



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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European Medicines Agency

EMA Account Management, what's new?

Q&A

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This document contains a direct record of all questions asked through Slido.com during the webinar and their written answers.

Questions not asked through Slido.com were not captured. Questions that did not receive written answers below were either responded to verbally or not relevant to the topic of the webinar.

Generally, the order of questions answered follows the order in which they were prioritised by the audience using the "thumbs up" feature of Slido.com. The responses represent the expert view of the development teams at the time of the Webinar and are not official statements by the European Medicines Agency nor its partners.

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

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1. Question and answers for EMA Account Management

Question text	Topic	Answer
With the new shopping cart functionality, if there are multiple ORG-ID selected and we have the same User Admin, will the user admin receive 1 or multiple emails?	Get Access	Multiple notifications via email address are sent because an approval for each role and organisation is required.
Are there any plans to grant the external administrator role all access roles for the legal entities that user is external administrator for. Currently, even after receiving the external administrator role, the user must apply for individual roles for each legal entity managed	Get Access	No there is no plan to grant access to other EMA systems rather than EMA Account Management for the organisation administrator. We will be looking instead in creating business roles simplifying the access request process.
Do the EMA user and password remain only for accessing EMA Account management? Or all the accesses are transitioned to email authentication?	Access to EMA Systems	EMA Account Management already offers the possibility to login via modern authentication. The EMA is working on providing modern authentication to: SPOR CDP Common Repository and PSUR EU NTC Epitt Human
When it is foreseen date that all EMA's external systems will start using SSO?	Access to EMA Systems	The EMA is working in moving all applications to modern authentication, but we don't have a date yet.
After switching to email authentication, will you still need the multi factor authentications you are using with the current login?	Access to EMA Systems	Yes, Multi Factor Authentication is still required
Does the list of users include the details of the EU QPPV?	Manage Access	The list of users available in manage access includes the EU QPPV of an organisation, to view that information you must a QPPV or a Trusted Deputy of the same organisation. More information on who to list the users of an organisation can be found here .
If the employee terminates his EMA account, will the user be automatically removed/revoked from CTIS user management tab?	Get an EMA Account	The account will be made inactive so it will not be possible to access CTIS system anymore. As some of the roles only resides in CTIS and are not available in EMA Account Management, these will not be removed.
The Email opt in authentication is applicable only for EMA Account management and not for EV web login/PMS PUI login?	Access to EMA Systems	The Email opt in authentication applies to all EMA systems using modern authentication including EMA Account Management, EV and PMS PUI. Systems that are not capable yet to use email authentication are: SPOR CDP Common Repository and PSUR EU NTC Epitt Human
how to reset app authenticator if Mobile Phone is damaged or Lost?	Access to EMA Systems	If you have an alternative Multi Factor Authentication (MFA) method you can

Question text	Topic	Answer
		change your MFA settings following this guidance . If an alternative MFA method is not available (your phone was the only MFA method) you should contact EMA support to reset Azure MFA by sending an email to servicenow@ema.europa.eu indicating your name, surname and your unique username.
Question about shopping cart: If I am asking access for an L2B access for ORG-XXX that has multiple locations. Do I have to request access for all the existing locations for ORG-XXX or just one is fine? In other words, I am not sure how the location is relevant for EV access requests.	Get Access	The location is not relevant for access request: access is always requested on behalf of an organisation. Location data is available in EMA Account only for informational purpose
When searching for the role name, we have an issue where the selection is gone when you search for another role. As a consultant, I sometimes need to have more than one role for an organisation.	Get Access	We will look into this and improve the search and selection of roles
How can we update email address of EMA account management of a person who is not contact person so in the case of the form "VET change contact person" does not apply? Because it was not possible for us to change such email address via ServiceNow.	Get an EMA Account	As described in the home page of EMA Account Management: to update your name, e-mail or any other details submit a request via EMA Service Desk.
How do we know if our organization is using Azure AD?	Access to EMA Systems	Please contact your IT department, they should be able to provide an answer for this question
One of the slides mentioned the ema applications are compatible with SAML and OIDC, could I ask if it's possible to link the login directly to an application such as OKTA which also uses these protocols rather than the B2B connection offered by email authentication.	Access to EMA Systems	Currently we are not planning to integrate with other identity providers. We will consider this as a future feature.
Currently the user must remember their User ID - why does the User ID format vary from last name and first name initial (e.g. surname_n) to a combination of letters and numbers which is very difficult to remember (e.g. x9y9z9)?	Access to EMA Systems	UserIDs composed a combination of letters and numbers were created by the self registration platform available before EMA Account Management.
When will it be possible to use the MFA for PMS PUI access?	Access to EMA Systems	Multi Factor Authentication is already available for PMS PUI
in ServiceNow how can we change the email address of our EMA account management (because of grouped email address)?	Get an EMA Account	Please create a service desk request in the EMA Service Desk platform to update your contact details
If the user is disabled due to inactivity, does this user also loses already assigned and approved user roles?	Get an EMA Account	User are disabled after six months of inactive, after further six months all access roles are removed as well.
Is it possible to reactivate an account that was deactivated due to inactivity? If so, how? (for example, if an inactivity was due to maternity leave) (maybe this was	Get an EMA Account	It is possible to re-activate an account by using the forgot password functionality. More information are available on the Recover your credentials and re-activate

Question text	Topic	Answer
mentioned in the webinar, I was having audio issues in the beginning)		your account page of the EMA Account Management Documentation
Re Termination: Will there be a time when the account can be restored, maybe after contacting Service Desk?	Get an EMA Account	It is possible to re-activate an account by using the forgot password functionality. Your access is retained for six months after your account is disabled, after this period, if you re-activate your account you must request again your access. More information are available on the Recover your credentials and re-activate your account page of the EMA Account Management Documentation
Can it be changed to not display inactivated locations upon access request? Otherwise, new users are getting confused.	Get Access	We will consider this as a future feature to only display inactive locations when the "Include Historical Records" checkbox is selected.
Change to e-mail authentication. In EMA System Demo it was mentioned that for some systems (e.g. Confluence) this will not work. How does login to Confluence then work when authentication is changed to e-mail?	Access to EMA Systems	Steps to access Confluence and WebEx are documented here .
How to deselect a vet MAH responsible?	Manage Access	Use the Manage Access functionality of EMA Account Management to remove access as MAH responsible in EudraVigilance Veterinary. Once you have submitted your request open an EudraVigilance Registration queries in the EMA Service Desk to complete the process.
When some people leave the company, we are allowed to revoke their roles, but should we request EMA Service Desk to delete their accounts? Or could this user reuse their EMA accounts in the new company?	Get an EMA Account	EMA Guidance is that users leaving a company and joining a new one should disable the old account and create a new one for the new company. Users can terminate their own account as documented here . If the user can not access anymore the old account a service desk request in the EMA Service Desk platform to terminate the account can be created.
Is there a plan to introduce ADFS?	Access to EMA Systems	Currently we are not planning to integrate with other identity providers. We will consider this as a future feature
If there is a change in the surname and therefore also in the email address of a user, how do I announce this change?	Get an EMA Account	Please create a service desk request in the EMA Service Desk platform to update your contact details
Confluence: what are the 2 steps that are required to log in? Do you mean multi factor authentication?	Access to EMA Systems	Steps to access Confluence and WebEx are documented here .
Does this replace the 2FA? Sorry if i missed this info	Access to EMA Systems	Yes, Multi Factor Authentication is still required
Have you informed the NCAs about this change? Do they need to do any change in their systems?	Access to EMA Systems	NCA were informed of this change via the NICTAC and the IT Directors meeting. No change is required by the NCAs at this moment in time.

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So for all order systems you still need to use id and password?	Access to EMA Systems	Yes, systems that are not relying yet on modern authentication still requires a username and password. This includes: <ul style="list-style-type: none"> - SPOR - CDP - Common Repository and PSUR - EU NTC - Epitt Human
If I switch to the new logon system and it does not work, how quickly will the service desk solve this problem? Is there an urgency option at the service desk to solve this?	Access to EMA Systems	If you are unable to access the EMA Service Desk, please send an email directly to servicenow@ema.europa.eu indicating your name, surname and your unique username and we will help you with your access request.
Can I switch my existing account (from .ema.europa.eu to log-in with my company email address) already on 30 Sep 24 or does my company first need to switch/integrate to Azure AD?	Access to EMA Systems	You can opt-in to email authentication any time, there is no need for your company to switch/integrate to Azure AD
Would it be possible to list roles in alphabetical order for easier categorization and navigation when requesting access?	Get Access	We will look into this and improve the search and selection of roles
Also this will be used for login in Experts Management Tool, the organisation or private email?	Access to EMA Systems	Yes, Email authentication is available also for the Expert Management Tool
Are there more people that cannot login with the edge browser? After inserting the password and after authentication has been completed the login window appears again and again.	Access to EMA Systems	Please report this issue by opening a service desk ticker in the EMA Service Desk platform
Can an external org admin also terminate accounts?	Get an EMA Account	To terminate another user account a ticket in EMA service desk platform is needed. The self-service account termination is available only for the user own account.

2. Question and answers for other EMA systems

Question text	Topic	Answer
Is there any improvement planned to allow exporting of all CTIS users within a sponsor workspace?	CTIS	Enhancements to the CTIS User Management module will be gathered in the CTIS Simplification Task Force. Your request has been noted.
Are there any plans in the future where IRIS case title can be generated upfront by the Applicant via new submission (for variation) creation in IRIS?	IRIS / PLM	EMA generates case number (title) upfront only for Work-sharing variations or IA groupings (since these are the only cases created as placeholders). Otherwise, it is not possible to predict the case number, since the case title is a serial number of all cases created in IRIS.
Are there any updates to the mandatory timelines of the web-eAF?	IRIS / PLM	EMA is not yet in a position to announce the predicted date for mandatory use. The timeline will be published on the eSubmission website and in the PLM Portal
In large pharma companies, users may not access all product information, especially when products are managed in alliances. Strong internal firewalls are used. EMA proposes that all company info be visible to everyone within the company. Can this be challenged to allow product segregation per user?	IRIS / PLM	During the design of PMS access management, the creation of a concept of a portfolio manager was discussed. This feature was deprioritised by SMEs, and currently only two roles are available: <ul style="list-style-type: none"> - Industry User who is able to see only public product data. - Qualified Industry User who is able to see public and confidential data. For the moment there is no plan to include the concept of portfolio. Nevertheless, for large pharma companies, the use of the API might allow them to segregate products per user if implemented internally in each company.
Could the IRIS manager/contributors also receive the IRIS notification assigned to the case (variation)? Currently only the MAH portal contact is receiving this notification.	IRIS / PLM	A requirement will be sent to the IRIS/PLM product team for evaluation.
Are there plans to update the interface of PIP modification in IRIS? Currently it is sharing the same process as initial PIP and many steps are not applicable to PIP modification.	IRIS / PLM	A requirement will be sent to the IRIS/PLM product team for evaluation.
When we receive email/notifications from IRIS, where does IRIS retrieve the email address contact for a given person: from IRIS profile, from EMA Account management, from SIAMED? Because the address can be different depending on the source (individual, grouped email) ...	IRIS / PLM	Email notifications sent by IRIS are generally addressed to the submission contact, the user which created the initial submission. This contact can be changed. More information is available in the IRIS guide for applicants .
How soon will EMA update the product list (following approval of additional EU MA presentations) in EMA account management to enable the Applicant to	IRIS / PLM	The products become available normally immediately after the authorisation is finalised

Question text	Topic	Answer
include as product affected (product selection) in the web eAF?		
Is EMA planning to also update Guidance regarding assignment of variation procedure numbers since IRIS case title now being enforced?	IRIS / PLM	<p>Yes, EMA will gradually update the guidance on the assignment of the case numbers allocated to procedures managed in IRIS</p> <p>Please find available guidance on IRIS case numbers in the IRIS guide for applicants.</p>
What makes an organisation inactive?	OMS	When an organisation ceased to exist in the National Business registry or if it was wrongly created.
How to deactivate an organization location address?	OMS	By submitting a Change Request in the OMS portal when a company is no longer operating/doing business in a certain location.
When you request to merge an existing company to your HQ account, how long does it take to approve such a request?	OMS	<p>An OMS Change Request should be submitted via OMS portal to request a merge of 2/more organisations if a duplicate/more exist in the system or if an organisation merge/acquires another and maintain the same National Business registry number. For such requests OMS have SLA of 5 to 10 working days.</p> <p>Specifically for EudraVigilance Human, the merger of organisations is detailed in section 6.2.1.1 of the Registration manual.</p>