

EUROPEAN  
MEDICINES  
AGENCY

## Introducing DADI – The Digital Application Dataset Integration Network Project to replace electronic application forms

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

Chair: Joris Wiemer, Change Management Lead, *EMA*

An agency of the European Union



# Welcome

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*Joris Wiemer*

*Change Management Lead, EMA*

1

## Welcome

10:30 – 10:35

2

## DADI Roadmap & Objectives in the framework of the Regulatory Business Optimisation

10:35 – 10:50

3

## New eAFs Main Changes

10:50 – 11:05

4

## Demonstration of the new interface

11:05 – 11:45

5

## Q&A Session

11:45 – 11:55

6

## Closing

11:55 – 12:00



**Joris Wiemer**

*Change Management Lead, EMA*

**Hilmar Hamann**

*Head of Information Management Division, EMA*

**Melanie Loveday**

*Regulatory Business Optimisation Programme Manager, EMA*

**Kristiina Puusaari**

*DADI Product Co-Owner, EMA*

**Noel Diamant**

*DADI Product Co-Owner, UNICOM/Austrian Medicines Agency*

**Moderator:**

**Cristina Pepato**

*DADI Change Manager*

**Joris Wiemer**

*Change Management Lead, EMA*



Please note that **this session is being live streamed.**  
**It 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.**

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## 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

# DADI Roadmap & Objectives in the framework of the Regulatory Business Optimisation

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*Hilmar Hamann*

*Head of Information Management Division, EMA*

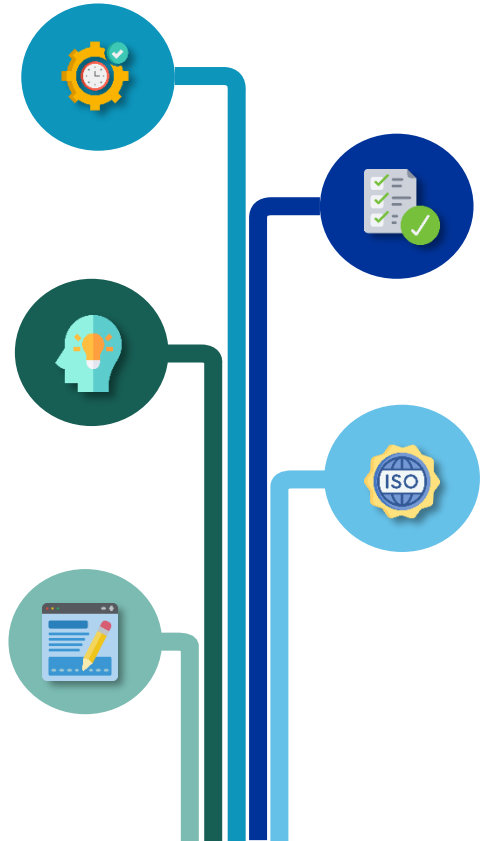
*Melanie Loveday*

*Regulatory Business Optimisation Programme Manager, EMA*

Longstanding need **to improve electronic application forms** to support **efficiency** and **interoperability**.

Capitalise on **momentum, relevant expertise & know-how** of predecessor project (CESSP Phase 1).

Current application form tools nearing end of life.



First step for **regulatory procedure improvements** needed in coming years.

The **UNICOM\* Horizon2020 project** received funding to foster the implementation of ISO IDMP and the usage of SPOR in the European Regulatory Network by 2023.

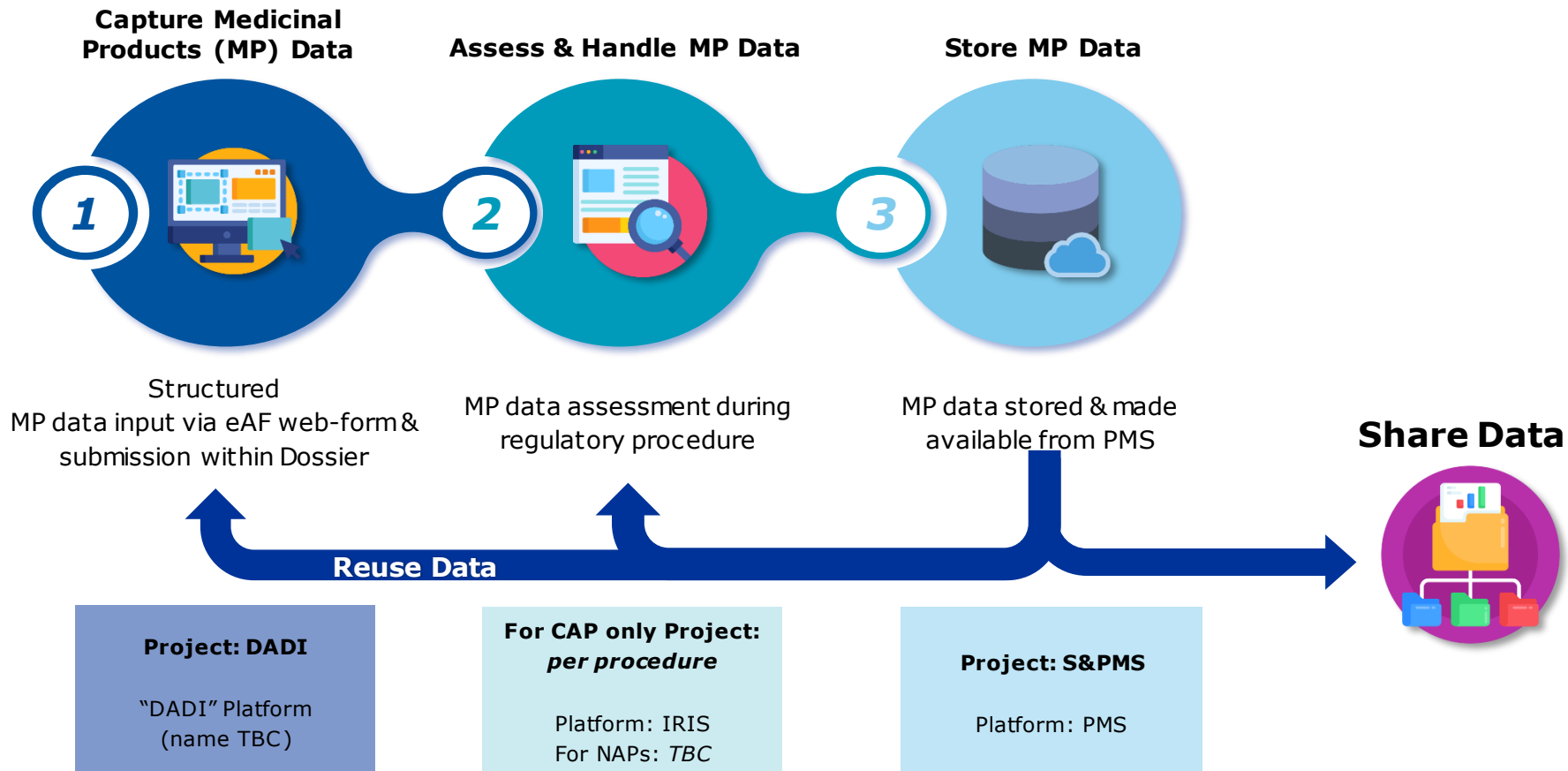
**In the context of the application form seven NCAs are working together with EMA experts in the DADI project.**

*UNICOM partners: AGES (Austria), BfArM (Germany), AEMPS (Spain), HPRA (Ireland), MEB-CBG (the Netherlands), NOMA (Norway) and SE MPA (Sweden) are part of the UNICOM consortium.*



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

# Moving to a Data-Centric Target Operating Model





## Network

**DADI** is a **Network project** led by the **European Medicines Agency (EMA)** which will support both **centrally authorised product (CAP)** applications and **nationally authorised product (NAP)** applications.

The project will replace forms used for **key EU procedures**, including:

- *centralised procedures managed by **EMA**,*
- *non-centralised procedures managed by **NCAs**.*

Both EMA and NCAs are involved to ensure that results can fulfil current and upcoming requirements.

## Product Owners

**Product ownership of the web-forms** is shared between **EMA and NCAs**. An EMA representative (Kristiina Puusaari) acts as product owner in collaboration with a **Network product owner funded by UNICOM\*** (Noel Diamant).

## SME Group

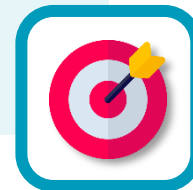
The DADI project has established a **group** representing **subject matter experts from EMA, NCAs and Industry**.



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## Project Objectives

1. Replace the **current PDF-format application forms** for marketing authorisation applications, variations and renewals for human medicinal products **with web-based application forms** compatible with ISO IDMP and FHIR standards and the EU Implementation Guide for human medicine
2. Provide a **structured data format (FHIR standard based)** which can be imported into PMS services and reused in other submission related tasks to support the PMS target operating model
3. Provide a **human readable PDF output** in line with the Notice to Applicants requirements
4. Use an **out of the box solution for the interface**





## So Far...



Artefacts/deliverables focused on:

- Set up an **infrastructure** to support all forms e.g. landing page, form structure, data model, solution design
- Develop an **initial version of the form for variations for human medicinal products**
- Progress with the development of a human readable PDF output

## Focus on 2022



- **Fine-tune and test of the form** for variations for human medicinal products
- Put **maintenance support** in place
- Perform **access management, security checks** and **deployment into production**
- Work in collaboration with PMS to establish the approach for **data cleansing**
- **Launch the form for variations for human medicinal products** and support the **transition** during the change
- Preparing work for next forms

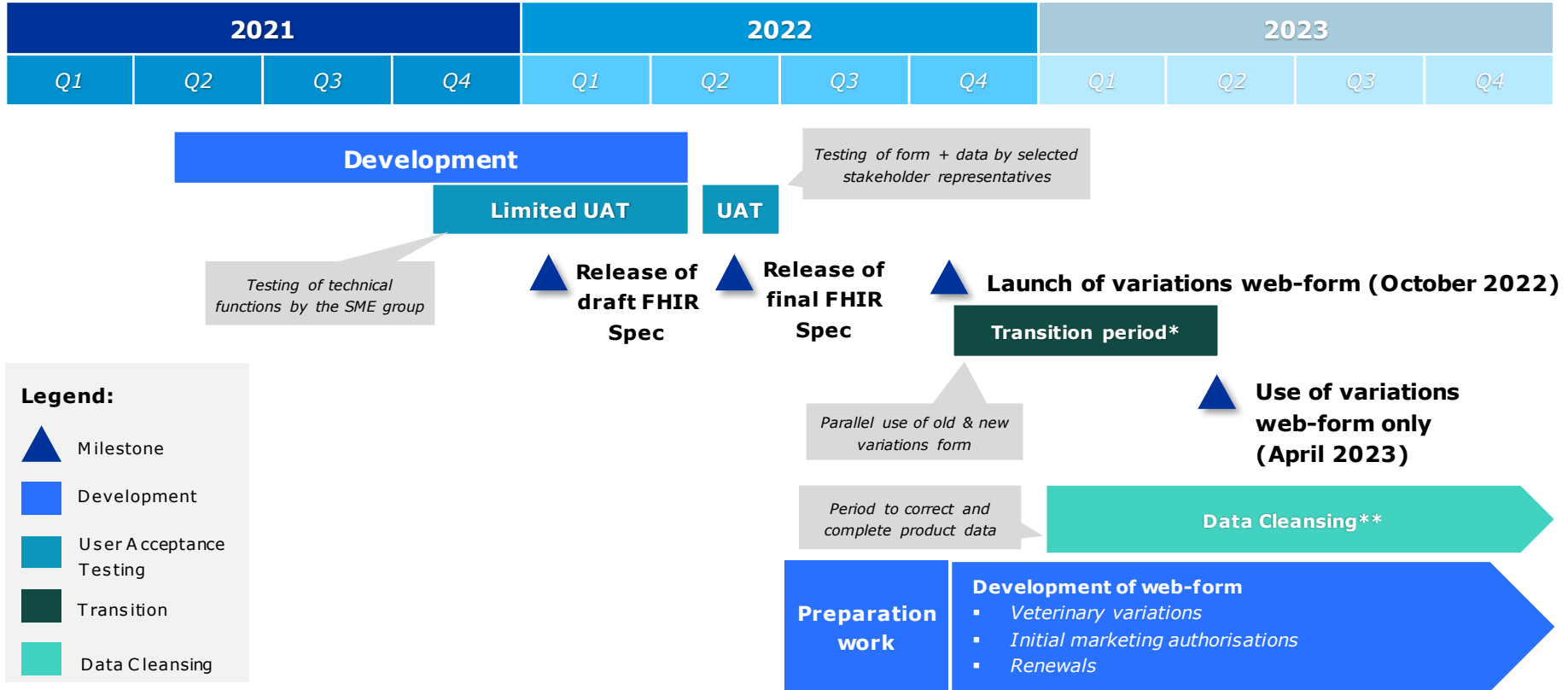
## For Future








- **Replace the eAFs for initial marketing authorisations** (human and vet), **variations for veterinary medicinal products** and **renewals forms** (human only) for CAPs and NAPs
- Support **data cleansing** in collaboration with **PMS**
- Support **releases of new versions of the forms**
- Explore further **machine-to-machine solutions**

# Human Variations Form Timeline

Please note this slide reflects an updated timeline from the one presented at the webinar.



**Legend:**

-  Milestone
-  Development
-  User Acceptance Testing
-  Transition
-  Data Cleansing

\* Any extension to transition periods to be agreed through consultation

\*\* Process and timeline to be confirmed for CAPs and NAPs following consultation

## New eAFs Main Changes

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*Kristiina Puusaari, DADI Product Co-Owner, EMA*

**FROM**

**TO**



Current PDF forms use outdated technology

A modern web based input form for applicants with a familiar, human readable pdf output and a new machine-readable xml for digital processing (FHIR data exchange)



Limited use of structured data

ISO IDMP/FHIR compliant structured data can be (re)used to populate web forms. They also guarantee two-way exchange of data between application web forms and PMS



Manual, labor intensive procedure management

Enable streamlined and simplified processes, with automated data imports facilitating procedure handling by regulators



## DADI will change:



### PDF-format electronic application forms to web forms for:

- Variations
- Initial marketing authorisations
- Renewals (human only)
- Other submissions under consideration



### Human and veterinary forms



### Centrally authorised product (CAPS) and Nationally authorised product (NAPS) applications



## DADI will NOT change:



The **current PDF *output* format**



The process to apply for or submit the **Marketing authorisation applications**

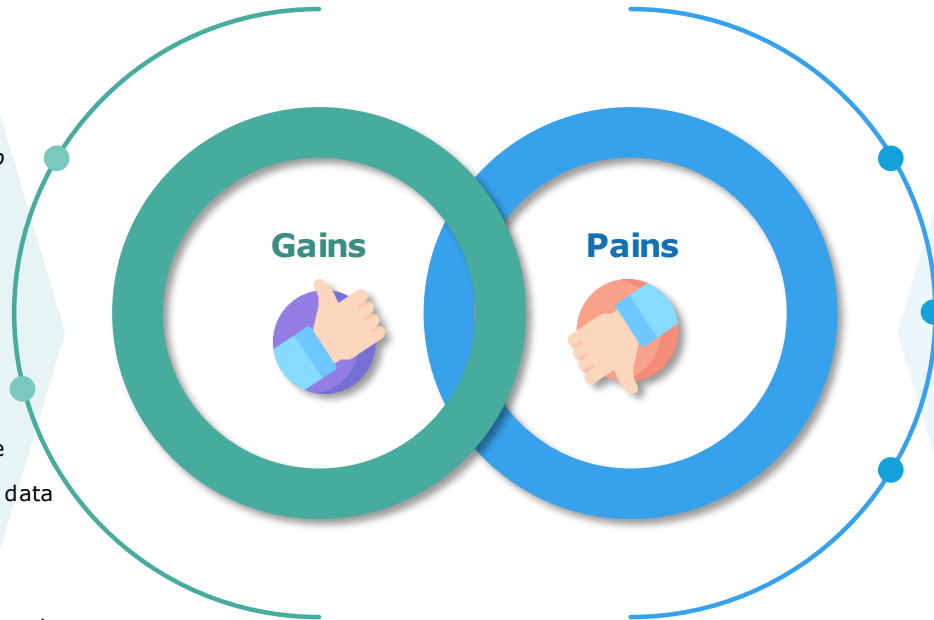


The content of the **application form in the submission package**



- Short term:**
- Usability improvement of forms (e.g. less time waiting for lists to load, available data prepopulated from EMA system)

- Long term:**
- Streamlined application interface
  - Use of predictable, standardised data
  - Less errors
  - Faster processing of applications
  - Machine-to-machine solutions based on FHIR can facilitate the application authoring process

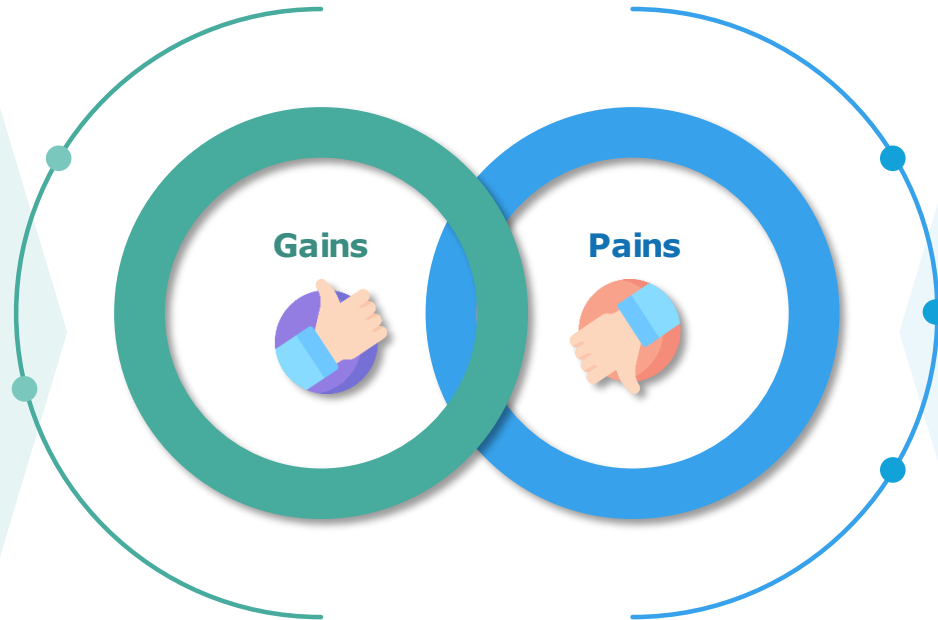


- Short term:**
- Different tools used until all PDF-based forms have been transitioned
  - Effort to cleanse and complete data for submissions

- Long term:**
- Registration and access management in the EMA portal
  - More details needed to fill in the application form



- Enabling more efficient processing, reducing errors and discrepancies
- Easier systems interoperability and data sharing among regulators
- Ensuring standardised data entry, thus making forms easier to process, validate, transmit and re-use



- Adapting IT systems to new FHIR standard
- Different tools used until all PDF-format forms have been transitioned
- Full benefits of PMS reached only once all data has been cleansed

**1. Regular communication on progress  
& how to get ready**



**2. User acceptance testing by  
selected Experts representing  
different stakeholder groups'  
experiences (Industry & NCAs)**



**3. Show & tell webinars**



**4. Training sessions prior to initial launch and  
during transition for users**



## Demonstration of the new interface

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*Noel Diamant, DADI Product Co-Owner, UNICOM\* / Austrian Medicines Agency*



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

## *Where we are:*



- Product selection from PMS
- Scope selection
- Calculation of procedural information
- Structured and unstructured changes for groupings and work-sharing
- System integration with Orphan and Paediatric
- Changing additional structured product data

## *For the Future:*



Product presentation selection; improvements to usability...

## Q&A Slido Live Session

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*Moderator: Cristina Pepato, DADI Change Manager*

## Closing

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*Joris Wiemer*  
*Change Management Lead, EMA*

## Further information

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

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

**Telephone** +31 (0)88 781 6000

**Send us a question** Go to [eSubProgofficer@ema.europa.eu](mailto:eSubProgofficer@ema.europa.eu)

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