input type="checkbox"/> Resolved      <input style="width: 100%;" type="text"/> </td> </tr> <tr> <td>Kinapse QA Status:</td> <td> <input type="checkbox"/> Accepted  <input type="checkbox"/> Accepted by EMA         </td> </tr> <tr> <td>Final QA Status:</td> <td style="text-align: right;"> <input style="border: 2px solid red;" type="button" value="Submit"/> </td> </tr> </table> </div> <p style="margin-top: 10px;">Repeat for entries retrieved from the DMTT Literature reviewing QA module for each case.</p> </div>	Enter Data		Kinapse QA	CASE NUMBER:	US-MLMSERVICE-20150703-0002605-1	Enter your comment here...	Literature reference (Vancouver style):	Case Reports in Medicine	Enter your comment here...	Author:	Al Danaf J, Madara J, Dietsche C.	Enter your comment here...	Country:	US	Enter your comment here...	Valid ICSR:	Yes	Enter your comment here...	Has Full text article been requested?	No	Enter your comment here...	Date Requested:		Enter your comment here...	Duplicate LMTT ID:	<input style="width: 100%;" type="text"/>	Error Type:	<input type="checkbox"/> Major <input type="checkbox"/> Minor <input type="checkbox"/> To discuss <input checked="" type="checkbox"/> No Error <input type="checkbox"/> Resolved <input style="width: 100%;" type="text"/>	Kinapse QA Status:	<input type="checkbox"/> Accepted <input type="checkbox"/> Accepted by EMA	Final QA Status:	<input style="border: 2px solid red;" type="button" value="Submit"/>
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## 4.5. Quality Assurance for the Submission of ICSRs

Quality Assurance for submission of ICSRs must be completed one day after submission.

The purpose of this review is to assess whether the case was entered within the correct timelines & was sent to the correct destinations.

The ICSR submission activities which are being quality assured should have been performed in accordance with MLM SOP-02 - Processing of Medical Literature Monitoring ICSRs, MLM WIN-03 – Processing and reporting of MLM ICSRs

Step	Action						
13. Login to DMTT	Access DMTT and enter the username and password.						
	<div>Data Management Tracking Tool</div> <div><div>Login</div><div><div>Username</div><div> </div></div><div><div>Password</div><div> </div></div><div>Login</div></div>						
13a.	<div>Upon successful login, select the Quality Assurance- DMTT Case processing link from the left-hand side of the screen</div> <div>Create and View Reports</div> <div><div>Quality Assurance</div><div><div>Quality Assurance - Duplicate Detection</div><div>Quality Review - Manual Recoding</div><div>Quality Assurance - ICSR Quality Review</div><div>Quality Assurance - xEVMPD Review (Art 57)</div><div>Quality Assurance - xEVMPD Review (Non EU products)</div><div>Quality Assurance - LMTT Screening</div><div>Quality Assurance - LMTT Review Reference</div><div>Quality Assurance - LMTT Case Processing</div><div>Quality Assurance - LMTT Case Submission</div></div></div>						
Retrival of cases	<div>Enter Appropriate Case Number in search field and hit submit:</div> <div><div><div>Hide</div><div>LMTT – Search Case Submission</div></div><div><div>Search QR checked articles:</div><div>&lt; Select &gt;</div></div><div><div>Search by Status:</div><div><div><div><input type="checkbox"/> Not Submitted</div><div><input type="checkbox"/> Case submitted</div><div><input type="checkbox"/> 01 ACK Received</div><div><input type="checkbox"/> Case corrected (not nullified)</div><div><input type="checkbox"/> Case nullified</div><div><input type="checkbox"/> Follow up required</div></div></div></div><div><div>Search by CASE Number:</div><div></div></div><div><div>Search by Substance Group:</div><div><div>Type at least two letters for automatic suggestions</div></div></div><div><div>Search by Error Type</div><div><div><input type="checkbox"/> Major<input type="checkbox"/> Minor<input type="checkbox"/> To discuss<input type="checkbox"/> No Error</div></div></div><div><div>Search by Library:</div><div>&lt; Select &gt;</div></div></div> <div>Select case from search results</div> <div><div>Show</div><div>QA – Search Case Process</div></div> <div><div>Search Results: 8</div><table><tr><th>LMTT ID</th><th>Final QA Status</th><th>ACTION</th></tr><tr><td>US-MLMSERVICE-20150703-0002605-1</td><td></td><td></td></tr></table></div>	LMTT ID	Final QA Status	ACTION	US-MLMSERVICE-20150703-0002605-1		
LMTT ID	Final QA Status	ACTION					
US-MLMSERVICE-20150703-0002605-1							

## Review of record

Select a record from the display for review and assess entry within review against the source. Where updates are required capture within Kinapse QA field.

Case submitted:	<input checked="" type="checkbox"/> EV 07-Jul-2015	Enter your comment here....
	<input type="checkbox"/> NCA	Enter your comment here....
01 ACK Received:	EV <input type="radio"/> YES <input checked="" type="radio"/> NO Date Received:	Enter your comment here....
	NCA <input type="radio"/> YES <input checked="" type="radio"/> NO Date Received:	Enter your comment here....
FU Case submitted:	<input type="checkbox"/> EV	Enter your comment here....
	<input type="checkbox"/> NCA	Enter your comment here....
01 ACK Received:	EV <input type="radio"/> YES <input checked="" type="radio"/> NO Date Received:	Enter your comment here....
	NCA <input type="radio"/> YES <input checked="" type="radio"/> NO Date Received:	Enter your comment here....

Once all fields have been reviewed, select appropriate 'Error Type' assessment, if applicable.

A Major error is defined as an ICSR which was submitted later than day 7 (for serious cases) or day 21 (for non-serious cases) or which was not sent to one or more of the receivers to which it should have been.

If the work was acceptable, with no errors, mark the Kinapse QA status as 'Accepted'

If it was not acceptable, do not mark the Kinapse QA status as 'Accepted'

Duplicate LMTT ID:	
Error Type:	<input type="checkbox"/> Major <input type="checkbox"/> Minor <input type="checkbox"/> To discuss <input checked="" type="checkbox"/> No Error <input type="checkbox"/> Resolved <input type="text"/>
Kinapse QA Status:	<input type="checkbox"/> Accepted
Final QA Status:	<input type="checkbox"/> Accepted by EMA
Submit	

Repeat for entries retrieved from the DMTT Literature reviewing QA module for each case.