



23 March 2011
EMA/234826/2011

Release notes

Version: 8.0.1

Version Goal: Patch Release

Date: 22/03/11

Environment: production

Version content (testable functionalities/use cases)

Functionality / use case	Comments
SUC Clinical Trials	
SUC Inspections	
BUC05 Fill in CT Application Form	
BUC07 Download and Print PDF Forms	
BUC54 Maintain 3rd Country CT Information	
BUC63 Maintain Clinical Trial Application Data	

Bugs fixed for this version (to be tested towards closure)

Incident Log ID	Summary	Comments
ECT-2897	Production call 98464 - Please remove info on the help in B.5 "If applicable, provide inspectors and other concerned parties..etc"	Help pages: external system



ECT-2890	Netherlands has two organizations. One should only be used within inspections and one anywhere else an NCA is required.	1. In inspections both organizations should be visible. 2. In any other form that prompts for an NCA, only Netherlands - NCA should be visible. Another thing that should be taken into consideration is the xml schematron that should allow only Netherlands NCA in CTA xmls.
ECT-2888	Problem with user's active organizations	If an ECD user has two business cards, one active and another one inactive. The active business card should only be retrieved, so that the user isn't erroneously recognized as from different organization.
ECT-2883	Production - Call : 97368 - CTA xml file with email address containing '&' fails to upload	Email validation pattern has been changed for both XMLs and GUI. The pattern used, complies with the rules described in http://en.wikipedia.org/wiki/Email_address . Moreover the implementation has been changed so it is allowed to upload XMLs containing emails with ending or starting whitespace, tabs and new lines. These ending or starting whitespace, tabs and new lines are removed and are not shown when viewing the CT in GUI, or when saving it to the database or when downloading it.
ECT-2881	Public Site: wrong redirection when selecting to create 3rd Country and then immediately to create EEA clinical trial	In public site, when selecting Create >> Clinical trial >> 3rd Country from the top level menu the Initial Required Page for 3rd Country is displayed. If then Create >> Clinical trial >> EEA is selected from the top level menu the Initial Required Page for 3rd Country is erroneously displayed instead of the EEA one. Note that the appropriate page is displayed if first create EEA is selected and then 3rd Country.
ECT-1391	EudraCT Public Site User - The fields A.1 and A.2 cannot be edited once completed.	Public users are allowed to upload and create EEA CTAs leaving field A1 blank. Note that this is valid only for non- logged in users, for the logged in ones the field cannot even be edited.

Change requests implemented for this version (to be tested towards closure)

Incident Log ID	Summary	Comments
ECT-2882	B.5.3.4 Country to include a word-wide list	Field B.5.3.4 country should include a word-wide list instead of the EEA one.

ECT-2861	Pop-up blocker - unable to save or download XML/PDF files on EudraCT v8 Application.	<p>Quite a few complaints had been sent from the sponsors about the inability to download or save an XML file in EudraCT v8.</p> <p>The solution we had given them was to change their settings by going to internet explorer select Tools> Internet Options> security>custom level> choose "Enable" for automatic promoting for file download. They were not happy with this alternative, as feel it's a breach of security measures. An intermediate page with the download link has been used in order to avoid changing the IE security settings.</p>
----------	--	---

Known issues (for major release EudraCT v8.0)

Incident Log ID	Summary	Comments
ECT-2862	Validation rule error FEAT6.2.4 D.2.1 "is a mandatory field".	Validation rule error: external schematron file
ECT-2757	When a country name is updated and you edit an existing CTA with this name, the field appears to blank out the value	EUTCT-EudraCT Integration Issue, when a country name changes in EUTCT, this should be reflected in the CTA
ECT-2718	biz-validation: FEAT6.2.1.11 is not triggered when D.3.10.2 = Range, and D.3.10.3 = 1 to abc	Validation rule error: external schematron file. The current v8 database model allows an alphanumeric entry to the D.3.10.3 field. This should be a numeric value hence user gets a validation rule error.
ECT-2435	PDF displaying D.4, D.6 D.7 as No even though the fields relating to them have been set to 'Not answered'	This is an issue with a PDF where initially the user selects Yes to fields in Section D, If the user goes back and changes their selection this time to Not Answered, in this scenario D.4, D.6, D.7, the PDF output automatically reset to No.
ECT-1527	CTA screen does not have a cancel button	The UI does not support a cancel button if the user decides in the middle of the edit then there is no button to cancel the current data. They can navigate back to other sections of the menu from the top or left of the screen.

ECT-1513	Clicked to add a Sponsor but then left the screen to view other sections of the CTA on returning a blank Sponsor record was created.	The system creates a record even if no data has been entered. Impacts Section B, G. e.g.; user clicks to 'Add sponsor' and does not enter any data, when you return to sponsor screen; A blank sponsor record is created.
----------	--	---

Additional information

None.

Installation steps deviating from the deployment guide

None.