



11 May 2022
EMA/226955/2022

DADI-PMS Webinar Agenda – ‘Variations Form for Human Medicinal Products - What will happen at Go-Live’

16 May 2022, 10:00 – 12:00 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.

The variations form for human medicinal products will be the first form to be released by DADI, with an expected go-live in October 2022. As part of the go-live, DADI will expose medicinal product data that have been migrated to the Product Management Service (PMS) for product master data for human medicinal products.

This event is a joint DADI-PMS webinar for business and technical audiences from industry and national competent authorities wishing to learn more about what will happen when the DADI web-based form for human medicinal products will go live. All stakeholders interested in DADI and its interaction with PMS are welcome.

Topics addressed in this webinar include:

- The process for selecting products, creating and submitting the variation form;
- Data in the form coming from PMS;
- The process after the approval of the variation;
- Electronic submission requirement to the Extended EudraVigilance Medicinal Product Dictionary ([xEVMPD](#)).

A video recording will be made available after the event.

Item	Agenda	Time	
1.	Welcome / Introduction <i>Joris Wiemer, Change Management Lead, EMA</i>	10:00-10:05	5 mins
2.	Web forms as part of the Data-centric Target Operating Model <i>Karl Hamilton, Product Lifecycle Management Value Stream Owner, EMA</i>	10:05-10:15	10 mins
3.	Human Variations Form Timeline <i>Hannes Kulovits, Product Lifecycle Management Value Stream Manager, EMA</i>	10:15-10:20	5 mins



4.	<ul style="list-style-type: none"> • Impact for Applicants and Regulators • Process at Go-live of DADI Variations Form <ul style="list-style-type: none"> ○ Selection of Products in the Variations Form ○ PMS Data in the Form at Go-live ○ Submission of Variations Form ○ Process after approval of a Variation ○ xEVMPD submissions <p><i>Kristiina Puusaari, DADI Product Co-Owner, EMA</i> <i>Noel Diamant, DADI Product Co-Owner, AGES/UNICOM*</i> <i>Marcos Fernandez, PMS Product Co-Owner, EMA</i> <i>Veronica Lipucci Di Paola, PMS Product Co-Owner, EMA</i></p>	10:20-11:20	60 mins
8.	<p>Q&A session Moderator: <i>Cristina Pepato, DADI & PMS Change Manager</i></p>	11:20-11:55	35 mins
9.	<p>Closing <i>Joris Wiemer, Change Management Lead, EMA</i></p>	11:55-12:00	5 mins

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