24 May 2018
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Information Management Division

EudraVigilance stakeholder change management plan: integration with the Identity and Access Management (IAM2) project deliverables

Pharmacovigilance Business Team (for consultation)	11 June 2018
EudraVigilance Expert Working Group (for consultation)	14 June 2018
Pharmacovigilance Risk Assessment Committee (PRAC) (for consultation)	14 June 2018

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Versions

Date	Version number	Summary of changes
27 March 2018		Original document.
30 March 2018	0.1	The first revision of the document has been carried out to include clarifications and updates.
11 April 2018	0.2	The second revision of the document has been carried out to include clarifications and updates.
24 May 2018	1.0	A final revision of the document has been carried out to include clarifications and updates.

Acronyms

Acronym	Description
EVDAS	EudraVigilance Data Analysis System
EVWEB	EudraVigilance Web application
IAM2	Identity and Access Management 2
ICSR	Individual case safety reports
MAH	Marketing Authorisation Holder
MPR	Medical Product Report
NCA	National Competent Authority
OMS	Organisation Management System
QPPV	Qualified Person Responsible for Pharmacovigilance
SPOR	Substance, Product, Organisation and Referential
xEVMPD	Extended EudraVigilance Medicinal Product Dictionary
xEVPRM	Extended EudraVigilance Product Report Message

Executive summary

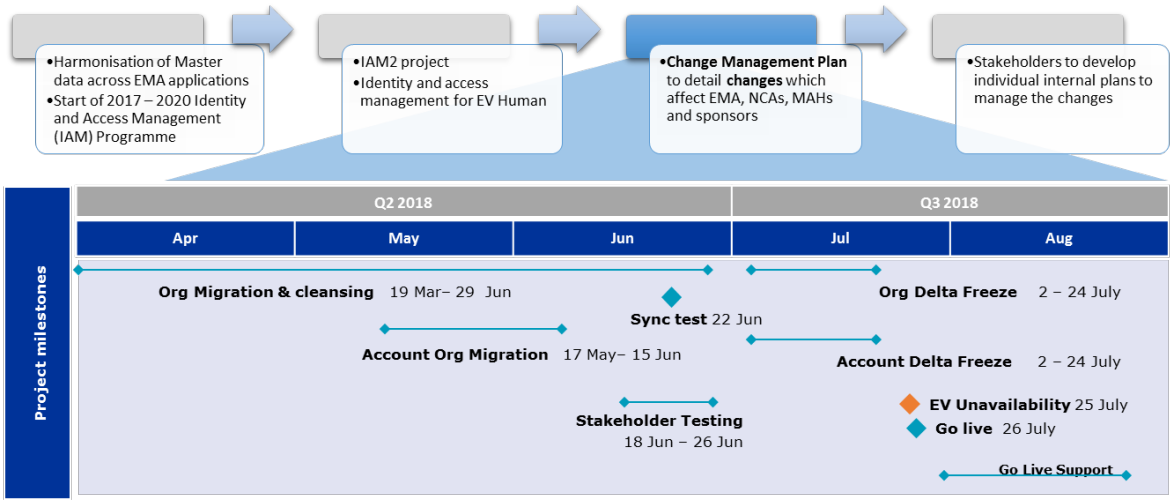
The Agency's Identity and Access Management (IAM2) project aims to simplify the registration and management of EudraVigilance organisations and users from a business process and technology point of view. As part of the project, the EudraVigilance platform will be integrated with two services/platforms already put in place by the Agency: the EMA Account Management Portal and the Organisation Management Services (OMS).

This document sets out the changes which are being implemented as part of the EudraVigilance Human registration and user access management, which will simplify the current process of handling organisations and users in the EV Human Production environment. EudraVigilance Human refers to the following components: EVWEB (for the electronic reporting and submissions of ICSRs), EVDAS (for the analysis of ICSRs data submitted to EudraVigilance) and XEVMPD (for the electronic reporting and submissions of data on medicines (Article 57)). These changes are triggered in the context of harmonising master data at EMA and will streamline the way how organisations and users are registered to access EU telematics systems and services.

The intended audience of this document are EudraVigilance stakeholders i.e. users of National Competent Authorities (NCAs), marketing authorisation holders (MAHs), sponsors of clinical trials and the EMA.

This document describes the changes that impact on the EudraVigilance organisation and user management process and how EudraVigilance stakeholders register, administer and maintain their registration details at organisation and user level. The integration of the IAM2 project deliverables with EudraVigilance does NOT require modifications or adaptations of IT systems operated by NCAs, MAHs and sponsors.

Organisations are advised to use this document as a starting point to familiarise and develop their own internal plans to manage the changes as of 26 July 2018 i.e. when the new registration, access and organisation management system for EudraVigilance is moved into production. Following the implementation of the new EudraVigilance system and processes, this document will no longer be updated and will be kept for reference purposes.



1. Introduction to the changes

This chapter provides an overview of the main changes to the registration, access and organisation management of EudraVigilance Human and associated systems as part of the integration with the IAM2 project deliverables.

1.1. Context

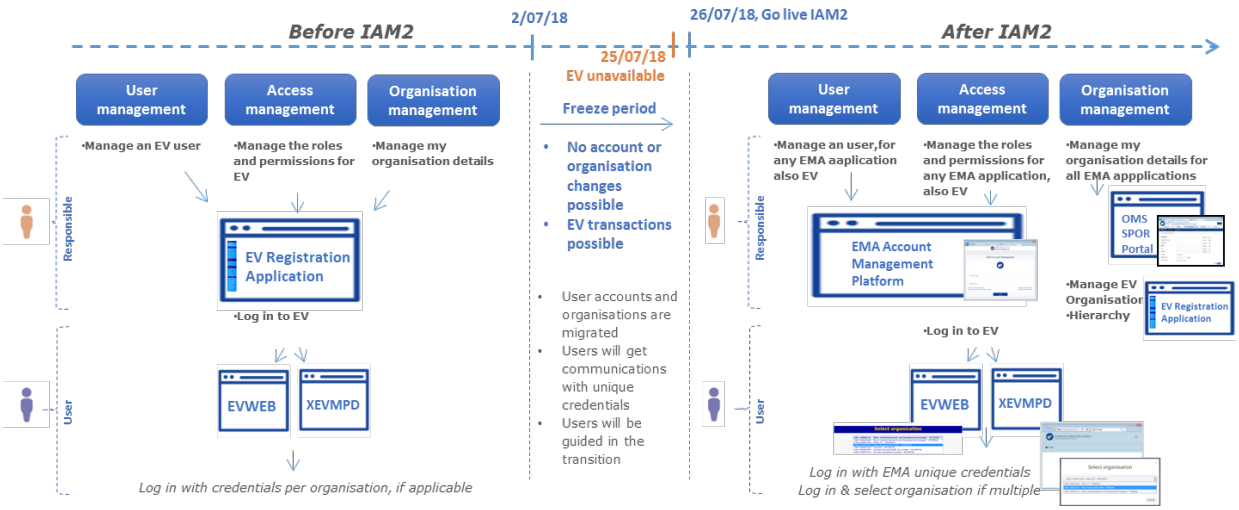
The IAM2 project is part of a series of initiatives that are deploying an EMA wide user and organisation management strategy; it is run under the Agency's Data Integration Programme.

The project is supporting the objective of the Agency's Information Management Division to improve information security.

The IAM2 project aims to **harmonise the registration process and integrate EudraVigilance Human users and organisations** with two services already in place in the Agency: the EMA Account Management and the OMS.

IAM2 streamlines the way EudraVigilance users manage their unique EMA user and organisation account and how they access EudraVigilance production applications.

Figure 1. Changes triggered by IAM2



1.2. No change to EudraVigilance core functionalities

There are no changes to the core functionalities of EudraVigilance.

1.3. Out of scope

The IAM2 project does not cover changes related to the registration process of EudraVigilance Veterinary. This will be part of an IAM implementation at a later stage.

As the IAM2 project currently only covers the production environment, the test environment (XCOMP) and the training environment are not in scope, i.e. the current registration process will continue to apply.

2. Benefits of IAM2 and EudraVigilance

IAM2 will deliver significant benefits to EudraVigilance stakeholders including:

Table 1. Benefits of IAM2

New feature	Benefit
• One unique EMA wide login to access EudraVigilance and other EU telematics systems and services, as applicable. For example, the user credentials for accessing EVWEB and EVDAS will be identical.	• No more need to maintain multiple credentials for EudraVigilance and other EU telematics systems and services, as applicable. • User details only need to be managed once centrally.
• Rationalised, more efficient and user friendly self-managed process for EudraVigilance stakeholders to register users, to grant access to users and to maintain the organisation and user information.	• Accelerated time to complete the registration process. • Improved monitoring and reporting functionalities to manage access and roles of users. • Reduced duplication of efforts by EV stakeholders and EMA staff.
• Harmonised organisation management across EU telematics systems and services.	• Organisation details only need to be managed once centrally.

3. Business Process Change Management

All impacted organisations should prepare plans concerning the launch of the changes resulting from the streamlined access, user and organisation management, which will become applicable to EudraVigilance on 26 July 2018.

This section highlights the main changes the new registration system will bring to business processes for all stakeholders. Chapter 6 provides more detailed guidance specific to each stakeholder group.

Until the implementation of the IAM2 project deliverables, the organisations and users who need to have access to EudraVigilance are managed directly in the EudraVigilance registration application.

3.1. User and registration management

It should be also noted that for certain types of organisations (e.g. clinical research organisations, third party service providers) often several user credentials have to be created as per the current process depending on contractual arrangements between organisations. This means that users, needing to access and support accounts of multiple organisations, have to request and maintain multiple sets of user credentials requiring duplication of efforts by the EMA registration team and the organisations managing these users.

Following the implementation of the IAM2 project deliverables, user accounts are managed centrally at the EMA and users will only require a single user account.

3.2. Access management

Until the IAM changes are applicable, there is no change to the current process for granting access to EudraVigilance or to register new organisations and users as set out at the dedicated webpage EudraVigilance: how to register.

The implementation of the IAM2 project deliverables does not impact on the EudraVigilance Access Policy. Equally the principle of responsible person and the appointed deputy remain unchanged. As a reminder, NCAs & MAHs need to ensure that heir user information is up to date, especially in case of persons leaving or being replaced.

The changes applicable to EudraVigilance are as follows:

- The end user will, as of implementation, be able to SELF-request a *given role* on behalf of a *given organisation.* The naming of these EV user roles has been clarified to allow for a user friendly and a comprehensible user role request processing by any user. The list is available in annex 1.
- The EudraVigilance "responsible person" (being either the head of the pharmacovigilance department of an NCA, the Qualified Person Responsible for Pharmacovigilance (QPPV) for a MAH or the Responsible Person for EudraVigilance for a sponsor organisation) can "self-grant" or "deny" access to users of their organisation in a simple and transparent way;
- The EudraVigilance "responsible person" for an organisation can self-manage the closure of any user account;
- The EMA registration team will still have to be contacted for the first user role of an organisation (i.e. the "responsible person") and for any future changes of their status (e.g. change of role, change of organisation, retirement).

The scenario to create user access to virtual affiliates is considered specific to EudraVigilance and is still managed consequently in the EudraVigilance Registration Application only.

3.3. Organisation management

As of 26 July 2018, the organisations currently registered with EudraVigilance (hereafter referred to as "legacy" organisations) and new organisations will be administered in the Organisation Management System (OMS) accessible via the Substance, Product, Organisation and Referential (SPOR) portal. EudraVigilance specific hierarchy details such virtual affiliates will still be managed in EudraVigilance.

What does an organisation need to do? During the migration process, the EMA is taking care of the migration, organisation are not supposed to contribute. After the migration, the organisation's responsible person will receive a communication, which will explain, where they can view and maintain their organisation data.

4. IAM2 implementation plan for EudraVigilance

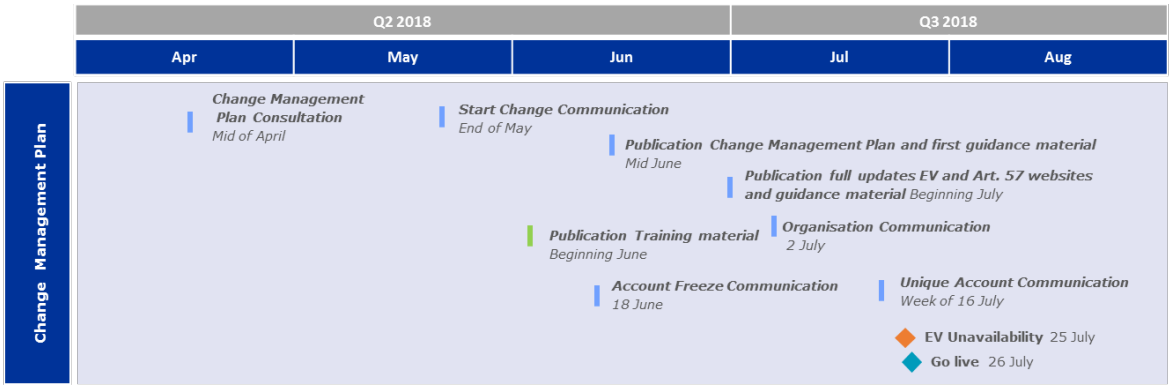
In line with the Data Integration Programme, the Agency announced the integration of EudraVigilance with the EMA Account Management Platform and SPOR.

The EudraVigilance Expert Working Group (EV-EWG) and the Pharmacovigilance Business Team (PhV BT) were consulted with the aim to launch the IAM2 project deliverables on 26 July 2018.

4.1. Implementation plan

The diagram illustrates the sequence of planned IT and business process changes to the EudraVigilance (EVWEB, EVDAS and XEVMPD) and the impact on stakeholders.

Figure 2. Change Planning



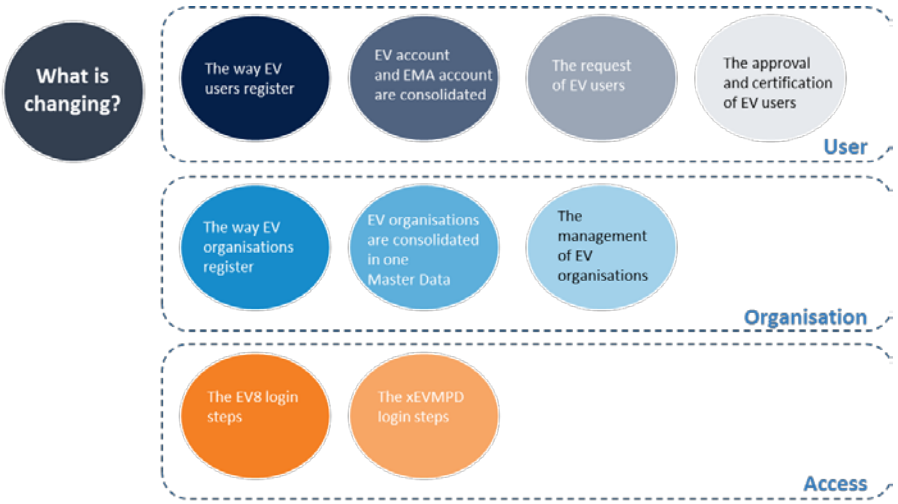
4.2. EudraVigilance Registration changes

The 'EudraVigilance organisation and user management' registration application of the EudraVigilance system has been amended as part of the IAM2 project deliverables to align it with the EMA Account Management portal and OMS.

The EVWEB (for ICSRs and XEVPRM electronic reporting) login page will be modified to enable access with the new unique user credentials and where applicable will provide the option to select the relevant organisation, for which the user will access EudraVigilance.

The EudraVigilance Restricted Area will now be synchronised with the central IAM components for user and organisation management.

Figure 3. Changes description



4.2.1. EudraVigilance user management

The EudraVigilance registration process has been simplified and further information is published on the EudraVigilance: how to register webpage. As of 26 July 2018, the user management does no longer take place via the EudraVigilance Restricted Area but through the EMA Account Management Platform.

Existing organisations and user registrations will be automatically migrated to OMS and the EMA Account Management Platform. The migration, cleansing and synchronisation testing activities are ongoing from March to May 2018.

From 27 June to 26 July 2018, EMA will be unable to register any new EudraVigilance users or organisations or update existing user accounts. However, EudraVigilance will remain fully operational during this period. On the 25rd of July, all the EudraVigilance system components will be unavailable. The systems changes and final migration and synchronisation will take place during that time frame.

4.2.2. EVWEB/EVDAS access management

EVWEB (for ICSRs and XEVPRM electronic reporting) has been redesigned to enable users to logon using only one unique EMA credential. EVDAS has no change to the application but both legacy and new users are enabled to log in.

4.2.3. EudraVigilance organisation management

The EVWEB application has been redesigned to display synchronised organisation information, created and maintained in OMS, and to maintain organisation data, only pertinent for EudraVigilance.

Existing organisation were automatically transferred to the EMA central systems and synchronised with EudraVigilance.

The organisation management process does not longer take place inside EudraVigilance but in the EMA OMS Portal. Certain organisations details and concepts such as the MedDRA license number and information on virtual affiliates are still maintained via the EudraVigilance Restricted Area.

4.3. Art 57 – Extended EudraVigilance Medicinal Product Dictionary (XEVMPD) registration changes

The XEVMPD has been amended as part of the IAM2 requirements. Two components, not part of the EudraVigilance system, but rather managed centrally at EMA, are now also synchronised with the XEVMPD:

- EMA Account Management Platform
- OMS

As of 26 July 2018, access to XEVMPD and users need to be administered through the EMA Account Management Platform and organisations need to be maintained or created via OMS.

The XEVPMD login page will be modified to enable the access with a unique set of user credentials and the option to select the organisation to perform transactions in the XEVMPD, where applicable .

4.4. EudraVigilance Data Analysis System (EVDAS)

The access to EVDAS will be requested through the EMA Accounts Management platform, where specific roles are available.

4.5. Supporting documentation for stakeholders

EudraVigilance related documents including user guides and training material are being updated as described below. Together, these documents provide additional information on the changes that the IAM2 project integration will entail.

Table 2. Supporting documents overview

Documentation	Description	Date available
Webpages		
EudraVigilance – Registration page	A set of paragraphs including descriptions & links to register for EV Human	In preparation – link will be included
EudraVigilance – Training page	A set of paragraphs including descriptions & links to find guidance and training material for EV Human	In preparation – link will be included
Art. 57 – Registration page	A set of paragraphs including descriptions & links to register for Art. 57.	In preparation – link will be included
Art. 57 – Training page	A set of paragraphs including descriptions & links to find guidance and training material for Art. 57.	In preparation – link will be included
Guidance Documents		
Change Management Plan	A document including the planning concerning the IAM2 changes and expected preparation by stakeholders	This document
Electronic registration process – EudraVigilance registration phases I, II and III	The document is updated with more information on the registration process.	In preparation – link will be included
EudraVigilance – registration user management	The document is updated with more information on the registration process.	In preparation – link will be included
EudraVigilance registration documents	The document is updated with more information on the registration process.	In preparation – link will be included
XEVMPD data-entry tool (EVWEB) user manual	The user manual for EVWEB	In preparation – link will be included
OMS User Registration Manual	A user manual including information how to register for OMS	Available now - link
Training Material		
EV- M1 How to register with	An e-learning including registration to	In preparation – link will be

Documentation	Description	Date available
EudraVigilance and EVDAS	EVDAS	included
Session 1.2: Registration with EudraVigilance	An e-learning including registration to EV	In preparation – link will be included
EVDAS Manual	A user manual with updated information how to register and access EVDAS	In preparation – link will be included
EVWEB Manual	A user manual with updated information how to register and access EVWEB	In preparation – link will be included
Release Notes		
Release Note	A document including more information on the release of the EMA Identity and Access Management solutions for EV Human	In preparation – link will be included

4.6. User training and elearning

Training material for the EudraVigilance face-to-face training course and online eLearning videos will be made available. In addition, the EMA support webinars will address the IAM2 project implementation topic and questions. This will allow organisations to become familiar with the changes.

Training planning is provided on the EudraVigilance change management webpage and the EudraVigilance: electronic reporting webpage.

4.7. User support

The process to follow in case of a failure to login with the provided credentials, erroneous creation of users, or failure to request or approve a new role, is to contact the EudraVigilance helpdesk contact:

- **EudraVigilance Registration (for support on access and registration and organisation)**

  Email - **eudravigilanceregistration@ema.europa.eu**
  Tel - 44 (0) 20 3660 7523

- **EudraVigilance Helpdesk**

  EMA IT Service Desk (for support with EudraVigilance and EMA gateway / webclient)

  Tel.: +44 (0)20 3660 8520 (for urgent technical matters)

4.8. EudraVigilance and IAM2 go-live planning

The migration of existing organisation and user accounts is planned to take place from March to June 2018. Before the go live date on 26 July, there will be a 15 days transition period from 2 July to 24 July 2018 to migrate and synchronise the most recently added organisations and users. During that

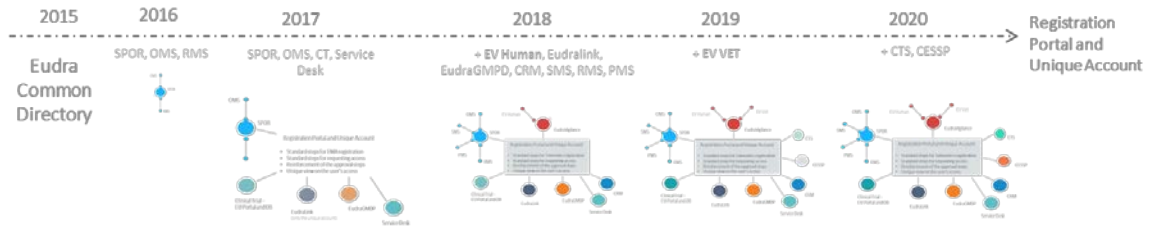
transition period from 2 to 24 July 2018, there will be no possibility to create new users, add user's roles or new organisations via the EudraVigilance Restricted Area. This will be possible via OMS and the EMA Account Management Platform but it will not be synchronised during the freeze period.

There will be a one day production downtime scheduled for the 25th of July. On this day, EVWEB, XEVMPD and the Restricted area will not be accessible.

After the go live on 26 July, for at least one month, support will be provided to ensure a smooth transition for users to the new account and login steps.

The Data Integration Programme has already integrated other systems and will further incorporate other systems over the next years.

Figure 4. Data Integration Planning



Further details on planned and potential updates will be communicated with stakeholders in the future.

More details on the SPOR and IAM roadmap can be found by clicking on this link.

5. Stakeholder Implementation planning

This section provides detailed guidance to each stakeholder group on what activities should be planned for the implementation of the new Identity and Access Management (IAM) for the EudraVigilance system on 26 July 2018.

5.1. EMA change management planning

This section of the change management plan focuses on the business process changes from an EMA perspective for the period leading up to and shortly after implementation of the IAM2 project deliverables.

5.1.1. EMA IT implementation plan

5.1.1.1. Testing of EudraVigilance integration with OMS and EMA Account Mgmt Platform

In addition to the internal testing performed by EMA, testing will be conducted in June 2018 with a selected number of external EudraVigilance stakeholders. The organisations participating in the external testing will be selected through a call for volunteers via the EudraVigilance Expert Working Group and the Pharmacovigilance Business Team.

Following the internal and external testing, the synchronised environments will be released to all stakeholders on 26 July 2018.

5.1.1.2. Migration and Synchronisation implementation

All organisation and user accounts for the EudraVigilance Restricted Area will be migrated to the EMA Account Management Platform and OMS. This migration is described in chapter 4.8.

All registered organisations at the time of the launch are automatically migrated and synchronised. The responsible persons of registered organisations will received a communication with a link to the applicable organisation in OMS. New organisations will need to follow the registration process as described at the EudraVigilance: how to register webpage.

All registered users at the time of the launch are automatically migrated and granted access to EudraVigilance. Registered users will receive a notification with their new unique account credentials and are requested to validate their account and change their password within a given period.

New users will need to follow the updated registration process as described at the EudraVigilance: how to register webpage.

Changes are being made to both the existing EudraVigilance and XEVMPD log in interface. The EVDAS log in interface remains unchanged.

The EudraVigilance helpdesk can be contacted for support with the updated systems. Their contact details remain the same ad can be found in detail on chapter 4.7.

5.1.2. Business process changes and resourcing requirements

The changes relating to business processes, which occur following the implementation of the IAM2 project deliverables are summarised in chapter 3. The following sections describe these changes in relation to the EMA and the potential changes in work load and internal process ownership.

5.1.2.1. EudraVigilance registration requests

Currently registered users are migrated to the EMA Account Management Platform with the same configuration settings for accessing EVWEB and the Restricted area of EudraVigilance.

Requests are no longer handled in the same way as the previous EudraVigilance process. The responsible person is now self-managing the process for their organisation. Registration of the first user still has to be processed and certified via EMA's registration team.

Any user can contact the EMA registration team, when they are facing issues. The answering of these requests is being performed by the EMA Registration team.

The long-term effect of a reduction of registration work on EMA resources has been planned for, allowing for engaging into more value added support to external organisations and users.

5.1.2.2. "EudraVigilance responsible"person

The request for replacing a responsible person is handled similarly as the current process. The EudraVigilance responsible person of an organisation still needs to communicate to the EMA registration team the changes and are accountable to ensure that the replacement of the EudraVigilance responsible person is managed correctly and in a timely manner. The approval and certification of the EudraVigilance responsible person is still performed by the EMA registration team.

Although a significant increase in volume of requests is not expected, any short term increase in support is taken into account by the EMA.

5.1.2.3. Handling of new organisation or modification of existing organisations

The EudraVigilance responsible person performs the request via OMS as part of the SPOR portal. Any additional documents to certify the valididity of the organisation can be added to the creation or modification request in the OMS tool.

Where previously the EudraVigilance registration team was performing the certification and validation of the request, this task will now be managed by the SPOR data stewards.

5.1.2.4. Account and organisation data quality review

A data quality review process as part of the migration of organisation und user accounts from the EudraVigilance registration application to OMS and the EMA Account Management Platform is performed by the EMA. No action is needed by the EudraVigilance responsible person or registered users. Migration and synchronisation tests will be performed by the EMA.

The resources required for the migration and synchronisation have been planned for by the EMA. Apart from the migration and synchronisation phase, any short term increase in support is taken into account by the EMA.

5.1.2.5. Helpdesk - business support

No major changes are expected to the helpdesk process for EudraVigilance business support. After the IAM2 project deliverables implementation, an increase in account and login support requests is expected short term. Mid and long term a decrease in registration requests is expected.

The EMA Service Desk and data stewards have been trained on the new processes as follows:

- Account registrations
- EVWEB and XEVMPD login account and password request handling
- EVWEB and XEVMPD login screen support
- Organisation creation and change requests.

The service desk is providing standard answers and links to documents to facilitate the handling of helpdesk queries.

5.1.2.6. IT operations support

No changes are expected to the support process for EudraVigilance. Any short term increase in required IT support is planned for by the EMA.

5.1.2.7. EVDAS

New users needing access to EVDAS will have to register on the EMA Account Management platform – only if they don't have an EMA Account. They will then have to request access to EVDAS on behalf of their organisation. Once their access is approved by the responsible person or designated deputy of the applicable organisation, the users will be able to access EVDAS.

5.1.3. EMA training

EMA has taken the necessary steps to ensure an update of the applicable training and support material. It will also provide support through the established NCA and MAH webinars.

5.1.4. EMA communication plan

A communication plan has been developed to ensure that the necessary information is circulated to relevant stakeholders at the appropriate time and to ensure that impacted parties are aware of the identity and access management modifications impacting on EudraVigilance. This is to ensure that

stakeholders are prepared for the business changes. Communications are undertaken through both general update communications and targeted communications based on key project deliverables and milestones.

Key project milestones and a summary of associated communication activities are available at the EudraVigilance change management webpage.

5.1.4.1. General update communications

Regular updates on the development of EudraVigilance are communicated via the bulletin 'What's new in Pharmacovigilance?'. This bulletin is distributed to both pharmaceutical industry and Member State stakeholders i.e., to Industry Associations, Qualified Persons for Pharmacovigilance (QPPVs), Heads of Medicines Agency (HMA), the Pharmacovigilance Business team, EU Commission, international partners, ENCePP. The bulletins can be accessed at the Agency's Newsletter webpage.

5.1.4.2. Targeted communications based on key milestones

Information on key milestones will be disseminated to relevant stakeholders through the following channels:

- Tailored emails to the registered EudraVigilance users following key project milestones; the guidance material readiness, the start of the freeze period, the organisations migration, the unique accounts readiness, the go-live of IAM2.
- Presentations and teleconferences with Pharmacovigilance Business team, the EudraVigilance Expert Working Group (EUDRAVIGILANCE-EWG), the Pharmacovigilance Risk Assessment Committee (PRAC), the EU Network Pharmacovigilance Oversight Group (EU-POG)and the IT Directors Group.

Additionally, targeted information announcing e.g. training dates and information days will be provided.

5.1.4.3. Dedicated EudraVigilance information on the EMA corporate website

The applicable EudraVigilance websites are being updated.

The content from the EudraVigilance website can be found in the section dedicated to EudraVigilance which can be accessed following the path: Human Regulatory > Pharmacovigilance > EudraVigilance

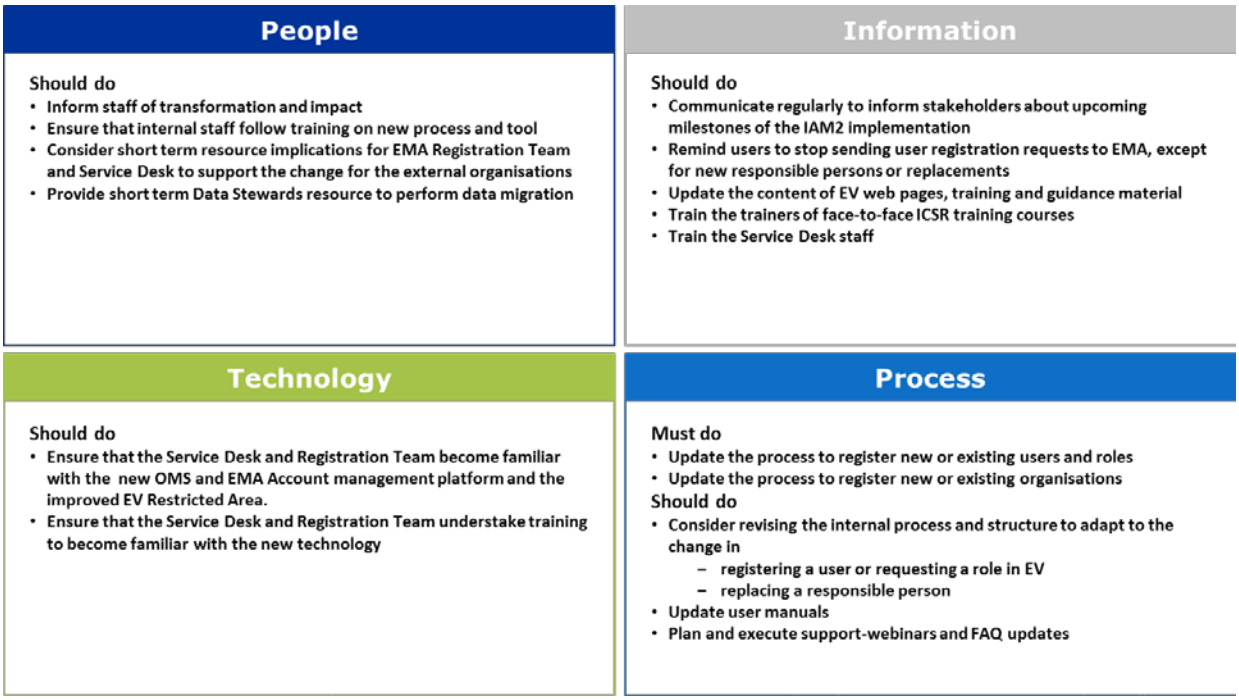
The relevant pages related to EudraVigilance include:

- Registration: provides an explanation of the registration process that stakeholders must undergo to use EudraVigilance for the electronic data interchange of pharmacovigilance information.
- EudraVigilance training and support: Provides an overview of the EudraVigilance training plan, and details of all existing and upcoming training materials.

5.1.5. EMA change management planning

The following EMA actions have been grouped by area and whether they were obligatory or recommended actions.

Figure 5: EMA Change Plan



5.2. NCAs change management planning

This chapter of the change management plan focuses on the business process changes that need to be considered by NCAs in the period of time leading up to and after the integration of the IAM2 project deliverables in EudraVigilance.

5.2.1. NCA IT changes

The implementation of the IAM2 deliverables as part of EudraVigilance does NOT required any adaptation of existing national IT systems.

5.2.2. NCA business process changes

5.2.2.1. EudraVigilance account and role registration requests

Any user can now self-register its account and request specific roles to access EudraVigilance for a given organisation (just like any other role for any other EMA system). The EudraVigilance responsible person or designated deputy can self-manage the registration and role validation process for their organisation. A registration of the EudraVigilance responsible person still has to be processed, validated and certified by the EMA data stewards.

The process to requesting and granting a given role for EudraVigilance on behalf of a given organisation does no longer take place as part of the EudraVigilance registration application but through the EMA Account Management platform.

Specific aspects such as granting user access to a virtual affiliate are still managed through the EudraVigilance registration application.

5.2.2.2. EudraVigilance responsible person replacement

The request for replacing a responsible person is handled similarly as done for the current process. The responsible or (designated) deputy of an organisation still need to communicate to EMA

Registration team the change and the needed documentation. They are accountable to perform the replacement in correct and timely manner.

5.2.2.3. Logging into the applications

EVWEB and XEVMPD have been redesigned to enable users to logon using unique credentials and sequentially to select the organisation for which the users would like to interact with EudraVigilance, where applicable.

5.2.2.4. Organisation creation or modification request

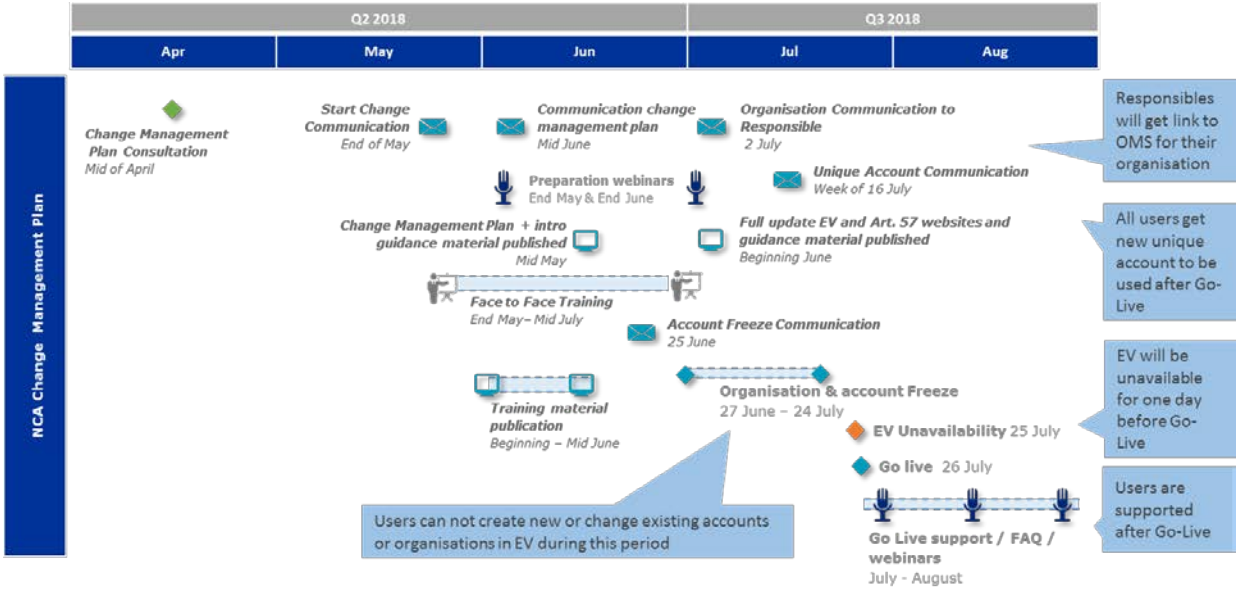
Any request for creation or modification does not longer take place using the EudraVigilance Registration Application. The responsible person (or designated deputy) or the organisation performs the request via OMS on the SPOR portal. Any additional documents to certify can be provided.

EVWEB and XEVMPD have been redesigned to display synchronised organisation information, maintained in OMS.

Certain organisations details and concepts such as the MedDRA license number and virtual affiliates need to be maintained via the EudraVigilance Registration Application.

5.2.3. NCA communications

Figure 6. NCA Change Planning



5.2.4. NCA training

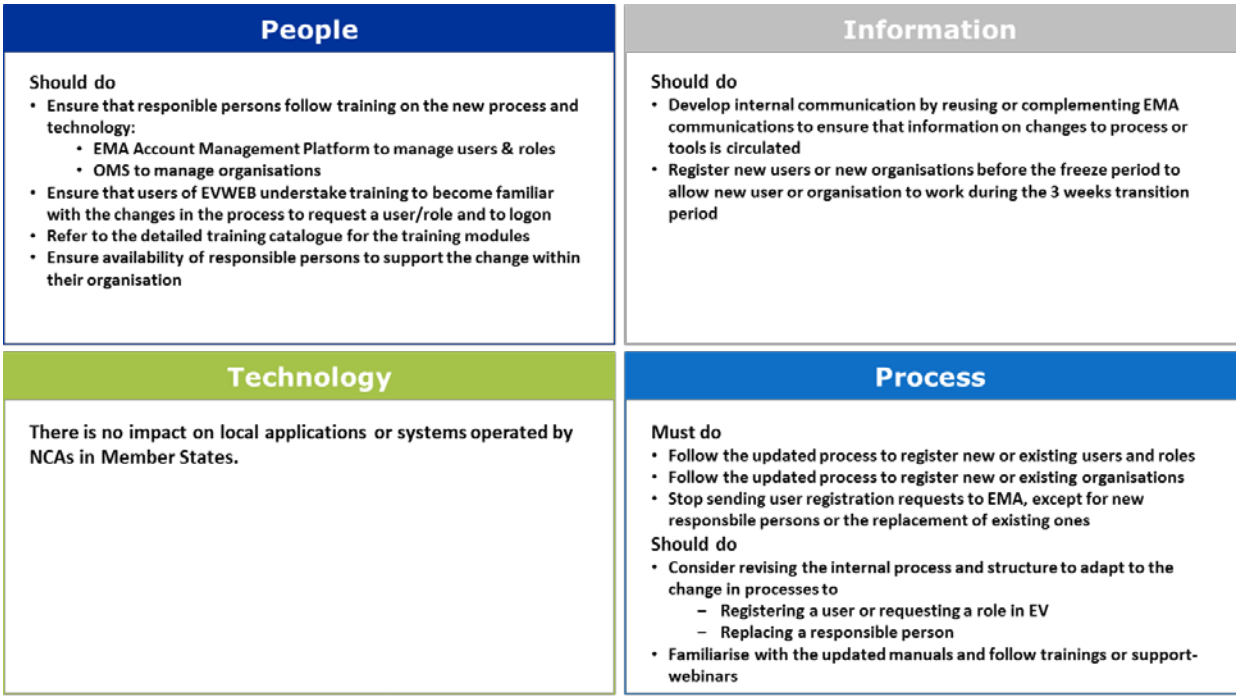
NCA users should follow the applicable training modules. It is advised to start familiarising with the changes through training in advance using the updated supporting documentation as referenced in chapter 4.5.

The key training materials and e-learnings have been made available on the EudraVigilance Training and Support page.

5.2.5. NCA change management plan summary

The following NCA actions have been grouped by area and whether they are obligatory or recommended actions.

Figure 7. NCA Change Plan



5.3. MAHs change management planning

This section of the change management plan focuses on the business process changes that should be followed by MAHs in the period of time leading up to and after the implementation of the new IAM for EudraVigilance.

5.3.1. MAH IT changes

The implementation of the IAM2 requirements to the EudraVigilance Human system does NOT require any adaptation of existing MAH IT systems.

5.3.2. MAH business process changes

5.3.2.1. EUDRAVIGILANCE account and role registration requests

Any user can now self-register its account and request specific roles to access EudraVigilance for a given organisation (just like any other role for any other EMA system). The external QPPV or designated deputy can self-manage the registration and role validation process for their organisation. Registration of the first user still has to be processed, validated and certified via the EMA registration team.

The process to requesting and granting given roles for a given EMA application, EudraVigilance in this case, on behalf of a given organisation, does no longer take place by means of the EudraVigilance restricted area but in the EMA Account Management Platform.

Specific aspects such as granting user access to a virtual affiliate are applicable to EudraVigilance only and are therefore still managed through the EudraVigilance Restricted Area.

5.3.2.2. QPPV replacement

A request for replacement is handled similarly in the way as per the previous process. The responsible (or designated deputy) or organisation still need to communicate to the EMA registration team the change and the needed documentation. They are accountable to organise their replacement in a correct and timely manner.

5.3.2.3. Logging into the applications

The EVWEB and XEVMPD application have been redesigned to enable the user to log on using only one unique EMA credential and sequentially to select the organisation for which the user will interact with EudraVigilance.

5.3.2.4. Organisation creation or modification request

Any request for creation or modification does no longer take place via EudraVigilance. The responsible person/designated deputy or organisation now needs to perform the request via OMS on the SPOR portal. Any additional documents required for certification can be submitted accordingly.

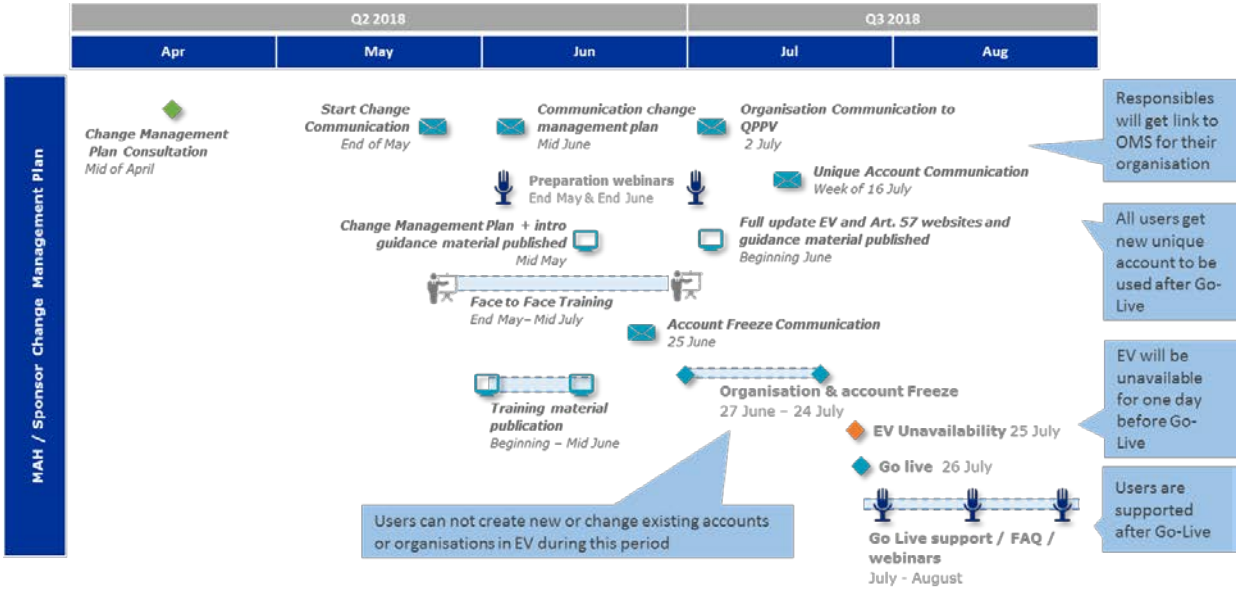
EVWEB and XEVMPD have been redesigned to display synchronised organisation information, maintained in OMS.

Certain organisation details and concepts such as the MedDRA license number and virtual affiliates are still maintained using the EudraVigilance Restricted Area.

5.3.3. MAH communications

MAHs should consider developing a communication plan to ensure that the necessary information is circulated within their own organisation and with other organisations that they work with. Communications should be made at appropriate times to ensure that impacted parties are aware of the changes to the reporting requirements and associated business processes.

Figure 8. MAH Change Planning



5.3.4. MAH training

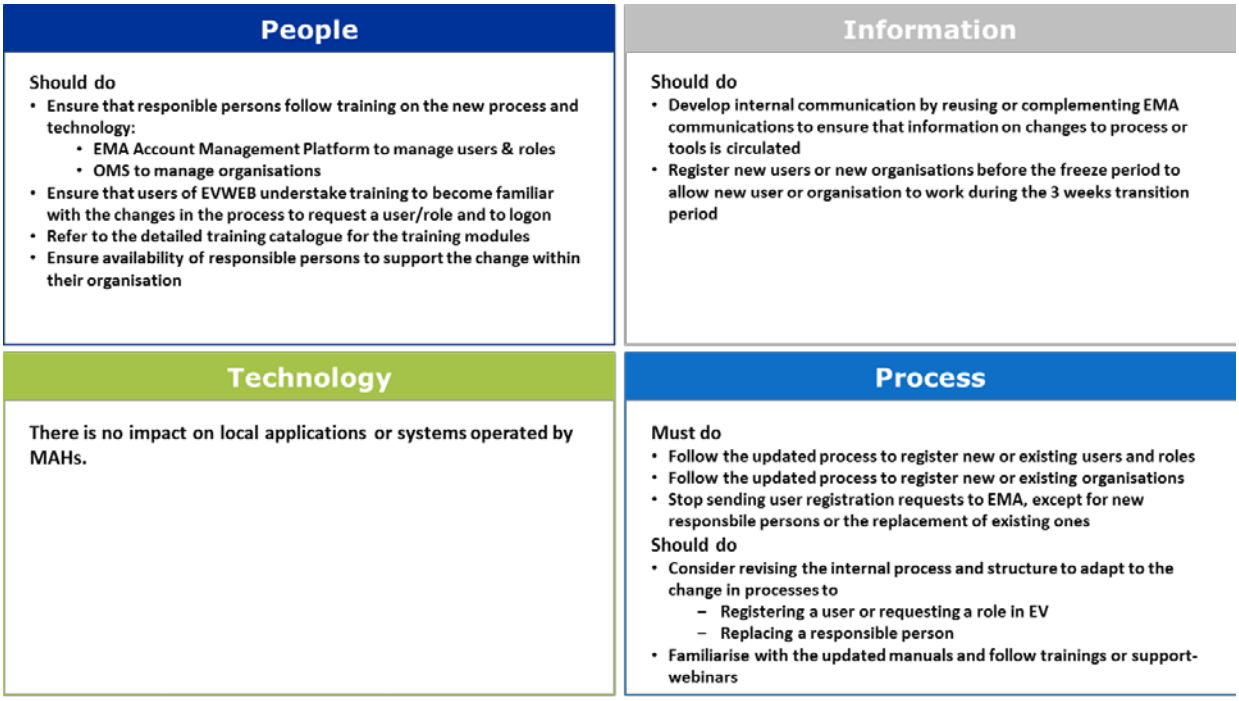
MAH users should follow the applicable trainings. It is advised to start familiarising with the changes through training in advance using the updated supporting documentation as referenced in chapter 4.5.

The key training materials and e-learnings are available on the EudraVigilance Training and Support page.

5.3.5. MAH change management summary

The following MAH actions have been grouped by area and whether they are obligatory or recommended actions.

Figure 9. MAH Change Plan



5.4. Sponsors of clinical trials change management planning

This section of the change management plan focuses on the business process changes that should be considered by sponsors of clinical trials in the period of the time leading up to and after implementation of the new IAM for EudraVigilance.

5.4.1. Sponsor of clinical trials IT changes

The implementation of the IAM2 requirements as part of EudraVigilance Human does NOT require any adaptation of existing MAH IT systems.

5.4.2. Sponsor business process changes

5.4.2.1. EUDRAVIGILANCE account and role registration requests

Any user can now self-register its account and request specific roles to access EudraVigilance for a given organisation (just like any other role for any other EMA system). The external QPPV or designated deputy can self-manage the registration and role validation process for their organisation. Registration of the first user still has to be processed, validated and certified via the EMA registration team.

The process to requesting and granting given roles for a given EMA application, EudraVigilance in this case, on behalf of a given organisation, does no longer take place by means of the EudraVigilance restricted area but in the EMA Account Management Platform.

Specific aspects such as granting user access to a virtual affiliate are applicable to EudraVigilance only and are therefore still managed through the EudraVigilance Restricted Area.

5.4.2.2. QPPV replacement

A request for replacement is handled similarly in the way as per the previous process. The responsible (or designated deputy) or organisation still need to communicate to the EMA registration team the change and the needed documentation. They are accountable to organise their replacement in a correct and timely manner.

5.4.2.3. Logging into the applications

The EVWEB and XEVMPD application have been redesigned to enable the user to log on using only one unique EMA credential and sequentially to select the organisation for which the user will interact with EudraVigilance.

5.4.2.4. Organisation creation or modification request

Any request for creation or modification does no longer take place via EudraVigilance. The responsible person/designated deputy or organisation now needs to perform the request via OMS on the SPOR portal. Any additional documents required for certification can be submitted accordingly.

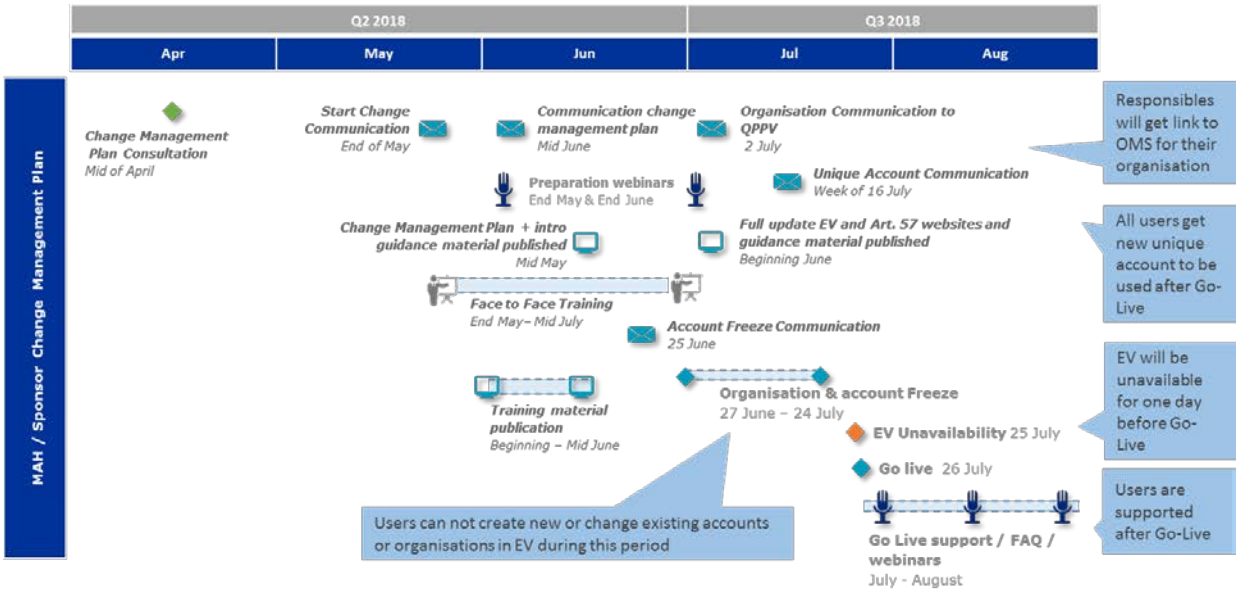
EVWEB and XEVMPD have been redesigned to display synchronised organisation information, maintained in OMS.

Certain organisation details and concepts such as the MedDRA license number and virtual affiliates are still maintained using the EudraVigilance Restricted Area.

5.4.3. Sponsor of clinical trials communications

Sponsors should have considered developing a communication plan to ensure that the necessary information was circulated within their own organisation and with other organisations that they work with. These communications should have been made at appropriate times to ensure that impacted parties were aware of the changes to the reporting requirements and associated business process.

Figure 10. Sponsor Change Planning



5.4.4. Sponsor of clinical trials training

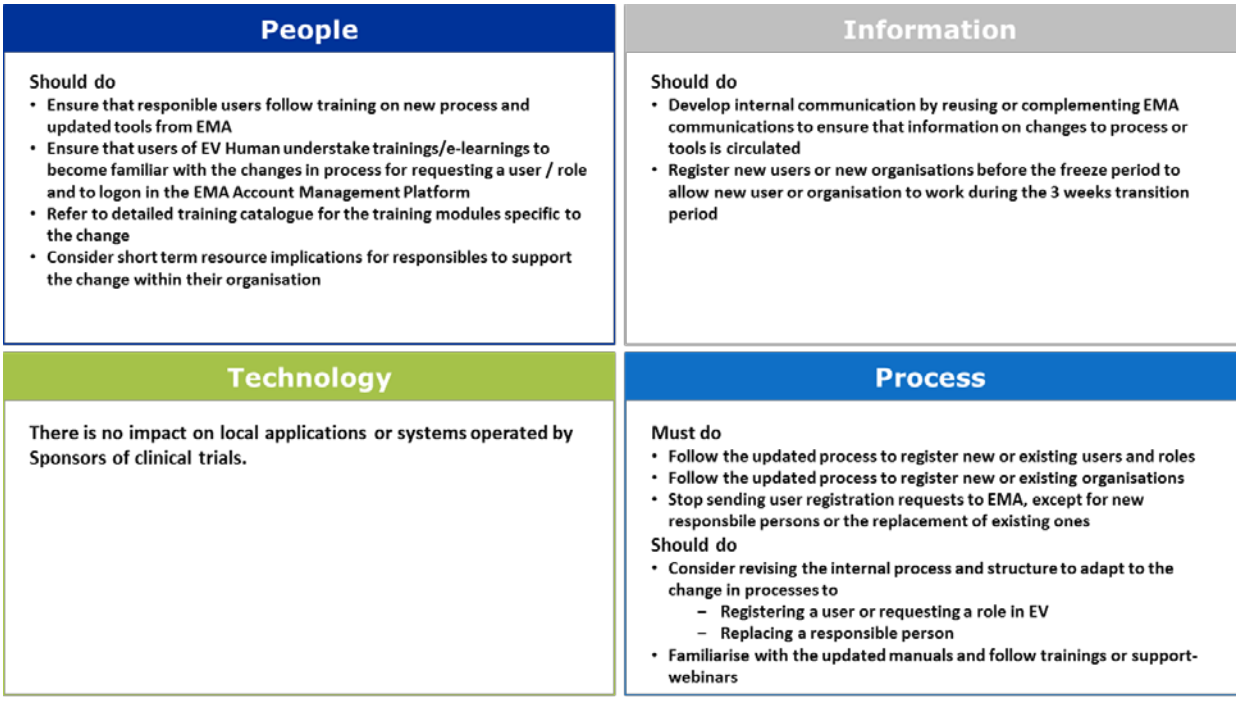
Sponsor user should follow the applicable trainings. It is advised to start familiarising with the changes through training in advance using the updated supporting documentation as referenced in chapter 4.5.

The key training materials, guidance documentation and e-learnings have been made available on the EudraVigilance Training and Support page.

5.4.5. Sponsor of clinical trials change management summary

The following Sponsor actions have been grouped by area and whether they were obligatory or recommended actions.

Figure 11. Sponsor Change Plan



6. Annexes

The following annexes are available:

- EV Roles

6.1. Annex 1: EV Roles

Table 3. EV Roles

Role name	MAH Description	NCA Description	CS/NCS Description
EV NCA Responsible		This user is the RP of the NCA or PH centre. They can perform administrative actions (such as approving user access), and also administrative tasks such as: build hierarchies; create additional transmission virtual affiliates; manage users assignment to the virtual affiliates).	This role is not applicable for NCS/CS
EU QPPV	This user is the EU QPPV of the Organisation selected. They can perform administrative actions (such as approving user access), and also administrative tasks such as: build hierarchies; create additional transmission virtual affiliates; manage users assignment to the virtual affiliates).	This role is not applicable for NCA	This role is not applicable for NCS/CS
EV CS/NCS Responsible	This role is not applicable for MAH	This role is not applicable for NCA	This user is the RP of the Organisation selected. They can perform administrative actions (such as approving user access), and also administrative tasks such as: build hierarchies; create additional transmission virtual affiliates; manage users assignment to the virtual affiliates).
EV NCA Trusted Deputy	This role is not applicable for MAH	This user is the administrator role for an Organisation. They can perform administrative actions (such as approving user access), and also administrative tasks such as: build hierarchies; create additional transmission virtual affiliates; manage users assignment to the virtual affiliates).	This role is not applicable for NCS/CS
EV Trusted Deputy	This user is the administrator role for an Organisation. They can perform administrative actions (such as approving user access), and also administrative tasks such as: build hierarchies; create additional transmission virtual affiliates; manage users assignment to the virtual affiliates).	This role is not applicable for NCA	This user is the administrator role for an Organisation. They can perform administrative actions (such as approving user access), and also administrative tasks such as: build hierarchies; create additional transmission virtual affiliates; manage users assignment to the virtual affiliates).

xEVMPD QPPV	Only for MAH, the user will select this role if they have been appointed by their EU QPPV or responsible as QPPV of an authorised medicinal product	This role is not applicable for NCA	This role is not applicable for NCS/CS
EV ICSR Browse	This allows the individual user to access EudraVigilance and to perform queries on a read only basis. He can access ICSR messages of the organisation assigned to.	This allows the individual user to access EudraVigilance and to perform queries on a read only basis. He can access ICSR messages of the organisation assigned to.	This allows the individual user to access EudraVigilance and to perform queries on a read only basis. He can access ICSR messages of the organisation assigned to.
EV ICSR Browse & Send	This allows the individual user to access EudraVigilance to perform queries as well as to create and send ICSRs. In addition, the user can receive safety messages with one or several ICSRs, store the safety messages locally and generate acknowledgement messages.	This allows the individual user to access EudraVigilance to perform queries as well as to create and send ICSRs. In addition, the user can receive safety messages with one or several ICSRs, store the safety messages locally and generate acknowledgement messages.	This allows the individual user to access EudraVigilance to perform queries as well as to create and send ICSRs. In addition, the user can receive safety messages with one or several ICSRs, store the safety messages locally and generate acknowledgement messages.
EV L2B Access	Access right that allows the user to visualize personal data of the patient. (Narrative) Level 2B access is an additional and specific access right that can be assigned by the QPPV or trusted deputy to registered EVWEB or EVDAS users of the MAH. It should only be assigned to users related to MAH and users assigned to an organisation with an existing role. (Only cumulative role). Previously, the users will only have L3.	This role is not applicable for NCA	This role is not applicable for NCS/CS
EV MPR Browse	This allows the individual user to access EudraVigilance and to perform queries on a read only basis. They can access MPR of the organisation assigned to.	This allows the individual user to access EudraVigilance and to perform queries on a read only basis. They can access MPR of the organisation assigned to.	This allows the individual user to access EudraVigilance and to perform queries on a read only basis. They can access MPR of the organisation assigned to.
EV MPR Browse & Send	This allows the individual user to access EudraVigilance to perform queries regarding Medical Products Reports(MPR) as well as to create and send extended medicinal product reports by means of extended medicinal product report messages and generate acknowledgement messages.	This role is not applicable for NCA	This allows the individual user to access EudraVigilance to perform queries regarding Medical Products Reports(MPR) as well as to create and send extended medicinal product reports by means of extended medicinal product report messages and generate acknowledgement messages.
EVDAS NCA Scientific	This role is not applicable for MAH	Role for EVDAS with access to individual case report forms and CIOMS	This role is not applicable for NCS/CS
EVDAS MAH Scientific	Role for EVDAS with access to individual case report forms and CIOMS	This role is not applicable for NCA	This role is not applicable for NCS/CS

EV Contributor	This role allows the user to be assigned to a Virtual affiliate by a responsible role of the organisation.