

Information Management

## Agenda: Training webinar on post-authorisation procedure management in IRIS for Marketing Authorisation Holders

12 November 2024, 10:00 – 11:30 (CET)

Webinar: WebEx meeting

In January 2025, the following EMA-led procedures will transition to IRIS for all Centrally Authorised Products (CAPs) (and involved non-CAPs): Periodic Safety Update Reports, Post-Authorisation Measures, Line Extensions, Renewals, Annual Reassessments, Post-Authorisation Safety Studies/Post-Marketing Surveillance Studies, and Referrals.

The first transition of Regulatory Procedure Management (RPM) for Product Lifecycle Management (PLM) to IRIS took place on 23 January 2024, onboarding variations, Article 61.3 notifications, and marketing authorisation (MA) transfer procedures for a subset of human and veterinary CAPs with low regulatory complexity. EMA is organising this training session to provide Marketing Authorisation Holders with key instructions to be prepared for the transition, showcase the IRIS system and answer questions.

The **registration form** is available [here](#).

Registration is open until the start of the meeting.

#	Item	Speaker	Mins
1.	<b>Welcome &amp; introduction</b>	<b>Madalina Duta-Mare</b> <i>Regulatory Procedure Management for PLM Product Owner</i>	10:00 – 10:05 (5 min)
2.	<b>Key actions for MAHs before the transition</b>	<b>Madalina Duta-Mare</b> <i>Regulatory Procedure Management for PLM Product Owner</i>	10:05 – 10:10 (5 min)
3.	<b>IRIS Access for MAHs</b>	<b>Madalina Duta-Mare</b> <i>Regulatory Procedure Management for PLM Product Owner</i>	10:10 – 10:25 (15 min)
4.	<b>Perform procedure management in IRIS</b>	<b>Sara Santos</b> <i>Regulatory Procedure Management for PLM Subject Matter Expert</i>	10:25 – 10:55 (30 min)

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5.	<b>Next steps</b>	<b>Sara Santos</b> <i>Regulatory Procedure Management for PLM Subject Matter Expert</i>	10:55 – 11:00 (5 min)
6.	<b>Q&amp;A Session</b>	Moderator: <b>Caterina Scarpati</b> <i>RPM Change Management Team</i>	11:00 – 11:25 (25 mins)
7.	<b>Closing</b>	<b>Madalina Duta-Mare</b> <i>Regulatory Procedure Management for PLM Product Owner</i>	11:25 – 11:30 (5 mins)