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

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- Join via **QR code** or **slido.com** - *please provide your questions and comments in Slido only*
- **Send or upvote the questions** you want to hear answered – *before raising a question check whether its has been raised already and vote for it*



Q&A Management

- Questions will be shown on the screen and managed live in the Q&A session
- EMA colleagues will attempt to **address questions in writing throughout the session**
- EMA colleagues will **verbally address (unanswered) top voted questions** at the end in the live Q&A session.



Unanswered questions

- This can be due to high volume of questions or assistance of a specific colleague not available today is required.
- Unanswered questions will be reviewed, and the **most relevant ones may be addressed** in other webinars or in a FAQ document.
- We may request that you ask **Questions on specific issues/cases** in Service Desk to be tracked, investigated and adequately assigned.



Presentations will be* available at:

- SPOR Portal Documents section
- EMA Events Web Page

*1st version of presentation already published,
to be updated with final version (if necessary)



Recordings will be available at:

- EMA YouTube Channel
- EMA Events Web Page



*If you would like to **receive recordings and presentations via email**, please register your e-mail address in Slido (www.slido.com) using the **event code #6326138**.*



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA Account Management Training Session




11 October 2023, 10:00 – 12:00 Central European Summer Time (CEST)

Presented by Carlo De Vittoria

SPOR Webinar Series – 2-12 October 2023



During **SPOR webinars**, EMA's Regulatory Data Management Service team talks about all aspects of regulatory data management and how it works today.

 Webinar title	 Date	 Time
SPOR and XEVMPD Data Governance	2 October 2023	10:00-12:00 CEST
Referentials Management Service (RMS)	3 October 2023	10:00-12:00 CEST
Organisation Management Service (OMS)	4 October 2023	10:00-12:00 CEST
Substance Management Service (SMS)	5 October 2023	10:00-12:00 CEST
Product Management Service (XEVMPD)	6 October 2023	10:00-12:00 CEST
Service Desk for SPOR and XEVMPD	10 October 2023	10:00-12:00 CEST
 EMA Account Management	11 October 2023	10:00-12:00 CEST
SPOR application programming interface (API) - SPOR API	12 October 2023	10:00-12:00 CEST



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



Introduction



Show **how the EMA Account Management works**



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

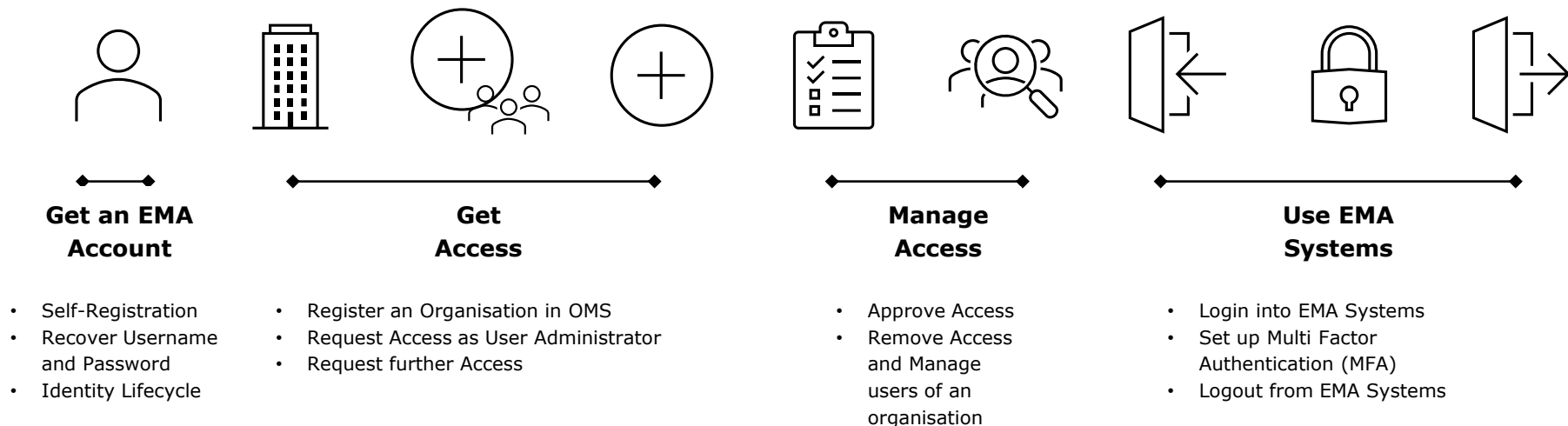


Provide tips & tricks on EMA Account Management



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, 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 '5185SP' which is highlighted by a blue box. An arrow points from this token value to the 'Confirm Token' field in the registration form. The email also includes contact information for the European Medicines Agency.

The image shows a screenshot of an email validation error. 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 ...'. Below this, a blue message 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](#)

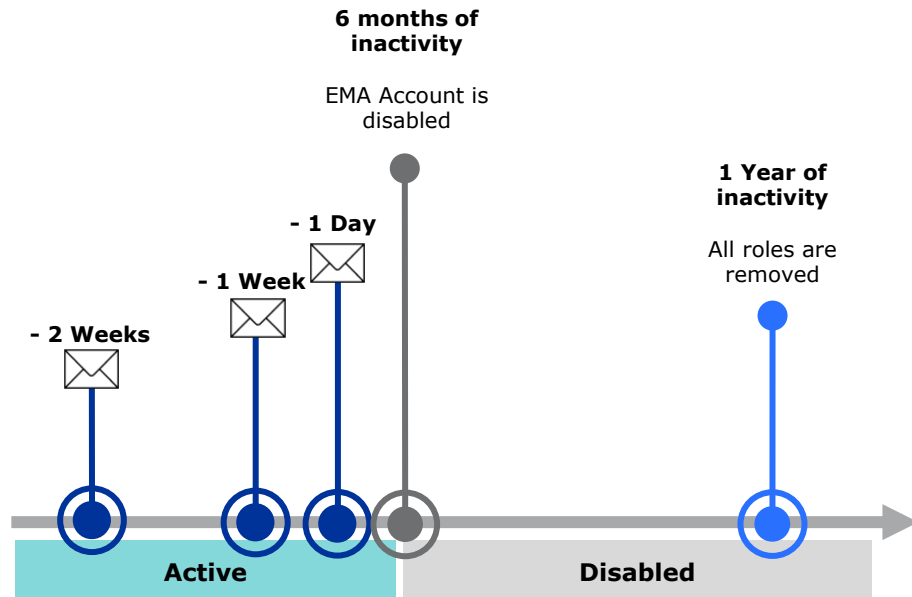
Note: Check your spam e-mail folder if you have not received the one-time token required to reset your password.





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](#).
- If your company has changed domain and you want to update users in bulk, open a ticket into the [EMA Service Desk](#) specifying the impacted domains.





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.





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



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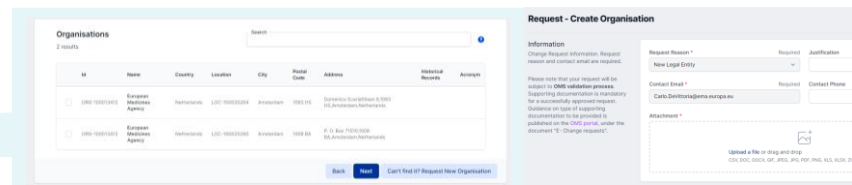
Register an Organisation in OMS

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

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, the user must ensure that the 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





Get Access



EUROPEAN MEDICINES AGENCY

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





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 EMA IRIS platform home page. The top navigation bar includes links for Welcome Page, Search your organ..., Manage My Access, Request Access fo..., Track My Requests, and Approvals (1). Below this, there are links for Edit Identity, EMA Service Desk, EV Role Admin, and External Role Admin. The main content area is divided into two sections: 'Your Pending Approvals' and 'Latest Forms'. The 'Your Pending Approvals' section contains a table with columns for Approval For Requester, Requested..., and Date. The table shows one pending approval for 'name sur...' requested on '23/09/202...'. The 'Latest Forms' section shows 'Currently no data'. A dashed blue line indicates a zoomed-in view of the pending approval request. The zoomed-in view shows the details of the request: '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 work item ID (125130). Below this, there are buttons for 'Approve All' and 'Deny All'. The request is assigned to 'IRIS Industry Manager (ORG-100031473) Approvers'. The detailed view also shows the role being requested: 'Add: IRIS Industry Manager (ORG-100031473 - European Union Reference Laboratory For Alternatives To Animal Testing)'. It includes a description of the role and a 'Read more' link.





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...
<input checked="" type="checkbox"/>	surname_n	name surname	name.surname@emaildomain.com	IRIS Industry Contributor (ORG-100032441 - Achilles - testcompany)	ORG-100032441	IRIS
<input type="checkbox"/>	surname_n	name surname	name.surname@emaildomain.com	IRIS Industry Manager (ORG-100032441 - Achilles - testcompany)	ORG-100032441	IRIS
<input type="checkbox"/>	account_e	Carlo Account	carlo.account@company.email.com	SPOR Unaffiliated User		
<input type="checkbox"/>	account_e	Carlo Account	carlo.account@company.email.com	IRIS Industry Manager (ORG-100032441 - Achilles - testcompany)	ORG-100032441	IRIS
<input type="checkbox"/>	account_e	Carlo Account	carlo.account@company.email.com	IRIS Individual User		
<input type="checkbox"/>	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





Access Review

- User administrators can be requested to certify the access granted to the users of their organisation through an **access review**
- An access review can be scheduled on a regular basis (e.g. every six months) or requested ad hoc
- The user administrators receive an access review for each role they need to certify
- To access the assigned access reviews:
 1. Click on the menu on the left next to the "Home" tab,
 2. select "Compliance Activities"
 3. Select "Access Reviews";
- For each item in the access review access can be confirmed (**Approved**) or **Revoked**

Type	Display Name	Application	Identity	Decision
Role	IRIS Competent Authority User (ORG-100003960 - Institute for State Control of Veterinary Biologicals and Medicaments)		Adam OrpReg	Revoked
Role	IRIS Competent Authority User (ORG-100003960 - Institute for State Control of Veterinary Biologicals and Medicaments)		foxtrot rkakki	Approved





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** October 2023: 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.





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

[Create a new EMA account](#)
Not sure if you have an EMA account?

[Forgot Password?](#)
[Forgot Username?](#)

Login



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

NEW
Version
1.10

Login to Eudralink AUTHORISED PERSONNEL ONLY

Login ID

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



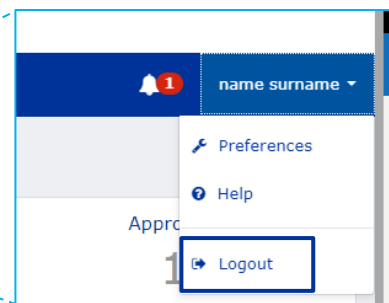
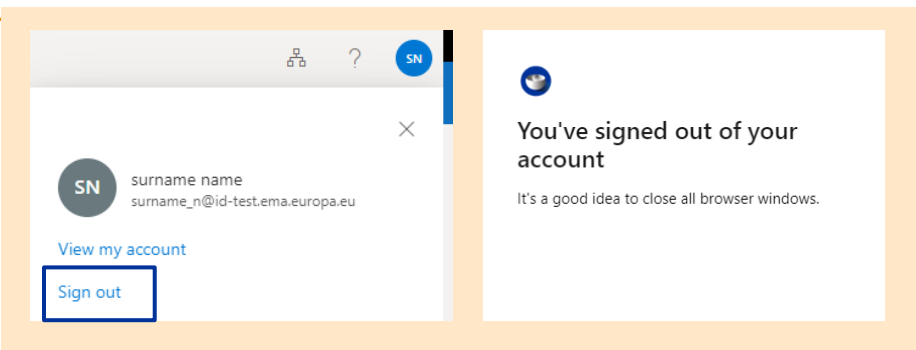


Logout from EMA Systems

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



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



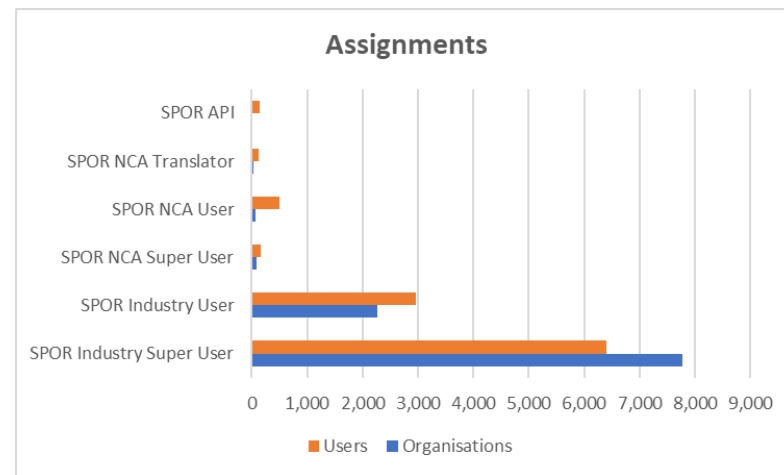
*On average of **200** requests per month are evaluated by Super users*



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



*Approval rate is **95%***



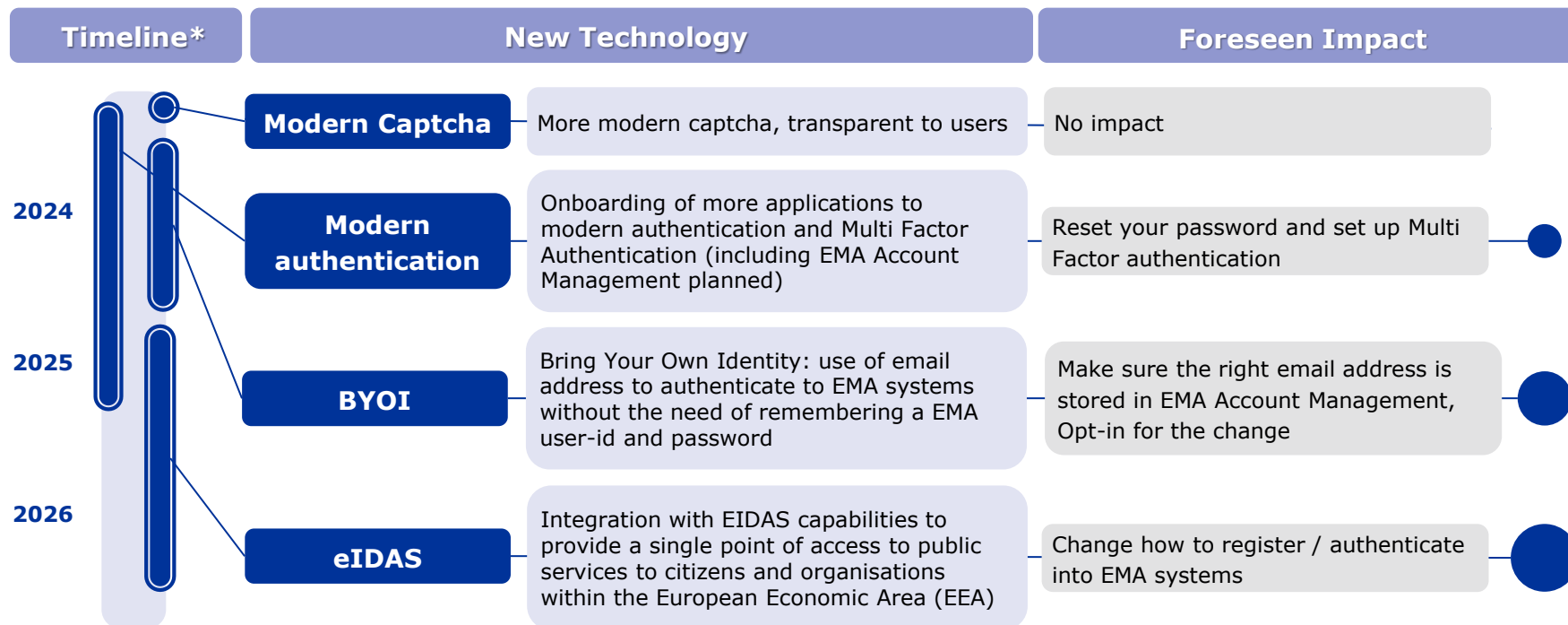
Role	Organisations	Users	Assignments
SPOR Industry Super User	7,776	6,408	11,499
SPOR Industry User	2,271	2,963	4,407
SPOR NCA Super User	89	162	166
SPOR NCA User	66	499	501
SPOR NCA Translator	30	129	137
SPOR API	-	136	108
Total	7,920	9,172	16,711



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
#6326 138





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>

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