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

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

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

Welcome

Joris Wiemer

Change Management Lead, EMA

Agenda

1. **Welcome**
   10:30 – 10:35
   Joris Wiemer
   Change Management Lead, EMA

2. **DADI Roadmap & Objectives in the framework of the Regulatory Business Optimisation**
   10:35 – 10:50
   Hilmar Hamann
   Head of Information Management Division, EMA
   Melanie Loveday
   Regulatory Business Optimisation Programme Manager, EMA

3. **New eAFs Main Changes**
   10:50 – 11:05
   Kristiina Puusaari
   DADI Product Co-Owner, EMA

4. **Demonstration of the new interface**
   11:05 – 11:45
   Noel Diamant
   DADI Product Co-Owner, UNICOM/Austrian Medicines Agency

5. **Q&A Session**
   11:45 – 11:55
   Moderator:
   Cristina Pepato
   DADI Change Manager

6. **Closing**
   11:55 – 12:00
   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**.*

*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.*

Send your questions via 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

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

Hilmar Hamann

Head of Information Management Division, EMA

Melanie Loveday

Regulatory Business Optimisation Programme Manager, EMA

Introducing DADI | Why now?

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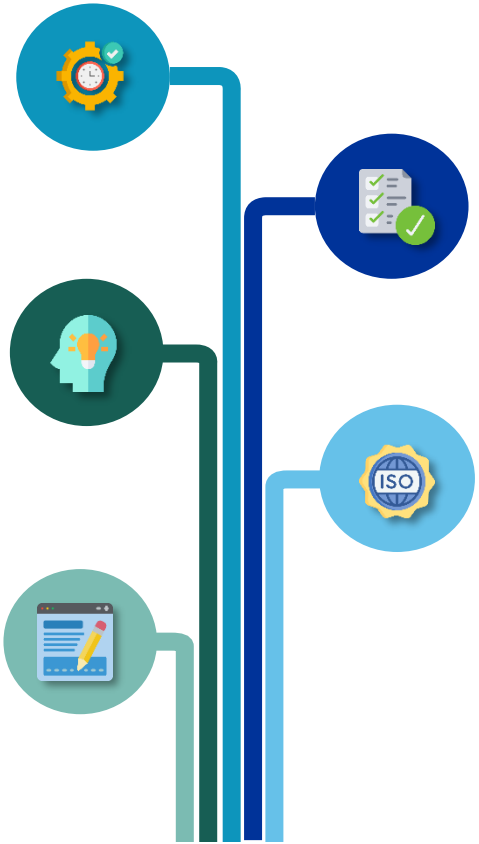
Longstanding need **to improve electronic application forms** to support **efficiency** and **interoperability**.

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

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Capture Medicinal Products (MP) Data

Assess & Handle MP Data

Store MP Data

Structured
MP data input via eAF web-form & submission within Dossier

MP data assessment during regulatory procedure

MP data stored & made available from PMS

Share Data

Reuse Data

Project: DADI

"DADI" Platform
(name TBC)

For CAP only Project:
per procedure

Platform: IRIS
For NAPs: *TBC*

Project: S&PMS

Platform: PMS

Introducing DADI | Project Set-Up

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.

Network

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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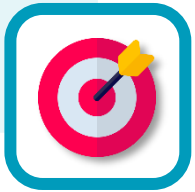
Project Objectives

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**



DADI Roadmap

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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

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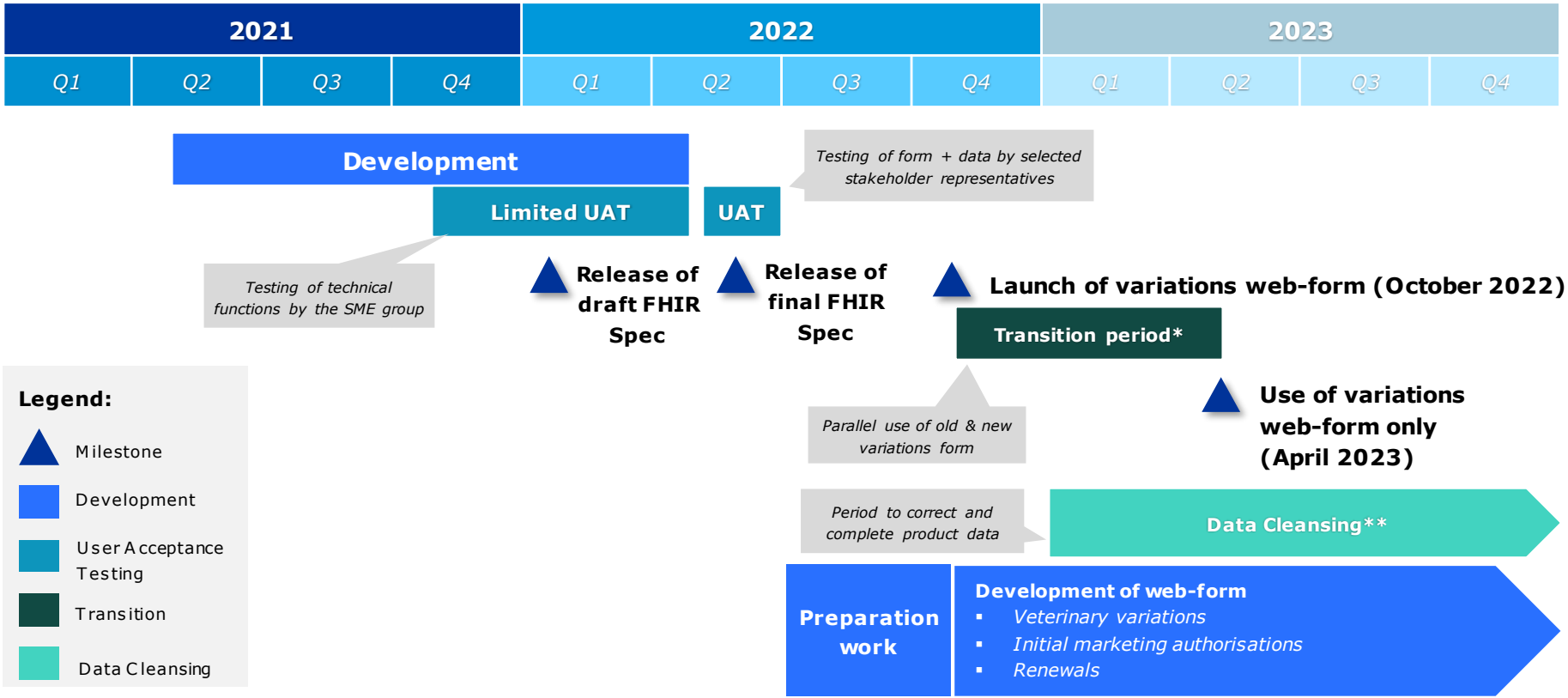
Please note this slide reflects an updated timeline from the one presented at the webinar.



* 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

Kristiina Puusaari, DADI Product Co-Owner, EMA

DADI Key Changes

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

What DADI will and will not change

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**

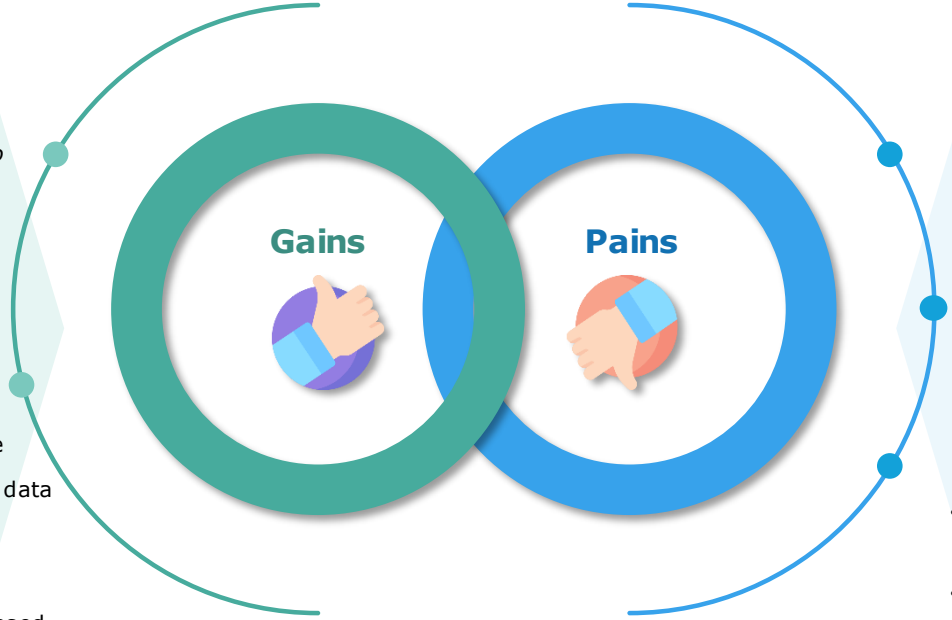
Industry pains & gains foreseen

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:

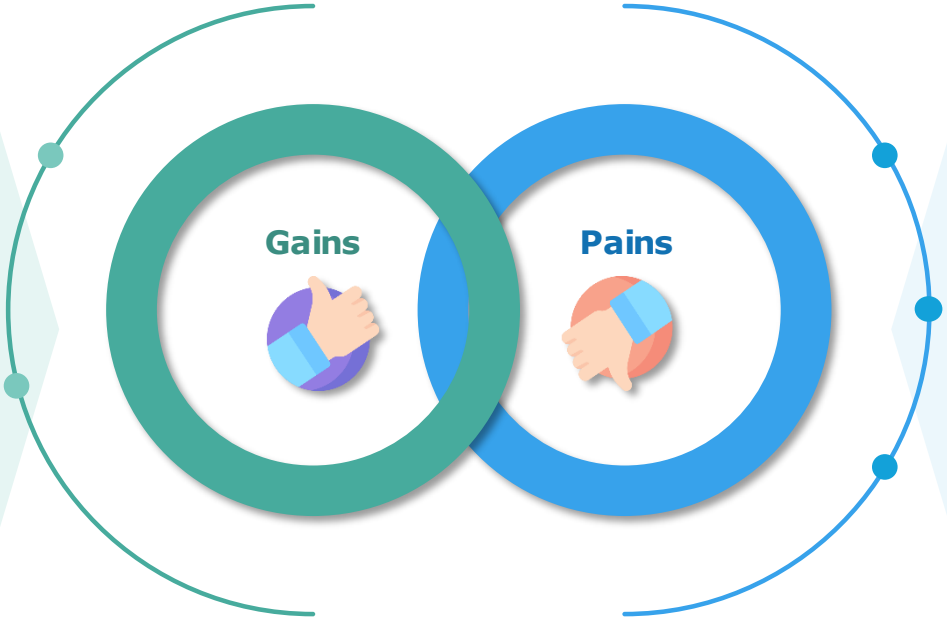
- Different tools used until all PDF-based forms have been transitioned
- Effort to cleanse and complete data for submissions

Long term:

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

Regulators pains & gains foreseen

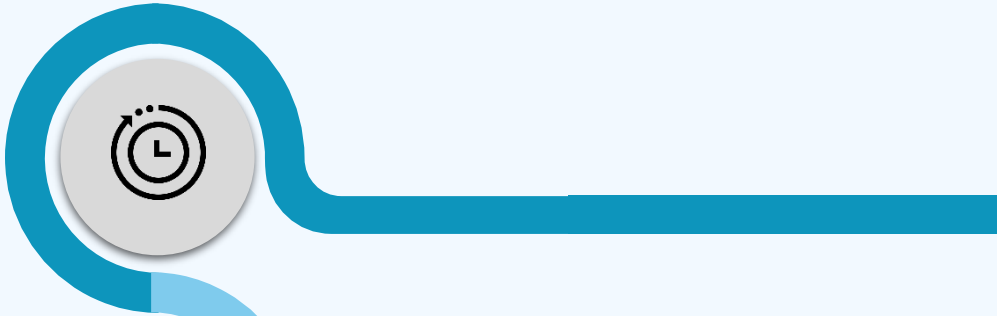
- Enabling more efficient processing, reducing errors and discrepancies
- Easier systems interoperability and data sharing among regulators
- Ensuring standardised data entry, thus making forms easier to process, validate, transmit and re-use



- 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

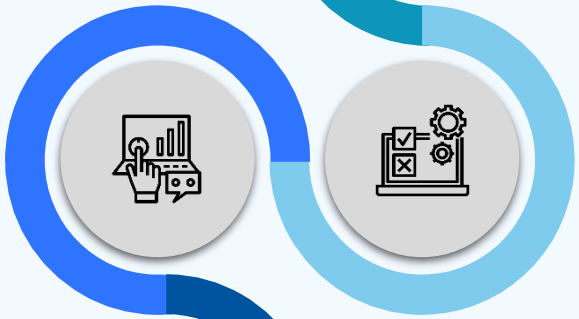
What you can expect between now & go live

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

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

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DADI Demonstration

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

Moderator: Cristina Pepato, DADI Change Manager

Closing

Joris Wiemer
Change Management Lead, EMA

Further information

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

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