EMA
EUROPEAN MEDICINES AGENCY

CTIS Training Environment

Updated access process and Safety Module instructions

Focus: sponsor access routes and ticket escalation rules

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Today’s focus

1	**What changes**	New access process and Safety Module in the Training Environment.
2	**Sponsor access route**	How sponsor users access and work in the CTIS Training Environment.
3	**Safety Module support**	Internal triage and ticket escalation rules.

What is changing in the Training Environment?

Two changes are relevant for users

New access process

Introduced from **24 July 2026, 12:00 CET.**

Users access the CTIS Training Environment through the updated access route.

Current and new users should follow the updated guidance and Sponsor Handbook section 6.2.3.

Safety Module available

Available in the CTIS Training Environment from **31 July 2026.**

Users can familiarise themselves with Safety Module functionalities, including ASR and SaMS, before CTIS Production use.

The Training Environment remains for training, practice and familiarisation.

The access process changes. The purpose of the Training Environment remains the same.

Summary of changes: new access process

What users will experience in the CTIS Training Environment

1 Login route

Users will log in to the CTIS Training Environment in the same way as in CTIS Production.

2 MFA enabled

Multifactor authentication will be enabled for access.

3 Personal accounts

Fictive user accounts will no longer be used. Users will use personal accounts linked to their email address. Access to existing data will not be possible.

4 New users

New users register in EAM Production via register.ema.europa.eu, following the same process as Production.

5 Existing users

Users with existing Production accounts can use them for the Training Environment after requesting the **Training Access Role in EAM Test.**

6 New Training Access Role

Both new and existing users must request a **new role *** via register-test.ema.europa.eu.

* for new accounts, the users will be able to request the "CTIS Training Environment Access" role **one** day after the new account registration in EAM

The access model becomes more aligned with Production and is based on personal, traceable accounts.

Sponsor users: access steps

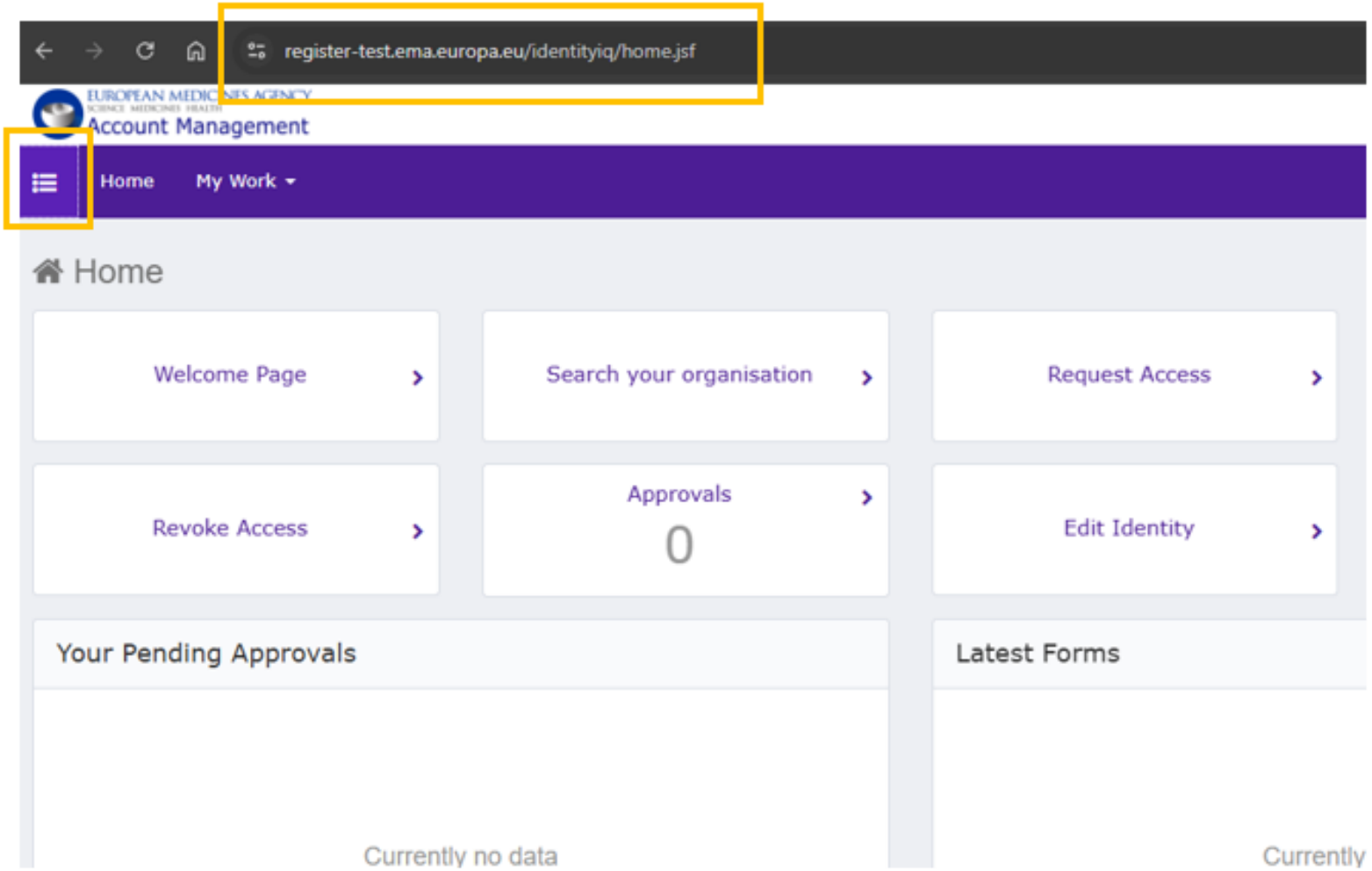
Practical steps for sponsors in the CTIS Training Environment

1	**Create or use EAM Production account**	Use the production registration environment (via register.ema.europa.eu) to access the CTIS Training Environment. (sponsor workspace)
2	**Request required sponsor access**	Sponsor users should follow the updated guidance and Sponsor Handbook section 6.2.3.
3	**Access sponsor workspace**	Sponsor users work with sponsor accounts only in the CTIS Training Environment (sponsor workspace).
4	**Work within training trials**	Access via CT-centric account approach: users interact with functionalities in relation to training trials and are admin for the trials they create.
5	**Arrange MS interaction separately**	If sponsor users want to interact with Member States in the system, they should self-arrange this with the relevant list of national contact points.

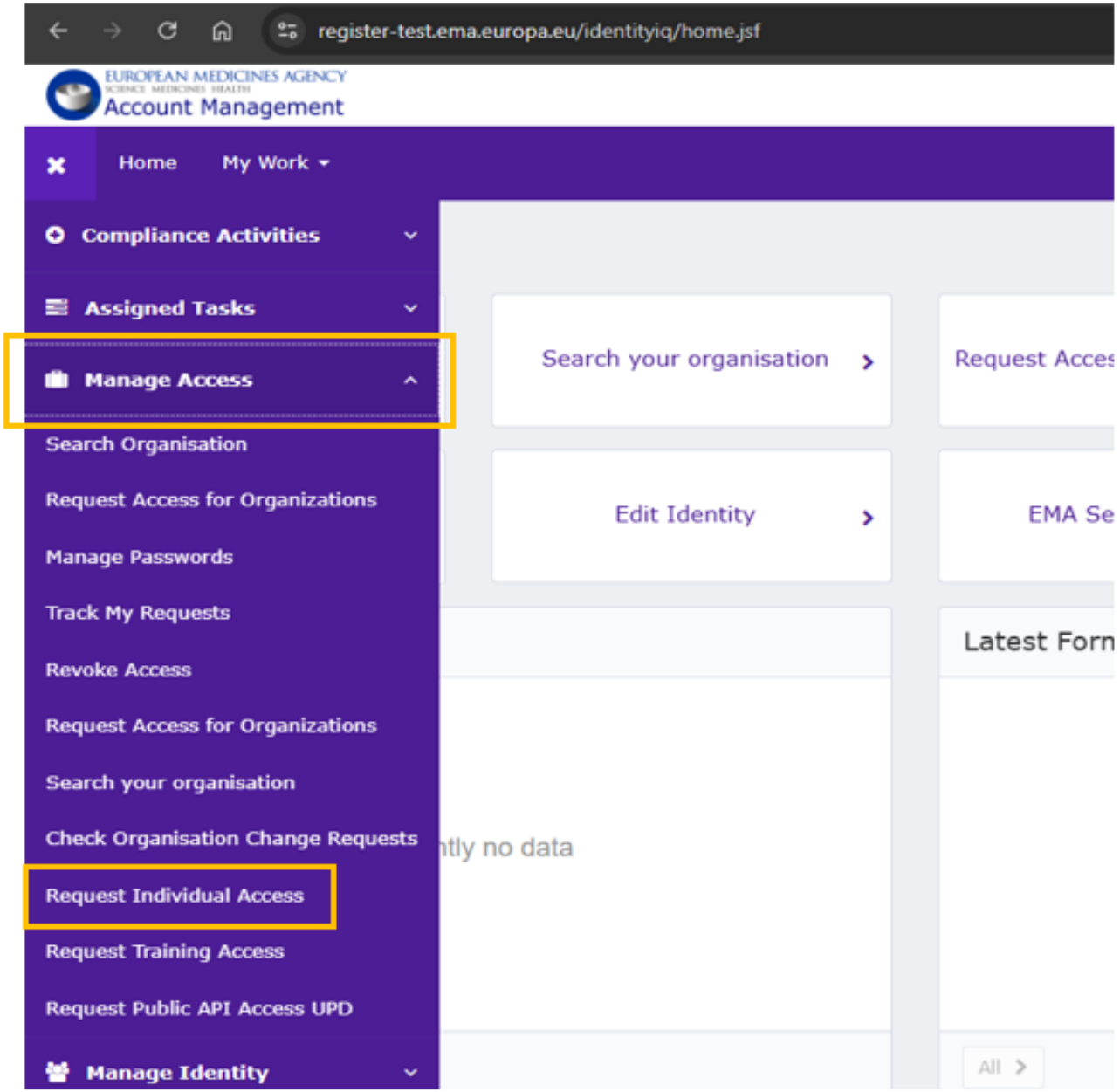
National list of contact points for clinical trials can be found here.

Step-by-step guide after EMA account registration

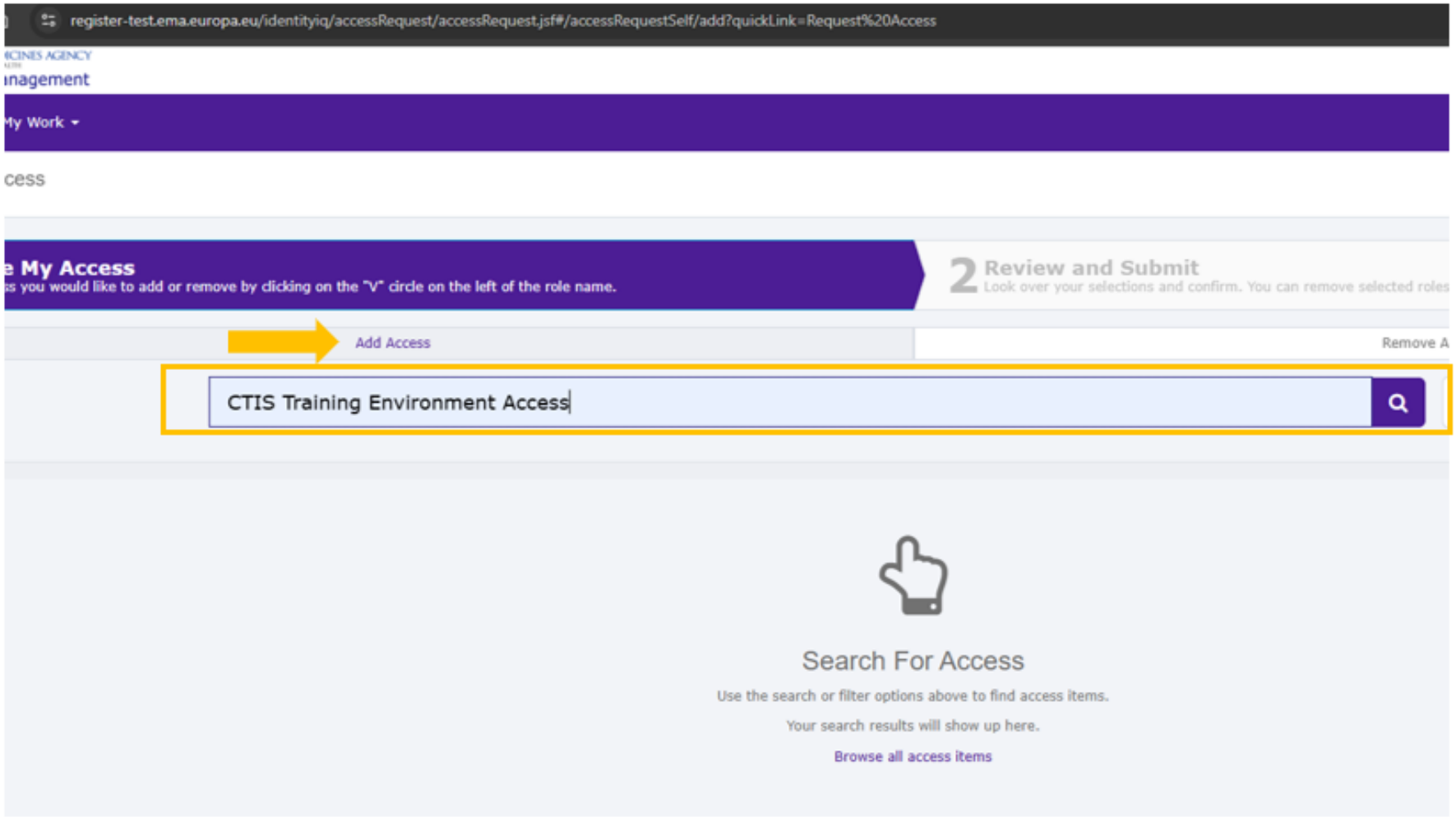
How to gain access to the CTIS Training Environment?



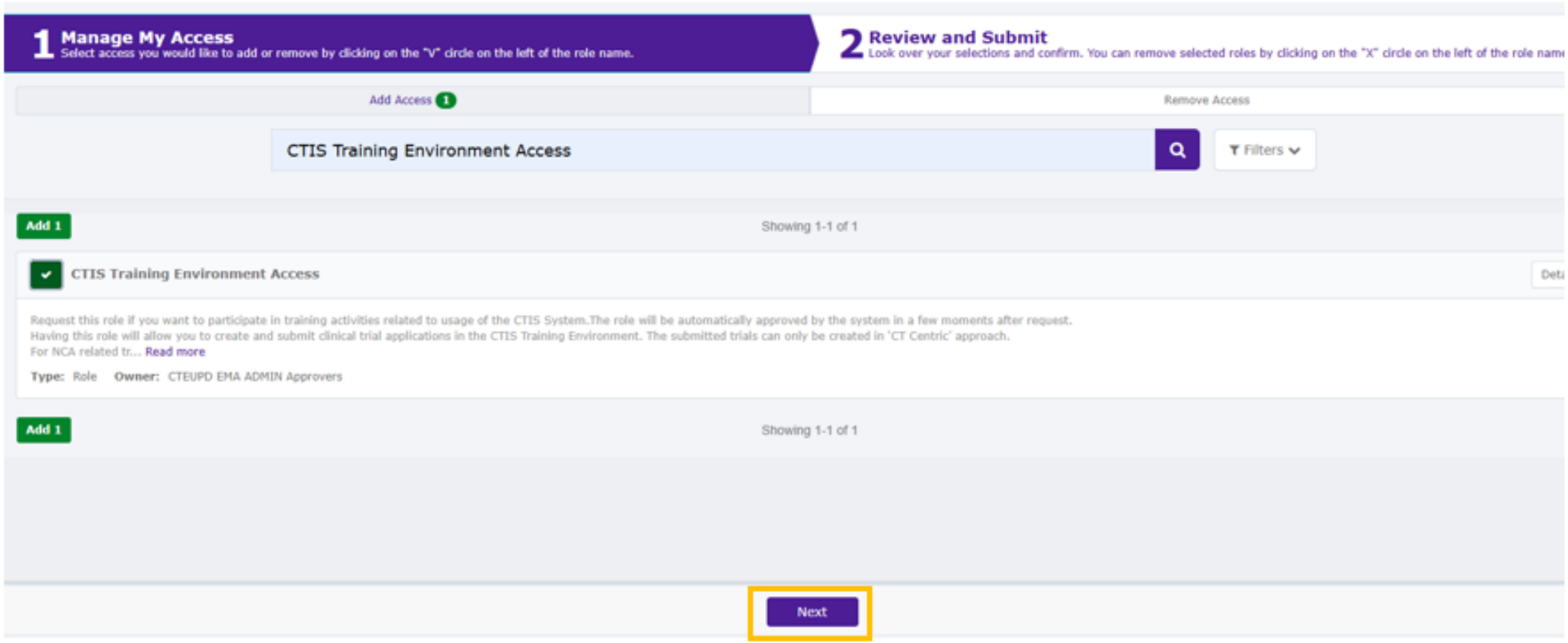
Step 1: Login the [EAM Test portal] and click on menu icon on the upper left corner of the landing page.



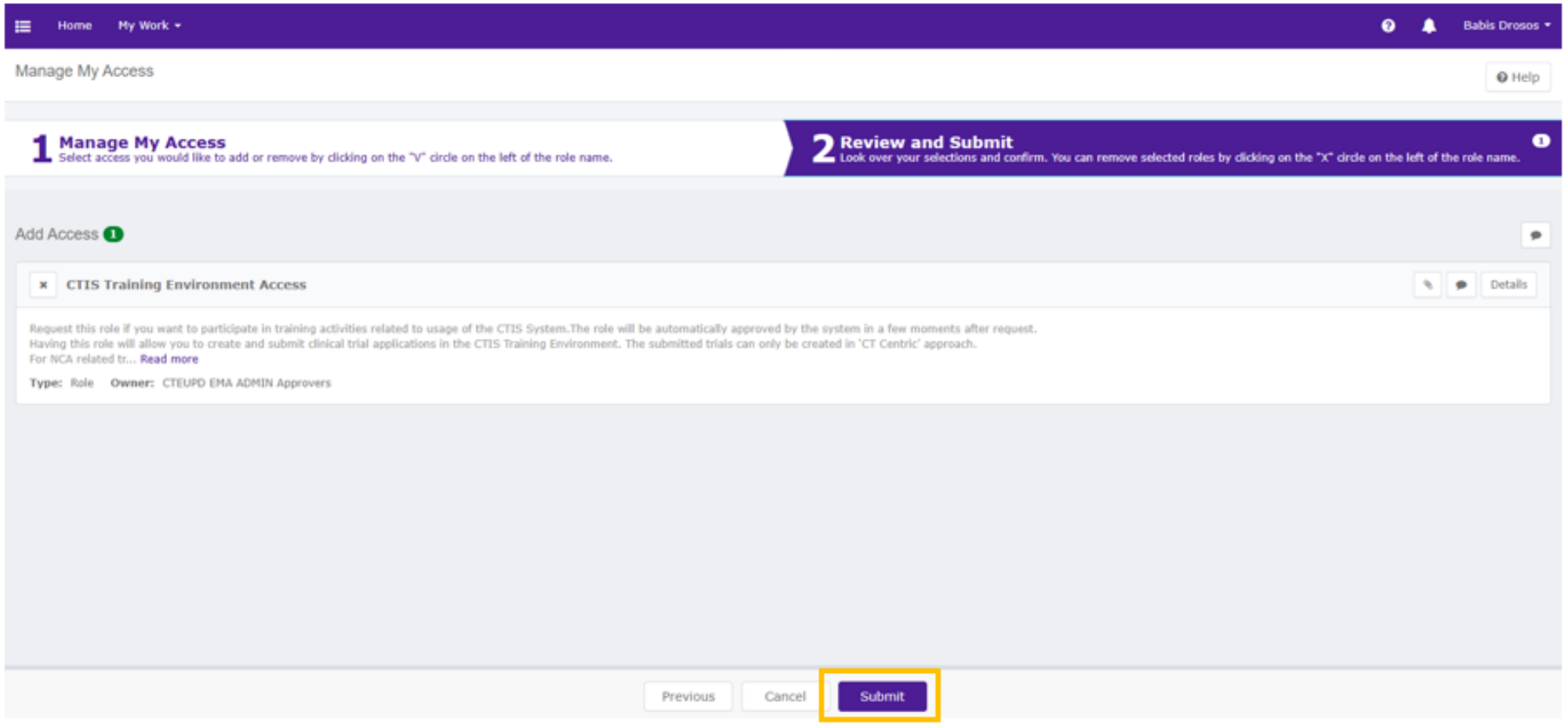
Step 2: Click on the "**Manage Access**" menu and then click on the option "**Request Individual Access**".



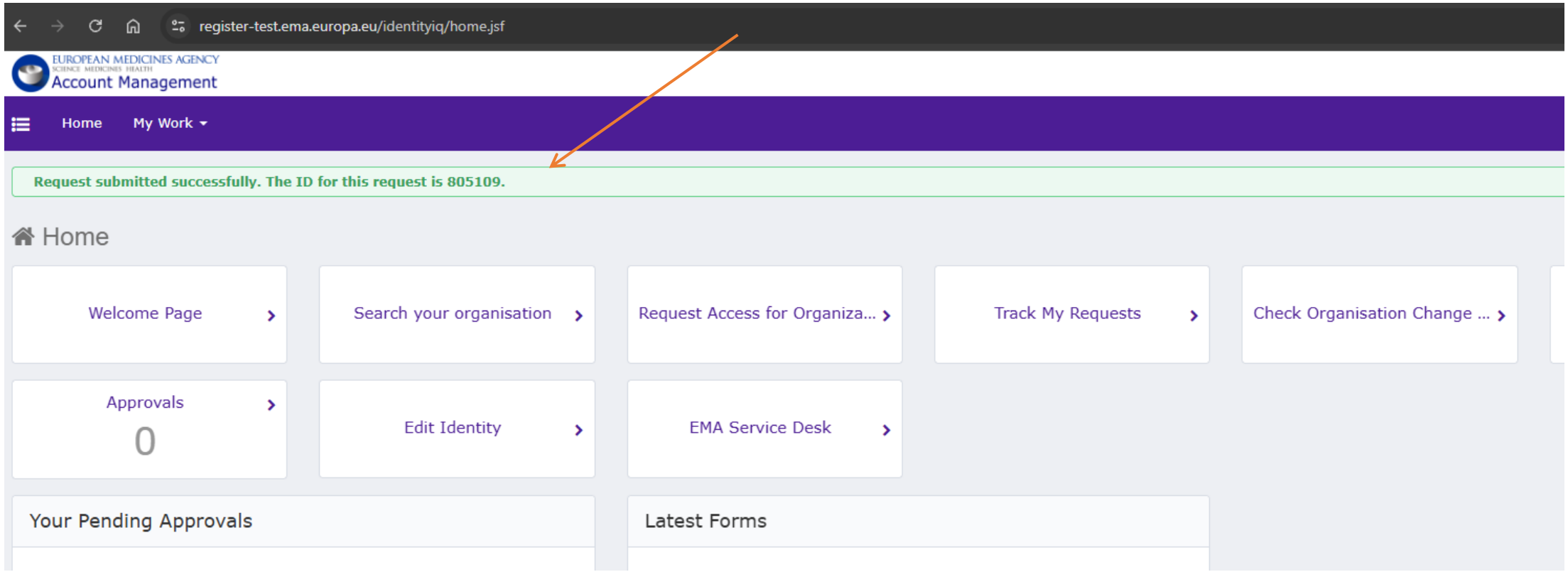
Step 3: Under the "**Add Access**" tab, use the search field to find the needed role "**CTIS Training Environment Access**".



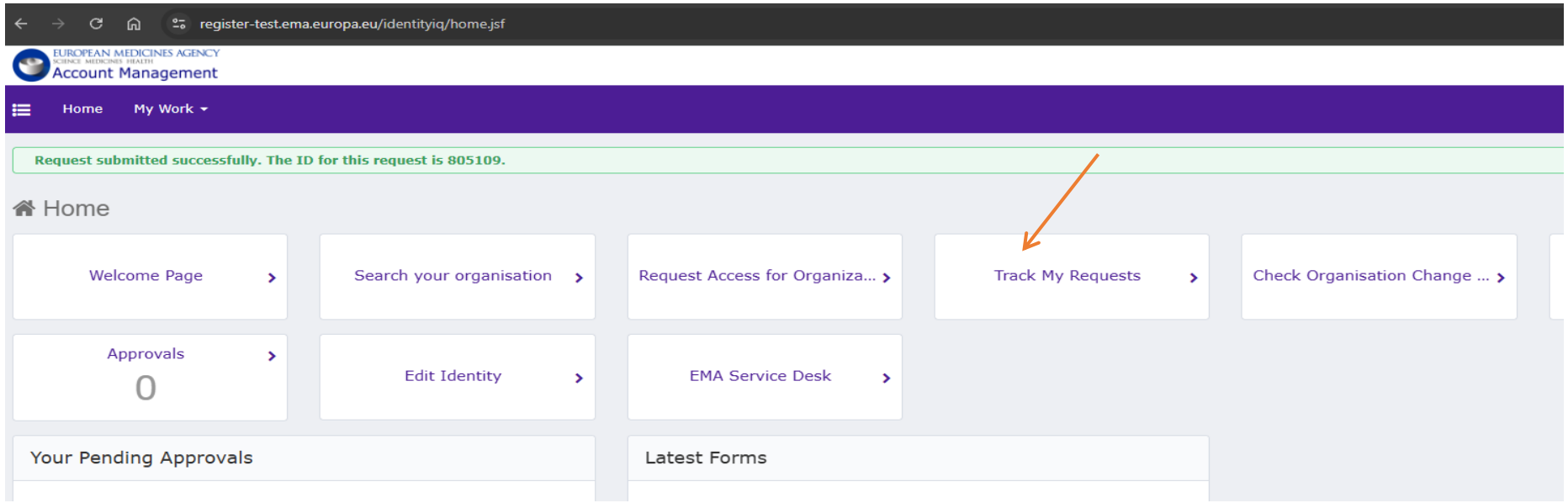
Step 4: Select the role found in the search results and click on the button “**Next**”.

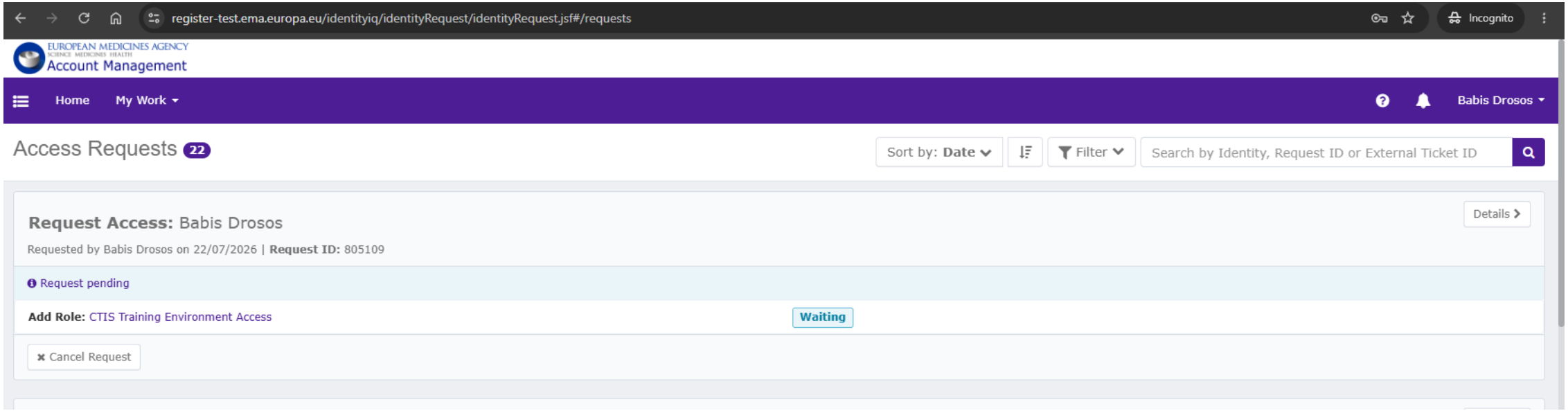


Step 5: Use the button "**Submit**". Your request is submitted and after a few minutes it will be approved automatically.



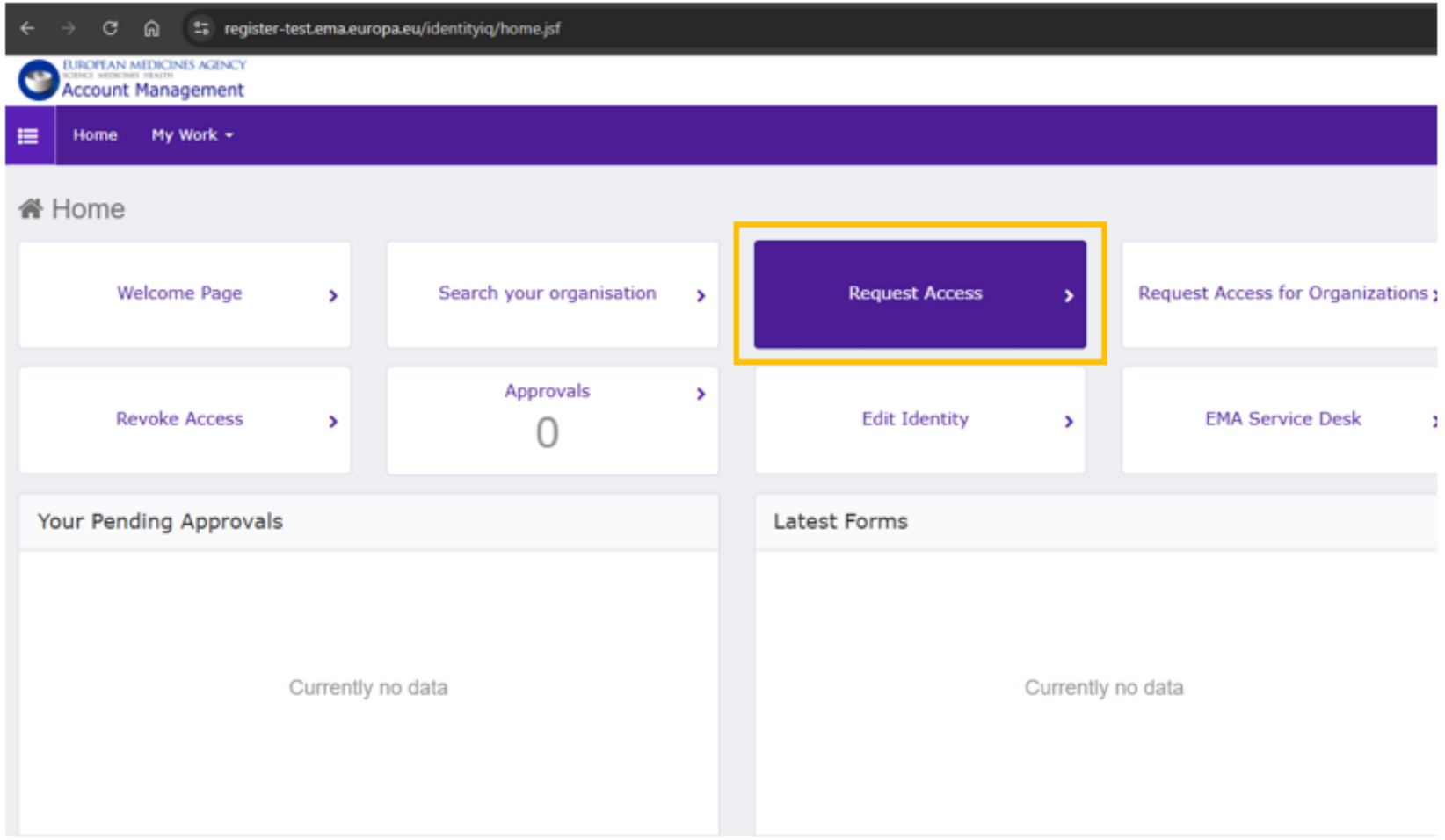
After submitting the request, the user will see this landing page with the message shown as in the **green box**.



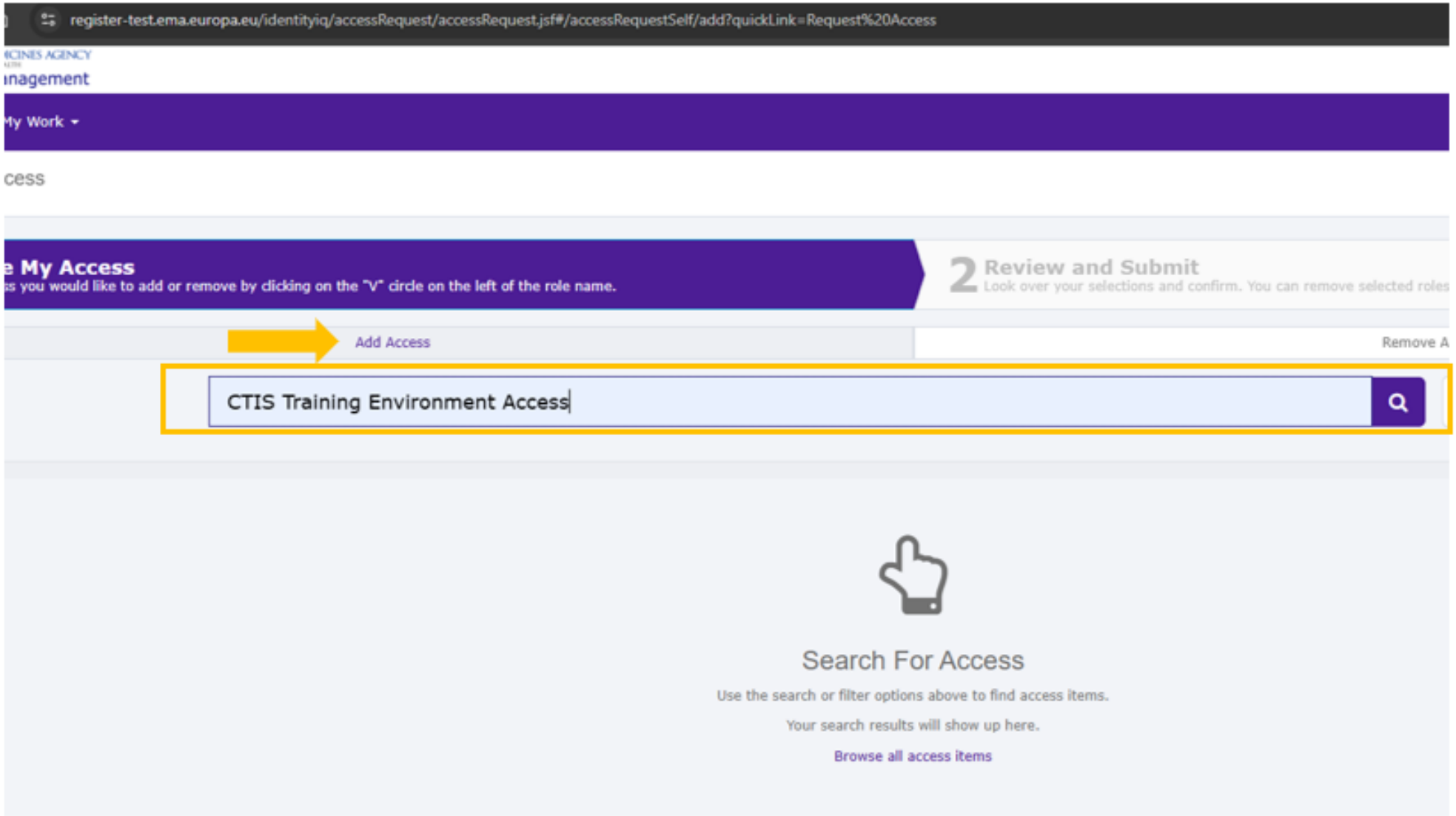


You will be able to monitor the progress on your request by clicking in “**Track My Request**”.

ALTERNATIVE PATH



Step 1: If you already have the tile of "**Request access**" in your dashboard, login to the [EAM Test portal] and click on the "**Request Access**" tile of the landing page



Step 2: Under the "**Add Access**" tab, use the search field to find the needed role "**CTIS Training Environment Access**". The steps are the same with those of the main path.

CTIS Safety Module in the CTIS Training environment

When should issues be escalated to EMA?

Escalate to EMA using Service Desk

Blocking issues preventing progress in the system

Blocking questions requiring EMA clarification

Blocking issues not addressed by the available guidance

Do not escalate as urgent tickets

General familiarisation questions (handle internally)

Non-blocking observations/issues/bugs

Feedback that can be considered during finalisation for Production

Report **non blocking issues via slido** by using the code **#sponsors** or the qr code below.

Blocking issue = prevents completion of a training activity or testing of key Safety Module functionality.

How to report a blocking issue

Use the CTIS issue reporting form and include the correct identifiers.

1	**Open the form**	Open the CTIS issue reporting form.
2	**Select request type**	CTIS Training Environment.
3	**Select affiliation**	Select your user affiliation from the list.
4	**Describe impact**	Include steps, expected/actual result, screenshots and impact.

Subject line

Safety issue – CTIS Training Environment

Using the prescribed subject line helps EMA route and prioritise the ticket correctly.

How to submit a Request for Information

Use this route for relevant Safety Module questions that require EMA clarification.

When to use

Relevant blocking question on the Safety Module

Additional guidance is needed to unblock issue

Question cannot be addressed using the available training material including the CTIS Sponsor Handbook

Subject line

Safety – Request for Information – CTIS Training Environment

Select CTIS Training Environment as request type and choose the relevant affiliation.

How users should report issues

If users identify an issue or have a question, they should first consult the available training materials, including the Sponsor Handbook.

If the issue is not resolved and is blocking progress in the system, raise a ticket and provide the **following information:**

- Module or screen affected
- Steps performed
- Expected result
- Actual result observed
- Supporting screenshots
- Impact on the training activity

Clear information helps EMA identify and prioritise issues as needed.

Guidance on how to report issues will be published in the following EMA website in due time: Clinical Trials Information System (CTIS): training and support | European Medicines Agency (EMA) under section: **Additional reference materials for CTIS users**

Key takeaways

New access process (SSO) applies in the CTIS Training Environment.

Sponsor users have sponsor accounts and a **CT-centric** approach.

Use the correct **ticket process** and **prescribed subject lines** to report issues in the Training Environment Safety module.

Only **blocking issues** and relevant blocking questions should be escalated to EMA.

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Thank you

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