



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 May 2023
Information Management

Agenda: Product Lifecycle Management (PLM) Portal Access Management Training Session

25 May 2023, 11:00 – 12:30 Central European Summer Time (CEST)

Webinar: WebEx

The web-based electronic application forms (eAF) will replace PDF eAFs used for regulatory submissions in the new Product Lifecycle Management (PLM) portal. This is a first step towards making the form-filling and submission-handling process more efficient.

The web-based variations form for Human medicinal centrally authorised products (CAPs) was released on 4 November 2022. Subsequently, the form will support all types of EU variation procedures (CAPs and NAPs).

This event is a training webinar for industry stakeholders with NAPs and CAPs and National Competent Authorities wishing to learn more about access management aspects related to the new PLM portal.

A video recording will be made available after the event.

Item	Agenda	Time	
1.	Welcome / Introduction <i>Kristiina Puusaari, eAF Product Owner, EMA</i>	11:00-11:10	10 mins
2.	Roles Overview <i>João Costa, Platform Manager, EMA</i>	11:10-11:20	10 mins
3.	Request Access & Sign in <i>João Costa, Platform Manager, EMA</i>	11:20-11:25	5 mins
4.	Access Management demonstration <i>João Costa, Platform Manager, EMA</i>	11:25-11:55	30 mins
5.	Q&A session <i>Moderator: Cristina Pepato, eAF & PMS Change Manager</i>	11:55-12:25	30 mins
6.	Closing <i>João Costa, Platform Manager, EMA</i> <i>Kristiina Puusaari, eAF Product Owner, EMA</i>	12:25-12:30	5 mins

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