Medical Literature Monitoring Service Contractor Work Instruction (MLM WIN-04)

Performing Follow-Up for MLM ICSRs

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 attempts for follow-up are stored in the Data Management Tracking Tool and on the SharePoint site for each ICSR.

Definitions

Term	Definition
EEA	European Economic Area
EMA	European Medicines Agency
EudraVigilance	The European data-processing network and management system, which has been developed according to internationally agreed standards and which allows the EMEA to manage the electronic data exchange of Individual Case Safety Reports (ICSRs) and to support the EU pharmacovigilance activities at Community level.
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

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3. Instructions

General principles

In accordance with the detailed guide regarding the monitoring of medical literature and the entry of relevant information into the EudraVigilance database by the European Medicines Agency (EMA/161530/2014), one attempt for follow-up is made with the primary author for confirmed serious cases based on a risk-based approach.

This refers to individual cases, where either the outcome is not known or pre-defined clinical information (EMA/409859/2015) is missing as regards important medical events (IME).

Follow-up is also sought for both serious & non-serious potential cases reactions where the reviewers suspect, or are certain, that there was an adverse drug reaction, but not all of the minimum reporting criteria for a valid ICSR are present in the article.

All personal data, received in the course of follow-up that could be used to identify the patient, such as name, initials or date of birth, is to be anonymised to ensure full compliance of the EU data protection legislation.

Any attempt to obtain follow-up information is documented and a check for potential duplicates in EudraVigilance is performed in the context of processing of any new-follow-up information.

Follow-up methods applied are tailored towards optimising the collection of missing information with the aim of encouraging the primary author(s) to submit new information relevant for the scientific evaluation of a particular safety concern.

3.1. Initiating Follow-up Process for Serious Valid ICSRs

Step	Action
• Assess the need for follow-up	During case processing, review information in serious ICSR, and determine additional information required. For example, this could include following up for an unknown outcome or information regarding test results where they were implied but not provided. Select that follow-up is to be requested in the DMTT.
• Create entry in follow-up tracker	Create row in Follow-up tracker on SharePoint, and enter • DMTT ID • Substance Group # • Author • Email ID • Valid ICSR = Y
3 Select relevant questions from library on a risk based approach.	Access the follow-up question library in the follow-up tracker. Select standardised questions in follow-up tracker to be sent and copy paste in in column F “follow-up questions to be asked”. Save the follow-up tracker on the SharePoint site.
4 Medical Review	Physician reviewing case, checks follow-up tracker and adds / updates questions as required based on medical judgement.
5 Follow-up sent.	Using the template in Annex 1, prepare the follow-up form in email format and paste the questions into the left hand column of the table. Send the email from

	MLM@kinapse.com. Update the follow-up tracker that the follow-up has been sent out. The expected date is auto populated to '30 days' time. Amend if necessary. Upload follow-up email into DMTT.

3.2. Follow-up of potential ICSRs

Step	Action
1 Potential ICSR identified	Following review of the full text article, if there is still an unconfirmed but potential ADR, enter follow-up required in DMTT review screen.
2 Create entry in follow-up tracker	Create row in Follow-up tracker on SharePoint, and enter • DMTT ID • Substance Group# • Author • Email ID • Valid ICSR = No
3 Select relevant questions from library on a risk based approach.	Access the follow-up question library in the follow-up tracker. Select questions to be sent to confirm the ADR, and any other relevant information. Copy paste in in column F "follow-up questions to be asked". Save follow-up tracker the follow-up tracker on SharePoint.
4 Medical Review	Physician reviews questions, checks follow-up tracker and updates questions as required based on medical judgement.
5 Follow-up sent.	Using the template in Annex 2, prepare the follow-up form in email format and paste the questions from the follow-up tracker into the left hand column of the table. Send the email from MLM@kinapse.com. Update the follow-up tracker on SharePoint that the follow-up has been sent out. The expected date is auto populated to '30 days' time. Upload follow-up email into DMTT.

3.3. Monitoring of responses

Step	Action
1 Assess the need for follow-up	Monitor mlm@kinapse.com for responses to follow-up on a continuous basis.
2 Triage follow-up	Review the responses received to determine if the information received is new information and requiring a case update, and determining associated timeliness (i.e. has a non-serious case become serious). The DMTT is updated with the follow-up received date and a new case version is created if new information is received. If no new information is received in the response, upload follow-up email into

	DMTT and notify service desk team to include footnote in spreadsheet that no new case version is to be created. If potential ICSR follow-up confirms the presence of an ADR, update DMTT with valid ICSR, upload source into DMTT.
3 Update case with new information	Process all new information as follow-up in accordance with WIN/MLM/003.
4 Archive email	Once action taken, save email on case file Shared Drive.

Annex 1 – Template for sending follow-up for valid ICSRs

Subject:

Our Reference: (DMTT ID) Request for follow-up for Adverse Drug Reaction reported in literature

Message body:
Dear [insert name of primary author]

Further to your publication (insert in Vancouver style) we would appreciate if you could provide us additional information in relation to the serious adverse reaction experienced by the patient(s).

To help facilitate this we have provided specific questions below, but also would gratefully receive any additional information that may be relevant to the patient and the adverse reaction.

We would be grateful if you could send your response by return email to MLM@kinapse.com.

Thank you in advance for your contribution to our ongoing safety surveillance activities.

With best regards,

Medical Literature Monitoring Team

Question	**Answer**
Additional Commentary	

Annex 2 – Template for sending follow-up for potential ICSRs

Subject:

Our Reference: (DMTT ID) Request for follow-up for potential Adverse Drug Reaction reported in literature

Message body:

Dear [insert name of primary author]

Further to your publication (insert in Vancouver style) we would appreciate if you could provide us additional information to help us determine if an adverse reaction was experienced by a patient in your article.

To help facilitate this we have provided specific questions below, but also would gratefully receive any additional information that may be relevant to the patient and the potential adverse reaction.

We would be grateful if you could send your response, confirming whether an adverse reaction occurred by return email to MLM@kinapse.com.

Thank you in advance for your contribution to our ongoing safety surveillance activities.

With best regards,

Medical Literature Monitoring Team

Question	**Answer**
Additional Commentary	