

System Demo 25Q3

Public System Demo

17 September 2025





Welcome & Introduction

Jean-Michel Becar, Head of EMA Portfolio Management Office

Housekeeping



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



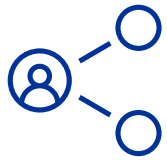
Participants may be able to ask questions or share feedback via Slido, with the option of remaining anonymous*.



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).

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.

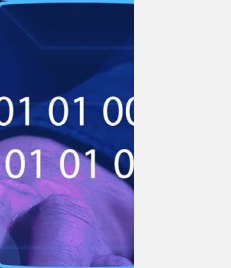
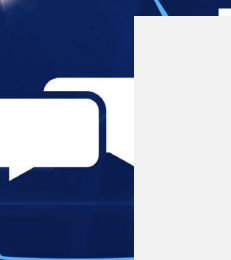


Enables the attendees to provide **instant feedback** allowing the Agile teams to make **necessary adjustments** to the solutions they are building



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

LLM
LARGE LANGUAGE MODELS



16 December

Is the next public system demo

Agenda

09:00	Welcome / Introductions
<i>09:05 – 09:45</i>	<i>Research & Development Value Stream (R&D VS)</i>
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
<i>09:45 – 12:10</i>	<i>Product Lifecycle Management Value Stream (PLM VS)</i>
09:45 – 10:00	Union Product Database (UPD)
10:00 – 10:25	Product Management Service (PMS)
10:25 – 10:50	Product user interface (PUI)
<i>10:50 – 11:00</i>	<i>Break</i>
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
<i>12:10 – 12:25</i>	<i>Monitoring Value Stream (MON VS)</i>
12:10 – 12:25	EudraVigilance data analysis system (EVDAS) – automated compliance reports
12:25	Closing

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



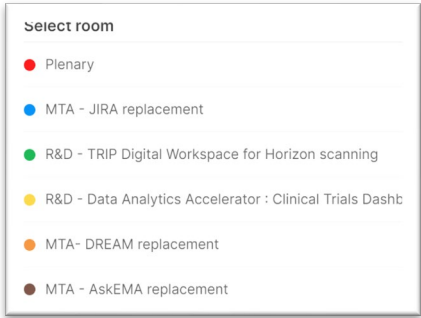
Option 2 - Poll

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

Join at
slido.com
#9116 064



Step 1 - Go to slido.com



Select room

- Plenary
- MTA - JIRA replacement
- R&D - TRIP Digital Workspace for Horizon scanning
- R&D - Data Analytics Accelerator : Clinical Trials Dashb
- MTA- DREAM replacement
- MTA - AskEMA replacement

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



Q&A | Polls

Step 3 - Choose Q&A or Polls as
appropriate

* 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).

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



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

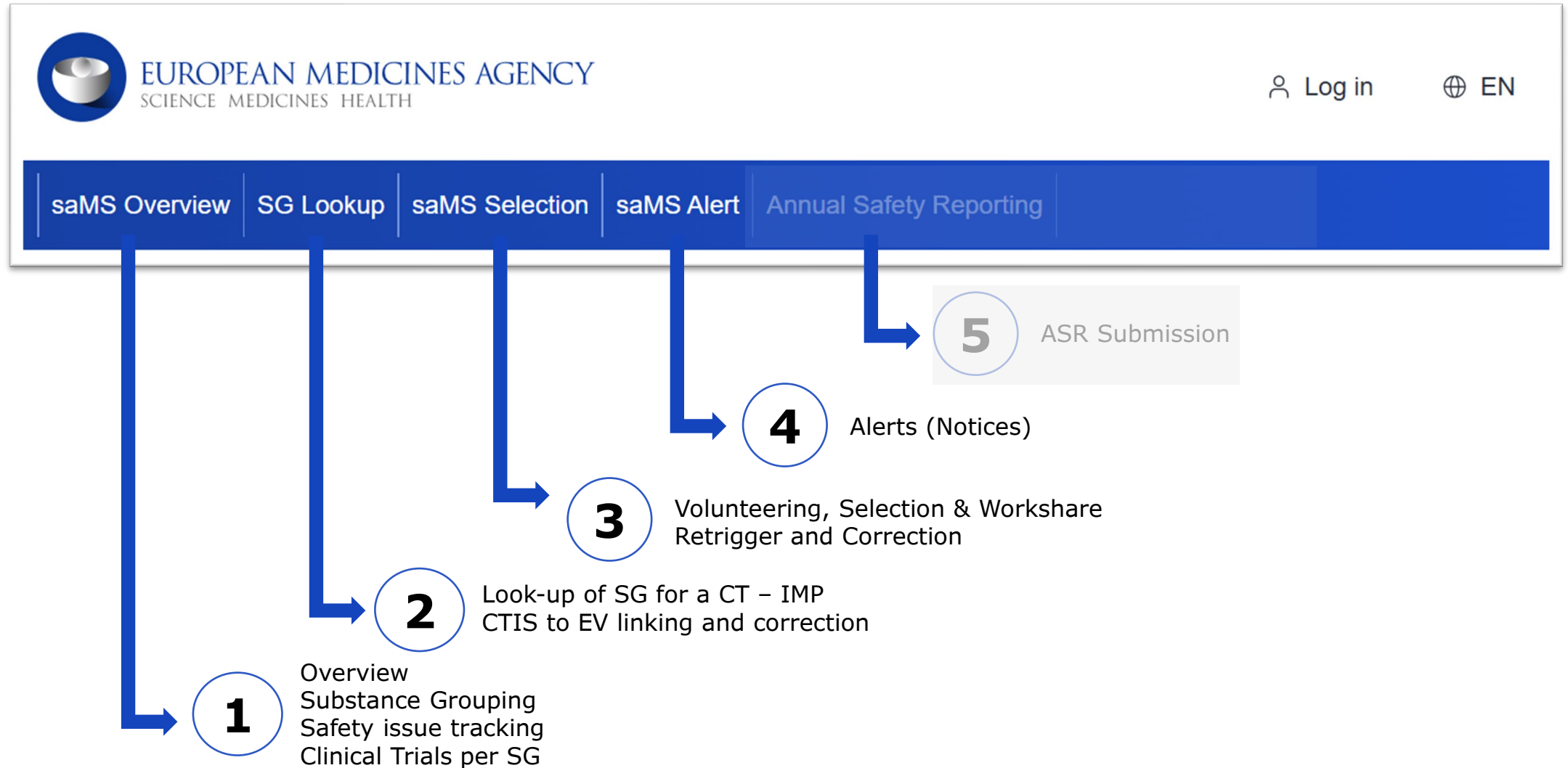
Ana Rodriguez, CTIS Product Owner

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

Safety Module MVP- saMS Selection



1. saMS Overview

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

The screenshot shows the 'saMS Overview' page in the European Medicines Agency (EMA) system. The page header includes the EMA logo and navigation links: 'saMS Overview' (highlighted with a red box), 'SG Lookup', 'saMS Selection', 'saMS Alert', and 'ASR Submission'. The main content area is titled 'saMS Overview' and includes a search prompt: 'Search for Scientific Group (SG) and associated information.' Below this is a table with the following columns: 'SG Name', 'saMS', 'Status', 'Mono/Multinational', 'MSC', 'Safety issues tracker', 'Working Folder', and 'CT's'. The table lists seven substances with their respective details.

SG Name	saMS	Status	Mono/Multinational	MSC	Safety issues tracker	Working Folder	CT's
CETOSTEARYLALCOHOL_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

1. saMS Overview

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

The screenshot shows the 'saMS Overview' page of the European Medicines Agency. The page includes a navigation bar with 'saMS Overview' highlighted, and a search bar for Scientific Groups (SG). The main content is a table listing SGs with various attributes. Annotations provide context for several elements:

- Status SG:** Inactive 3 months after the last associated trial ends for the SG.
- Mono- only one MSC for the SG/Multi- several MSC for the SG:** Indicates the type of Marketing Authorization (MA) for the SG.
- Indicates the number of authorised CTs concerned with the SG:** Points to the 'CT's' column.
- Overview of the linked Active Substance Low-Level for the SG:** Points to the SG Name column.
- Overview of the SG safety issues (if any). Date last update:** Points to the 'Safety issues tracker' column.
- Overview of the current and historical SG Names:** Points to the search filters on the left.

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	
VALOFANE	PT	Active	Multinational	FR* GR	+	Link to Sharepoint	4
AMYGDALUS PERSICA	GR	Active	Mono-national	GR* RO	2025-09-08	Link to Sharepoint	1
METHOTREXATE	FR	Active	Multinational	FR* NL DE GR	+	Link to Sharepoint	1
NINTEDANIB	FR	Active	Mono-national	FR*	+	Link to Sharepoint	3
[Unlabeled]	FR	Active	Mono-national	FR*	+	Link to Sharepoint	3

1. saMS Overview

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

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Log in EN

saMS Overview | SG Lookup | saMS Selection | saMS Alert | ASR Submission

Home > saMS Overview > Clinical Trials

Clinical Trials

Scientific Group: VALOFANE Filter columns

EU CT Number	Sponsor Protocol Identifier	CT Title	Medical Condition(s)	Trial Phase Population(s)	Sponsors	RMS	MSC	Other CT SGs	Product Name(s)
2025-519602-40-00	CSET 2015-2329	CT2 IN ATC L3 / L4 / L5 Aug/08	Carcinoma	Human Pharmacology (Phase I)-Other Women of child bearing potential using contraception, Patients	Institut Gustave Roussy	FR	FR GR		ADENOSINE, -, ARSENIC TRIOXIDE, -, -, -, AMINOCAPROIC ACID, -
2025-519603-25-00	CSET 2015-2329	Event CT IN 05-09	Carcinoma	Human Pharmacology (Phase I)-Other Patients, Women of child bearing potential using contraception	Institut Gustave Roussy	FR	FR		ACECLOFENAC, Vargatef 100 mg soft capsules, -, -, -
2025-519601-20-00	CSET 2015-2329	CT IN 1.2 11-08 ATC-L4	Carcinoma	Human Pharmacology (Phase I)-Other Patients, Women of child bearing potential using contraception	Institut Gustave Roussy	FR	FR		-, -, -, Vargatef 100 mg soft capsules
2025-519600-10-00	CSET 2015-2329	CT IN 1.2 11-08 ATC-L4	Carcinoma	Human Pharmacology (Phase I)-Other Women of child bearing potential using contraception, Patients	Institut Gustave Roussy	FR	FR		-, -, -, Vargatef 100 mg soft capsules

1. saMS Overview

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

The screenshot shows the saMS Clinical Trials interface. The top navigation bar includes 'saMS Overview', 'SG Lookup', 'saMS Selection', 'saMS Alert', and 'ASR Submission'. The main content area is titled 'Clinical Trials' and shows a search filter for 'VALOFANE'. A table lists clinical trials with columns for EU CT Number, Sponsor Protocol Identifier, CT Title, Medical Condition(s), Trial Phase | Population(s), Sponsors, RMS, MSC, Other CT SGs, and Product Name(s). Callouts provide the following information:

- Provides a hyperlink to the CT in CTIS.** (points to the EU CT Number column)
- List of other associated SG tested in the CT** (points to the MSC column)
- Allows the user to select the columns that are shown next to the default columns.** (points to the 'Filter columns' dropdown)
- List of all product names of this CT IMPs (test only)** (points to the Product Name(s) column)

EU CT Number	Sponsor Protocol Identifier	CT Title	Medical Condition(s)	Trial Phase Population(s)	Sponsors	RMS	MSC	Other CT SGs	Product Name(s)
2025-519602-40-00	CSET 2015-2329	CT2 IN ATC L3 / L4 / L5 Aug/08	Carcinoma	Human Pharmacology (Phase I)-Other Women of child bearing potential using contraception, Patients	Institut Gustave Roussy	FR	FR GR		ADENOSINE, -, ARSENIC TRIOXIDE, -, -, -, AMINOCAPROIC ACID, -
2025-519603-25-00	CSET 2015-2329	Event CT IN 05-09	Carcinoma	Human Pharmacology (Phase I)-Other Patients, Women of child bearing potential using contraception	Institut Gustave Roussy	FR	FR		ACECLOFENAC, Vargatef 100 mg soft capsules, -, -, -
2025-519601-20-00	CSET 2015-2329	CT IN 1.2 11-08 ATC-L4	Carcinoma	Human Pharmacology (Phase I)-Other Patients, Women of child bearing potential using contraception	Institut Gustave Roussy	FR	FR		-, -, -, Vargatef 100 mg soft capsules
2025-519600-10-00	CSET 2015-2329	CT IN 1.2 11-08 ATC-L4	Carcinoma	Human Pharmacology (Phase I)-Other Women of child bearing potential using contraception, Patients	Institut Gustave Roussy	FR	FR		-, -, -, Vargatef 100 mg soft capsules

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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saMS Overview **SG Lookup** saMS Selection saMS Alert ASR Submission

Home > SG Lookup

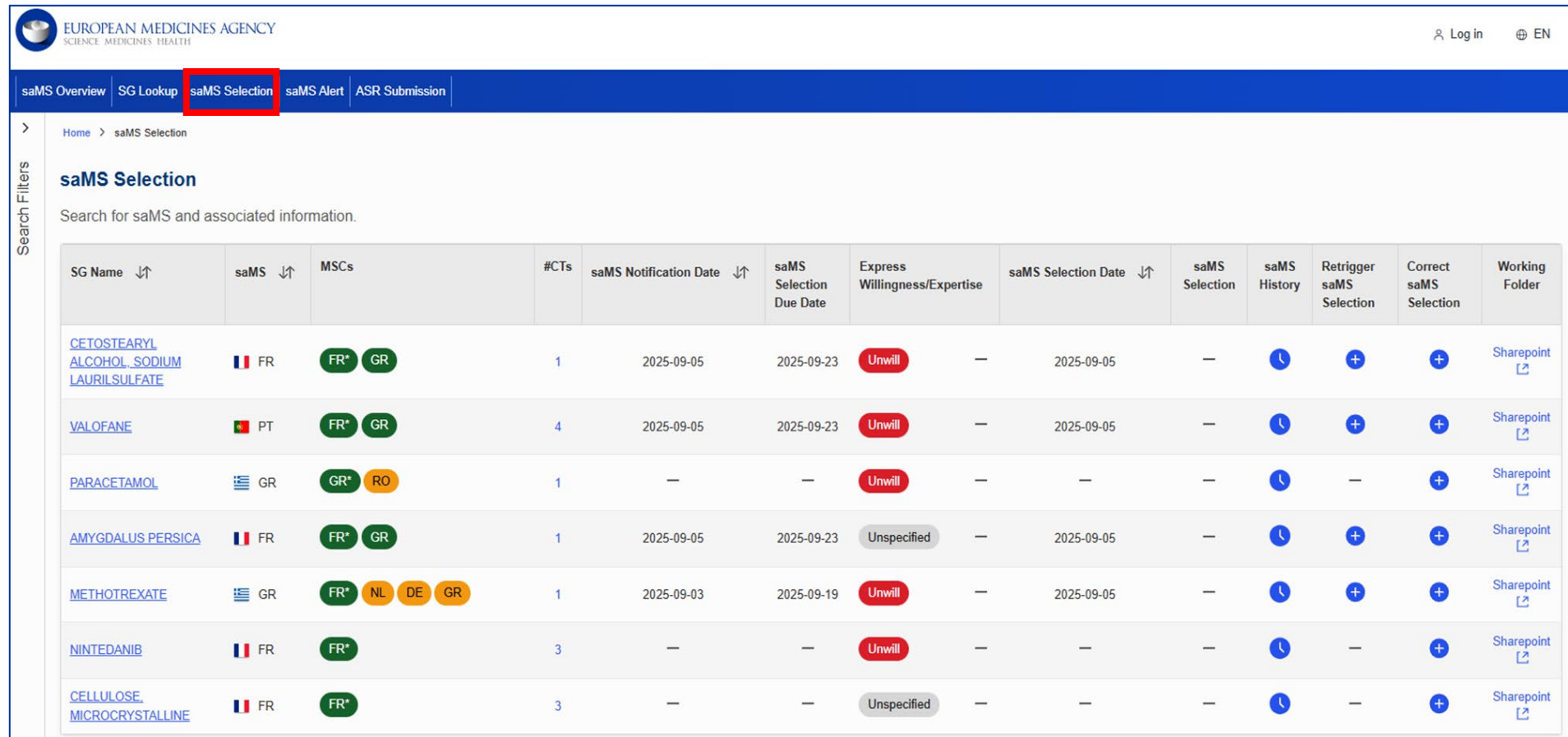
Clinical Trials

EU CT Number	IMP	Product Name	Active Substance	AS LL ID	AS LL Name	AS HL ID	AS HL Name/SG
2025-519600-10-00	PRD2282342	Vargatef 100 mg soft capsules	nintedanib	AI=SUB120728;	+ NINTEDANIB	AI=SUB120728;	NINTEDANIB
2025-519601-20-00	D11AH	—	—	AI=SUB00011MIG;	+ VALOFANE	AI=SUB00011MIG;	VALOFANE
2025-519603-25-00	PRD2282342	Vargatef 100 mg soft capsules	nintedanib	AI=SUB120728;	+ NINTEDANIB	AI=SUB120728;	NINTEDANIB
2025-519267-34-00	PRD10040098	Methotrexate 2,5 mg film-coate...	methotrexate	AI=SUB08856MIG;	+ METHOTREXATE	AI=SUB08856MIG;	METHOTREXATE
2025-519602-40-00	A04A	—	—	—	+ —	—	NO SG (for review)
2025-519602-40-00	C01EB10	ADENOSINE	adenosine	—	+ —	—	NO SG (for review)
2025-519602-40-00	D11AH	—	—	AI=SUB00011MIG;	+ —	AI=SUB00011MIG;	VALOFANE
2025-519600-10-00	D11AH	—	—	AI=SUB00011MIG;	+ —	AI=SUB00011MIG;	VALOFANE
2025-519602-40-00	L01XX27	ARSENIC TRIOXIDE	arsenic trioxide	AI=SUB13300MIG; AI=SUB72702;	+ CETOSTEARYL ALCOHOL, SODIUM LA...	AI=SUB13300MIG; AI=SUB72702;	CETOSTEARYL ALCOHOL, SODIUM LA...
2025-519605-18-00	PRD10008795	Paracetamol Accord 1000 mg com...	paracetamol	AI=SUB09611MIG;	+ PARACETAMOL	AI=SUB09611MIG;	PARACETAMOL

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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SCIENCE MEDICINES HEALTH

Log in EN

saMS Overview SG Lookup **saMS Selection** saMS Alert ASR Submission

Home > saMS Selection

saMS Selection

Search for saMS and associated information.

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

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**

The screenshot shows the 'saMS Selection' page in the European Medicines Agency's Safety Module. The page includes a search bar, a table of SGs, and various action buttons. Callouts highlight the following features:

- Start and due date of saMS selection procedure:** Points to the 'saMS Notification Date' and 'saMS Selection Due Date' columns.
- Info on the current and previous saMS for the SG:** Points to the 'saMS Selection' and 'saMS History' columns.
- Possibility to retrigger the saMS Selection:** Points to the 'Retrigger saMS Selection' button.
- Possibility to correct the saMS for the SG (without triggering the full process):** Points to the 'Correct saMS Selection' button.
- All MS are able to express willingness/expertise to become saMS:** Points to the 'Express Willingness/Expertise' column.
- Temporary assignment- RMS of the first CT authorized for the SG:** Points to the 'saMS' column for NINTEDANIB.
- RMS acting as saMS/saMS is able to select a new saMS:** Points to the 'saMS Selection' column for METHOTREXATE.

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 LAURIL SULFATE	FR	FR* GR	1	2025-09-05	2025-09-2	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				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*				Unwill					+	Sharepoint
CELLULOSE MICROCRYSTALLINE	FR	FR*	3	-	-	Unspecified	-	-			+	Sharepoint

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**.

The screenshot displays the EMA's saMS Selection interface. The main table lists various substances and their associated Member States (MS) with their willingness and MSC status. A pop-up window titled 'Select saMS' is overlaid on the table, showing a detailed view of the selection process for METHOTREXATE. The pop-up table includes columns for MS, Willingness, MSC, Work Share, Comment, and a 'Select as saMS' checkbox. The PT (Portugal) row is highlighted, indicating it is the selected Member State.

MS	Willing	MSC	Work Share	Comment	Select as saMS
PT	Willing with expertise	No	1	—	<input checked="" type="radio"/>
DE	Unwilling	Yes	0	—	<input type="radio"/>
NL	Unwilling	Yes	0	—	<input type="radio"/>
GR	Unwilling	Yes	0.4	—	<input type="radio"/>
FR	Unwilling	Yes	0.6666666666666666	—	<input type="radio"/>
AT	Unwilling	No	0	—	<input type="radio"/>
BE	Unwilling	No	0	—	<input type="radio"/>
BG	Unwilling	No	0	—	<input type="radio"/>
CY	Unwilling	No	0	—	<input type="radio"/>
CZ	Unwilling	No	0	—	<input type="radio"/>
DK	Unwilling	No	0	—	<input type="radio"/>
EE	Unwilling	No	0	—	<input type="radio"/>
ES	Unwilling	No	0	—	<input type="radio"/>

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**

The screenshot shows the 'saMS Alert' page for the 'PARACETAMOL' Safety Group. The page includes a navigation bar with 'saMS Alert' highlighted, a breadcrumb trail 'Home > saMS Alert', and a title 'saMS Alert'. There are filters for 'All events' and 'Sort By: Newest'. A list of three 'New SG Added' events is shown on the left, with the most recent at 2025-09-05 12:40. On the right, a table shows the 'Authorized Status' for a CT ID of 2025-519605-18-00, which is 'Authorised'. A list of actions is provided on the right side of the screenshot.

CT ID	Authorized Status
2025-519605-18-00	Authorised

- 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

Safety Module MVP- ASR Submission



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

The screenshot displays the EMA saMS interface for ASR Submission. At the top, the European Medicines Agency logo and navigation links are visible. The 'ASR Submission' menu item is highlighted with a red box. Below the navigation bar, the page title is 'Annual Safety Reports' with a subtitle 'Safety profile of an investigational medicinal product used in a clinical trial'. A search bar is present with the text 'Search ASR (to search for multiple IDs, separate them with commas)'. Below the search bar, there are three search results:

ASR ID	Status	Submitted Date	Sponsor	saMS
ASR-2025-00005	Submitted	2025-09-04		FR
ASR-2025-00011	Draft	1970-01-01	NovaHealth Systems	FR
ASR-2025-00015	Draft	1970-01-01		FR

5. ASR Submission

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

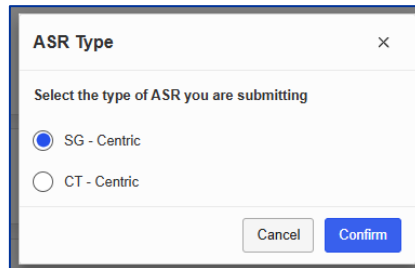
- Sponsor is able to **visualize all** submitted ASR
- Sponsor is able to **create** a new ASR as draft- **New**
- Sponsor is able to **edit** draft ASR- **New**
- Sponsor is able to **delete** draft ASR- **New**

The screenshot shows the EMA ASR Submission interface. At the top, the navigation menu includes 'saMS Overview', 'SG Lookup', 'saMS Selection', 'saMS Alert', and 'ASR Submission' (highlighted with a red box). The main content area is titled 'Annual Safety Reports' and includes a search bar with the text 'Search ASR (to search for multiple IDS, separate them with commas)'. Below the search bar, there are three search results. The first result is 'ASR-2025-00009' (highlighted with a green box), which is 'Submitted: 2025-09-04'. The second result is 'ASR-2025-00011' (EU CT Number: 2025-519567-34-00), which is 'Submitted: 1970-01-01' and 'Sponsor: NovaHealth Systems'. The third result is 'ASR-2025-00015' (EU CT Number:), which is 'Submitted: 1970-01-01' and 'Sponsor: NovaHealth Systems'. On the right side of the search results, there are icons for 'Submitted', 'Draft', 'Edit', and 'Delete'. A '+ New ASR' button is highlighted with a red box. Annotations with green boxes and arrows point to the '+ New ASR' button (labeled 'Create a new ASR'), the search results (labeled 'Provides a visualisation of the ASR once submitted.'), the 'Edit' icon (labeled 'Edit a draft ASR.'), and the 'Delete' icon (labeled 'Delete a draft ASR.').

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



ASR Type

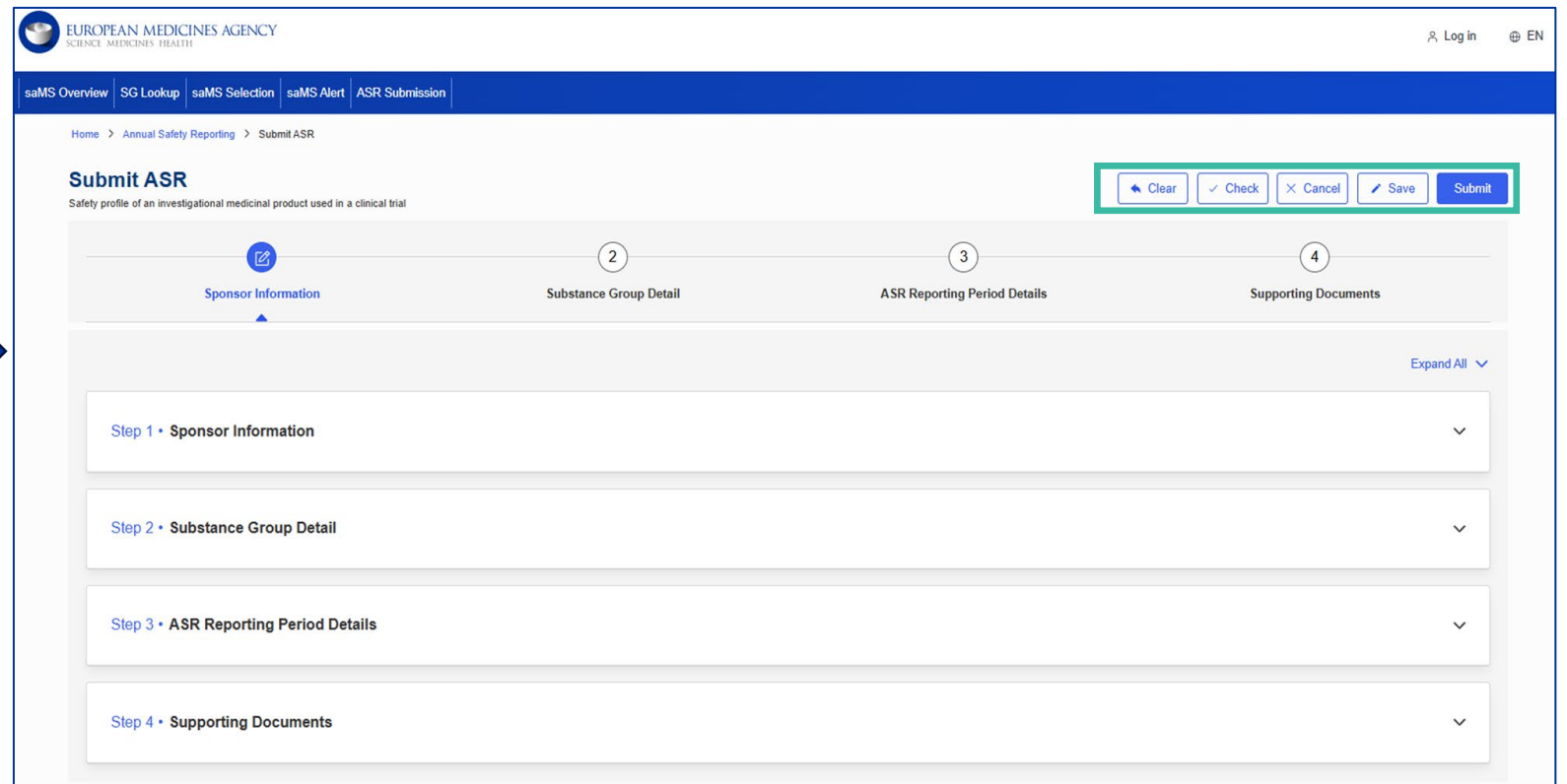
Select the type of ASR you are submitting

SG - Centric

CT - Centric

Cancel Confirm

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



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saMS Overview | SG Lookup | saMS Selection | saMS Alert | ASR Submission

Home > Annual Safety Reporting > Submit ASR

Submit ASR
Safety profile of an investigational medicinal product used in a clinical trial

Clear Check Cancel Save Submit

1 Sponsor Information 2 Substance Group Detail 3 ASR Reporting Period Details 4 Supporting Documents

Expand All

Step 1 • Sponsor Information

Step 2 • Substance Group Detail

Step 3 • ASR Reporting Period Details

Step 4 • Supporting Documents

5. ASR Submission

Step 1 • Sponsor Information

Organisation details of the selected sponsor

This ASR is a consolidated report following a co-development agreement*

Are any of the sponsors or co-sponsors commercial? *

Yes No

Organisation responsible for the ASR submission*

Please select

Organisation name	Post Code
—	—
Address 1	City
—	—
Address 2	Country
—	—
Address 3	Email
—	—
Address 4	Phone Number
—	—

Use invoice address different from the correspondence address? *

Contact details for ASR submission

Step 2 • Substance Group Detail

Select the CT(s) of your substance group selection

CARBAMAZEPINE

Step 3 • ASR Reporting Period Details

Development International Birth Date (optional)

International Birth Date (optional)

ASR Reporting Period * to

Substantial Modification on RSI has been submitted during the reporting period? *

Yes No

Provide EU CT Number of first SM new RSI version *

During the reporting period ASR includes *

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

Step 4 • Supporting Documents

ASR document*

Smpc if the Smpc includes RSI and not submitted as part of the ASR document

Investigator Brochure if the Investigator Brochure includes RSI and not submitted a part of the ASR document

Other documents

1. on behalf of the sponsor, confirm that the

1. Information provided is complete
2. Attached documents contain an accurate account of the information available
3. The Sponsor, declares that the Annual Safety Report is prepared and hereby submitted to the Agency in accordance with Article 43 of Regulation (EU) No 536/2014 and all other applicable legal provisions.

RSI Document(s) have been uploaded (old and new version when applicable) *

I agree with the above statements *

Submit

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



R&D VS | Trial Map

IJsbrand den Rooijen, Trial Map developer

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

Join at
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Select room

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- MTA - JIRA replacement
- R&D - TRIP Digital Workspace for Horizon scanning
- R&D - Data Analytics Accelerator : Clinical Trials Dashb
- MTA- DREAM replacement
- MTA - AskEMA replacement

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



Q&A | Polls

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appropriate

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R&D VS | Scientific Explorer

Jane Moseley, Scientific Explorer SME

Give feedback & ask questions



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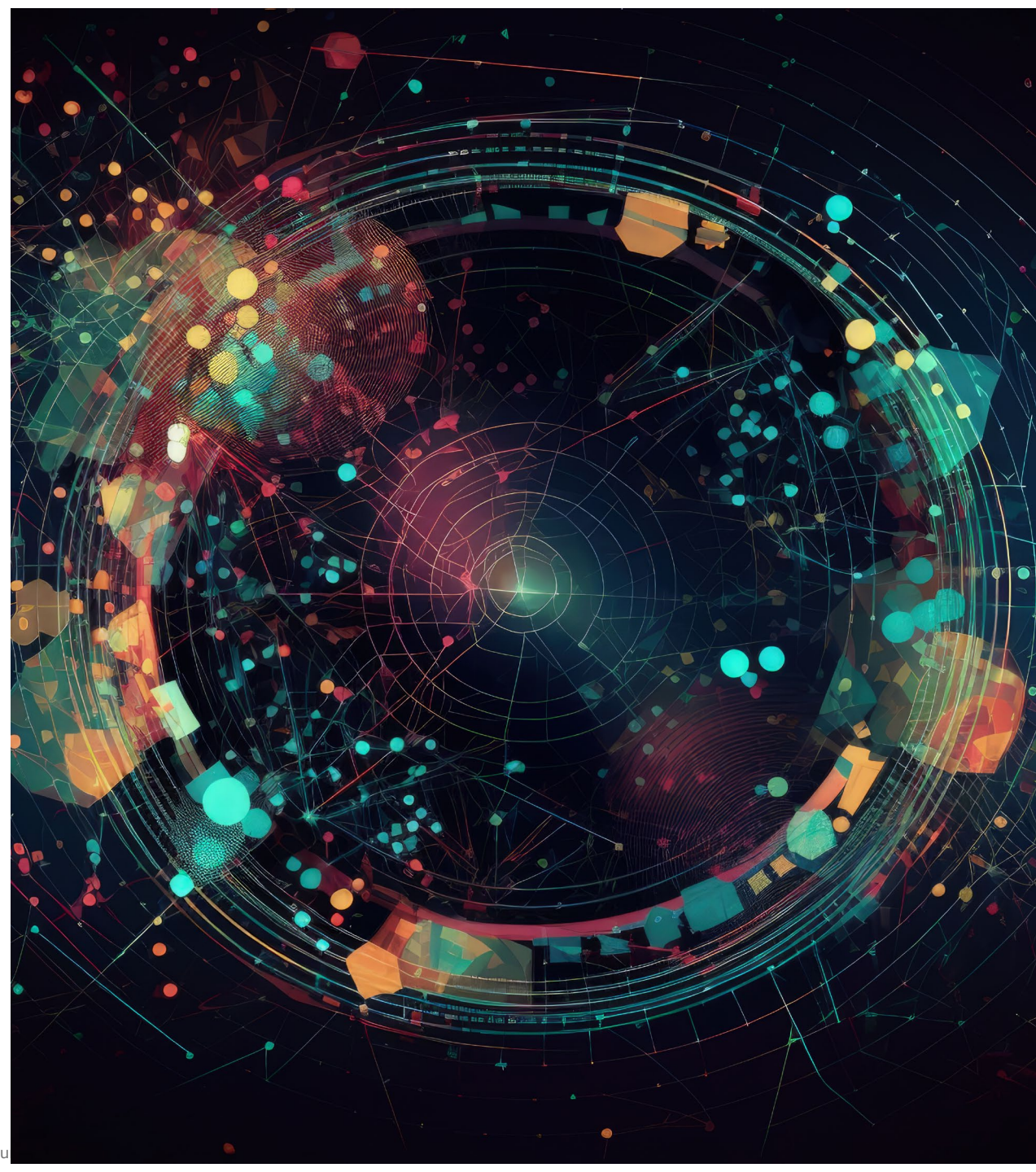
 Q&A  Polls

Step 3 - Choose Q&A or Polls as
appropriate

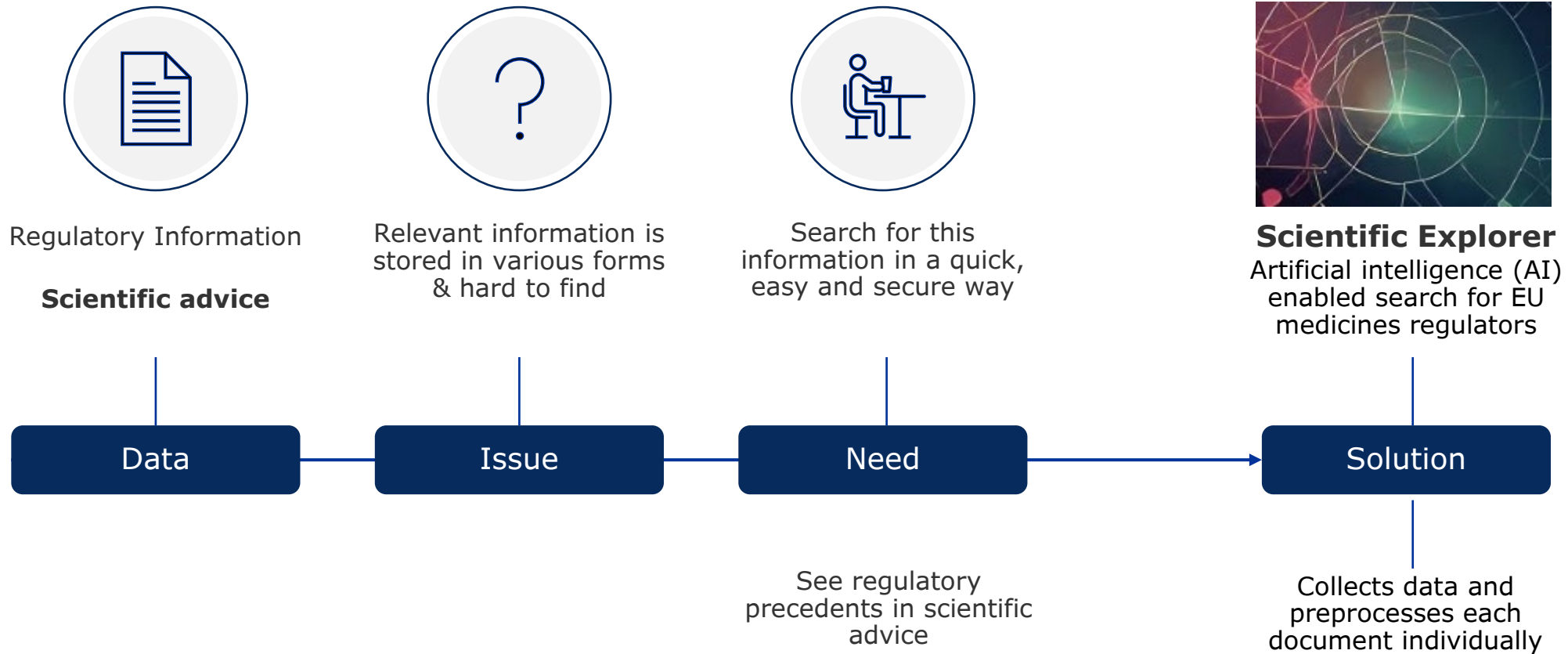
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Outline

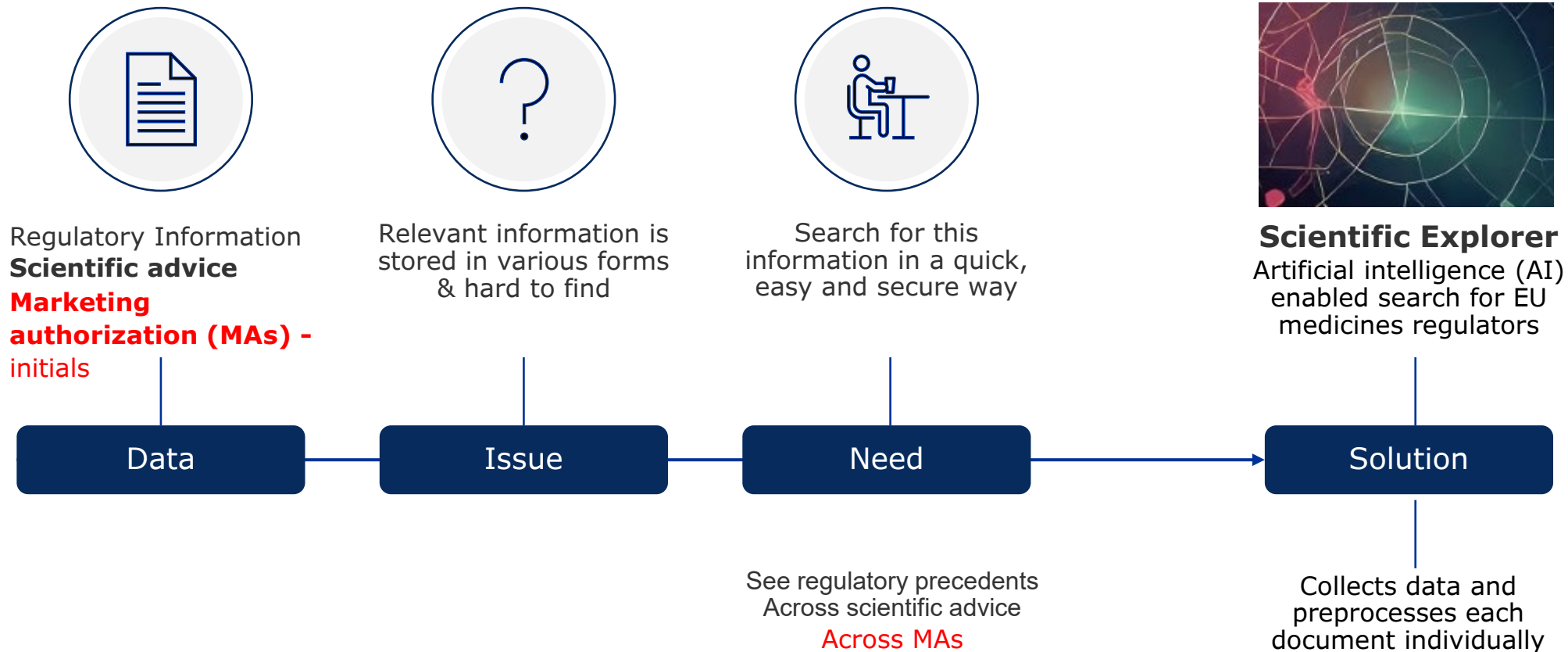
- Scientific explorer;
 - why, what, who, what's coming
- AI extraction fields for Marketing authorisation (initial)
 - Clinical trial features
 - Application features
 - Quality
 - PASS features
- Demo- video
- Next steps



Problem and solution

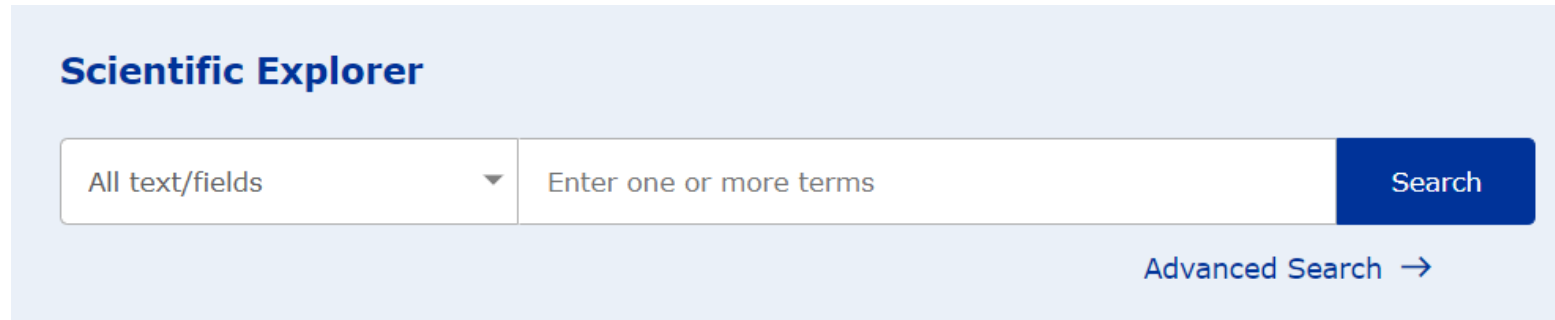


Problem and solution **Expanding the content**



Scientific Explorer Enables

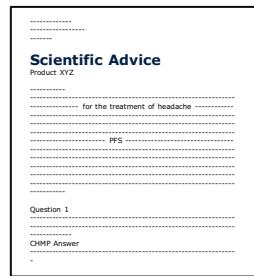
Fast, easy, precise **searching** and **interacting** with regulatory precedents, to support efficiency, quality, consistency of assessment



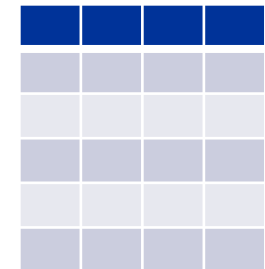
Scientific Explorer

All text/fields ▼ Enter one or more terms Search

Advanced Search →

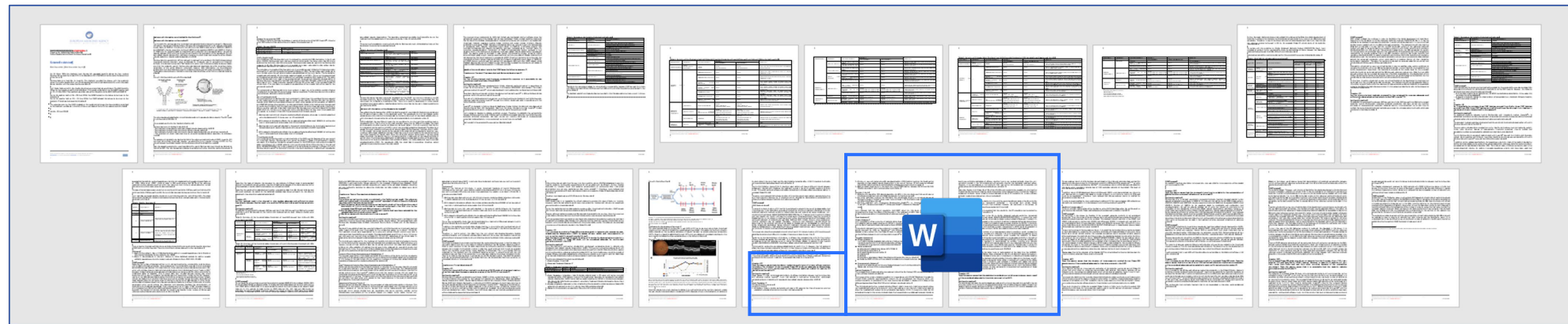


Across structured and unstructured data



Available to European Medicines Network only

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)

AI use for MAs: extractions –study features

Comparator	Primary endpoint ✕
Enter your text	Enter your text
Safety issues	Trial population
Enter your text	Enter your text

Inter-current events	Pivotal trials ✕
Enter your text	Enter your text
Main favourable effects	Controlled access program
Enter your text	Enter your text
Specific obligations	Final indication
Enter your text	Enter your text

AI allows us to tag specific text of interest in the documents, and then this “extracted” text of interest can be 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

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

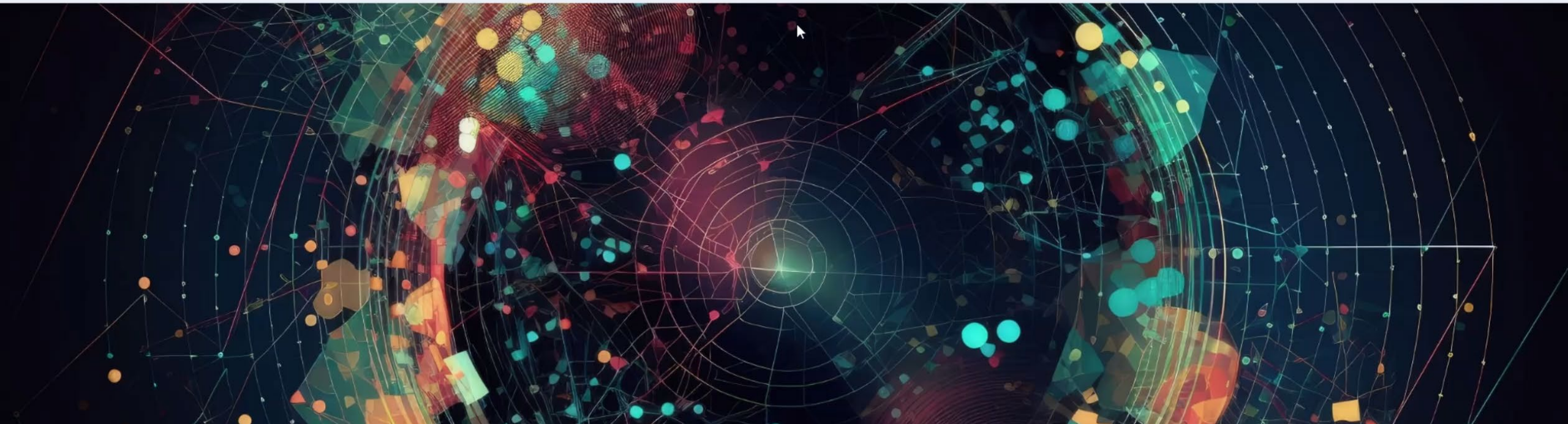


Demonstration

Search Scientific Explorer - Human Data

All text/fields

[Advanced Search](#) →



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

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



PLM VS | Union Product Database(UPD)

Saskia Schiemann, UPD Network Product Owner

Beyhan Mustafov, UPD Product Owner

Give feedback & ask questions



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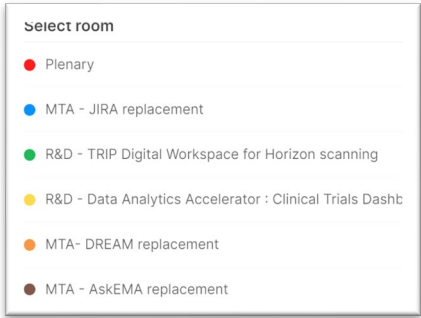
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Q&A | Polls

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.
- **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.

YES*

NO

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

Live Demo: Consequential VNRA checkbox



Live Demonstration

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

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](#)



PLM VS | Product Management Service (PMS)

Marcos Fernandez Gomez, PMS Co-Product Owner

Give feedback & ask questions



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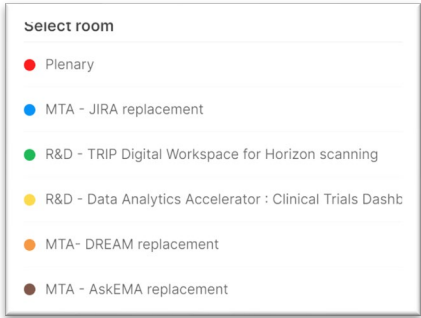
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Q&A | Polls

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PMS – Product Management Service



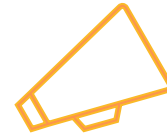
Committed objectives 25Q3	Demo
▪ Release in production the write PMS API (next week)	-
▪ Start the implementation of the public read PMS API	-
▪ Perform the data fix for products not capturing the authorised dose form and were not shown in the Product UI	YES
▪ BUG: units of measurement or presentation 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)	-

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](#)



Live Demonstration



PLM VS | Product User Interface (PUI)

Marcos Fernandez Gomez, PMS UI Co-Product Owner

Give feedback & ask questions



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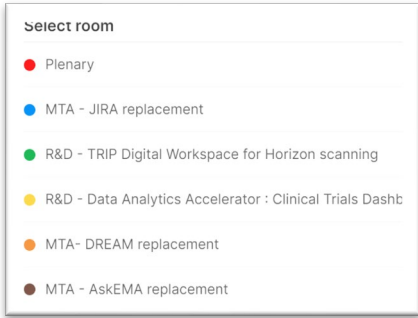
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Q&A | Polls

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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)

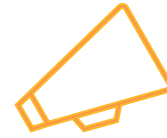
YES

PMS upcoming events



Q&A clinics on PMS UI and API

- **18 September 2025** (10:00 – 11:00 CET): [Event page](#)
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SPOR & XEVMPD status update webinars

- Live broadcast on event page**
- **8 October 2025** (10:00 – 12:30 CEST): [Event page](#)



Live Demonstration



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

Give feedback & ask questions



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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

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).*

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.

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.

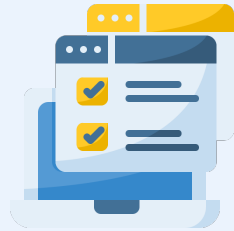
2. Duplicate Products (*affecting CAPS and non-CAPs*)

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.

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

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

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](#)

Live Demo: UX/UI Updates



Live Demonstration



PLM VS | electronic product information (ePI)

Evinn Drusys, ePI Network Product Owner,
Elizabeth Scanlan, ePI Product Owner

Give feedback & ask questions



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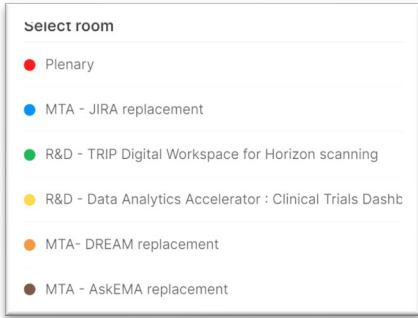
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Q&A | Polls

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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

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!

Live Demo: Validation report



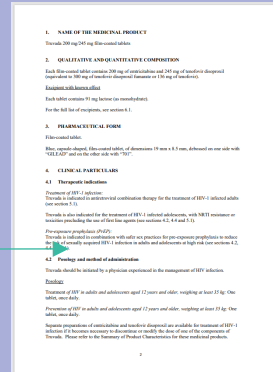
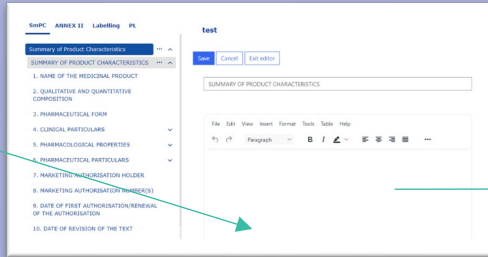
Live Demonstration

ePI Styling

Before:



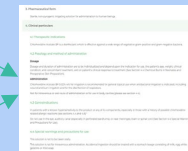
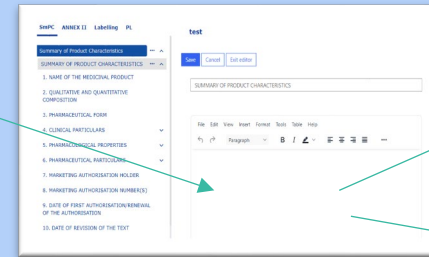
Copy paste from **Word** & **Keep** styling
All styling in-line in ePI FHIR



After:



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



ePI - Style Guide



Purpose and Context

Styling information in the context of ePI refers to the way content can be displayed. Styling information is important for compliance with regulator requirements and user experience.

This style guide aims to:

- instruct applicants how to incorporate styling information when importing data
- outline how and when QRD styles, as outlined in the QRD templates and QRD style guides, should be used
- inform consumers of ePI data about what styling information to expect in the data

Coming soon! The guide will be accompanied by:

- the ePI QRD Cascading Style Sheet (CSS), which is used to apply QRD styles to the data
- an Extensible Stylesheet Language Transformation (XSLT), which can be used to transform the data into a format that can be displayed in a browser

> 1 - ePI creation

> 2 - Viewing and accessing ePI

> 3 - How to style ePI

> 4 - Accessibility

Live Demo: Styling, Preview page UI



Live Demonstration



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

Madalina Duta-Mare, RPM Product Owner

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Step 3 - Choose Q&A or Polls as
appropriate

* 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).

Regulatory Procedure Management (RPM) for PLM on IRIS



Committed objectives 25Q3

Demo

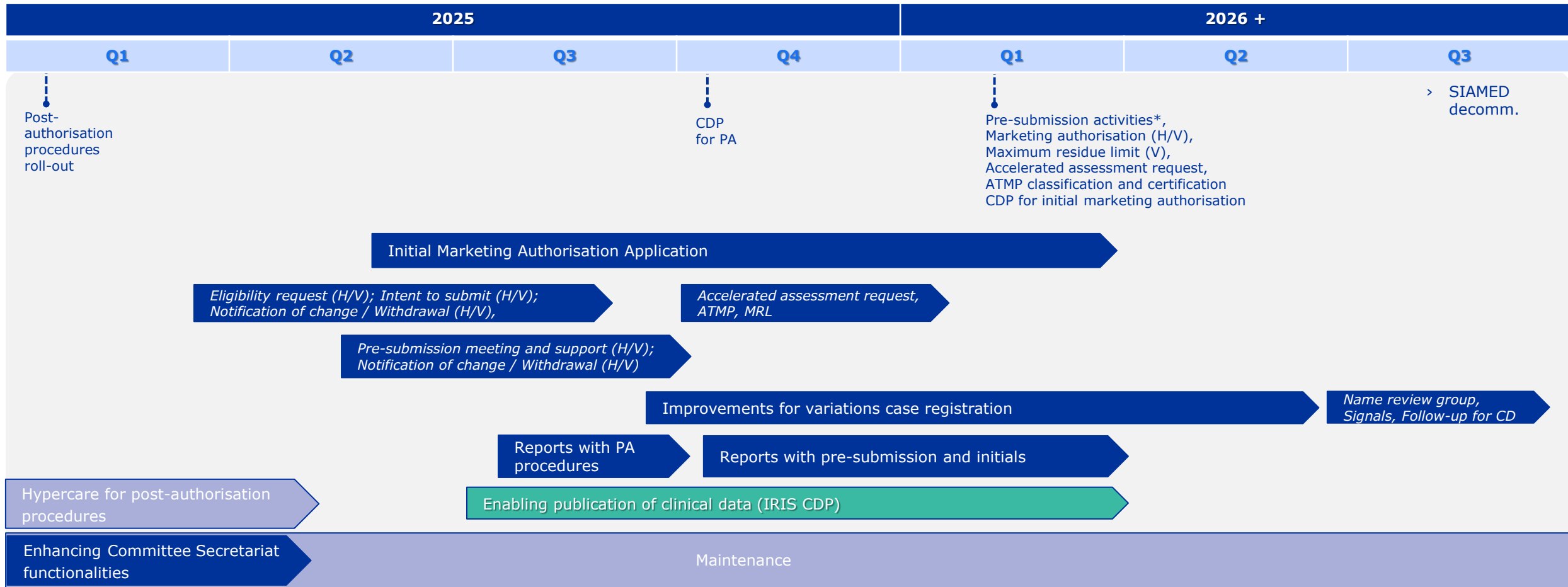
Continue the development of **Eligibility & Intent process** by delivering features to capture and validate applicant eligibility and intent, aligned with business and regulatory rules

YES

Enable pre-submission meeting support by building tools for scheduling, tracking, and documenting pre-submission meetings within existing workflows

YES

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 slide # 9116064

Development

Maintenance/
Hypercare

Enabler

Acronyms

- **CDP:** Clinical data publication
- **PA:** Post-Authorisation

- **ATMP:** Advanced Therapy Medicinal Products
- **CD:** Companion Diagnostic



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](#)

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



Live Demonstration

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



MON VS | EudraVigilance data analysis system (EVDAS)

Sophie Groeneveld, EVDAS Product Owner

Tom Paternoster-Howe EVDAS SME

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

Join at
slido.com
#9116 064



Step 1 - Go to slido.com



Select room

- Plenary
- MTA - JIRA replacement
- R&D - TRIP Digital Workspace for Horizon scanning
- R&D - Data Analytics Accelerator : Clinical Trials Dashb
- MTA- DREAM replacement
- MTA - AskEMA replacement

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



Q&A | Polls

Step 3 - Choose Q&A or Polls as appropriate

* 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).

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

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

Example: MLM Service

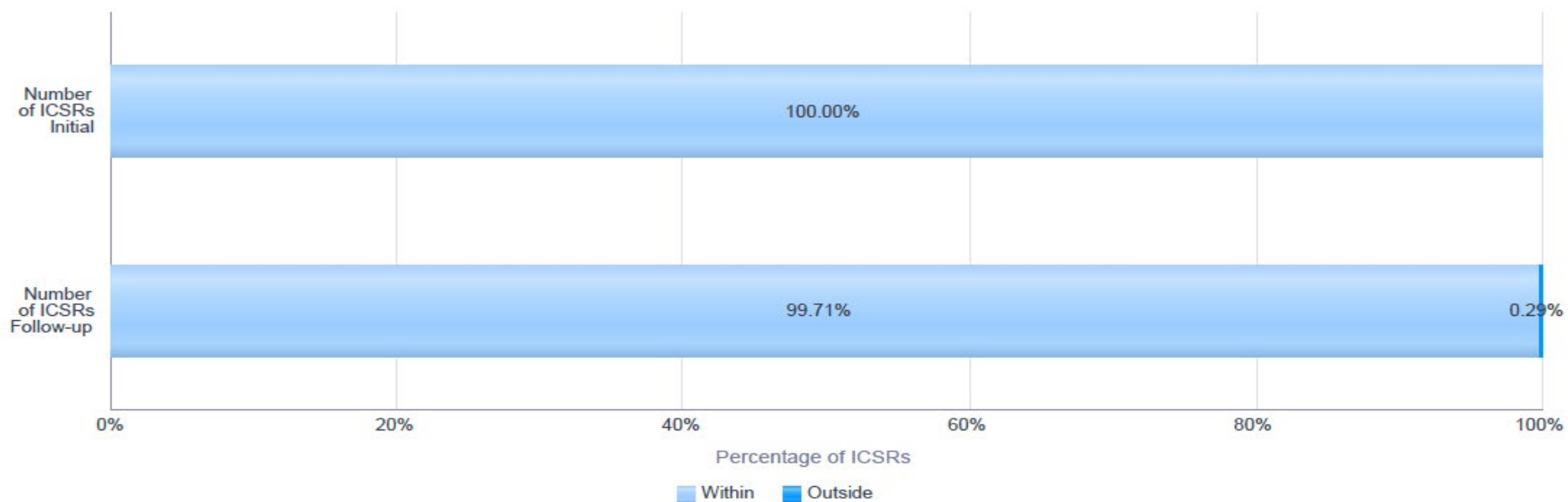
Organisation Sender ID: MLMSERVICE
Organisation Name: EMA MLMSERVICE

**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**



Example: MLM Service

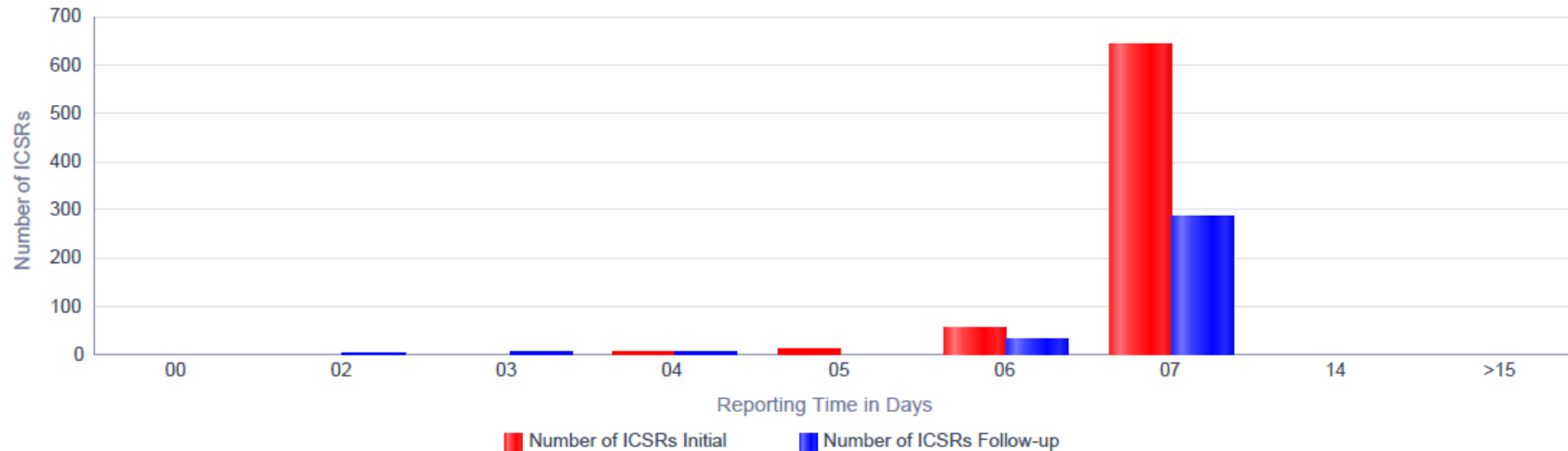
Organisation Sender ID: MLMSERVICE
Organisation Name: EMA MLMSERVICE

**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**



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

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".

The screenshot displays the EudraVigilance Gateway interface. The top navigation bar includes 'EV WEB', 'Create and send ICSRs', 'WEB Trader', 'ICSRs', 'Post', and 'MedDRA'. The 'ICSRs' tab is highlighted. Below the navigation bar, there is a search bar with 'Safety reports' and 'ICH/ICSR messages' selected. A red box highlights the 'ICSRs' tab and the 'ICH/ICSR messages' search filter. Below the search bar, there is a warning message: 'The ICSR search section gives access to all ICSRs (both EEA and Non-EEA) at either level 1 (public), level 2A (if the ICSR is associated with your XEVMPD data) or level 3 (if your organisation sent the case). You should NOT use this section to routinely retrieve cases to fulfil your pharmacovigilance obligations. To obtain cases with Level 2A access to fulfil your pharmacovigilance obligations you should use the section "ICSR Download".' Below the warning, there is a 'Criteria (0)' section with a '+ More criteria' button. Below the criteria section, there is a 'Fields (6)' section with a dropdown arrow. Below the fields section, there is a table with columns: 'Message Number', 'Message Date', 'Message Received Date', and 'Document Type'. The 'Message Received Date' column contains the value '2025/08/11 10:59:38', which is highlighted with a red box. Below the table, there is a 'Previous' and 'Next' button. At the bottom left, there is a '90 slido # 9116064' text.

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".

LLM
LARGE LANGUAGE MODELS



01 01 00
01 01 0

16 December

Is the next public system demo



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Thank you

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