EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Standard operating procedure

| Title: EPITT user registration and management | | |
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## 1. Purpose

This Standard Operating Procedure (SOP) describes the process followed by the members of the EPITT Business Team in the Surveillance and Epidemiology Service of the Pharmacovigilance and Epidemiology Department (P-PE-SVE) to handle all activities related to the user registration and management of the European Pharmacovigilance Issues Tracking Tool.

## 2. Scope

This SOP applies to the EPITT Business Team of P-PE-SVE and to the IT Service Helpdesk of I-OP-CUS. It covers the following situations:

- Creation of a new EPITT account
- Maintenance of an EPITT account (reset of a password, transfer of a FileMaker license and deletion of an EPITT account)

## 3. Responsibilities

It is the responsibility of the Head of Department to ensure that this procedure is adhered to within their own Department. The responsibility for the execution of each step of this procedure is identified in the right-hand column of **9. Procedure**.

## 4. Changes since last revision

- Updated process to create new users in EPITT and to include the involvement of the IT Service Desk via the EMA Service Desk portal.

## 5. Documents needed for this SOP

- WIN/H/3367 - EPITT User Registration and Management - Assessment of eligibility to an EPITT account:

  http://www.ema.europa.eu/docs/en_GB/document_library/Work_Instruction_-_WIN/2011/04/WC500105226.pdf

- WIN/H/3369 - EPITT User Registration and Management – Maintenance of the EPITT accounts and provision of trainings to users: http://www.ema.europa.eu/docs/en_GB/document_library/Work_Instruction_-_WIN/2011/04/WC500105227.pdf

- EPITT application form: G:\External Information Draft\EPITT\Application form

- "EPITT users tracking table" (for Member State and EMA users): where all the information pertaining to EPITT user accounts per NCA is stored. It includes users' details, current status and past movements of accounts (e.g. transfers) as well as information on training participation and access levels:

  Cabinets/03. Pharmacovigilance/PhV - Human/3.1 Data collection management/03 EPITT/02 EPITT Documentation and Users Support/EPITT Trainings/EPITT training sessions and users

## 6. Related documents

- EPITT User Guide (EMA/240784/2012): Cabinets/13. Projects/zz. Closed projects 2004-2014/00220 EPITT/02.0 Meetings/2010-09-07 System handover and Project closure/EPITT User Guide - Annexes - QA document/Status April 2012 and after

## 7. Definitions

**EPITT:** **European Pharmacovigilance Issues Tracking Tool** is a web-based system that tracks and monitors the safety of medicinal products regardless of their authorisation type. The objectives include the monitoring of life-cycles of a sub-set of safety signals and safety issues discussed at the level of the Pharmacovigilance Risk Assessment Committee (PRAC), the tracking of the Periodic Safety Update Report (PSUR) cycles' and timetables' assessments in the context of the PSUR Work Sharing project, and Risk Management activities.

**EPITT Business Team:** The EPITT Business team is composed of members of the P-PH-MIM Service in charge of the maintenance of EPITT. The maintenance includes the monitoring of data quality and information update; the monitoring of the use of EPITT such as trainings, EPITT helpdesk (business queries only); and the activities related to the management of EPITT accounts.

**File Maker Licence keys DB:** File Maker database in which users details are stored.

**Licence types and numbers:** There are two types of licenses which can be granted to new users: site license and single license. The site license (UK and NO) is a unique license shared by all users within the same NCA. The single license (all other countries) is a license granted to individual users. The decision on the type of license is made at NCA level depending on their IT requirements. The EMA currently provides up to 10 File Maker licence keys per NCA (for members working in the scientific departments). For additional EPITT accounts (when the 10 provided by the EMA have been reached), the NCAs need to purchase their own File Maker licences (one per extra user).

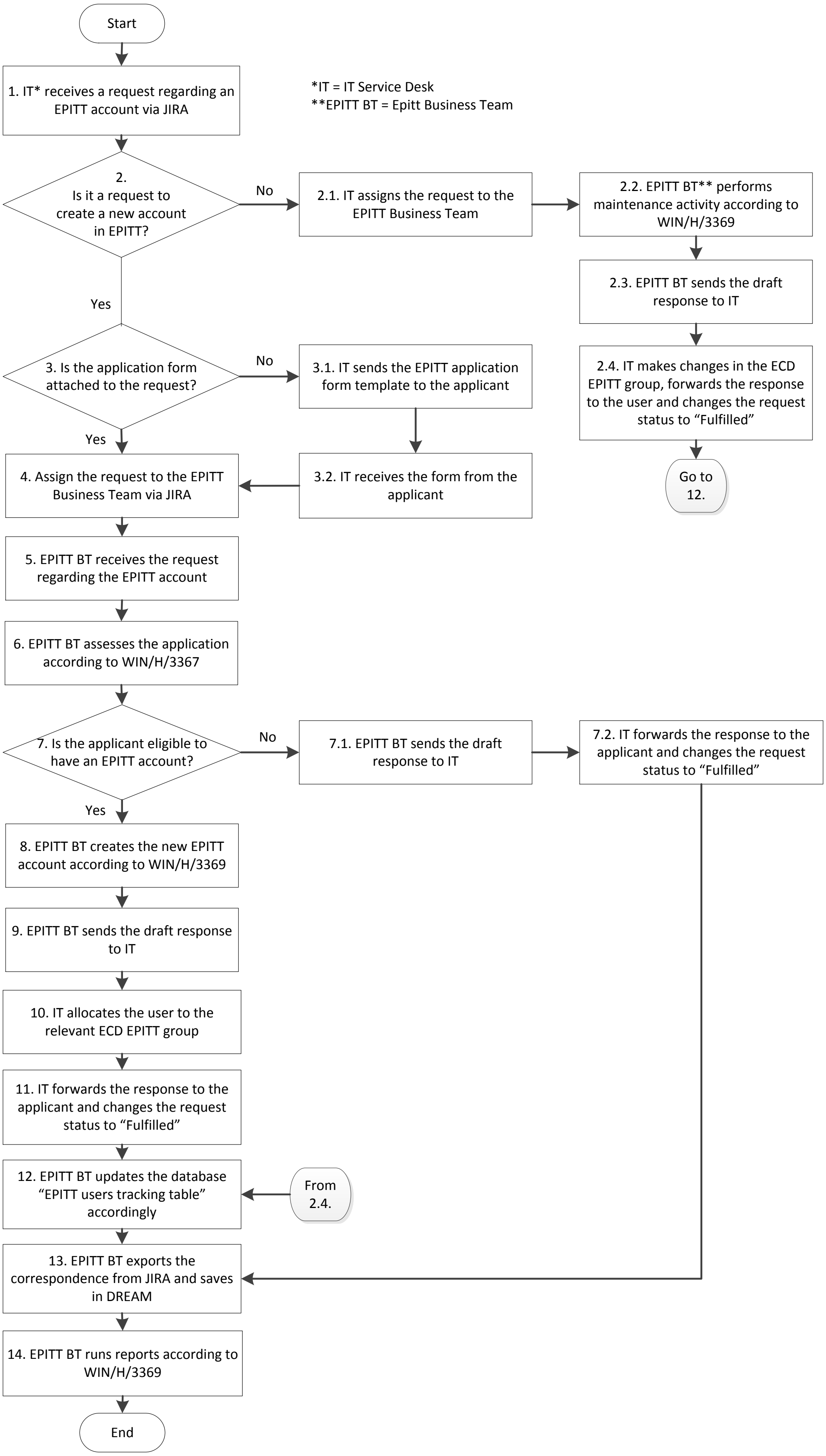
**EPITT access levels:** There are two different levels of access to EPITT: Read-Only and Data Entry. If the users have Read-Only Access, they are able to view the contents of the various topics in EPITT but they cannot add any information to the system. This level of access is granted to all users by default. On the other hand, Data Entry Access gives the users the possibility to not only view but also add contents in EPITT. This level of access is only granted upon request and following the user's participation in one of the regular EPITT trainings.

**ECD:** Central repository for current contact information at the Agency. The system is the Agency contact and organisation management system and is used to provide contact and organisation data to other Agency systems such as Experts database; MMS; SIAMED; CorpGXP; etc.

ECD User Manual

**JIRA:** 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.

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



# 9. Procedure

| Step | Action | Responsibility |
|---|---|---|
| 1. | Receive a request regarding an EPITT account via JIRA | IT Service Desk |
| 2. | Is it a request to create a new account in EPITT?<br>If yes, go to step 3.<br>If no, go to step 2.1. | IT Service Desk |
| 2.1. | Assign the request to the EPITT Business Team via JIRA | IT Service Desk |
| 2.2. | Perform maintenance activity in EPITT (e.g. transfer of a File Maker license, deletion of an EPITT account), according to WIN/H/3369 - EPITT User Registration and Management – Maintenance of the EPITT accounts and provision of trainings to users. | EPITT Business Team |
| 2.3. | Send the draft response to the IT Service Desk via JIRA and if relevant, indicate whether any changes should be made in the ECD EPITT group | EPITT Business Team |
| 2.4. | Make the necessary changes in the ECD EPITT group and forward the response to the user via JIRA. Change the status of the request to “Fulfilled”.<br>Then go to step 12. | IT Service Desk |
| 3. | Is the application form attached to the request?<br>If yes, go to step 4.<br>If no, go to step 3.1. | IT Service Desk |
| 3.1 | Send the EPITT application form template to the applicant via JIRA | IT Service Desk |
| 3.2 | Receive the form from the applicant via JIRA | IT Service Desk |
| 4. | Assign the request to the EPITT Business Team via JIRA | IT Service Desk |
| 5. | Receive the request regarding the EPITT account via JIRA | EPITT Business Team |
| 6. | Assess the application, according to WIN/H/3367 - EPITT User Registration and Management – Assessment of eligibility for an EPITT account. | EPITT Business Team |
| 7. | Is the applicant eligible to have an EPITT account?<br>If yes, go to step 8.<br>If no, go to step 7.1. | EPITT Business Team |
| 7.1. | Send the draft response to the IT Service Desk via JIRA | EPITT Business Team |
| 7.2. | Forward the response to the applicant via JIRA and change the status of the request to “Fulfilled”. Go to step 13 | IT Service Desk |
| 8. | Create the new EPITT account according to WIN/H/3369 - EPITT user registration and management – Maintenance of the EPITT accounts and provision of trainings to users | EPITT Business Team |
| 9. | Send the draft response including the instructions on how to access EPITT to the IT Service Desk and specify what access rights should be | EPITT Business Team |

| Step | Action | Responsibility |
|---|---|---|
| | allocated to the new user (ECD EPITT group fm_epitt_readonly or fm_epitt_country). By default the user will be provided with read only access (fm_epitt_readonly) until she/he has participated to the EPITT training. | |
| 10. | Allocate the user to the relevant ECD EPITT group | IT Service Desk |
| 11. | Forward the instructions on how to access EPITT to the new user via JIRA and change the status of the request to "Fulfilled". | IT Service Desk |
| 12. | Update the database "EPITT users tracking table" accordingly (e.g. by adding information on the new user or on the maintenance activity performed). | EPITT Business Team |
| 13. | Export the string of correspondence as well as the EPITT Application Form as applicable from JIRA and save them in the sub-folder corresponding to the applicant's country under the main folder '*EPITT correspondences with new users, including application forms*' or '*EPITT applications rejected*' as applicable. | EPITT Business Team |
| 14. | Run report for management purposes according to WIN/H/3369 - EPITT user registration and management – Maintenance of the EPITT accounts and provision of trainings to users.<br>Go to END | EPITT Business Team |
| | END | |

# 10. Records

- Once the account has been created and the new user informed, the EPITT application form and the JIRA correspondence with the details for accessing EPITT addressed to the new user are saved in the sub-folder dedicated to the user's country within the folder "EPITT correspondences with new users including application forms":

  Cabinets/03. Pharmacovigilance/PhV - Human/3.1 Data collection management/03 EPITT/02 EPITT Documentation and Users Support/Helpdesk Support for EPITT/EPITT correspondences with new users including application forms

- Whenever an application to access EPITT is rejected, the email sent to the applicant is saved in the folder "EPITT applications rejected":

  Cabinets/03. Pharmacovigilance/PhV - Human/3.1 Data collection management/03 EPITT/02 EPITT Documentation and Users Support/Helpdesk Support for EPITT/EPITT applications rejected

- The database "EPITT users tracking table" needs to be updated in the following events:
  - Change in users' details
  - Creation/deletion/transfer of accounts
  - Participation in training and subsequent change in access privileges

  Cabinets/03. Pharmacovigilance/PhV - Human/3.1 Data collection management/03 EPITT/02 EPITT Documentation and Users Support/EPITT Trainings/EPITT training sessions and users