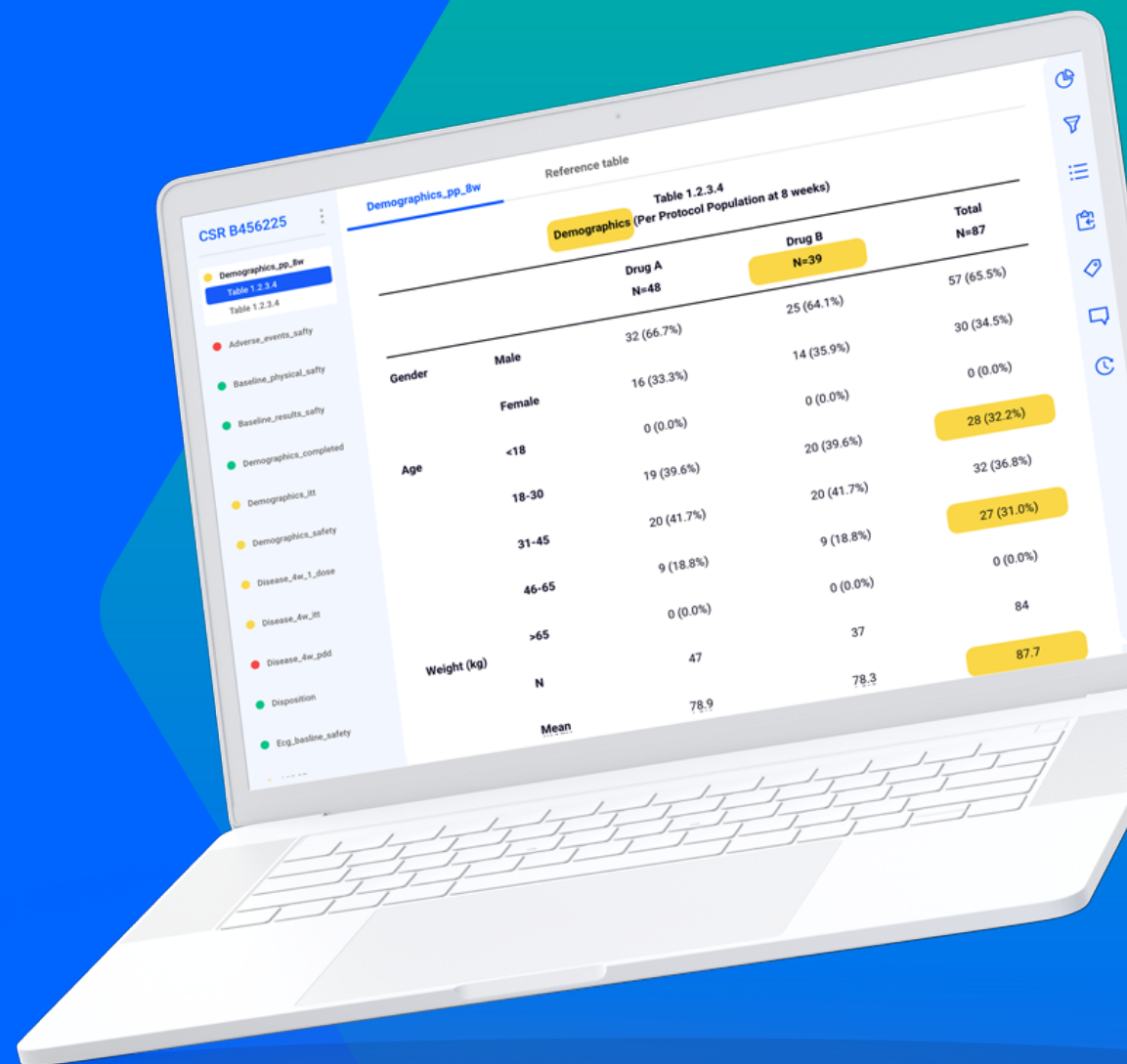


The Emerging Use of Automation to Address the Challenges of Cross-Table Checks

CHECKING OF OUTPUT USED IN THE REPORTING OF CLINICAL TRIALS



Reference table

Demographics_pp_8w

Table 1.2.3.4

Table 1.2.3.4

Demographics (Per Protocol Population at 8 weeks)

		Drug A N=48	Drug B N=39	Total N=87
Gender	Male	32 (66.7%)	25 (64.1%)	57 (65.5%)
	Female	16 (33.3%)	14 (35.9%)	30 (34.5%)
Age	<18	0 (0.0%)	0 (0.0%)	0 (0.0%)
	18-30	19 (39.6%)	20 (39.6%)	28 (32.2%)
	31-45	20 (41.7%)	20 (41.7%)	32 (36.8%)
	46-65	9 (18.8%)	9 (18.8%)	27 (31.0%)
	>65	0 (0.0%)	0 (0.0%)	0 (0.0%)
Weight (kg)	>65	0 (0.0%)	37	84
	N	47	78.3	87.7
	Mean	78.9		

Hugh Donovan | Beaconcure Senior Advisor

Naama Feilchenfeld | Data Analytics Team Leader

Topics

- ▶ Current QC Processes
- ▶ Cross Table QC Challenges
- ▶ Benefits of Automation
- ▶ Implementing Automation
- ▶ Examples
- ▶ Conclusion

Current QC Processes

2021 INDUSTRY SURVEY

The current QC approach is double programming for all companies

28%

Double program the complete table including format.

The remainder check
Numbers only

68%

Double program all output. The rest QC a subset of the outputs

44%

Do manual checking in addition to double programming

Current QC Processes

2022 INDUSTRY SURVEY

86%

Perform cross table checks

50%

Write programs to perform some of the cross table checks

50%

Have specifications for the cross table review

- ▶ In all cases, a biostatistician performs the consistency review

Cross Table QC Challenges



Lack of Completeness



Lack of Consistency



Human Error



Labor Intensive



Manual > Automated



Tasks are unattractive
to Biostatisticians

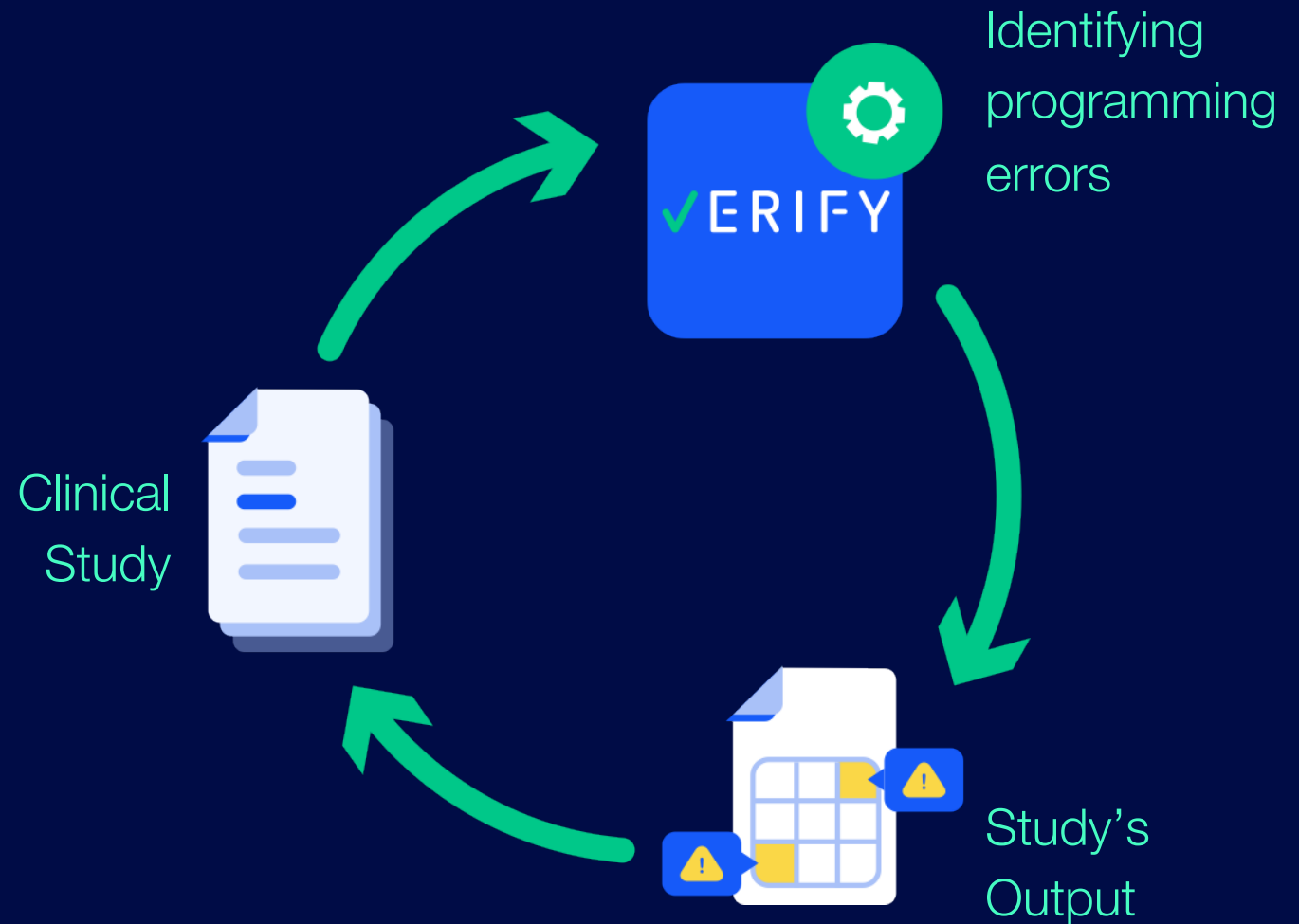
Benefits of Automation

- ✓ Ensures a review that is:
 - ✓ Consistent
 - ✓ Comprehensive
 - ✓ Replicable
- ✓ Significant time and cost saving
- ✓ Frees up highly skilled resources
- ✓ Improves job satisfaction for Biostatisticians

Implementing Automation

Beaconcure's Verify automation is designed to implement cross-table checks throughout the study.

The technology can be used multiple times as data accumulates



Use *Verify* for Multiple reports

- ✓ Clinical Study Reports
- ✓ Interim Analyses
- ✓ Safety Updates
- ✓ Output for Data Monitoring Committees

How is This Implemented?

- ▶ Reference Table
- ▶ General Cross Table (cell matching)
- ▶ Summation Cross Table
- ▶ Footnote Comparison

Reference Table

Table 14.1.1.2 Analysis Population			
	Drug A	Drug B	Total
Randomized Population	120	117	237
Safty Population	119	117	236
Received at least one dose	119	117	236
Completed 4 weeks	89	87	176
Per Protocol Population at 4 weeks	80		
Completed 8 weeks	82		
Per Protocol Population at 8 weeks	48		
Completed Study (12 weeks)	75		
CONFIDENTIAL SDTM Creation: 08OCT2021 (00:55) Source Data: advs Table Generation: 09OCT2021			

Table 14.1.1.19 Summary of Treatment Emergent Adverse Events & Serious Adverse Events (Safety Population)			
	Drug A (N=119)	Drug B (N=117)	Total (N=236)
Any TEAEs	61 (51.3%)	69 (59.0%)	130 (55.1%)
TEAE Causing Death	0 (0.0%)	0 (0.0%)	0 (0.0%)
Severe TEAEs	5 (4.2%)	1 (0.9%)	6 (2.5%)
Treatment-Related TEAE	6 (5.0%)	19 (16.2%)	25 (10.6%)
Discontinued due to TEAEs	5 (4.2%)	6 (5.1%)	11 (4.7%)
Serious Adverse Events	3 (2.5%)	1 (0.9%)	4 (1.7%)
Treatment-Related Serious Adverse Events	1 (0.8%)	0 (0.0%)	1 (0.4%)
N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.			
CONFIDENTIAL SDTM Creation: 08OCT2021 (00:55) Source Data: advs Table Generation: 09OCT2021			

General Cross Table (cell matching)

Disposition.rtf

Overall_AE.rtf

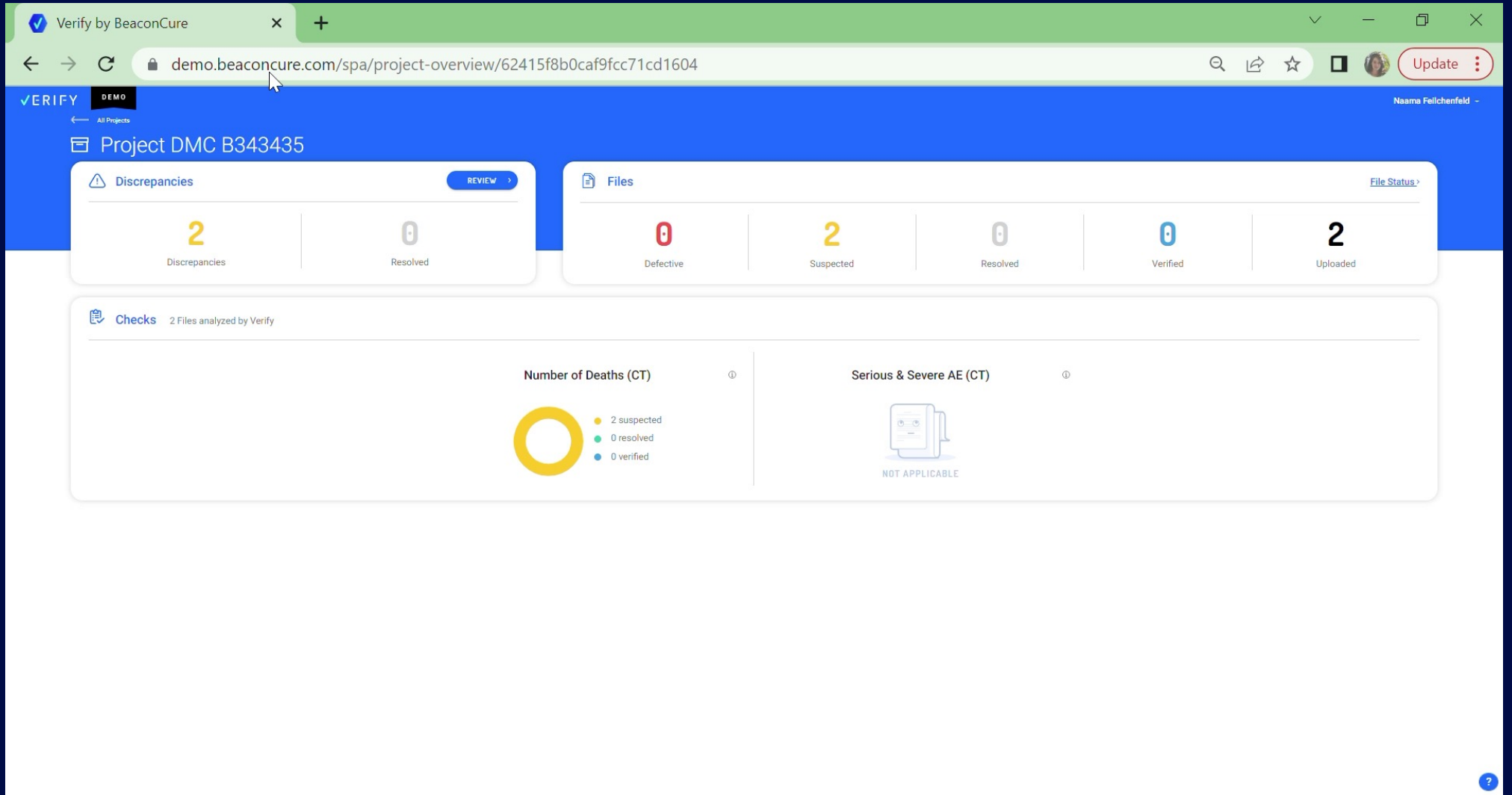
Table 4 Overall Summary of Treatment Emergent Adverse Events (Safety Population)			
	Drug A (N=119)	Drug B (N=117)	Total (N=236)
Number (%) of Participants	n (%)	n (%)	n (%)
Any AEs	73 (61.3)	88 (75.2)	161 (68.2)
Any TEAEs	75 (63.0)	85 (7.2)	156 (66.1)
Serious TAEs	3 (2.5)	6 (5.1)	8 (3.4)
Drug Related TEAs	17 (14.3)	27 (23.1)	44 (18.6)
Discontinued due to TEAEs	7 (5.9)	6 (5.1)	13 (5.5)

Disposition.rtf

Overall_AE.rtf

Table 7 End of Study Disposition				
	Drug A (N=119)	Drug B (N=117)	Total (N=236)	
Number (%) of Participants	n (%)	n (%)	n (%)	
Completed	101 (84.9)	99 (84.6)	200 (84.7)	
Discontinued	18 (15.1)	18 (15.4)	36 (15.3)	
Treatment Emergent Adverse Events	5 (4.2)	6 (5.1)	11 (4.7)	
Death	1 (0.8)	2 (1.7)	3 (1.3)	
Lost to Follow-up	7 (5.9)	4 (3.4)	9 (3.8)	
Protocol Deviation	3 (2.5)	0	1 (0.4)	
Withdrawal by Subject	2 (1.7)	0	2 (0.8)	
Other	0	0	0	

Display in Verify



Summation CT

Table 14.1.2.4
Overall Summary of Treatment Emergent Adverse Events
(Safety Population)

	Drug A (N=119)	Drug B (N=117)	Total (N=236)
Any AEs	73 (61.3%)	88 (75.2%)	161 (68.2%)
0-4 Weeks:			
Any TEAEs	75 (63.0%)	85 (72.6%)	156 (66.1%)
Serious TEAEs	3 (2.5%)	17 (14.3%)	7 (5.9%)
Drug-Related TEAEs	17 (14.3%)	27 (23.1%)	44 (18.6%)
Discontinued due to TEAEs	7 (5.9%)	9 (7.7%)	16 (6.8%)
4-8 Weeks:			
Any TEAEs	48 (40.3%)	38 (32.5%)	86 (36.4%)
Serious TEAEs	1 (0.8%)	3 (2.6%)	4 (1.7%)
Drug-Related TEAEs	12 (10.1%)	20 (17.1%)	40 (16.9%)
Discontinued due to TEAEs	3 (2.5%)	4 (3.4%)	7 (3.0%)
8-12 Weeks:			
Any TEAEs	25 (21.0%)	20 (17.1%)	45 (19.1%)
Serious TEAEs	0 (0.0%)	1 (0.9%)	1 (0.4%)
Drug-Related TEAEs	7 (5.9%)	5 (4.3%)	12 (5.1%)
Discontinued due to TEAEs	1 (0.8%)	1 (0.9%)	2 (0.8%)
0-12 Weeks:			
Any TEAEs	83 (69.7%)	93 (79.5%)	176 (74.6%)
Serious TEAEs	3 (2.5%)	7 (6.0%)	10 (4.2%)
Drug-Related TEAEs	28 (23.5%)	30 (25.6%)	58 (24.6%)
Discontinued due to TEAEs	11 (9.2%)	14 (12.0%)	25 (10.6%)

Note: Subject 003-005 was randomized to Drug A but received Drug B in error.
The Safety Population is all subject who received at least one dose of medication.
Any AE is any adverse event that began after the beginning of the screening period.
Any TEAE is any adverse event that began after the first dose.
Cutoff date: 03MAY2021 Snapshot date: 03MAY2021

Table 14.1.1.4
Demographics (Received at Least One Dose)

	Drug A	Drug B	Total
Gender			
Male	60 (51.3%)	60 (50.8%)	120 (50.8%)
Female	59 (48.7%)	57 (49.2%)	116 (49.2%)
Age			
<18	1 (0.8%)	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	1 (0.4%)
Weight			
n	118	115	233
Mean	75.12	75.34	77.79
SD	7.34	7.52	7.74
Median	77.8	78.1	77.9
Min	62	67	62
Max	88	89	89

Note: Subject 003-005 was randomized to Drug A but received Drug B in error.
Cutoff date: 03MAY2021 Snapshot date: 03MAY2021

Footnotes Comparison

Table 01

N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.		
n = Number of subjects with the sp		
CONFIDENTIAL SDTM Creation	16SEP2021	Source Data: advs Table Generation: 09OCT2021

Table 02

N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.		
BEACONCURE CONFIDENTIAL SDTM Creation		
	03OCT2021	Source Data: advs Table Generation: 09OCT2021

Questions?

Schedule a Demo
At booth 27



A large teal triangle graphic pointing to the right, located on the left side of the slide.

Visit us at booth 27

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