



Work instructions

Title: EPITT user registration and management – Maintenance of the EPITT accounts and provision of trainings to users		
Applies to: EPITT Business Team members in the Surveillance and Epidemiology Service		
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1. 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 (JIRA).

2. Records

- "EPITT users tracking table" (for Member State and EMA users): 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
- Email template for new EPITT user: Cabinets/03. Pharmacovigilance/PhV - Human/3.1 Data collection management/03 EPITT/02 EPITT Documentation and Users Support/EPITT User Guide - Annexes - QA document
- Email template for MSs for bi-annual review of users: Cabinets/03. Pharmacovigilance/PhV - Human/3.1 Data collection management/03 EPITT/02 EPITT Documentation and Users Support/EPITT User Guide - Annexes - QA document
- EPITT application form template: [G:\External Information Draft\EPITT\Application form](#)
- Folder "EPITT accounts to be deleted or transferred": Cabinets/03. Pharmacovigilance/PhV - Human/3.1 Data collection management/03 EPITT/02 EPITT Documentation and Users Support/Helpdesk Support for EPITT/EPITT accounts to be deleted or transferred



- 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
- Folder "Review of the EPITT users list - <month> <year>":
Cabinets/03. Pharmacovigilance/PhV - Human/3.1 Data collection management/03 EPITT/02 EPITT Documentation and Users Support/Helpdesk Support for EPITT/Maintenance of the users list/Review of the EPITT users list - <month> <year>
- Email template for the next EPITT training session using Adobe - Call for expression of interest:
Cabinets/03. Pharmacovigilance/PhV - Human/3.1 Data collection management/03 EPITT/02 EPITT Documentation and Users Support/EPITT User Guide - Annexes - QA document
- Email template for the next EPITT training session using Adobe – Instructions on how to join:
Cabinets/03. Pharmacovigilance/PhV - Human/3.1 Data collection management/03 EPITT/02 EPITT Documentation and Users Support/EPITT User Guide - Annexes - QA document
- EPITT user guide: 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
- EPITT presentation - Adobe basic training: 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

3. Instructions

This WIN refers to SOP/H/3341 – EPITT User Registration and Management.

It provides instructions on how to deal with the following requests relating to the maintenance of EPITT accounts:

- Creation of an EPITT account;
- Deletion of an EPITT account;
- Transfer of File Maker licenses between former and new users;
- Generation of the user reports and description of the steps to follow to review the list of EPITT users on a bi-annual basis.

All requests linked to an EPITT account should be sent to the EMA Service Desk portal (JIRA) at <https://servicedesk.ema.europa.eu/>.

The IT Service Desk will then assign the requests to the EPITT Business Team via JIRA and all correspondence between the EPITT Business Team and the IT Service Desk should thereafter be done via JIRA.

This WIN is divided into 10 chapters:

1. Logging to "File Maker license keys database"
2. Searching for the Member State to which the applicant belongs
3. Creating an EPITT account
4. Changing EPITT access levels in ECD
5. Resetting the password of a user
6. Deleting an EPITT account
7. Transferring the File Maker license to a new user
8. Creating user reports
9. Performing the bi-annual review of users
10. Providing trainings to EPITT users

1. Logging to "File Maker license keys database":

1. a. To login to the database, click on the following link:

fmp://fmapps3.emea.eu.int/FM%20License%20keys_v4.fmp12

Enter user name and password provided by the EPITT Business Team.

Note: if the password for EPITT is different from that used to access the File Maker licenses database, the system may prompt to enter both, one at a time. However, if the same password is used for both databases, it will only have to be entered once.

2. Searching for the Member State to which the user belongs:

2. a. Click on the button 'FIND' on the left hand side to clear the screen (Image 1).

EMEA EXTERNAL FILEMAKER KEY AND USER EPITT MANAGEMENT

AGENCY NAME: AGES / PharmMed [Email] 28/05/2015

CITY: [] MAIN CONTACTS: []

COUNTRY: Austria

FIRST NAME	LAST NAME	PHONE NUMBER	EMAIL	DEPARTMENT
[]	[]	[]	[]	[]
[]	[]	[]	[]	Added by: Admin
[]	[]	[]	[]	Removed by:
[]	[]	[]	[]	[]
[]	[]	[]	[]	Added by: Admin
[]	[]	[]	[]	Removed by:

Image 1

Note: Always click on 'FIND' to clear the screen before selecting a country from the drop down list. If this step is omitted, the users and the related countries will be mixed up.

2. b. Select the country of the user using the drop down list 'Country' (Image 2).

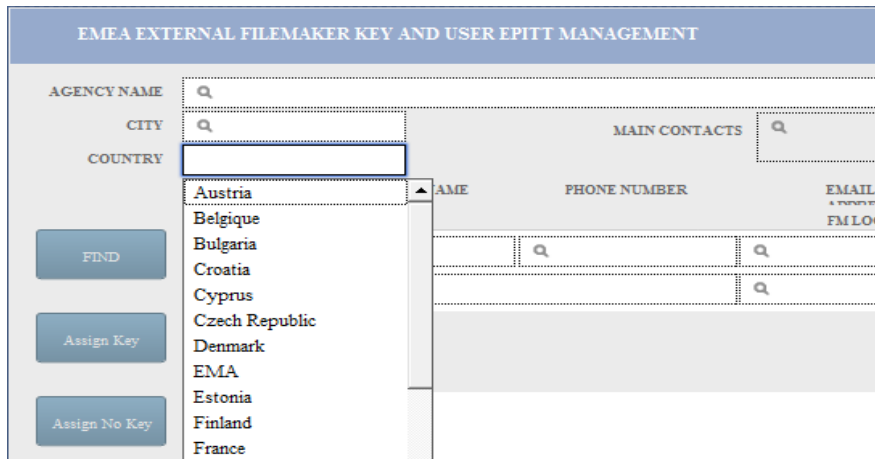


Image 2

2. c. Click on "Enter" in order to display the names and number of users from the country selected (Image 3).

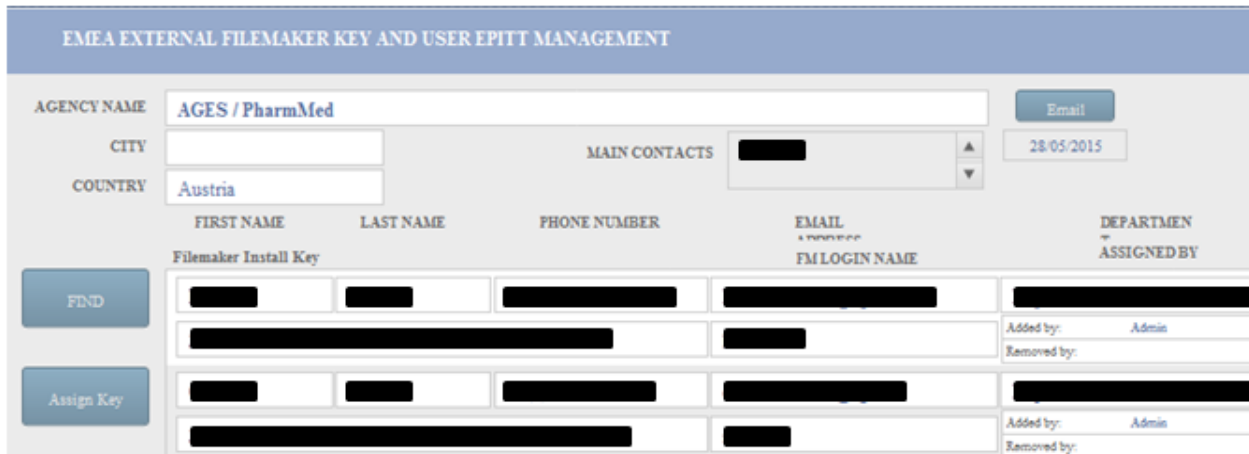


Image 3

3. Creating an EPITT account

3. a. Requests for new accounts are received by the IT Service Desk via JIRA and are then assigned to the EPITT Business Team for action. A request is only valid when accompanied by an application form duly completed and signed by the PRAC member/alternate/contact point for EPITT. Reference should be made to WIN/H/3367 on the "Assessment of eligibility for an EPITT account".

3. b. Check that the requester does not already have an EPITT account by searching for the relevant Member State following the instructions provided in steps 2.a. to 2.c. Once the user list for the selected Member State is displayed on the screen, scroll down and make sure that an account has not already been created for this user. Once it is confirmed that there is no existing account, click on 'Assign Key' if the request is for a new account with a license assigned to it. A window will appear on the screen requesting confirmation of the type of license key to be assigned. Click on 'Site' for the UK and NO, and on 'Single' for all other countries (Image 4).

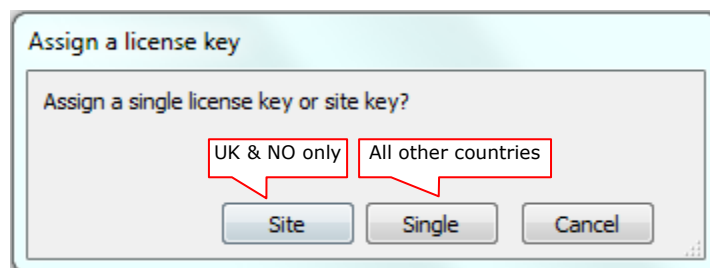


Image 4

If the new account is to be created without a license, click on 'Assign No Key'. Both of these commands are displayed on the left side of the screen directly underneath the 'FIND' button (see Image 3).

Note: FR, NL, DE, IT and DK have their own licenses thus always click on 'Assign No Key' when the request comes from one of these Member States.

3. c. A new empty row will show at the top (in case it does not, click anywhere outside the list of users for the empty row to be displayed). Use the information provided in the application form to manually populate the mandatory fields, which are identified below.

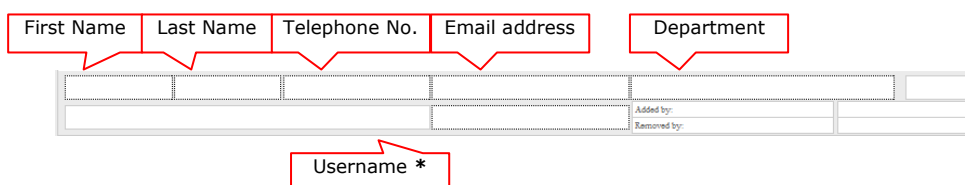


Image 5

* The user name corresponds to the ECD ID of the applicant.

3. d. Click on the button "Email" which is displayed on the right hand side of the screen. This will automatically generate an email addressed to the new user including the instructions on how to access EPITT.

Note: until the new email template is implemented in the system within the EPITT release 5.1, please replace the content of the email automatically generated from the database with the one saved in DREAM entitled "Email template for new EPITT user". Complete the parts highlighted in yellow font with the relevant information included in the File Maker license keys database.

3. e. Send this email template to the IT Service Desk, highlighting to which ECD EPITT group should the user be allocated:

- **fm_EPITT_country**: data entry access
- **fm_EPITT_readonly**: read only access
- **fm_EPITT_country-rmoe**: data entry access with extra rights in the RMP module (only for Risk Management Specialist community)
- **fm_EPITT_business**: data entry access with extra rights such as recording of PRAC records (only for specific EMA staffs working in the Pharmacovigilance Department)
- **fm_EPITT_admin**: all rights (only for the EPITT business team in the MIM Service of the Pharmacovigilance Department)

By default, a read only access (fm_epitt_readonly) will be provided until the user will have participated to the EPITT training.

3. f. Once the IT Service Desk will have allocated the user to the appropriate EPITT ECD group and forwarded the instructions on how to access EPITT to the new user, save the string of correspondence exported from JIRA as well as the EPITT Application Form in the DREAM subfolder dedicated to the new user's country within the folder "EPITT correspondences with new users including application forms".

3. g. Update the "EPITT users tracking table" by adding information on the new user account.

4. Changing EPITT access levels in ECD

If "Data Entry Access" was requested in the application form and the user has already participated in one of the regular EPITT trainings, her/his access privileges should be updated accordingly.

4. a. Only the IT Service Desk can modify the access privileges of an EPITT user in ECD. Send a request to update the users' privileges.

4. b. Update the document "EPITT users tracking table" accordingly.

5. Resetting the password of a user:

The user should submit a request via the EMA Service Desk portal at <https://servicedesk.ema.europa.eu/>.

6. Deleting an EPITT account (to be requested by the PRAC member/alternate/contact point for EPITT)

6. a. In the "File Maker license keys database", scroll down in the list obtained in step 2.c. until the row specific to the user is displayed.

If a File Maker license was allocated by the EMA to the user but there is no immediate need to transfer this license to another person working at the same NCA, click on 'Free Key' and on "Delete" at the end of the row (Image 6). The license is then released and available to a new EPITT user. However, if there is an immediate need to transfer this license to another person working at the same NCA, please refer to chapter 7.

If the EMA did not allocate any File Maker license to the user, click only on 'Delete'.

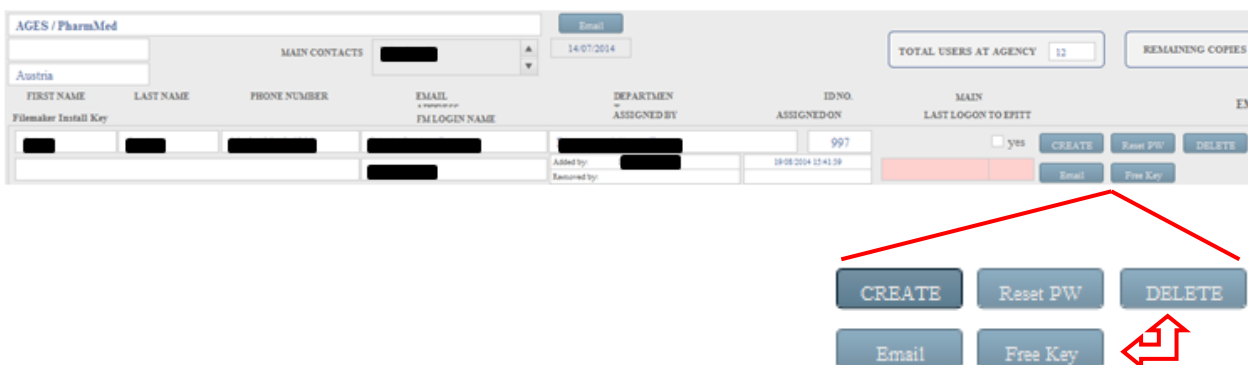


Image 6

6. b. Update the document "EPITT users tracking table" accordingly.
6. c. Request the IT Service Desk to delete the user from the ECD EPITT.
6. d. Once the IT Service Desk will have informed the requester that the account has been deleted, save the string of correspondence exported from JIRA in the DREAM subfolder dedicated to the new user's country within the folder "EPITT accounts to be deleted or transferred".

7. Transferring the File Maker license to a new user (to be requested by the PRAC member/alternate/contact point for EPITT)

7. a. In the "File Maker license keys database", scroll down in the list obtained in step 2.c. until the row specific to the user is displayed. Overwrite the details of the current user with the ones provided by the PRAC member/alternate/contact point for EPITT in the EPITT application form.

Note: The user name corresponds to the ECD ID of the applicant.

7. b. Click on the button "Email" which is displayed on the right hand side of the screen. This will automatically generate an email addressed to the new user including the instructions on how to access EPITT.

Note: until the new email template is implemented in the system within the EPITT release 5.1, please replace the content of the email automatically generated from the database with the one saved in DREAM entitled "Email template for new EPITT user". Complete the parts highlighted in yellow font with the relevant information included in the File Maker license keys database.

7. c. Send this email template to the IT Service Desk, highlighting the ECD EPITT group to which the new user should be allocated, and requesting the deletion of the former user from the ECD EPITT Group:

- **fm_EPITT_country:** data entry access
- **fm_EPITT_readonly:** read only access
- **fm_EPITT_country-rmoe:** data entry access with extra rights in the RMP module (only for Risk Management Specialist community)
- **fm_EPITT_business:** data entry access with extra rights such as recording of PRAC records (only for specific EMA staffs working in the Pharmacovigilance Department)
- **fm_EPITT_admin:** all rights (only for the EPITT business team in the MIM Service of the Pharmacovigilance Department)

By default, a read only access (fm_epitt_readonly) will be provided until the user will have participated to the EPITT training.

7. d. Once the IT Service Desk will have allocated the user to the appropriate EPITT ECD group and forwarded the instructions on how to access EPITT to the new user, save the string of correspondence exported from JIRA as well as the EPITT Application Form in the DREAM subfolder dedicated to the new user's country within the folder "EPITT accounts to be deleted or transferred".

7. e. Update the "EPITT users tracking table" by adding information on the new user account.

8. Creating user reports

On a monthly basis, the EPITT Business Team provides the Head of the Surveillance and Epidemiology Service with figures on user/account activities i.e. creation and deletion of accounts. Below are instructions on how to run user reports in order to obtain these figures. User reports are discarded once the relevant figures have been retrieved.

8. a. Log into the "File Maker license keys database" as explained in chapter 1.
8. b. In the top left-hand corner of the screen, select 'User activity' from the drop-down list 'Layout'.

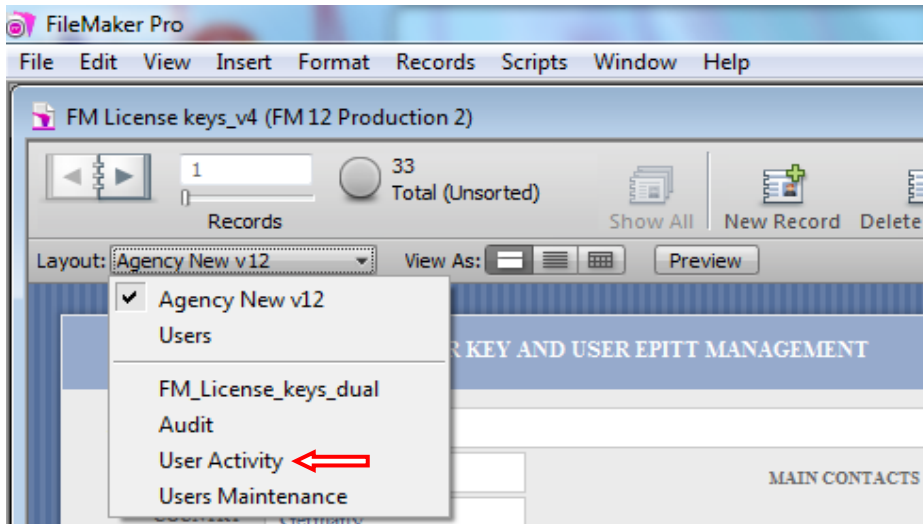


Image 7

8. c. The User Activity screen displays the list of current EPITT users along with information on their accounts. Click on 'EXCEL' to export the results into a spreadsheet.

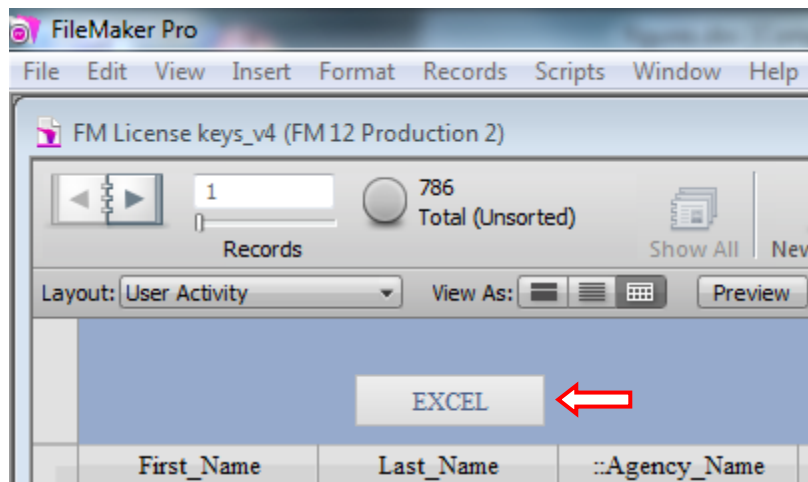


Image 8

Apply filters to the top row of the Excel table. To determine the number of accounts created within a given timeframe, filter by column F 'Assigned On' selecting only the relevant dates. For the number of accounts deleted, filter by column H 'Deleted On'.

A	B	C	D	E	F	G	H
First Name	Last Name	Agency Name	Agency Country	Assigned By	Assigned On	Deleted By	Deleted On

Image 9

Alternatively, information on the newly created users, deletions and transfers can also be found in the document "EPITT users tracking table". To determine the number of accounts created within a given timeframe, select the tab 'Current users' at the bottom of the "EPITT users tracking table" and filter by column H 'Date of creation of EPITT account' selecting only the relevant dates. For the number of accounts deleted and transferred, select the tab 'Former users' at the bottom of the "EPITT users tracking table" and filter by column G 'Date of deletion of former user' selecting only the relevant dates.

9. Performing the bi-annual review of users

Every six months (i.e. in January and June), a review of EPITT users across the various national agencies and the EMA is conducted. The goal is to keep the database up-to-date and thus ensure that accounts and license keys are only assigned to active users. To this end, national competent authorities are requested within a set deadline of 2 weeks to review their list of current users and provide the EMA with feedback upon which action can be taken e.g. delete an old user. Should no input be received by the set deadline, a reminder is sent by the EPITT Business Team. If no response is received, another 2 reminders in weekly intervals are sent, after which access is suspended to all users of the concerned NCA. Access is only restored upon receipt of a response from the NCA. Instructions are provided below.

9. a. Follow the instructions in chapter 2 to come to the screen shown in Image 3. Click on the button 'Email' next to the AGENCY NAME field.

Image 10

Click 'Yes' in the confirmation window that appears on the screen.

Image 11

An email addressed to the contact point of the NCA will be generated automatically.

Note: until the new email template is implemented in the system with release 5.1, please replace the content of the email automatically generated from the database with the one saved in DREAM entitled "Email template for MSs for bi-annual review of users".

Address the email to the EPITT contact person for the country (this is the user whose details are highlighted in bold in the File Maker licenses database).

A list of accounts/license keys currently assigned to the particular NCA should be attached to the email in PDF format. Open it and look for any missing information (some accounts will not have license keys assigned to them, thus in such cases the license key field will be left blank; however all other fields should be populated).

Manually attach application form template (located in G:\External Information Draft\EPITT\Application form). Finally check the body of the email for any inconsistencies/errors and add any additional questions/comments as appropriate to the email an EPITT.

Repeat this step for every country in the list.

9. b. Create a new DREAM folder named "Review of the EPITT users list - <month> <year>" and save all emails in this folder.

9. c. Responses will be received over the following 2 weeks as per set deadline. Should no changes be required, the EPITT contact point is likely to answer to the EPITT Business Team directly, which will then acknowledge receipt. However should changes be required, the response should be sent to the IT Service Desk via the EMA Service Desk portal (JIRA) as indicated in the original email.

9. d. Save the responses in the DREAM folder "Review of the EPITT users list - <month> <year>" and name it "Response from <country initial> to bi-annual review of EPITT users - <month> <year>". Link the response in the relevant DREAM folders "EPITT accounts to be deleted or transferred" or "EPITT correspondences with new users including application forms" as appropriate.

9. e. Take the necessary actions i.e. create accounts as referred to chapter 3; delete accounts as referred to chapter 6; or transfer accounts as referred to chapter 7.

10. Providing trainings to EPITT users

Any new EPITT users should follow the EPITT training proposed on a regular basis (every month or every other month). This is mandatory for users wishing to get "Data entry access". The steps below describe how these training sessions are organised.

10. a. Choose a two hours-slot on a specific date that suits you.

10. b. Book a room via Outlook with a computer and audio conference (Adobe) facility. In order to allow enough time to set up the equipment, book the room 30 minutes prior to the starting time of the training.

10. c. Send an Outlook invitation entitled "EPITT training via Adobe" to the EPITT business team members, VirtualMeetings (VirtualMeetings@ema.europa.eu) and to the EMA EPITT File Maker developer contact point including the following information in the core of the email (replace the parts in yellow font with the relevant details):

Date, time and duration of your meeting:

- *Meeting Title - EPITT training via Adobe*
- *Physical meeting room - xxx*

- Adobe Connect room (including URL) - <https://connect.ema.europa.eu/epitt>
- Number of remote participants – xxx
- Host of the meeting (who will connect as the meeting Host from EMA) – xxx
- Support required – Yes, only remotely
- User training required - No

10. d. Send the following request regarding a copy of EPITT to the IT Service Desk:

Dear Colleagues,

*Can you please create a recent copy of EPITT in the File Maker Dev. server and allow us access from the meeting room xxx from the xx/xx/xxxx to the xx/xx/xxxx close of business. Please send the link to the EPITT Business Team
Many thanks and Best regards*

10. e. Inform the Network of the EPITT training date by sending an email to the All Human PV mailbox (LIST-H-PHARMACOVIGILANCE@EUDRA.ORG) and the All Human RA mailbox (LIST-H-RA@EUDRA.ORG). Use the email template “Email template for the next EPITT training session using Adobe - Call for expression of interest” (replace the parts in yellow font with the relevant details, do not forget to update the training date in the email title) and copy any colleagues who may have expressed their interests in taking part in the EPITT training as well as all new users created since the last session took place. The contact details of these colleagues can be found in the document “EPITT users tracking table”.

10. f. Update the EPITT training date in the free text field of the welcome page of EPITT. To login to the system, click on the following link and enter your ECD credentials:

<fmp://fmapps3.eudra.org/EPITT.fmp12>

Next EPITT training via Adobe: xx/xx/xxxx from xx.xx to xx.xx UK time
Please contact epitt@ema.europa.eu if interested

10. g. Upon receipt of positive responses from users, update the relevant column of the document “EPITT users tracking table” to create a list of participants.

10. h. Three days before the training, send an email to all the participants including the details on how to join, the latest versions of the EPITT user guide and of the EPITT power point presentation. Use the email template “Email template for the next EPITT training session using Adobe – Instructions on how to join” (replace the parts in yellow font with the relevant details; do not forget to update the training date in the email title).

10. i. One day before the training, print the list of participants and make sure you can access EPITT from the meeting room.

10. j. After the training, ask IT to upgrade the access privileges of EPITT users who requested the data entry access in their EPITT application form.

10. k. Update the “EPITT users tracking table” accordingly.

10. l. Inform the EPITT users whose access privileges have been upgraded.