

5 April 2024 European Medicines Agency

RWD Catalogues – features and bug fixes

Release notes v. 1.0 (April 2024)

This is a summary of the expected improvements and known issues that will be addressed in the near future for the Real-World Data Catalogues. The document will be updated every 3 months. Next update is expected in July 2024.

Table 1. Features in release pipeline

ID	Brief description	Details	Estimated timeline
1	Feature to re-direct study links from the former EU PAS Register to the migrated specific study in the RWD Catalogues	The individual studies indexed in the EU PAS Register had specific individual links. This feature will re-direct the user to the specific study record migrated in the RWD Catalogues when the user clicks on the links.	April 2024
2	'Add a Data Source' form: 'Data Holder'	Possibility to find the 'Data Holder' of the Data Source registered in the Catalogues by searching for the Institution name instead of having to scroll-down through the list.	April 2024
3	Increase character limit for study objectives and study description fields	The character limit will be increased to 10,000 characters for the study objective and study description fields. Previously cut off words due to the migration will be re-instated automatically.	April 2024
4	Uploading files	 The user will be able to upload more than one file in the following fields: 'Composition of steering group and observers' ('Add a Study' form). 'Conflicts of interest of investigators' ('Add a Study' form). 	April 2024

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

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 Telephone +31 (0)88 781 6000
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ID	Brief description	Details	Estimated timeline
		• 'Procedure of results generation' ('Add a Study' form).	
		 'Protocol document' ('Add a Study' form). 	
		• 'Results tables' ('Add a Study' form).	
		 'Signed checklist for study protocols' ('Add a Study' form). 	
		 'Signed code of conduct' ('Add a Study' form). 	
		 'Signed code of conduct checklist' ('Add a Study' form). 	
		• 'Study report' ('Add a Study' form).	
		 'Study, other information' ('Add a Study' form). 	
		 'Data characterisation details' ('Add a Data Source' form). 	
		 'Governance details' ('Add a Data Source' form). 	
5	User notification system	A notification system will allow users to receive email notifications on record submission and validation, annual update of records, study milestone reminders, change of authorship and collaboration request/co-author added.	May 2024
		The user will be able to search data	
6	Enhanced search functionality	sources by data source acronym. There will be more filters to search for studies (e.g., ATC code).	May 2024
7	Integration with EMA corporate website	Catalogue records will be visible in the relevant medicines overview page, on the EMA website, linking to summary of Risk Minimisation Plans, EPARs, Product Information etc.	Q4 2024
8	Change authorship of a record by user/editor	The user will be able to transfer the record ownership to another user in the authorship information at the end of the form using the username of the new owner.	ТВС

Table 2. Bug fixes in release pipeline

ID	Brief description	Details	Estimated timeline
1	'Add a Network' form: 'Other organisations' field	The missing values will be displayed in the 'Network' record.	April 2024
2	'Add a Study' form: 'Medical Conditions to be studied' field	The drop-down menu for this field will display more than a limited number of options. The missing values will be displayed in the 'Study' record.	April 2024
3	'Add a Study' form: 'Study drug International non- proprietary name (INN) or common name' field	The user will be allowed to choose more than one value in this field. The missing values will be displayed in the 'Study' record.	April 2024
4	'Add a Study' form: 'Study timelines' field	The user will be able to fill in the Actual dates in 'Study timelines'. To edit an Actual date previously validated, the user needs to raise a ticket in ServiceNow.	April 2024
5	'Add a Study' and 'Add a Data Source' forms: 'Population age group' field	This field will no longer display veterinary values (e.g., Adult animal and Young animal). The age groups will be displayed in age ascending order.	April 2024
6	Not all linked studies displaying under an Institution	All studies linked to a specific Institution will be displayed in the institution record.	April 2024

Table 3. Features and bug fixes released since last update (January to April 2024)

ID	Brief description	Details	Deployed date
1	'Add a Study' form: ENCePP seal	The 'ENCePP Seal' section in the 'Add a Study' form has been improved.	February 2024
2	'Add a Data Source' form: 'Data source ETL frequency' field	The user can add decimal values (e.g., 0.25).	February 2024
3	'Add a Study' form: 'Other study identifiers' field (e.g., ClinicalTrials.gov ID)	The missing values are shown in the 'Study' record.	February 2024
4	'Add a Study' form: 'Clinical Trial Phase' field	The user can choose more than one value in this field. The missing values are shown in the 'Study' record.	February 2024

IC	D Brief description	Details	Deployed date
5	Save progress through steps in the record form	The filled information while navigating through steps in the 'Add a Study' and 'Add a Data Source' forms are saved in case the user is disconnected.	March 2024