



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Information Management

DADI eAF Project List of Features for the Variations web-based form

Disclaimer

This document contains a summary of the features of the variations web-based form. This list is for information and not intended for consultation. The list of features and prioritization of their implementation is determined by the product owners of the web-based form in consultation with the project's requirements group.

We recommend reviewing this feature list together with "DADI eAF Replacement Project" and "DADO FAQ" explanatory PDF files.

Please contact the project team via esubprogofficer@ema.europa.eu with your questions.

About DADI

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.

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Feature Title	User story title	Description
WP 3 - Variation Form		Web based form(s) allowing applicants to easily fill the variation form, improving data quality, reducing time and errors.
	Application Form Lifecycle	As an applicant I want to have an overview of my draft applications to manage them and continue editing.
	User journey Variation Form	As an applicant I want to be guided through the logical sequence of the variation form.
	Navigation of forms	As an applicant I want to have some navigation on the form and sections so that I can easily switch between sections and see where I am and what I still need to fill in.
	Entering procedural information	As an applicant I want to be guided through the input of the main procedural information after selecting the product and classification, so that the system shows me the correct application type and domain.
	Type of Variation and Classification	As an applicant I want to define the type of variation and chose the possible classifications associated, so that the related fields for change can be displayed.
	Organisation Search	As an applicant I want to search OMS so that I can select an organisation in the context of a variation.
	Product Selection from IRIS	As an applicant I want to select the concerned products and their authorisations, from master data systems, so that I can relate them to my variation form.
	Product Selection from PMS	As an applicant I want to select the concerned products and their authorisations, from master data systems, so that I can relate them to my variation form.
	Product Security Model	As an Applicant I want to be able to securely access products in order to add them to the application form.
	PMS Updates	As an applicant I want to be informed if my PMS entry was changed while my dataset is not finalised.
	Change of Non-Product Fields	As an applicant I want to see the non-product fields I can change in accordance to the variation classification so that I can provide further details.

Feature Title	User story title	Description
	Change of Product Fields	As an applicant I want to see the product fields I can change in accordance to the variation classification so that I can provide further details.
	Add Orphan, paediatric and data exclusivity information	As an applicant I want to enter information on orphan designations, paediatric requirements and data exclusivity/market protection, for IB and Type II variations so that these specifics are captured.
	Declaration of the applicant	As an applicant I want to provide the declaration and signatory information, so that I meet the legal requirements.
	Proof of payment	As an applicant I want to provide information on the proof of payment so that the regulator can easily tie it back.
	Contextual guidelines for section and fields	As an applicant I want to have contextual guidelines for sections and fields so that I know what input is required here.
	Section-level Form Validation	As an applicant I want the system to validate my data so that I can be sure the entered data follows the business rules.
	Copy application	As an applicant I want to copy an existing application to create a new dataset based on previously entered data.
	Co-authoring on Application Forms	As an applicant I want to share my application for other authors so that they can contribute.
	Finalisation of the form	As an applicant I want to finalise or reopen my application for the web form to be (un)locked.
	Placeholder - Medical Device section on variation form	Placeholder for the medical device section on variation form. Details are unknown yet.
	Cross-section form validation	As an applicant I want the system to validate my data across all sections of application form as soon as I click on buttons "Export" and "Finalise" so that I can be sure the information is saved correctly according to the business rules before triggering Export and Finalise routine.
	Procedure Integration with SIAMED	As an applicant, I want to select other Applications for Centrally Authorised Products from SIAMED.
	Indication for completion of sub-sections	As an applicant I would like to see a green tick or some sort of other indication that also sub-sections are completed and validated so that I know which sub-sections are still missing.

Feature Title	User story title	Description
WP 3 - Export in PDF Format		Export in PDF Format to facilitate attachment to the eCTD package
	Ability to see modifications	As a regulator I want to see the fields that have been changed within the exported PDF so that I can continue to validate the application after resubmission more quickly
	Export into PDF	As an applicant I want to export my application into a PDF so that it can be included in an eCTD submission package.
	PDF - Generate Application Form PDF from FHIR Message	Ability to generate the PDF using FHIR file from third party pdf generator.
WP 5 - FHIR		Export and import FHIR compatible standard to facilitate data exchange for EMA and National Regulatory Authority.
	Export as FHIR attachment	As an applicant, I want to have the FHIR XML attached to the PDF file exported from the application form, so that I can submit FHIR XML file together with PDF file.
	Validation of information against FHIR schema	As an EMA / NCA regulator or a RIM system user I want to validate a variation FHIR message against its profile and business rules.
	Receive Validated PDF file with FHIR XML	As an applicant, I want to receive the PDF file including FHIR XML file which is already validated against publicly available FHIR Profiles and their business rules.
	FHIR Profile	As an applicant I want to have a FHIR profile to validate my messages against.