



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

DADI Q&A Webinar

Variations form for Human Medicinal Products Go-Live

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

Chair: Joris Wiemer, Change Management Lead, EMA





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Welcome / Introduction

11:00 – 11:05

Joris Wiemer

Change Management Lead, EMA

2

DADI Variations Form revised Go-Live Scope

11:05 – 11:35

Kristiina Puusaari

DADI Product Owner, EMA

Noel Diamant

*DADI Network Product Owner, AGES/UNICOM**

3

Q&A Session

11:35 – 12:25

Moderator:

Cristina Pepato

DADI & PMS Change Manager

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Closing

12:25 – 12:30

Joris Wiemer

Change Management Lead, EMA



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



Please note that **this session is being recorded** and **will be made available** through **EMA Corporate Website**.



At certain points throughout the session, participants will be able to ask questions or give their input via the audience interaction tool **Slido**.

Interaction via Slido is voluntary, and you may opt to remain anonymous. If you chose to use Slido, **you consent to the processing of your personal data** as explained in the [EMA Data Privacy Statement for Slido](#).



1. Join via the QR code or link



2. Send or upvote the questions you want to hear answered



3. Questions will be shown on the screen and managed live in the Q&A session



Welcome

Joris Wiemer, *Change Management Lead, EMA*

Context

- > The **Digital Application Dataset Integration (DADI) Network Project** will replace current interactive PDF format electronic application forms with **new web-based application forms** hosted on a **dedicated portal**
- > The new web-forms will facilitate compliance with **ISO Identification of Medicinal Products (IDMP)** standard for human medicinal products in accordance with Commission Implementing Regulation (EU) No 520/2012 (art. 25 and 26)
- > DADI will provide a human readable PDF output in line with the Notice to Applicants requirements
- > The PDF output will contain a machine-readable component with a larger dataset in a **FHIR** xml format, that facilitates exchange of the applications information across different systems



DADI will change:



- > **PDF-format electronic application forms to web forms for:** Variations; Initial marketing authorisations; Renewals (human only); Forms for other procedures under consideration
- > **Human** and **veterinary** forms
- > **Centrally authorised product (CAPs)** applications at initial release of the form, and **Nationally authorised product (NAPs)** applications at second release.

DADI will NOT change:



- > The **current PDF output format**
- > The process to apply for or submit **Variations** and **Marketing authorisation applications**
- > The content of the **application form in the submission package**



DADI Variations Form revised Go-Live Scope

Kristiina Puusaari, *DADI Product Owner, EMA*



October 2022 Go-live

- > **First release** of the web-based variation form for human medicinal products



Scope

- > Limited to **Centrally Authorised Products (CAPs)** only
- > **Applications containing NAPs**, including National Procedures, Mutual Recognition Procedure and Decentralised Procedure **not yet supported**
- > **Available data for CAPs** coming from **EMA's internal database**



The scope change is due to the **complexity in synchronisation of the data between xEVMPD and PMS**



March 2023 Release

- > **Second release** of the web-based variation form for human medicinal products



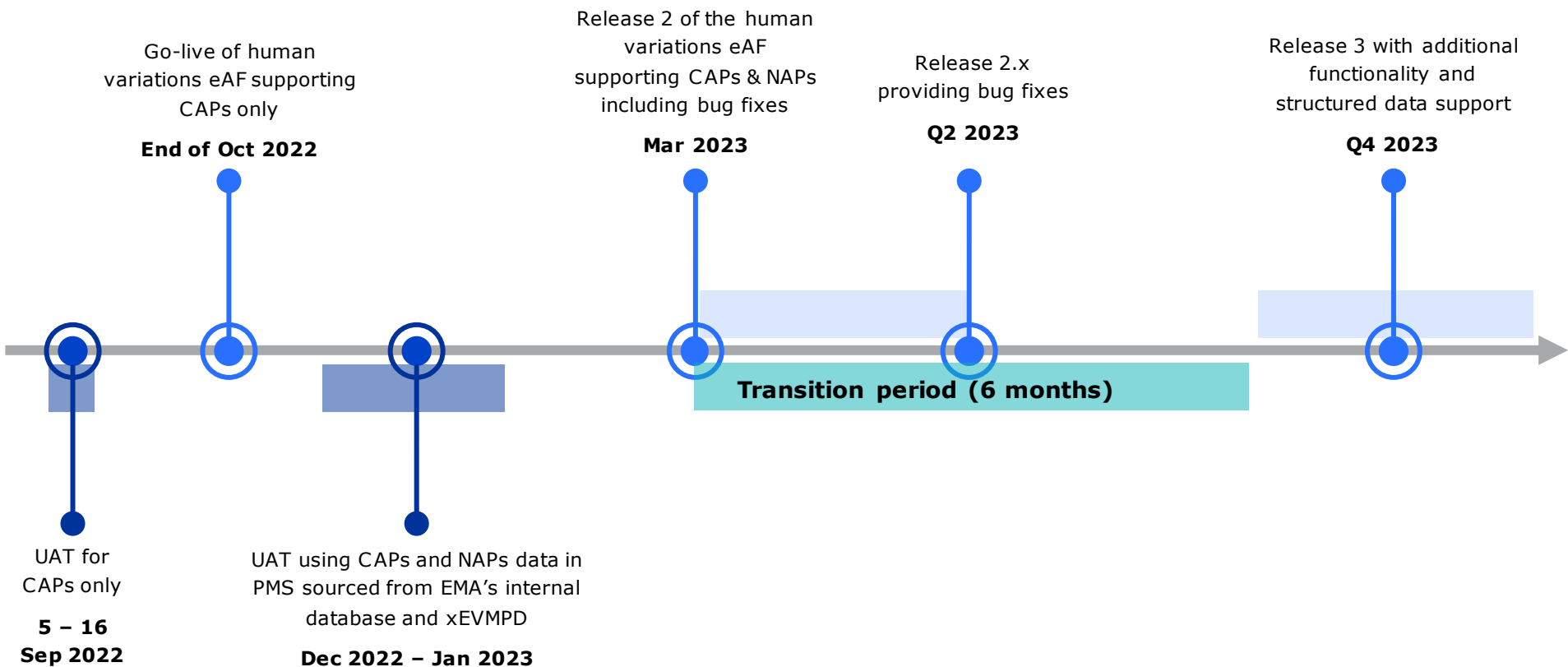
Scope

- > Support **all** types of EU variations procedures (**both CAPs and NAPs**)
- > Includes **bug fixes**



Progressive release model following the EMA Agile development approach

Updated DADI Human Variation Form Timeline





1st DADI UAT September 2022

- > As a consequence of the revised scope, the **DADI UAT** will be limited to **CAPs only**



Go-Live October 2022

- > **Go-live of the DADI human variations form supporting CAPs only**
- > Create variation forms in a new Web application and export to PDF & IDMP FHIR standard



2nd DADI UAT December 2022 – January 2023

- > Testers will use **CAPs and NAPs data** in PMS sourced from EMA's internal database and xEVMPD



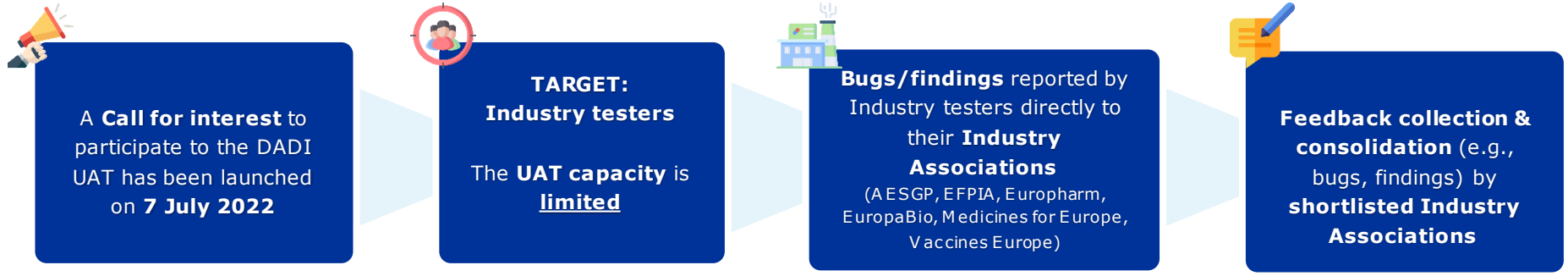
2nd Release March 2023

- > A **subsequent release of the form** will support all types of EU variation procedures (**CAPs and NAPs**)



Transition March – September 2023

- > **6-month transition period** including early-life support releases i.e., during transition users can use the old PDF eAF for variations and/or web-based DADI variations form



How to candidate

Send an email to eAF-testing@ema.europa.eu
(cc: industry@ema.europa.eu)

- ✓ **First name, last name, and e-mail address** of members interested in participating to the UAT
- ✓ **Name of your organisation** and, if already available, **OMS Location ID**
- ✓ **Name of the Industry Association** to which you aim to report findings/bugs (if/when applicable)



Deadline:
15 July
2022

Prior to the UAT

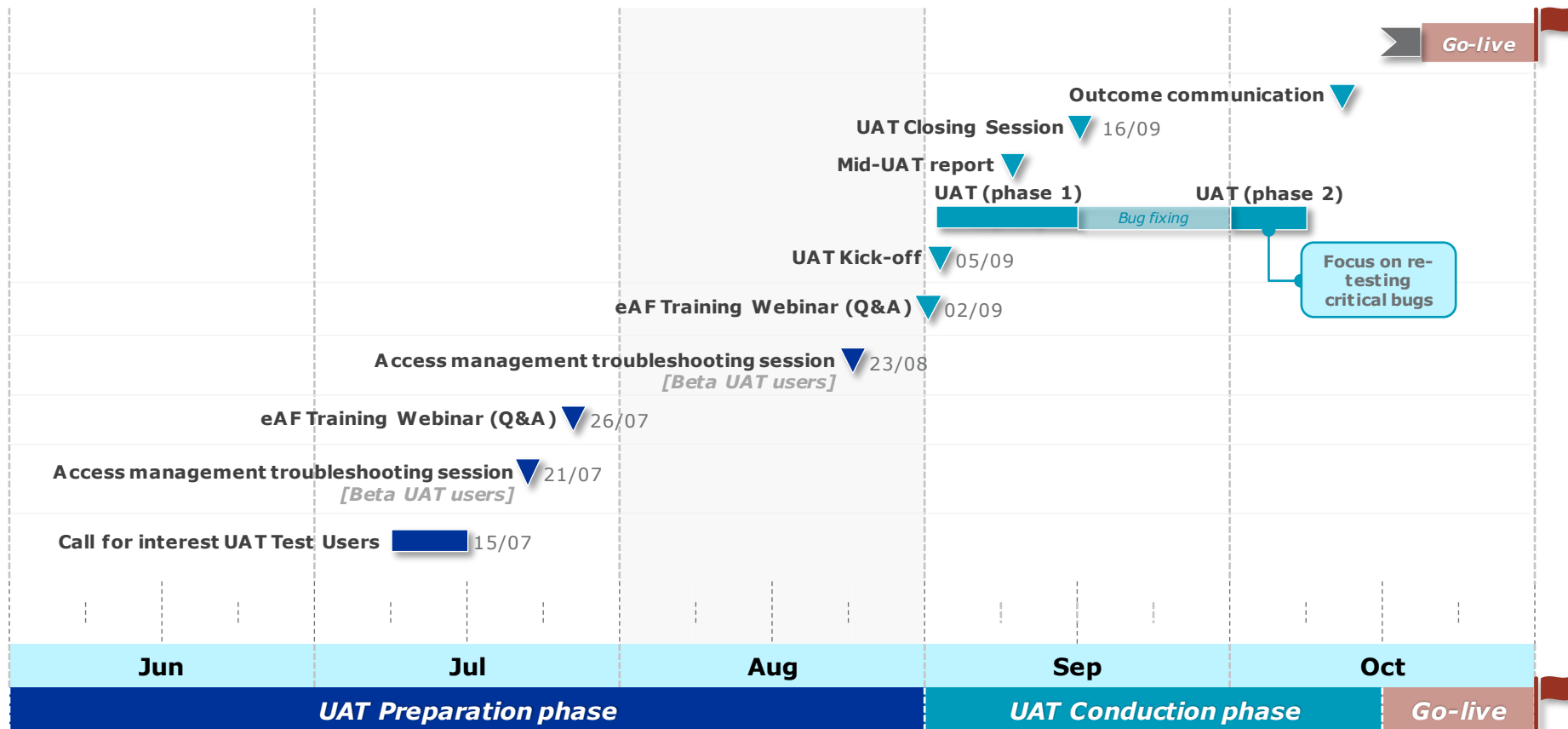
Pre-requisites to participate

- have an active EMA user account
- request the necessary user access role(s), via the [EMA Account Management](#) portal

What will be provided

- User Guide
- Troubleshooting sessions
- Training & Q&A webinars

DADI UAT Timeline





Q&A Slido Live Session

Moderator: Cristina Pepato, DADI & PMS Change Manager



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Closing

Joris Wiemer, *Change Management Lead, EMA*



An **update to chapter 7 of the EU Implementation Guide for ISO IDMP** covering details of what a CAPs only go-live will mean (release expected by end of July)

A **DADI Q&A document around what will happen at go-live** (to be made available after the Q&A webinar)

Two **eAF training sessions** are scheduled on **26th July 2022** & **2nd of September 2022**.



Further information

<http://esubmission.ema.europa.eu/cessp/cessp.htm>

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