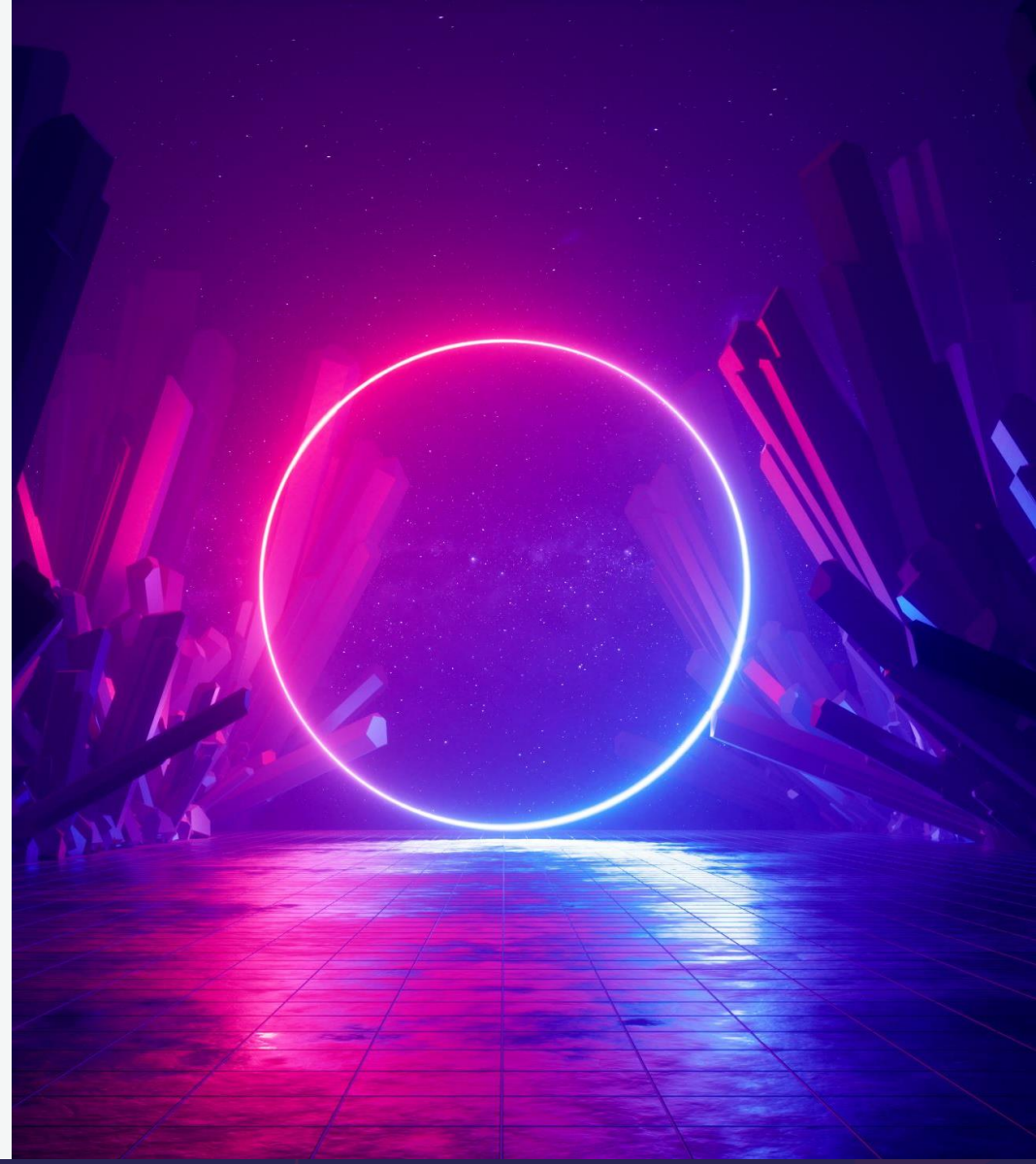
AI-Automation for Post-Text to In-Text Conversion

Mark Pittman

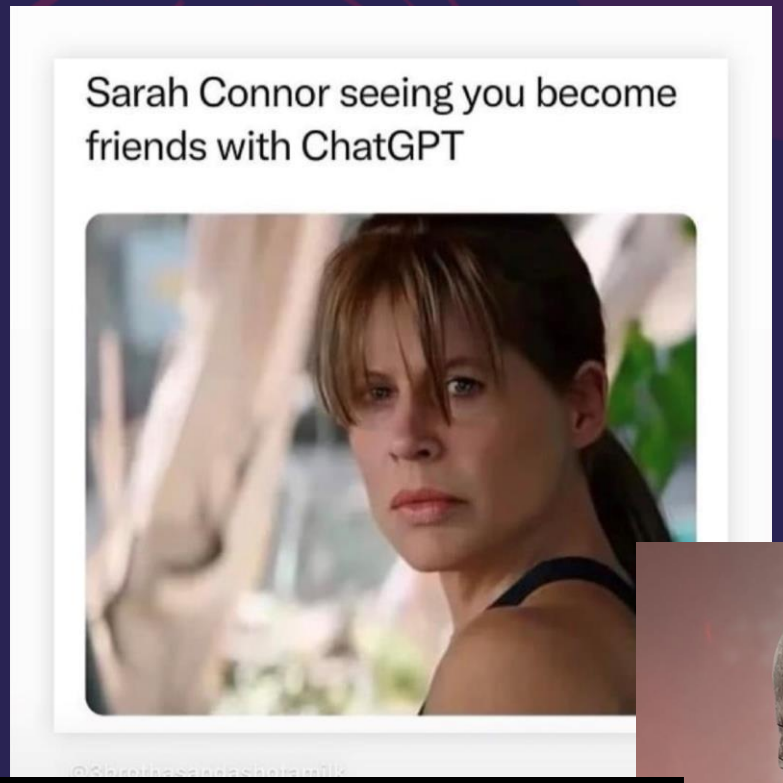
Symbiance/ZYLiQ



AI Fears

- Taking Jobs
- Unsupervised Creation
- AI Bias

- Taking over the world…

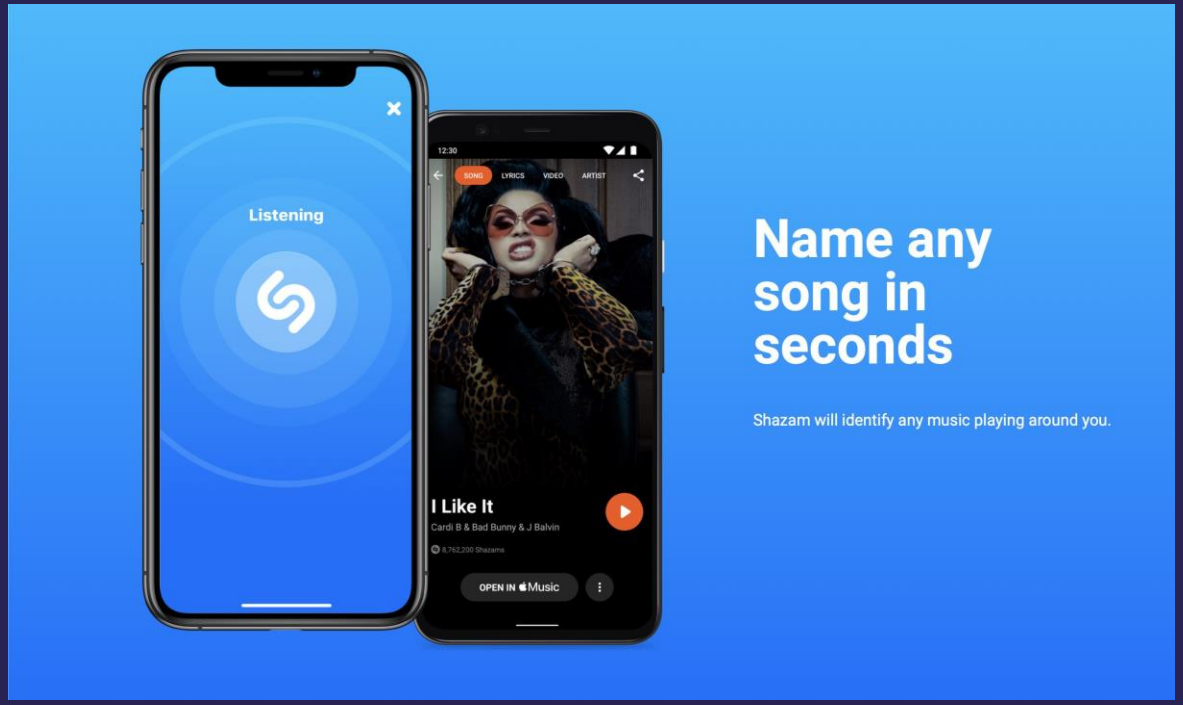


AI Reality

- Man-plus machine (human IS needed)
- Time and place for letting a machine work
  - Formatted processes
  - Repetitive
  - Data-heavy

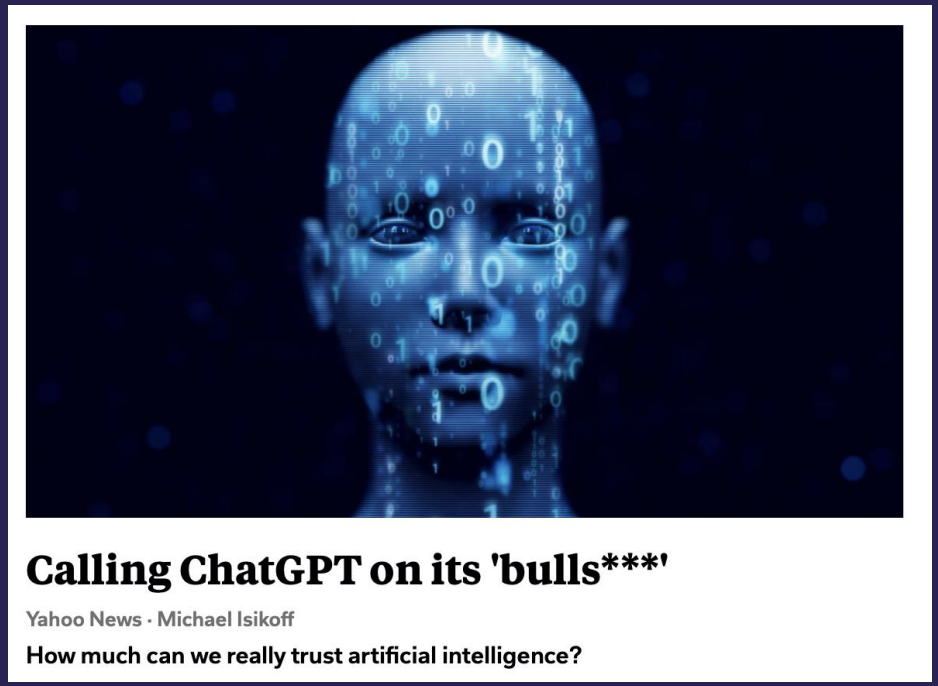
AI/ML We Don’t Think About

- Where we already trust/use AI/ML
  - Siri & Alexa
  - Shazam
  - Predictive Texting (names)



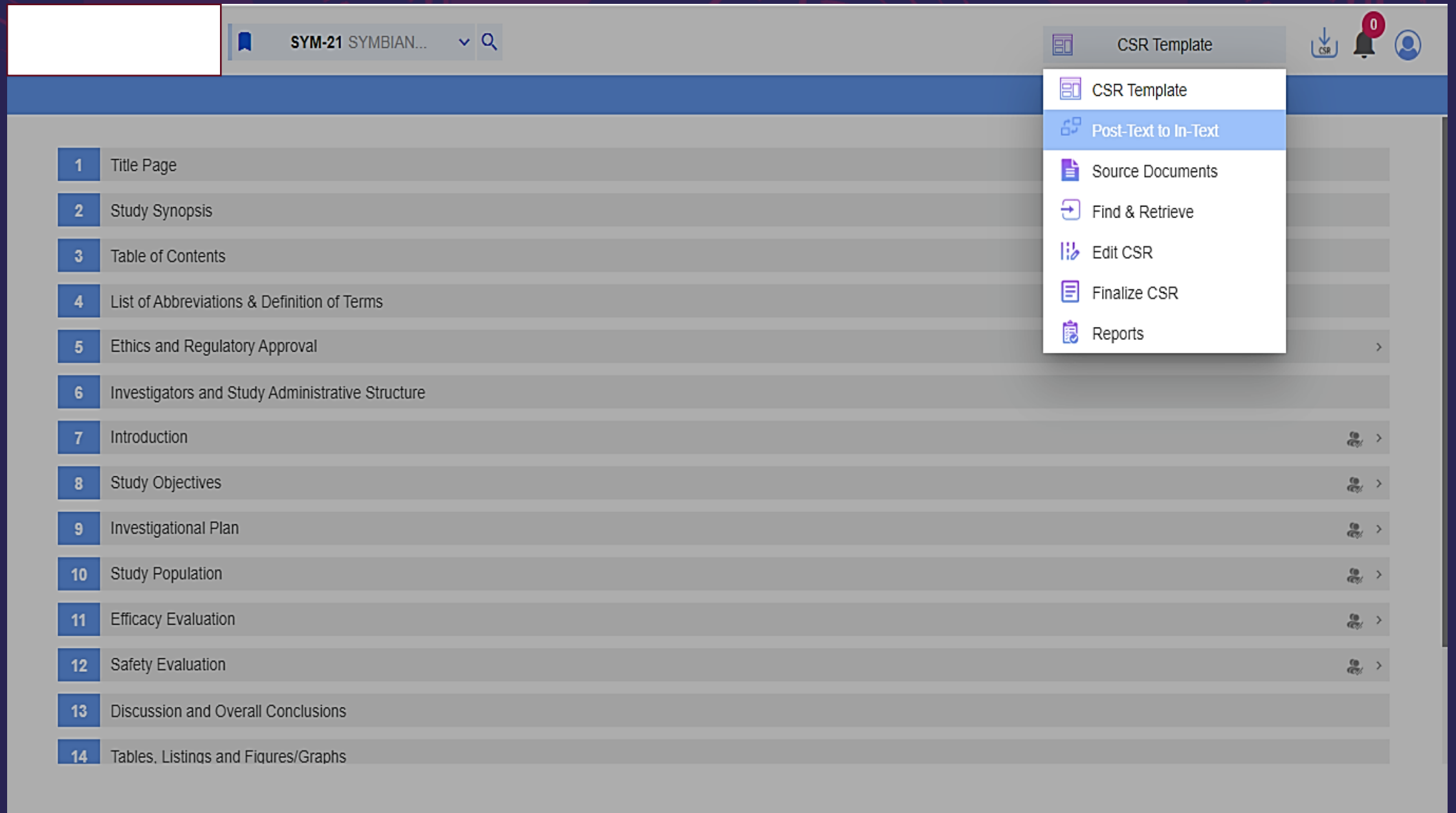
The Digital Elephant

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

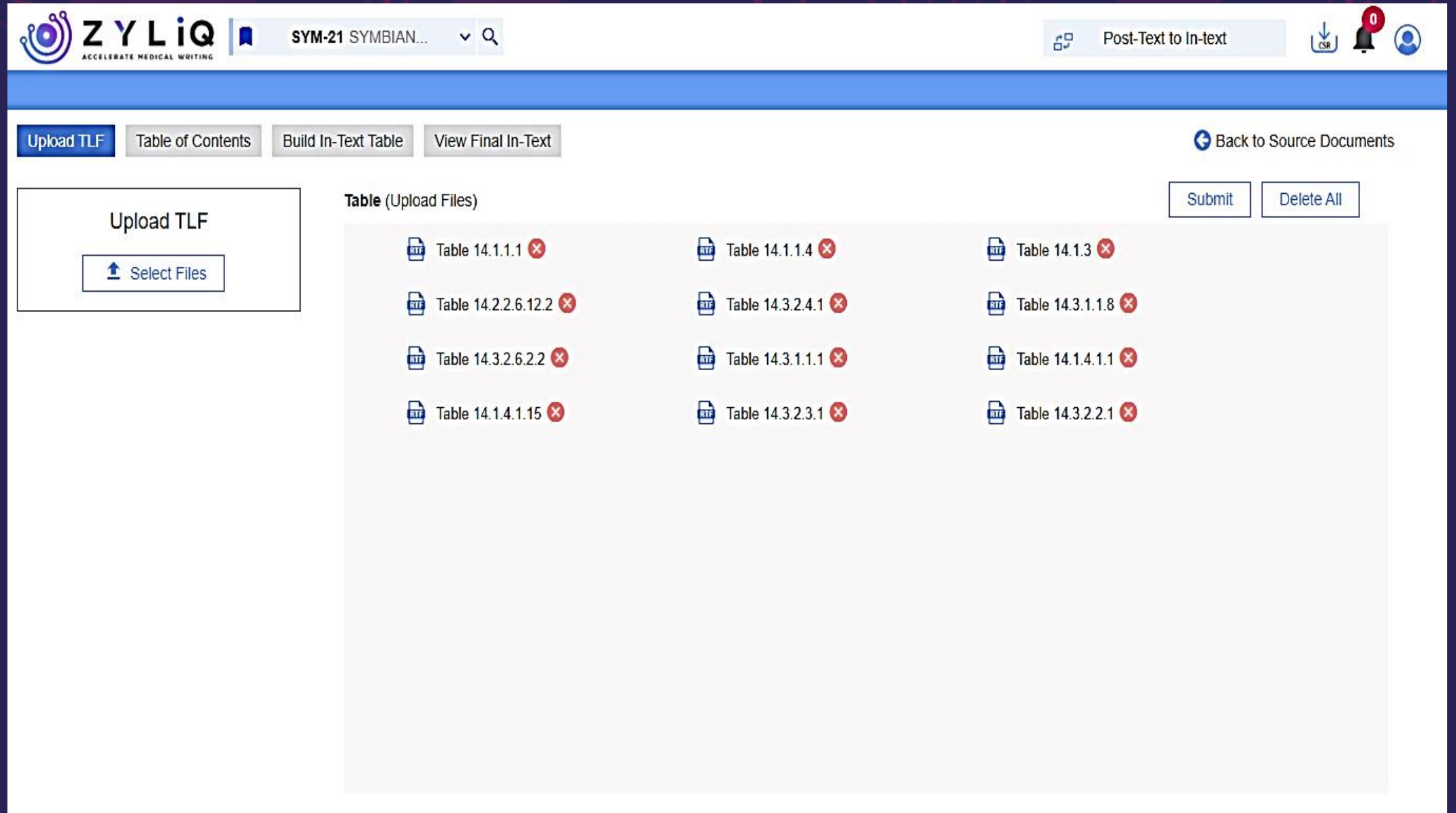


AI Bridging Biostats/Medical Writing

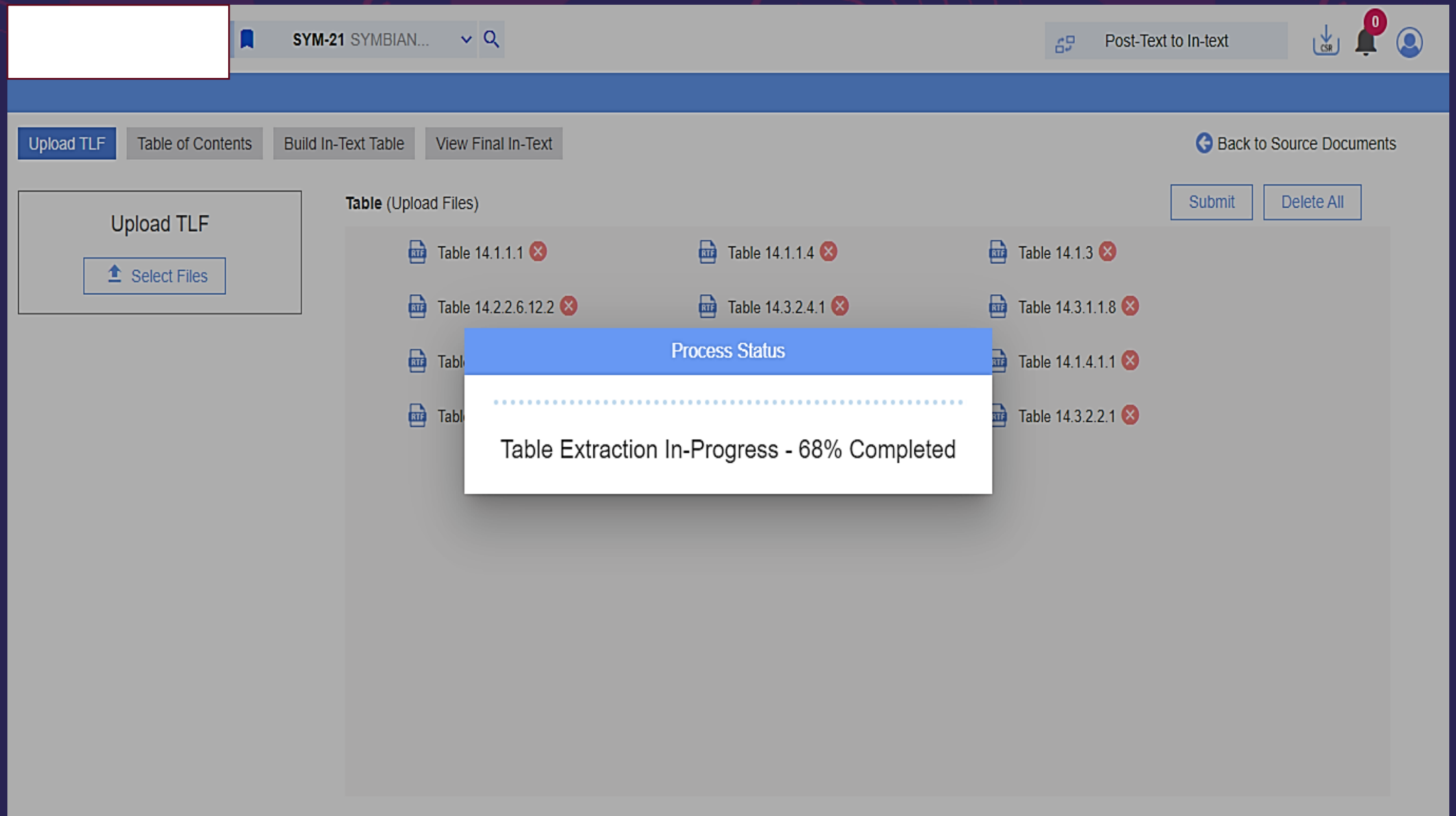
- High Biostat programming time/cost for In-text tables
- Medical Writing's In-text needs
  - Specific Formatting
  - Removing Irrelevant Results
- Errors arise from copy/paste of table data


SYM-21 SYMBIAN...
CSR Template
0
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

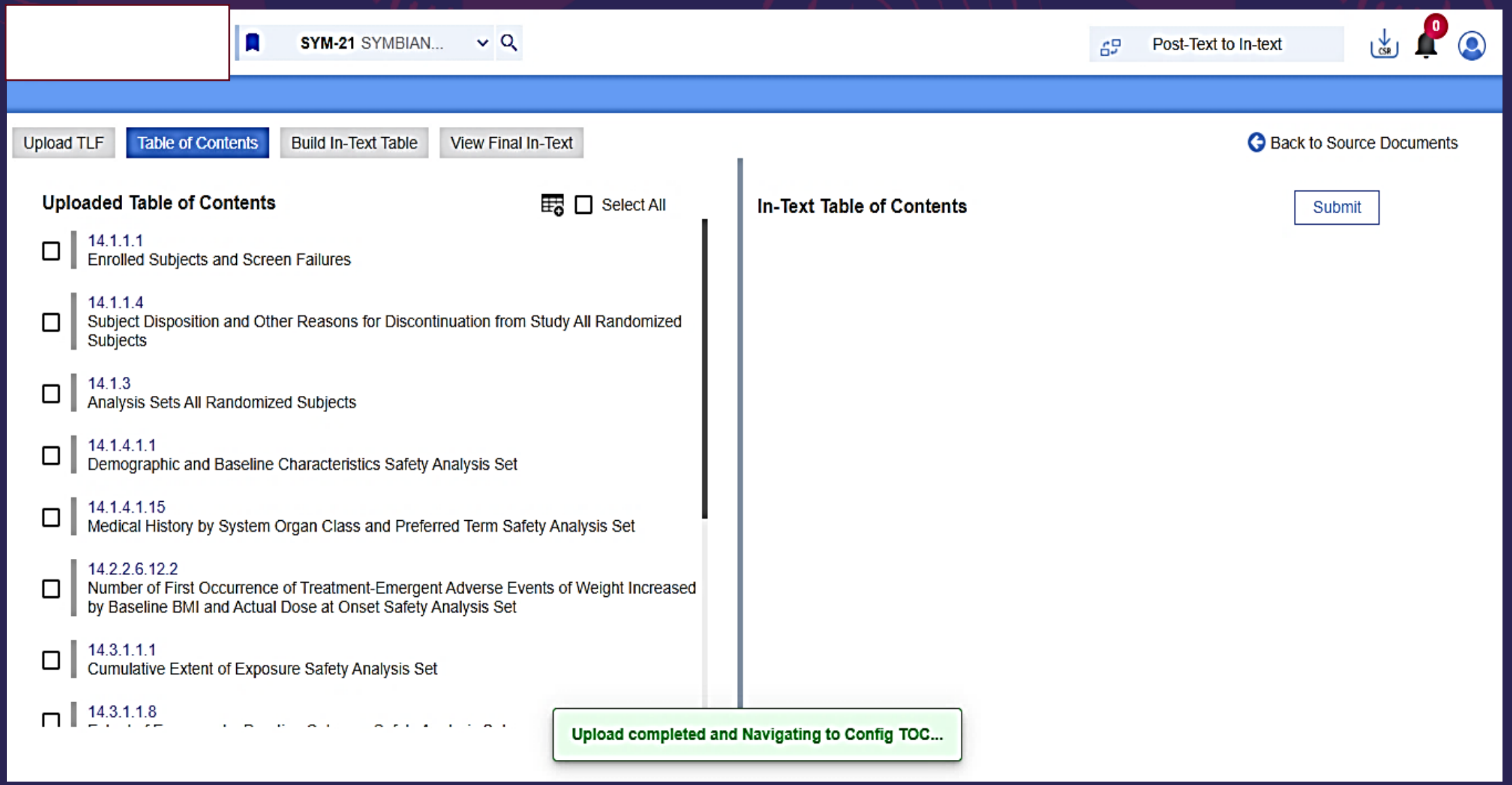
Upload Post-Text Tables



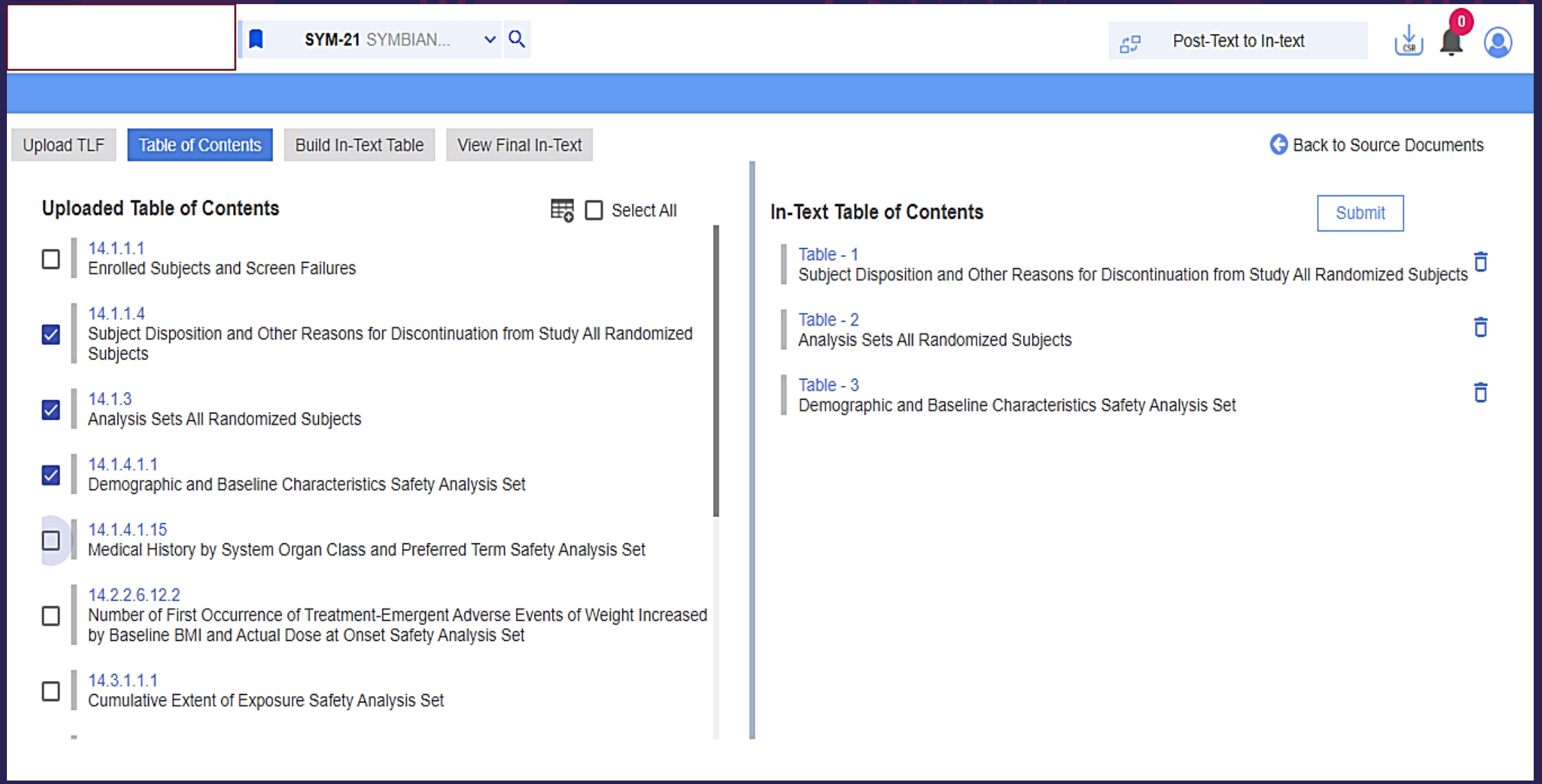
Post-Text Table Extraction



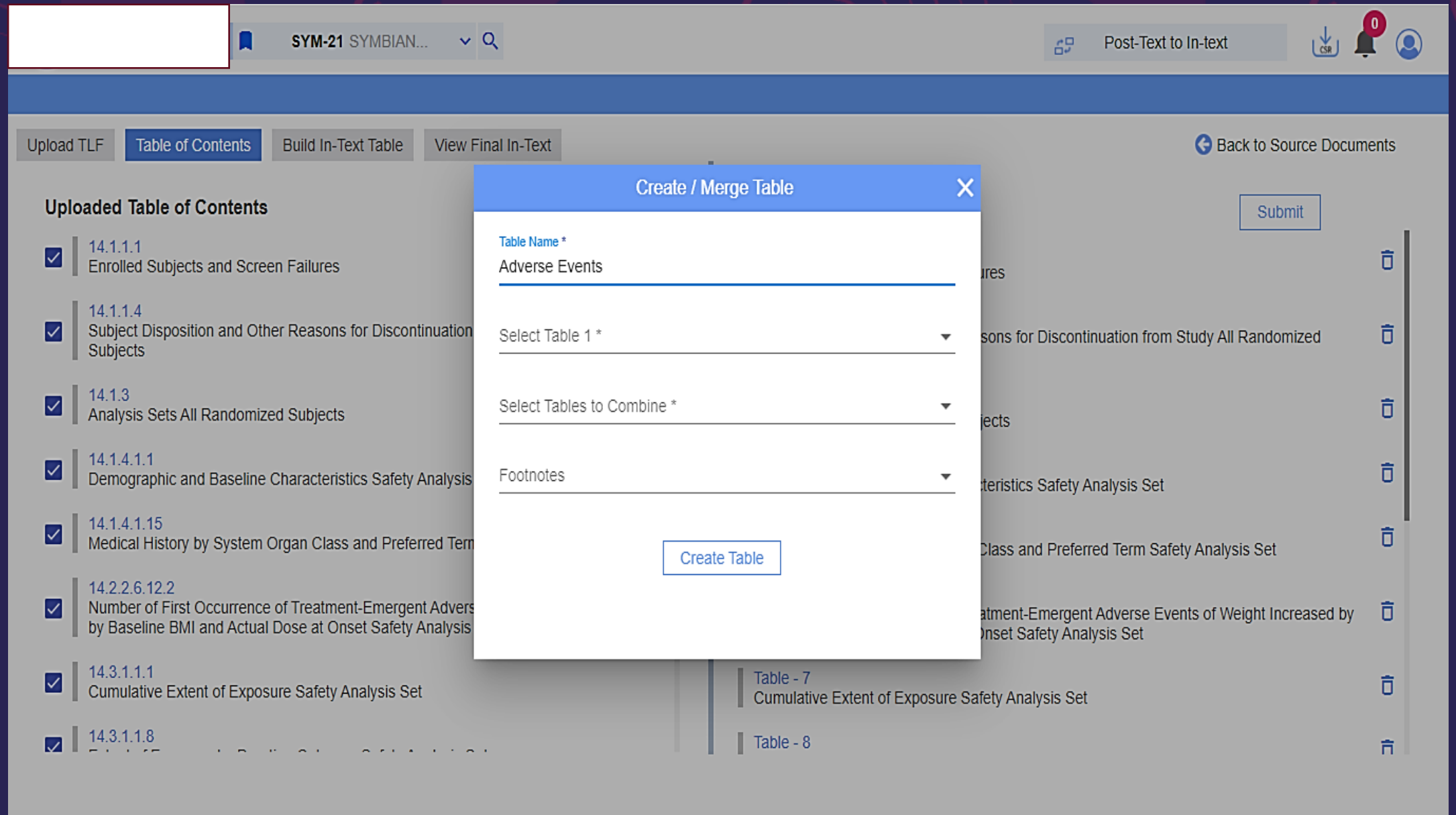
Create Table of Contents Post-Text Tables



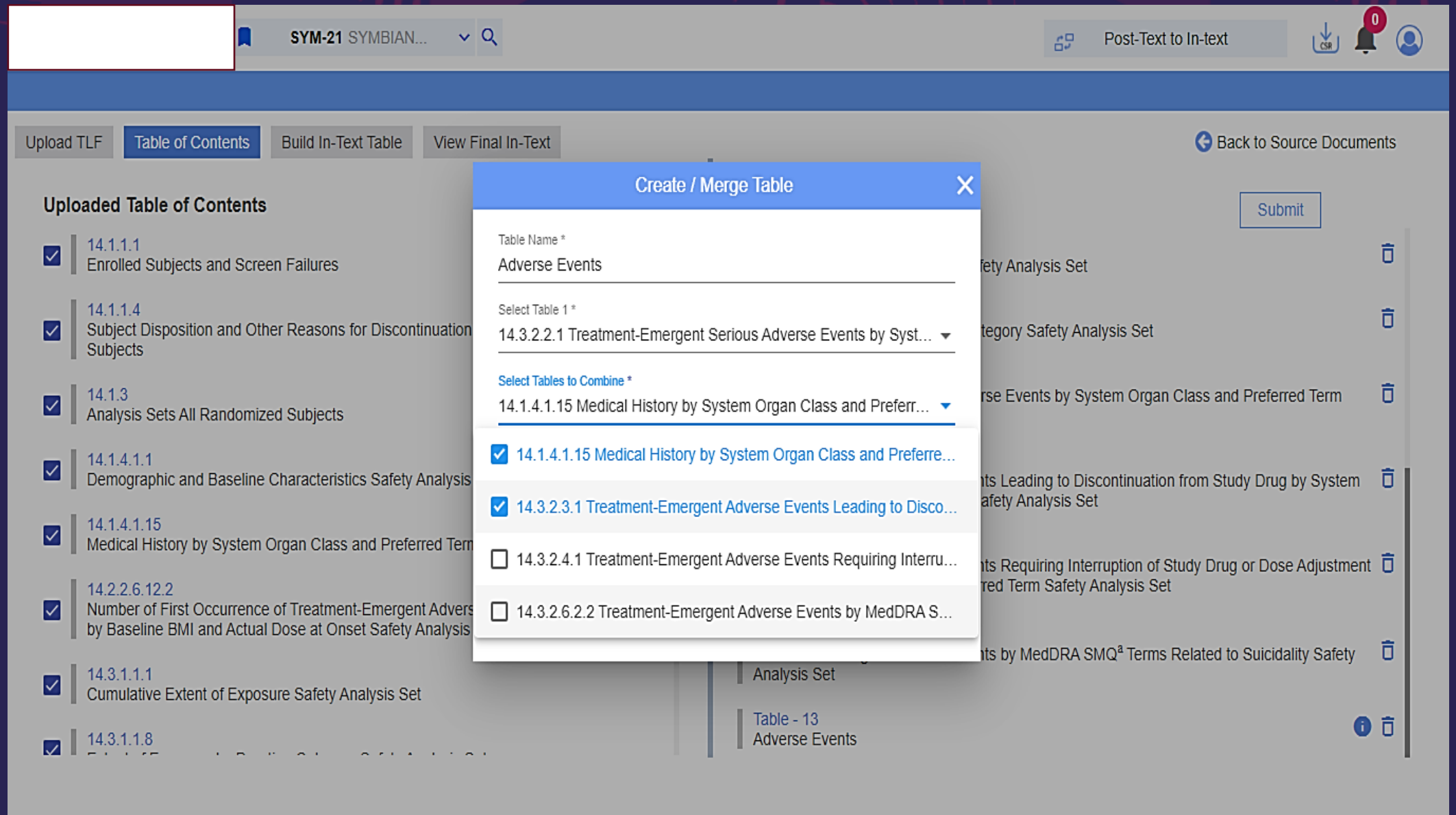
Begin to build the In-Text Table of Contents



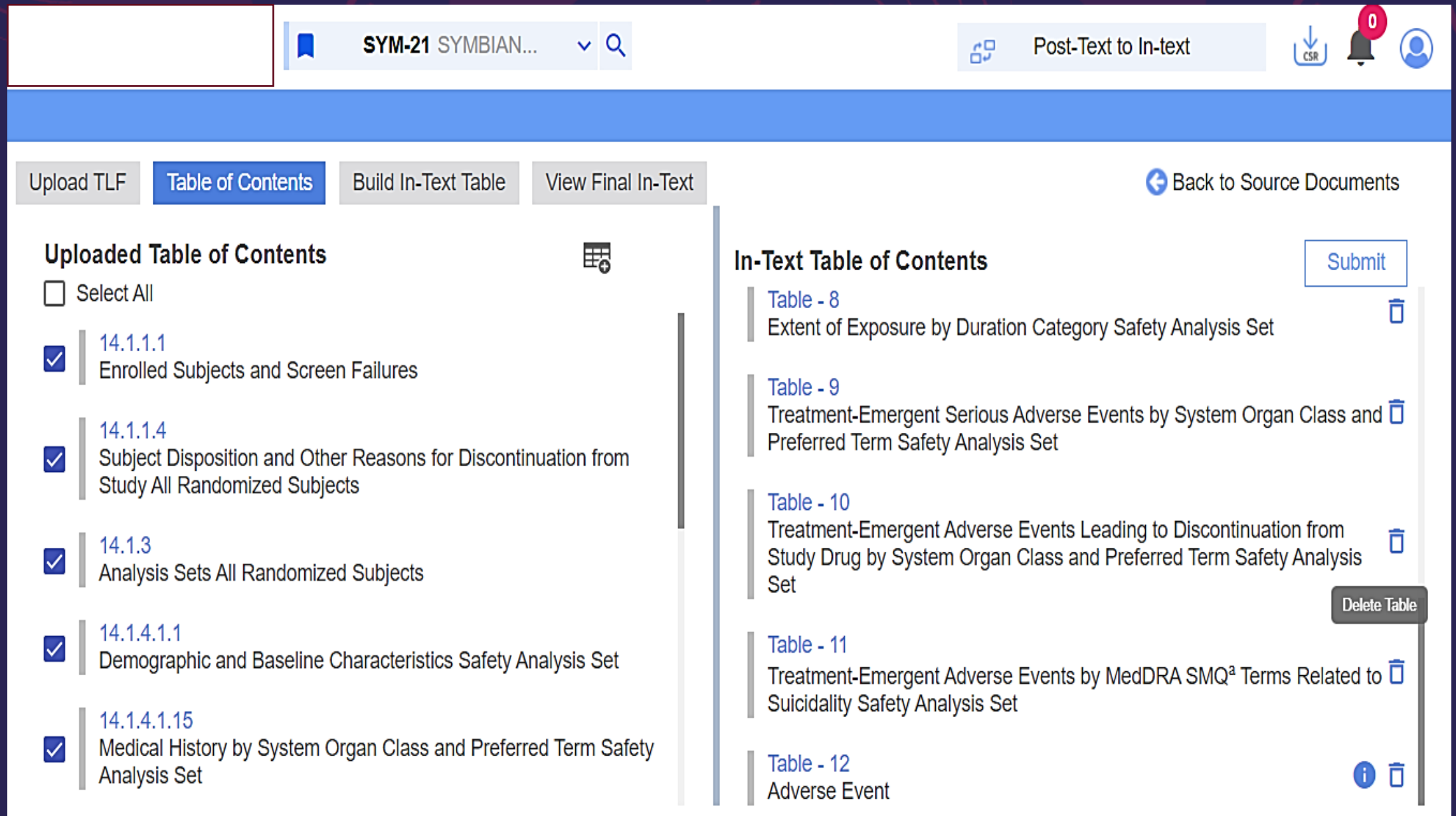
Create and/or Merge Table



Select Tables to Merge



Create as part of In-Text Table of Contents



Ability to Edit Title, Footer…

SYM-21 SYMBIAN…

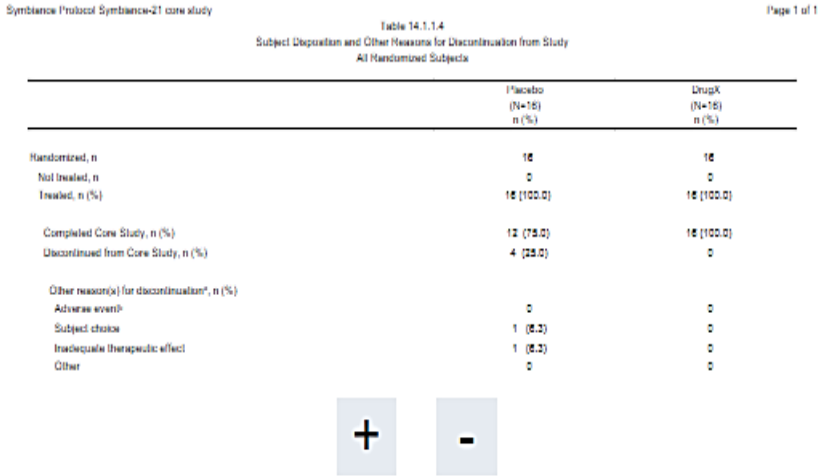
Post-Text to In-text

Upload TLF | Table of Contents | Build In-Text Table | View Final In-Text

Back to Source Documents

In-Text Table of Contents

14.1.1.4 Subject Disposition and Other Reasons for Discontinuation from St…



Symbiance Protocol Symbiance-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 (%)
☐	Randomized, n	16
☐	Not treated, n	0
☐	Treated, n (%)	16 (100.0)
☐	Completed Core Study, n (%)	12 (75.0)
☐	Discontinued from Core Study, n (%)	4 (25.0)
☐	Other reason(s) for discontinuation[a], n (%)	
☐	Adverse event[b]	0
☐	Subject choice	1 (6.3)
☐	Inadequate therapeutic effect	1 (6.3)

Ability to Filter…

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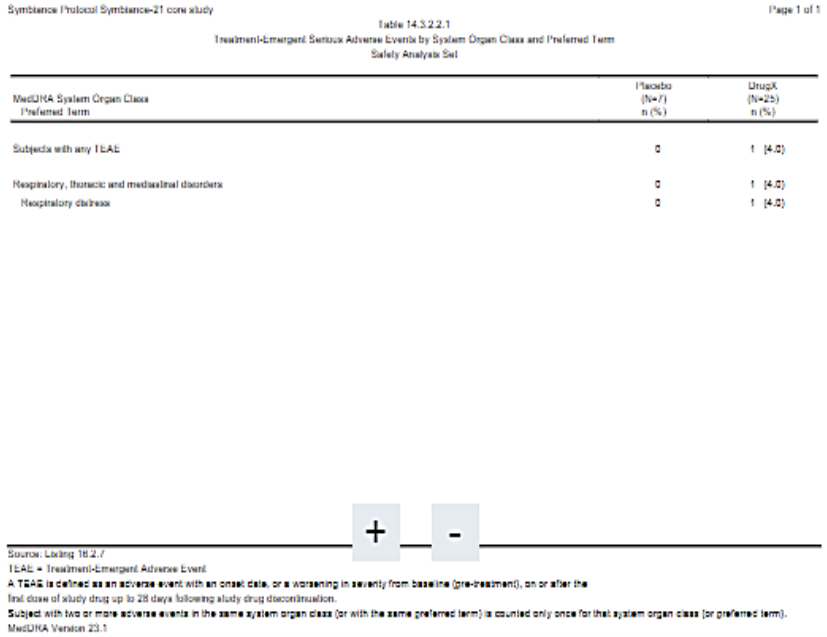
In-Text Table of Contents

Adverse Events



Symbience Protocol Symbience-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)

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

Title | Footer | Save

Create Filters

Table 13 - Adverse E

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

Table Filter Value Selection…

SYM-21 SYMBIAN...

Post-Text to In-text

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In-Text Table of Contents

Adverse Events

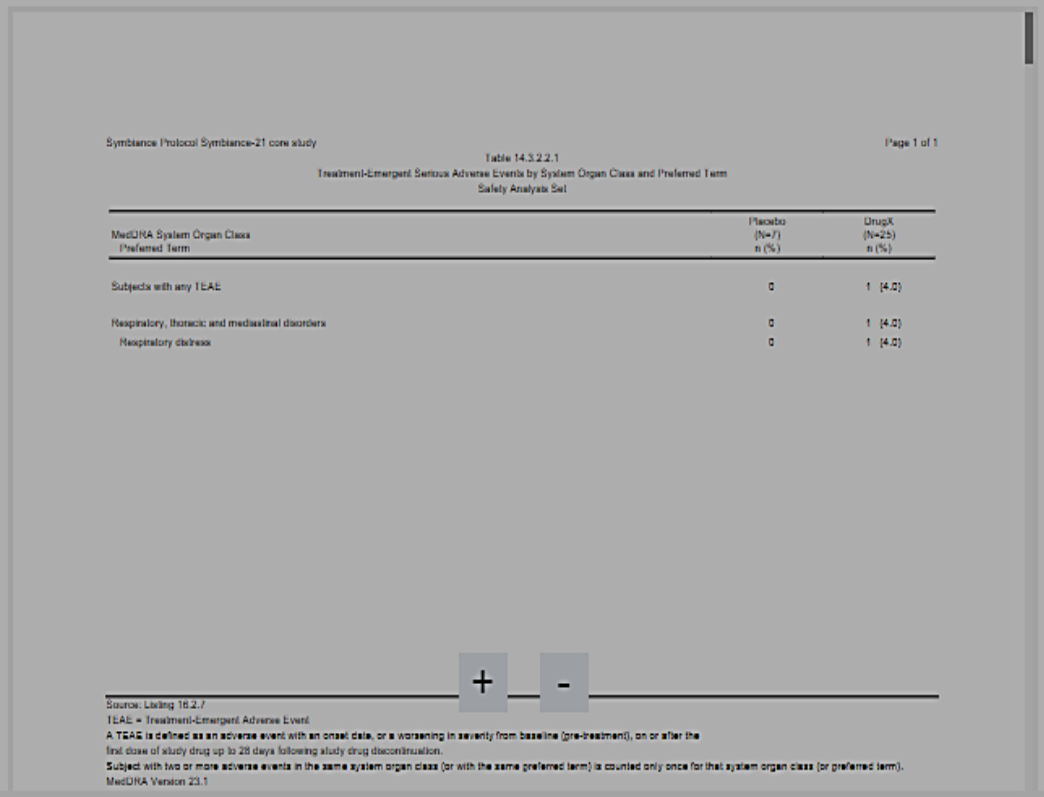
Symbiance Protocol Symbiance-21 core study

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Table 14.3.2.2.1

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Safety Analysis Set

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Respiratory distress	0	1 (4.0)

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In-Text Configuration

Title | Footer | Save

Table Filter ○ Column Filter

Cohort >= 100

All Values Required**

Save | Cancel

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

Final In-Text Preview

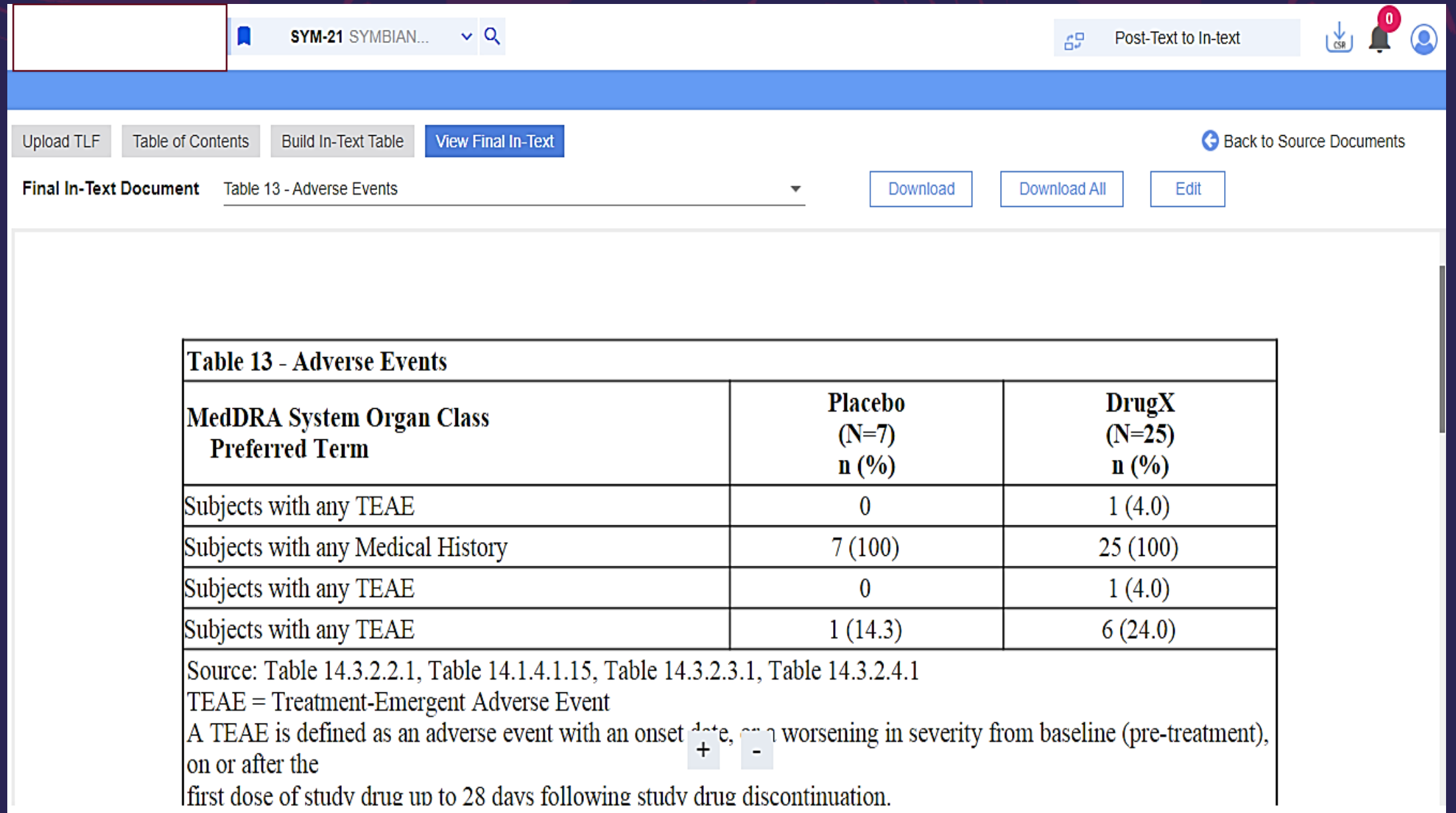
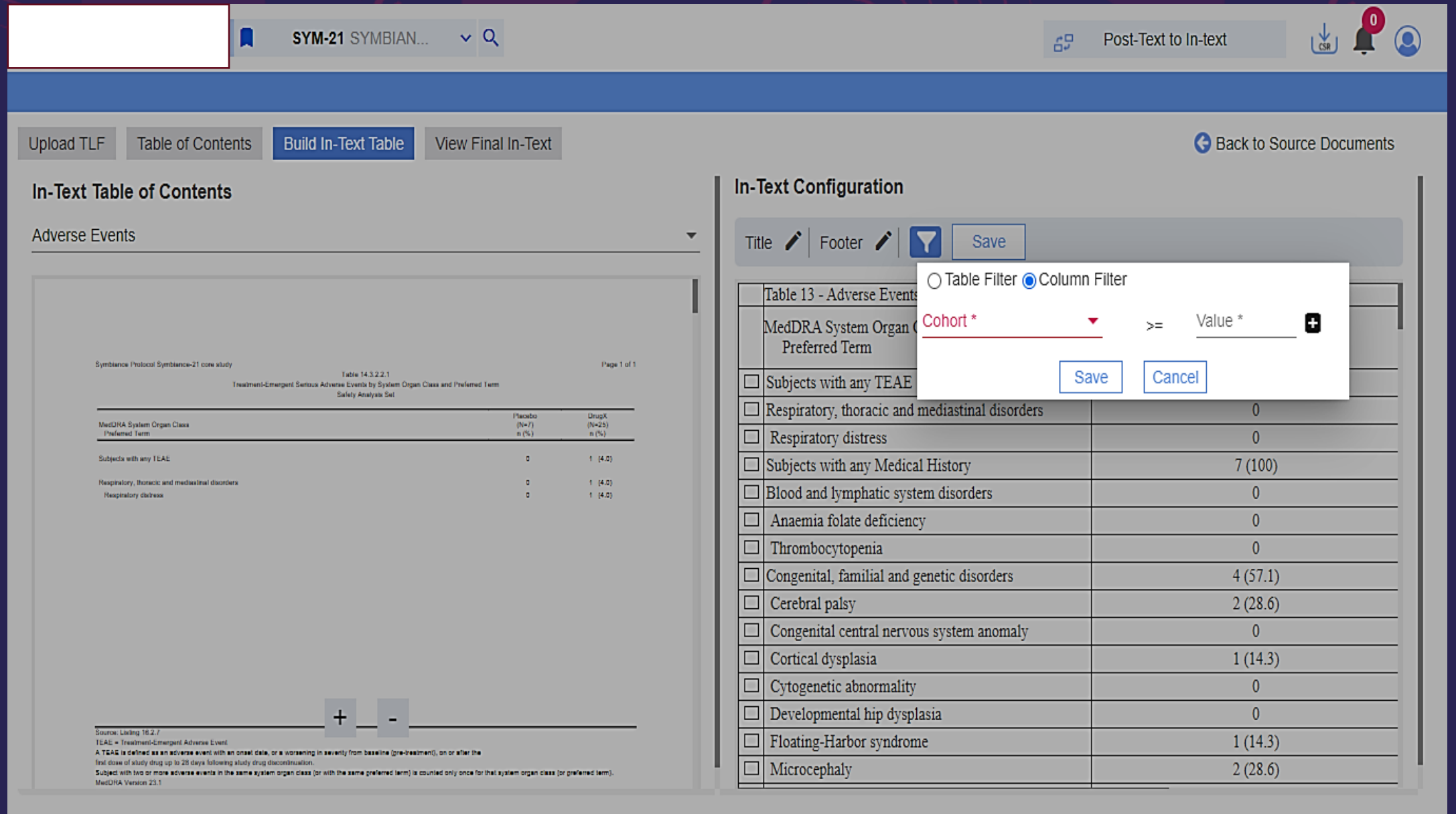


Table 13 - Adverse Events

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



Column Filter Selection…

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In-Text Table of Contents

Adverse Events

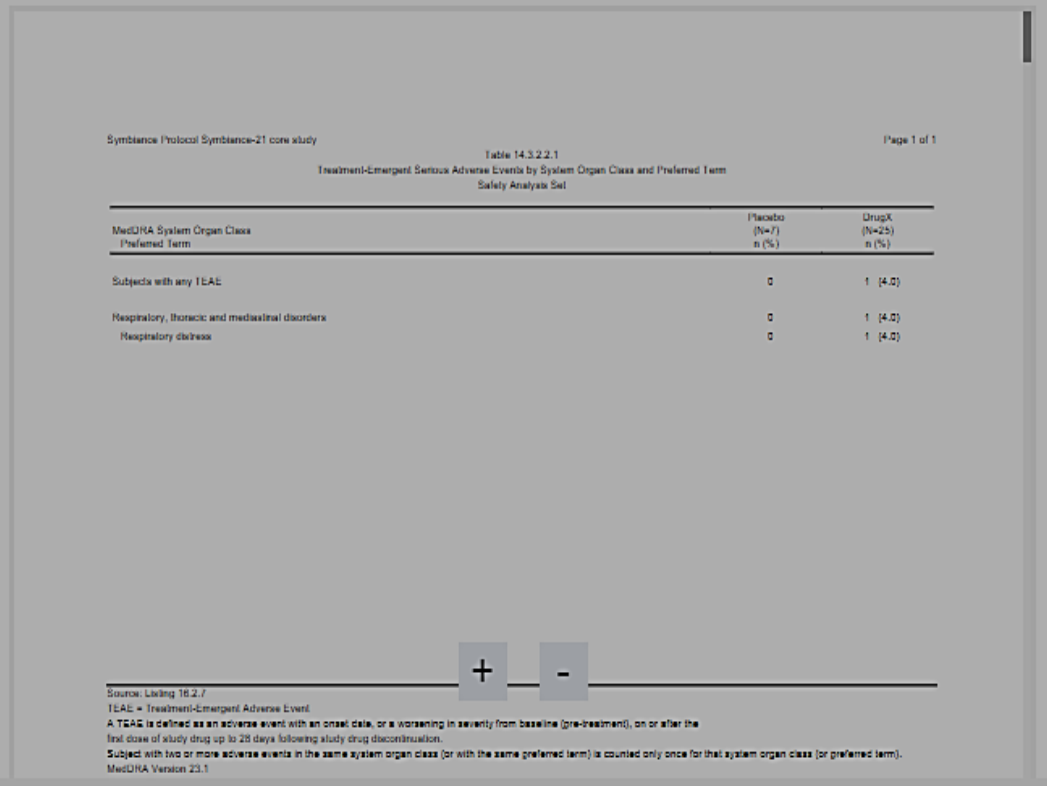
Symbience Protocol Symbience-21 core study

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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 (%)
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Respiratory distress	0	1 (4.0)

Source: Listing 16.2.7

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+ -

In-Text Configuration

Title | Footer | Save

Table Filter Column Filter

Cohort *

Column 2 - Placebo

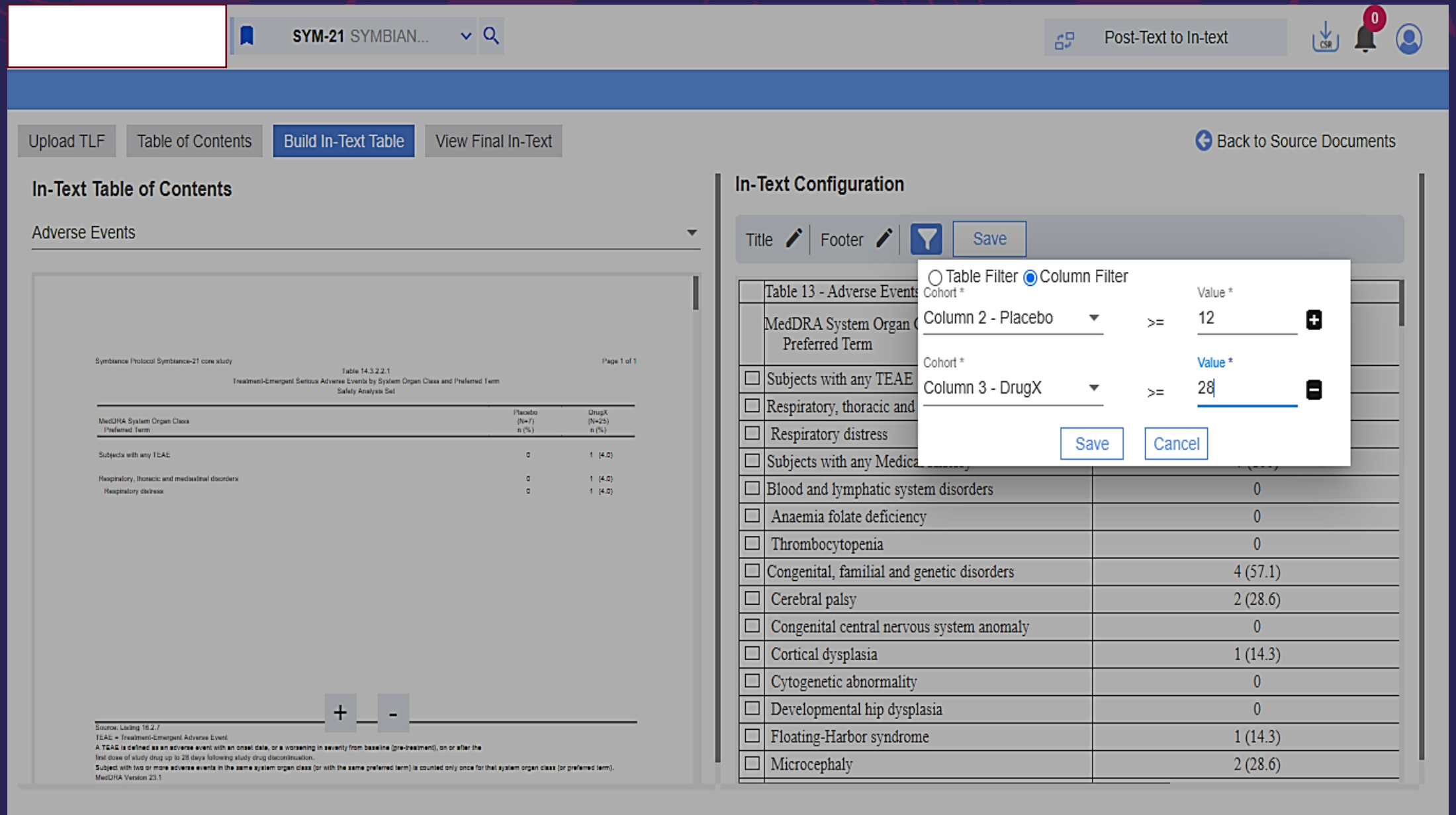
Column 3 - DrugX

>= Value *

Cancel

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

Column Filter Value Selection…



Column Filter Preview…

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Post-Text to In-text

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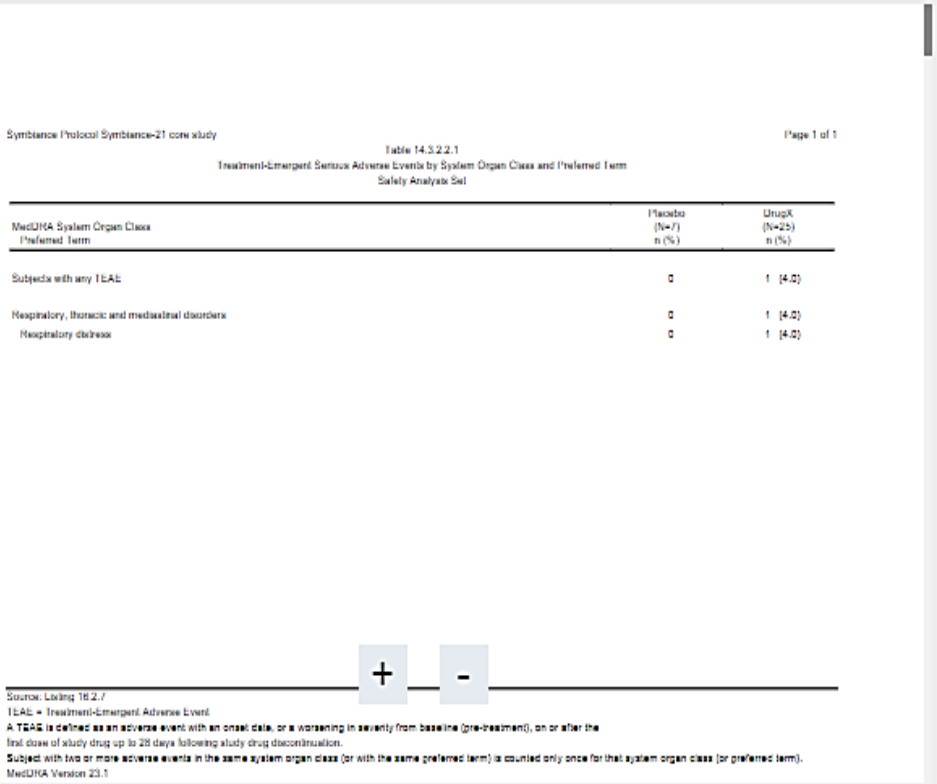
In-Text Table of Contents

Adverse Events



In-Text Configuration

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

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

Row Selection… to Hide Irrelevant Results…

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Post-Text to In-text

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In-Text Table of Contents

Adverse Events

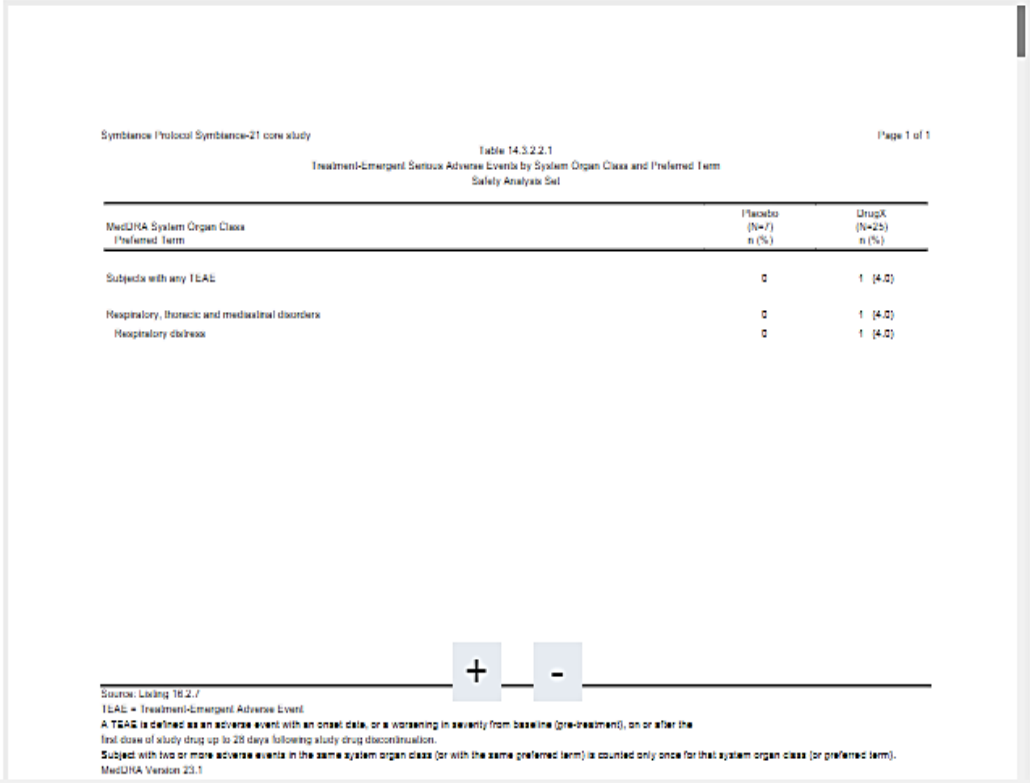
Symbiance Protocol Symbiance-21 core study

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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

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MedDRA Version 23.1

In-Text Configuration

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

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

Preview Final In-Text Table…

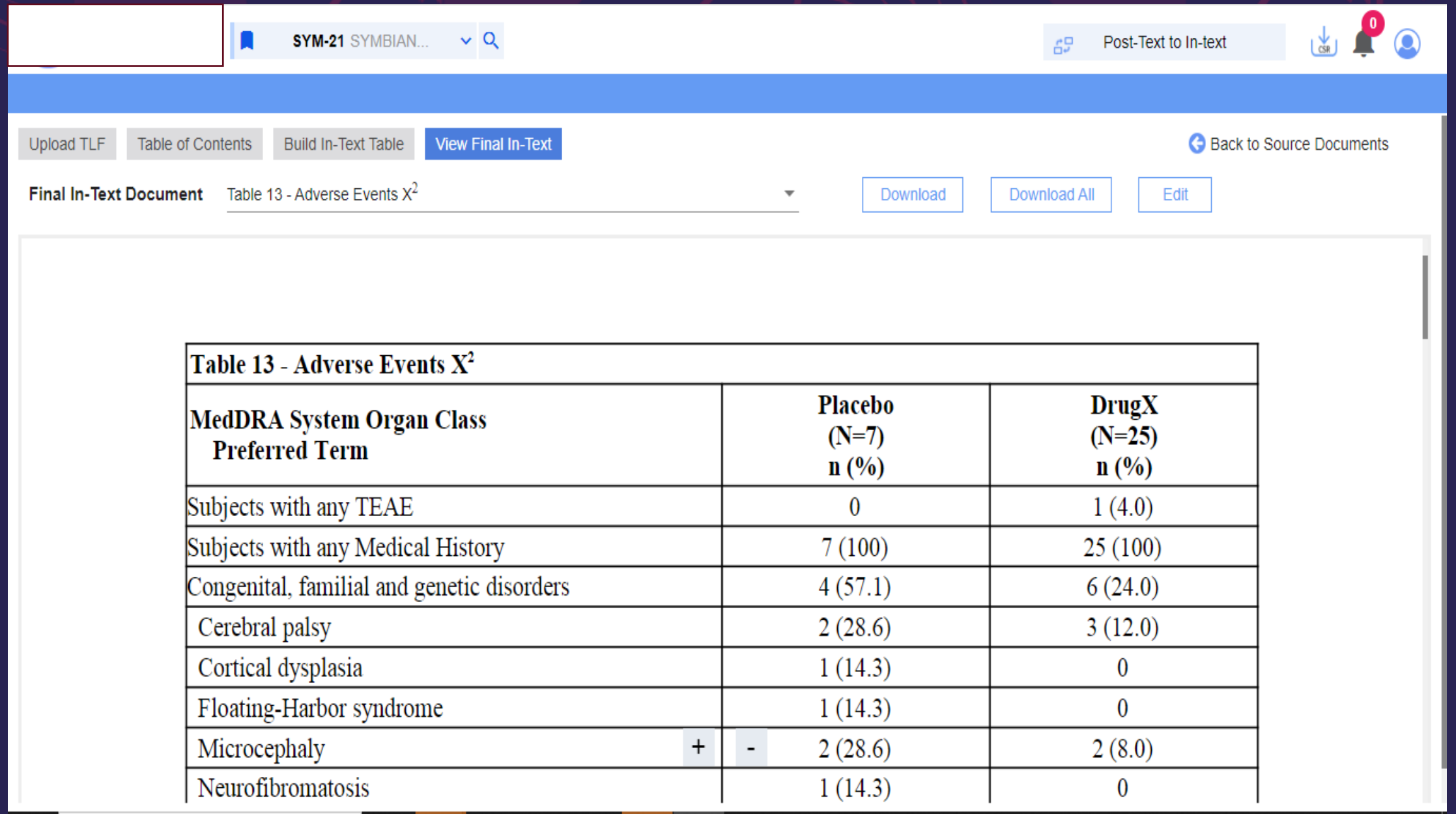
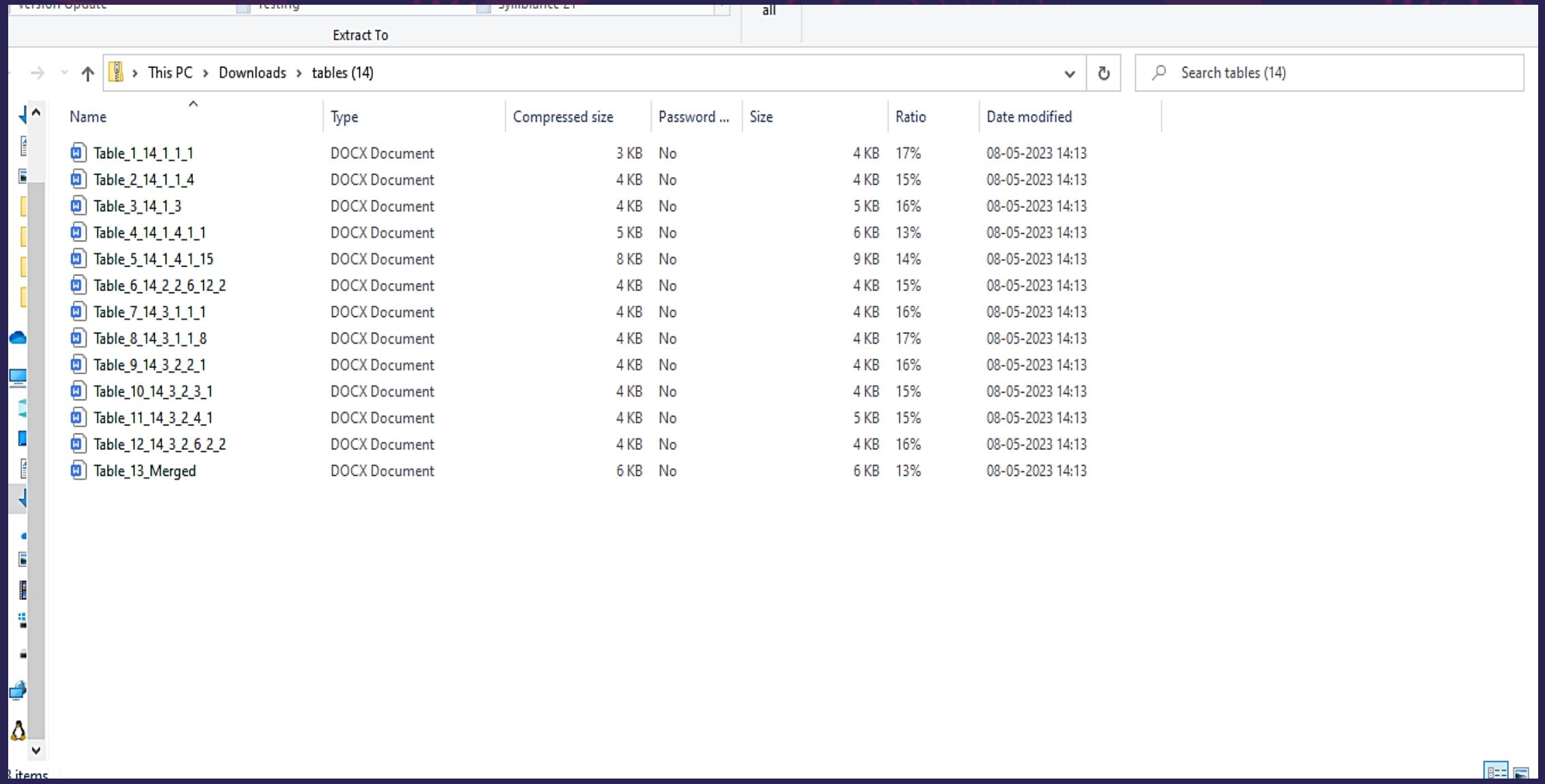


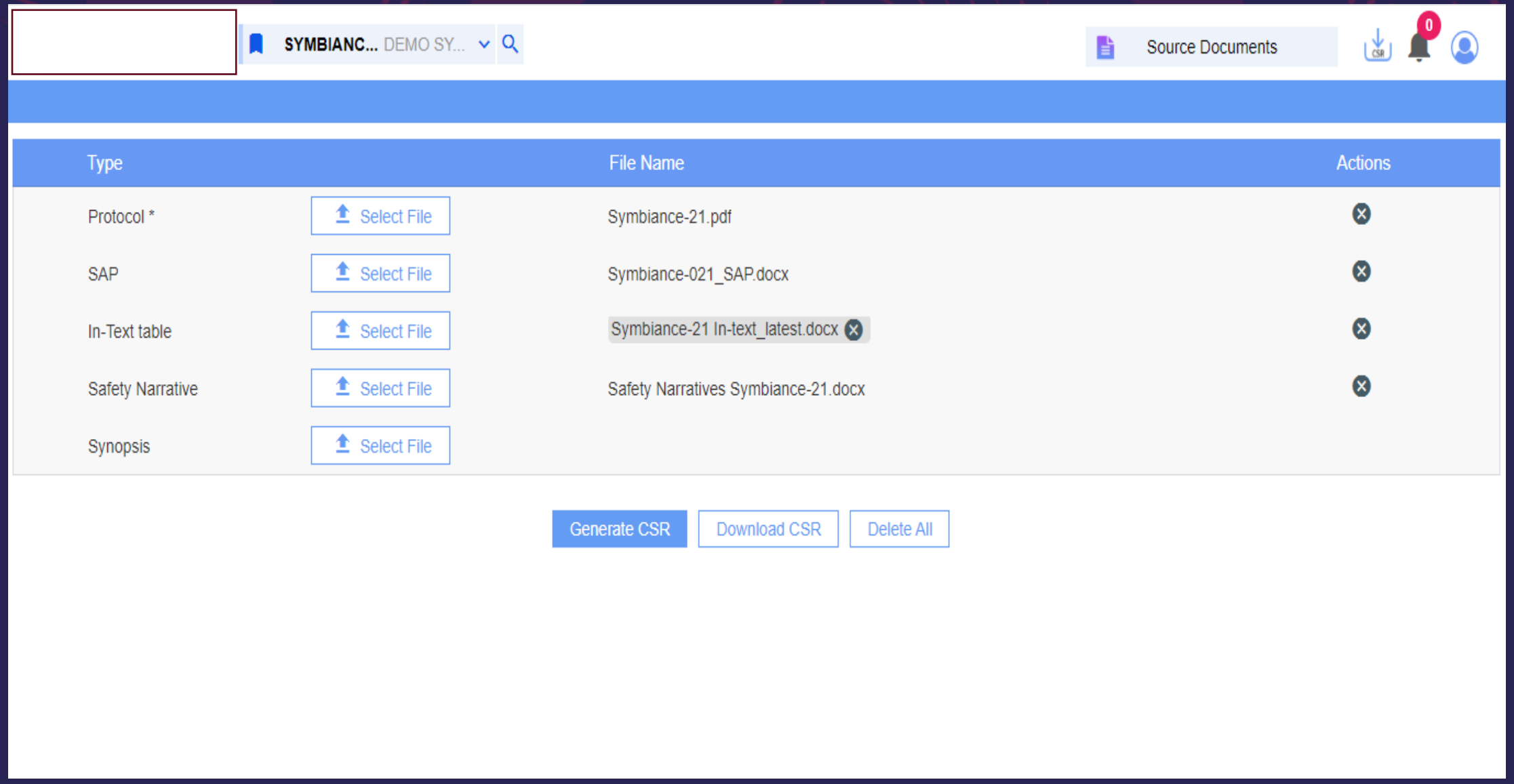
Table 13 - Adverse Events X^2

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

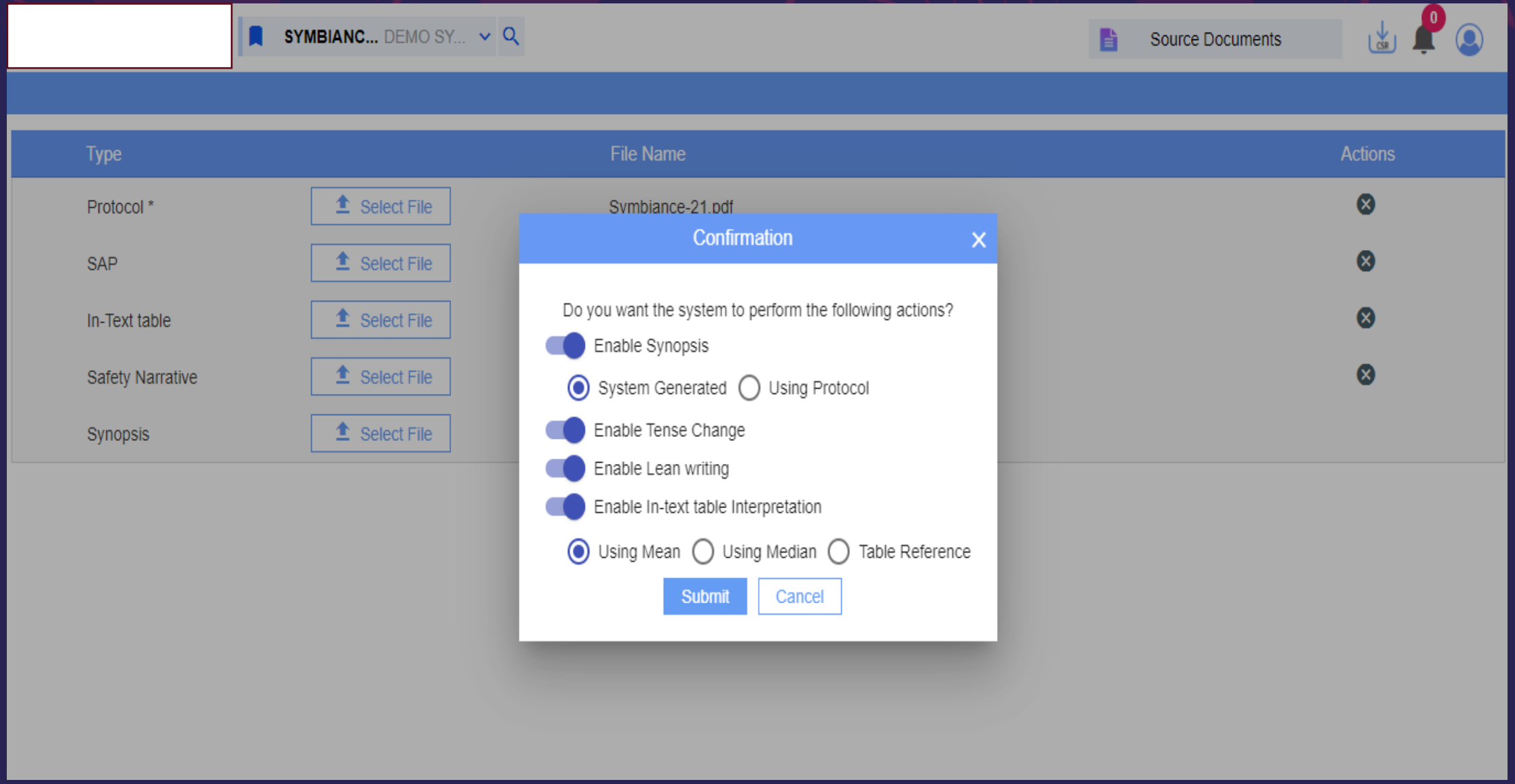
Download Bulk of Created In-Text Tables…



Post-Text are Ready to Ingest Into Larger Tool…



Engage the AI - Medical Writing Features



Thank You!

- Q&A

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

Symbiance
a relationship for success

ZYLiQ
ACCELERATE MEDICAL WRITING