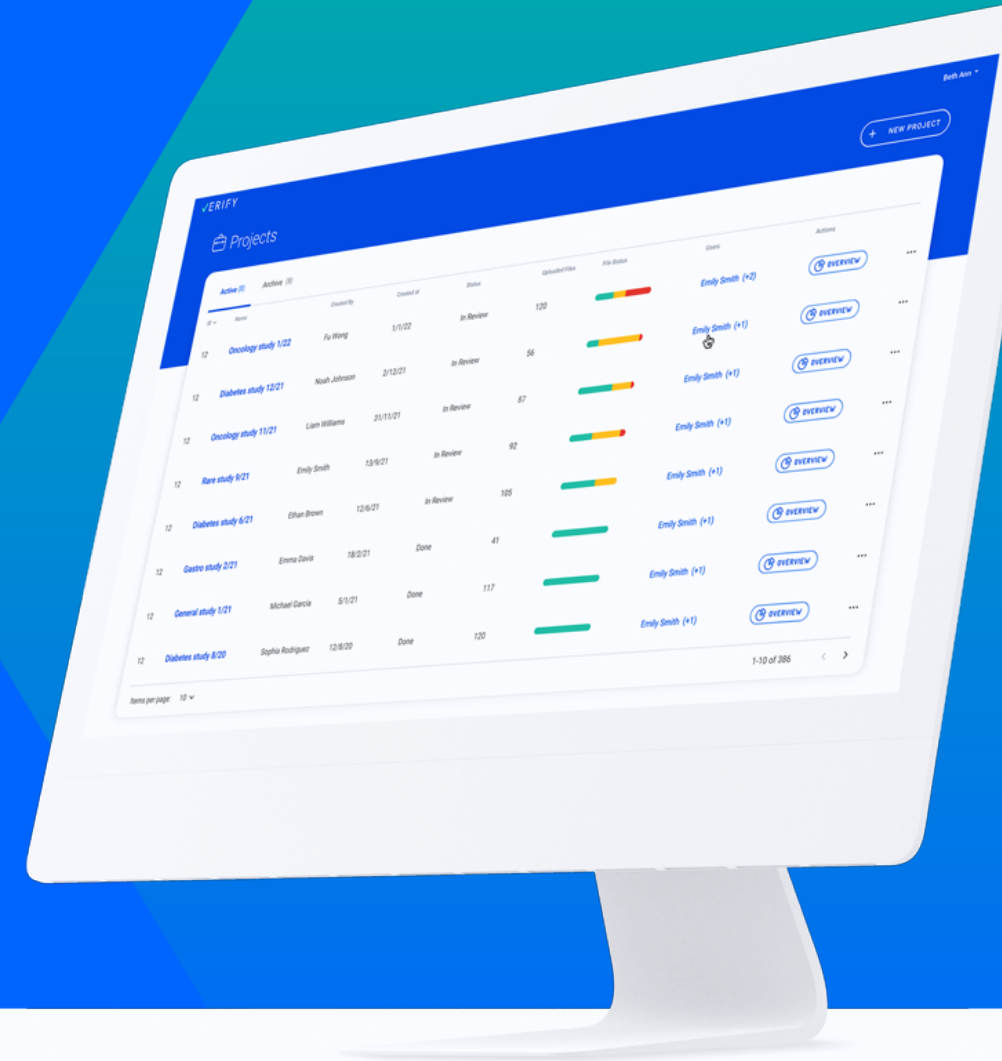


VERIFY PRODUCT DEMONSTRATION:

Validation of Statistical Outputs Using Automation

Yoran Bar | CEO and Co-Founder of Beaoncure
Ilan Carmeli | CPO and Co-Founder of Beaoncure



Agenda

- ▶ Challenge
- ▶ Outcomes
- ▶ Why discrepancies occur
- ▶ Solution
- ▶ Use Cases
- ▶ Product Advantages
- ▶ Product Demonstration
- ▶ Summary
- ▶ Q&A

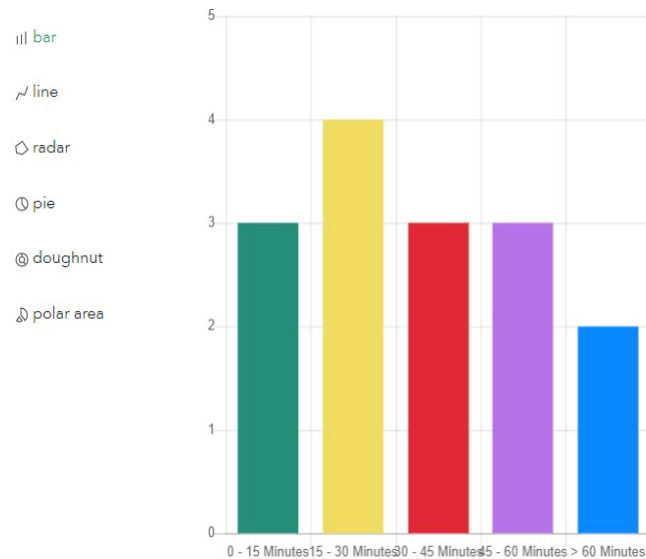
The Current Challenge:

Validation of statistical output
is performed manually,
is time consuming
and error prone.

Beaconcure run a survey with 15 leading industry companies

Question 1

How much time does it take to perform QC a table on average, using manual review?



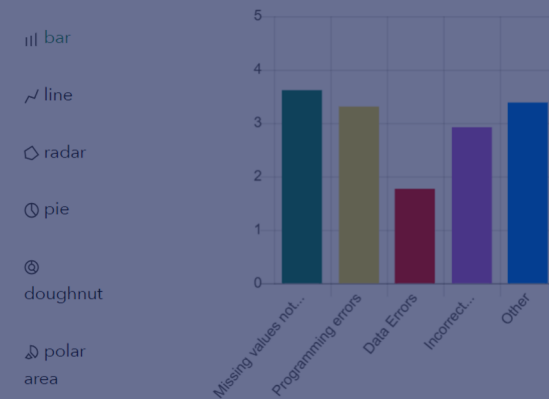
Hide question

Add a filter to this question

Weighting the results

Question 2

Rate below as the most common reasons for discrepancies discovered in the QC. 1 - Unusual to 5 - Extremely Common



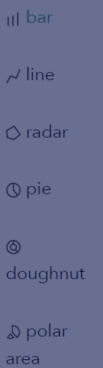
Hide question

Add a filter to this question

Weighting the results

Question 3

Rate below as the most common reasons for discrepancies discovered in the QC. 1 - Unusual to 5 - Extremely Common



Survey Findings on Work Efficiency:

15

Companies
participated

34

Minutes
Per table

28

Hours
Per small study

Survey Findings on Collaboration:



Communication on studies is performed via **email**



Tasks are shared using Excel with no **workflow**

Survey Findings on Reasons for Discrepancies :



Incorrect
Specification



Data
Issues



Programing
Errors

✓VERIFY Software

Together with Pfizer's stats programming team,
Beaconcure developed Verify.

Pharma and CRO groups use verify for:

Data Accuracy

Accelerated Delivery

Risk Reduction

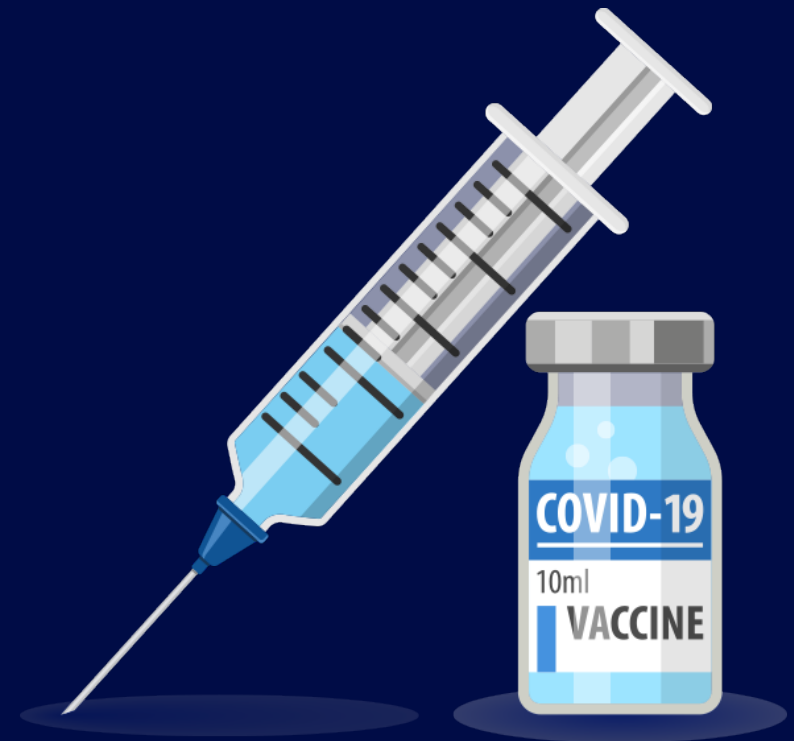
Process Improvement



BUSINESS USE CASE 1:

COVID-19 VACCINE CATALYST

Proven results in expediting the approval of the COVID 19 vaccine to market.



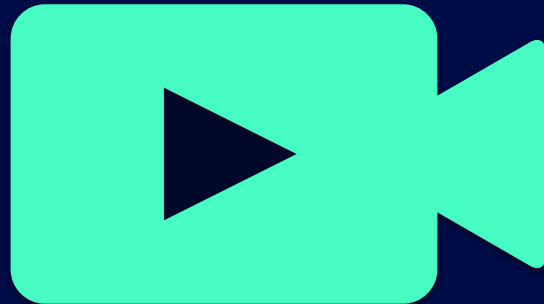
BUSINESS USE CASE 2:

Finding Errors in Data

Disposition.rtf OverallIII_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 OverallIII_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	

Verify Demo



https://drive.google.com/drive/folders/1w_JnAzOfT0lEdFGxRvpuU8KcCe9JtT_E?usp=sharing

Available Checks

Cross Tables Checks

Table 14.1.1.31 Summary of Complete Healing Rate (%) for each population by Treatment (Randomized Population)			
Randomized	Drug A (N=118)	Drug B (N=117)	Total (N=235)
	(%)	(%)	(%)
4 weeks ITT	46.7	35.0	40.9
8 weeks ITT	60.0	39.3	49.8

Table 14.1.1.2 Analysis Population			
	Drug A	Drug B	Total
Randomized Population	120	117	237
Safety 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	61	141
Completed 8 weeks	82	75	157
Per Protocol Population at 8 weeks	48	39	87
Completed Study (12 weeks)	75	69	144

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Within Tables Checks

Table 14.1.1.1 Subject Disposition by Site						
	Randomized	Treated	Completed 4 weeks of treatment	Completed 8 weeks of treatment	Completed Study	Completed 4 weeks T
Site 001	25	24	24	23	20	1
Site 002	25	25	22	20	19	1
Site 003	24	24	22	22	21	1
Site 004	22	22	19	18	16	1
Site 005	0	0	0	0	0	0
Site 006	18	18	14	13	11	0
Site 007	25	25	22	20	17	1
Site 008	25	25	22	22	20	1
Site 009	24	23	20	20	18	1
Site 010	25	25	22	21	16	1
Site 011	25	25	22	21	17	1
Total	237	236	209	200	175	10

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Available Checks

Specs Checks

ae_over_5_safety.rtfMock shell

	Drug A (N=119)	Drug B (N=117)	Total (N=236)
Any TEAEs	61 (51.3%)	69 (59.0%)	130 (55.1%)
Gastrointestinal Disorders	39 (32.8%)	48 (41.0%)	87 (36.5%)
Diarrhoea	25 (21.0%)	35 (29.9%)	60 (25.4%)
Vomiting	20 (16.8%)	30 (25.6%)	50 (21.1%)
Infections & Infestations	10 (8.4%)	10 (8.5%)	20 (8.5%)
Respiratory, Thoracic and Mediastinal Disorders	11 (9.2%)	10 (8.5%)	21 (8.9%)
Cough	10 (8.4%)	8 (6.8%)	18 (7.6%)

N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
Subjects are only counted once per event in each row.

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Date Checks

	Drug A (N=119)	Drug B (N=117)	Total (N=236)
Any TEAEs	61 (51.3%)	69 (59.0%)	130 (55.1%)
Gastrointestinal Disorders	39 (32.8%)	48 (41.0%)	87 (36.5%)
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Lessons learned from processing 100+ studies

1. Supporting Programmers and Statisticians with automation de-risks the submission through increased quality.

Visualizing the discrepancies promotes team discussions within the platform.

Finding issues in content and format earlier in the process accelerates delivery.

Verify Roadmap



WorkFlow
Features



Specs
Digitization



DIY
Mode



Adding More
Checks



Support
Additional
Data

Questions?

Schedule a Demo
At booth 27



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

Visit us at booth 27

llan@beaconcure.com

www.beaconcure.com