



Taking down the fence between Biostatistics and Medical writing

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Presentation overview

- Goal
- What is needed to reach our goal
- Result so far
- Challenges
- Still to-do
- Conclusion



- Faster CSR generation
- Better quality/accuracy

Example of generated text

Unsolicited AEs were reported in **123 (12.3%)** of the patients in the **study drug** and **123 (12.3%)** of the patients in the **control group**.

Grade 3 adverse events were reported in **1 (1%)** of the patients in the **study drug** and **1 (1%)** of the patients in the **control group**.

What is needed to reach our goal?

- Stop working in 2 silos (medical writing and biostatistics)
- Better quality/accuracy
- New technology using natural language generation available for medical writing
- Structured results-data generated by biostats

Structured results data

- 2 key needs for the results data
 - Consistent dataset structure
 - Metadata within the data

Structured results data

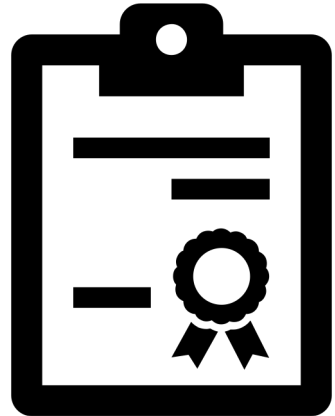
Consistent dataset structure

TITLE	POP	ANALYSISVAR	GROUP1	GROUP2	RESULTVAR	RESULTVAL
Summary of Basline Characteristics	Exposed Set	REF	Table 14.1.1	Table 14.1.1		
Summary of Basline Characteristics	Exposed Set	n	200	100		
Summary of Basline Characteristics	Exposed Set	n	200	100	Age	
Summary of Basline Characteristics	Exposed Set	Mean	51	50	Age	
Summary of Basline Characteristics	Exposed Set	Median	52	49	Age	
Summary of Basline Characteristics	Exposed Set	Minimum	3	1	Age	
Summary of Basline Characteristics	Exposed Set	Maximum	98	100	Age	
Summary of Basline Characteristics	Exposed Set	n	110	60	Age category	>=50
Summary of Basline Characteristics	Exposed Set	%	55	60	Age category	>=50

Metadata

Result so far

- 50% time saving in authoring draft compared with manual interpretation of results



- No errors
- Consistency between CSR's



Challenges

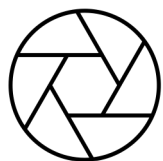
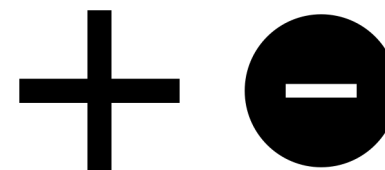
Fear of losing job



Mindset change: Continues delivery of updated results



Planning: Last minute addition or removal of analysis



Seamless integration of tools required coordination between many parties

Still to-do

- Add more interpretation content for the CSR to increase automation
- Reporting tools modernization, including generating Analysis Results Data and aligning copilot tool with ARD
- Full automated flow from SCE to copilot tool

Conclusion

- Large part of the CSR can be written pre-SAC and content refreshed with push of a button
- Medical writers, after having used the tool, don't want to do without and can't wait to have more content automation
- Professional change management is needed to help with mindset change
- Proper analysis results data is needed for full benefit
- Biostatistics can focus more on the content, instead of formatting numbers

Thank You



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