



6th October 2011
EMA/814364/2011

Release notes

EudraCT Version: 8.1.2

Goal: Patch/Maintenance Release

Release Date: 10/10/11

Environment: Production (Public)

Release Contents:

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

- Removal of Enhanced form logic for certain fields in the Clinical Trial Application form in section E.8.1.
- Inclusion of additional instructions on IMP Identification form explaining how to access section D.3.8 to D.3.10 of the Clinical Trial Application form.
- Validation rule (Schematron file) corrections and changes for EEA and 3rd Country trials.
- Updates to help text.

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	Additional instructions on IMP Identification form explaining how to access sections D.3.8 to D.3.10. Help text changes and defect fixes.
BUC55 Validate 3rd Country CT Information	Validation rule corrections/updates for 3 rd Country form. Specifically: <ul style="list-style-type: none">• FEAT6.2.1.9• FEAT 6.2.10• removal of FEAT 6.2.1.41• change in description of FEAT6.2.1.55 (so



Functionality / Use Case	Comments
	<p>in line with EEA)</p> <ul style="list-style-type: none"> removal of mandatory rules for E.8.10.2
BUC58 Validate Clinical Trial Application	<p>Validation rule updates/corrections for EEA form. Specifically:</p> <ul style="list-style-type: none"> removal of FEAT 6.2.1.41 removal of mandatory rules for E.8.10.2

Below is the complete list of improvements, changes and defect fixes included in this release.

Issue Type	Priority	Key	Summary
Improvement	Major	ECT-3101	Validation rule correction for FEAT 6.2.1.41 G4 Trial Networks.
Improvement	Major	ECT-3288	Change description of validation rule error message in FEAT6.2.1.55 for third country Clinical Trials to be in line with EEA rule.
Change Request	Major	ECT-3278	Remove enhanced form logic changes from section E.8.1.
Improvement	Major	ECT-3275	Addition of layout improvements to section D.3.8 to D.3.10 to make the section easier for users to locate.
Improvement	Major	ECT-3238	Implementation of validation rules FEAT 6.2.1.9 and FEAT 6.2.1.10 for third country trials (fields D.2.2.3 and D.2.2.4)
Defect Fix	Minor	ECT-3259	Deleting or updating data entered in ATC code field "D.3.3" works incorrectly when user selects a route of administration in section D.3.6.1 or D.3.6.2.
Defect Fix	Minor	ECT-3258	Fix to minor formatting issue in Spanish version of CTA PDF form.
Defect Fix	Minor	ECT-3257	Change "Trial identification" to "Trial Identification".
Defect Fix	Major	ECT-3256	All fields in E.7.1 to E.7.4 now have green circle indicating that they are public fields in the EU Clinical Trials Register.
Defect Fix	Major	ECT-3255	Removal of green circle against fields: "D.2.1.1.3 Marketing authorisation number", "A.4.2 Sponsor's Protocol" and "A.4.3 Sponsor's Protocol Date" as they are not public fields in the EU Clinical Trials Register.
Defect Fix	Major	ECT-3284	Deleting route of administration auto populated in D.3.7 returns the same deleted terms when user updates D.3.6.1 and D.3.6.2.
Defect Fix	Major	ECT-3290	New Business rule for "E.8.10.2 In any country". It should not be mandatory to complete the field if E.8.5 and/or E.8.6.1 is "No".
Defect Fix	Minor	ECT-3287	Fix to Spanish PDF (showing English text "To be Requested" against field H.3.1 rather than Spanish text).
Improvement	Minor	ECT-3295	Improve help text displayed for Initial Required Information screen when creating a new clinical trial.

Defect Fix	Major	ECT-3291	Help text to be corrected or removed on 3rd Country screen for fields E.8.9.2 and E.8.10.2.
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Additional information

None.

Installation steps deviating from the deployment guide

None.