15 September 2017
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Information Management Division

Release notes

EudraCT Result Version: 10.4.0.0

Scheduled Maintenance Release for Production

Release date: 28 September 2017

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Release Contents:

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

Issue Type	Key	Summary	Resolution
RFC	SD-90924	Fix for the EudraCT Result users being locked out when there are more than 1000 trials	A technical limitation of 1000 trials per user in retrieving a trial list has been removed.
RFC	SD-90802	Fix for a business rule reporting an error related to the number of deaths when they are not causally related to treatment, in the adverse event section.	The validation rule has been corrected by changing the fields used in the comparison. The tooltip for one of the field was also amended to be more explicit.
BRC	SD-84414	Change the name of Parameter Type in the Parameter Estimates (Hazard ratio, log).	The following new values were added to the drop down: End Points > End Points Values > Statistical Analysis>Parameter estimate>parameter type: - Log hazard ratio - Log odds ratio - Log risk ratio
RFC	SD-82986	An email sent by Results did not have the URL for service desk website.	The service desk link has been revised in line with current EMA practice.
RFC	SD-80084	In Results, where there are HTML tags in the text, the superscript tag was interpreted incorrectly.	The PDF generation is not interrupted when escape characters like '>','<', etc. are present in the text and the superscript '<sup>' is now working as expected. **[Appendix I]**
BRC	SD-57605	Sponsors were not allowed to manage users when the results were in the finalised state.	The change now allows the sponsors to manage the users even if the results are in finalised status.
BRC	SD-42976	Allow duplicates for Adverse Event terms.	The system allows duplication of terms even if they belong to

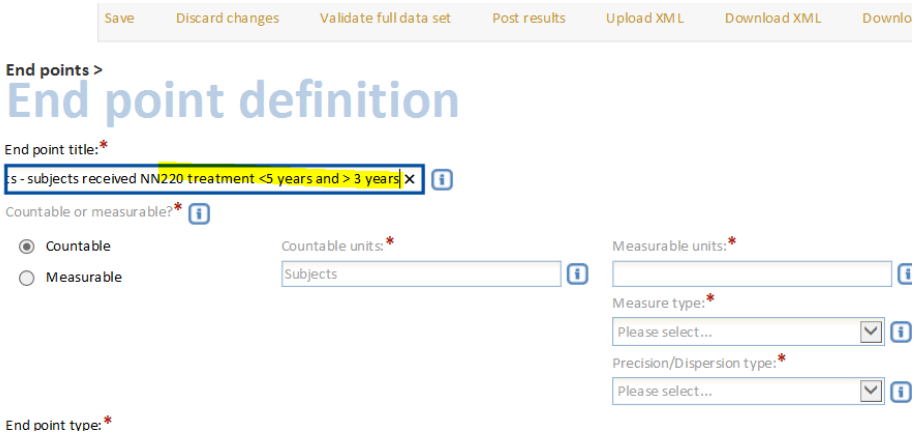
Issue Type	Key	Summary	Resolution
			different system organ class.
BRC	SD-17401	Numbers with trailing zero after a decimal.	The system now outputs the values with the same trailing zero after a decimal. This was done by storing the input value as a string before numerical representation transformation. Values already in the system will not benefit from this enhancement.

1.1. Appendix I

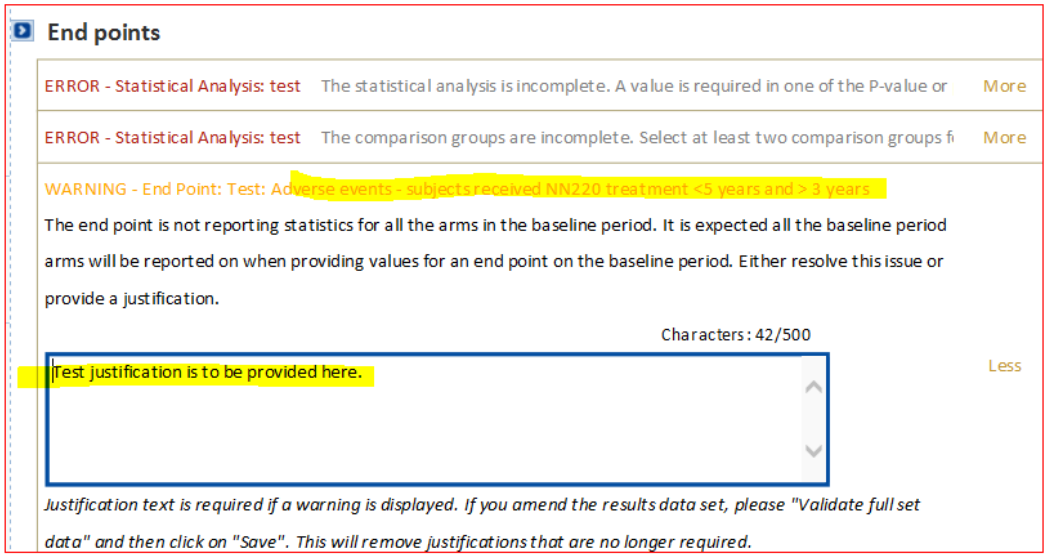
Illustration of Issue SD-80084.

The issue occurs for a certain scenario as follows:

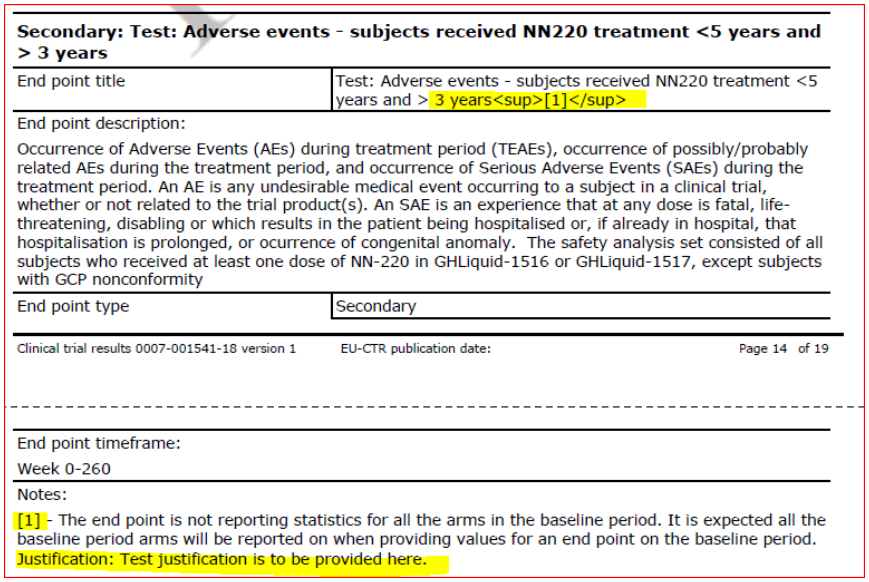
1. Consider the scenario where the end point title contains characters like '>', '<', '≥' , '≤'



2. On clicking 'Validate Full Data set', if the validation report displays warning for that particular end point, a justification text is required (which will appear as a footnote in the PDF).



3. Issue reported: After providing the justification text in step 2 and clicking on ‘Save’, if the PDF is downloaded, the PDF downloaded displays the footnote superscript with ^{as prefix and} as suffix (highlighted in yellow below). This was due to misinterpretation by the PDF generator engine of the symbols ‘>’, ‘<’ in the end point title text as special tags (as a part of rendering code) resulting in incorrectly displaying the superscript to the footnote.



Secondary: Test: Adverse events - subjects received NN220 treatment <5 years and > 3 years

End point title	Test: Adverse events - subjects received NN220 treatment <5 years and > 3 years^[1]

End point description:

Occurrence of Adverse Events (AEs) during treatment period (TEAEs), occurrence of possibly/probably related AEs during the treatment period, and occurrence of Serious Adverse Events (SAEs) during the treatment period. An AE is any undesirable medical event occurring to a subject in a clinical trial, whether or not related to the trial product(s). An SAE is an experience that at any dose is fatal, life-threatening, disabling or which results in the patient being hospitalised or, if already in hospital, that hospitalisation is prolonged, or ocurrence of congenital anomaly. The safety analysis set consisted of all subjects who received at least one dose of NN-220 in GHLiquid-1516 or GHLiquid-1517, except subjects with GCP nonconformity

End point type	Secondary

Clinical trial results 0007-001541-18 version 1 EU-CTR publication date: Page 14 of 19

End point timeframe:

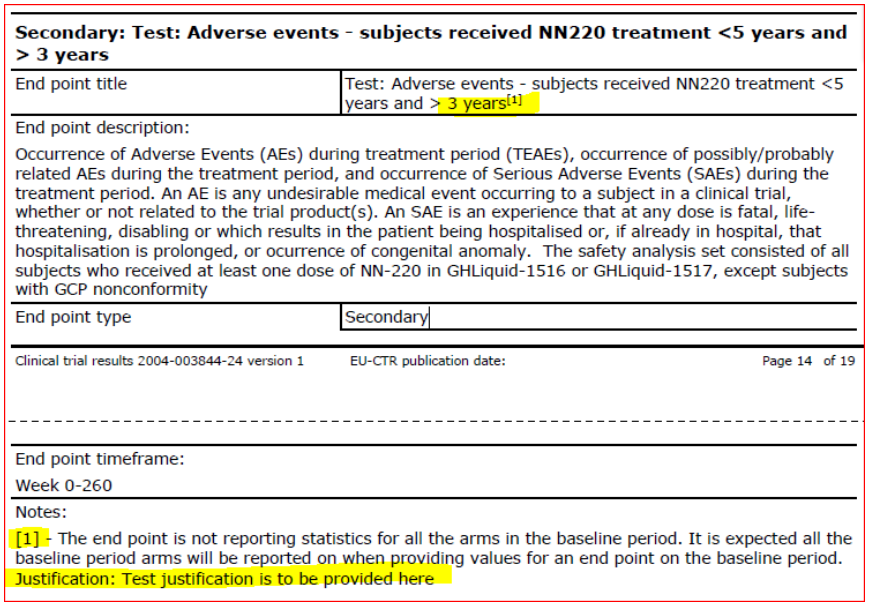
Week 0-260

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Test justification is to be provided here.

4. The current release has resolved the issue occurring in step 3.

So for an end point title containing the symbols ‘>’,’<’, if there exists one or more justification texts for that end point, in the PDF download, the symbols ‘>’, ‘<’, ‘≥’, ≤ are displayed correctly as expected, and the footnote ‘superscript’ appears correctly (highlighted in yellow below). The prefix ^{and suffix} do not appear but is correctly interpreted as superscript commands.



Secondary: Test: Adverse events - subjects received NN220 treatment <5 years and > 3 years

End point title	Test: Adverse events - subjects received NN220 treatment <5 years and > 3 years[1]

End point description:

Occurrence of Adverse Events (AEs) during treatment period (TEAEs), occurrence of possibly/probably related AEs during the treatment period, and occurrence of Serious Adverse Events (SAEs) during the treatment period. An AE is any undesirable medical event occurring to a subject in a clinical trial, whether or not related to the trial product(s). An SAE is an experience that at any dose is fatal, life-threatening, disabling or which results in the patient being hospitalised or, if already in hospital, that hospitalisation is prolonged, or ocurrence of congenital anomaly. The safety analysis set consisted of all subjects who received at least one dose of NN-220 in GHLiquid-1516 or GHLiquid-1517, except subjects with GCP nonconformity

End point type	Secondary

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End point timeframe:

Week 0-260

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Test justification is to be provided here