

IRIS - Regulatory Procedure Management (RPM)



What?

RPM is the new feature of IRIS that allows Management of post-authorisations product life-cycle procedures



From when?

January 2025.



Applicable for

CPs (also applicable for non-CAPs for procedures where EMA acts as the reference authority)



Changes

RPM platform will be used for all maintenance activities, including:

- Variations
- Article 61.3 notifications
- MA transfers
- Periodic Safety Update Reports (PSURs)
- Post-Authorisation Measures (PAM)
- Line Extensions
- Renewals
- Post-Authorisation Safety Studies (PASS)
- Referrals



Action required

- Use of personal mailboxes as product contacts
- Register all contacts in EMA Account Management System
- Request applicable IRIS Industry roles