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EMA/19969/2016
Information Management Division

EudraCT release notes

Results version: 10.2.1.0

Goal: Restoration of service

Release date: 13 January 2016

Environment: Production

Contents

Summary of release 10.2.1.0

Release 10.2.1.0 is an unscheduled release to restore EudraCT – Results functionality following withdrawal of the service on 31 July 2015.

The focus of this release is fixing bugs that potentially affect data submitted to the system, and addressing issues that introduce difficulties in submitting results information.

Major items fixed in release 10.2.1.0

The full release contents listing includes instances of multiple symptoms that relate to a single root cause. The major items fixed, being the root causes described, are summarised in this section.

Type	Description	Resolution
Timestamp	Some data might be displayed incorrectly, due to the use of a timestamp as a key (which is non-unique in some circumstances). Trying to fix the data on screen lead to incorrect allocation of data in the database. This happened in the "Baseline Characteristics" and in the "Adverse Events" sections.	The application has been amended to prevent the creation of duplicated constructed timestamps. Display also uses other identifiers to ensure correct allocation.
Category	Some data might be displayed incorrectly due to the use of the internal sequence of data to order that display, when that order does not necessarily mirror the one being used to sequence the categories they belong to. Trying to fix the data on screen lead to incorrect allocation of data in the database. This happened in the "End Points" section.	The application is now sorting the data using the specific Arm and Category identifiers.
Subject non-completion reasons display	In the Non-Completed/joining Reasons, some of the 'Other' reasons definitions were duplicated preventing some information to be grouped. This occurred in instances where the data was prepared outside of the EU CTR application where some Non-Completed/joining Reasons, rather than being defined once and re-used, were defined multiple times – often slightly differently (leading/trailing spaces or difference in case).	Validation has been added on loading to prevent such duplicates in XML files from being loaded. A data fix has been applied to eliminate data left behind by previous versions following significant changes in results submitted.
Grouping of subject non-completion	In the table displaying the number of subjects for non-other non-completion/joining reasons, some of the values are missing and the total number	The XML upload now prevents duplicates from being accepted, rejecting the XML upload with appropriate message identifying the

Type	Description	Resolution
reasons	of subjects does not add up. Moreover XMLs downloaded from EudraCT could not be uploaded back due to missing non-other non-completion/joining reasons reference. This is because some of the 'non-Other' reason definitions were duplicated preventing some information to be grouped. This occurred in instances where the data was prepared outside of the EU CTR application where some non-other Non-Completed/joining Reasons, rather than being defined once and re-used, were defined multiple times.	duplicate.
PDF Page-break	If a field containing a long text is printed across page boundaries, some of the data might be not displayed correctly or might be missing	The description field settings have been amended in order to cope with page breaks.
Data missing	In the Adverse Events, both in the Serious AE and Non Serious AE, some rows could have been not displayed as the code searched for the address of containers of information, rather on the basis of the content itself. Thus, if the same value was entered twice, it would be considered as different as the container would not be the same.	When searching for the rows, the application now compares the contents themselves rather than the containers.
Milestones apparently repeated	The same milestone was defined more than once. The definition differed by either a leading or trailing space or difference in case (lower case/upper case), resulting in the application considering the two instances as different milestones.	(1) Introduced a feature to eliminate leading and trailing spaces on online load into the database for milestones. Introduced validation on these aspects within the XML upload feature to prevent duplication for both milestones. (2) For existing data with spaces, added quotation mark to assist users identify the fact that the space(s) is/are there, in case of milestone.

Known issue in release 10.2.1.0

The issue that causes the order of display of reporting groups and results to differ through the results set has not been addressed. The reporting groups and results themselves are correct; it is only the display order that is affected.

Full release contents – Issues fixed

Issue Type	Key	Service Desk Reference	Priority	Summary
Bug	ECTRESIII-1909	428466 439226	Major	When trying to re-order category names (endpoint section) by clicking MOVE UP or MOVE DOWN and then clicking SAVE, error message: ?An unexpected application error has occurred?
Bug	ECTRESIII-1913	436358	Minor	?Subjects? is spelt incorrectly in two headings in the pdf on Adverse Events
Bug	ECTRESIII-1915	436554 437428 443201	Major	PDF is not completely displaying all the data where a page break has been entered into the system
Bug	ECTRESIII-1916	436822	Major	SAEs entered into the record do not show up when I take a pdf download
Bug	ECTRESIII-1919	428465	Major	Entering an endpoint that has approximately 45 categories - after approx 36th, error message: "Component categoriesList has invalid value expression null"
Bug	ECTRESIII-1920	441518	Major	The values are changing automatically such that the measure value is not between the low and high range values.
Bug	ECTRESIII-1921	444575	Major	The values of Confidence Intervals in Outcome Measures # 2 and 3 interchange among the categories within the respective outcome measures
Bug	ECTRESIII-1922	442555	Major	(1) the text of the measure description of endpoints is found missing; (2) there is an unwanted 'enter' in PDF
Bug	ECTRESIII-1945	465016	Major	Confidence intervals are not correct in the Endpoints
Bug	ECTRESIII-1952	470568	Critical	Several arms were swapped within the platform; tried to update the results according to the presented (swapped) groups as seen in the second screenshot, however when I save the results the values "jump back" to what they were initially.

Issue Type	Key	Service Desk Reference	Priority	Summary
Bug	ECTRESIII-1953	465739	Minor	when an intermediate milestone is deleted from a result record on the user interface, these entries are not deleted; Leads to validation error as intermediate milestone is empty
Bug	ECTRESIII-1954	N/A	Minor	Data entered for a period is deleted when 'Copy product' is clicked
Bug	ECTRESIII-1957	N/A	Major	Clinical Trial Result XML upload generic error "Unexpected error while uploading/processing the selected file"
Bug	ECTRESIII-1962	N/A	Minor	Why XML tag for superscript is coming up on result PDF? - 473994
Bug	ECTRESIII-1964	N/A	Critical	Upon doing various downloads and upload of the XML the data are swapped around i.e. given to another reporting group.
Bug	ECTRESIII-1965	450452	Major	The data that I entered for the two arms swapped places.
Bug	ECTRESIII-1967	N/A	Major	Field mapping error when providing reasons for update
Bug	ECTRESIII-1970	N/A	Major	The end points categories id was picking the first category values ID instead of picking the correct categories id
Bug	ECTRESIII-1971	N/A	Major	Result view only : Some information missing on the view screen if there are a lot of reporting groups/categories
New	ECTRESIII-1973	N/A	Major	XMLs uploaded to results (Full result set or adverse events) should be archived so that a history of XMLs uploaded is maintained
Bug	ECTRESIII-1976	478920 478932 467155 469689	Major	(1) Day 1 and Day 5 least squares means had switched places, but the confidence intervals did not. (2) Data in the baseline characteristics section switching between groups when the record was saved
Bug	ECTRESIII-1978	447314	Major	The values of Confidence Intervals in End points # 2, 3 and 9 interchange among the categories within the respective end points

Issue Type	Key	Service Desk Reference	Priority	Summary
Bug	ECTRESIII-1979	450904	Minor	On the training platform, pre-assignment intermediate milestone data is validated in the incorrect order
Bug	ECTRESIII-1981	N/A	Major	in Results subject disposition, 2 rows created by the system for 'Not specified' and there should only be 1.
Bug	ECTRESIII-1982	453681	Major	Study arms for adverse event section are interchanging (reshuffling) automatically
Bug	ECTRESIII-1985	459520	Major	Going from the xml to the pdf file, data are interchanging between rows (and sometimes between columns) for certain reporting groups
Bug	ECTRESIII-1986	460735	Major	The values of Confidence Intervals in Secondary End points # 5 and 9 interchange among the categories within the respective end points
Bug	ECTRESIII-1987	462091	Major	The mean, lower limit and upper limit data are frequently switched around
Bug	ECTRESIII-1989	467994	Major	14 different SAEs were entered in the system and can be seen in edit mode; the view and pdf modes, however, shows only 12 SAEs
Bug	ECTRESIII-1990	473453	Major	Comparison groups in the statistical analysis section of secondary endpoint #3 are being doubled when previewed
Bug	ECTRESIII-1991	464454	Major	In the Non-Serious Adverse events section, the event "Malnutrition (SOC-Metabolism and Nutrition Disorders)" is not appearing in the preview of results
Bug	ECTRESIII-1993	451387	Major	Text is missing from the endpoint measure description
Bug	ECTRESIII-1994	441244	Major	RE: values are not being displayed properly in the PDF
Bug	ECTRESIII-1995	452151	Major	One of the endpoints was not fully converted to PDF (Description field in the first secondary endpoint)
Bug	ECTRESIII-1996	453458	Major	Text being cut off in the PDF preview following a page break

Issue Type	Key	Service Desk Reference	Priority	Summary
Bug	ECTRESIII-1997	548759	Major	When you download a PDF copy of the study results oftentimes I have noticed that not all of the text is transferred over to the PDF
Bug	ECTRESIII-1998	459551	Major	The text gets truncated when in the downloaded to pdf format
Bug	ECTRESIII-1999	473531	Minor	I have entered 2 patients discontinued due to consent being withdrawn, but this is not displaying on the pdf preview
Bug	ECTRESIII-2000	N/A	Major	A row ('deaths casually related to treatment / all) in the serious adverse event is missing and the data entered
Bug	ECTRESIII-2003	454470	Major	Several of the reasons for discontinuation display twice
Bug	ECTRESIII-2004	N/A	Major	(1) Data in the categories appeared in the wrong row (were swapped); (2) Data in the baseline measure arms were switched.
Bug	ECTRESIII-2006	474820	Major	Safety XML is not loading into the attached full result record
Bug	ECTRESIII-2007	N/A	Major	Disposition table: In PDF, one category's label of "Not completed reason" repeated in the disposition table where as System had the label only once.
Bug	ECTRESIII-2008	N/A	Major	Second upload of full dataset XML to EudraCT system failed; data for some of categories in both periods of "not completed reason" found missing in PDF whereas those data existed in the system
Bug	ECTRESIII-2009	N/A	Major	Text of Measure description truncated after page break
Bug	ECTRESIII-2011	N/A	Major	When adding late recruitment and other, they are merging together in the same cell
Bug	ECTRESIII-2012	N/A	Major	When created a PDF of the record or check the view only screen, the term 'Redness: Any' and its corresponding data does not appear
Bug	ECTRESIII-2021	N/A	Major	Incomplete data appearing for the term 'Redness:Any' for non-serious adverse

Issue Type	Key	Service Desk Reference	Priority	Summary
				event
Bug	ECTRESIII-2025	436554	Major	Truncated text in fields that fall over a page break
Bug	ECTRESIII-2039	N/A	Major	2 rows in the subject disposition displayed when there should be only 1
Bug	ECTRESIII-2044	463947	Major	Error message on saving removal of the category "Number of AEs" from the category title section
Bug	ECTRESIII-2052	442510	Major	Reporting Group 1 shows the incorrect strain sequence
Bug	ECTRESIII-2056	N/A	Major	XML import error in the Training environment
Task	ECTRESIII-2063	N/A	Critical	Check that the duplicate timestamp issue is not a problem here for the subject analysis sets when new version created by copying existing results
Task	ECTRESIII-2066	N/A	Major	Investigation to find out which results sets have been affected by the data swapping issue
Bug	ECTRESIII-2068	N/A	Major	Adverse Event missing data in the PDF
Bug	ECTRESIII-2072	N/A	Major	Two new categorical titles in the baseline characteristics not showing later in the edit screen even though the value screens had them and the values entered - 2 users had worked on the trial
Bug	ECTRESIII-2073	N/A	Major	Two users assigned the trial but one user working on it at a time; entering & saving categories and the values in the age categorical characteristics - error message on clicking Your page [Same as 2072?]
Bug	ECTRESIII-2074	N/A	Major	upload of xml to a different result record expecting error "EudraCT number in the XML is not the same as the trial being used "; Unexpected error reported
Bug	ECTRESIII-2075	N/A	Major	Created 3 intermediate milestones with the number of subjects then saved - could

Issue Type	Key	Service Desk Reference	Priority	Summary
				not delete [Same as 1953]
Bug	ECTRESIII-2076	N/A	Minor	leading & trailing spaces in milestone titles that are otherwise duplicates should generate an error - did not
Bug	ECTRESIII-2079	N/A	Major	Non completion reasons selected online appears to add non serious adverse event twice
Bug	ECTRESIII-2080	N/A	Major	Unexpected error when saving categories in End points with trailing or leading spaces
Bug	ECTRESIII-2081	486551	Major	Example for problem EudraCT xml (File crashes the system)
Bug	ECTRESIII-2082	N/A	Major	Upload result XML error: 'Exception while parsing xml'
Bug	ECTRESIII-2084	N/A	Major	Unable to upload result XML where the milestone title in Pre-assignment and Post assignment are the same
Bug	ECTRESIII-2085	N/A	Major	Upon validating the result an error message indicated that the measure type value is not between the low and high values reported. Go to page' by the error message shows the categories are not sorted; Go from the 'Edit' or 'Enter values' screen & the categories are sorted correctly
Bug	ECTRESIII-2087	N/A	Major	Unable to upload a result xml
Bug	ECTRESIII-2088	N/A	Major	Other type Milestones with null pre and post assignment should be restored
Bug	ECTRESIII-2089	N/A	Blocker	When xml is uploaded, if there are multiple 'long term follow-up rationale' entries, only the last one is uploaded
Bug	ECTRESIII-2090	N/A	Major	Entered category title and started counting the values, but on the value screen the category titles entered were not displayed
Task	ECTRESIII-2091	N/A	Minor	Trim other reasons for non-completion and subject joining reasons so as to avoid

Issue Type	Key	Service Desk Reference	Priority	Summary
				duplicate being created with a space.
Bug	ECTRESIII-2092	438764	Major	XML "blinded" flag always "false"
Bug	ECTRESIII-2093	N/A	Major	Chrome Issue : pdf button is off the page on the right, and there is no scroll bar to go further to the right
Bug	ECTRESIII-2094	N/A	Major	Created a results set with the following dataset: An overall period with 2 arms; In both 1st and 2nd arms I entered non completion reasons ' other - Dropped off'. When I tried to upload the downloaded result xml I couldn't. This error message was displayed that a duplicate non-completion reason exists.
Bug	ECTRESIII-2095	N/A	Major	Created an arm for a period; Within the arm selected a number of reasons from the pre-defined list as non-completion reason and number of subjects. Saved this XML and then at uploading an error was displayed that ''Element 'otherReason' is not required for reasonNotCompleted with id = 'ReasonNotCompleted-38466'
Bug	ECTRESIII-2096	N/A	Major	When large data sets are uploaded there is often a transaction timeout resulting in a failure to upload
Bug	ECTRESIII-2098	N/A	Major	The categories list does not support category titles with multiple spaces in between words.
Bug	ECTRESIII-2099	N/A	Major	This is timing out when the xml marshalling takes place
Bug	ECTRESIII-2101	N/A	Major	In 'Arm' page, when arm title, arm description etc are entered and then the Copy Product is clicked, it goes to another screen. Clicking 'done' or 'delete product' brings us to the Arm page again. However the data entered prior to copy product is not retained.
Bug	ECTRESIII-2104	N/A	Major	Unable to upload the attached result xml. Error 'Reason: Other reason should be

Issue Type	Key	Service Desk Reference	Priority	Summary
				filled in when reason is of type Other.'
Bug	ECTRESIII-2105	N/A	Major	Clicking 'copy product' when no product exists takes you out of the application and when you return a null product is inserted.
Bug	ECTRESIII-2107	N/A	Major	Clicked 'Download PDF' or 'View' for a result set which has large data sets in the Adverse event sections = 1174 serious adverse events. When the PDF is finally generated & opened none of the data in the adverse event appear in the report.
Bug	ECTRESIII-2110	N/A	Critical	Unexpected error when uploading a valid adverse event xml file
Bug	ECTRESIII-2111	N/A	Major	Error "Unexpected error while uploading/processing the selected file" when uploading an adverse event XML
Bug	ECTRESIII-2112	N/A	Major	UAT Feedback - End point Data presentation - view screen displays data in the wrong row
Bug	ECTRESIII-2117	N/A	Major	Cut-off date for accepting an attachment only post in training is incorrect
Bug	ECTRESIII-2127	N/A	Major	Large XML files fail when saved after upload
Bug	ECTRESIII-2132	N/A	Major	Database locks were observed during performance testing
Bug	ECTRESIII-2134	N/A	Major	Transaction Response is Not Acceptable for Save Adverse Event

Known errors

Related fixed issue	Description	Workaround	Key (issue to be fixed)
ECTRESIII-1931	The justification is not explicitly removed when no longer required, after clicking on validate, unless the 'Save' button is clicked.	The 'save' must be clicked after validation to ensure justification note no longer relevant, is removed	ECTRESIII-1944

Related fixed issue	Description	Workaround	Key (issue to be fixed)
N/A	Shuffling of Subject analysis set order	None	ECTRESIII-1934
N/A	Arms are switched randomly throughout the sections	None	ECTRESIII-1988

New Validation Violation Messages (for XML upload) in EudraCT - Results 10.2.1.0

Type of error	Example message	Description
Duplicate non-completion Reason	Duplicate value 'NOT_COMPLETED_REASON.adverse SeriousFatal' in element 'reasonNotCompleted' with id = 'ReasonNotCompleted-3862411'	This message is displayed when the same non-other non-completion reason is defined more than once in the XML
Duplicate Joining Reason	Duplicate value 'JOIN_REASON.lateRecruitment' in element 'reasonJoined' with id = 'ReasonJoined-4114111'	This message is displayed when the same non-other joining reason is defined more than once in the XML
Duplicate Other non-completion Reason	Duplicate NOT_COMPLETED_REASON.other otherReason 'dropped off' in element 'reasonNotCompleted' with id = 'ReasonNotCompleted-38626'	This message is displayed when more than one 'Other' non-completion reason has the same 'otherReason' text (ignoring case and leading and trailing spaces) in the XML
Duplicate Other joining Reason	Duplicate JOIN_REASON.other otherJoinedReason 'sent home' in element 'reasonJoined' with id = 'ReasonJoined-41131111'	This message is displayed when more than one 'Other' joining reason has the same 'otherReason' text (ignoring case and leading and trailing spaces) in the XML
Missing otherReason for 'Other' non-completion reason	Element 'otherReason' is required for reasonNotCompleted with id = 'ReasonNotCompleted-38623'	The 'otherReason' text is required when an 'Other' non-completion reason is defined.
otherReason for non-Other non-completion reason not required	Element 'otherReason' is not required for reasonNotCompleted with id = 'ReasonNotCompleted-3862411'	The 'otherReason' text is not required for a non-Other non-completion reason defined.
Missing otherJoinedReason	Element 'otherJoinedReason' is required for reasonJoined with id =	The 'otherJoinedReason' text is required when an 'Other' Joining reason

Type of error	Example message	Description
for 'Other' joining reason	'ReasonJoined-41131111'	is defined.
otherJoinedReason for non-Other joining reason not required	Element 'otherJoinedReason' is not required for reasonJoined with id = 'ReasonJoined-4114'	The 'otherJoinedReason' text is not required when a non-Other joining reason is defined.
Non-existent Arm comparison group id	Incorrect \<armComparisonGroupId\> value Arm-55871'. It needs to be the value of the 'id' attribute of \<armReportingGroup\>	The armComparisonGroupId value should be one of the existing id attribute of armReportingGroup element in the XML
Non-existent subjectAnalysisSetComparisonGroupId reference	Incorrect \<subjectAnalysisSetComparisonGroupId\> value '123456'. It needs to be the value of the 'id' attribute of \<subjectAnalysisSetReportingGroup\>	The subjectAnalysisSetComparisonGroupId value should be one of the existing id attribute of subjectAnalysisSetReportingGroup in the XML
Duplicate other milestone in pre-assignment period	Duplicate otherMilestone \<title\> value 'Milestone 1' in preAssignmentPeriod. Please note the "\<otherMilestone\>" comparision above ignores case, leading and trailing spaces.	The other milestone title (ignoring case and leading & trailing spaces) cannot be repeated in the pre-assignment period.
Duplicate other milestone in post-assignment period	Duplicate otherMilestone \<title\> value 'Milestone 1' under \<otherMilestone\> in postAssignmentPeriod with id 'OtherMilestone-25361'. Please note the "\<otherMilestone\>" comparision above ignores case, leading and trailing spaces.	The other milestone title (ignoring case and leading & trailing spaces) cannot be repeated in the same post-assignment period.
Non-existent otherMilestone reference in preAssignmentPeriod otherMilestoneAchievements	Element otherMilestone with id='OtherMilestone-25361' referenced by otherMilestoneAchievement is not defined in preAssignmentPeriod otherMilestones	The otherMilestoneId attribute in otherMilestoneAchievements element in the preAssignmentPeriod should refer to an existing otherMilestone id
Non-existent EudraCT	EudraCT Number provided in the	If the XML uploaded contains reference

Type of error	Example message	Description
number	XML does not exist	to a non-existent eudract number in the 'eudractNumber' attribute, the system displays the message
End Point: Values absent	End Point: The attribute selected is not consistent with the ready for values selection	The <readyForValues> has a value of true but the reporting group dispersion or tendency values are missing.

Additional information

None.

Installation steps deviating from the deployment guide

None.