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Release notes

EudraCT Version: 8.1.0

Goal: Release 8.1 Iteration 1

Release Date: 02/08/11

Environment: Production

Release Contents:

This is the release to production of the first iteration of EudraCT 8.1. It includes the following main functional changes:

- User Interface improvements to enhance the design of data entry forms, eliminating manual data entry on some fields where information can be auto populated based on the information provided to earlier questions using enhanced form logic i.e. auto population of data and hiding questions where not applicable. (See Additional Information on Enhanced Form Logic below). Improved navigation flow to make data entry more consistent and easier to use and fill in. Consistent user interface to allow expand / collapse sections of the CTA particularly section D that is now accessible in a single view.
- Re-enforcement of the use of the MPD to look-up active substances before necessitating adding them directly in EudraCT.
- New feature for displaying other language field as a default against free text fields.
- Various help text improvements and changes for EEA and Third Country forms.
- Validation Rule improvements to make it more user friendly and to simplify data entry

The release also includes some further changes to address identified defects in the main application.

The impacted use cases / testable functionalities are listed below:

Functionality / Use Case	Comments
BUC05 Fill in CT Application Form	Enhanced form logic changes, expand / collapse and other UI changes



Functionality / Use Case	Comments
BUC12 Enter EEA CTA Application	Include a new feature 'enter reasons for change information' to be displayed
BUC55 Validate 3 rd country CT Form	Validation rules update to 3 rd Country
BUC58 Validate Clinical Trial Application	Validation rules update to EEA.
BUC59 Submit 3 rd Country CT Information	Confirmation message on submitting Third Country form

Below is the complete list of new features including improvements and help text changes, defect fixes identified and addressed in this release and technical improvements included in this release.

Type	Priority	Key	Summary
New Feature	Critical	ECT-3033	BUC05/FEAT 21.8.6 - Enhanced Form Logic - F.1.1 Less than 18 Years
New Feature	Critical	ECT-3032	BUC05/FEAT 21.8.5 - Enhanced Form Logic E.8.1. - If E.8.1 Controlled is No then E.8.1 and E.8.2 sub-questions until E.8.2.4 should be hidden.
New Feature	Critical	ECT-3031	BUC05/FEAT 21.8.4 - Enhanced Form Logic H.2.1
New Feature	Critical	ECT-3030	BUC05/FEAT21.8.3 - Enhanced Form Logic D.3.7 - Routes of administration
New Feature	Critical	ECT-3021	BUC05/FEAT 21.7.1 & FEAT 21.7.2 - D.3.6.1 & D.3.6.2 Grey out the redundant fields
New Feature	Critical	ECT-2981	BUC05/FEAT 21.7.3 - Display other languages as a default- applies to all free text fields in EudraCT
New Feature	Critical	ECT-2750	BUC05/FEAT21.7.4 - Enforce the use of MPD when adding active substance information
New Feature	Major	ECT-3085	Enhanced Form Logic - BUC05/ FEAT 21.8.30 Section E
New Feature	Major	ECT-3076	Enhanced Form Logic - BUC05 / Section D.4
New Feature	Major	ECT-3075	Enhanced Form Logic - BUC05/ Section D.3
New Feature	Major	ECT-3074	Enhanced Form Logic - BUC05 - Section D.2
New Feature	Major	ECT-3072	E.8.7 Trial having an independent data monitoring committee - Help Text update
New Feature	Major	ECT-3070	Help Text Update - Section D.2.1 IMP has a MA
New Feature	Major	ECT-3069	A.8 EMEA Decision number of Paediatric Investigation Plan renamed to EMA
New Feature	Major	ECT-3068	Renaming of 3rd Country Fields on UI - EudraCT

Type	Priority	Key	Summary
New Feature	Major	ECT-3066 ECT-2996	Implement business logic validation when trying to upload an XML that is part PIP and not have a PIP decision number a validation error will appear. (3 rd country trials only)
New Feature	Major	ECT-3053	Redundant fields D.3.6.1/D.3.6.2 in EudraCT - Help Text Update
New Feature	Major	ECT-3051	Help Text correction on D.2.6
New Feature	Major	ECT-3050	Remove references to the core data set in Help as it no longer applies in EudraCT V8
New Feature	Major	ECT-3046	BUC59/Section 2.2.2.5-Confirmation message on submitting a 3rd country CT
New Feature	Major	ECT-3045	Make consistent the field length of Sponsor Protocol code - 35 Characters
New Feature	Major	ECT-3042	Increase EudraCT session out time from 30 to 45 minutes
New Feature	Major	ECT-3040	BUC53/FEAT2.2.2- Update to 3rd Country Form
New Feature	Major	ECT-2996	BUC05/FEAT21.4.5 - A.7 Trial part of a PIP" should always be YES and "A.8 PIP Decision Number" should be mandatory in 3rd Country Information XML.
New Feature	Major	ECT-2982	E.8.9.1 And E.8.9.2 - Field Spacing
New Feature	Major	ECT-2811	Renumbering of the fields to align with the CTA Form (D.9.1 And D.9.2)
New Feature	Critical	ECT-3043	BUC05/FEAT21.8.1 Enhanced Form Logic - C.1.1 and C.1.2 Sponsor Information/Legal Representative auto-fill
New Feature	Critical	ECT-3024	BUC13/FEAT1.4.7 - New Fields required in Section N: Review of the clinical trial application from - Initial Data Screen
New Feature	Major	ECT-3073	Enhanced Form Logic - BUC05/FEAT 21.8.8 - B.2 Legal Representative
New Feature	Major	ECT-3112	Field D.3.6.1 & D.3.6.2 - Data shall be displayed as Read only
New Feature	Major	ECT-3084	Help Text Update A.8 EMA Decision number of PIP
New Feature	Major	ECT-3124	Help Text Update - E.8.9.2, E.8.10.2, F.4.2
New Feature	Major	ECT-3039	3rd Country - Help Text Updates
New Feature	Critical	ECT-3029	BUC05/FEAT21.8.2 Enhanced Form Logic - D.2.1.2.1 Is this MS concerned with this application
New Feature	Major	ECT-3142	D.2 & D.2.1 - Help Text Update

Type	Priority	Key	Summary
New Feature	Major	ECT-3144	D.3.6.1 & D.3.6.2 Reduce the width of the read only fields
New Feature	Major	ECT-3143	Change the label from Search active substance to Add active substance. Add some guidance text to aid data entry using MPD.
New Feature	Major	ECT-3141	Add a new field VHP Number in Section N
New Feature	Major	ECT-3139	Expand/Collapse D.1/D.2.2, D.2.3, D.2.4, D.2.5, D.2.6
New Feature	Major	ECT-3094	D.3.6.1 & D.3.6.2 Need a label to indicate Read Only fields
New Feature	Minor	ECT-2921	Field Label changes on UI And Help Text on Section D.9 Sites where the QP Certifies batch release
Change Request	Major	ECT-3100	Find CTA search results, change the order of the columns to display EudraCT Number, Resubmission Letter, Reg Authority, Version, CA Decision etc..
Change Request	Major	ECT-3138	F.3.3 Specific Vulnerable Population - Disable the Enhanced Form Logic as hiding of F.3.3.1 and F.3.3.2 is not desired.
Change Request	Major	ECT-3131	Changes to field A.7 - Is the trial part of PIP = Yes then it is not mandatory to complete A.8 EMA decision Number (For EEA Trials)
Bug	Critical	ECT-1516	BUC05/FEAT2.4.1 - Expand/Collapse feature in section B, C, D, G and H of the CTA form
Bug	Major	ECT-3109	Updated 3rd Country PDF so the latest version is available
Bug	Major	ECT-3022	3rd Country: Inconsistency of versioning when the same clinical trial is submitted from 2 different browsers by PIP addressee
Bug	Minor	ECT-2666	Portuguese language name when selected the last letter 'e' appears on the next line on the PDF.
Bug	Major	ECT-3120	PDF Form shows incorrect user entries on D.5.4.1.1 and D.5.4.1.2. The answers are reversed when printing the pdf.
Technical Improvement	Major	ECT-2632	Improve the resolution of the components that should have a field help tooltip

Additional information

Important note regarding Enhanced Form Logic

In v8.1, when specific values are entered into certain fields in an entry form, this will also auto fill other relevant fields without requiring a manual input. The enhanced form logic is based on the following criteria:

- Auto-population of child/dependant fields with the contents of parent fields to make the form sections easier and quicker to fill in, reducing the amount of duplicate data entry.

Please note that the auto-population of child/dependent fields is only activated on initial data entry but subsequent changes/corrections of the parent field are not carried over to child fields. For example the initial entry in A.1 Member state in which the submission is being made will be auto-filled in D.2.1.2, Country that granted the MA, however if the user changes the value in A.1, the update will not be cascaded to D.2.1.2.

- For subsequent changes/corrections, the child/dependent fields need to be updated manually – they do not change automatically. This approach is taken to avoid users having entered data changed or deleted without their knowledge.

Installation steps deviating from the deployment guide

None.