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Release notes

EudraCT Version: 8.2.1

Goal: Major Release

Release Date: 01/06/2012

Environment: Production

Release Contents:

This is an enhancements release to production of the EudraCT application. It includes the following main functional changes:

- Revision of the validation rules including, in particular, the mandatory validation rules. The validation of the fields at the time of data entry has been enhanced focusing on those fields which are to be made public in the EU Clinical Trial Register (EU CTR) in order to improve the overall quality of data recorded in EudraCT and displayed in the EU CTR.

- Certain validation rules have been improved for clearer and more user-friendly data entry.

- Help text updates and changes for EEA and third country forms reflecting the changed functionality.

- Also included in the secure release is EMA's Gateway functionality. This enables participating NCAs with access to EudraNet to use EMA's Axway Gateway to submit zipped Clinical Trial Applications to EudraCT. Guidance is available through the announcement on the front page of the EudraCT SECURE website, and can be found under Technical Information ➢ Gateway Schemas section of the Supporting Documentation page.

Further software enhancements were made to improve the indexing functionality to enhance the search in EudraCT as well as an Enhanced NCA Search (own NCA or others). It should be noted that for the implementation of these enhancements, the searchable data fields in EudraCT have been reduced to 20.

The impacted use cases are listed below:

Functionality / Use case	Comments
Annex B in relation BUC 55 Validate 3rd country CT Form	Validation rules update to 3rd country
BUC 65 Axway Gateway	NCA Gateway interface to EudraCT
BUC 58 Validate Clinical Trial Application	Validation rules update to EEA

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

Issue Type	Priority	Key	Summary
Change Request	Major	ECT-3640	Change the text description for FEAT6.2.4.
Change Request	Major	ECT-3628	UAT v8.2.1.1 - Should there be a validation in F1.2.1 and F.1.3.1 that a number greater than 0 is entered if F.1.2 or F.1.3 is Yes.
Change Request	Major	ECT-3617	Remove FEAT6.2.2.7a for 3rd country trial as it is not applicable also the green text "If *D.2.1 is No then D.2.3 must be completed".
Change Request	Major	ECT-3610	FEAT6.2.1.28 rule description does not make sense and needs to be re-defined so the users can understand it.
Change Request	Minor	ECT-3606	Add a green text under "*D.3.11.13 Another type of medicinal product?" stating that if "Yes" then "*D.3.11.13.1 'another type of medicinal product'" will have to be completed.
Improvement	Major	ECT-3602	Searching for an inspection record by site country or even trying to open up an inspection record seems to be taking exceptionally long (almost 2 mins) for the record to be displayed.
Improvement	Major	ECT-3594	Clarification required from the business regarding Business rule section D: FEAT6.2.2.9 and FEAT6.2.2.7.
Change Request	Minor	ECT-3579	Move green text "*If F.3.3.7 is 'Yes' then F.3.3.7.1 must be answered" under the field "F.3.3.7" so appears under the field it is referring to.
Change Request	Minor	ECT-3572	Move the green text "If E.6.13 is 'Yes' then E.6.13.1 must be answered" above field E.6.13.
Change Request	Minor	ECT-3571	No rule triggered if E.7.1 is 'Yes' and none of the subsections E.7.1.1, E.7.1.2, E.7.1.3 = Yes.
Improvement	Major	ECT-3570	A green text should be displayed at the top of "E.2.3.1 Sub-study details" explaining that the field only needs to be answered if E.2.3 is 'Yes'.
Improvement	Trivial	ECT-3557	Field descriptions to the rules to be updated so as to be in line with EudraCT forms.
Change Request	Major	ECT-3448	NCA to gateway id mapping.
Change Request	Major	ECT-3435	Changes to gateway message header.
New Feature	Major	ECT-3429	Gateway processing of batch files in a go.
Change Request	Minor	ECT-3425	Find CTAs: 3rd Country option should be added to the 'selected NCA' list.

Issue Type	Priority	Key	Summary
Improvement	Major	ECT-3407	Add cache for EU TCT Countries.
New Feature	Major	ECT-3397	Collect only files with .zip extension.
Bug	Minor	ECT-3590	Selecting to associate a placebo to a responsible site with validation errors does not properly work.
Bug	Minor	ECT-3576	For 3rd country - Incorrect description of feature 6.2.2.22.
Bug	Minor	ECT-3566	Cannot see the words "if" and "LVLS" in the green text description on field E.8.8.
Bug	Minor	ECT-3562	Clicking the "X" icon to delete a MedDRA term does not delete the term, instead the screen is refreshed and you are taken to the top of the screen.
Bug	Minor	ECT-3556	Searching by Sponsor protocol code, sponsor organisation name and Product Trade-name and Product name are case sensitive when using "equals" and at times "Starts with".
Bug	Trivial	ECT-3554	Inspection IMP Reference - fields "Product Name" and "Trade Name" do not display the maximum character length when you click into them.
Bug	Minor	ECT-3552	Searching for a valid inspection reference number, site org name, sponsor protocol code, organisation sponsor name, etc. If a trailing and/or leading space is mistakenly added in the search field, the record is not found.
Bug	Major	ECT-3549	Java exception returned with saving inspection record that has maximum characters in the "inspection comments" field.
Bug	Major	ECT-3543	Searching for trial by selecting NCAs and then ticking to include 3rd Country trials, only return 3rd country trials result.
Bug	Major	ECT-3542	Searching for a disease in own NCA or select NCAs and choose just your own NCA, the result returned includes other organisations.
Bug	Minor	ECT-3536	Editing field "A.5.4 Other Identifier - Identifier" data entered are not retained when viewed back.
Bug	Trivial	ECT-3519	3rd Country forms: Links to add sponsor, IMP, placebos are not centre-aligned on webpage.
Bug	Minor	ECT-3506	Remove from section E the information message concerning E.8.9.1 for 3rd Country.
Bug	Minor	ECT-3504	Remove the green asterisks and information message in the placebos form for 3rd Country.
Bug	Major	ECT-3502	C.1.1 - C.1.3 Legal Rep for Sponsor incorrectly showing same information entered in B.1 Sponsor information when record is edited back.
Bug	Minor	ECT-3490	Without clicking the option to include 3rd country trials when you search for all NCAs, 3rd country trials are also included in the results.

Issue Type	Priority	Key	Summary
Bug	Major	ECT-3488	Logged in as a PIP addressee and entered a few details in some sections of the CT then clicked submit and java exception returned.
Bug	Minor	ECT-3484	Results not only displaying only your own record when you select "Own NCA".
Bug	Trivial	ECT-3483	The field "Include 3rd country results:" should be "Include 3rd country trials". So replace the results with "trials".
Bug	Minor	ECT-3462	Section D8: Error message is displayed twice in the web.
Bug	Major	ECT-3449	Selecting to upload on the public site any CTA that is in edit mode (i.e. reserved by an NCA) you get an error that the record is already being edited.
Bug	Minor	ECT-3445	Inconsistent behaviour - inspection does not seem to process Zip files in which the attachments have been zipped whereas IoC does.
Bug	Minor	ECT-3443	Option selected in "Inspection Organisation" not retained when return to view the search criteria you selected.
Bug	Minor	ECT-3437	Find CTAs: some search criteria are lost when selecting the option "Select NCAs".
Bug	Major	ECT-3436	I do not receive emails for Overnight and Immediate alerts.
Bug	Minor	ECT-3423	Find CTAs: the results are not properly updated when removing NCAs from the list and selecting to view own NCAs.
Bug	Trivial	ECT-3404	CTA View for section D.9 text is not displayed properly.
Bug	Minor	ECT-3388	Section C - Instructions are missing from the contact information fields and from C.1.5.1.
Bug	Major	ECT-3365	Exception occurs when a review is being edited at the same time by concurrent users.
Bug	Trivial	ECT-3364	Section D.8 Placebo Information detail table is not aligned.
Bug	Minor	ECT-3363	Wrong error message is displayed if you upload an invalid xml (IoC, review etc.) and double click on upload button.
Bug	Minor	ECT-3361	Inspection IMP References: Labels are missing on validation errors for product and trade name.
Bug	Major	ECT-3360	Inspections>>Search by Inspection Organisation does not return any records.

Issue Type	Priority	Key	Summary
Bug	Major	ECT-3359	Issue with Placebos-association with IMPs.
Bug	Major	ECT-3324	Inspections >> Exception occurs when clicking on Find.
Bug	Major	ECT-3323	Cannot add a Temporary halt, exception occurs.
Bug	Major	ECT-3317	Field 'A.3 Full title of the trial' is not saved.

Additional information

None.

Installation steps deviating from the deployment guide

None.