

Product Update

LoT/ToC validation, new checks and table visualization improvement

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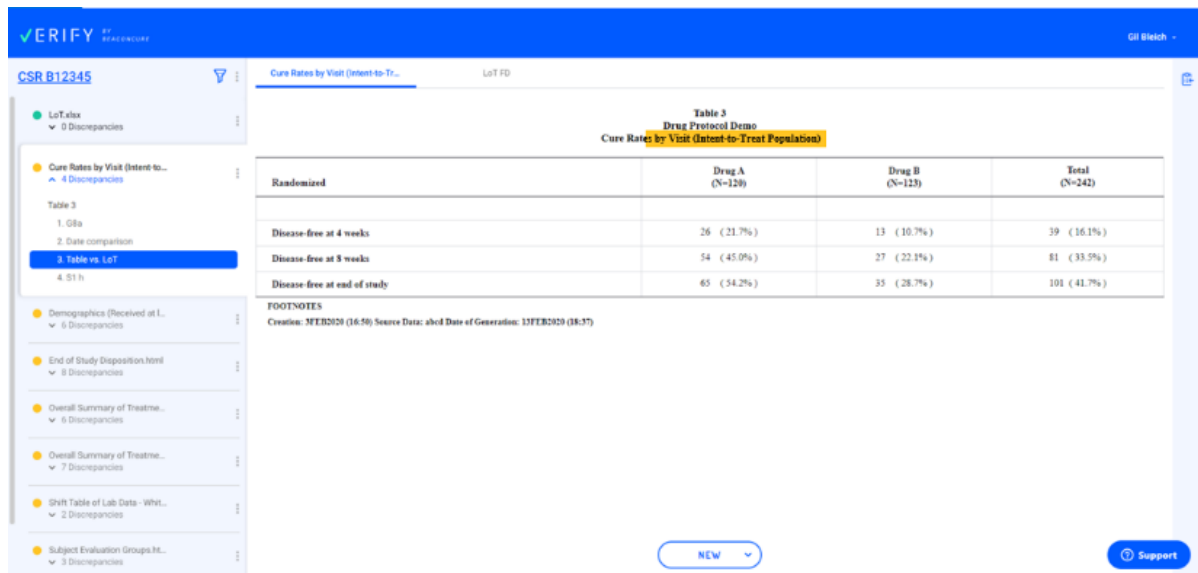
'List of Tables'/'Table of Content' Validation

The List of Tables (LoT) is one of the most important documents produced by the biostatistician for a new study. It defines all the deliverables required for the study. This file is the source of truth for the generation of the deliverables.

'Verify Outputs' can now validate the LoT to find discrepancies at a very early stage and prevent tables to be produced with mistakes. Also, 'Verify Outputs' will use the LoT to validate tables, ensuring they follow the LoT's requirements.

A display of the LoT in 'Verify Outputs' with discrepancies originating from the LoT (Table 1):

Table 1



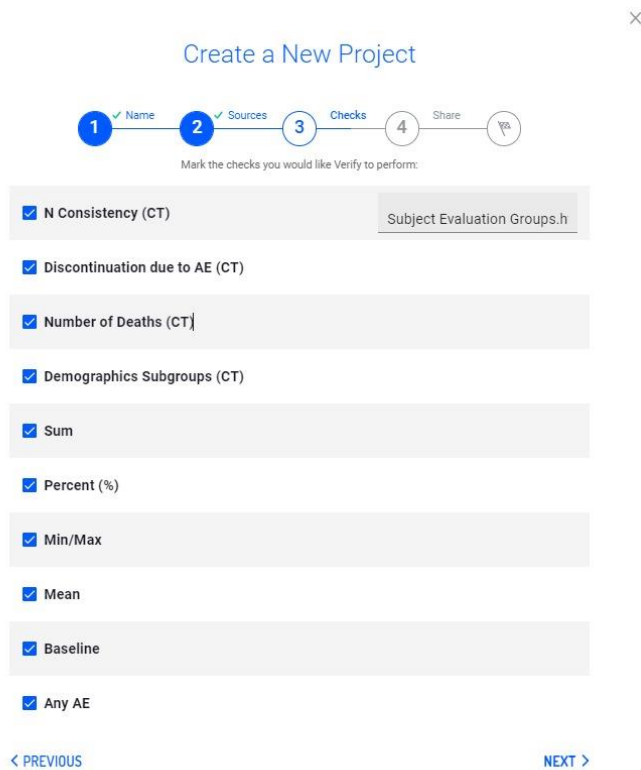
Randomized	Drug A (N=129)	Drug B (N=123)	Total (N=242)
Disease-free at 4 weeks	26 (21.7%)	13 (10.7%)	39 (16.1%)
Disease-free at 8 weeks	54 (45.0%)	27 (22.1%)	81 (33.5%)
Disease-free at end of study	65 (54.2%)	35 (28.7%)	101 (41.7%)

FOOTNOTES
Creation: 3FER020 (16:50) Source Data: ahd Date of Generation: 13FER020 (18:37)

Adding New Checks to the System

- 1. Number of Characters** - validates the LoT file. The check ensures that the number of characters in the Number and Title of each table, listing and figure does not exceed a defined number of characters.
- 2. Table Uniqueness** - validates the LoT file. This check assures that there are no duplicate titles or numbers within the LoT
- 3. Table vs. LoT** - compares uploaded tables to uploaded LoT files. This check compares the number and the title of each uploaded table to the relevant number and title in the LoT. Finding the relevant row in the LoT is done using the file name. The check assures that the number (if it exists) is similar and that the title from the uploaded table is the same as the title from the LoT.

4. **Date Comparison** - comparing the date, the output was produced with the date the data that the tables were run on is ensures that all data is included in the check of the outputs by 'Verify Outputs' and that the reviewers are viewing the most up to date tables. The uploaded tables are validated against the 'Snapshot Date' specified by the user, using the 'Create Project' wizard. Example below:



×

Create a New Project

1 ✓ Name — 2 ✓ Sources — 3 Checks — 4 Share — 5 Yes

Mark the checks you would like Verify to perform:

- N Consistency (CT) Subject Evaluation Groups.h
- Discontinuation due to AE (CT)
- Number of Deaths (CT)
- Demographics Subgroups (CT)
- Sum
- Percent (%)
- Min/Max
- Mean
- Baseline
- Any AE

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Tables Visualization

Our goal is to make it as easy and helpful as possible for our users to work on their tables in 'Verify Outputs'. In the new version, each file is displayed with its status helping the user to focus on the suspected files first. The user will be able to filter by file status and see only the files with discrepancies.

Additional improvement in the visualization of the tables is that now, the faulted files (in yellow) are presented with its cause to better understand why it was flagged as a faulted file.

The hierarchy of files > tables > discrepancies make it easy for the user to find what he is looking for.

See example below:

Demographics (Received at lea... Subject Evaluation Groups.html)

Table 2
Drug Protocol Demo
Demographics (Received at least one dose)

		Drug A (N=119)	Drug B (N=117)	Total (N=236)
Gender	Male	60 (50.4%)	60 (51.3%)	120 (50.8%)
	Female	59 (49.6%)	57 (48.7%)	116 (49.2%)
Age	<18	1 (0.8%)	0 (0.0%)	1 (0.4%)
	18-30	34 (28.6%)	33 (28.2%)	68 (28.8%)
	31-45	36 (30.3%)	37 (31.6%)	73 (30.9%)
	46-65	46 (38.7%)	47 (40.2%)	93 (39.4%)
	>65	1 (0.8%)	0 (0.0%)	1 (0.4%)
Weight (kg)	n	118	115	233
	Mean	75.12	75.34	77.79
	SD	7.34	7.52	7.44
	Median	77.8	78.1	77.9
	Min	62	67	60
	Max	88	89	89

FOOTNOTES
Creation: 3FEB2020 (16:40) Source Data: abed Date of Generation: 13FEB2020 (18:37)

NEW

Support

Summary

Using 'Verify' for LoT validation will ensure that all required outputs are produced, with the correct table number and title throughout the life cycle of the CSR production. This is important as the LoT is a dynamic document that changes frequently. At the same time, it greatly reduces the effort to perform these checks.

The improved visualization will allow users to identify discrepancies much more quickly, greatly improving their productivity.

For more information on implementing a state-of-the-art validation solution, visit Beaconcure today <https://beaconcure.com/> hello@beaconcure.com