



Standard operating procedure

Title: Management of general external pharmacovigilance-related queries assigned to the Pharmacovigilance Dashboard in JIRA		
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1. Purpose

This Standard Operating Procedure describes the management of general, external Pharmacovigilance-related queries received by the Pharmacovigilance Dashboard Coordinator.

2. Scope

This Standard Operating Procedure applies to the Pharmacovigilance Dashboard Coordinator within the Pharmacovigilance Department of the Inspections and Human Medicines Pharmacovigilance Division.

3. Responsibilities

It is the responsibility of the Head of Department to ensure that this procedure is adhered to within his/her Department. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of "9. Procedure"

4. Changes since last revision

- The Pharmacovigilance Helpdesk inbox (P-PV-Helpdesk@ema.europa.eu) was deleted;
- External Pharmacovigilance-related queries are received and handled only through JIRA.

5. Documents needed for this SOP

None.



6. Related documents

None.

7. Definitions

AskEMA and JIRA: The AskEMA management tool (JIRA) is used to record, manage and track all requests for information received via the web form (http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/landing/ask_ema_landing_page.jsp&mid=). Each request is allocated a unique reference number and the start date (the date when the query is received) and deadline (2-month deadline the query should be answered by) are recorded and tracked.

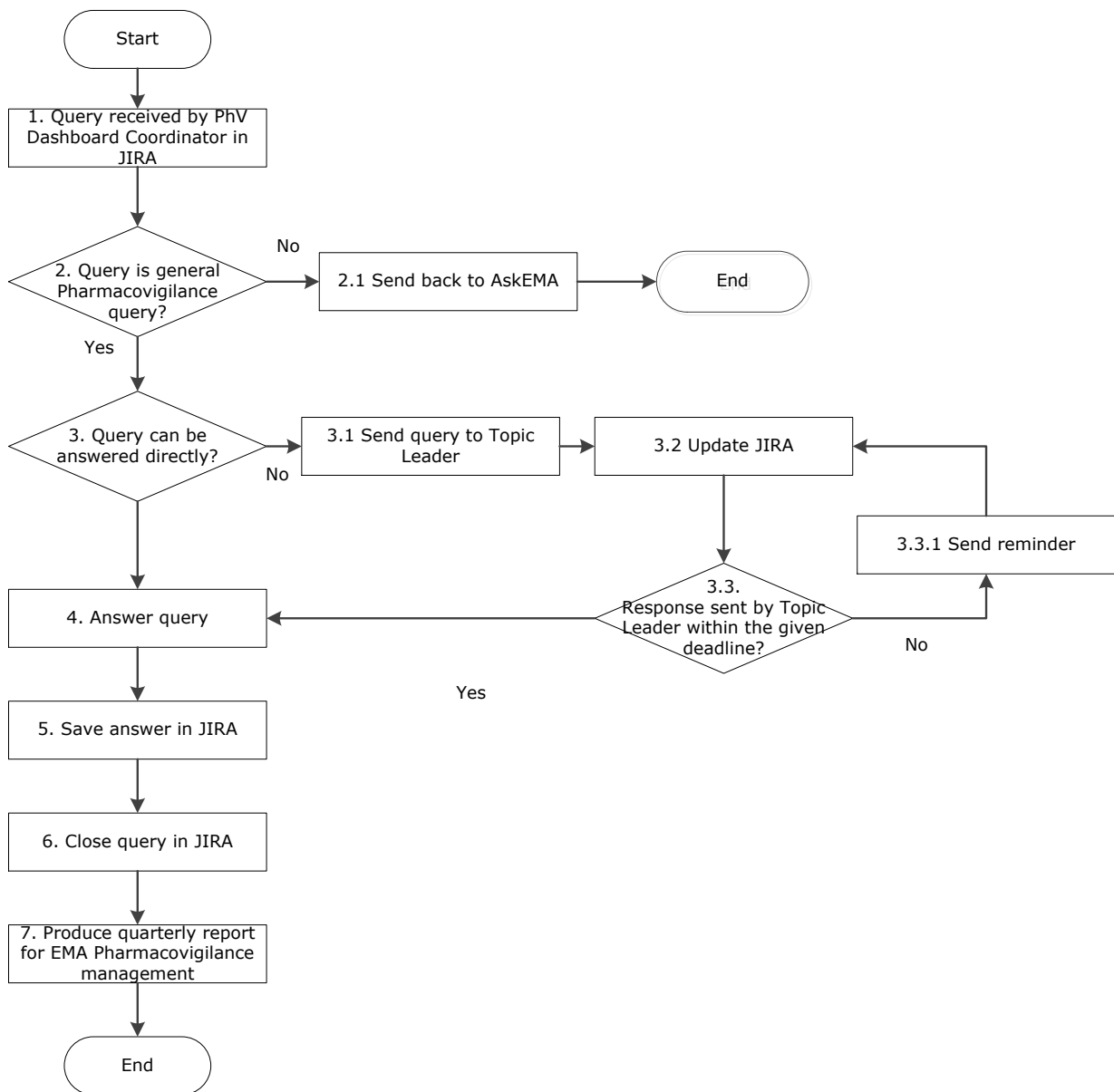
Pharmacovigilance Topic Leader: staff members within the Agency identified as contact points for providing answers to the queries in their area of expertise (list to be updated in case of any changes).

Pharmacovigilance Dashboard Coordinator: The staff member within P-PH who manages the external Pharmacovigilance-related queries submitted to the Pharmacovigilance Dashboard.

Pharmacovigilance Dashboard: Dedicated dashboard to the Pharmacovigilance queries in JIRA.

RFI: Request for information. RFI colleagues allocate the queries in JIRA to the relevant Dashboard Coordinators.

8. Process map(s)/ flow chart(s)



9. Procedure

Step	Action	Responsibility
1.	Receive external query by Dashboard coordinator in JIRA, allocated by the RFI team.	PhV Dashboard Coordinator
2.	Is it general Pharmacovigilance query? (Some specific queries should be addressed by different teams e.g. upcoming PSUR procedure; Art57, pharmacovigilance fees.) If NO, go to step 2.1 If YES, go to step 3	PhV Dashboard Coordinator
2.1	Send query back to AskEMA.	PhV Dashboard Coordinator
3.	Check if query can be answered directly (e.g. answer is straightforward or similar questions were answered in the past) If NO, go to step 3.1 If YES, go to step 4	PhV Dashboard Coordinator
3.1	Forward query to the relevant Pharmacovigilance Topic Leader to provide an answer within the given timeline / forward query with a proposed answer for validation within the given timeline. Go to step 3.2	PhV Dashboard Coordinator
3.2.	Update JIRA with the current status of the query, name and response of the Topic Leader.	PhV Dashboard Coordinator
3.3	Has a response arrived from the Topic Leader within the given timeframe? If NO, go to step 3.3.1 If YES, go to step 4	PhV Dashboard Coordinator
3.3.1	Send reminder to the Topic Leader.	PhV Dashboard Coordinator
4.	Send out the answer from JIRA.	PhV Dashboard Coordinator
5.	Save the response in JIRA when resolving the query.	PhV Dashboard Coordinator
6.	Close query in JIRA.	PhV Dashboard Coordinator
7.	Produce quarterly report for EMA Pharmacovigilance Division management based on the data available in JIRA.	PhV Dashboard Coordinator

10. Records

All queries and responses can be retrieved from JIRA on the Pharmacovigilance Dashboard at:

<http://askema.eudra.org/>

All responses sent out from JIRA are saved in DREAM (14. Working areas/14.04 P-Division/03. P-PH Activities/P-PH-MIM/Pharmacovigilance Helpdesk/2015/External correspondence)

The Topic Leaders list is located in DREAM (14. Working areas/14.04 P-Division/03. P-PH Activities/P-PH-MIM/Pharmacovigilance Helpdesk)

The quarterly EMA Management reports are stored in DREAM (Cabinets/14. Working areas/14.04 P-Division/03. P-PH Activities/P-PH-MIM/Pharmacovigilance Helpdesk/2015/Reports_2015)