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Summary of the
Digital Application Dataset Integration Project (DADI) for partners and stakeholders

Digital Transformation of electronic Application Forms

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In short:

The Digital Application Dataset Integration Project (DADI) will replace current PDF-based electronic application forms with new web-forms.

DADI will replace the form for variations for human medicinal products first in 2022, followed by other submissions forms in 2022-2023 for centrally and nationally authorised products.

Introducing new technology for forms is a key step to optimizing submissions handling processes and enabling the full use of product management services master data.

In this summary:

- why forms are changing
- what will and will not change
- how partners and stakeholders are involved in development
- the timeline for the forms

DADI is part of EMA's Regulatory Business Optimisation

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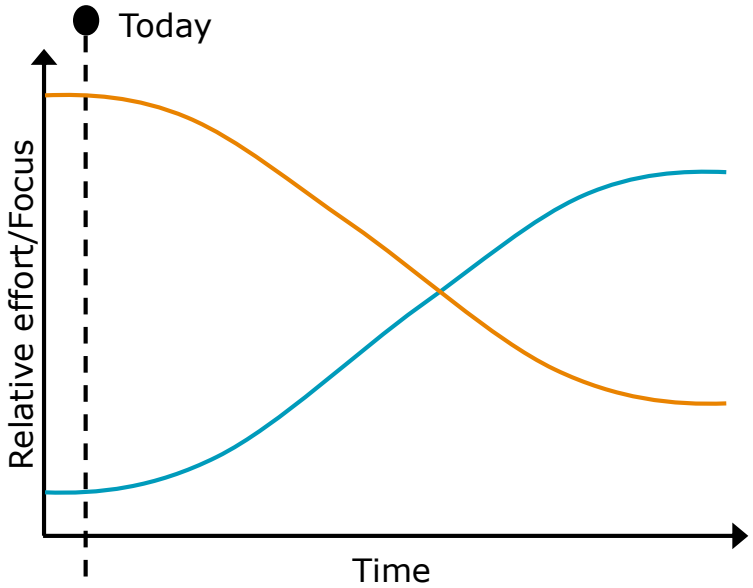
Core regulatory business optimisation → **Regulatory digital business transformation**

1. Harmonizing regulatory process
2. Enable & improve processes digitally
3. Increase reliability & usability of data

- ✓ Absorb new regulatory requirements
- ✓ Prepare for extended mandate
- ✓ Create room to focus on adding value & transformation



- Better decision-making using artificial intelligence and real-world data
- Transform processes using digital technology
- Enabling data supply chains on medicinal products for patients
- Develop new capabilities among EMA staff & stakeholders

- ✓ Benefits for patients,
- ✓ Benefits for regulators
- ✓ Benefits for industry

Regulatory business optimization lays & will continue to be the foundation for EMA's digital transformation

Three focus areas for optimisation

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Core regulatory business optimisation

1. Harmonizing regulatory process
2. Enable & improve processes digitally
3. Increase reliability & usability of data

Transform processes and identify common process elements for harmonisation across the Agency

e.g. rethinking the variations process

Move to digital solutions for manual processes & improve existing digital solutions

e.g.

- *orphan designation, marketing status & inspections on the IRIS portal*
- *Applying data analytics to existing business needs by Analytics Centre of Excellence*

Create a single, high quality, source of data to use and exchange across processes and systems inside and outside the agency – especially product and substances master data

i.e. Product Management Service (PMS)

Details in European Medicines Agency Final programming document 2021-2023

DADI is an enabler and catalyst for process optimisation

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Core regulatory business optimisation

1. Harmonizing regulatory process
2. Enable & improve processes digitally
3. Increase reliability & usability of data

Enabled by:

Digital Application Dataset Integration Project (DADI)

Making future electronic application form (eAF) filling and submission handling more efficient.

DADI goals:

- ✓ Replace current PDF-file based input eAFS with web forms on an updated portal.
- ✓ Enable both the familiar human-readable (PDF) output and a new machine-readable output for digital processing (FHIR data exchange standard for medicinal products).
- ✓ Structure input of eAFs to capture standard product data (PMS), ensuring ISO IDMP compliance.
- ✓ Reuse PMS data to prepopulate application inputs wherever relevant.
- ✓ EMA will integrate the forms with improved processes for handling CAPs submissions, reducing manual processing, errors and processing time.

DADI will change the format, not content or process

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DADI will change:

- ✓ PDF-based electronic application *input* forms to **web forms** for
  - Variations
  - Initial marketing authorisations
  - Renewals (human only)
  - Other submissions under consideration
- ✓ **Human** and **veterinary** forms
- ✓ **Centrally** authorized product (CAPS) and **nationally** authorized 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 of the application form in the submission package

Involvement of network and industry in the project

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Electronic Application Forms are used by applicants on the front end and EMA and NCA on the back end. To ensure a solution that works for all these groups, DADI has:

Two "product owners" for the development of new forms representing EMA & National Competent Authorities.

A requirements group

- Subject matter experts representing EMA, NCAs and the pharmaceutical industry
- Provide expert insight into the use of forms
- Support testing of the forms
- Meet weekly

DADI Roadmap v1.1 August 2021

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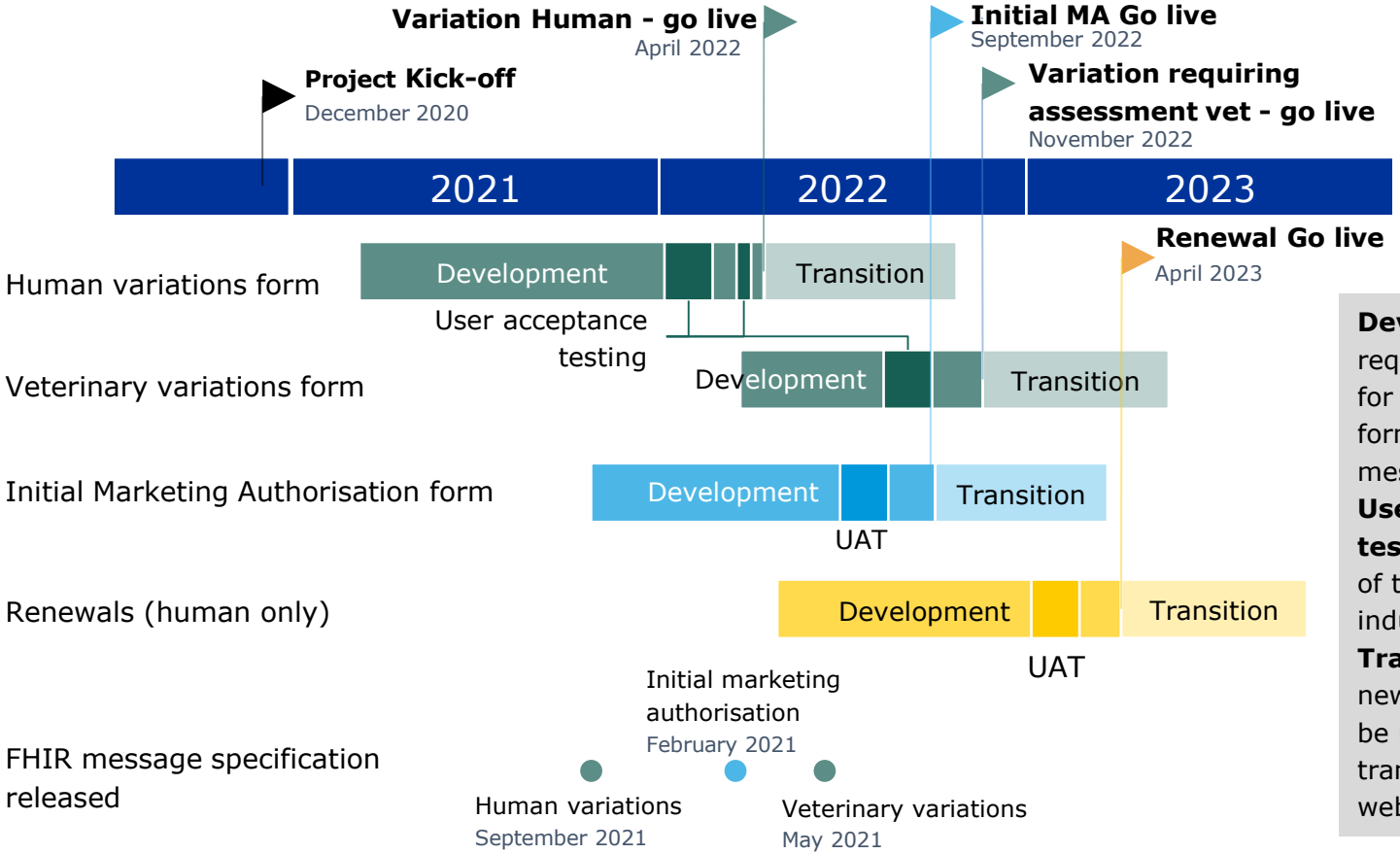

The timeline will be updated and republished as needed.

Development – requirements gathering for and programming the forms & underlying FHIR message.
User acceptance testing (UAT) - testing of the forms with industry users.
Transition - old PDF and new web-form can both be used. At the end of transition, only the webform can be used.

Resources

- DADI FAQ
- eSubmissions (all information about eSubmissions + news about DADI)
- SPOR Data
- ISO IDMP
- FHIR

Get in touch!

- EMA Servicedesk for eSubmissions technical support
- DADI Project team for questions about DADI

Glossary

CAP	A medicine with a single marketing authorisation issued by the European Commission and valid across the European Union.
eAF	Electronic Application Form
EMA	European Medicines Agency
EMRN	European medicines regulatory network, within which EMA coordinates and supports interactions between over fifty national competent authorities for both human and veterinary medicines.
NCA	National Competent Authority
NAP	A medicine authorised in a Member State in accordance with its national authorisation procedure
PMS	Product Management Services, managing master data for medicinal products
Product owner	The person responsible for the requirements of the form.
FHIR	Fast Healthcare Interoperability Resources, an international data exchange standard
ISO IDMP	International Organization for Standardization for the identification of medicinal products, an international identification standard