



5 July 2022  
EMA/627535/2022

## Agenda – ‘DADI Go-Live - Q&A Webinar’

12 July 2022, 11:00 – 12:30 Central European Time (CET)

Webinar: WebEx

The Digital Application Dataset Integration (DADI) Network project will replace PDF electronic application forms (eAF) used for regulatory submissions with web-forms, making the future form-filling and submission-handling process more efficient.

**EMA will launch the eAF variations web form in October 2022.** This is a first release of the web-based variation form for human medicinal products that will be improved and expanded in subsequent releases in 2023.

**The scope of the October release has been limited to Centrally Authorised Products (CAPs)**, due to complexity in synchronisation of the data between xEVMPD and PMS. A subsequent release of the form in March 2023 will support all types of EU variation procedures (CAPs and NAPs).

This event is a dedicated Q&A webinar for business and technical audiences from industry and national competent authorities to address questions about the revised scope of the DADI October Go-live.

A video recording will be made available after the event.

Item	Agenda	Time	
1.	<b>Welcome / Introduction</b> <i>Joris Wiemer, Change Management Lead, EMA</i>	11:00-11:05	5 mins
2.	<b>DADI Variations Form revised Go-Live Scope</b> <i>Kristiina Puusaari, DADI Product Co-Owner, EMA</i> <i>Noel Diamant, DADI Product Co-Owner, AGES/UNICOM*</i>	11:05-11:35	30 mins
3.	<b>Q&amp;A Session</b> <i>Moderator: Cristina Pepato, DADI &amp; PMS Change Manager</i>	11:35-12:25	50 mins
4.	<b>Closing</b> <i>Joris Wiemer, Change Management Lead, EMA</i>	12:25-12:30	5 mins

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