Release notes

Version: 8.0

 Goal: Final Release

Release Date: 10/03/2011

Version content (testable functionalities/use cases)

Functionality / use case
SUC Consult Data
SUC Clinical Trials
SUC Administration
SUC56 Make Public CT Protocol Information
SUC04 Generate EudraCT Number
SUC Inspections
SUC General Functionality
SUC CT Transcode
BUC04 Generate EudraCT Number
BUC05 Fill in CT Application Form
BUC07 Download and Print PDF Forms
BUC12 Enter EEA CT Application

Functionality / use case
BUC25 Consult Data
BUC49 Use MedDRA
BUC52 Prepare 3rd Country CT Information Package
BUC53 Enter 3rd Country CT Information Package
BUC54 Maintain 3rd Country CT Information
BUC55 Validate 3rd Country CT Information
BUC56 Make Public CT Protocol Information
BUC58 Validate Clinical Trial Application
BUC59 Submit 3rd Country CT Information
BUC62 Submit Clinical Trial Application Package
BUC63 Maintain Clinical Trial Application Data
BUC001 XML Conversion Utility

Known Functional issues/Bugs for this version (to be considered for future release)

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-2530	No alert raised after editing the current record of an Suspension or Prohibition by NCA changing radio buttons from 'No' to 'Not answered'	In v7 there were only two options to select an answer. User could choose Yes or No. In v8 we have three selections Yes, No, or Not Answered. If an NCA chooses to interrupt a trial where the reason IMP, Safety and Efficacy = No then an alert is sent to all NCAs. Few minutes later, NCA goes back and edits the record where reason IMP, Safety and Efficacy = Not Answered then no alerts are sent.
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-2209	Overnight and Immediate alerts - corresponding text entered in the multilingual fields does not appear in the email content	Issue where a CTA has multiple languages. V8 allows other languages in free text fields. When NCA receive any alert they only get the information in English and do not get data entered in other languages e.g. A.3 and E.1.1 fields.
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-1516	BUC05 Fill in CT Application form. FEAT2.4.1 Expand/Collapse sections. But only sections C, E and H are can be expanded	The UI supports expanding or collapsing of a view only in certain sections, this feature is implemented only in Section C, E, and H and not in sections A, B, D, F, and G hence is inconsistent.
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.
ECT-1000	'FEAT 21.5: Reuse of information' not implemented	Validation rule error: external schematron file, automatic load of data fields with already submitted data to minimise data entry e.g.; If the sponsor is also the Applicant there should be a means of populating the field without re-keying

Note: Minor and trivial issues are not included in the release notes.

Additional information

None.

Installation steps deviating from the deployment guide

None.