23 November 2016

Information Management Division

Release notes
EudraCT Result Version: 10.3.0.0
Scheduled Maintenance Release for Production

Release date: 29 November 2016

Release Contents:

The following is a list of the defect fixes identified and change request addressed in this release:

Issue Type	Key	Priority	Summary	Resolution
Change Request	ECTRESIII-2162	Minor	Other milestone achievement comment field size in the Results XML is insufficient and results in the XML submission failing with an unexpected error message if the field size is greater than 50 characters.	The field size has been increased from 50 to 3500 characters.
Change Request	ECTRESIII- 1944	Important	The justification message does not disappear after the result data set is modified as a result of which the justification is no longer required.	This is a workflow step missed by the users. After changing the results data set as a result of which the justification is no longer required, users should validate and save the result. This step is displayed as a message below the text field as a reminder to users to provide a justification comment.
Bug	ECTRESIII-2078	Minor	Pre-assignment milestone -In the PDF, unwanted tags or 'Null' appears in the fields 'Number of subjects Started' and 'Number of subjects Completed' if blank (no data) is available.	Null has been replaced by blank
Bug	ECTRESIII-2083	Important	In the online results, after the end point measure type has been changed from measurable to countable (and saved), if the XML is downloaded , the same XML could not be uploaded due to some measurable values remaining.	During the change from measurable to countable (done by the user), all measurable values are completely reset.
Bug	ECTRESIII- 2106	Important	XML results upload does not prevent upload where duplicate categories exist in the	Duplicate categories (ignoring case, multiple spaces and preceding and trailing spaces) for the same baseline

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			baseline characteristics or in End points	characteristic or end points are detected and upload prevented with an appropriate message.
Change Request	SD-17461	Important	Increase the number of options for letter refusal with the new updated list of reasons	The existing letter refusal reasons were updated and new ones added as per the list provided.
Change Request	SD-25469	Important	Update EMA contact information in the EudraCT Results footer.	EMA contact information in EudraCT Result footer has been updated
Bug	SD-17674	Important	Missing <tendencyValue> and <dispersionValue> for End points in the XML resulted in an error when clicking on 'View' or 'download PDF'.	The missing values error has been fixed and the PDF is displayed correctly.
Change Request	SD-17399	Important	Extend confidence interval/geometric mean field length in end points to accommodate up to 15 digits before decimal and 10 digits after decimal	The field name has been increased to 15 digits before the decimal and 10 digits after the decimal.
Bug	SD-17589	Important	XML with countableValue / tendencyValue / dispersionValue provided with no categoryId for End points with category should be rejected.	If the Endpoints define categories, the system prevents upload of XML that have an Endpoint with values without a link to any categories.
Bug	SD-17596	Minor	Correctly handle Endpoint validation if the 'Countable' or 'Measurable' is not selected online, or in the XML.	If no countable or measurable is selected, the validation now displays appropriate message highlighting the missing data instead of failing with unexpected error.
Bug	SD-17597	Minor	Baseline Characteristics data in PDF was missing but appears when PDF was generated again.	This issue could not be replicated. The quality control team confirmed that the system behaves as expected.
Change Request	SD-53337	Minor	Request to add a new dosage (concentration) unit 'vector genomes (vg)/mL' in section D 3.6.1 of CTA.	A new dosage (concentration) unit 'vector genomes (vg)/mL' as been added and appears in the list for D 3.6.1 in the CTA online form.