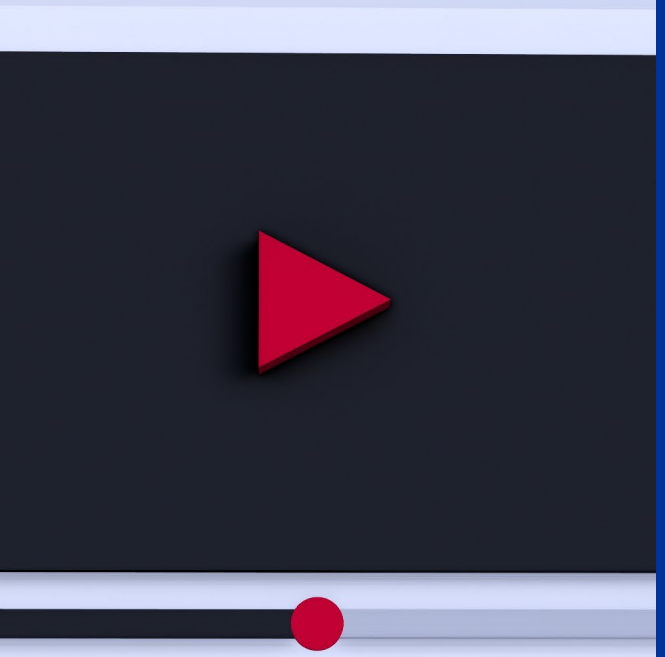
EMA
EUROPEAN MEDICINES AGENCY

System Demo 25Q3

Public System Demo

17 September 2025



Welcome & Introduction

Jean-Michel Becar, Head of EMA Portfolio Management Office

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Housekeeping

Please note that this session is being live streamed.
It is being recorded and will be made available through the EMA Corporate Website

Participants may be able to ask questions or share feedback via Slido, with the option of remaining anonymous*.

To view the video in the highest quality, click on the settings symbol and select 720p or a higher resolution
To watch the video in full screen mode, click on watch on Youtube to watch it on YouTube.com

* If you choose to use Slido, you consent to the processing of your personal data as explained in the EMA Data Protection Notice for Webex (europa.eu).

slido # 9116064

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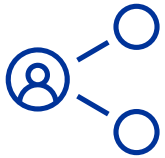
System demo at EMA



Agile teams showcase the features they have been working on in the last 3 months

Creates an opportunity to gain a **shared understanding** of the current **state of the products and solutions** on a regular cadence.

It provides an objective measure of **progress** towards the goal of the PI.

Creates a safe space for early identifications of defects or design flaws and for the generation of new ideas to improve over time.

Enables the attendees to provide **instant feedback** allowing the Agile teams to make **necessary adjustments** to the solutions they are building

Is recorded and published on the EMA **Corporate web site**

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16 December

Is the next public system demo

Agenda

09:00	**Welcome / Introductions**
09:05 – 09:45	*Research & Development Value Stream (R&D VS)*
09:05 – 09:25	Clinical Trials Information System (CTIS) modernisation – roles simplification and safety
09:25 – 09:30	Trial Map
09:30 – 09:45	Scientific Explorer
09:45 – 12:10	*Product Lifecycle Management Value Stream (PLM VS)*
09:45 – 10:00	Union Product Database (UPD)
10:00 – 10:25	Product Management Service (PMS)
10:25 – 10:50	Product user interface (PUI)
10:50 – 11:00	*Break*
11:00 – 11:15	Electronic application form (eAF)
11:15 – 11:40	Electronic product information (ePI)
11:40 – 12:10	Regulatory Procedure Management (RPM) for Product Lifecycle Management on IRIS
12:10 – 12:25	*Monitoring Value Stream (MON VS)*
12:10 – 12:25	EudraVigilance data analysis system (EVDAS) – automated compliance reports
12:25	**Closing**

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Give feedback & ask questions

Option 1 - Q&A

Questions and answers are public
You may upvote the questions
Top questions are answered verbally
Questions & available answers published on event page

Option 2 - Poll

Feedback shared only with product team
Stays open for comments till 24 September
Please identify yourself
Give the product team feedback and suggestions about your priorities

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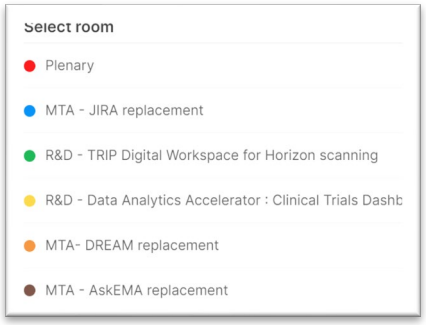

Step 2 – Choose/switch to the room for the right product

Step 3 - Choose Q&A or Polls as appropriate

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EMA Value Streams

Managing the Agency

Capabilities to empower EMA staff and support the Network through modernisation and digitalisation of the Agency's systems, processes and ways of working, increasing efficiency, transparency and collaboration

Research and Development

Capabilities to support the development of new medicines and generation of scientific evidence

Product Lifecycle Management

Capabilities to manage the authorisation and lifecycle of medicinal products and certain medical devices

Monitoring

Capabilities to monitor availability and safety of products

Technology Lifecycle Management and Information Security

Capabilities to manage information technology and security

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R&D VS | Clinical Trials Information System (CTIS) Modernisation

Ana Rodriguez, CTIS Product Owner

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CTIS Modernisation- New Safety Module

Committed objective 25Q3	Demo
Safety Module MVP – Design and implement the **saMS Selection** process.	**YES**
Safety Module MVP – Design and implement the **ASR Creation & Submission** processes.	**YES**

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Safety Module MVP- saMS Selection

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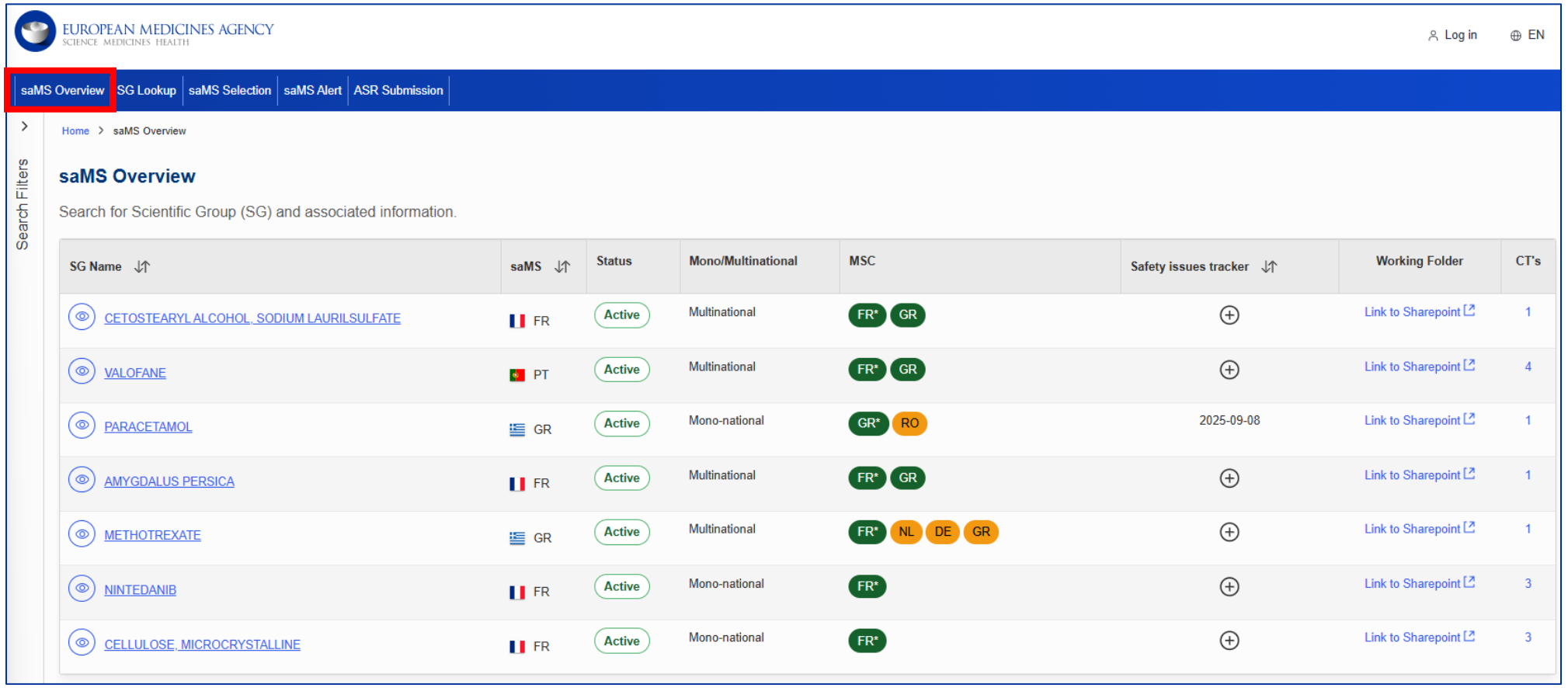
1. saMS Overview

Provides a **saMS overview per Substance Group (SG)** present in the Safety Module.



SG Name	saMS	Status	Mono/Multinational	MSC	Safety issues tracker	Working Folder	CT's
CETOSTEARYL ALCOHOL, SODIUM LAURILSULFATE	FR	Active	Multinational	FR* GR		Link to Sharepoint	1
VALOFANE	PT	Active	Multinational	FR* GR		Link to Sharepoint	4
PARACETAMOL	GR	Active	Mono-national	GR* RO	2025-09-08	Link to Sharepoint	1
AMYGDALUS PERSICA	FR	Active	Multinational	FR* GR		Link to Sharepoint	1
METHOTREXATE	GR	Active	Multinational	FR* NL DE GR		Link to Sharepoint	1
NINTEDANIB	FR	Active	Mono-national	FR*		Link to Sharepoint	3
CELLULOSE, MICROCRYSTALLINE	FR	Active	Mono-national	FR*		Link to Sharepoint	3

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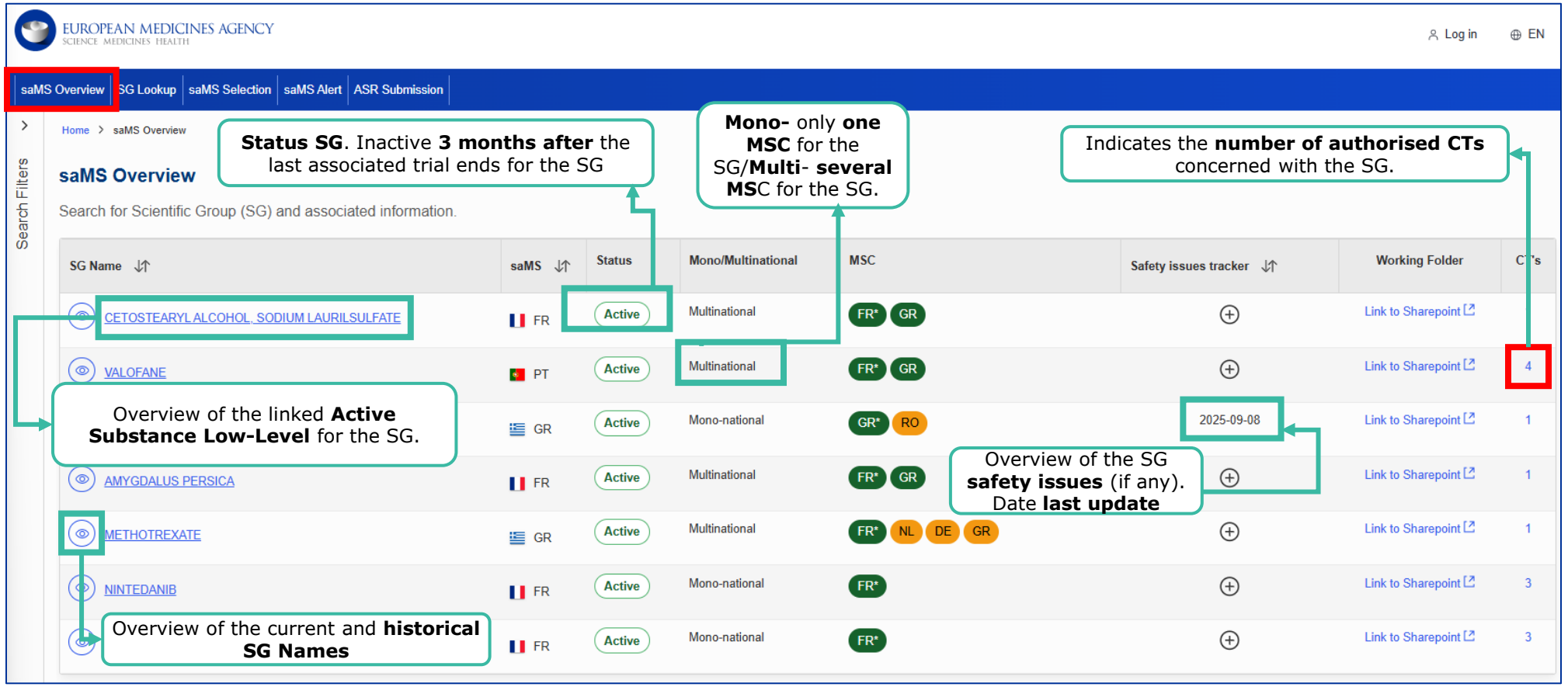

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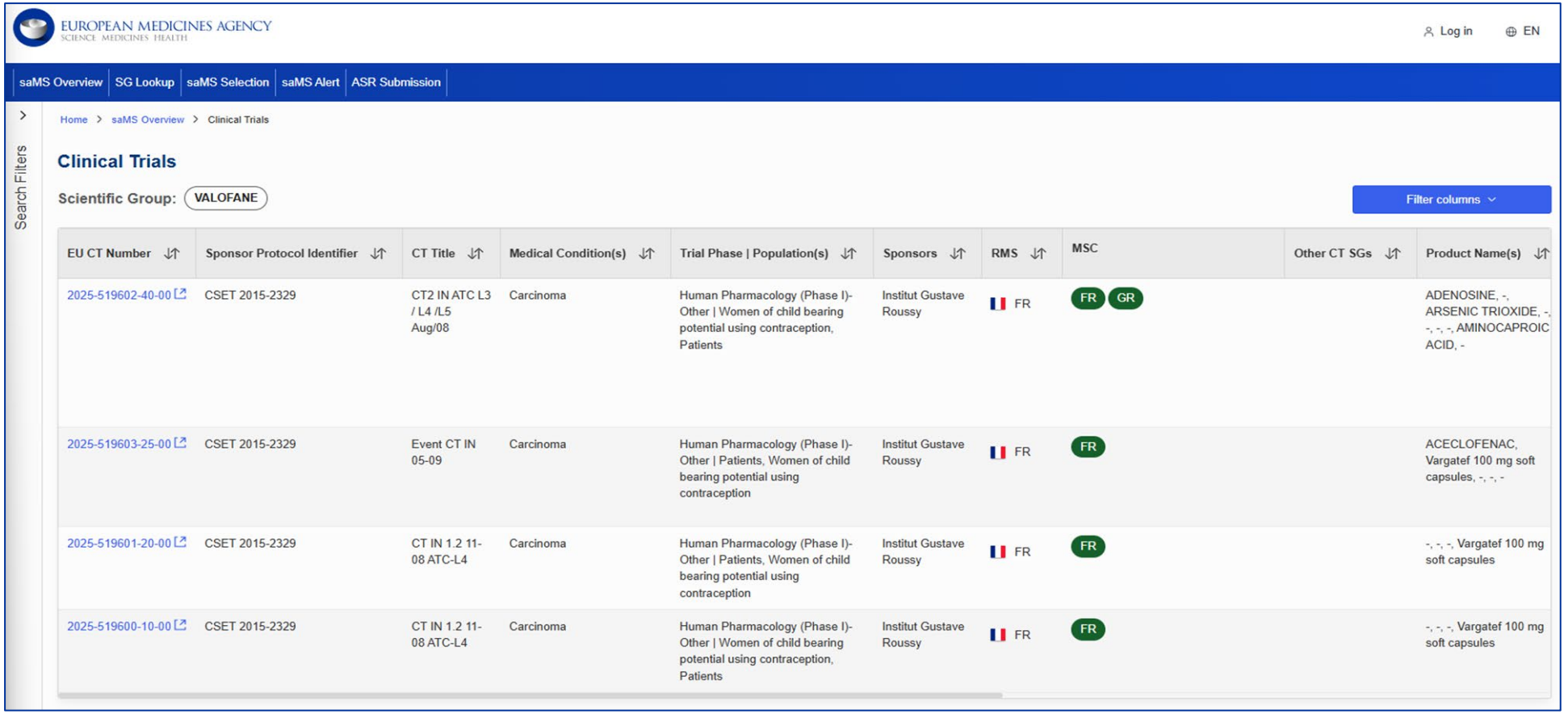
1. saMS Overview

Upon clicking the number of concerned authorized CTs, the system provides the **details for each CT**.



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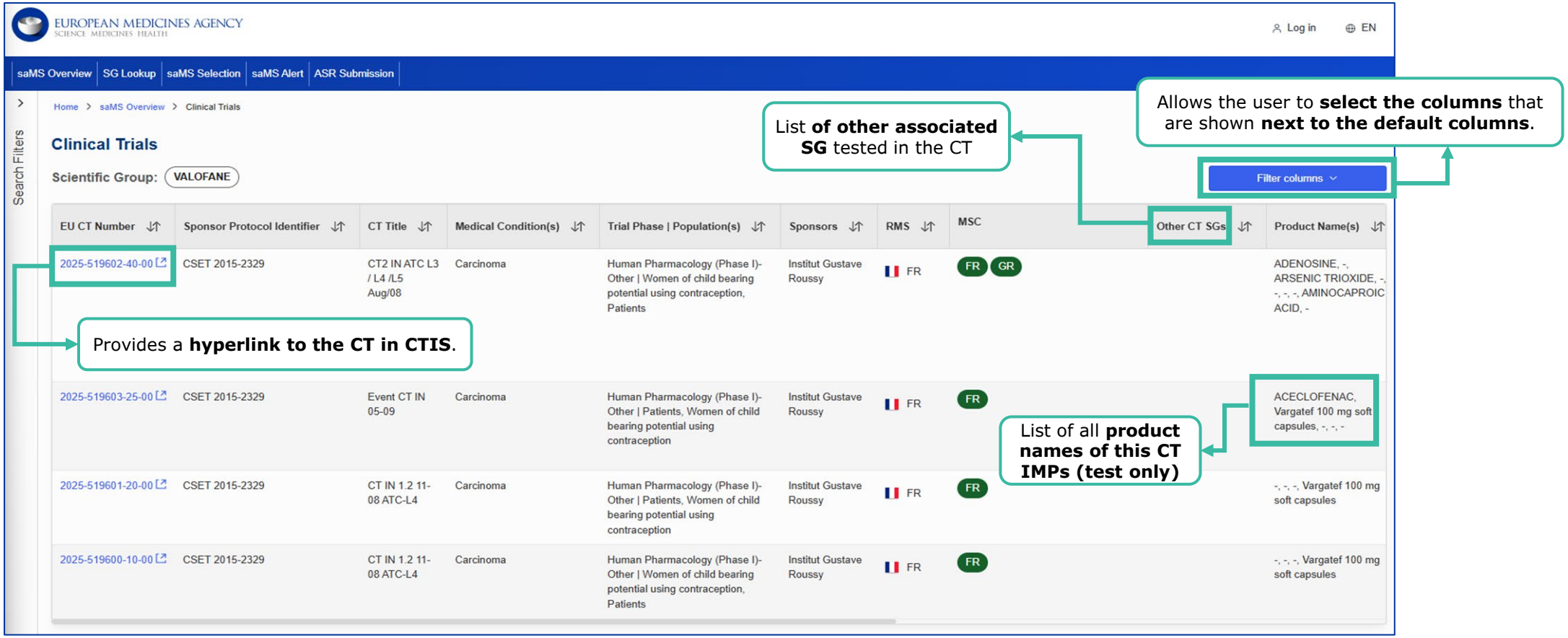

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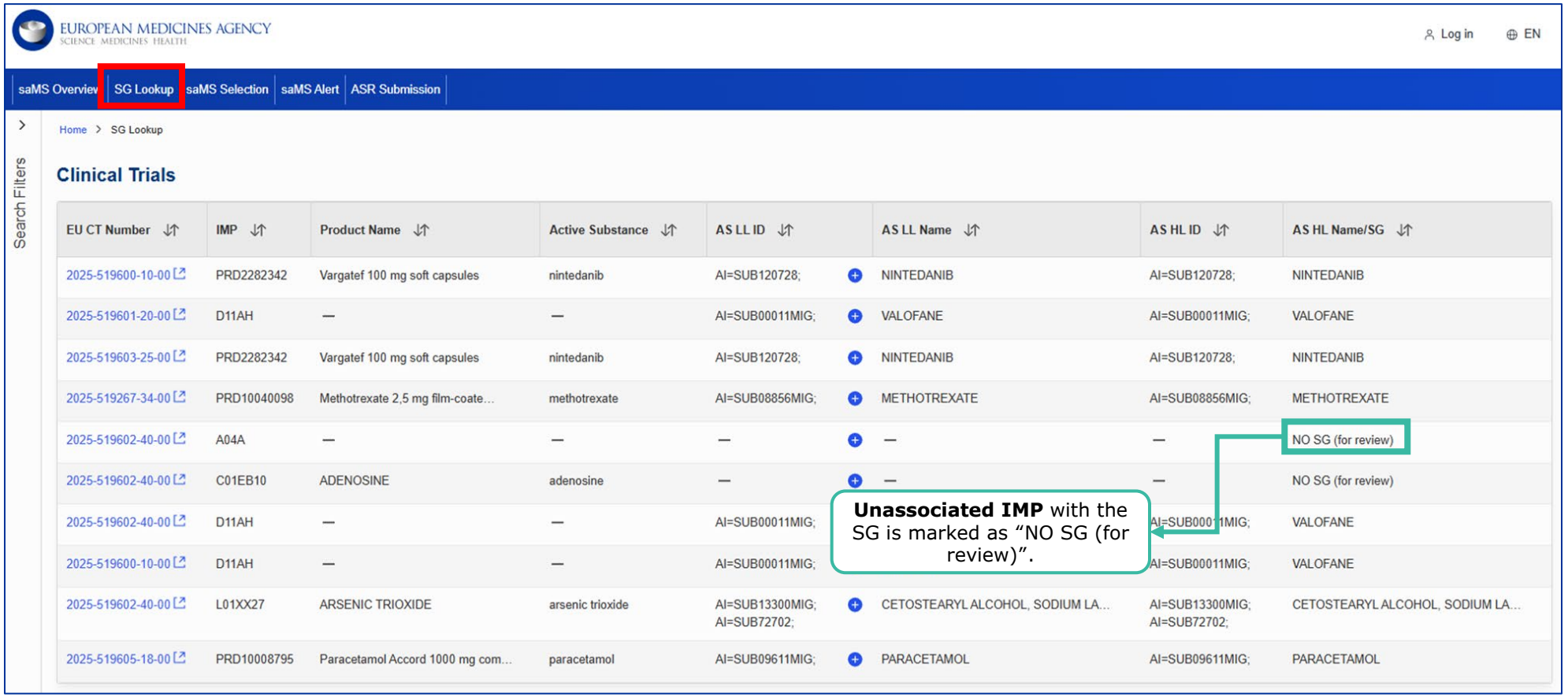
2. SG Lookup

Provides an **overview of each individual test IMP linked in a CT as well as the link to the SG**. The EMA Admin is able to **correct the EV links**.



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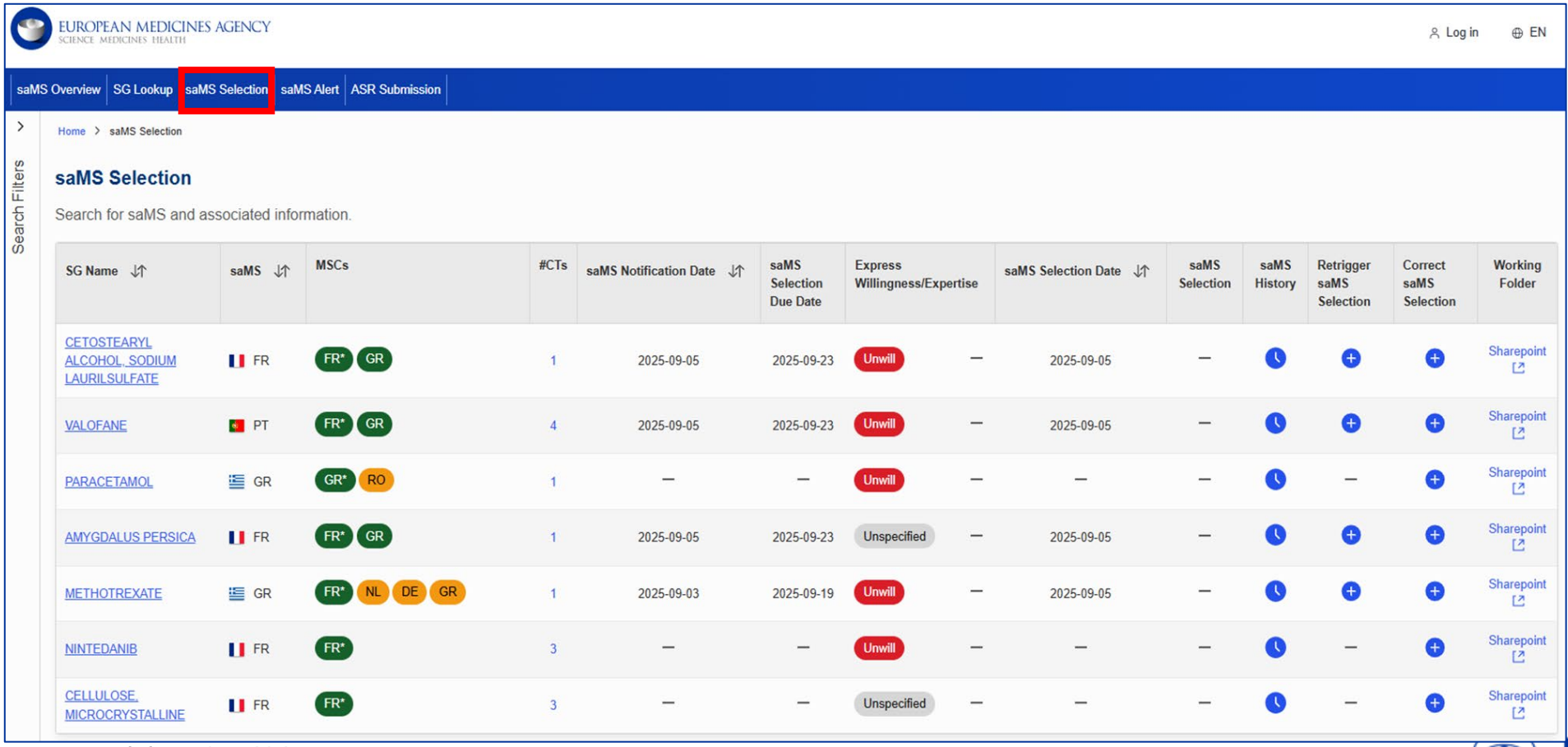
3. saMS Selection

Provides an overview of the **saMS Selection Procedure** for each SG in the Safety Module.

- The **MS** are able to **provide willingness and expertise**
- The **RMS acting as saMS/saMS** is able to **select a new saMS**



SG Name	saMS	MSCs	#CTs	saMS Notification Date	saMS Selection Due Date	Express Willingness/Expertise		saMS Selection Date	saMS Selection	saMS History	Retrigger saMS Selection	Correct saMS Selection	Working Folder
CETOSTEARYL ALCOHOL, SODIUM LAURILSULFATE	FR	FR* GR	1	2025-09-05	2025-09-23	Unwill	–	2025-09-05	–				Sharepoint
VALOFANE	PT	FR* GR	4	2025-09-05	2025-09-23	Unwill	–	2025-09-05	–				Sharepoint
PARACETAMOL	GR	GR* RO	1	–	–	Unwill	–	–	–		–		Sharepoint
AMYGDALUS PERSICA	FR	FR* GR	1	2025-09-05	2025-09-23	Unspecified	–	2025-09-05	–				Sharepoint
METHOTREXATE	GR	FR* NL DE GR	1	2025-09-03	2025-09-19	Unwill	–	2025-09-05	–				Sharepoint
NINTEDANIB	FR	FR*	3	–	–	Unwill	–	–	–		–		Sharepoint
CELLULOSE, MICROCRYSTALLINE	FR	FR*	3	–	–	Unspecified	–	–	–		–		Sharepoint

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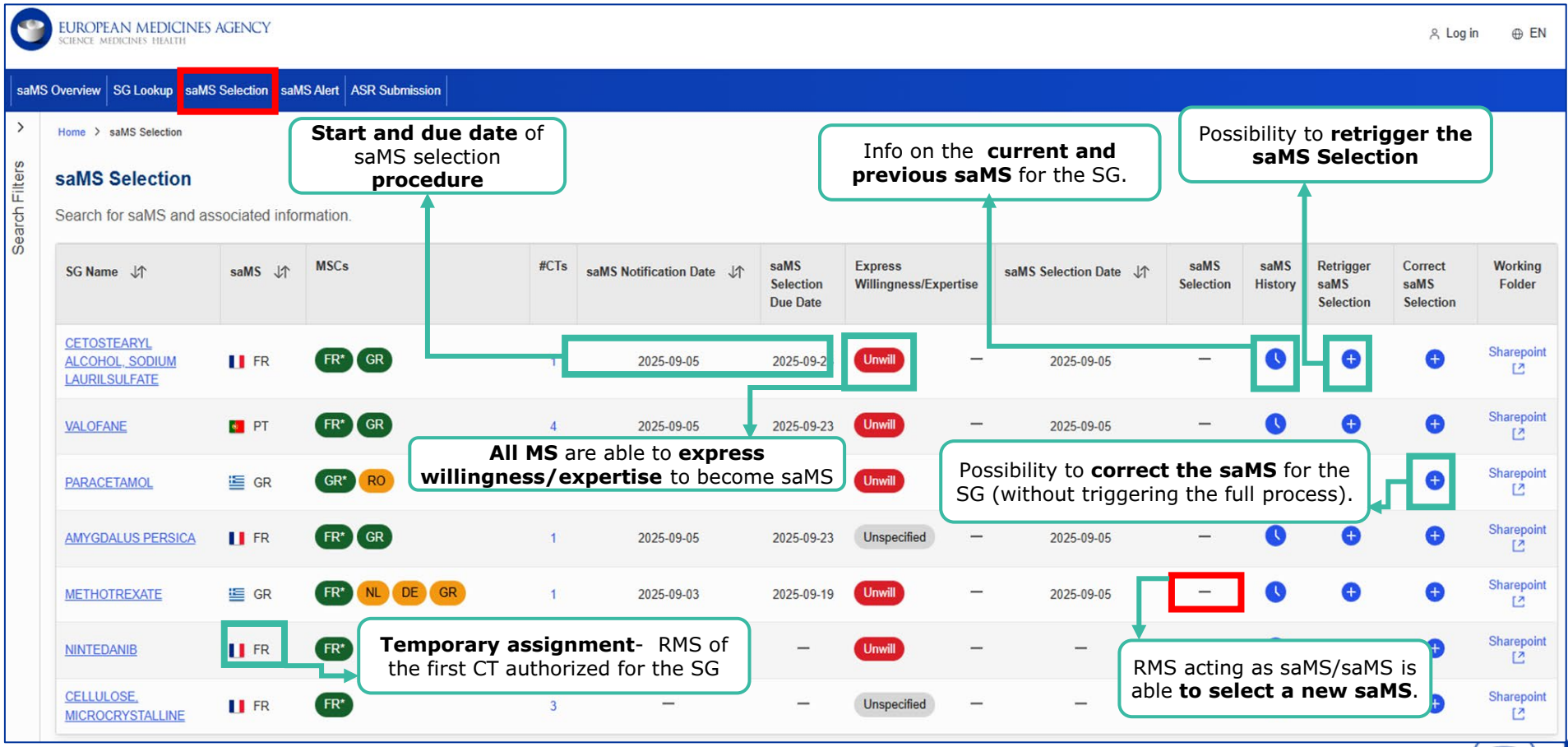
3. saMS Selection

Provides an overview of the **saMS Selection Procedure** for each SG in the Safety Module.

- The **MS** are able to **provide willingness and expertise**
- The **RMS acting as saMS/saMS** is able to **select a new saMS**



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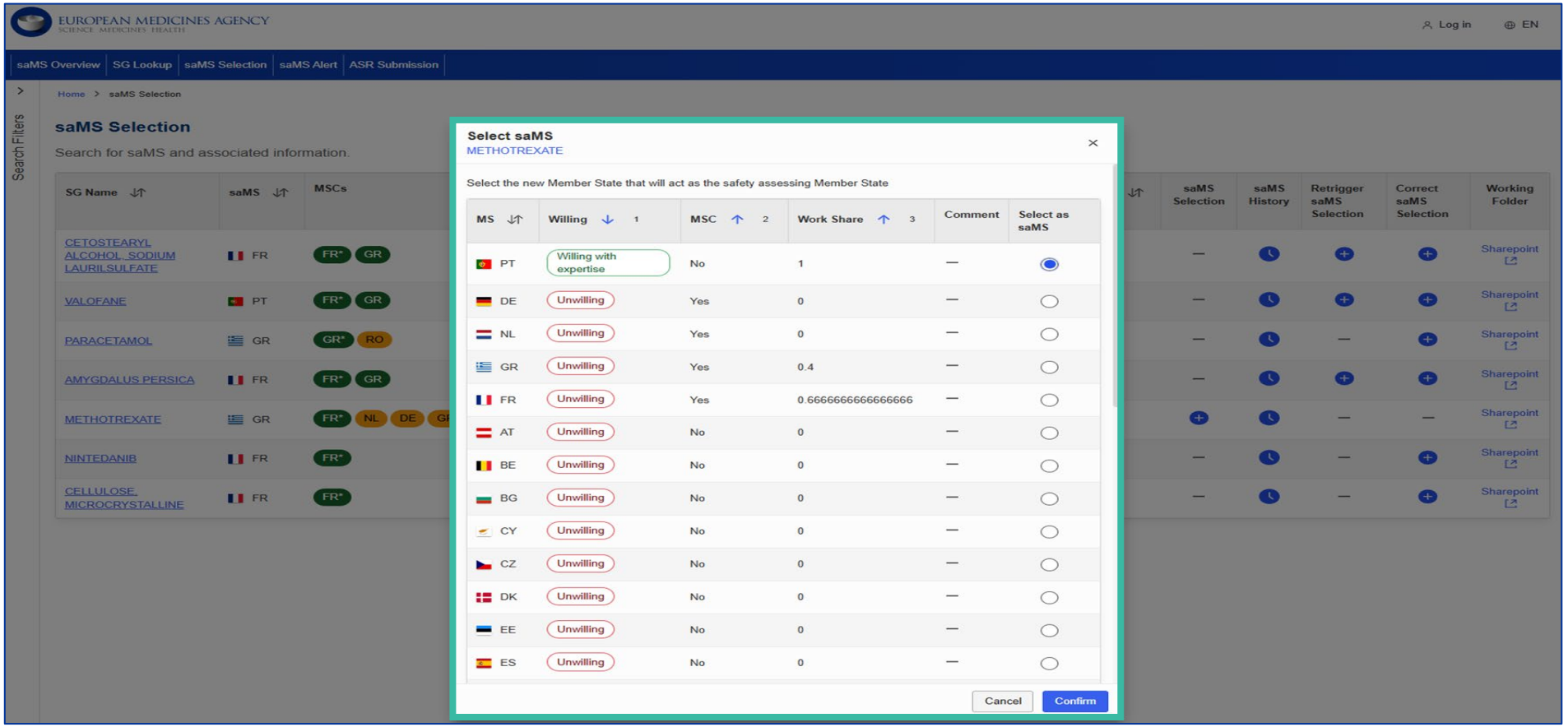
3. saMS Selection

In order to **facilitate and guide the saMS Selection**, the pop-up displays **per MS** the **provided willingness**, **MSC status**, **workshare** and **optional comment**.



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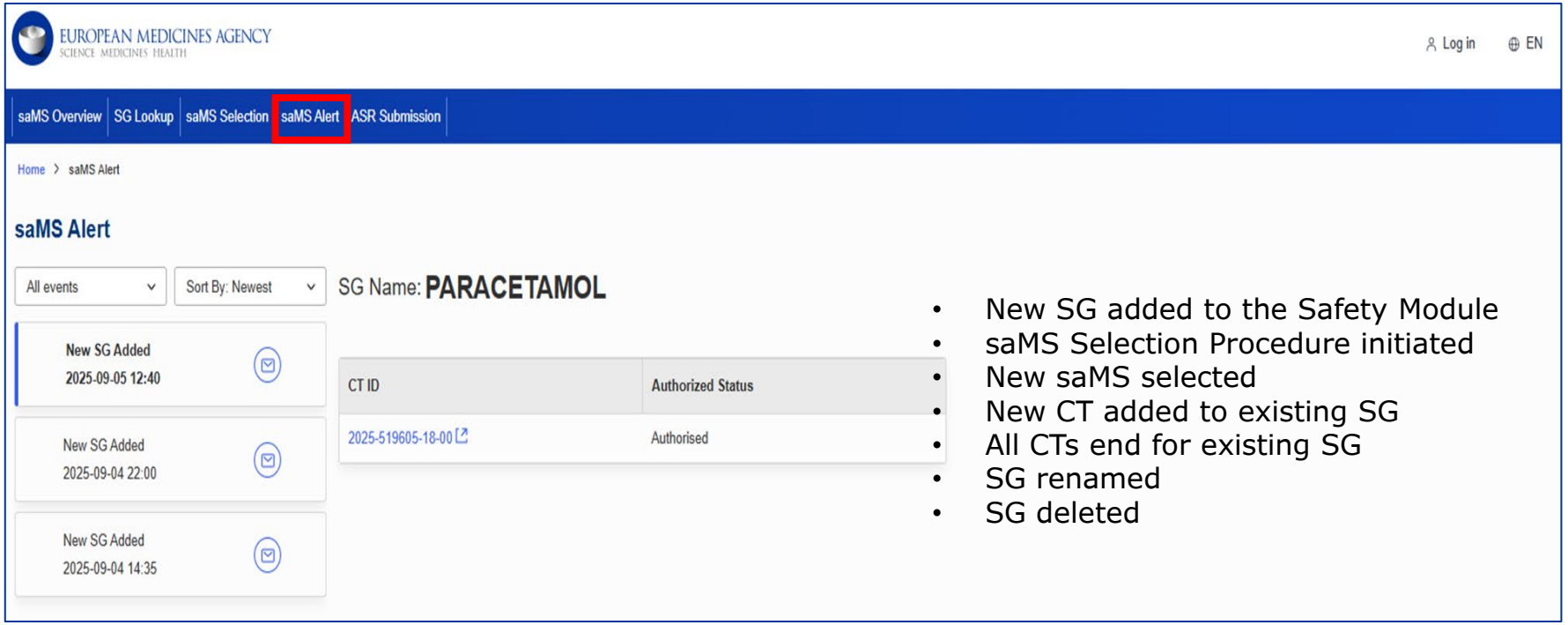
4. saMS Alert

Notices are sent out to inform MS users on the next actions, in two ways:

- **In the Safety Module itself –** Provides an **overview of all notices related to saMS Selection**.
- **Via e-mail**



- New SG added to the Safety Module
- saMS Selection Procedure initiated
- New saMS selected
- New CT added to existing SG
- All CTs end for existing SG
- SG renamed
- SG deleted

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Safety Module MVP- ASR Submission

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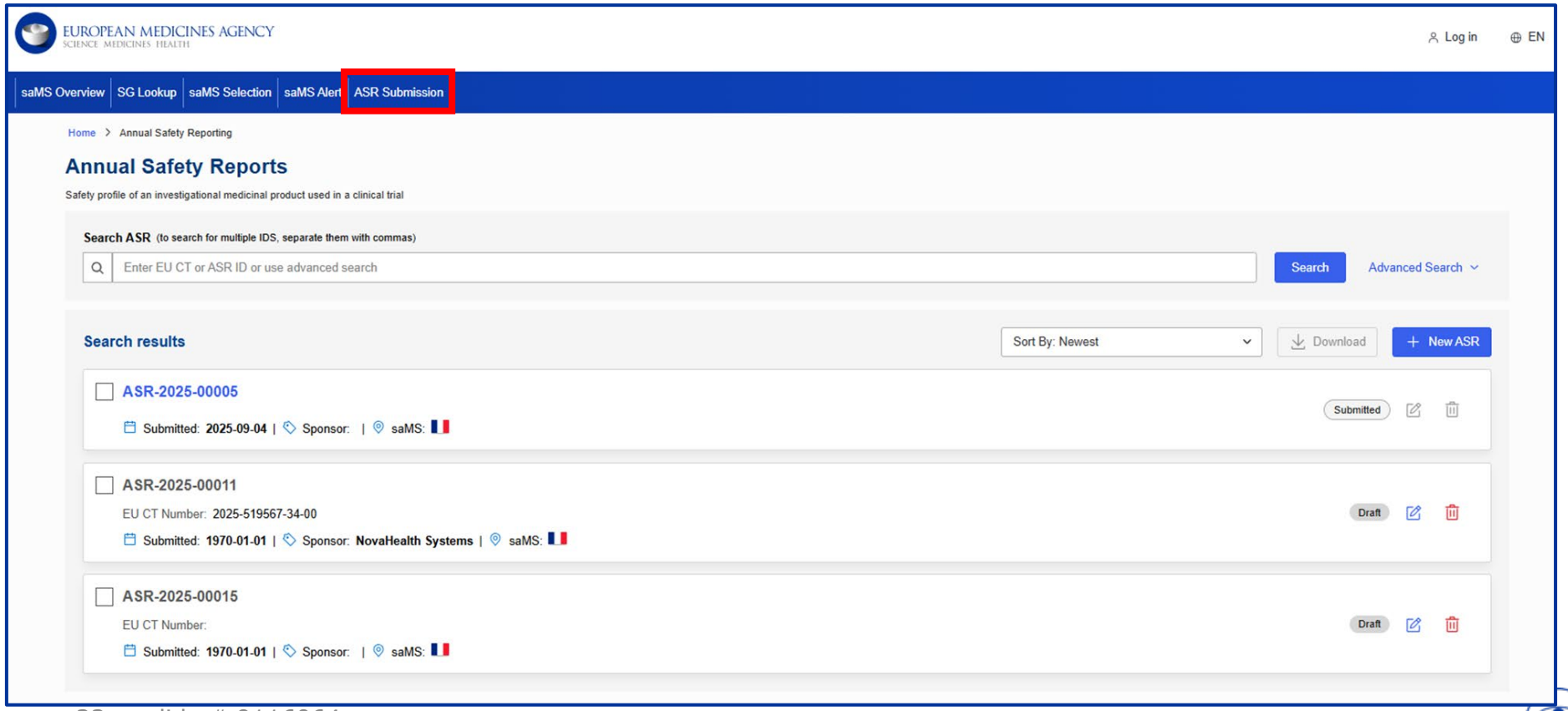
5. ASR Submission

Provides an **overview** of **all** ASRs, regardless of the status.

- Sponsor is able to **visualize all** submitted ASR
- Sponsor is able to **create** a new draft ASR
- Sponsor is able to **edit** draft ASR
- Sponsor is able to **delete** draft ASR



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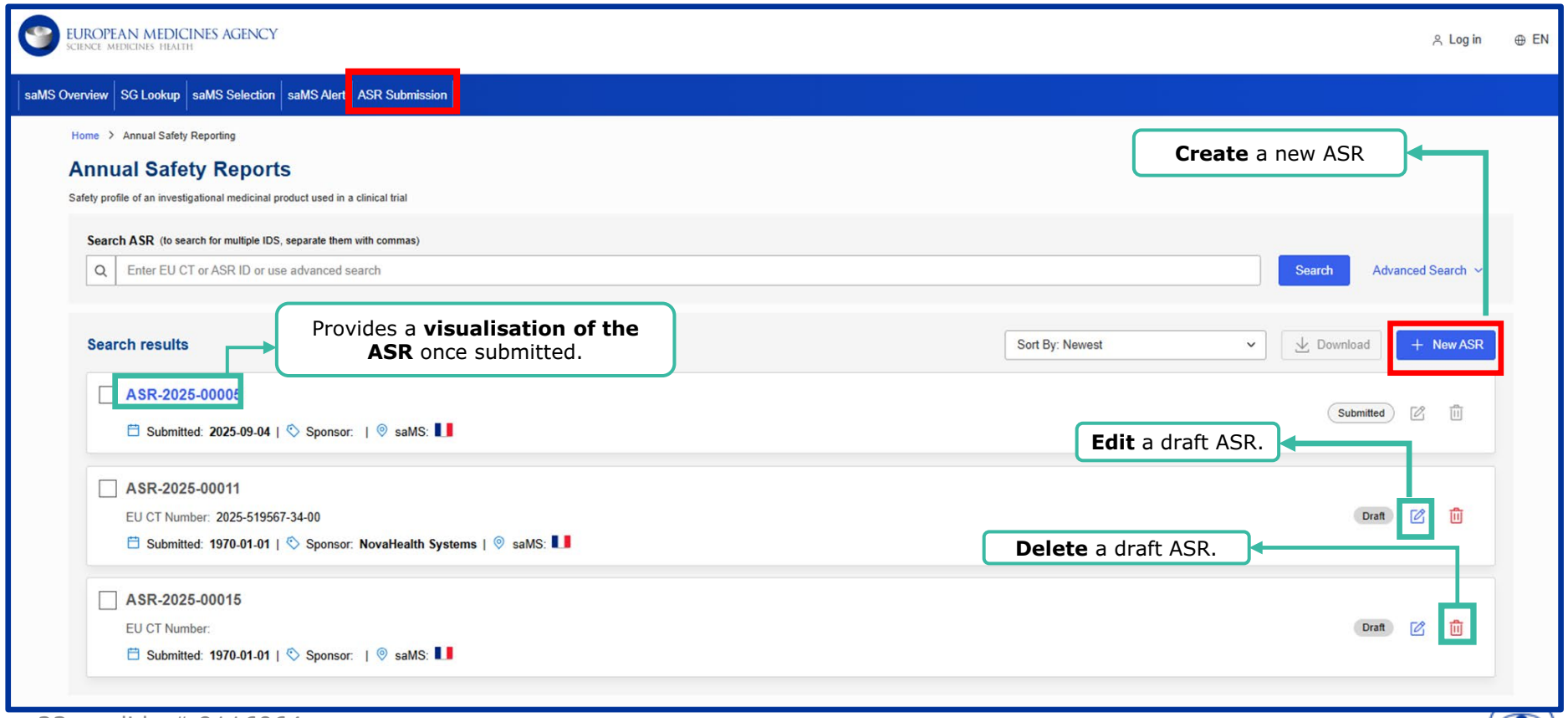
5. ASR Submission

Provides an **overview** of **all** ASRs, regardless of the status

- Sponsor is able to **visualize all** submitted ASR
- Sponsor is able to **create** a new ASR as draft- **New**
- Sponsor is able to **edit** draft ASR- **New**
- Sponsor is able to **delete** draft ASR- **New**



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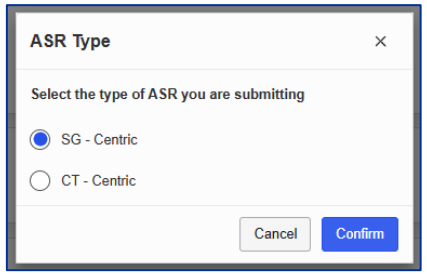
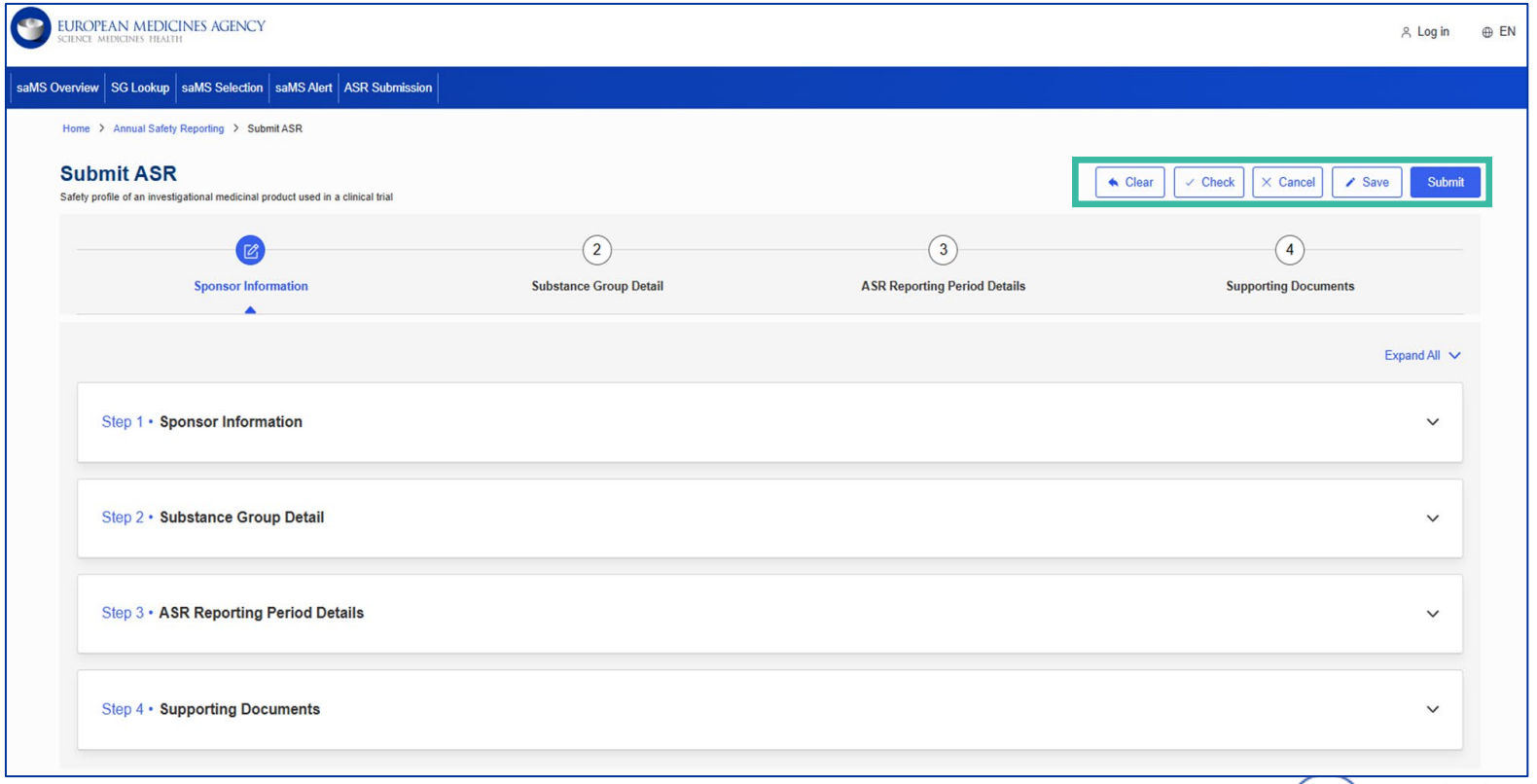
5. ASR Submission

Provides an **overview** of **one** ASR

- Sponsor is able to **check** the draft ASR
- Sponsor is able to **cancel** the draft ASR
- Sponsor is able to **save** the draft ASR- **New**
- Sponsor is able to **submit** the draft ASR



New: Indication whether **ASR is SG-centric or CT-centric**



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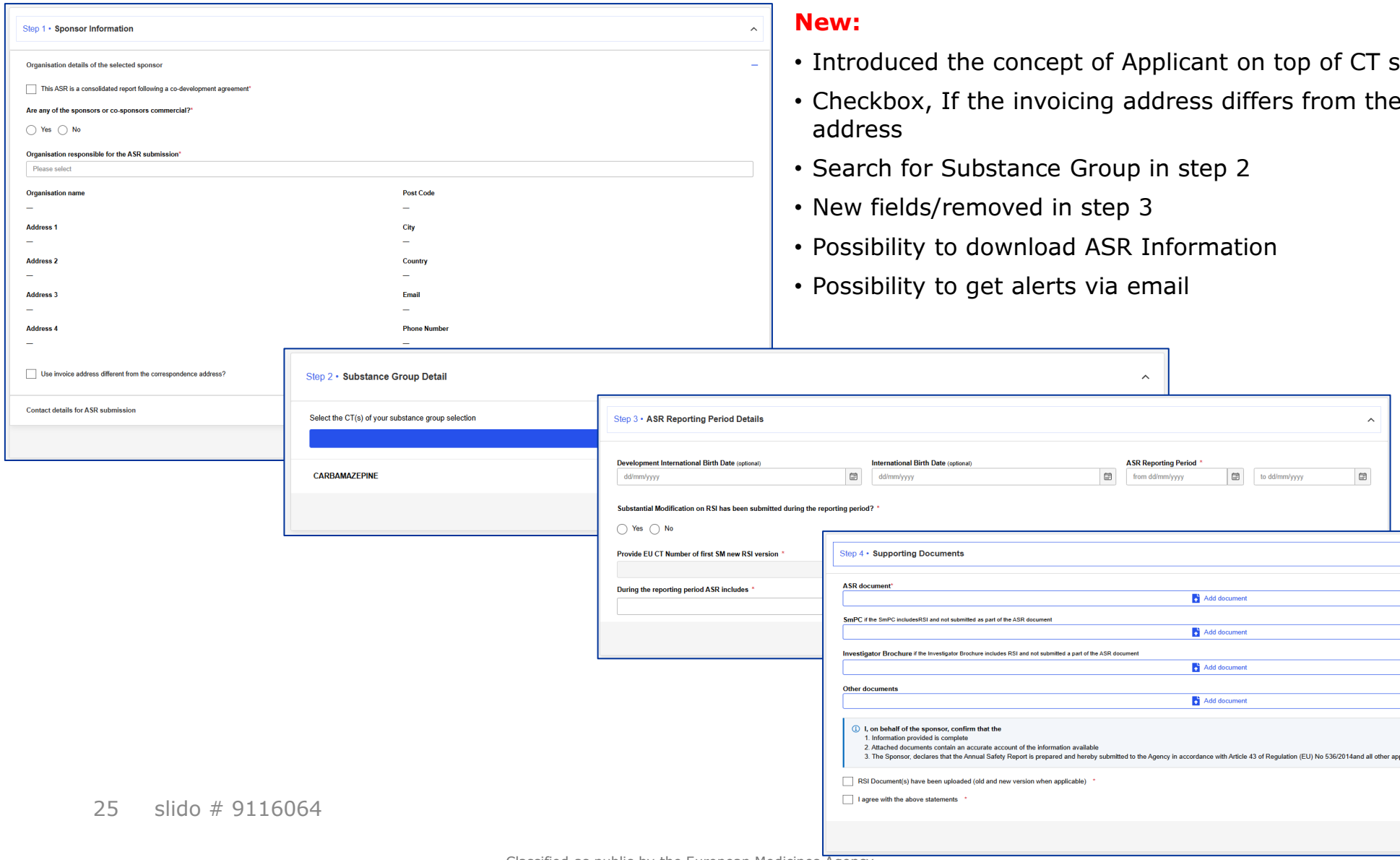
5. ASR Submission



New:

- Introduced the concept of Applicant on top of CT sponsor(s)
- Checkbox, If the invoicing address differs from the organization address
- Search for Substance Group in step 2
- New fields/removed in step 3
- Possibility to download ASR Information
- Possibility to get alerts via email

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Safety Module: Safety Roles

	Roles for current Safety Module	Roles upcoming new Safety Module	Comments
Sponsor	ASR submitter	**ASR submitter**	No change
MS	ASR Assessor ASR Decision Maker-Submitter	**MS Evaluator Supervisor full rights**	**No specific MS safety role**. Permissions for CTA and ASR assessment included now in one role

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R&D VS | Trial Map

IJsbrand den Rooijen, Trial Map developer

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Give feedback & ask questions

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Join at
slido.com
#9116 064

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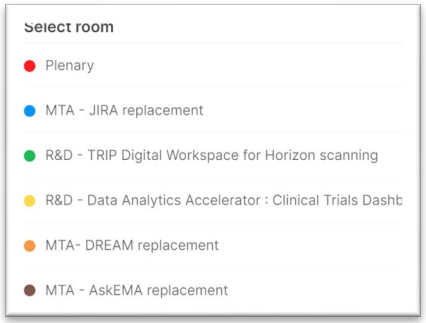

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R&D VS | Scientific Explorer

Jane Moseley, Scientific Explorer SME

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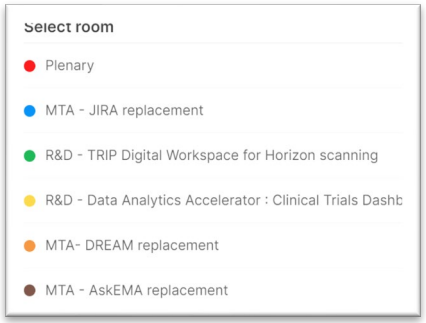

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Outline

- Scientific explorer;
    - why, what, who, what's coming
- AI extraction fields for Marketing authorisation (initial)
    - Clinical trial features
    - Application features
    - Quality
    - PASS features
- Demo- video
- Next steps

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Problem and solution

Regulatory Information

Scientific advice

Relevant information is stored in various forms & hard to find

Search for this information in a quick, easy and secure way

Scientific Explorer

Artificial intelligence (AI) enabled search for EU medicines regulators

Data → Issue → Need → Solution

See regulatory precedents in scientific advice

Collects data and preprocesses each document individually

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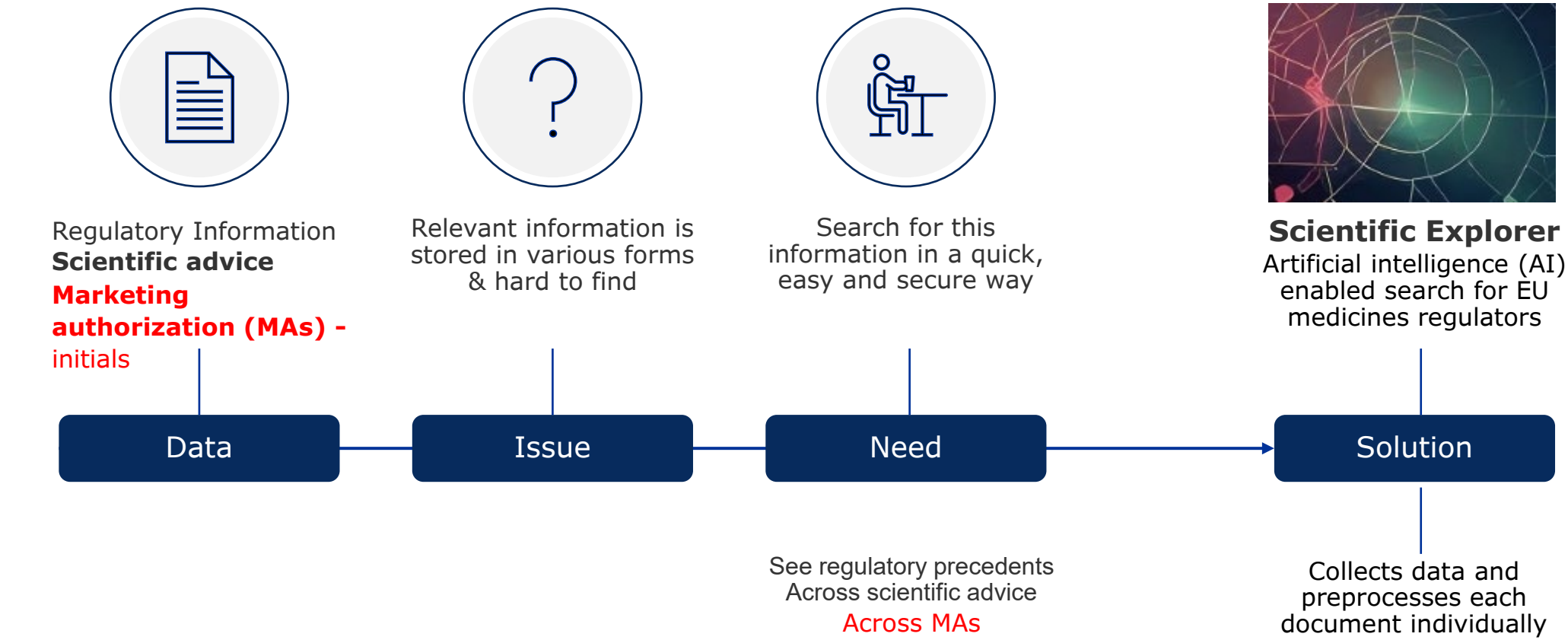
Problem and solution Expanding the content



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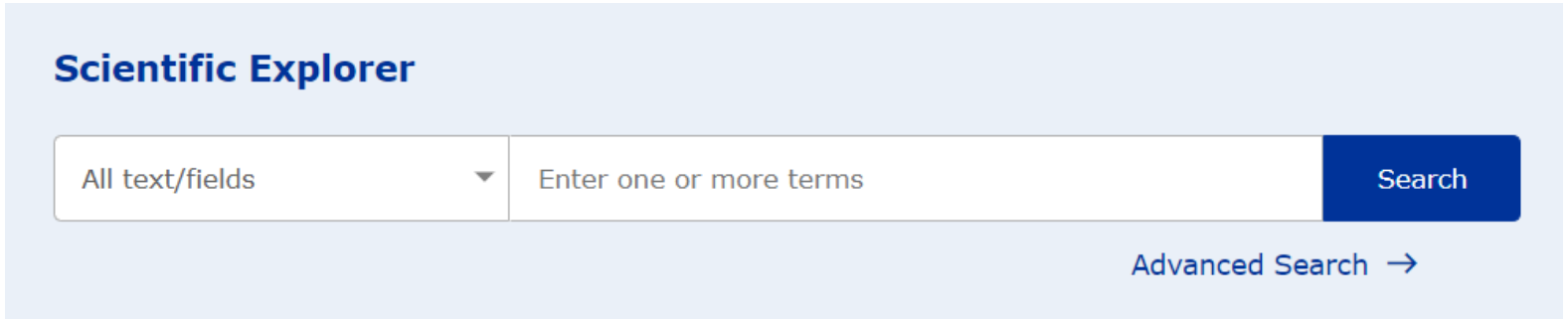
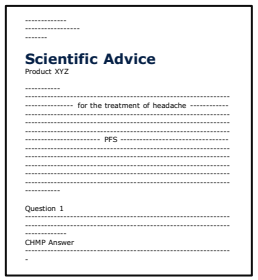
Scientific Explorer Enables

Fast, easy, precise **searching** and **interacting** with regulatory precedents, to support efficiency, quality, consistency of assessment





Across structured and **unstructured data**

Available to European Medicines Network only

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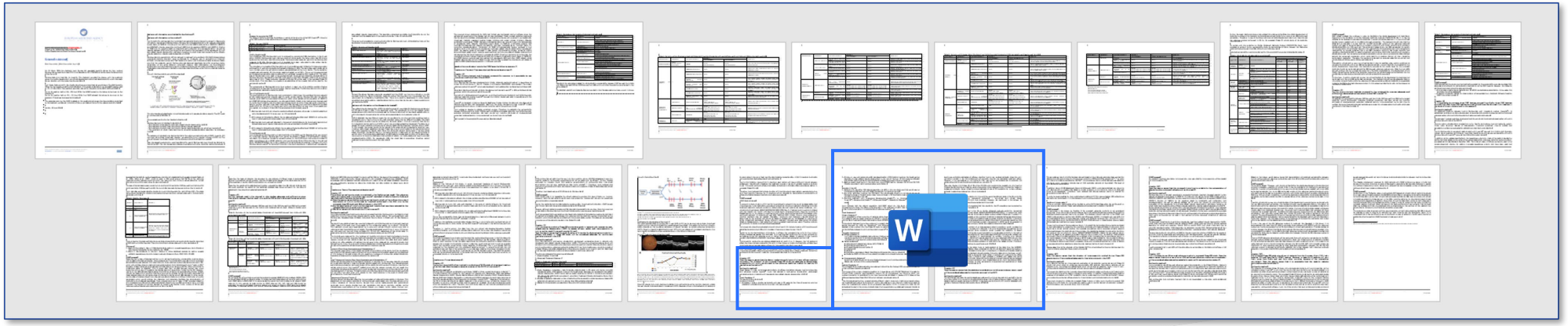
How: Example of unstructured document text and clinical AI extraction



Primary endpoint proposed	Primary endpoint agreement	Primary endpoint caveats	Primary endpoint references
1. Proportion of patients losing fewer than 15 letters from baseline BCVA in the study eye at the end of 3 months (Phase III Efficacy Study)	1. Disagreed (Phase III Efficacy Study)	1. A more sensitive endpoint (e.g. mean change in BCVA from baseline) should be used instead. (Phase III Efficacy Study)	1. 8 (Phase III Efficacy Study)

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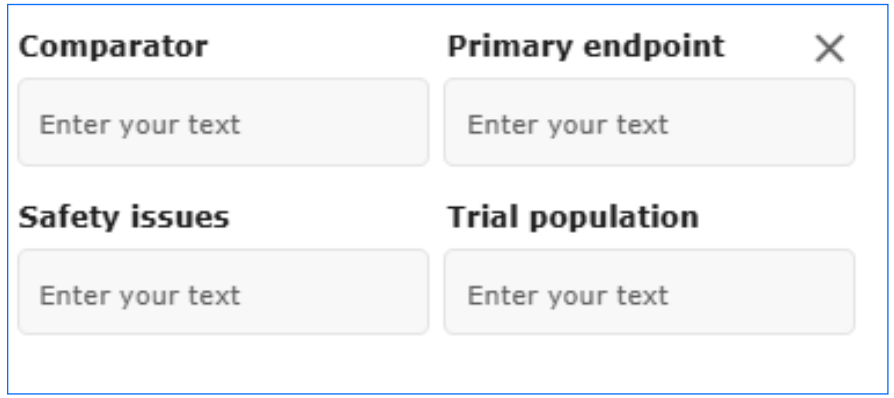
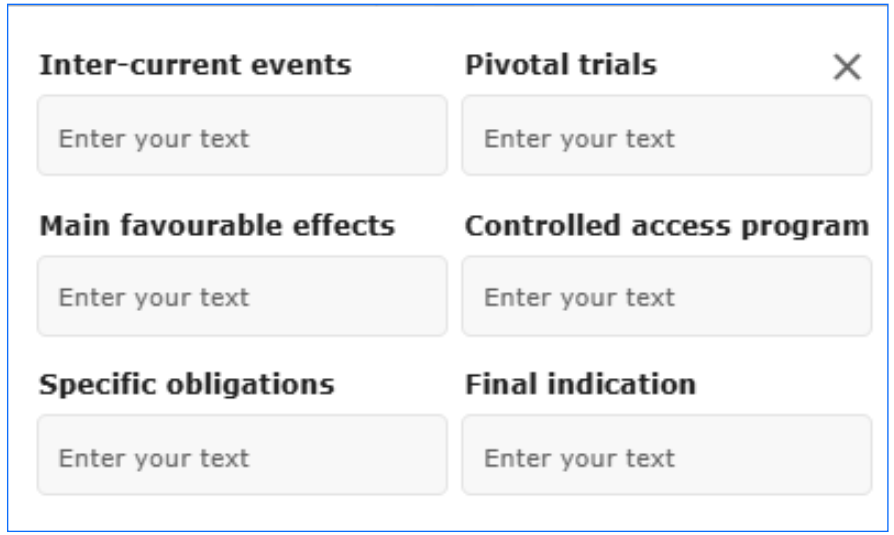
AI use for MAs: extractions –study features





AI allows us to tag specific text of interest in the documents, and then this "extracted " text of interest can searched or displayed

Clinical trials

PASS features

Comparator	Placebo
Primary endpoint	Change from baseline in the CDR-SB at 18 months
Handling of intercurrent events	initiation of new AD concomitant treatment or change of AD concomitant treatment or treatment discontinuation; treatment policy

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AI use for MAs: extractions – procedure features

- [ ] Complex trials (532)
- [ ] Conditional marketing authorisation (1023)
- [ ] Decentralised trials (63)
- [ ] Digital therapeutics (72)
- [ ] Exceptional circumstances (235)
- [ ] Extrapolation (3989)
- [ ] Medical devices (1247)
- [ ] Modelling (2771)
- [ ] Orphan similarity (240)
- [ ] Real world evidence (581)
- [ ] Repurposing (432)

Application AI extractions

- [ ] Companion diagnostic
- [ ] Data exclusivity
- [ ] New active substance
- [ ] PAES
- [ ] PASS
- [ ] Significant clinical benefit
- [ ] Single arm trials

AI allows us to tag procedures of interest, yes/ no to provide additional structure information

Then procedures of interest can be flagged

Specific quality flags also developed

Additional Risk Minimisation measures

Specific ADR follow up questionnaires

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Demonstration

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EMA | Scientific Explorer

Home | Go to Veterinary Data | Status | Information

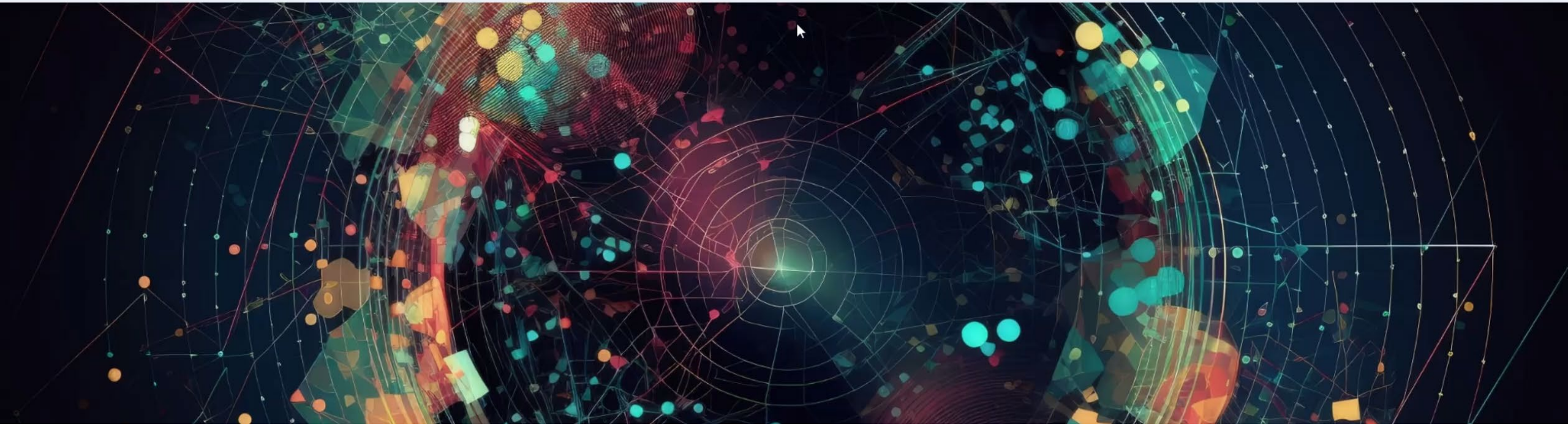
Confidential for the European Medicines Regulatory Network

Moseley Jane
Logout

Search Scientific Explorer - Human Data

All text/fields | Enter one or more terms | Search

Advanced Search →



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Next steps Scientific Explorer

- Development of Initial MAA including AI extractions ongoing
- Planning for UAT, go live date, change management communications, training materials, FAQS in progress

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PLM VS | Union Product Database(UPD)

Saskia Schiemann, UPD Network Product Owner

Beyhan Mustafov, UPD Product Owner

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#9116 064

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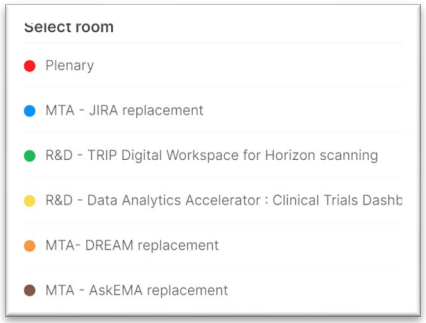

Step 2 – Choose/switch to the room for the right product

Step 3 - Choose Q&A or Polls as appropriate

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UPD – Union Product Database

Committed objectives 25Q3	Demo
• **Enrich Variation Not Requiring Assessment (VRNA) submissions** by an additional checkbox to allow MAH user to add Variation Requiring Assessment (VRA) procedure number for consequential VNRA.	**YES***
▪ **Remove several system validation checks for VNRA codes A.1.a, A.4, C.1, C.5 and C.6** to allow smooth submissions, approval and automatic update of the product data when products are missing mandatory data or having data quality issues.	**NO**

Released on 9 September and **after users feedback it has been revamped on 16 September 2025*

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Live Demo: Consequential VNRA checkbox

Live Demonstration

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Union Product Database (UPD) – Q3 achievements

Key achievements:

Consequential VNRA checkbox added

A **new check box for "Consequential VNRA as a result of a variation requiring assessment(VRA)"** has been introduced. When selected, it prompts users to enter the corresponding VRA procedure number in the submission comment field, ensuring that consequential changes (those directly resulting from a main VRA) are clearly identified.

Certain system validation removed

Several system validation checks for VNRA codes A.1.a, A.4, C.1, C.5 and C.6 have been removed to allow smooth submissions, approval and automatic update of the product data when products are missing mandatory data or having data quality issues.

Webpage / guidance documents updated

- The **UPD webpage** on the EMA website has been updated
- **Chapter 2** of the EU IG has been updated and will soon be published

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Upcoming UPD events and useful materials

UPD webinar for National Competent Authorities on available UPD APIs (Application Programming Interfaces)

6 November 2025 (10:30 – 12:00 CET) – Registration are open via EU NTC

Guides

- UPD registration guide *for UI and API users*
- UPD Implementation Guide
- Guidance for NCAs *on email addresses configuration, updating packages and VNRA highlighting*
- Guidance for MAHs *on the calculation of dose factor, how to configure email addresses for UPD notifications*

Release notes

- Periodically published on EMA's UPD webpage

Webinars and Trainings

- EMA's UPD webpage
- Video tutorials (divided by all users, NCAs and MAHs)

Q&A Documents

- UPD Q&As for Industry users – SOON to be updated
- UPD Q&As about VoS

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PLM VS | Product Management Service (PMS)

Marcos Fernandez Gomez, PMS Co-Product Owner

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Give feedback & ask questions

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Questions and answers are public
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Questions & available answers published on event page

Option 2 - Poll

Feedback shared only with product team
Stays open for comments till 24 September
Please identify yourself
Give the product team feedback and suggestions about your priorities

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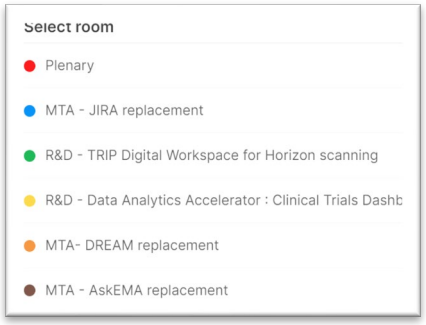

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PMS – Product Management Service

Committed objectives 25Q3	Demo
▪ Release in production the **write PMS API** (next week)	–
▪ Start the implementation of the **public read PMS API**	–
▪ Perform the **data fix** for products not capturing the **authorised dose form** and were not shown in the **Product UI**	**YES**
▪ BUG: **units of measurement or presentation** not captured at ingredient level (data fix for impacted products still missing)	–
▪ BUG: **authorisation status for pending products** will be correctly assigned now (data fix for impacted products still missing)	–

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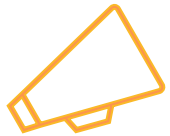
PMS upcoming events



Q&A clinics on PMS UI and API

- **18 September 2025** (10:00 – 11:00 CEST): Event page
- **14 October 2025** (11:00 – 12:00 CEST): Event page
- **18 November 2025** (11:00 – 12:00 CET): Event page
- **18 December 2025** (11:00 – 12:00 CET): Event page

PMS PUI & API public webinars

- *PMS PUI Training: Product data submission & bulk edit made easy* **6 October 2025** (10:00-12:00 CEST) Event page
- *Unlocking PMS API potential: Edit functionality training for MAHS* **16 October 2025** (10:00-11:30 CEST) Event page

SPOR & XEVMPD status update webinars

Live broadcast on event page

- **8 October 2025** (10:00 – 12:30 CEST): Event page

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Live Demonstration

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PLM VS | Product User Interface (PUI)

Marcos Fernandez Gomez, PMS UI Co-Product Owner

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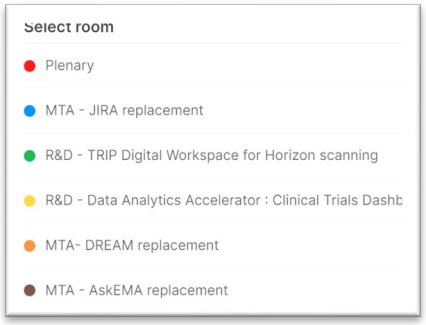

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Product UI

Committed objectives (PMS UI) 25Q2	Demo
▪ Release the **bulk update functionality** in Production (next week)	**YES**
▪ Implement **UX improvements**	**YES**
▪ Implement improvements in the **BI reports** (creation of report to support Shortage Mitigation Plans as well as Shortage Prevention Plans)	**YES**

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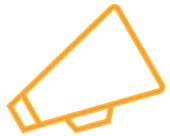
PMS upcoming events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Coffee break

We're back at 11:00

Housekeeping

Please note that this session is being live streamed.
It is being recorded and will be made available through the EMA Corporate Website

Participants may be able to ask questions or share feedback via Slido, with the option of remaining anonymous*.

To view the video in the highest quality, click on the settings symbol and select 720p or a higher resolution
To watch the video in full screen mode, click on watch on Youtube to watch it on YouTube.com

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PLM VS | electronic application form (eAF)

Kristiina Puusaari, eAF Product Owner

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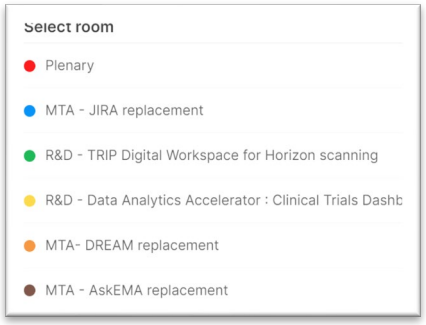

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eAF – Human Variations electronic Application Form

Committed objectives 25Q3	Demo
Enable **use of two parallel PLM Portal eAF versions** (UI/FHIR/PDF) so applicants can submit variations under both classification guidelines and meet legal requirements	**YES**
Add remaining (functional) UX/UI **features** to the **present/proposed section** to improve usability and to support future structured changes	**YES**
Allow the applicant to **select an organisation directly from OMS** in the present and **proposed** section so that they can reflect the desired organisation in the form and hence avoid having to use the interactive pdf eAF in case where the latest OMS information is not available in dataverse (workaround to a known issue)	**NO**
Add remaining (functional) UX/UI **features** to **product selection** so the eAF can better handle large applications	**NO**

Other deliverables and non-committed objectives 25Q3	Demo
Performance improvements	**NO**
Bug fixes	**NO**
Training session on non-CAPs in preparation for the launch for the Strongly recommended use	**NO**
Training session on CAPs	**NO**

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Human variations eAF – **Strongly Recommended** use for all Variations

- The PLM Portal web-based variation form will be **in Strongly Recommended use for all non-CAP variations** from Wednesday 29 September 2025.

- Issues, concerns, bugs should be reported via the **EMA ServiceNow tool** – please pay attention to the correct category.

Note: ***Strongly Recommended Use*** *=The web-based eAF should be used in most cases. The interactive PDF should only be used if specific constraints prevent the use of the web-based eAF (e.g., technical issues or missing features).*

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Known Issues and Bugs

List of **known issues and bugs** is **continuously reviewed** and fixes are planned for each sprint.

Reminder

Please review the eAF **Release Notes** and **Navigation Guide** if you have issues. If you experience a known issue please consider if you need to raise a service desk ticket and carefully select the correct category in ServiceNow

PMS and IRIS dataverse dependencies – corrupted products and organisational data issues

1. Corrupted Products (*affecting CAPS and non-CAPs)*

A small number of corrupted products are still visible in the eAF causing errors when selected, and while a list of these products is unavailable, the PMS team is working on a fix and users should raise a service desk ticket if affected.

2. Duplicate Products (*affecting CAPS and non-CAPs)*

Some packaged medicinal products appear under two different medicinal products due to data errors from xEVMPD/PMS, causing eAF errors that block progress, users should report the issue via a service desk ticket. In most of these cases you may be asked to use the interactive PDF version instead.

3. Missing Products (*affecting only non-CAPs)*

Approximately 19,000 non-CAP medicinal products (mainly with combined dose forms) are missing from PMS due to data errors, making them unavailable in the PLM Portal eAF. In most of these cases you may be asked to use the interactive PDF version instead.

4. Organisational data issues (*affecting CAPS and non-CAPs)*

A known issue in the intermediate dataverse layer from where the Organisation data is fetched to the eAF is continuing to impact number of products/users/applications. A platform level review is ongoing to ensure that the issue can be solved without negatively affecting various different systems that feed from this data

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Human variations eAF - statistics

3646 non-CAP applications
created in the PLM Portal since February 2025

3229 Centralised Procedure application forms received by EMA
since the go-live

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Upcoming eAF events

Q&A Clinic on web-based electronic application form functionalities

30 September 2025 (Link to the Event Page)

Q&A Clinic on web-based electronic application form functionalities

09 October 2025 (Link to the Event Page)

Guidance Material to be consulted

- **Training Videos available on PLM Portal at this Link**
- **User Guide available on PLM Portal at this Link**
- **Q&A document available on PLM Portal at this Link**

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Live Demo: UX/UI Updates

Live Demonstration

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PLM VS | electronic product information (ePI)

Evinn Drusys, ePI Network Product Owner,

Elizabeth Scanlan, ePI Product Owner

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Give feedback & ask questions

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Join at
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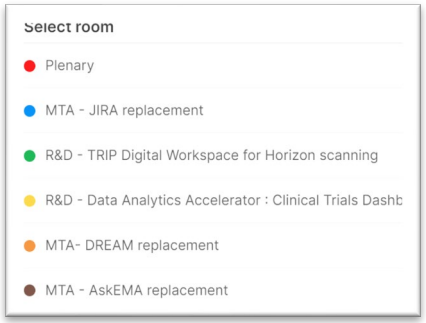

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ePI – electronic Product Information

Objectives 25Q3	Demo
▪ Document ePI business process for CAPs	**In review**
▪ Triage and begin working on FHIR import UAT feedback	✓
▪ Complete ePI styling strategy	✓
▪ Introduce UI/UX improvements	✓
▪ Enable versioning of the QRD template	**Ongoing**

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ePI FHIR Import User Acceptance Testing

UAT Scope

- **Kick-off 16 June – UAT closed 27 June**
- **Testers created and imported their own test files**

ePI FHIR Import UAT in numbers

20 organisations
(companies and service providers)

8 bugs identified

100 test epi imported

12 work items created

51 feedback surveys

Headlines results

Validation report

- Optimisations of validation report needed: naming, reporting of errors and display

Features

- Functionality should be put in place to replace existing ePI and default ePI templates when new ePI imported

Guidance

- Guidance helpful & well-structured
- Requests for: entry-level technical guidance, additional complex samples, style guide and style sheet

Thank you to our valuable testers!

slido # 9116064

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Live Demo: Validation report

Live Demonstration

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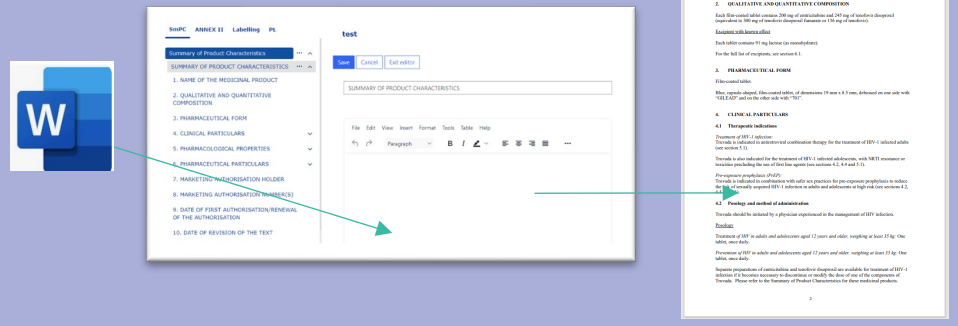
ePI Styling

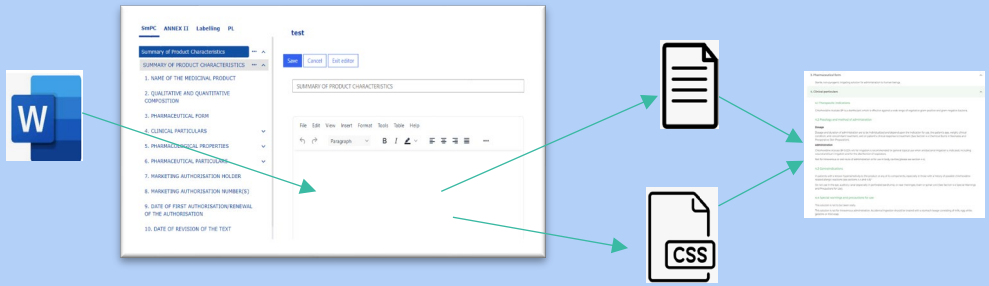
Before:

Copy paste from **Word** & **Keep** styling
All styling in-line in ePI FHIR



After:

Copy paste from **Word** & **Lose** styling
Some styling in line, most styling **external in style sheet**



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Live Demo: Styling, Preview page UI

Live Demonstration

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PLM VS | Regulatory Procedure Management (RPM) for Product Lifecycle Management on IRIS

Madalina Duta-Mare, RPM Product Owner

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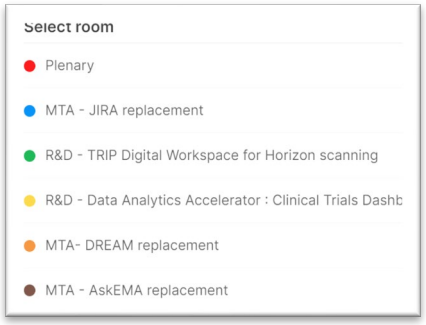

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Regulatory Procedure Management (RPM) for PLM on IRIS

Committed objectives 25Q3	Demo
Continue the development of **Eligibility & Intent process** by delivering features to capture and validate applicant eligibility and intent, aligned with business and regulatory rules	**YES**
Enable pre-submission meeting support by building tools for scheduling, tracking, and documenting pre-submission meetings within existing workflows	**YES**

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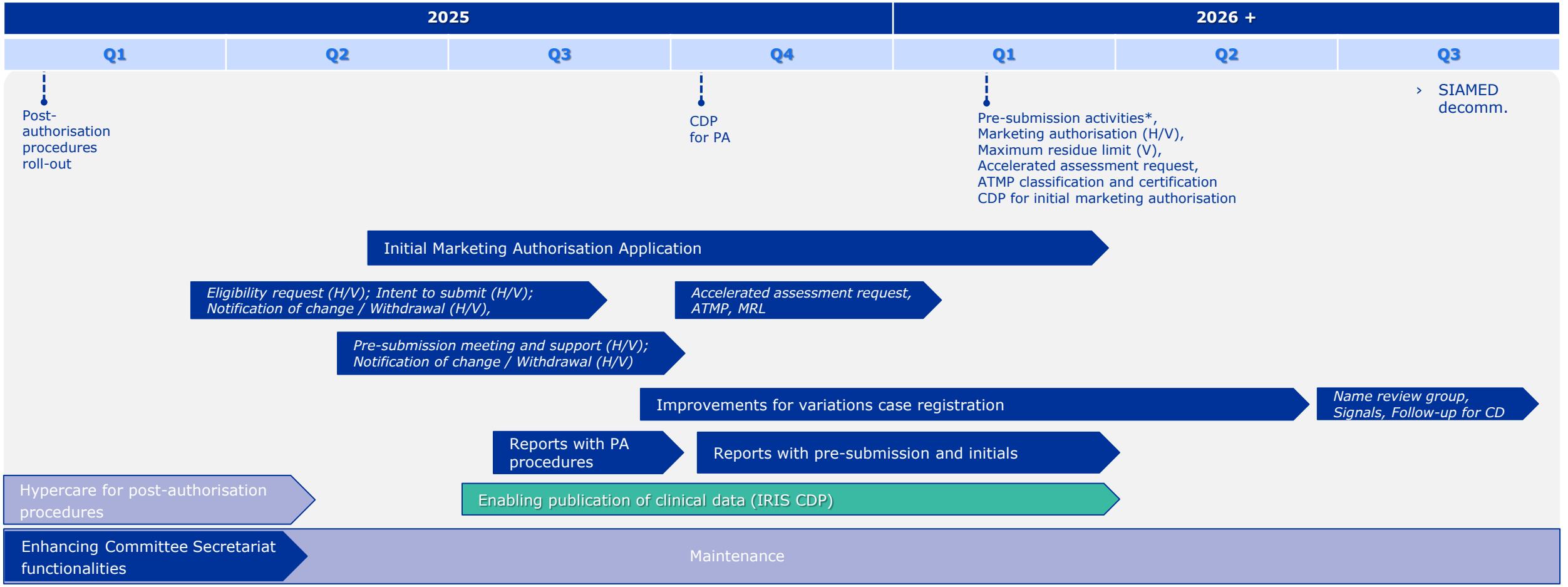
Regulatory Procedure Management in IRIS roadmap



Please note the ongoing development of Regulatory Procedure Management in IRIS will happen in stages, with incremental improvements across the entire regulatory procedure management landscape.

**Eligibility request (H/V); Intent to submit (H/V); Pre-submission meeting and support (H/V); Notification of change / Withdrawal (H/V)*

Legend

Milestone/ go-live

Development

Maintenance/ Hypercare

Enabler

slido # 9116064

Acronyms

- **CDP:** Clinical data publication
- **PA**: Post-Authorisation
- **ATMP:** Advanced Therapy Medicinal Products
- **CD**: Companion Diagnostic

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IRIS for RPM: Available guidance and upcoming training

The IRIS for RPM team will host a Webinar on 30 September (10:00 – 12:00) for all Industry users providing a recap of available functionalities and an overview of the upcoming developments. Register here!

In the IRIS Forum, you can find the updated support document that provides key resources such as: Actions, training materials and Service desk triage guidelines for support requests for MAHs

On the IRIS website, under Guidance, please find the recently updated FAQ document

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Live Demo: Eligibility & Intent process, pre-submission meeting support

Live Demonstration

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EMA Value Streams

Managing the Agency

Capabilities to empower EMA staff and support the Network through modernisation and digitalisation of the Agency's systems, processes and ways of working, increasing efficiency, transparency and collaboration

Research and Development

Capabilities to support the development of new medicines and generation of scientific evidence

Product Lifecycle Management

Capabilities to manage the authorisation and lifecycle of medicinal products and certain medical devices

Monitoring

Capabilities to monitor availability and safety of products

Technology Lifecycle Management and Information Security

Capabilities to manage information technology and security

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MON VS | EudraVigilance data analysis system (EVDAS)

Sophie Groeneveld, EVDAS Product Owner

Tom Paternoster-Howe EVDAS SME

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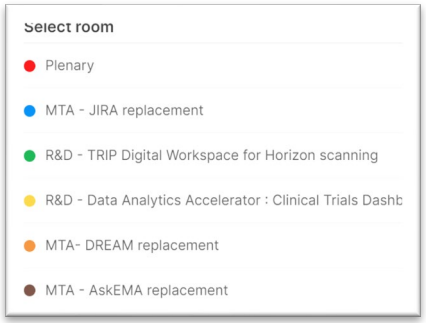

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Compliance Notifications

- **What?** Up to three ICSR compliance reports (for 7/15/90-day timelines), each in separate notification emails submitted through automated reports generated by EVDAS. Each compliance report is 5 pages long containing tables and graphs
- **Who?** QPPVs/RPs of all sender organisations will be automatically contacted (For Sep/Oct/Nov only top 20 MAHs who sent the most ICSRs to EV & NCAs)
- **How?** By email from donotreply@ema.europa.eu
- **When?** Launched on Wednesday 3rd September 2025
- **How often?** Every month with compliance reports covering the submissions made to EV the previous month. Next notification will be on 01 Oct 2025

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But why?

1. To ensure compliance with the legal basis:
   - Directive 2001/83/EC, Article 107(3) – MAHs 15/90 days
   - Directive 2001/83/EC, Article 107(a)(4) – NCAs 15/90 days
   - Regulation (EU) No 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use, Article 42(2) Sponsors 7/15 days
   - Commission Implementing Regulation (EU) No 520/2012 Articles 26(2)(a) and 25(1)(f) of chapter IV
   - Regulation (EC) No 762/2004, Article 24(3) SOPs & Article 11(1)c -quality system
2. To complement your own Quality System and to assist with timely root cause analysis
3. To quickly visualise compliance and comprehend the volume of non-compliant cases
4. To understand the types of cases/timelines that are non-compliant e.g. SUSARs or post marketing cases 7/15/90-day timelines

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Example: MLM Service

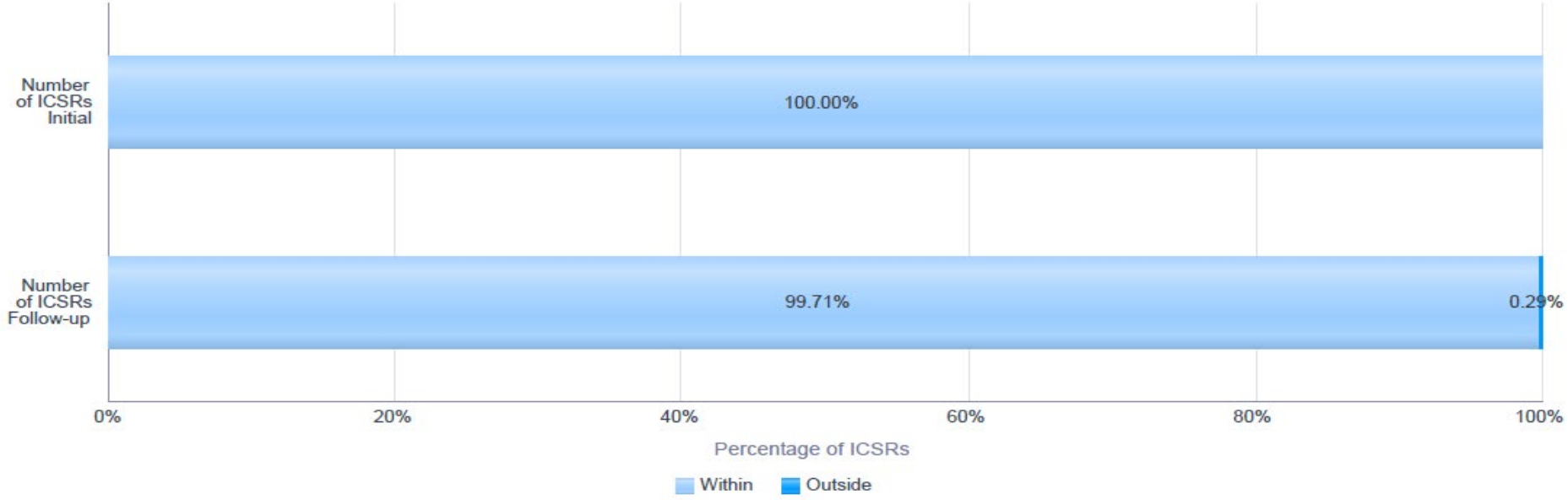
Organisation Sender ID: MLMSERVICE
Organisation Name: EMA MLMSERVICE

Listing of Non-Compliant Individual Cases Submitted to EVPM Outside 15 Days Reporting Period – August 2025

Reporting Time in Days	EV Local Report Number	EV World Wide Unique Case Identifier	Number of ICSRs - Initial	Number of ICSRs - Follow-up
0			0	0
372	10019886109	US-MLMSERVICE-20240320-4896634-1	0	1

Organisation Sender ID: MLMSERVICE
Organisation Name: EMA MLMSERVICE

Overview of ICSRs Submission to EVPM Within/Outside 15 Days Reporting Period – August 2025



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Example: MLM Service

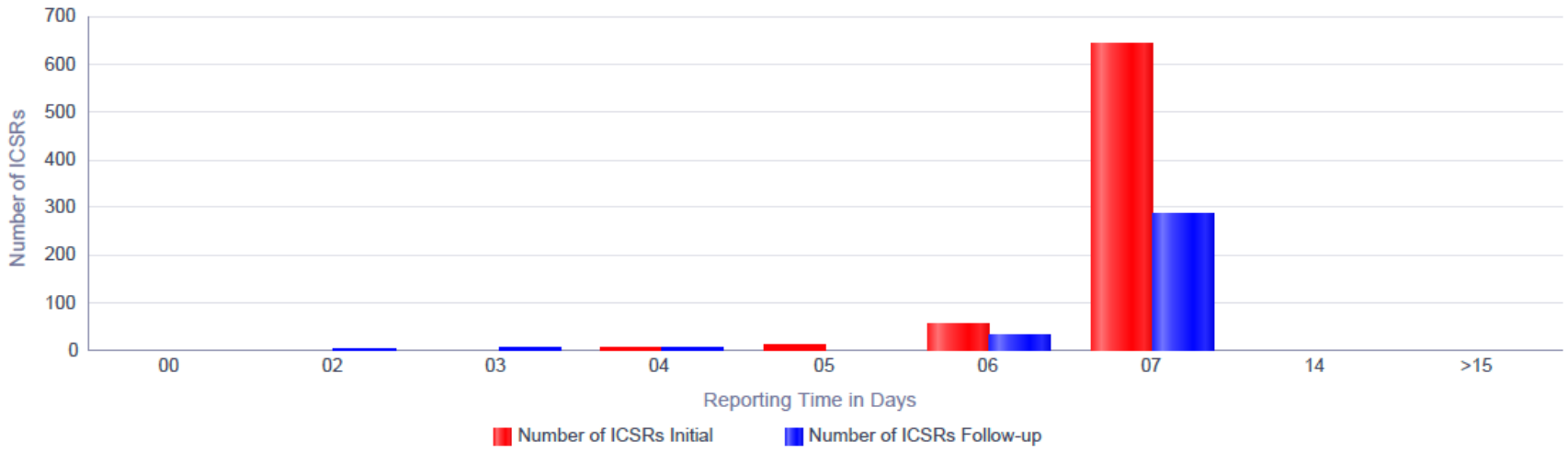
Organisation Sender ID: MLMSERVICE
Organisation Name: EMA MLMSERVICE

Overview of ICSRs Submission to EVPM Within/Outside 15 Days Reporting Period – August 2025

15 Days Reporting Period	Number of ICSRs - Initial	Number of ICSRs - Follow-up
Within	719	342
Outside	0	1

Organisation Sender ID: MLMSERVICE
Organisation Name: EMA MLMSERVICE

Overview of Submission Timelines of ICSRs to EVPM: 15 Days Reporting Period – August 2025



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Example: MLM Service

Organisation Sender ID: MLMSERVICE
Organisation Name: EMA MLMSERVICE

Overview of Submission Timelines of ICSRs to EVPM: 15 Days Reporting Period – August 2025

Reporting Time in Days	Number of ICSRs - Initial	Number of ICSRs - Follow-up
00	0	0
02	0	6
03	0	8
04	9	8
05	12	3
06	55	32
07	642	285
14	1	0
>15	0	1

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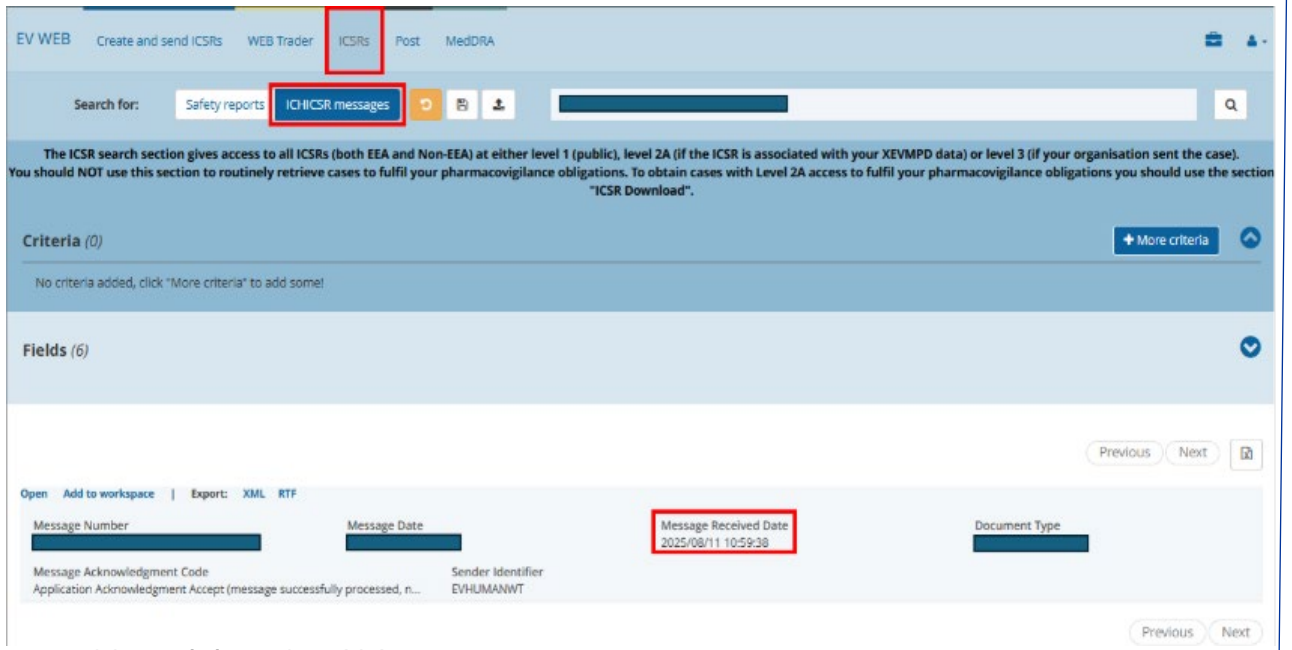
How is compliance measured?

- The compliance is calculated per ICSR as the difference between the data element "Date (of receipt) of most recent information for this report" (ICH E2B(R3) C.1.5) and the "EudraVigilance Gateway date".



Are any ICSRs excluded from the compliance notification?

Yes:

1. "**Error reports":** ICSRs for which the sender received an acknowledgement code "CR" in data element "Acknowledgment Code for a ICSR Message" (ICH E2B(R3) ACK.B.r.6);

2. "**Nullification reports**": ICSRs where the data element "Report Nullification/Amendment" (ICH E2B(R3) C.1.11.1) is populated with "1";

3. "**Amendment reports**": ICSRs where the data element "Report Nullification/Amendment" (ICH E2B(R3) C.1.11.1) is populated with "2".

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