



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

7 November 2022

Human Variations eAF Form training session

8 November 2022, 10:00 – 11:30 Central European Time (CET)

Webinar: WebEx

The web-based electronic application forms (eAF) will replace PDF eAFs used for regulatory submissions in the new dedicated PLM portal, making the form-filling and submission-handling process more efficient.

The web-based variations form for Human medicinal centrally authorised products (CAPs) will be released on 4 November 2022.

This event is a training webinar for industry and national competent authorities' stakeholders wishing to learn more about the use of the new PLM portal and web forms features after the go-live.

You can register to the training [here](#).

A video recording will be made available after the event.

Item	Agenda	Time	
1.	Welcome / Introduction <i>Kristiina Puusaari, eAF Product Owner</i>	10:00-10:05	5 mins
2.	Scenarios for which the eAF can be used <i>Kristiina Puusaari, eAF Product Owner</i>	10:05-10:10	5 mins
3.	Access management & data visibility by role <i>Joao Costa, Platform Manager</i>	10:10-10:25	15 mins
4.	- Filling in the eAF: • Search product • Select product • Search for the scope • Select scope • Add present/proposed changes - Exporting the eAF <i>Kristiina Puusaari, eAF Product Owner</i> <i>Noel Diamant, eAF UNICOM* Product Owner</i>	10:25-11:10	45 mins

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

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5.	Q&A session <i>Moderator: Cristina Pepato, eAF & PMS Change Manager</i>	11:10-11:25	15 mins
6.	Closing <i>Kristiina Puusaari, eAF Product Owner</i>	11:25-11:30	5 mins



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