



Please note that **this session is being recorded** and **will be made available** through **EMA Corporate Website**.



At certain points throughout the session, participants will be able to ask questions or give their input via the audience interaction tool **Slido**.

Interaction via Slido is voluntary, and you may opt to remain anonymous. If you chose to use Slido, **you consent to the processing of your personal data** as explained in the [EMA Data Privacy Statement for Slido](#).

1

Join via **QR code** or **slido.com**

Join at
slido.com
#2456 820



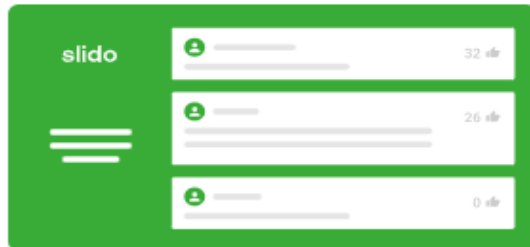
2

Send or upvote the questions
you want to hear answered



3

Questions will be shown on the screen
and **managed live in the Q&A session**



4

Questions not addressed
during this session may be
addressed in **subsequent**
webinars and/or in **FAQ** document
in SPOR Portal

SPOR week is a **full week of webinars** during which EMA's Regulatory Data Management Service team talks about all aspects of regulatory data management and how it works today.

 Webinar title	 Date	 Time
<u>SPOR and XEVMPD Data Governance</u>	17 April 2023	10:00-12:00 CET
<u>Service Desk for SPOR and xEVMPD</u>	17 April 2023	14:00-16:00 CET
<u>Referentials Management Service (RMS)</u>	18 April 2023	10:00-12:00 CET
<u>Organisation Management Service (OMS)</u>	18 April 2023	14:00-16:00 CET
<u>Substance Management Service (SMS)</u>	19 April 2023	10:00-12:00 CET
<u>Product Management Service (xEVMPD)</u>	19 April 2023	14:00-16:00 CET
<u>Substance, product, organisation and referential (SPOR) application programming interface (API) - SPOR API</u>	20 April 2023	10:00-12:00 CET
 <u>EMA Account Management</u>	20 April 2023	14:00-16:00 CET



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA Account Management Training Session

20 April 2023

SPOR Week – 17-20 April 2023

Carlo De Vittoria
Information Security, EMA





- 1** **Introduction**
- 2** **EMA Account Management Features Overview,**
including Q&A
- 3** **What's Next**
- 4** **Closing**



Introduction



Show **how the EMA Account Management works**



Clarify use of **main functionalities of EMA Account Management**

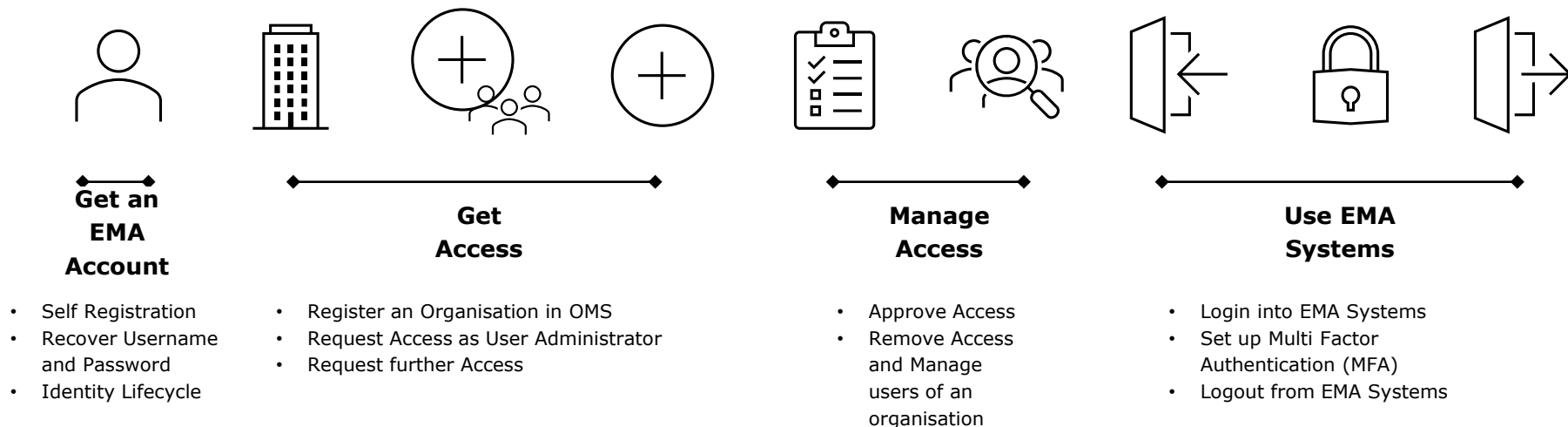


Provide tips & tricks on EMA Account Management



Collaboration with our stakeholders is at the core of the EMA's activities. This interaction is mainly facilitated by the Agency's systems and applications such as, SPOR IRIS, CTIS, EudraVigilance, UPD.

The first interface with the Agency's stakeholders is through the [EMA Account Management](#) platform. As the gateway to EMA's applications, the Agency has embarked on a project aimed at **ensuring that the registration and access management process delivers a simple, secure, consistent and user-friendly** way for EMA's stakeholders to work together with the Agency.



Past Context

- Possible roles are unclear to potential users
- Mandatory documents required as part of the registration process are unclear
- High waiting times and rejections
- Multiple log-ins required

Key Changes

- An enhanced **Organisation Search function**, making it easier for users to find their affiliated organisation based on different criteria
- Ability to **select multiple organisations within the same request**, meaning greater efficiency for our users associated with multiple entities
- Clearer **overview and description of potential roles**, providing users with clarity on documentation requirements and mandatory roles dependent on needs



Get an EMA Account

- Self Registration
- Recover Username and Password
- Identity Lifecycle



Self Registration

The first step to access EMA services is to have an **active EMA Account**.

If you have access to any of the following systems, you **already have an active EMA account**.

If you don't have an EMA Account, [self registration](#) is a 2 steps process:

- 1) Insert your data, provide agreement to EMA Privacy Statement and user agreement, tick the CATCHPA
- 2) Verify your email address by providing a code received on your email address and confirm the successful registration

If your email is already in use you can retrieve your username with the [Forgot Username?](#)

Self registration is granting basic birth-rights to access some EMA applications like the Service Desk, IRIS as an individual, OMS as unaffiliated user, CTIS.

IRIS, CTIS, SPOR, Eudralink, EudraCT Secure, Service Desk portal, European Union telematics controlled terms (EUTCT), Meeting Management System (MMS), Managing Meeting Document system (MMD), EudraVigilance data analysis system (EVDAS), full list [here](#)

The image shows two overlapping screenshots from the EMA registration process. The background screenshot is the 'EMA - Self-service Registration Confirmation Form'. It has sections for 'Your EMA Account' (with fields for Username and Surname), 'Your Details' (with fields for First Name, Last Name, Email, and Mobile), and 'One-time Token' (with fields for Token Expiration and Confirm Token). The foreground screenshot is an email titled 'EMA Registration - One-time Token' sent to 'register@ema.europa.eu'. It contains a 'Dear Name,' salutation, a thank you message, and a one-time token value '18H5SP' highlighted in a box. An arrow points from this token box to the 'Confirm Token' field in the registration form. The email also includes contact information for the European Medicines Agency.

The image shows a validation error message for an email address. It features a red border around the email input field which contains 'name.surname@domain.com'. Below the field, a red error message states: 'The email you have chosen is already in use. Please retrieve your ...'. At the bottom, it says 'We require a valid/active email address to create an EMA Account.'





Recover your username and password

To recover your username click on the "[Forgot Username?](#)" link and you will receive an email with your username.

To reset your password click on the "[Forgot Password?](#)" link and follow the instructions.

Forgot EMA account name?

Email address

Please enter the email address that you used to create your account.

[Login to EMA Account Management](#) [Submit](#)

EMA - Forgotten Password - Username

Username

Enter your username

[Cancel](#) [Next](#)

EMA - Forgotten Password - Token Verification

One-time Token

Enter the value of the one-time token emailed to the address associated with your account

[Cancel](#) [Next](#)

EMA - Forgotten Password - New Password

New Password

Enter your new password.

Confirm Password

Re-enter password to confirm

[Cancel](#) [Submit](#)

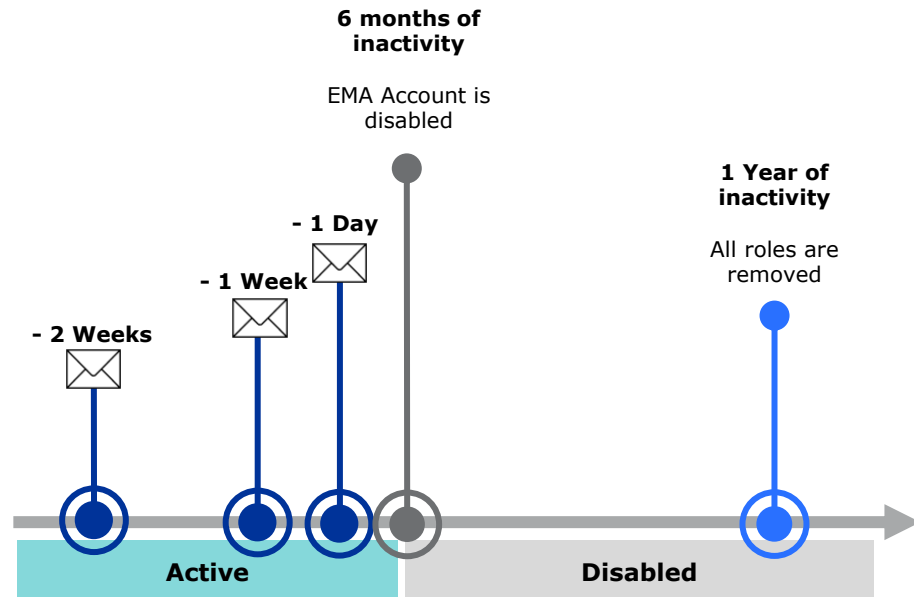
Note: Check your spam e-mail folder if you have not received the one-time token required to reset your password.





Identity Lifecycle

- All EMA accounts are automatically disabled after **6 months of inactivity**.
- Prior to disabling the account, the system sends **three reminders** to the user (two weeks, one week and one day before the account is disabled).
- To **re-activate your account** you will need to use the "[Forgot Password?](#)" process. By re-setting your password your account will be re-activated and a notification sent to your email address.
If you are affiliated to an organisation, your 'User Administrator' will also be notified.
- If you want to **change your details** (Name, Surname and email address) or you want to disable your account open a ticket into the [EMA Service Desk](#).





The new EMA Account Management experience demo





Changes

- > March 2022: Security questions are not in use anymore
- > March 2022: New Captcha was introduced



DOs

- > Do use your **professional** email address and not your private email, it will facilitate EMA checks
- > Do open a [EMA Service Desk](#) ticket if the **e-mail domain** of your organisation has been changed, a bulk change will be performed for all users of that domain.



DON'Ts

- > Do not use **generic** (i.e. info@) and private (i.e. Gmail or Yahoo) To create an account only personal e-mail address must be used e.g. [name.surname@domain.com](#).
- > Do not request to update your email address if you are leaving your company, open instead a [EMA Service Desk](#) ticket to **disable** your current account and **self register** a new account.





Q&A session

Moderator: Miriam Narodova

Join at
slido.com
#2456 820





Get Access

- Register an Organisation in OMS
- Request Access as User Administrator
- Request further Access



Action

Register an **EMA account**
(external e-mail address)

Register an **organisation**

Request the first **User Administrator** with a signed proof of authority
(only applicable to the first Administrators)

Further access role(s)
can be requested by the same or different users.

Validation

EMA Data Stewards validates and master the **organisation** (up to 10 working days)

EMA User Administrators validate the request (up to 2 working days)

User Administrator of the Organisation validate the request

Outcome

An active **EMA account**
(external e-mail address)

An **organisation** on whose behalf you will be acting listed in the EMA's Organisation Management Service (OMS)

An approved **User Administrator** for the specific EMA **OMS organisation**

Access role(s) assigned on behalf of the specific EMA **OMS organisation**



Get Access



EUROPEAN MEDICINES AGENCY

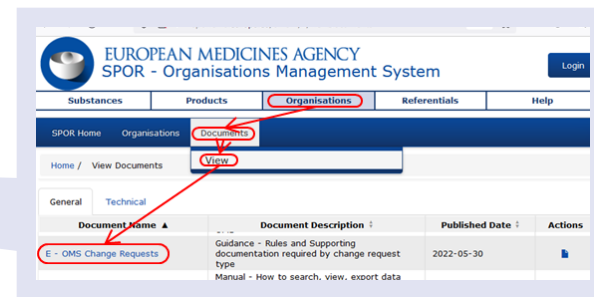
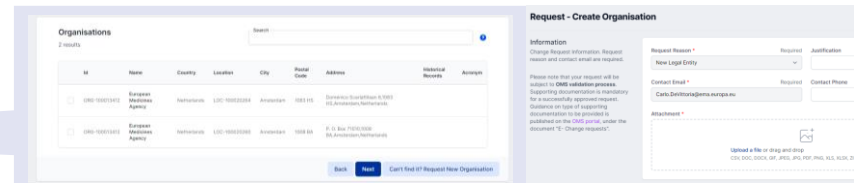
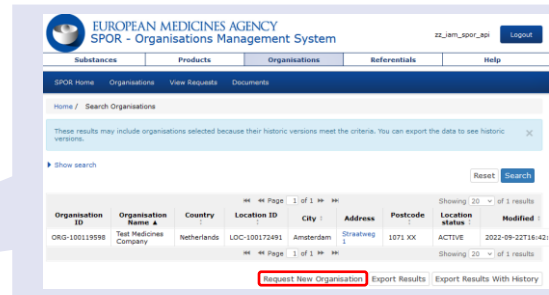
Register an Organisation in OMS

Before requesting access the **organisation** on whose behalf you will be acting must be listed in the EMA's **Organisation Management Service (OMS)**

The possibility to request a new organisation is shown only after checking that the required organisation is not listed in OMS. It is now possible to request the registration of an organisation also from **EMA Account Management**.

Don't forget to provide **mandatory supporting documentation** for a successfully approved request. Guidance on type of supporting documentation is published on the **OMS portal**, under the document "E- Change requests".

The validation of a Change Request can take up to 10 working days.





Request Access as User Administrator

The new access request workflow is available on the home page of EMA Account Management on the "[Request Access for Organisations](#)" tab.

Further roles cannot be requested before a user administrator role is appointed for an organisation.

The first user Administrator of an Organisation is approved by EMA by validating a [proof of authority to represent the organisation](#) (affiliation letter).

The [External Organisation Administrator](#) is a special role that can reduce the number of administrators validated by EMA.

More details on the different user administrator roles are available in [this presentation](#)

The **person signing** the affiliation letter should be **different** from the person requesting the user administrator access, however, if you are the sole representative of a one-person company, please state this in the letter.

Sign the affiliation letter stating **name** and **role** of the signing person for the relevant organisation.

Submit the affiliation letter with a **work email** from the same **domain** as the organisation domain otherwise, please state in the letter that the email won't match the company's domain, and get the letter signed

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Amsterdam 3/10/2022
EMA Account Management Portal

Subject: IRIS Industry User Admin (for Orphan Designation, ITF, Scientific Advice) – ORG-100013412

Dear Sir/Madam

We are hereby requesting that <name of the IRIS User Admin/SPOR Super User/CTIS User Administrator / UPD Industry Super User> is authorised to obtain the first <IRIS Industry User Admin/Parallel Distribution User Admin/SPOR Super User/CTIS High Level Administrator / UPD Industry Super User> for <name of the Organisation> <the Organisations listed below> and therefore is empowered for the approval/rejection of <IRIS/SPOR/CTIS/UPD> user access requests within the same organisation(s).

Details of the <IRIS/SPOR/CTIS/UPD> User Admin/Super User are provided below:

(all fields marked with an asterisk are mandatory)

Name*: John Smith
Organisation name*: European Medicines Agency
Organisation Address*: Domenico Scardafalano 6
Post Code: 1083 NH
Country*: the Netherlands

By obtaining the IRIS Industry User Admin/Parallel Distribution User Admin/CTIS Sponsor High Level Administrator, the user accepts the rights of IRIS Industry User Admins/SPOR Super Users/CTIS User Admins representing the same organisation(s), for ensuring that there is a Admin/SPOR Super User/CTIS User Administrator acting on behalf represent and that the rights of access for all their users are kept

<If the User Admin/Super User has requested multiple roles linked to the same organisation(s), for ensuring that there is a Admin/SPOR Super User/CTIS User Administrator acting on behalf represent and that the rights of access for all their users are kept

List of Organisations for which the first <IRIS Industry User Admin/SPOR Super User> needs to be affiliated

Organisation Name	Country	Organisation ID
European Medicines Agency	Netherlands	ORG-100013412
European Test Agency	Netherlands	ORG-102013412

Yours faithfully,
David Jones
Head of Medicines

[Signature]

Don't forget to include the **OMS Organisation ID** in your affiliation letter and make sure that it matches the one in your request





Request Further Access

- Once a user administrator for an organisation is appointed **further access to EMA applications** can be requested.
- Some roles are available only for specific organisation type (e.g. Regulatory roles for National Competent Authorities) and some roles are restricted only to specific email domains.
- The request is evaluated by the user administrator of the organisation.
- Third party providers (Consultants)**
- Consultants can access on behalf of several organisations. Based on the policy defined by the organization they can use a work email provided by the organisation (e.g. john@pharma.com) or the work email of the consultancy (e.g. john@pharmaconsultant.com).
- Consultants can request User Admin role by providing an additional letter stating that the organisation authorises this person to have the User Admin role in their behalf.



EMA User Admin



External Organisation Administrator *(optional)*



SPOR Industry Super User



SPOR Industry User



SPOR Industry User





Available SPOR Roles

Activities	Guest User (Any member of the public)	Unaffiliated User (assigned by default)	Industry User	Industry Super User	NCA User	NCA Translator	NCA Super User
Login to SPOR	Not Required	✓	✓	✓	✓	✓	✓
Grant/revoke access to SPOR in EMA Account Management				✓			✓
View and Search RMS/OMS	✓ only public data	✓	✓	✓	✓	✓	✓
Download and export RMS/OMS Data		✓	✓	✓	✓	✓	✓
Submit a Change Request to RMS/OMS Data		✓ in OMS only	✓	✓	✓	✓	✓
Perform Translations in RMS						✓	



Get Access



EUROPEAN MEDICINES AGENCY

The new EMA Account Management experience demo





Changes

- › March 2022: External Organisation Administrator role allows to manage users for an organisation
- › August 2022: New request access for organisations workflow
- › October 2022: Possibility to request a new organisation from EMA Account Management
- › January 2023: Possibility to request multiple OMS change requests with SPOR unaffiliated role



DOs

- › Do **sign** the affiliation letter stating **name** and **role** of the signing person for the relevant organisation.
- › Do have **more than one user administrator** this will ensure that your access request are always evaluated on time and a smooth transition in case a user administrator is leaving your organisation.



DON'Ts

- › Do not forget to provide **mandatory details** in the proof of affiliation letter to avoid unnecessary rejection





Q&A session

Moderator: Miriam Narodova

Join at
slido.com
#2456 820





Manage Access

- Approve Access
- Remove Access and Manage users of an organisation



Approve Access

- A 'User Administrator' of an organisation is accountable and responsible for **approving** and **revoking** access for users of the same organisation.
- They are also notified when users accounts are reactivated or when the email address of a user has changed.
- Pending Approvals are displayed on the home page of the platform.
- When multiple User Administrators are available, requests to access on behalf of the organisation can be approved by any of the User Administrators.

The screenshot shows the 'Home' page of the EMA IRIS platform. A blue box highlights the 'Your Pending Approvals' section, which contains a table with the following data:

Approval For Requester	Requested ...	Date
name sur...	name sur...	23/09/202...
name sur...		

Below the table, a dashed blue line indicates a zoomed-in view of the approval details. The details show an 'Owner Approval - Account Changes for User: surname_n - name surname - name.surname@emaildomain.com | 1 Request'. It includes the request date (23 Sep 2022 15:56:06), the requester (name surname), and the assigned role (IRIS Industry Manager (ORG-100031473) Approvers). At the bottom, there are 'Approve All' and 'Deny All' buttons, and a detailed description of the role's responsibilities.





Remove Access and Manage users of an organisation

- Each user can remove its own access using the Manage Access functionality
- User Administrators can list and revoke access for the users they manage.
- User Administrators are encouraged to **list and review** the user accessing in behalf of their organisation on a regular basis.
- For specific roles EMA requires periodic access reviews, if this is not performed access is revoked.
- When two organisations are merged User Administrators of the merged organisations should take action in the different EMA systems including EMA Account Management.
- Change of User Administrator:** If a unique user administrator left your organisation and the person does not have access to the account anymore, a ticket in the EMA Service Desk is required. A change of user administrator can take up to 5 working days if performed by the EMA

Old

1. Set a filter to search an organisation, you can use its ID or its name

2. Select your organisation by clicking on the dropdown icon

3. If you want to revoke access select the user from the dropdown and click on the **Revoke Roles** button

Click On List roles to have a list of users accessing your organisation for the selected application

New

Manage Access

Revoke 1 selected roles X Clear selection Search Export XLS Export CSV

	Name	Display Na...	Email	Role	Organisat...	Applicat...
☒	surname_n	name surname	name.surname@emaildomain.com	IRIS Industry Contributor (ORG-100032441 - Achilles - testcompany)	ORG-100032441	IRIS
☐	surname_n	name surname	name.surname@emaildomain.com	IRIS Industry Manager (ORG-100032441 - Achilles - testcompany)	ORG-100032441	IRIS
☐	account_e	Carlo Account	carlo.account@company.email.com	SPOR Unaffiliated User		
☐	account_e	Carlo Account	carlo.account@company.email.com	IRIS Industry Manager (ORG-100032441 - Achilles - testcompany)	ORG-100032441	IRIS
☐	account_e	Carlo Account	carlo.account@company.email.com	IRIS Individual User		
☐	account_e	Carlo Account	carlo.account@company.email.com	IRIS Industry User Admin (ORG-100032441 - Achilles - testcompany)	ORG-100032441	IRIS

Showing 1 to 6 of 6 results

Previous 1 Next





The new EMA Account Management experience demo





Changes

- > March 2022: External Organisation Administrator role allows to manage users for an organisation
- > October 2022: Revamped role administrators' page
- > Coming soon: notification of merged organisations



DOs

- > Do **review regularly** the users accessing on behalf of an organisation and revoke access



DON'Ts

- > Do not **ignore** notifications coming from register@ema.europa.eu to perform user administrator's task.





Q&A session

Moderator: Miriam Narodova

Join at
slido.com
#2456 820





Access EMA Systems

- Login into EMA Systems
- Set up Multi Factor Authentication (MFA)
- Logout from EMA Systems



Login into EMA Systems

The European Medicines Agency is migrating its applications to **modern authentication** methods. These methods are available for applications like IRIS, UPD, EV VET and they provide capabilities like Multi-Factor Authentication and Single Sign On

The transition of EMA applications to modern authentication and Multi Factor Authentication is **ongoing**. Some EMA applications like SPOR, EV Human and Eudralink authenticates users with username and password **without the suffix @id.ema.europa.eu** and without Multi Factor Authentication capabilities.

If your username and password are not working use the forgot password capabilities of [EMA Account Management](#) to reset them.

Sign in

surname_n@id.ema.europa.eu

Can't access your account?

Back Next

EMA users: sign in with your email address

Other users: sign in with your username followed by @id.ema.europa.eu

Follow this [guidance](#) to recover your username and password.

Further guidance and [common error messages](#) can be found [here](#)

You must sign in with your username followed by @id.ema.europa.eu: [username@id.ema.europa.eu](#)

The password is the same as in <https://register.ema.europa.eu>

Multifactor authentication is required

Username

Password

Login

Create a new EMA account

Not sure if you have an EMA account?

Forgot Password?

Forgot Username?

EUROPEAN MEDICINES AGENCY

SCIENCE MEDICINES HEALTH

document

NEW VERSION 1.10

Login to Eudralink

AUTHORISED PERSONNEL ONLY

Login ID Enter your Eudralink ID

Password Password

Log in

Note: Account name is not case-sensitive

For technical support or to open a Eudralink account, please visit the EMA Service Desk portal: <https://servicedesk.ema.europa.eu>

For urgent technical matters, telephone +31 (0) 88751 6000





Set up Multi Factor Authentication (MFA)

- First time you log in you are asked to set up your Multi Factor Authentication.
- We advise to use a mobile authenticator application as more secure method.
- In addition to MFA we use also the authentication context, like the device and the location from you are authenticating, and behaviour, like the time of the day or the frequency of your authentication to determine risk factors.
- You can review your MFA settings here and you can check your recent sign-ins [here](#)
- Further guidance are available [here](#)



Something you **know**

A password
A pin
NOTE: a code on email falls in "Something you know" as to access an email you are probably using a password



Something you **are**

Your fingerprint
Your face
Your eye
Your voice



Something you **have**

A mobile phone
An office phone
A security Key
A code generator

Not applicable at the moment to SPOR Users



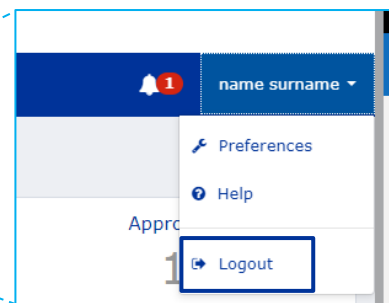
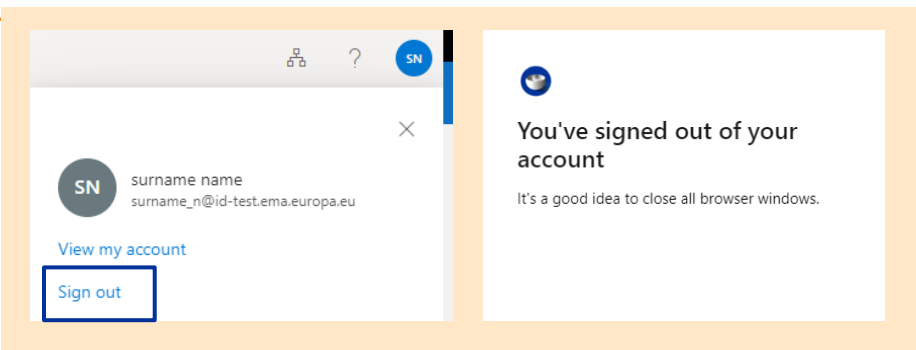


Logout from EMA Systems

Most EMA systems have a **session timeout**, disconnecting the user after a **period of inactivity**.

EMA systems using modern authentication allow **single sign out**, meaning that logging out from one system logs out from all other EMA connected applications.

Other EMA systems may require you to logout independently or to wait a session timeout to log you out





Changes

- › Ongoing: EMA applications migrated to modern authentication



DOs

- › Do **review** regularly your Multi Factor Authentication settings
- › Do register more than one MFA method to ensure you are not locked out from you EMA Account



DON'Ts

- › Do not **share** your credentials (username and password), and EMA Account should be used by one single person
- › Do not **disclose your password** with anybody, EMA will never ask you to provide your password to support you



Q&A session

Moderator: Miriam Narodova

Join at
slido.com
#2456 820





EMA Account Management Statistics

Carlo De Vittoria, *Information Security, EMA*



The **Super User** is approved by the Service Desk based on a validation of the proof of authority to represent an organisation:



*On average of **300** requests per month are evaluated by the service desk*



*Median wait of **0.8 days** has been reduced to **0.7 days** with an integration with ServiceNow*



*Approval rate went from **63%** to **86%***



125 Organisation per month are requested through IAM with an approval rate of **60%**



Other roles are approved by the appointed Super Users of each organisation



*On average of **200** requests per month are evaluated by Super users*

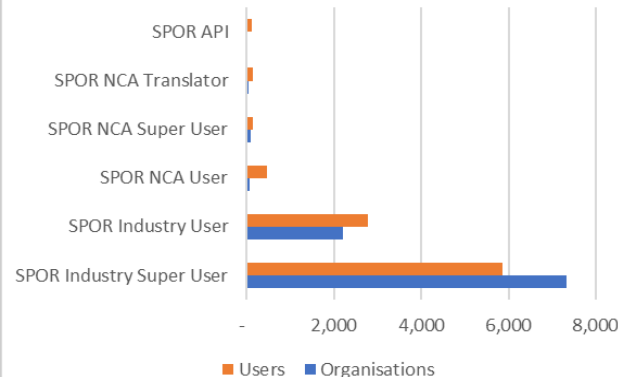


*Median wait of **1.5 days** for Industry and **0.8 days** for Competent Authority users*



*Approval rate is **95%***

Assignments



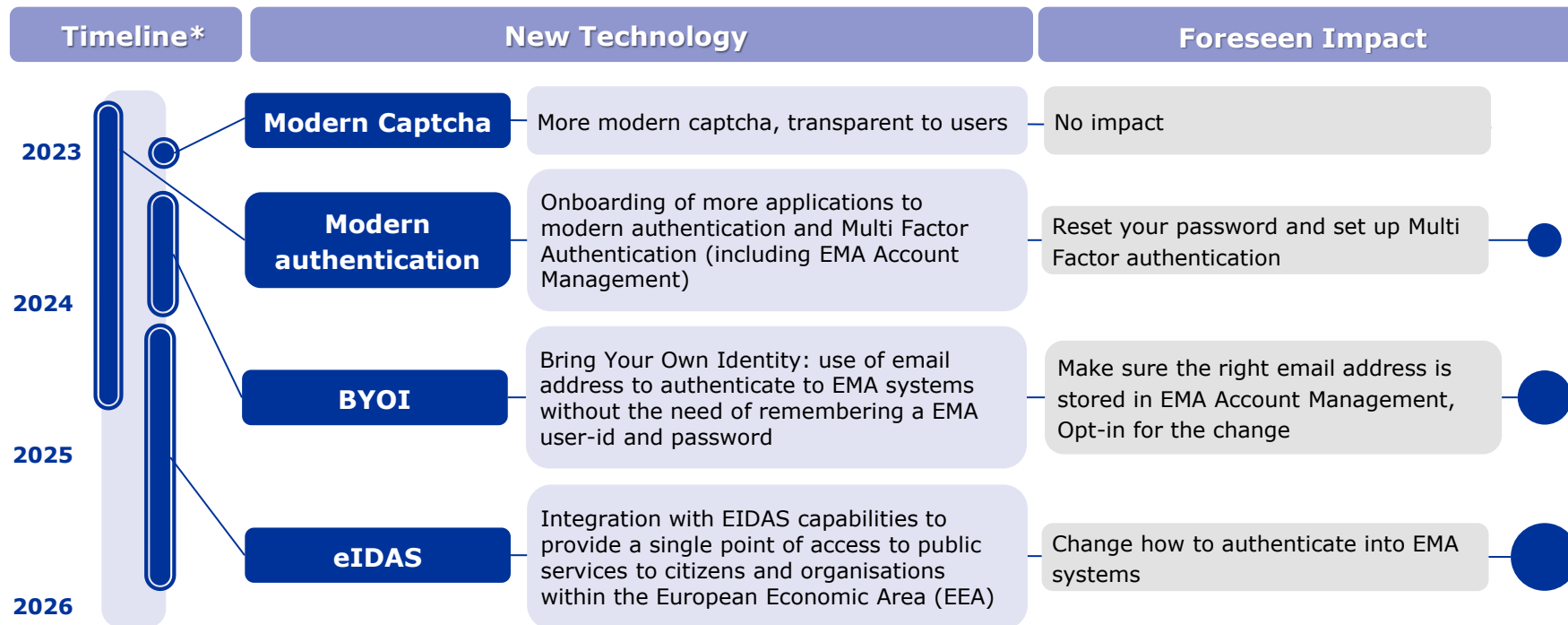
Role	Organisations	Users	Assignments
SPOR Industry Super User	7,320	5,864	10,978
SPOR Industry User	2,211	2,767	4,279
SPOR NCA User	64	464	467
SPOR NCA Super User	83	151	156
SPOR NCA Translator	29	133	141
SPOR API	-	108	108
Total	7,450	8,483	16,129



What's next

Carlo De Vittoria, *Information Security, EMA*

To enhance security and usability of EMA applications, EMA is looking into new technologies to support its digital services like:





Q&A session

Moderator: Miriam Narodova

Join at
slido.com
#2456 820





Closing



The [EMA Account Management](#) is the online platform where you can request and manage access to EMA applications. Refer to this platform to seek guidance on how to:

- [Look up whether you already have an EMA account](#)
- [Re-activate your EMA account](#)
- [Recover your credentials](#)
- [Retrieve your username](#)
- [Reset your password](#)
- [Create an EMA account](#)
- [Request a user access role](#)
- [Manage users' access for your organisation as an "User Admin"](#)
- [Log into EMA systems and manage Multi Factor Authentication](#)
- [FAQs](#)



Improved management of SPOR users and organizations in EAM
– more available features



Possibility to submit OMS change requests for new Organisations through IAM Platform



Account Management is a shared Responsibility, each organisation should review and maintain users accessing EMA systems and follow EMA guidelines



Further information

<https://register.ema.europa.eu/identityiq/home.html>

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

Telephone +31 (0)88 781 6000

Send us a question Go to EMA Service Desk <https://support.ema.europa.eu/esc>

Follow us on  **@EMA_News**