



26 April 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

Item	Agenda	Time	
1.	<b>Welcome / Introduction</b> <i>Joris Wiemer, Change Management Lead, EMA</i>	10:00-10:05	5 mins
2.	<b>Web forms as part of the Data-centric Target Operating Model</b> <i>Karl Hamilton, Product Lifecycle Management Value Stream Owner, EMA</i>	10:05-10:15	10 mins
3.	<b>Human Variations Form Timeline</b> <i>Hannes Kulovits, Product Lifecycle Management Value Stream Manager, EMA</i>	10:15-10:20	5 mins
4.	<ul style="list-style-type: none"><li>• <b>Process at Go-live of DADI Variations Form</b><ul style="list-style-type: none"><li>○ <b>Selection of Products in the Variations Form</b></li><li>○ <b>PMS Data in the Form at Go-live</b></li><li>○ <b>Submission of Variations Form</b></li><li>○ <b>Process after approval of a Variation</b></li><li>○ <b>xEVMPD submissions</b></li></ul></li><li>• <b>Impact for Industry and NCAs</b></li></ul> <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>	10:20-11:20	60 mins
5.	<b>Q&amp;A session</b> <i>Moderator: Cristina Pepato, DADI Change Manager</i>	11:20-11:55	35 mins
6.	<b>Closing</b> <i>Joris Wiemer, Change Management Lead, EMA</i>	11:55-12:00	5 mins

\*The UNICOM Innovation Action has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No. 875299.

