

Agenda: Network users training for Regulatory Procedure Management 1st roll-out on IRIS

16 January 2024, 10:00 – 12:00 (CET)

Webinar: WebEx

On 23 January 2024, Variation*, Article 61.3 notification** and Marketing Authorisation (MA) Transfer procedures will transition to the EMA's IRIS platform for a limited selection of human and veterinary medicinal products. This is a first, small step towards eventually transferring all products and procedures.

This training session focuses on fundamental IRIS aspects, starting with Access Management instructions, continuing with an overview of the Network Portal, and concluding with key SharePoint functionalities. Participants will explore case management tailored to their roles, gaining insights into handling transitioned procedures in the IRIS platform.

Target Audience:

This event is designed for Network users, including Committee members, involved in Variations, Article 61.3 notifications, and MA Transfers for selected products. The selected medicinal products for the 1st IRIS roll-out have been already communicated to impacted Network users.

* Variations for veterinary use products not requiring assessment (VNRA) are to be submitted and managed via the Union Product Database (UPD)

** For human medicinal products

#	Item	Speaker	Mins
1.	Welcome	Madalina Duta-Mare <i>RPM for PLM Product Owner</i>	5 min
2.	Background	Madalina Duta-Mare <i>RPM for PLM Product Owner</i>	10 min
3.	Introduction to IRIS Basics	Simona Griniene <i>RPM for PLM Subject Matter Expert (SME)</i>	10 min
4.	Case Management on Network Portal	Simona Griniene <i>RPM for PLM Subject Matter Expert (SME)</i>	20 min
5.	Cases in IRIS for Committee Meetings	Simona Griniene <i>RPM for PLM Subject Matter Expert (SME)</i>	10 min
6.	Q&A Session	Moderator: Caterina Scarpati <i>RPM for PLM Change Management team</i>	20 min

7.	Working on documents related to IRIS procedures in SharePoint	Simona Griniene <i>RPM for PLM Subject Matter Expert (SME)</i>	25 min
8.	Q&A Session	Moderator: Caterina Scarpati <i>RPM for PLM Change Management team</i>	10 min
9.	Next Steps	Simona Griniene <i>RPM for PLM Subject Matter Expert (SME)</i>	5 min
10.	Closing	Madalina Duta-Mare <i>RPM for PLM Product Owner</i>	5 min