EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Regulatory Procedure Management for PLM overview for Network stakeholders

Agile Value Stream:
Research & development
Product lifecycle management
Monitoring
Managing the Agency
Technology Lifecycle Management & Information Security

Housekeeping

*Please note that **this session is being recorded** and **will be made available** through **EMA Corporate Website and YouTube channel.***

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

*Interaction via Slido is voluntary, and you may opt to remain anonymous. If you chose to use Slido, **you consent to the processing of your personal data** as explained in the EMA Data Privacy Statement for Slido.*

Agenda

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1	**Welcome** 10:00 – 10:05	**Madalina Duta-Mare** *Regulatory Procedure Management for PLM Product Owner*
2	**Background** 10:05 – 10:15	**Madalina Duta-Mare** *Regulatory Procedure Management for PLM Product Owner*
3	**Access to IRIS & introduction to IRIS Basics** 10:15 – 10:25	**Simona Griniene** *Regulatory Procedure Management for PLM Subject Matter Expert*
4	**Case Management on Network Portal** 10:25 – 10:45	**Simona Griniene** *Regulatory Procedure Management for PLM Subject Matter Expert*
5	**Cases in IRIS for Committee Meetings** 10:45 – 10:55	**Simona Griniene** *Regulatory Procedure Management for PLM Subject Matter Expert*
6	**Q&A Session** 10:55 – 11:15	**Moderator: Caterina Scarpati** *RPM for PLM Change Management team*
7	**Working on documents related to IRIS procedures in SharePoint** 11:15 – 11:40	**Sara Santos** *Regulatory Procedure Management for PLM Subject Matter Expert*
8	**Q&A Session** 11:40 – 11:50	**Moderator: Caterina Scarpati** *RPM for PLM Change Management team*
9	**Next Steps** 11:50 – 11:55	**Simona Griniene** *Regulatory Procedure Management for PLM Subject Matter Expert*
10	**Closing** 11:55 – 12:00	**Simona Griniene** *Regulatory Procedure Management for PLM Subject Matter Expert*

Send your questions via Slido

1. Join via the QR code or link

2. Send or upvote the questions you want to hear answered

3. Questions will be shown on the screen and managed live in the Q&A session

Background

EMA's approach to transferring procedures to IRIS

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Stage 1 *(2018-2021)*

- Learning to use IRIS (Microsoft dynamics)
- Transfer relatively standalone procedures

Stage 2 *(2022-2025)*

- Move post-authorisation procedures to IRIS in a controlled manner to have a system ready for new fee regulation in 2025

*Variations, Art 61.3, Transfers, PSURs, PAMs, Line extensions, Renewals, Annual Reassessments, PASS, Referrals**

Stage 3 *(2025 onwards)*

- Move Initial MA procedure to IRIS
- Integrate necessary changes: build improvements, create new opportunities for efficiency
- Integrate regulation & improve

A controlled transition

Procedures will be developed and transitioned in phases in a lean and simple way and in the shortest possible time. This will:

- Enable a gradual **learning curve** & **evolve with users' feedback**
- Enable **incremental migration of procedural data** starting from products with lower regulatory complexity
- Allow to **meet new fee regulation implementation** deadline (Jan 2025)

*note: Development started with the lifecycle procedures to enable processing of high number submissions such as variations

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Regulatory Procedure Management for PLM Timeline (December 2023)

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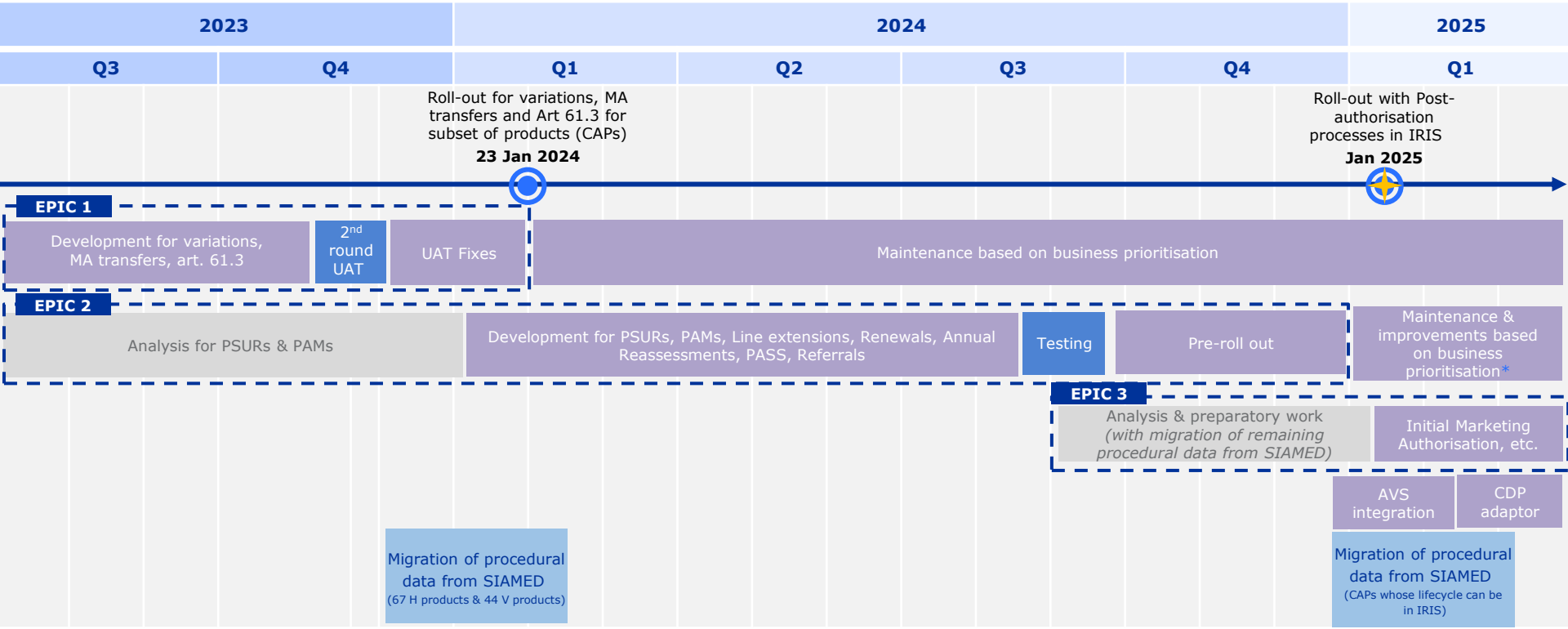


Acronyms

AVS: Assisted Validation System

CAPs: Centrally Authorised Products

CDP: Clinical Data Publication adaptor

CEs: Change Enablers

MA: Marketing Authorisation

PAMs: Post-Authorisation Measures

PASS: post-authorisation safety study

PSURs: Periodic Safety Update Reports

SMEs: Subject Matter Experts

UAT: User Acceptance Testing

Legend

Milestone

Development activities

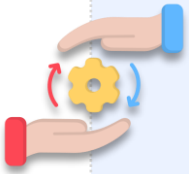
Migration activities

UAT activities

Analysis & preparatory activities

New Fee Regulation

Focus on 1st roll-out & next steps



- **1st roll-out** of variations, art. 61.3 notifications, Marketing Authorisation Transfers on IRIS will take place on **23 January 2024**
- For the first transition to IRIS, EMA has selected a **subset of medicinal products**: ***67 human generic products*** *out of 150 (unlimited MA generics) and* ***44 veterinary products***
- This will impact you, as the Network users **need to access IRIS** to contribute to the procedures and procedural documents

Next Steps:

- After 1st roll-out, **additional functionalities** will be incrementally released.
- By January 2025, **all post-authorisation processes will be managed on IRIS**.

What is changing for Network users after 1st roll-out (1/3)

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Procedure number

While the current format contains detailed information within the procedure numbers, IRIS offers this **visibility through dashboards and views** within the system.

The format is {agency ID}/{process group type (case form)}/{unique case number (10digits)}

The system has been designed to make relevant information easy to find and complies with IRIS model already in place for years for other regulatory procedures.

***E.g.,** it will be possible to search for procedures by product name, status, etc. allowing you to locate all related procedures easily.*

Examples of new procedure numbers:

- **Variation:** EMA/**VR**/0000076556
- **MA transfer:** EMA/**T**/0000076539
- **Art.61.3 notifications:** EMA/**N**/0000076579
- **Veterinary variations requiring assessment:** EMA/**VRA**/0000076550

What is changing for Network users after 1st roll-out (2/3)

EMA's communication format

EMA will send a **notification email** to the Rapporteurs and Committee eudranet mailbox with a **link to IRIS SharePoint** location where templates and other procedural documents can be accessed by all Network users.

The notifications and emails will contain the procedure number, type, product name and stage of the procedure for easier identification.

Please note confidential or procedural information will be accessed through SharePoint and not attached via email.

No documents to be sent as an attachments

No use of generic emails within NCAs– automatic forwarding can be set up as per individual NCA's needs

Important to use the same subject for your reply in order to ensure correct routing

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Example of the notification email to Rapporteur

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Kriptazen (EMEA/V/C/004868) - VRA-I (EMA/VRA/0000077807) - Assessment report IRIS:01556000064 - Saved

Email · Email

21/11/2023 13:52 Due | Pending Send Status Reason | CI CRM Integration Owner

Email Related

Dear Rapporteurs,

Please be informed that the following procedure has received a positive validation by the EMA:

Procedure number: EMA/VRA/0000077807
Procedure type: VRA-I
Product(s): Kriptazen

Further details on the case including the timetable can be found in the IRIS Network Portal.

The template for the assessment report and the product information can be found in the evaluation subfolder of the case folder.

Case Folder

The deadlines for the procedure are available in the case dashboard on the IRIS Network portal.

We will share this initial version of the report with the Applicant; therefore, we would be grateful if you could take care not to include any commercially confidential information (e. g. on competitor products) in the assessment.

Upon completion, please notify all CVMP members via LIST-V-CVE@EUDRA.ORG, and if nationally authorised products involved, concerned Member States via LIST-V-MRVE@EUDRA.ORG. *Please use the same subject for your reply in order to ensure correct routing.*

Kind regards,

European Medicines Agency

Automated message sent by the IRIS system

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What is changing for Network users after 1st roll-out (3/3)

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Working on documents in IRIS SharePoint

EMA generates the templates and saves them in the **SharePoint folder** related to the case.

Rapporteurs **access the templates**, and the team works on it simultaneously (up to 50 users at the same time).

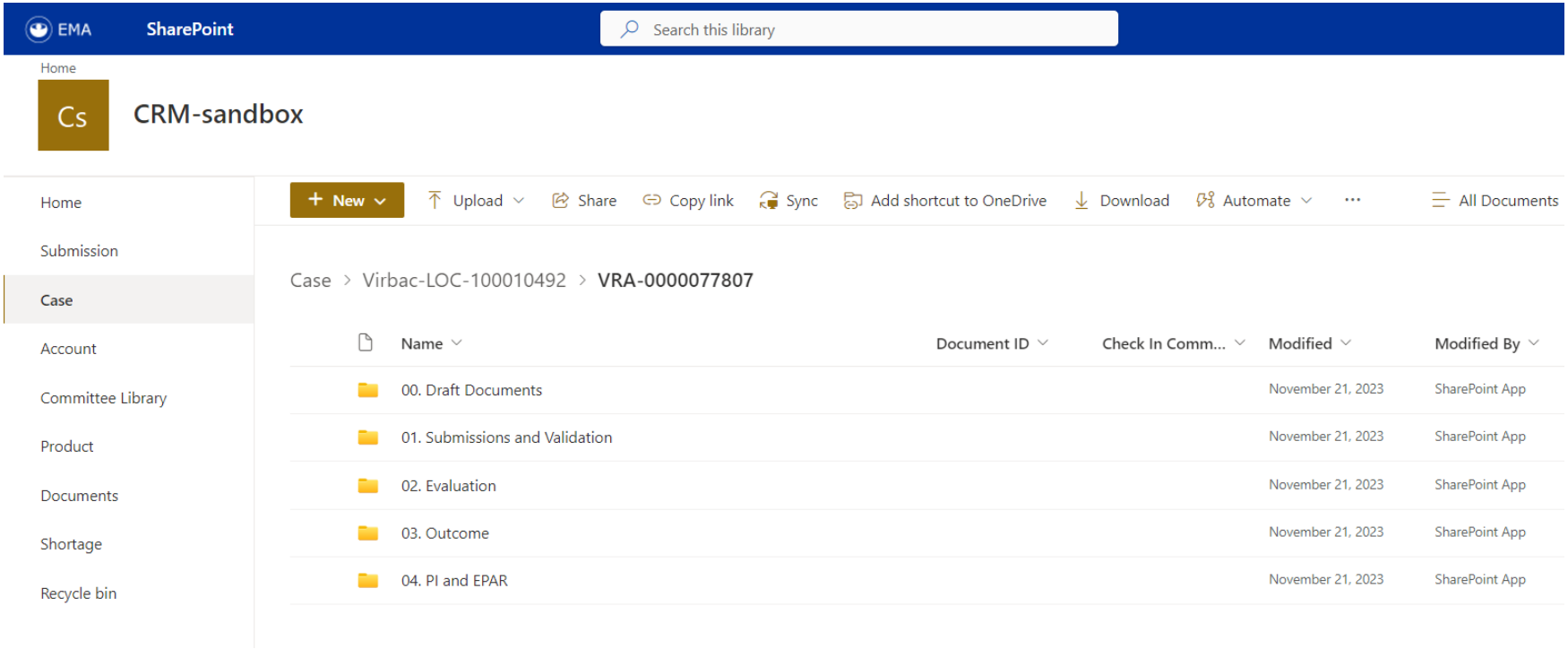
Committee members provide **comments directly in the document in SharePoint** or upload the **separate comments document** in the subfolder for Rapporteurs consideration.

Committee meetings

Committee members **upload their presentations or any other additional documents** for Committee meetings directly in the case subfolder in the SharePoint.

All procedural documents to be discussed and adopted at the meeting to be accessed via IRIS portal. No documents to be duplicated in MMD.

Example of the folders in SharePoint related to the case



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What stays the same for Network users after 1st roll-out

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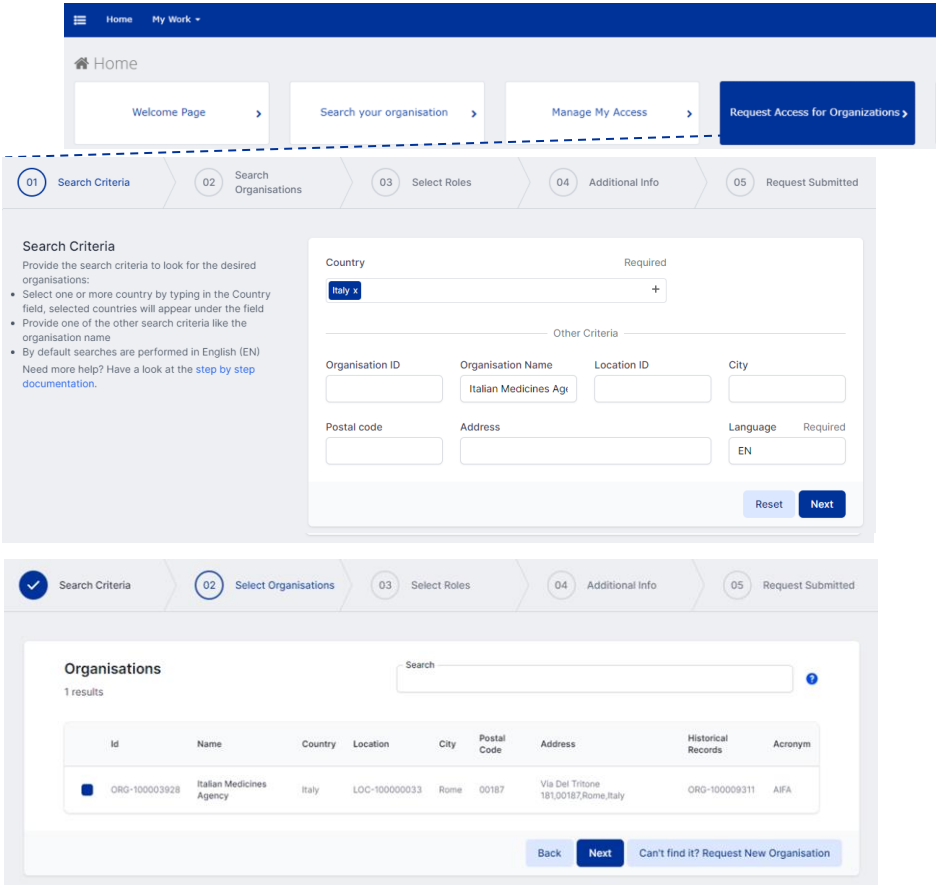
What stays the same

- **Timelines** for the active notifications
- **Procedures managed in IRIS will be added to the current committee Agenda and Minutes for completeness and publication**
- **Content** of the documentation
- **Guarantee of confidentiality**
- **MAH's submission and responses to RsI via ECTD/VNeeS submissions**

Access to IRIS

Request Access (1/2)

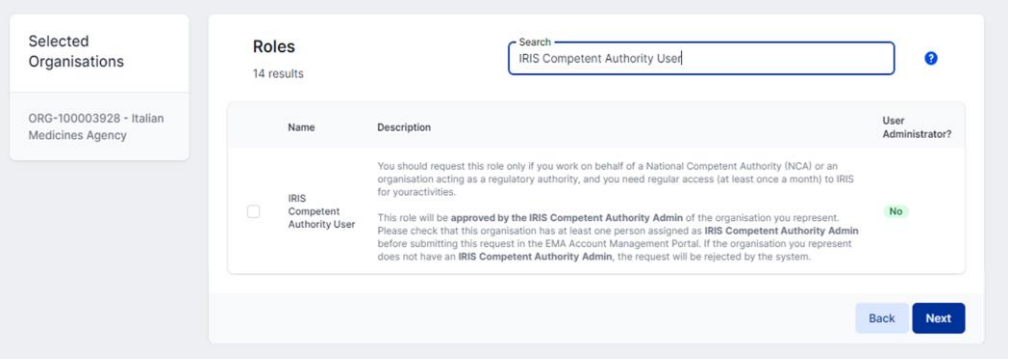


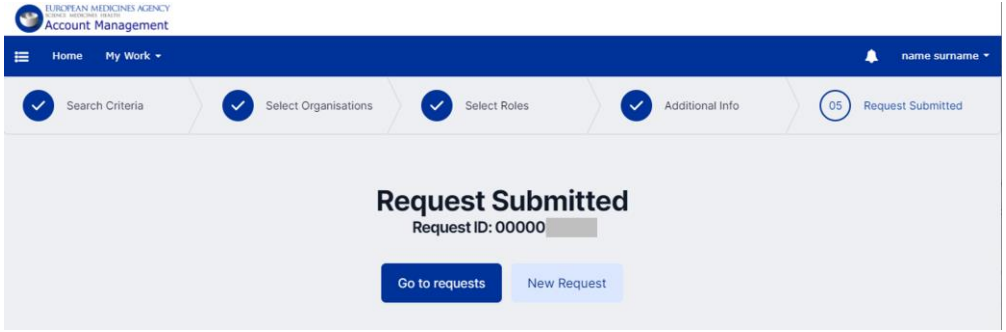
Request Access

1. Go to https://register.ema.europa.eu
2. Select **Single sign on** or create an account (to create an account, follow the information on this page)
3. Click on "Request Access for Organisations" and **look for** the NCA Organisation ID.
4. **Select** one of the records representing the **Organisation.**

! *The system displays all available locations, but access is granted at Organisation level.*

Request Access (2/2)





Request Access

5. Search and **select** the **roles** *(see figure)*:
   - IRIS Competent Authority user
- *Multiple roles can be selected at the same time.*

! *Competent authorities roles are only available for specific email domain addresses (e.g. aifa.gov.it and ext. aifa.gov.it) and they will not be displayed if the user is registered with a different email address.*

✓ Submit the request

Available user roles

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Activities	IRIS Competent Authority User Admin	IRIS Competent Authority User
Approve IRIS Competent Authority users in EMA Account Management Portal (Note: no access to IRIS portal)	V	
Access to the IRIS Network Portal to search open and ongoing cases and access related information.		V
Access to procedures documents in SharePoint Online		V
Notes:	First user admin is assigned by the EMA after communication with the Competent Authority	Roles assigned by the EMA for Committee Members
	Further user admins are approved by appointed user admins to the organisation	Roles approved by each Competent Authority user admin for users not member of Committees

SharePoint access roles - EMA users vs. Network users

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	EMA IRIS user (CRM users)	EMA Regulatory user (Network Portal)	Network Portal User (EU, CXMP, NCA Assessors, EC)
Create / upload files and folders	+	+	+
Edit files	+	+	+
SharePoint search and advanced search	+	+	+
Delete, move or rename files and folders	+	+	-
See “private” EMA folders	+	+	-

Introduction to IRIS Basics

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IRIS | Regulatory & Scientific Information Management Platform

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IRIS

All IRIS components are installed in the cloud (Microsoft servers in the EU)

IRIS **Portal**	**Public area** (no credentials)	• Public registers and lists • Guidance for applicants • Forums (credentials needed to post)
	Industry Portal (Industry credentials)	• Online web form replaces PDF Application form • View of submitted applications
	Network Portal (Network user credentials)	• Accessed by EMA staff and regulatory Network • Network users can look for cases, products, CXMP "agendas"
Dynamics 365 database (CRM)	Accessed by EMA staff	• Customer and Product Data • Case Management • Interactions with Customers
Document Repository (SharePoint CRM site)	Accessed by EMA staff and regulatory Network	• One secure platform for document sharing and viewing, editing, archiving files • Similar to EDMS/Dream

User requirements for IRIS

IRIS can be accessed on **any modern Web Browser**, including *but not limited to:*

- Google Chrome (latest version);
- Internet Explorer 11 and above;
- Edge (including the new, Chromium-based Edge);
- Safari 12 and above;
- Firefox (latest version);
- Vivaldi.

IRIS components: User Interfaces (UI) (1/2)

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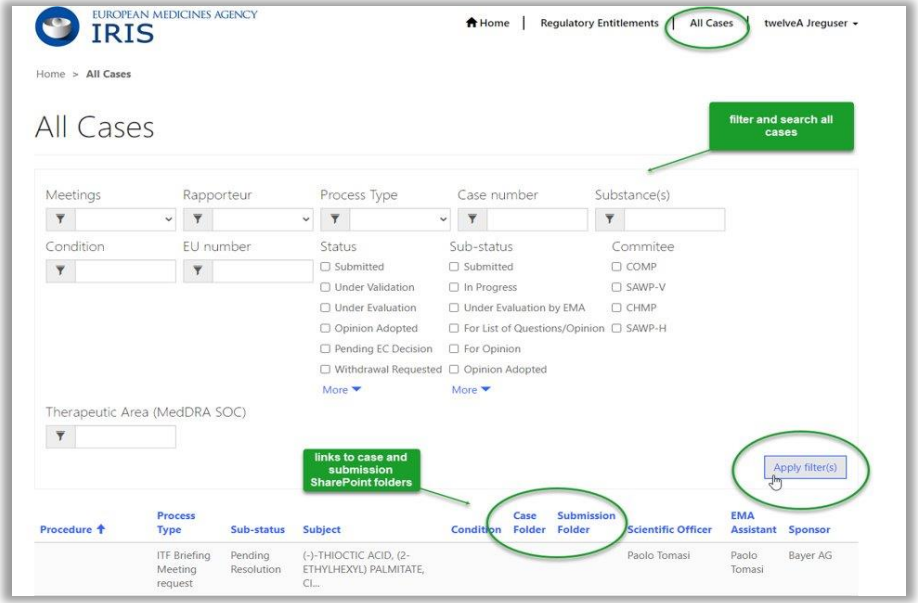
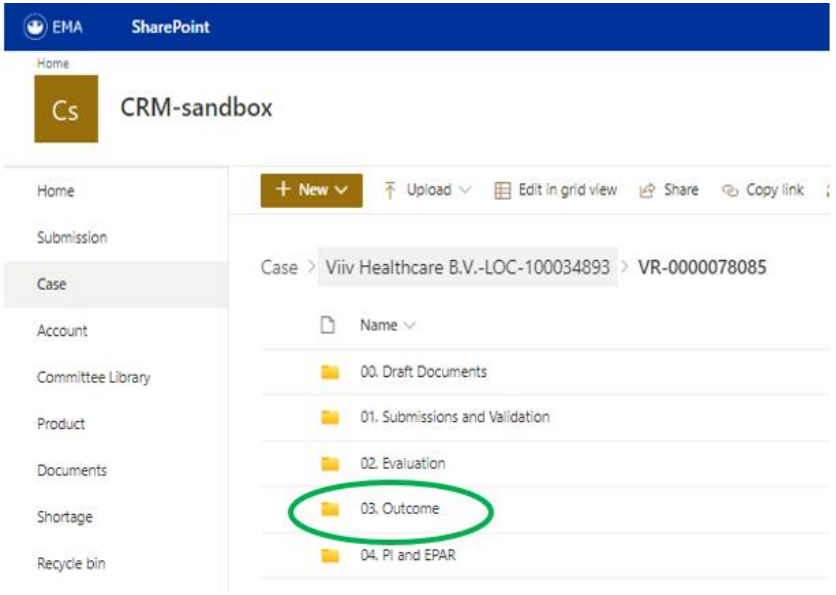
Network Portal



Case folder in SharePoint



- Filter by **"Pending EC decision"** - PLM procedures with immediate and pending EC decision
- Visible by Network Users and EMA staff (*requires login*)

IRIS components: User Interfaces (UI) (2/2)

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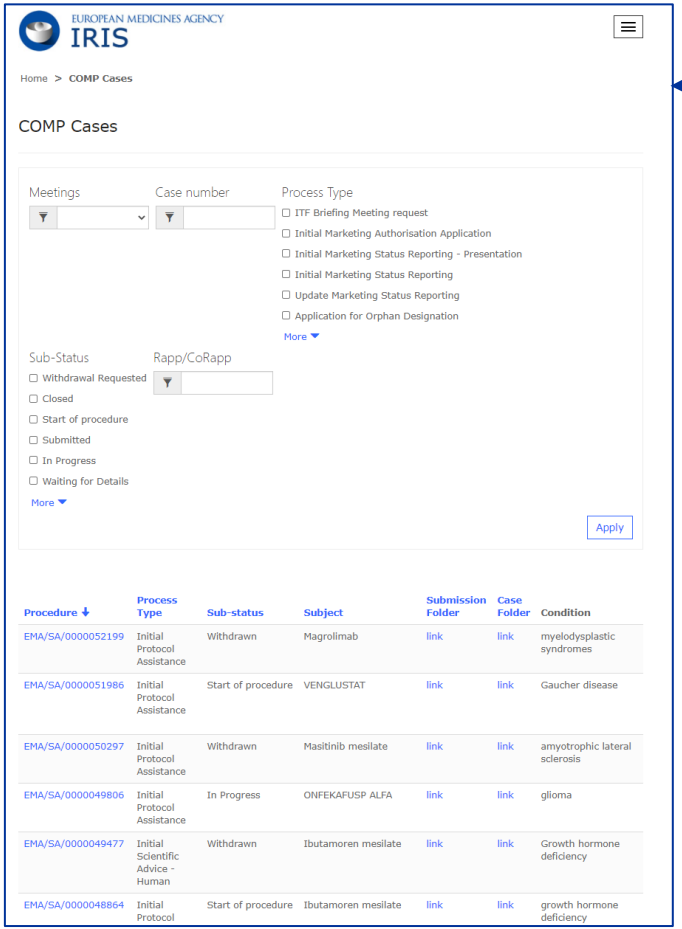
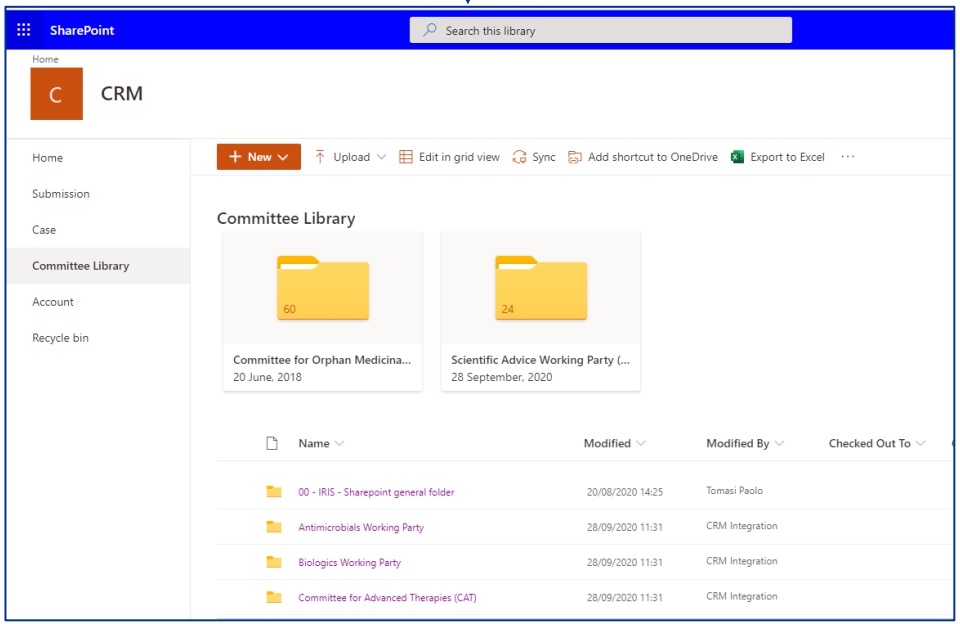


Network portal (Agenda! list of cases with direct link to related documents in SharePoint)

SharePoint (documents not related to the cases)



IRIS Basics: How to log in into the platform

How to access the IRIS Portal for the first time

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Step 1 Type "iris.ema.europa.eu" in your browser and add it as a favourite

Step 2 Click on either "Sign In" (Fig. 1)

Step 3 Click on "EMA Account" (Fig. 2)

Step 4

- **External users:** Enter **username** and password
  - ✓ follow instructions to setup MFA (MultiFactor Authentication)
  - ✓ it is suggested to download the Microsoft Authenticator app on your phone, for MFA (also works if there is only WiFi, unlike SMS)

Figure 1

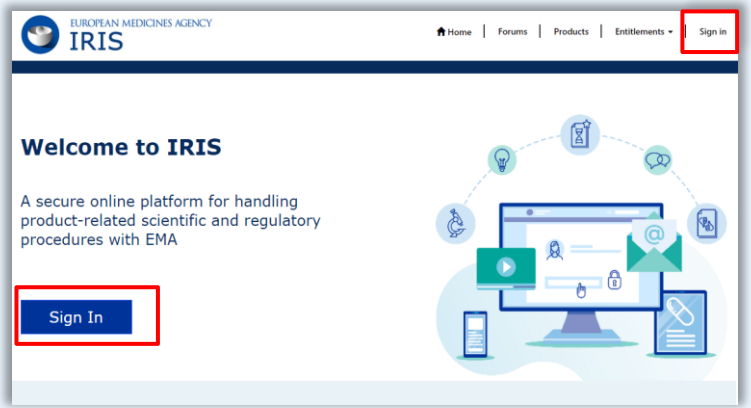
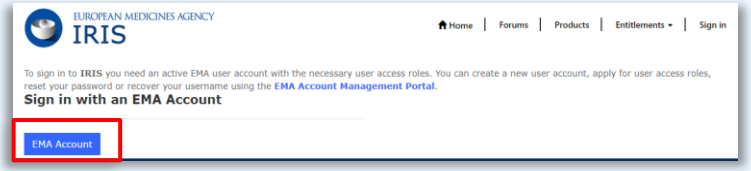


Figure 2



Set up Multi Factor Authentication (MFA)

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- First time you log in you are asked to set up your **Multi Factor Authentication**.
- We advise to use a **mobile authenticator application** as more secure method.
- In addition to MFA, we use also the **authentication context** (i.e. the device and the location from where you are authenticating) and **behaviour** (i.e. the time of the day or the frequency of your authentication) to determine risk factors.
- You can review your **MFA settings** here and you can check your recent sign-ins here
- **Further guidance** are available here

Something you **know**

- A password
- A pin

NOTE: a code on email falls in "Something you know" as to access an email you are probably using a password

Something you **are**

- Your fingerprint
- Your face
- Your eye
- Your voice

Something you **have**

- A mobile phone
- An office phone
- A security Key
- A code generator

Demonstration

- Case Management on Network Portal
- Cases in IRIS for Committee meetings
- My ongoing cases
- Favourite cases

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Live Demonstration

- Case Management on Network Portal
- Cases in IRIS for Committee meetings
- My ongoing cases
- Favourite cases

Q&A Session

IRIS SharePoint

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Principles

Note on IRIS principles of collaborative working on documents in SharePoint

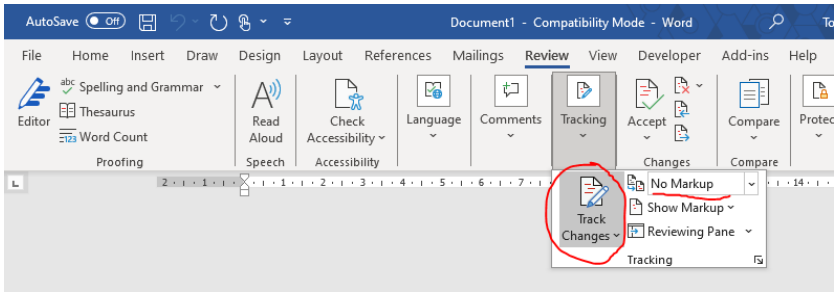
IRIS has been built to implement **online, parallel, collaborative working**. Improvement over the previous sequential, offline, compartmentalised way of working.

Documents in the IRIS system (SharePoint) should be **edited online**, and **never downloaded and re-uploaded**.

Bulk downloading of documents from multiple folders at the same time is not recommended in IRIS, as it creates a **security risk**.

It is however possible (for now…) to download a single document or folder, for **offline reading**.

Important* Word document: "**Track changes**" activated, possibly with "**No Markup**" (*AR, EPAR, Opinion)



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Principles - SharePoint vs Dream/MMD

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Dream	SharePoint
Need to **table documents to MMD** to make them visible to CXMP members/Network users	**No need to table anything in MMD**. Documents immediately visible to CXMP members. **No need to table documents or links to Meeting folders!**
CXMP members/Network users **cannot edit** MMD (or Dream) documents	Network users can edit SharePoint documents, upload new documents to any folder, create folders
Only one person can edit a Dream file at a time	Up to 50 users (EMA/CXMP) can work on the same document at the same time, on different paragraphs/cells
Need to **check out** a file to edit it	**No need** to check-out a file to edit it. Check-out and check-in still possible but rarely necessary
Links to a document can be created in other folders	Links to a document can be created in other folders
• "Subscription" to files (list of favorites) • "Change notification" (via email)	• "**Favorites**" in Microsoft 365 • "**Alerts**" are possible, with more choices and granularity (e.g. entire folders, daily emails, etc.)
No native automated flows (robotisation of processes)	Automatic flows (e.g. for sign-off or for "publishing" for the applicant)

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Making documents available to CXMP

- What needs to be done, to make documents available to CXMP members/alternates, for each committee? (Hint: nothing)
- All documents, for all meetings, for all committees (in IRIS) are always visible and editable in the Network portal.
- Links to case and submission folders allow quick access to the document(s) needed
- Note that **CXMP members (and NCA Assessors) can edit all the documents in SharePoint for IRIS**!
- **No MMD, no tabling, no Eudralink attachments, no sending of documents, no agenda entries for procedures (not yet developed).**

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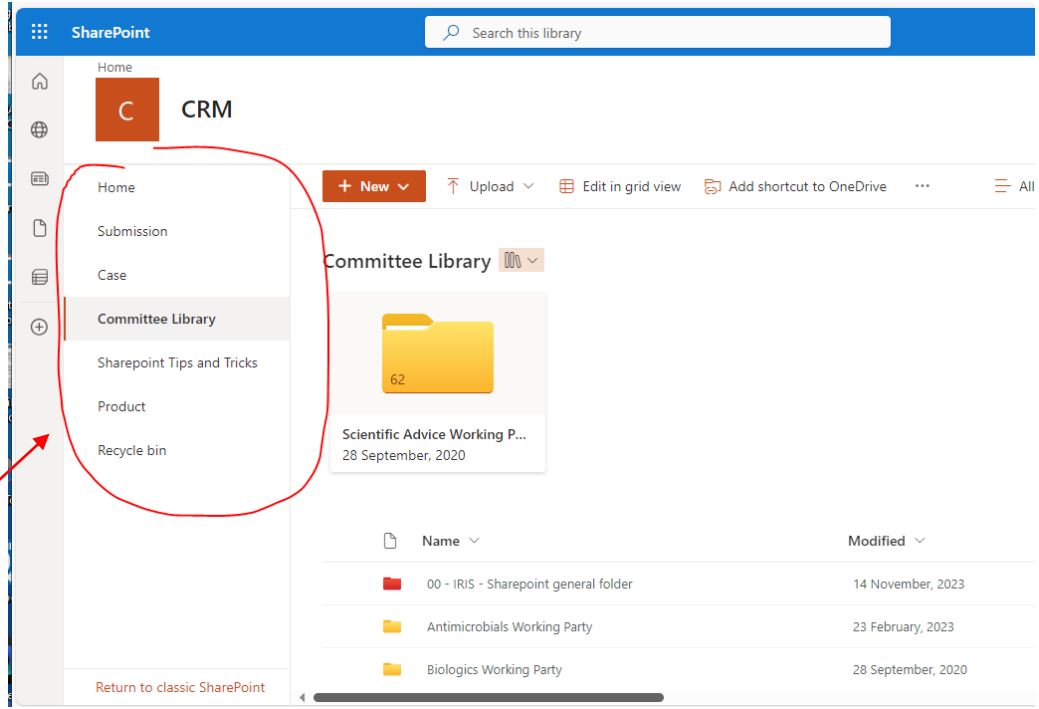
Site and Library structure

- Similar to MMD
- Site → Library → Folders → subfolders
- Multiple levels of subfolder NOT recommended
- Powerful search function
- For documents without cases in IRIS (e.g. guides, lists)



IRIS (CRM) site libraries

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Where are the files?

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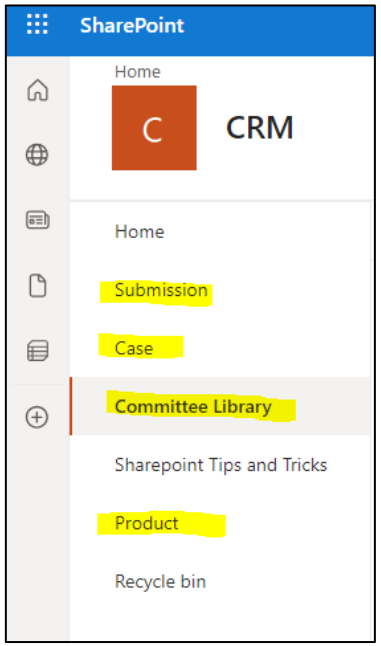
4 Libraries:



- **Submission library**: contains folders with the documents submitted by the applicant (*except for variations / MAA / MA transfers, where they remain in the Repository/EURS)*, and the documents shared by EMA to applicants (instead of sent via Eudralink) for all procedures.
- **Case Library**: contains the folders with the working documents generated by EMA or Network for individual cases (procedures): assessment reports, joint report, EPAR, Opinions, presentations, etc.
- **Committee Library**: contains folders for each meeting of each Committee and General folder (automatically created by IRIS – NEVER create folders for new meetings or committees manually!) for docs NOT related to a case or a product, or for links. E.g.: time-schedules, agendas, presentations, guides etc.
- **Product Library**: contains a folder for each RPI and each Authorisation Product. Can contain documents that apply to a product rather than a specific case, e.g. Early Background Summary (in the folder for the RPI).

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The Committee Library (and meetings)

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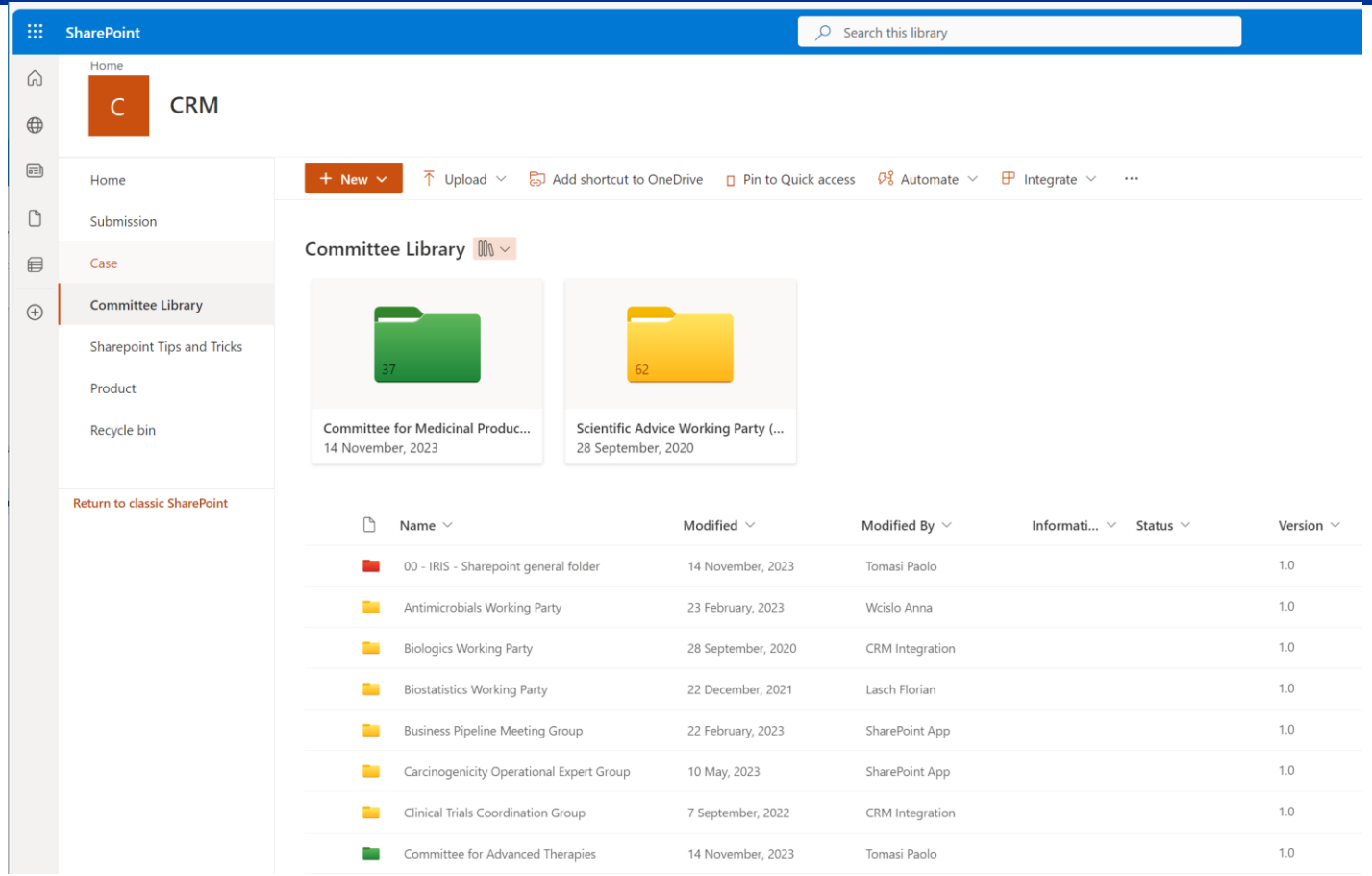

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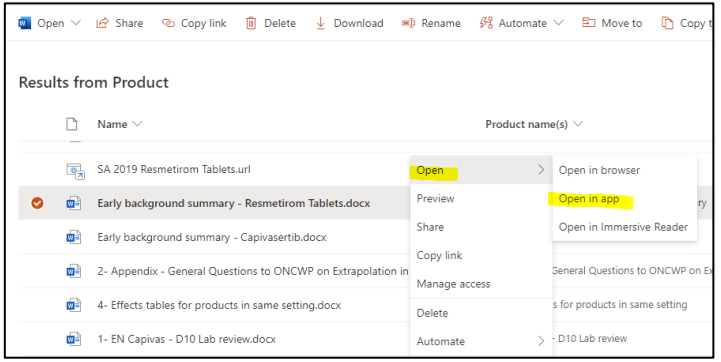
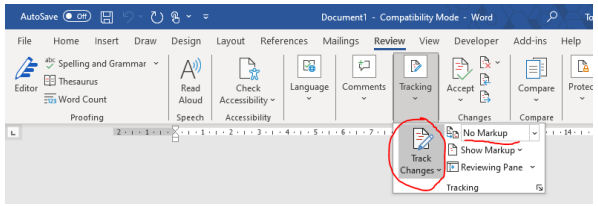
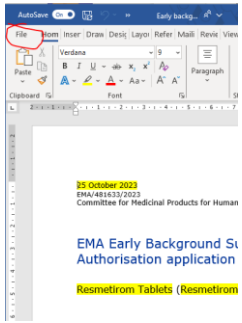
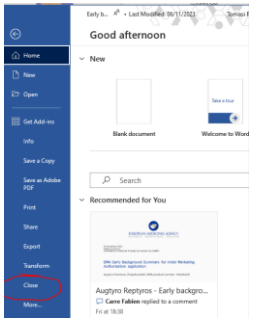
Editing documents in browser vs. "App"

- Editing files: when you need to edit a document, you are advised to **open it in the "Desktop App"** (new name of Word/Powerpoint/Excel desktop software), by right-clicking on the document and choosing "Open in App";
- Always make sure that **"track changes" are enabled** in all important documents (and "no markup" if many changes)
- To close a document in the app, **use the File/Close menu** in the Desktop App, or returning to the folder, rather than closing the Desktop App with the "X" at the top right. This also speeds up loading the next file.









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Collaborative working, versions

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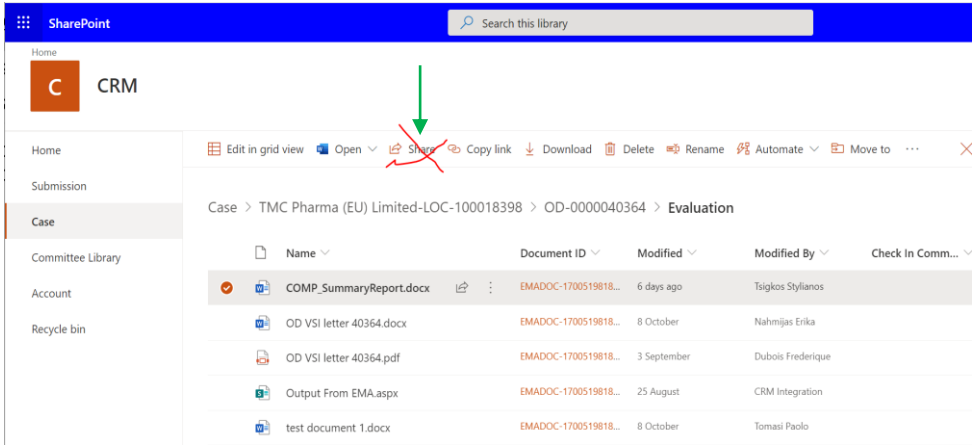
- When a user opens any document, in the browser or in the app, this gets a **partial lock** for a while. Other users can still edit, but the document cannot be deleted or renamed or overwritten with a new version. (also in case of check-out)
- **Check-out and check-in** still possible (for Office files only), but rarely necessary. Useful to add check-in labels.
- **Notes on Versions**:
- New version every time a single user opens a document in edit mode. Even if no modifications are done to the document



- ✓ When <u>multiple users co-author</u>, separate versions are NOT created for each user (activate "track changes"!).
- ✓ It is possible to <u>restore</u> an old version as the current version. This does not delete any version.
- ✓ It is possible to <u>delete a version</u> entirely (this should almost never be necessary)

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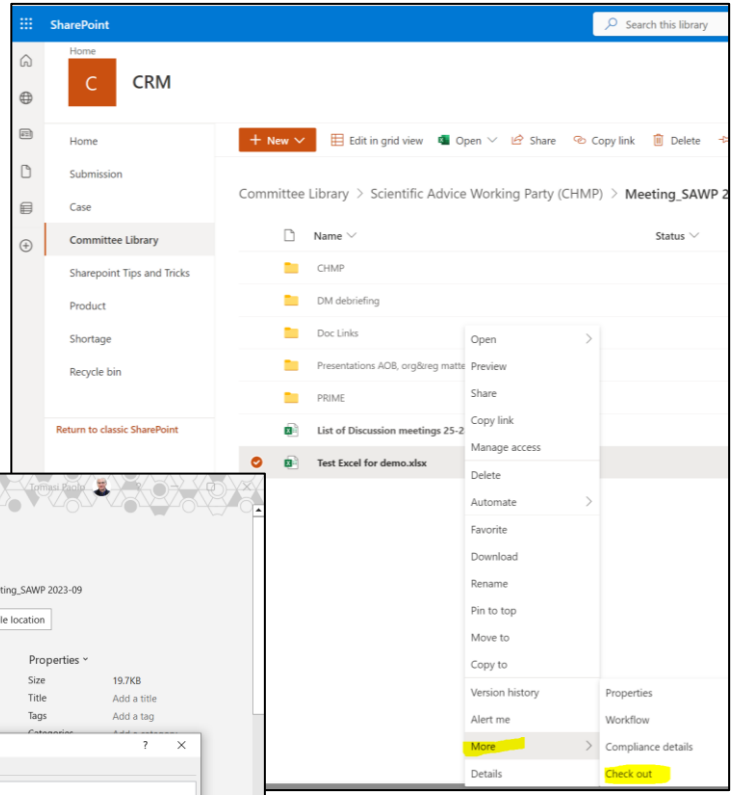
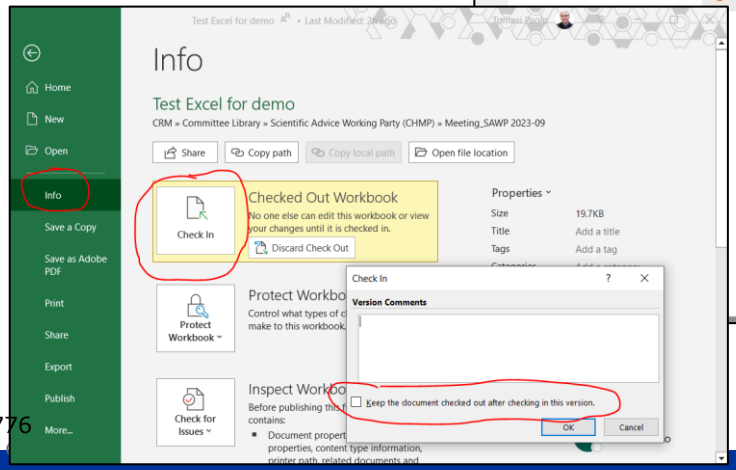
Checking out a document

- Right click on document, click on “More” and then “check out”.
- Once checked out, only owner can edit the document or check it back in.
- If modifications are made, need to check in and immediately check out to make them visible, but keep doc checked out (done easily **if editing in the app**: File/Info/Check in).
- File is visible to all, without a password.





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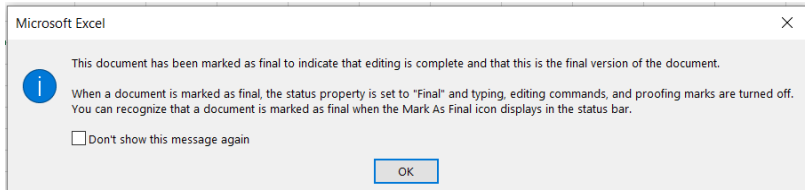
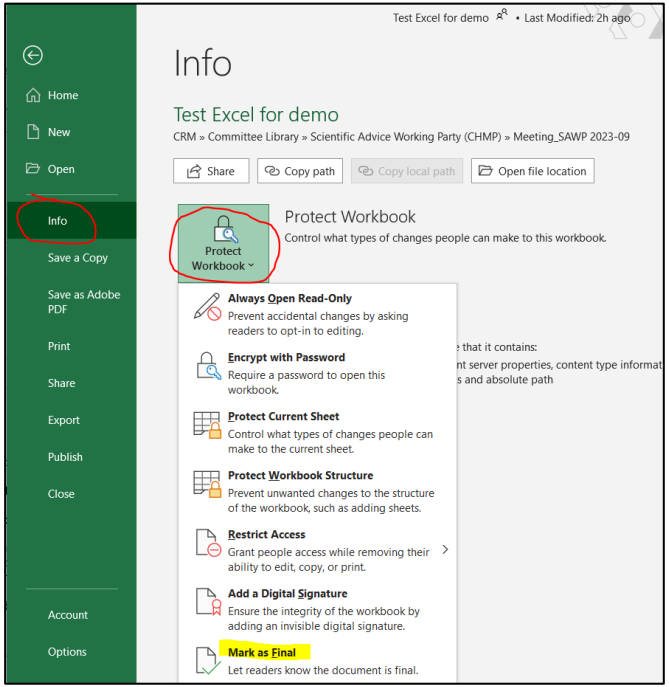
Mark document as final

- File/ Info/ Protect Workbook/ Mark as Final
- Very similar to “Always Open Read-Only”: will also open document by default in read-only mode
- Any user can override this and also open for edit (and make any change)
- Weak protection (mainly advice), but additional discouragement: doc is marked as “final”
- Can be associated with other protections (always the case)
- Do not confuse with "retention label" (declare as a record)





Alert me (“Turn on Change notification” in Dream)“Alert me”)

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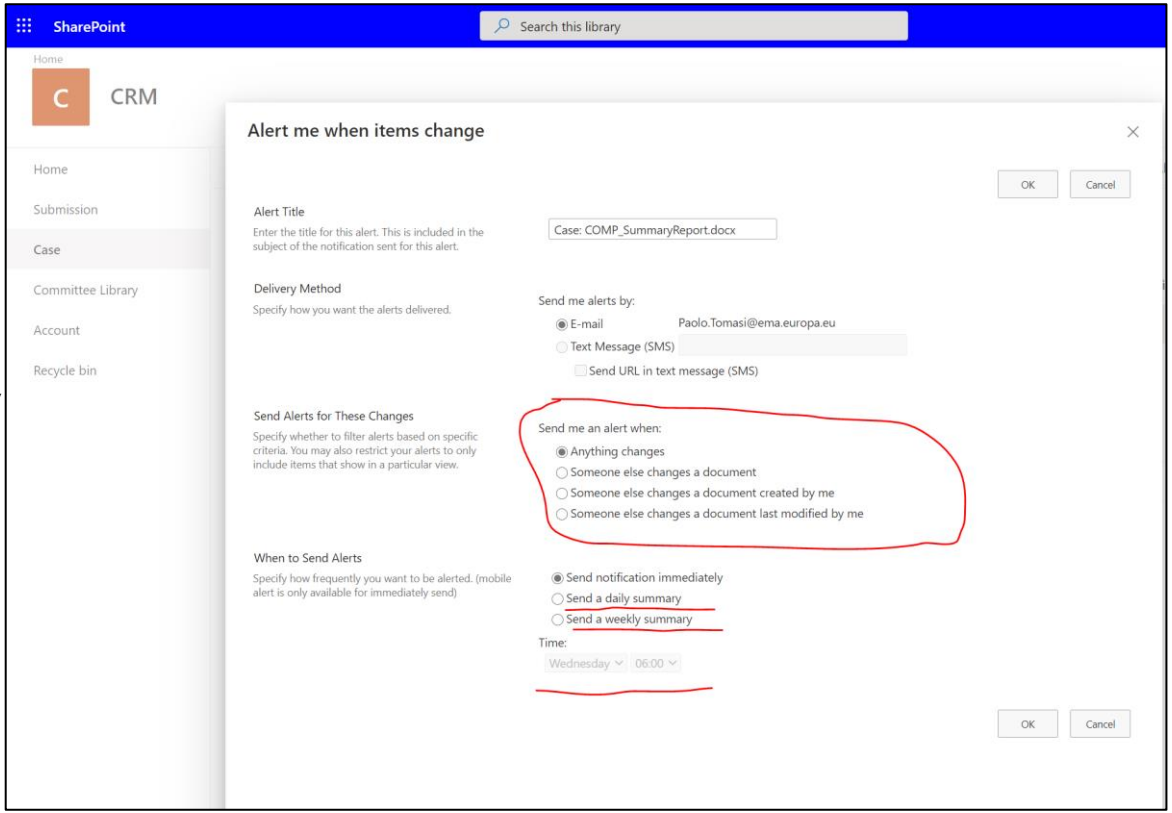
- Similar to Dream function “**Turn on Change notification**”
- Select a file **or folder**, right click, choose “alert me”
- Choose the triggers for the alert
- Choice of email timing (immediate, daily, weekly)
- See and modify all your alerts in one place: [My Alerts on this Site (sharepoint.com)]



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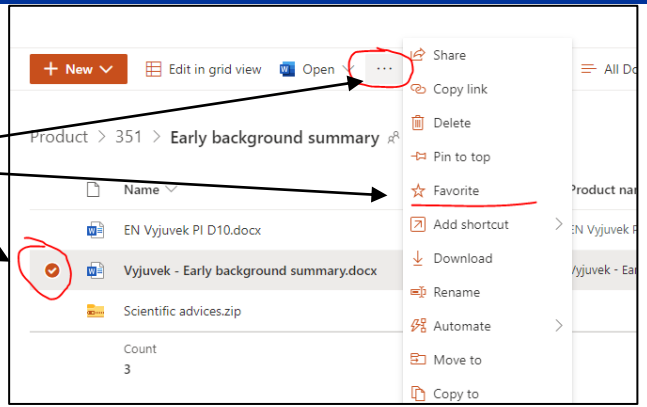
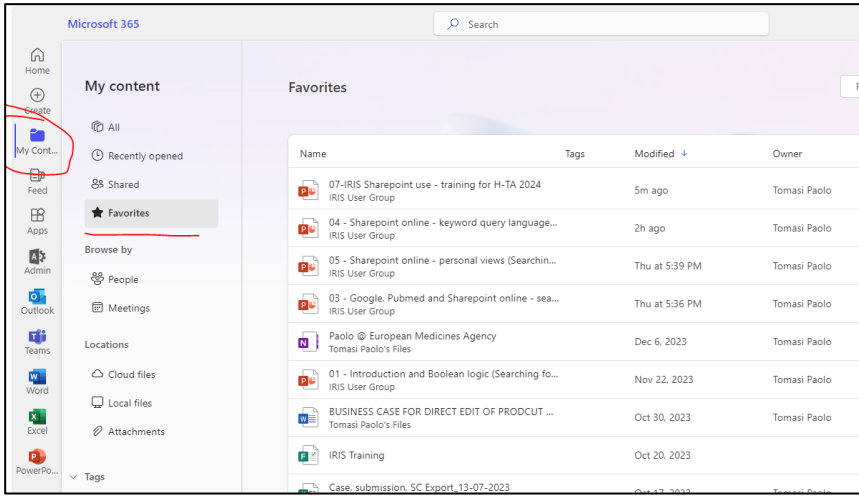
Favourites

- Right-click and select “favorite”, or select a file in a folder, then click on “favorite”: done!
- Your favourites are visible in My content, in Microsoft 365.
- You can further filter your favourites by file type, etc.
- See all “favorite” files in the tab
- Microsoft 365 also shows you all recently opened files from **any SharePoint site**, including files from Teams and other SharePoint sites (different from the IRIS CRM site)





Things NOT to do in SharePoint

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- **Do not download files and work offline**: not necessary, not useful → duplication and confusion.
  Instead, always edit files in place (also applies to Network users!)
- **Do not delete files**: you don't have a personal wastebasket, and you cannot restore them after 30 days. Instead, rename them as "Obsolete - XXXX".
- **Do not check-out files**: not necessary for editing, and 5 or more people can work simultaneously on the document
  Check-out is however available for the rare cases when it is needed, e.g. time schedules. You can protect sections of documents, mind.
- **Do not use the 'Share' function** to share documents with non-EMA users. It will not work, and in the past it has generated malfunctions.
  Access rights are determined by the user role; to share a file, just send a link to the file (right click on the file name and select 'copy link'.)
- **Never create folders** for new Committees/WPs/OEGs or for new meetings.
  Never rename folders of existing Committees or meetings.
  These folders are automatically created by IRIS when a new committee or meeting is created in Dynamics 365, and must never be renamed

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Things NOT to do in SharePoint

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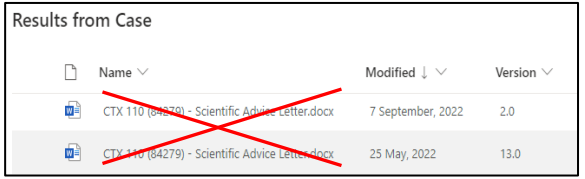
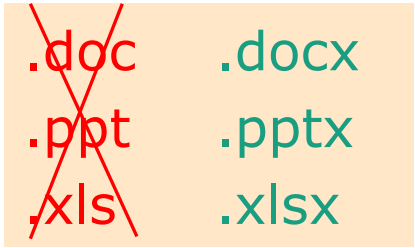
- **Do not create multiple files for the same document:** use versions of the same file, instead. To create a new version, just drag and drop a file with the exact same name and extension in the same folder of the old file.
  If duplicates are already present, rename them with an "Obsolete - " prefix.



- **Do not upload old format files** (".doc", ".ppt, often old templates) in SharePoint, to prevent duplication of documents.
  *Word/Excel/Powerpoint **online** can only manage new format files (e.g. ".**docx, .pptx**"), so they convert any old format file before editing, creating a duplicate copy of it in the new format.*



- **Do not create multiple levels of subfolders** e.g. in the General subfolder of a meeting. Not needed and confusing.

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Q&A Session

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Next Steps

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Next Steps

- **User guide & FAQ document publication** – 17 January 2024
- **Roll-out on IRIS** – 23 January 2024
- **Technical webinar** – Mid-February 2024
- **Public system demo** – 26 March 2024

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Guidance & Support

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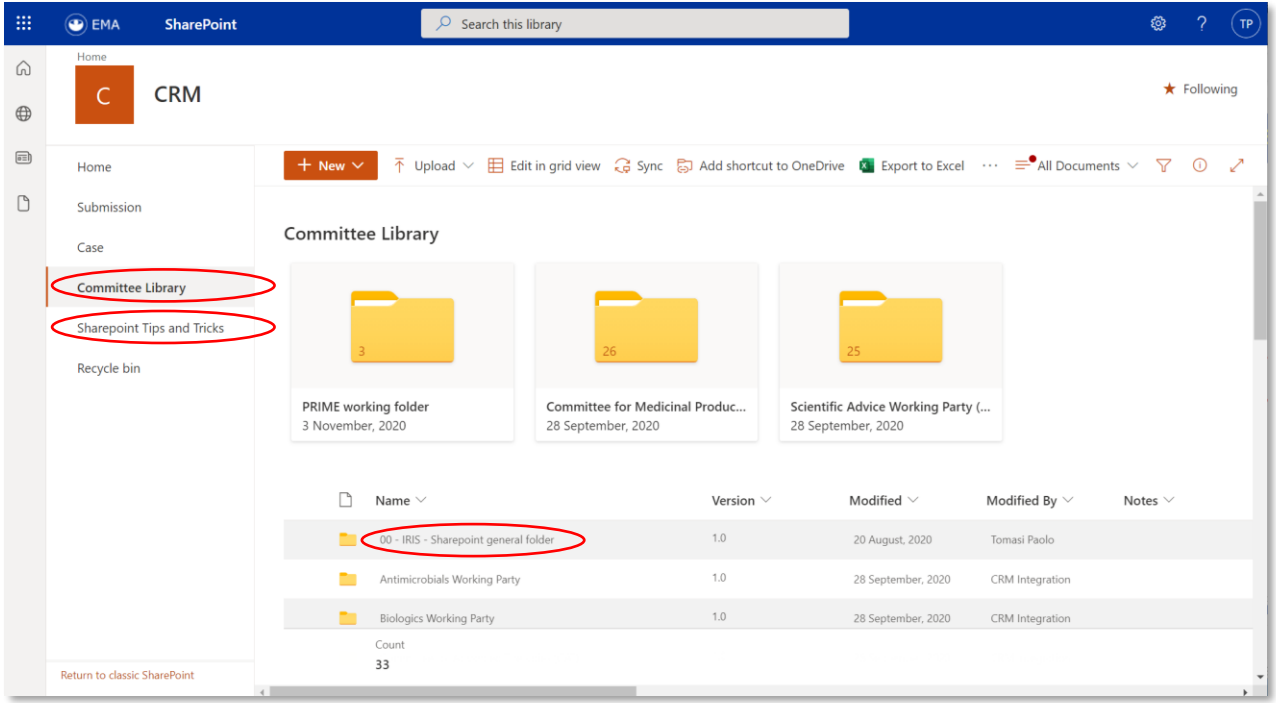
Read the guidance which is available on the SharePoint:

- ***SharePoint tips and tricks library***
- ***Committee Library, "00" folder*:**
  - IRIS guide for Network users
  - FAQ on RPM
  - IRIS quick guide for Committees & Working Parties
  - Training videos and presentations



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Support for IRIS users

Contact the EMA Service Desk (IRIS – Report an issue) for technical queries.
If you cannot access IRIS, please make sure to specify "EMA Account Management" in the ticket, rather than "IRIS".

Contact the IRIS team (iris@ema.europa.eu) with questions and/or comments

Product concept in IRIS

Back-up slides

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Simplified hierarchy (no AS, no medicinal product)

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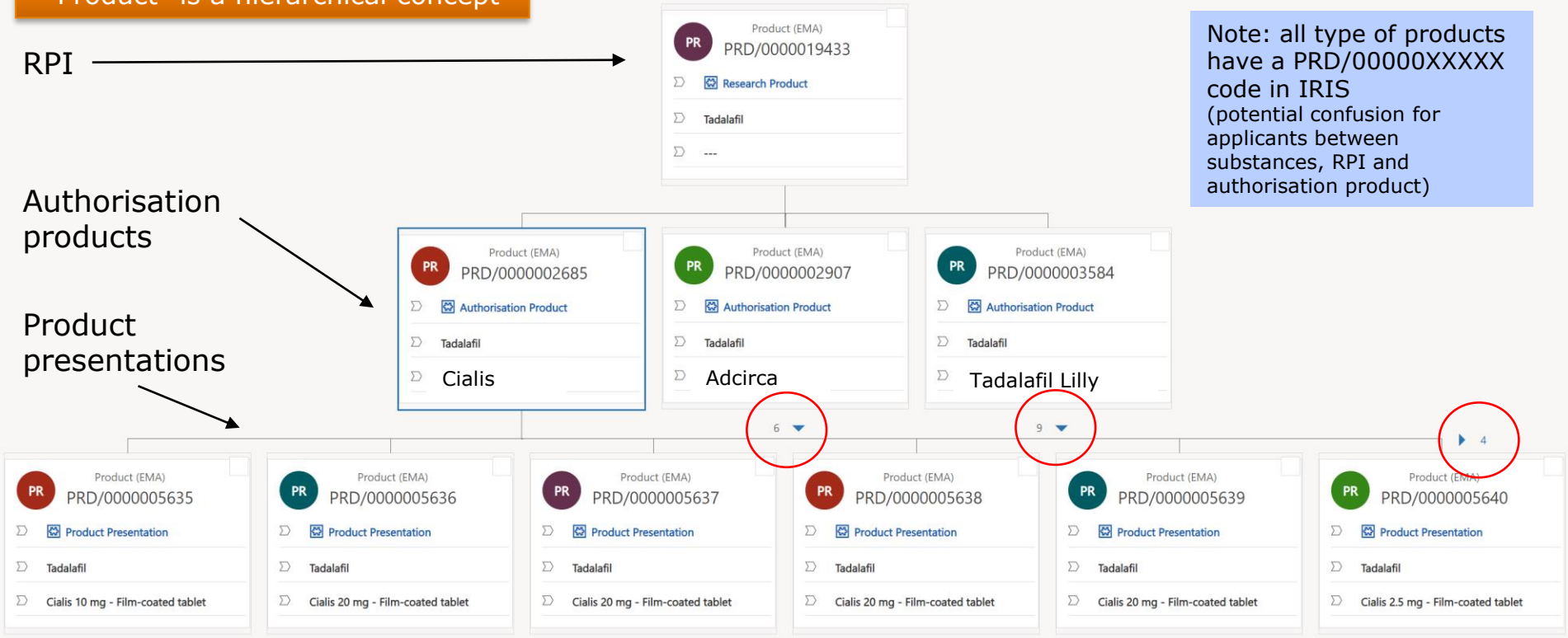
"Product" is a hierarchical concept

RPI

Authorisation products

Product presentations



Note: all type of products have a PRD/00000XXXXX code in IRIS
(potential confusion for applicants between substances, RPI and authorisation product)

10 presentation products for Cialis, 6 for Adcirca (4 surrendered), 9 for tadalafil Lilly

Complete substance and product model in IRIS

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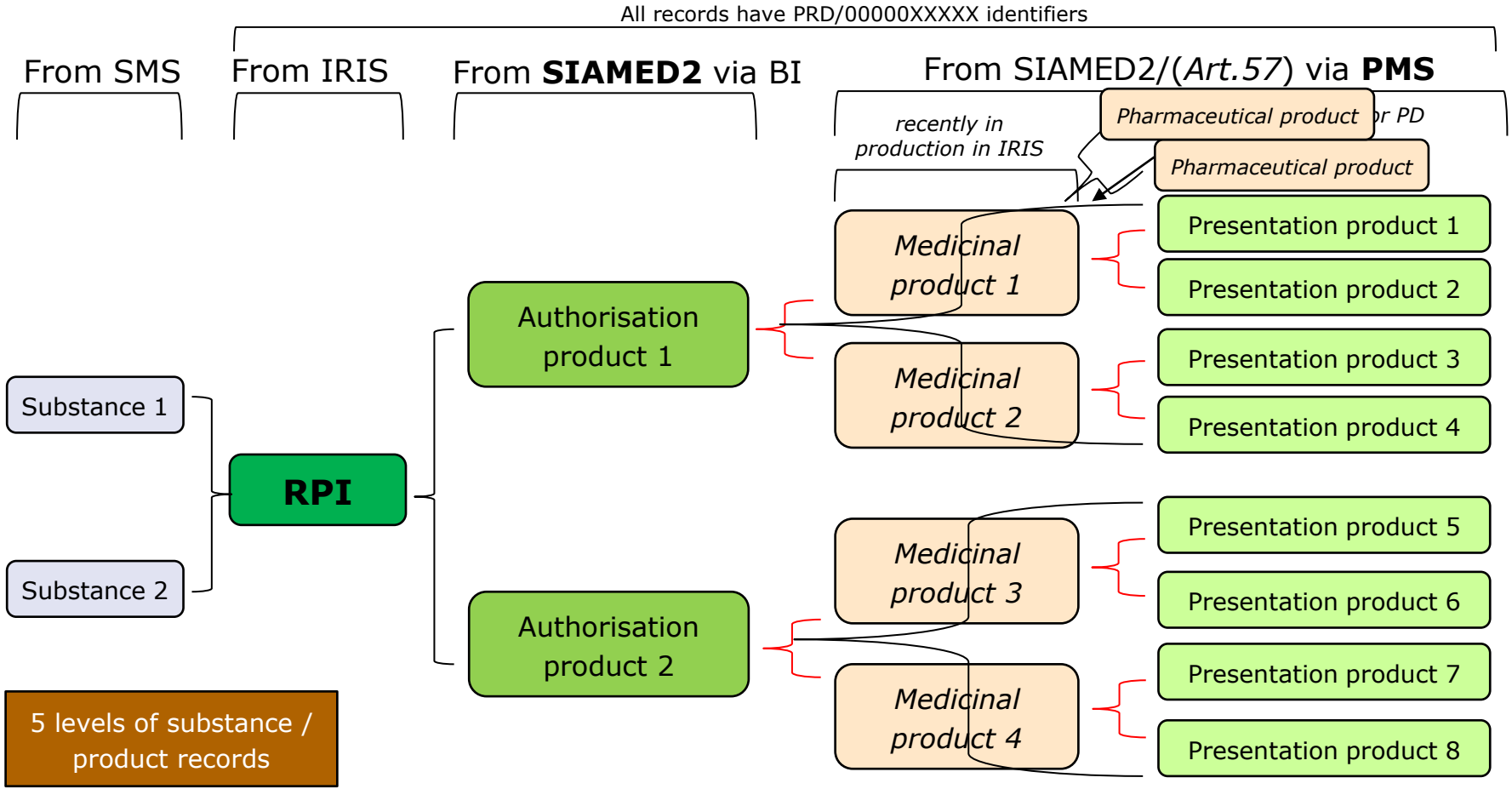

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