

Product Update Verify Outputs Q4 2021

## **Product Update** Verify Outputs

Resolution Feature, Mock shells and Highlights

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## **Resolution Feature:**

Verify Outputs by Beaconcure performs validation checks for clinical trial data. The software analyzes the output tables and alerts if discrepancies were encountered in the data.

Until now, if any issues were detected the users had to find them and fix them. However, there was no track of changes or progress within the platform.

The Resolution Feature was developed to allow users to work on the issues found by Verify while having the progress status recorded. This tool allows teammates to be updated during the process as well.

The main evolution of the resolution feature is that now users can directly add comments in the discrepancy without having to leave the environment. Consequently, users now can write notes, questions, or check comments on other tables, being a faster and more transparent way to keep track of the quality validation process, all in one place.

emo Project 34567	又:		Resolution Notes ×				
tus File	Resolution	A	В	C	D	E	Project File
file_01.html O Discrepancies	:			Placebo	100mg QD	200mg QD	Pending Yesterday, 10:45 AM
Table 1.2.3.4				(N=77)		(N=1556) (N=77)	
				n (%)	n (%)	n (%)	adnr_infr_chg_res_mic.html
file_02.html v 0 Discrepancies		2 Baseline	NI	0	0	0	I will check the data sets
file_name-can be very long.html       0 Discrepancies       file_name-can be very long.html       0 Discrepancies			CLEAR	0	0	0	✓ Ilan Carmeli
		ALMOST CLEAR	5 (50.0%)	5 (50.0%)	5 (50.0%)		
			MILD	5 (50.0%)	5 (50.0%)	5 (50.0%)	D Open 25.10.21, 9:45 AM
		MODERATE	65.50	65.50	65.50	G10	
file_name-can be very long.html			SEVERE	63.50	63.50	63.50	adnr_infr_chg_res_mic.html
		8 Week 2	N1	10.65	10.65	10.65	The subjects missing do not have this information
file_name-can be very long.html			CLEAR	10.65	10.65	10.65	
			ALMOST CLEAR	8 (100.0%)	8 (100.0%)	8 (100.0%)	✓ Ilan Carmeli
file_name-can be very long.html			MILD	0	0	0	Resolved 25.10.21, 845 AM
			MODERATE	0	0	0	G8a
			SEVERE	0	0	0	File2.html
file_name-can be very long.html v 0 Discrepancies			NI	0	0	0	We need to discuss this
			CLEAR	0	0	0	✓ Ilan Carmeli
file_name-can be very long.html v 0 Discrepancies			ALMOST CLEAR	0	0	0	
			MILD	0	0	0	
file_name-can be very long.html v 0 Discrepancies			MODERATE	5 (50.0%)	5 (50.0%)	5 (50.0%)	
			SEVERE	5 (50.0%)	5 (50.0%)	5 (50.0%)	
file_name-can be very long.html • 0 Discrepancies		9 Week 8	N1	0	0	0	
			CLEAR	0	0	0	
file_name-can be very long.html v 0 Discrepancies			ALMOST CLEAR		0	0	
			ALMOST CLEAR	O PENDING -	0	0	



## Mock shell:

In addition to analyzing the output tables, Verify also compares tables to other sources, such as the List of Tables (LoT) and the Mock shells.

The mockshell file is a specification document that describes the desired appearance of the tables in the study, along with the titles, footnotes, and all other information. Each output table must match the text and structure of the reference table in the Mockshell file, and this comparison is currently done manually by the programmer. This checking is time consuming and labor-intensive, however, when done by a machine the situation is different.

ny TEAEs	Drug A ae_over_5_safety.rtf	Drug B Mock shell	Total							
ny TEAEs	ae_over_5_safety.rtf	Mock shell								
ny IEAEs		All Contractions and the								
			Tab	le 14.1.1.16						
	Treatment Emergent Ad	verse Events Occurri	ng in >5% of Subjec		Group by System Organ Cla	ass and Prefer				
astrointestinal Disorders				ver_5_safety						
Diarrhoea		Table 14.1.1.16								
Vomiting	Treatment Emergent adverse Events Occuring in >5% of Subjects in One Treatment Group by System Organ Class and Preferred T (Safety Population)									
	-		(Safety F	pulation)						
efections & Infestations										
			TABLE VI	EW, COMING SOON						
espiratory, Thoracic and Mediastinal Disorders										
Cough										
					and calculations					
number of subjects in the specified group, or the total sample.	This value is the de N = number of subjects in th	e specified group, or the t	otal sample. This value is	s the denominator for the percent	age calculations.					

## **Highlight:**

Furthermore, the highlight feature was created to capture all the differences in the text. This element is responsible for distinguishing any word changes, removal, or addition. Beaconcure's text difference algorithm can recognize those cases and mark the differences accordingly. In consequence, the user can locate and fix the issues rapidly and smoothly.