EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA Account Management Training Session

3 October 2022, 10:30 – 12:25 Central European Time (CET)
Webinar: WebEx

Agenda

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1. **Introduction**
   10:30 – 10:40
   Carlo De Vittoria
   Information Security, EMA

2. **EMA Account Management Features Overview,** including Q&A
   10:40 –12:00
   Carlo De Vittoria
   Information Security, EMA
   Moderator:
   Miriam Narodova

3. **What's Next**
   12:00 – 12:15
   Carlo De Vittoria
   Information Security, EMA

4. **Closing**
   12:15 – 12:30
   Carlo De Vittoria
   Information Security, EMA

*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.*

Send your questions via Slido

1. Join via the QR code or link

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

Introduction

Carlo De Vittoria, *Information Security, EMA*

Introduction

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Vision

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, 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.

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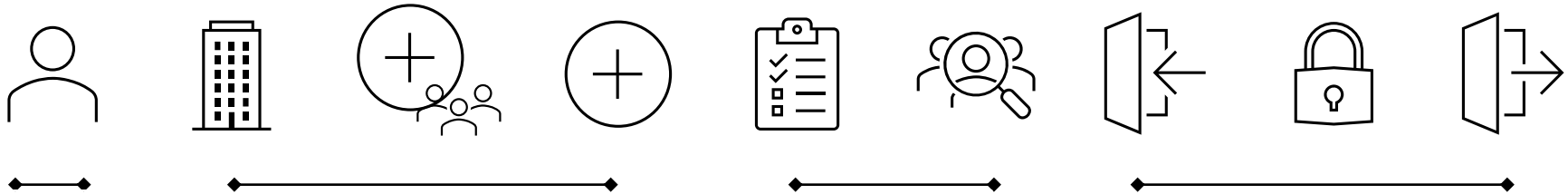
Introduction



Get an EMA Account

- Self Registration
- Recover Username and Password
- Identity Lifecycle

Get Access

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

Manage Access

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

Use EMA Systems

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

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Introduction

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Current 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

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Get an EMA Account

- Self Registration
- Recover Username and Password
- Identity Lifecycle

Self Registration

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

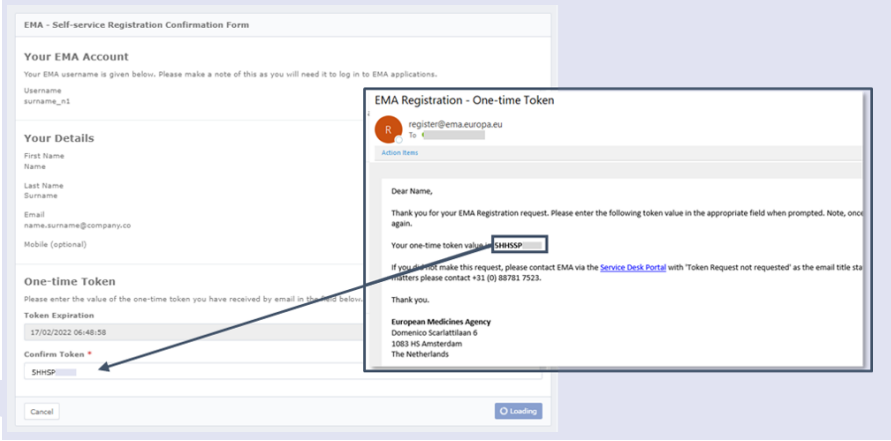
The first step to access EMA services is to have an **active EMA Account**.

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

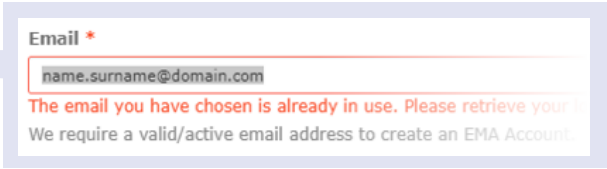
If you don't have an EMA Account, self registration is a 2 steps process:

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



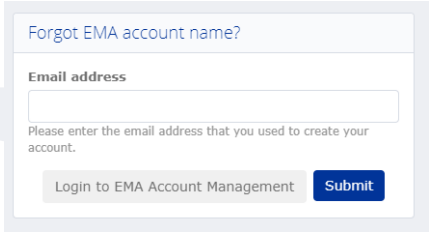
If your email is already in use you can retrieve your username with the Forgot Username?



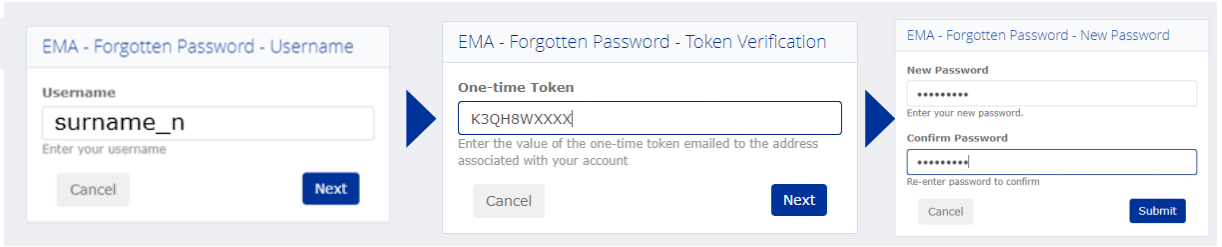
Self registration is granting basic birth-rights to access some EMA applications like the Service Desk, IRIS as an individual, OMS as unaffiliated user, CTIS.

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.



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

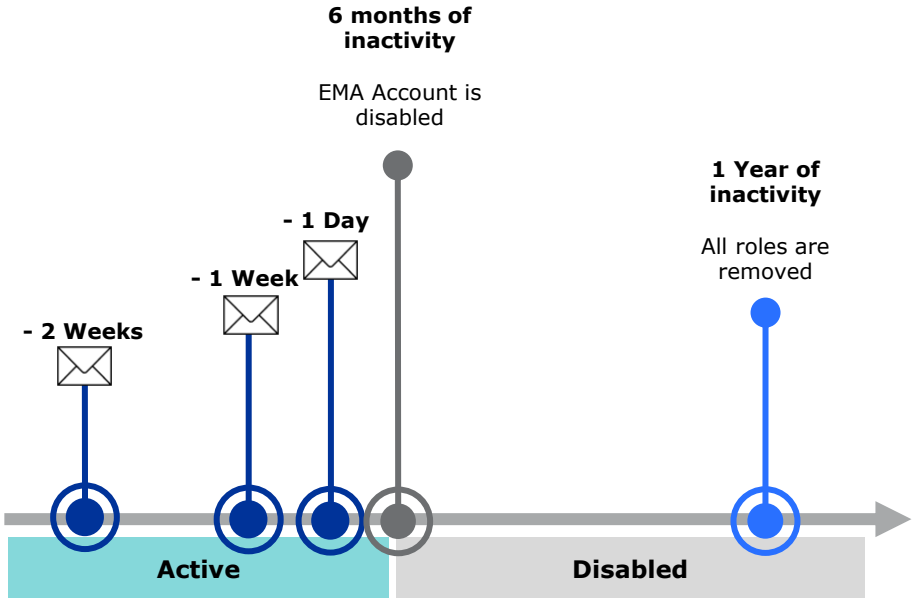
Identity Lifecyle

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 that your account has been re-activated.

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

Get an EMA Account

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Changes

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

Do's:

- 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.

Do nots:

- 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

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Passcode: yvoobo

Get Access

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

Get 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**

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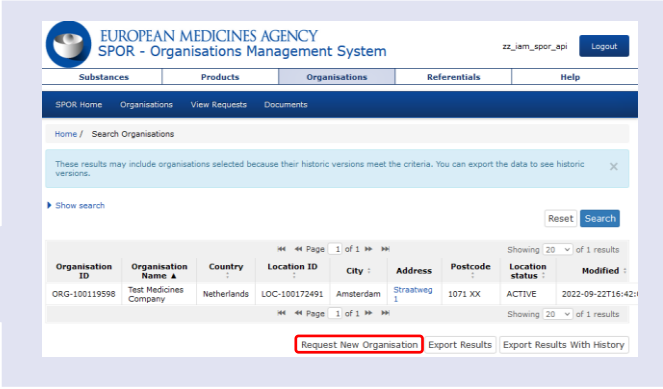
Register an Organisation in OMS

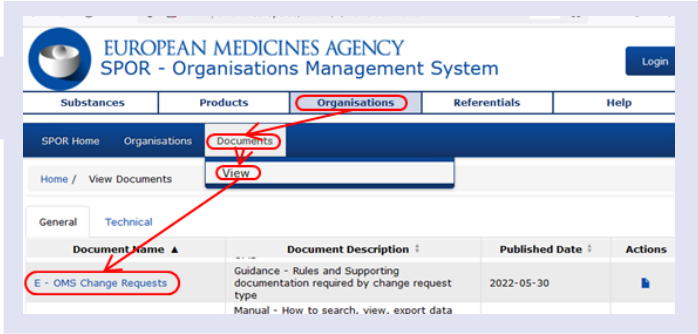
Before requesting access the **organisation** on whose behalf you will be acting must be listed in the EMA's **Organisation Management Service (OMS)**

The possibility to request a new organisation is shown only after checking that the required organisation is not listed in OMS.

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.

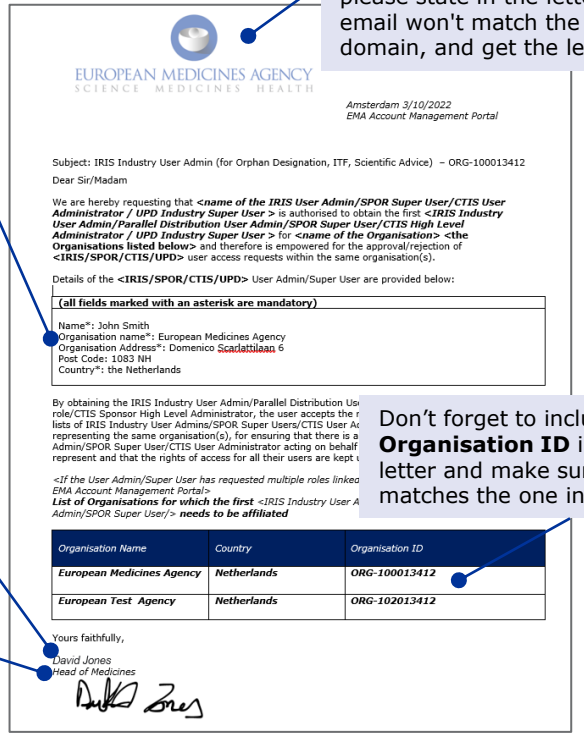
The first user Administrator of an Organisation is approved by EMA by validating a proof of authority to represent the organisation (affiliation letter).

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

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

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.



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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 Scarlattilaan 6
Post Code: 1083 NH
Country*: the Netherlands

By obtaining the IRIS Industry User Admin/Parallel Distribution Us
role/CTIS Sponsor High Level Administrator, the user accepts the r
lists of IRIS Industry User Admins/SPOR Super Users/CTIS User Ac
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
EMA Account Management Portal>
***List of Organisations for which the first** <IRIS Industry User A*
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

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

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

Request further Access

Once a user administrator for an organisation is appointed **further access to EMA applications** can be requested.

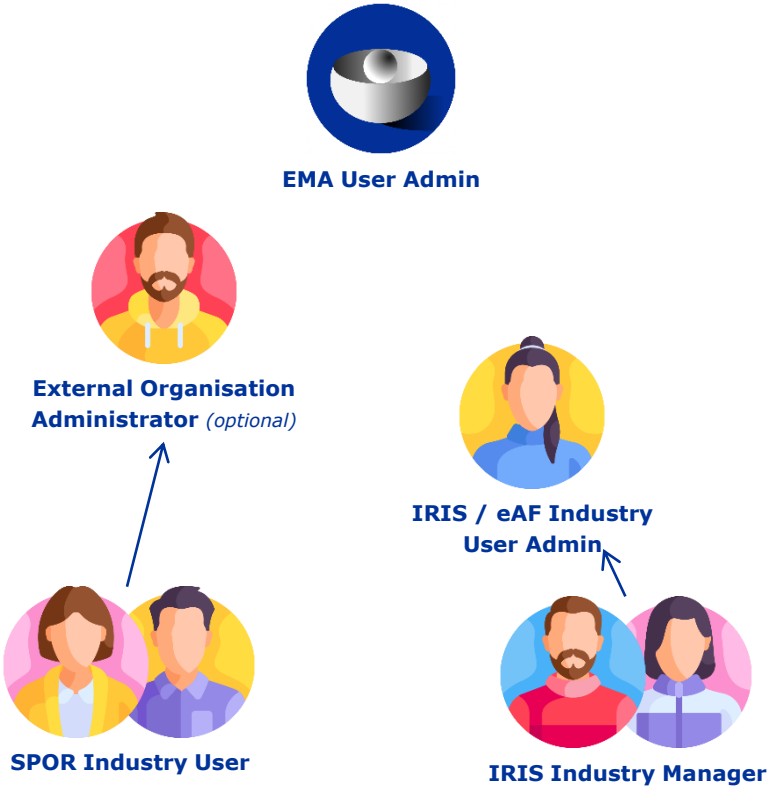
Some roles are available only for specific organisation type (e.g. Regulatory roles for National Competent Authorities) and some roles are restricted only to specific email domains.

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.



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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
- Coming Soon: Possibility to request a new organisation from EMA Account Management

Do's:

- 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.

Do nots:

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

Q&A session

Moderator: Miriam Narodova

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Passcode: yvoobo

Manage Access

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

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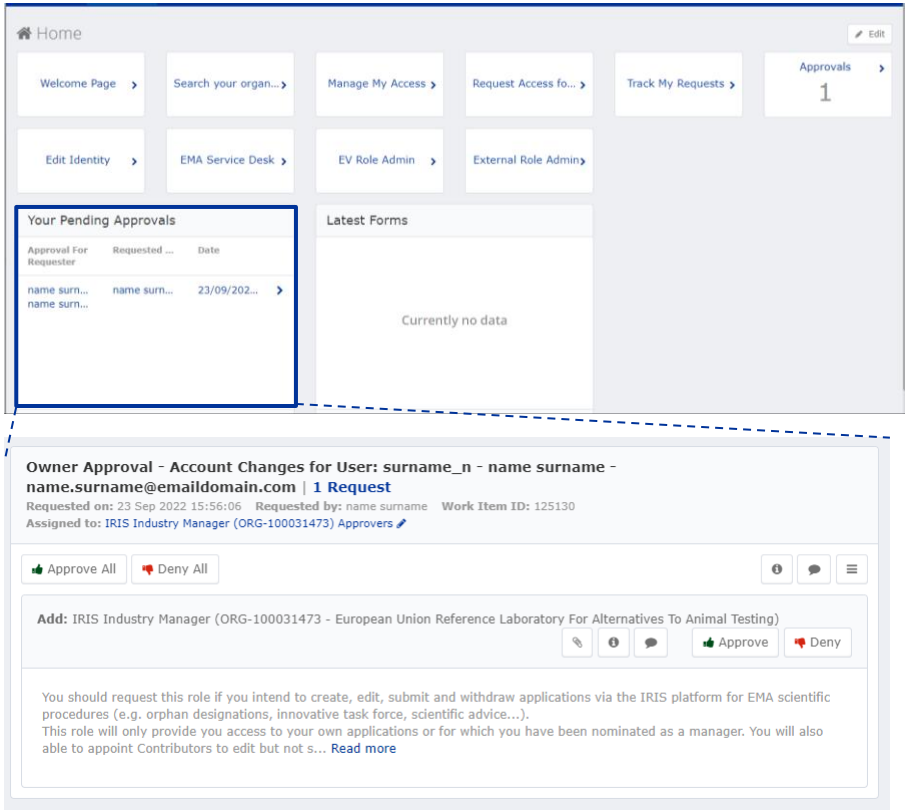
Approve Access

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.



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Remove Access and Manage users of an organisation

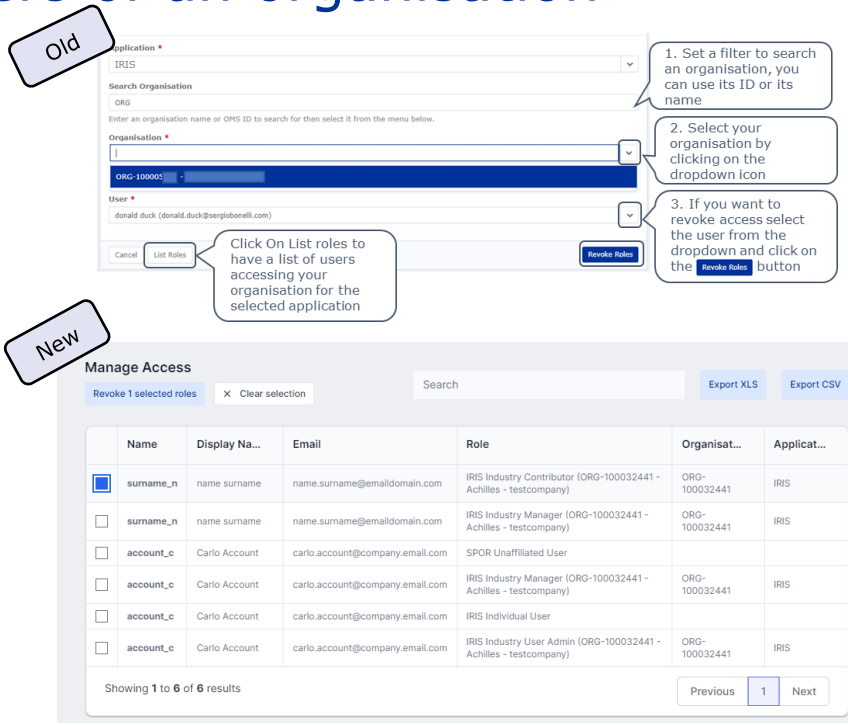
Each user can remove its own access using the Manage Access functionality

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.

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



Manage Access

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[The new EMA Account Management experience demo]

Manage Access

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Changes

- March 2022: External Organisation Administrator role allows to manage users for an organisation
- Coming Soon: Revamped role administrators page

Do's:

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

Do nots:

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

Q&A session

Moderator: Miriam Narodova

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Access EMA Systems

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

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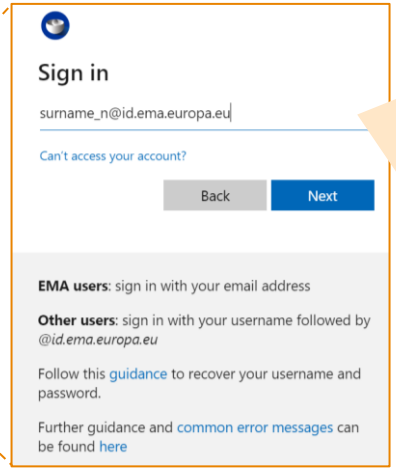
Login into EMA Systems

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.

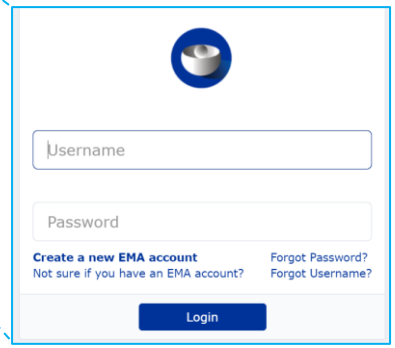
If your username and password are not working use the forgot password capabilities of [EMA Account Management] to reset them.



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



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

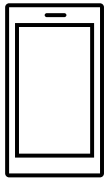
Further guidance are available here

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

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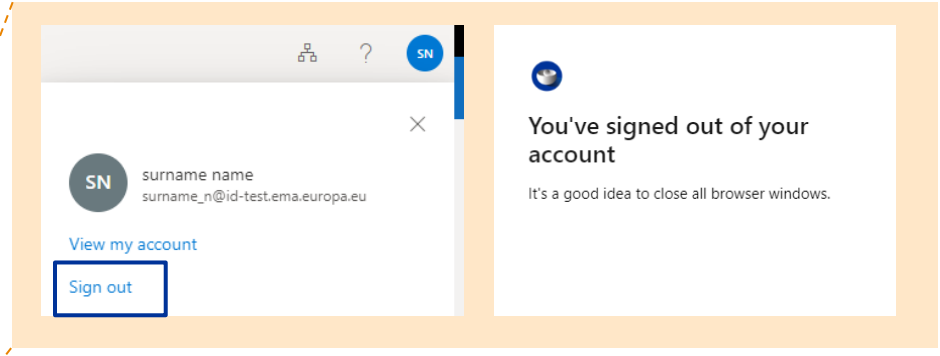
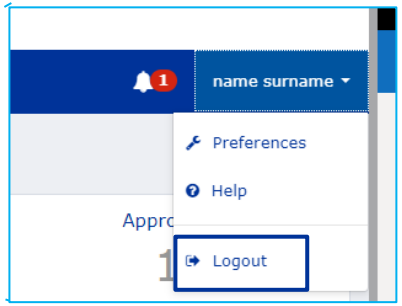
Logout from EMA Systems

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





Access EMA Systems

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The new EMA Account Management experience demo

Access EMA Systems

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Changes

- Ongoing: EMA applications migrated to modern authentication

Do's:

- 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

Do nots:

- 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

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Q&A session

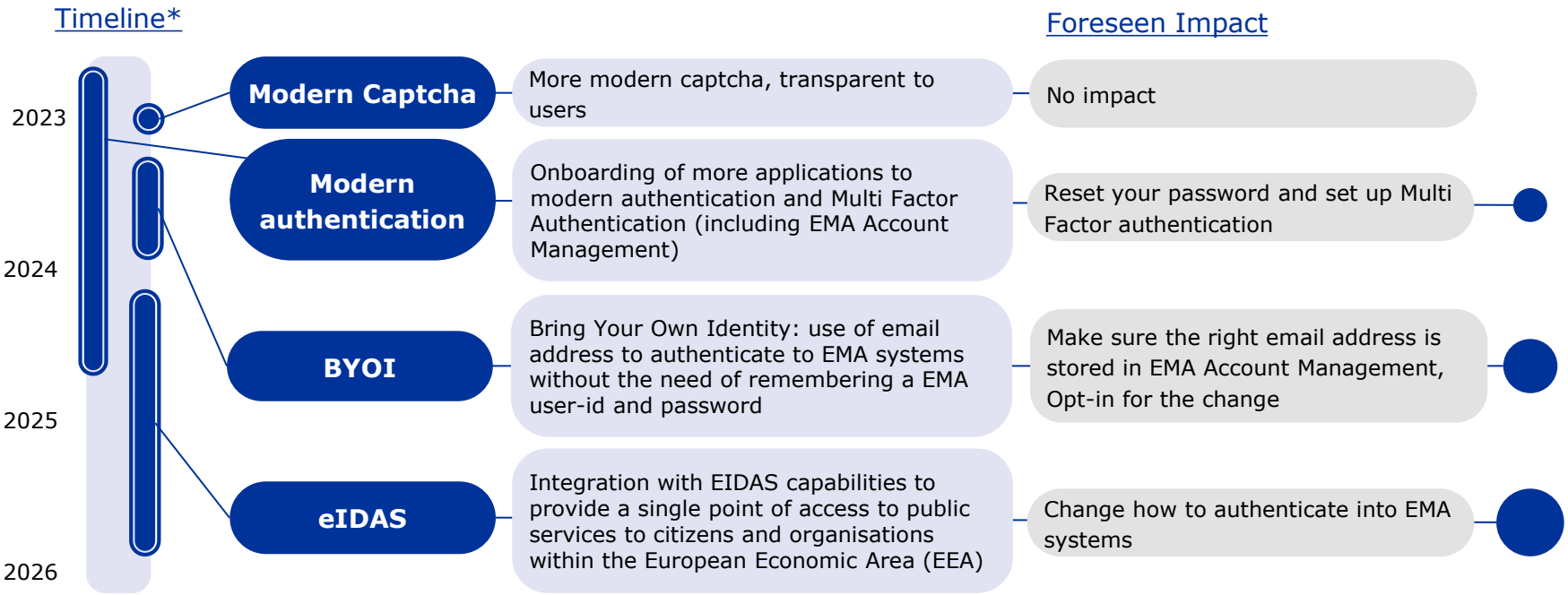
Moderator: Miriam Narodova

What’s next

Carlo De Vittoria, *Information Security, EMA*

What's next

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



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* Provided timelines could change over time and only used as an indication of when future activities may happen

Q&A session

Moderator: Miriam Narodova

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Passcode: **yvoobo**

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

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Further information

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

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

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