

7 December 2021 EMA/729278/2021 Information Division

DADI Webinar Agenda - Common factors in the Fast Healthcare Interoperability Resources (FHIR) data standard for Art57(2) and eAF

25 January 2022, 10:30–12:00 Central European Time (CET), Webinar: WebEx

Chair: Joris Wiemer, EMA

Item	Agenda	Time	
1.	Welcome / Introductions Joris Wiemer, EMA	10:30-10:35	5 mins
2.	 Introduction to the Variation FHIR Message Conceptual model for application procedures Conceptual model for the medicinal product and how it links to variation Source of the data elements - SIAMED, Art 57 & new data to be received prospectively via Variations EMA & Noel Diamant, AGES/UNICOM Veronica Lipucci Di Paola, EMA & Marcos Fernandez Gomez, EMA 	10:35-11:15	40 mins
3.	 Mapping & examples Mapping from eAF variation & MAA medicinal product to FHIR and PMS IG 2.1 EMA & Noel Diamant, AGES/UNICOM 	11:15-11:25	10 mins
4.	Q&A session Moderator: <i>Cristina Pepato, DADI Change Manager</i>	11:25 -11:55	30 mins
5.	Closing Joris Wiemer, EMA	11:55-12:00	5 mins

