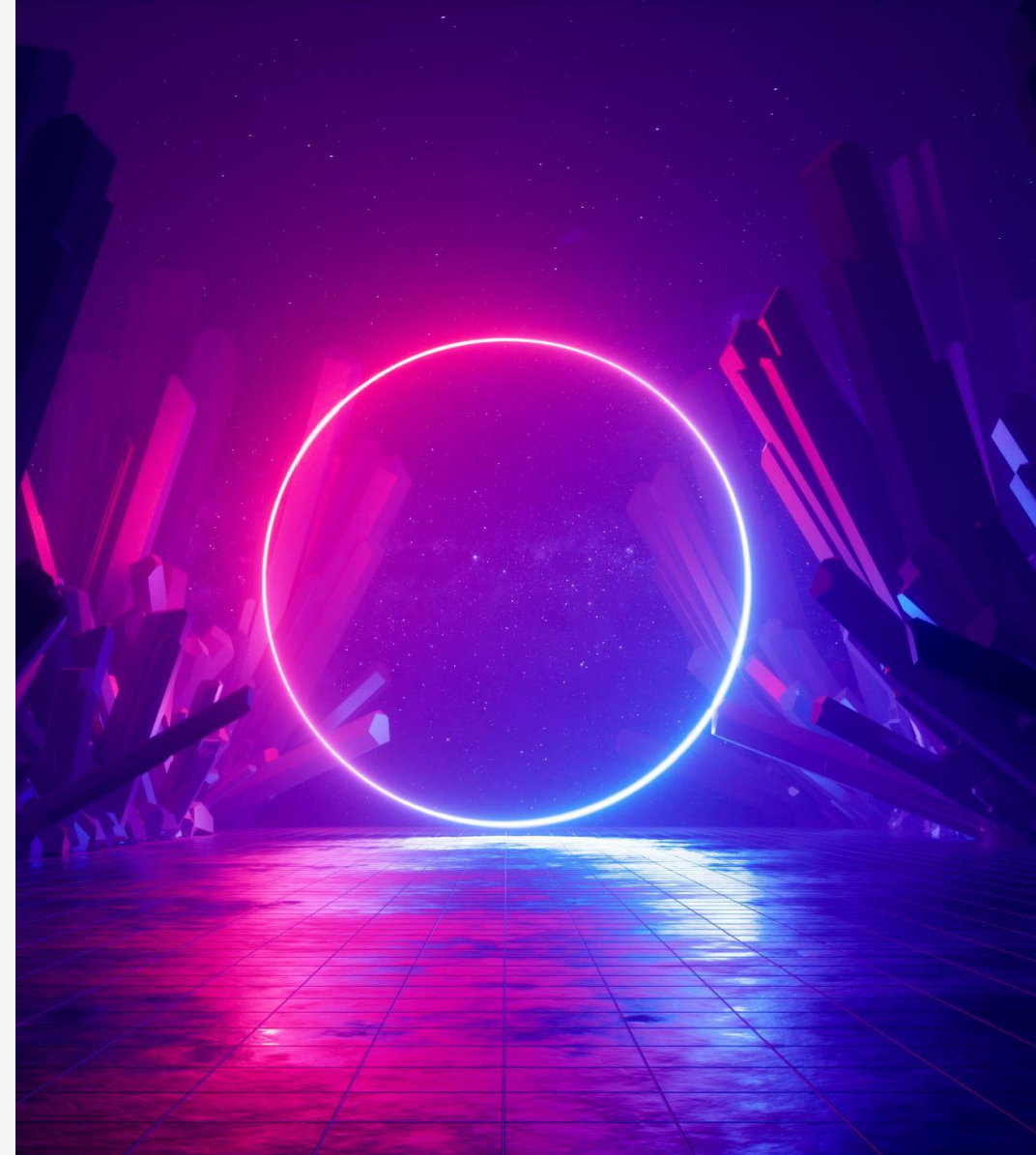


AI-Automation for Post-Text to In-Text Conversion

Mark Pittman

Symbiance/ZYLiQ



AI Fears

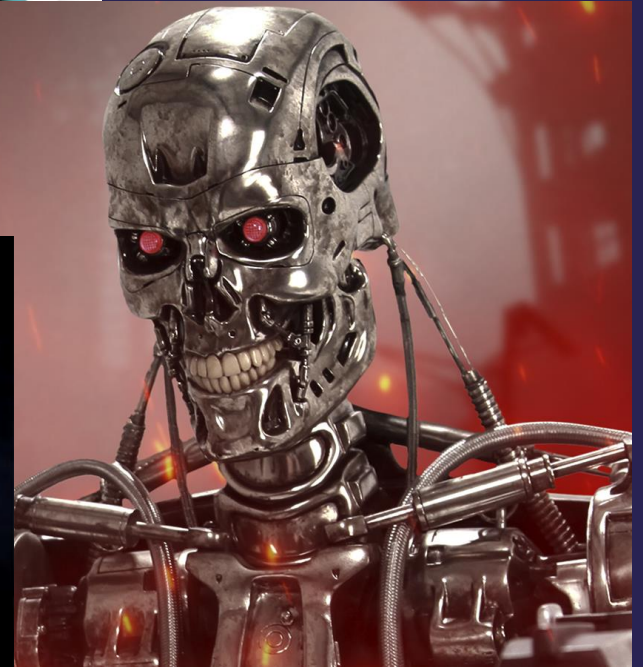
- Taking Jobs
- Unsupervised Creation
- AI Bias

- Taking over the world...

Sarah Connor seeing you become friends with ChatGPT



SHALL WE PLAY A GAME



AI Reality

- Man-plus machine (human IS needed)
- Time and place for letting a machine work

Formatted processes

Repetitive

Data-heavy



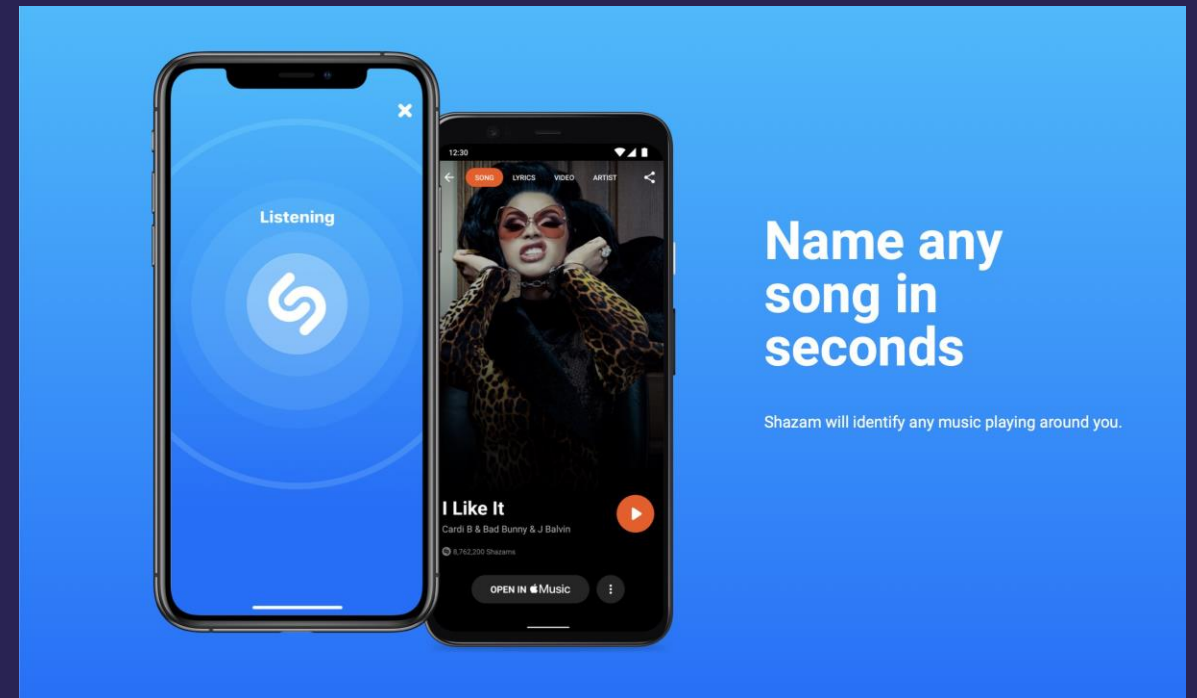
AI/ML We Don't Think About

- Where we already trust/use AI/ML

Siri & Alexa

Shazam

Predictive Texting (names)



The Digital Elephant

- Why Chat GPT is not a fit for CSR's
- Why you need AI focused (ML) fed ONLY by your data/sources




Calling ChatGPT on its 'bulls*'**

Yahoo News · Michael Isikoff


How much can we really trust artificial intelligence?


AI Bridging Biostats/Medical Writing

- High Biostat programming time/cost for In-text tables
- Medical Writing's In-text needs
 - Specific Formatting
 - Removing Irrelevant Results
- Errors arise from copy/paste of table data


 CSR Template

 Post-Text to In-Text

 Source Documents

 Find & Retrieve

 Edit CSR

 Finalize CSR

 Reports

1	Title Page	
2	Study Synopsis	
3	Table of Contents	
4	List of Abbreviations & Definition of Terms	
5	Ethics and Regulatory Approval	
6	Investigators and Study Administrative Structure	
7	Introduction	 >
8	Study Objectives	 >
9	Investigational Plan	 >
10	Study Population	 >
11	Efficacy Evaluation	 >
12	Safety Evaluation	 >
13	Discussion and Overall Conclusions	
14	Tables, Listings and Figures/Graphs	

Upload Post-Text Tables



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Table of Contents

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📁 Select Files

Table (Upload Files)

Submit

Delete All

📄 Table 14.1.1.1 ✖

📄 Table 14.1.1.4 ✖

📄 Table 14.1.3 ✖

📄 Table 14.2.2.6.12.2 ✖

📄 Table 14.3.2.4.1 ✖

📄 Table 14.3.1.1.8 ✖

📄 Table 14.3.2.6.2.2 ✖

📄 Table 14.3.1.1.1 ✖

📄 Table 14.1.4.1.1 ✖

📄 Table 14.1.4.1.15 ✖

📄 Table 14.3.2.3.1 ✖

📄 Table 14.3.2.2.1 ✖

Post-Text Table Extraction

The screenshot displays a software interface for document processing. At the top, a document titled "SYM-21 SYMBIAN..." is open, with a "Post-Text to In-text" button and a notification bell icon. Below this, a navigation bar includes "Upload TLF", "Table of Contents", "Build In-Text Table", and "View Final In-Text" buttons, along with a "Back to Source Documents" link. The main area is titled "Table (Upload Files)" and contains a list of files, each with a "RTF" icon and a red "X" mark. A "Process Status" dialog box is overlaid on the file list, showing a progress bar and the text "Table Extraction In-Progress - 68% Completed".

SYM-21 SYMBIAN... | Post-Text to In-text | 0

Upload TLF | Table of Contents | Build In-Text Table | View Final In-Text | Back to Source Documents

Table (Upload Files) | Submit | Delete All

Table 14.1.1.1 | Table 14.1.1.4 | Table 14.1.3

Table 14.2.2.6.12.2 | Table 14.3.2.4.1 | Table 14.3.1.1.8


Table 14.1.4.1.1




Table 14.3.2.2.1

Process Status


Table Extraction In-Progress - 68% Completed

Create Table of Contents Post-Text Tables

SYM-21 SYMBIAN... 

Post-Text to In-text   

Upload TLF **Table of Contents** Build In-Text Table View Final In-Text [Back to Source Documents](#)

Uploaded Table of Contents  Select All

- 14.1.1.1 Enrolled Subjects and Screen Failures
- 14.1.1.4 Subject Disposition and Other Reasons for Discontinuation from Study All Randomized Subjects
- 14.1.3 Analysis Sets All Randomized Subjects
- 14.1.4.1.1 Demographic and Baseline Characteristics Safety Analysis Set
- 14.1.4.1.15 Medical History by System Organ Class and Preferred Term Safety Analysis Set
- 14.2.2.6.12.2 Number of First Occurrence of Treatment-Emergent Adverse Events of Weight Increased by Baseline BMI and Actual Dose at Onset Safety Analysis Set
- 14.3.1.1.1 Cumulative Extent of Exposure Safety Analysis Set
- 14.3.1.1.8

In-Text Table of Contents

Upload completed and Navigating to Config TOC...

Begin to build the In-Text Table of Contents

SYM-21 SYMBIAN... Post-Text to In-text CSB 0 User Profile

Upload TLF Table of Contents Build In-Text Table View Final In-Text Back to Source Documents

Uploaded Table of Contents

Select All

- 14.1.1.1
Enrolled Subjects and Screen Failures
- 14.1.1.4
Subject Disposition and Other Reasons for Discontinuation from Study All Randomized Subjects
- 14.1.3
Analysis Sets All Randomized Subjects
- 14.1.4.1.1
Demographic and Baseline Characteristics Safety Analysis Set
- 14.1.4.1.15
Medical History by System Organ Class and Preferred Term Safety Analysis Set
- 14.2.2.6.12.2
Number of First Occurrence of Treatment-Emergent Adverse Events of Weight Increased by Baseline BMI and Actual Dose at Onset Safety Analysis Set
- 14.3.1.1.1
Cumulative Extent of Exposure Safety Analysis Set
-

In-Text Table of Contents

- Table - 1
Subject Disposition and Other Reasons for Discontinuation from Study All Randomized Subjects
- Table - 2
Analysis Sets All Randomized Subjects
- Table - 3
Demographic and Baseline Characteristics Safety Analysis Set

Create and/or Merge Table

SYM-21 SYMBIAN... Post-Text to In-text CSB 0

Upload TLF **Table of Contents** Build In-Text Table View Final In-Text Back to Source Documents

Uploaded Table of Contents

- 14.1.1.1 Enrolled Subjects and Screen Failures
- 14.1.1.4 Subject Disposition and Other Reasons for Discontinuation Subjects
- 14.1.3 Analysis Sets All Randomized Subjects
- 14.1.4.1.1 Demographic and Baseline Characteristics Safety Analysis Set
- 14.1.4.1.15 Medical History by System Organ Class and Preferred Term Safety Analysis Set
- 14.2.2.6.12.2 Number of First Occurrence of Treatment-Emergent Adverse Events by Baseline BMI and Actual Dose at Onset Safety Analysis Set
- 14.3.1.1.1 Cumulative Extent of Exposure Safety Analysis Set
- 14.3.1.1.8 ...

Create / Merge Table

Table Name *
Adverse Events

Select Table 1 *
▼

Select Tables to Combine *
▼

Footnotes
▼

Create Table

Submit

- Table - 7
Cumulative Extent of Exposure Safety Analysis Set
- Table - 8

Select Tables to Merge

SYM-21 SYMBIAN... Post-Text to In-text CSR 0

Upload TLF **Table of Contents** Build In-Text Table View Final In-Text Back to Source Documents

Uploaded Table of Contents

- 14.1.1.1 Enrolled Subjects and Screen Failures
- 14.1.1.4 Subject Disposition and Other Reasons for Discontinuation Subjects
- 14.1.3 Analysis Sets All Randomized Subjects
- 14.1.4.1.1 Demographic and Baseline Characteristics Safety Analysis
- 14.1.4.1.15 Medical History by System Organ Class and Preferred Term
- 14.2.2.6.12.2 Number of First Occurrence of Treatment-Emergent Adverse Events by Baseline BMI and Actual Dose at Onset Safety Analysis
- 14.3.1.1.1 Cumulative Extent of Exposure Safety Analysis Set
- 14.3.1.1.8

Create / Merge Table

Table Name *
Adverse Events

Select Table 1 *
14.3.2.2.1 Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term

Select Tables to Combine *
14.1.4.1.15 Medical History by System Organ Class and Preferred Term

- 14.1.4.1.15 Medical History by System Organ Class and Preferred Term
- 14.3.2.3.1 Treatment-Emergent Adverse Events Leading to Discontinuation from Study Drug by System Organ Class and Preferred Term
- 14.3.2.4.1 Treatment-Emergent Adverse Events Requiring Interruption of Study Drug or Dose Adjustment by System Organ Class and Preferred Term
- 14.3.2.6.2.2 Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term

Submit

Safety Analysis Set

Category Safety Analysis Set

se Events by System Organ Class and Preferred Term

ts Leading to Discontinuation from Study Drug by System Organ Class and Preferred Term Safety Analysis Set

ts Requiring Interruption of Study Drug or Dose Adjustment by System Organ Class and Preferred Term Safety Analysis Set

ts by MedDRA SMQ^a Terms Related to Suicidality Safety Analysis Set

Analysis Set

Table - 13
Adverse Events

Create as part of In-Text Table of Contents

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Upload TLF **Table of Contents** Build In-Text Table View Final In-Text ← Back to Source Documents

Uploaded Table of Contents

Select All

- 14.1.1.1 Enrolled Subjects and Screen Failures
- 14.1.1.4 Subject Disposition and Other Reasons for Discontinuation from Study All Randomized Subjects
- 14.1.3 Analysis Sets All Randomized Subjects
- 14.1.4.1.1 Demographic and Baseline Characteristics Safety Analysis Set
- 14.1.4.1.15 Medical History by System Organ Class and Preferred Term Safety Analysis Set

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Submit

- Table - 8**
Extent of Exposure by Duration Category Safety Analysis Set 🗑️
- Table - 9**
Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term Safety Analysis Set 🗑️
- Table - 10**
Treatment-Emergent Adverse Events Leading to Discontinuation from Study Drug by System Organ Class and Preferred Term Safety Analysis Set 🗑️
- Table - 11**
Treatment-Emergent Adverse Events by MedDRA SMQ³ Terms Related to Suicidality Safety Analysis Set 🗑️
- Table - 12**
Adverse Event 🗑️ 📄

Delete Table


Ability to Edit Title, Footer...

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14.1.1.4 Subject Disposition and Other Reasons for Discontinuation from St... 

Symbian Protocol Symbian-21 core study Page 1 of 1

Table 14.1.1.4
Subject Disposition and Other Reasons for Discontinuation from Study
All Randomized Subjects

	Placebo (N=16) n (%)	DrugX (N=16) n (%)
Randomized, n	16	16
Not treated, n	0	0
Treated, n (%)	16 (100.0)	16 (100.0)
Completed Core Study, n (%)	12 (75.0)	16 (100.0)
Discontinued from Core Study, n (%)	4 (25.0)	0
Other reason(s) for discontinuation ^a , n (%)		
Adverse event ^b	0	0
Subject choice	1 (6.3)	0
Inadequate therapeutic effect	1 (6.3)	0
Other	0	0

+ -

In-Text Configuration



Title  Footer  Save

Table 1 - Subject Disposition and Other Reasons for Discontinuation from Study All	
	Placebo (N=16) n (%)
<input type="checkbox"/> Randomized, n	16
<input type="checkbox"/> Not treated, n	0
<input type="checkbox"/> Treated, n (%)	16 (100.0)
<input type="checkbox"/> Completed Core Study, n (%)	12 (75.0)
<input type="checkbox"/> Discontinued from Core Study, n (%)	4 (25.0)
<input type="checkbox"/> Other reason(s) for discontinuation ^a , n (%)	
<input type="checkbox"/> Adverse event ^b	0
<input type="checkbox"/> Subject choice	1 (6.3)
<input type="checkbox"/> Inadequate therapeutic effect	1 (6.3)

Ability to Filter...

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Adverse Events

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Table 14.3.2.2.1
Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

MedDRA System Organ Class Preferred Term	Placebo (N=7) n (%)	Drug (N=25) n (%)
Subjects with any TEAE	0	1 (4.0)
Respiratory, thoracic and mediastinal disorders	0	1 (4.0)
Respiratory distress	0	1 (4.0)

+ -

Source: Locking 10.2.7
TEAE = Treatment-Emergent Adverse Event
A TEAE is defined as an adverse event with an onset date, or a worsening in severity from baseline (pre-treatment), on or after the first dose of study drug up to 28 days following study drug discontinuation.
Subject with two or more adverse events in the same system organ class (or with the same preferred term) is counted only once for that system organ class (or preferred term).
MedDRA Version 23.1

Title Footer Save

Table 13 - Adverse Events	Placebo (N=7) n (%)
<input type="checkbox"/> MedDRA System Organ Class Preferred Term	
<input type="checkbox"/> Subjects with any TEAE	0
<input type="checkbox"/> Respiratory, thoracic and mediastinal disorders	0
<input type="checkbox"/> Respiratory distress	0
<input type="checkbox"/> Subjects with any Medical History	7 (100)
<input type="checkbox"/> Blood and lymphatic system disorders	0
<input type="checkbox"/> Anaemia folate deficiency	0
<input type="checkbox"/> Thrombocytopenia	0
<input type="checkbox"/> Congenital, familial and genetic disorders	4 (57.1)
<input type="checkbox"/> Cerebral palsy	2 (28.6)
<input type="checkbox"/> Congenital central nervous system anomaly	0
<input type="checkbox"/> Cortical dysplasia	1 (14.3)
<input type="checkbox"/> Cytogenetic abnormality	0
<input type="checkbox"/> Developmental hip dysplasia	0
<input type="checkbox"/> Floating-Harbor syndrome	1 (14.3)
<input type="checkbox"/> Microcephaly	2 (28.6)

Table Filter Value Selection...

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Upload TLF | Table of Contents | **Build In-Text Table** | View Final In-Text Back to Source Documents

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Adverse Events

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Table 14.3.2.1
Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

MedDRA System Organ Class Preferred Term	Placebo (N=7) n (%)	DrugX (N=25) n (%)
Subjects with any TEAE	0	1 (4.0)
Respiratory, thoracic and mediastinal disorders	0	1 (4.0)
Respiratory distress	0	1 (4.0)

Source: Listing 16.2.7
TEAE = Treatment-Emergent Adverse Event
A TEAE is defined as an adverse event with an onset date, or a worsening in severity from baseline (pre-treatment), on or after the final dose of study drug up to 28 days following study drug discontinuation.
Subject with two or more adverse events in the same system organ class (or with the same preferred term) is counted only once for that system organ class (or preferred term).
MedDRA Version 23.1

In-Text Configuration

Title | Footer | **Filter** | Save

Table Filter Column Filter

Cohort >=

All Values Required**

Save Cancel

<input type="checkbox"/> Table 13 - Adverse Events	
<input type="checkbox"/> MedDRA System Organ Class Preferred Term	
<input type="checkbox"/> Subjects with any TEAE	
<input type="checkbox"/> Respiratory, thoracic and mediastinal disorders	
<input type="checkbox"/> Respiratory distress	
<input type="checkbox"/> Subjects with any Medical History	7 (100)
<input type="checkbox"/> Blood and lymphatic system disorders	0
<input type="checkbox"/> Anaemia folate deficiency	0
<input type="checkbox"/> Thrombocytopenia	0
<input type="checkbox"/> Congenital, familial and genetic disorders	4 (57.1)
<input type="checkbox"/> Cerebral palsy	2 (28.6)
<input type="checkbox"/> Congenital central nervous system anomaly	0
<input type="checkbox"/> Cortical dysplasia	1 (14.3)
<input type="checkbox"/> Cytogenetic abnormality	0
<input type="checkbox"/> Developmental hip dysplasia	0
<input type="checkbox"/> Floating-Harbor syndrome	1 (14.3)
<input type="checkbox"/> Microcephaly	2 (28.6)

Final In-Text Preview

Table 13 - Adverse Events		
MedDRA System Organ Class Preferred Term	Placebo (N=7) n (%)	DrugX (N=25) n (%)
Subjects with any TEAE	0	1 (4.0)
Subjects with any Medical History	7 (100)	25 (100)
Subjects with any TEAE	0	1 (4.0)
Subjects with any TEAE	1 (14.3)	6 (24.0)

Source: Table 14.3.2.2.1, Table 14.1.4.1.15, Table 14.3.2.3.1, Table 14.3.2.4.1
TEAE = Treatment-Emergent Adverse Event
A TEAE is defined as an adverse event with an onset ^{date} ₊ ₋ or a worsening in severity from baseline (pre-treatment), on or after the first dose of study drug up to 28 days following study drug discontinuation.

Column Filter Options

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Adverse Events

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Table 14.3.2.2.1
Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

MedDRA System Organ Class Preferred Term	Placebo (N=7) n (%)	DrugX (N=25) n (%)
Subjects with any TEAE	0	1 (4.0)
Respiratory, thoracic and mediastinal disorders	0	1 (4.0)
Respiratory distress	0	1 (4.0)

Source: Listing 16.2.7
TEAE = Treatment-Emergent Adverse Event
A TEAE is defined as an adverse event with an onset date, or a worsening in severity from baseline (pre-treatment), on or after the first dose of study drug up to 28 days following study drug discontinuation.
Subject with two or more adverse events in the same system organ class (or with the same preferred term) is counted only once for that system organ class (or preferred term).
MedDRA Version 23.1

In-Text Configuration

Title Footer Save

Table Filter Column Filter

Cohort * Value *

Save Cancel

Table 13 - Adverse Events	
MedDRA System Organ Class Preferred Term	
<input type="checkbox"/> Subjects with any TEAE	
<input type="checkbox"/> Respiratory, thoracic and mediastinal disorders	0
<input type="checkbox"/> Respiratory distress	0
<input type="checkbox"/> Subjects with any Medical History	7 (100)
<input type="checkbox"/> Blood and lymphatic system disorders	0
<input type="checkbox"/> Anaemia folate deficiency	0
<input type="checkbox"/> Thrombocytopenia	0
<input type="checkbox"/> Congenital, familial and genetic disorders	4 (57.1)
<input type="checkbox"/> Cerebral palsy	2 (28.6)
<input type="checkbox"/> Congenital central nervous system anomaly	0
<input type="checkbox"/> Cortical dysplasia	1 (14.3)
<input type="checkbox"/> Cytogenetic abnormality	0
<input type="checkbox"/> Developmental hip dysplasia	0
<input type="checkbox"/> Floating-Harbor syndrome	1 (14.3)
<input type="checkbox"/> Microcephaly	2 (28.6)

Column Filter Selection...

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Adverse Events

Symbiance (Protocol Symbiance-21 core study) Page 1 of 1

Table 14.3.2.2.1
Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

MedDRA System Organ Class Preferred Term	Placebo (N=7) n (%)	DrugX (N=25) n (%)
Subjects with any TEAE	0	1 (4.0)
Respiratory, thoracic and mediastinal disorders	0	1 (4.0)
Respiratory distress	0	1 (4.0)

In-Text Configuration

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Table 13 - Adverse Events	Cohort *
MedDRA System Organ Class Preferred Term	>= Value * +
<input type="checkbox"/> Subjects with any TEAE	0
<input type="checkbox"/> Respiratory, thoracic and mediastinal disorders	0
<input type="checkbox"/> Respiratory distress	0
<input type="checkbox"/> Subjects with any Medical History	7 (100)
<input type="checkbox"/> Blood and lymphatic system disorders	0
<input type="checkbox"/> Anaemia folate deficiency	0
<input type="checkbox"/> Thrombocytopenia	0
<input type="checkbox"/> Congenital, familial and genetic disorders	4 (57.1)
<input type="checkbox"/> Cerebral palsy	2 (28.6)
<input type="checkbox"/> Congenital central nervous system anomaly	0
<input type="checkbox"/> Cortical dysplasia	1 (14.3)
<input type="checkbox"/> Cytogenetic abnormality	0
<input type="checkbox"/> Developmental hip dysplasia	0
<input type="checkbox"/> Floating-Harbor syndrome	1 (14.3)
<input type="checkbox"/> Microcephaly	2 (28.6)

Table Filter
 Column Filter

Cohort *

Column 2 - Placebo

Column 3 - DrugX

Cancel

Source: Listing 16.2.7

TEAE = Treatment-Emergent Adverse Event

A TEAE is defined as an adverse event with an onset date, or a worsening in severity from baseline (pre-treatment), on or after the first dose of study drug up to 28 days following study drug discontinuation.

Subject with two or more adverse events in the same system organ class (or with the same preferred term) is counted only once for that system organ class (or preferred term).

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Column Filter Value Selection...

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Adverse Events

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Table 14.3.2.2.1
Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

MedDRA System Organ Class Preferred Term	Placebo (N=7) n (%)	DrugX (N=25) n (%)
Subjects with any TEAE	0	1 (4.0)
Respiratory, thoracic and mediastinal disorders	0	1 (4.0)
Respiratory distress	0	1 (4.0)

In-Text Configuration

Title
Footer

Save

Table 13 - Adverse Events	Cohort *	Value *
MedDRA System Organ Class Preferred Term	Column 2 - Placebo	>= 12
<input type="checkbox"/> Subjects with any TEAE	Column 3 - DrugX	>= 28
<input type="checkbox"/> Respiratory, thoracic and mediastinal disorders		
<input type="checkbox"/> Respiratory distress		
<input type="checkbox"/> Subjects with any Medical Illness		
<input type="checkbox"/> Blood and lymphatic system disorders		0
<input type="checkbox"/> Anaemia folate deficiency		0
<input type="checkbox"/> Thrombocytopenia		0
<input type="checkbox"/> Congenital, familial and genetic disorders		4 (57.1)
<input type="checkbox"/> Cerebral palsy		2 (28.6)
<input type="checkbox"/> Congenital central nervous system anomaly		0
<input type="checkbox"/> Cortical dysplasia		1 (14.3)
<input type="checkbox"/> Cytogenetic abnormality		0
<input type="checkbox"/> Developmental hip dysplasia		0
<input type="checkbox"/> Floating-Harbor syndrome		1 (14.3)
<input type="checkbox"/> Microcephaly		2 (28.6)

Source: Listing 182.7
TEAE = Treatment-Emergent Adverse Event
A TEAE is defined as an adverse event with an onset date, or a worsening in severity from baseline (pre-treatment), on or after the first dose of study drug up to 28 days following study drug discontinuation.
Subject with two or more adverse events in the same system organ class (or with the same preferred term) is counted only once for that system organ class (or preferred term).
MedDRA Version 23.1

Column Filter Preview...

In-Text Table of Contents

Adverse Events

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Table 14.3.2.2.1
Treatment-Emergent, Serious Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

MedDRA System Organ Class Preferred Term	Placebo (N=7) n (%)	DrugX (N=25) n (%)
Subjects with any TEAE	0	1 (4.0)
Respiratory, thoracic and mediastinal disorders Respiratory distress	0	1 (4.0)

Source: Listing 16.2.7
TEAE = Treatment-Emergent Adverse Event
A TEAE is defined as an adverse event with an onset date, or a worsening in severity from baseline (pre-treatment), on or after the first dose of study drug up to 28 days following study drug discontinuation.
Subject with two or more adverse events in the same system organ class (or with the same preferred term) is counted only once for that system organ class (or preferred term).
MedDRA Version 23.1

In-Text Configuration

Title Footer **Placebo >= 12 OR Drugx >= 28**

Table 13 - Adverse Events <input type="button" value="X<sup>2</sup>"/>	
MedDRA System Organ Class Preferred Term	Placebo (N=7) n (%)
<input type="checkbox"/> Subjects with any TEAE	0
<input type="checkbox"/> Respiratory, thoracic and mediastinal disorders	0
<input type="checkbox"/> Respiratory distress	0
<input type="checkbox"/> Subjects with any Medical History	7 (100)
<input type="checkbox"/> Blood and lymphatic system disorders	0
<input type="checkbox"/> Anaemia folate deficiency	0
<input type="checkbox"/> Thrombocytopenia	0
<input type="checkbox"/> Congenital, familial and genetic disorders	4 (57.1)
<input type="checkbox"/> Cerebral palsy	2 (28.6)
<input type="checkbox"/> Congenital central nervous system anomaly	0
<input type="checkbox"/> Cortical dysplasia	1 (14.3)
<input type="checkbox"/> Cytogenetic abnormality	0
<input type="checkbox"/> Developmental hip dysplasia	0
<input type="checkbox"/> Floating-Harbor syndrome	1 (14.3)
<input type="checkbox"/> Microcephaly	2 (28.6)

Row Selection... to Hide Irrelevant Results...

SYM-21 SYMBIAN...

Post-Text to In-text

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Adverse Events

Symbiance Protocol Symbiance-21 core study Page 1 of 1

Table 14.3.22.1
Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

MedDRA System Organ Class Preferred Term	Placebo (N=7) n (%)	DrugX (N=25) n (%)
Subjects with any TEAE	0	1 (4.0)
Respiratory, thoracic and mediastinal disorders	0	1 (4.0)
Respiratory distress	0	1 (4.0)


In-Text Configuration




Title
Footer
Save
Placebo >= 12 OR Drugx >= 28

MedDRA System Organ Class Preferred Term	Placebo (N=7) n (%)
<input checked="" type="checkbox"/> Subjects with any TEAE	0
<input type="checkbox"/> Respiratory, thoracic and mediastinal disorders	0
<input type="checkbox"/> Respiratory distress	0
<input type="checkbox"/> Subjects with any Medical History	7 (100)
<input checked="" type="checkbox"/> Blood and lymphatic system disorders	0
<input checked="" type="checkbox"/> Anaemia folate deficiency	0
<input checked="" type="checkbox"/> Thrombocytopenia	0
<input type="checkbox"/> Congenital, familial and genetic disorders	4 (57.1)
<input type="checkbox"/> Cerebral palsy	2 (28.6)
<input type="checkbox"/> Congenital central nervous system anomaly	0
<input type="checkbox"/> Cortical dysplasia	1 (14.3)
<input type="checkbox"/> Cytogenetic abnormality	0
<input type="checkbox"/> Developmental hip dysplasia	0
<input type="checkbox"/> Floating-Harbor syndrome	1 (14.3)
<input type="checkbox"/> Microcephaly	2 (28.6)

Source: Listing 162.7
TEAE = Treatment-Emergent Adverse Event
A TEAE is defined as an adverse event with an onset date, or a worsening in severity from baseline (pre-treatment), on or after the first dose of study drug up to 28 days following study drug discontinuation.
Subject with two or more adverse events in the same system organ class (or with the same preferred term) is counted only once for that system organ class (or preferred term).
MedDRA Version 23.1

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Final In-Text Document Table 13 - Adverse Events X² [Download](#) [Download All](#) [Edit](#)

MedDRA System Organ Class Preferred Term	Placebo (N=7) n (%)	DrugX (N=25) n (%)
Subjects with any TEAE	0	1 (4.0)
Subjects with any Medical History	7 (100)	25 (100)
Congenital, familial and genetic disorders	4 (57.1)	6 (24.0)
Cerebral palsy	2 (28.6)	3 (12.0)
Cortical dysplasia	1 (14.3)	0
Floating-Harbor syndrome	1 (14.3)	0
Microcephaly + -	2 (28.6)	2 (8.0)
Neurofibromatosis	1 (14.3)	0

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Table_12_14_3_2_6_2_2	DOCX Document	4 KB	No	4 KB	16%	08-05-2023 14:13
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Post-Text are Ready to Ingest Into Larger Tool...

SYMBIANC... DEMO SY...

Source Documents



Type		File Name	Actions
Protocol *	<input type="button" value="Select File"/>	Symbiance-21.pdf	
SAP	<input type="button" value="Select File"/>	Symbiance-021_SAP.docx	
In-Text table	<input type="button" value="Select File"/>	Symbiance-21 In-text_latest.docx 	
Safety Narrative	<input type="button" value="Select File"/>	Safety Narratives Symbiance-21.docx	
Synopsis	<input type="button" value="Select File"/>		

Engage the AI - Medical Writing Features

The screenshot shows a web application interface for medical writing. At the top, there is a search bar and a navigation menu with 'Source Documents'. Below this is a table with the following columns: 'Type', 'File Name', and 'Actions'. The table contains five rows, each with a 'Type' and a 'Select File' button. A 'Confirmation' dialog box is overlaid in the center of the screen, asking for confirmation to perform the following actions:

- Enable Synopsis
- Enable Tense Change
- Enable Lean writing
- Enable In-text table Interpretation

The dialog also offers options for 'System Generated' (selected) vs 'Using Protocol' and 'Using Mean' (selected) vs 'Using Median' vs 'Table Reference'. There are 'Submit' and 'Cancel' buttons at the bottom of the dialog.

Type	File Name	Actions
Protocol *	Symbiance-21.pdf	✕
SAP		✕
In-Text table		✕
Safety Narrative		✕
Synopsis		

Thank You!

- Q&A
- For more info or capabilities in the larger tool context, please visit us at the Symbiance/ZYLiQ Booth



ZYLiQ
ACCELERATE MEDICAL WRITING