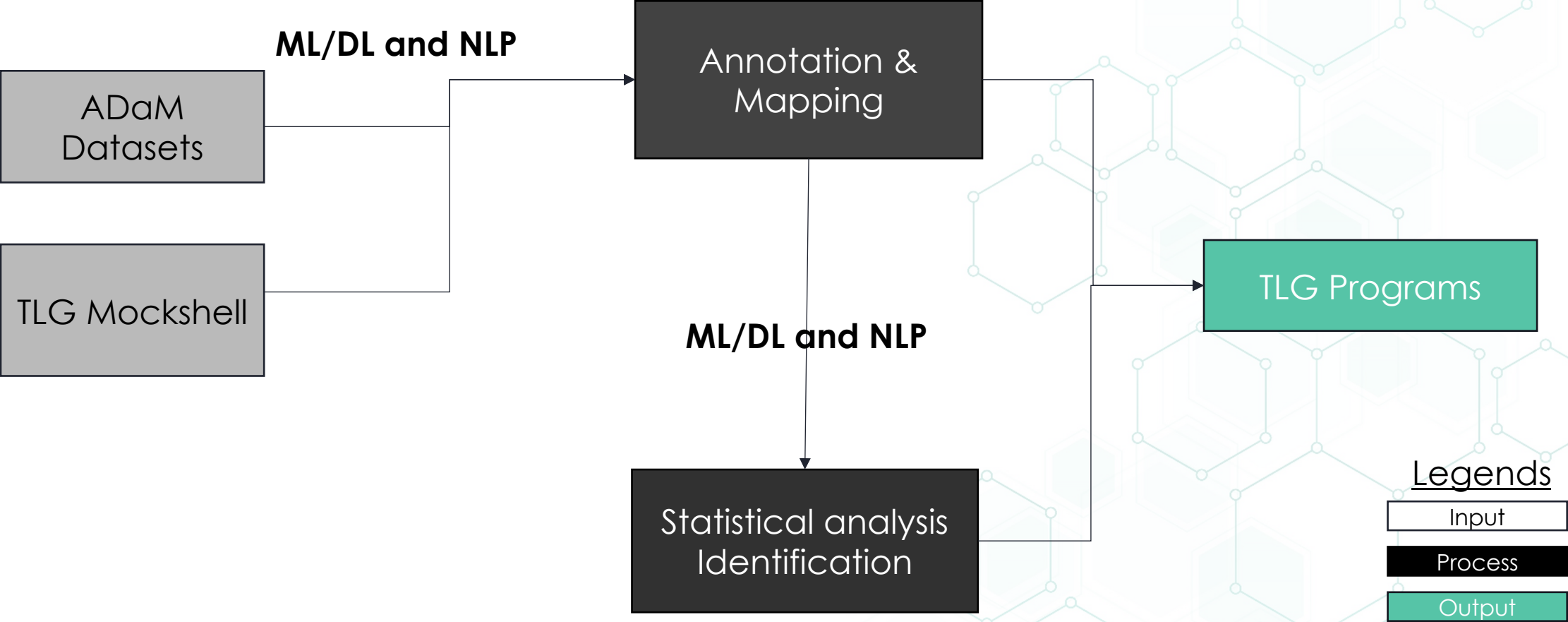


Role of AI (ML/NLP) in producing Statical reports.

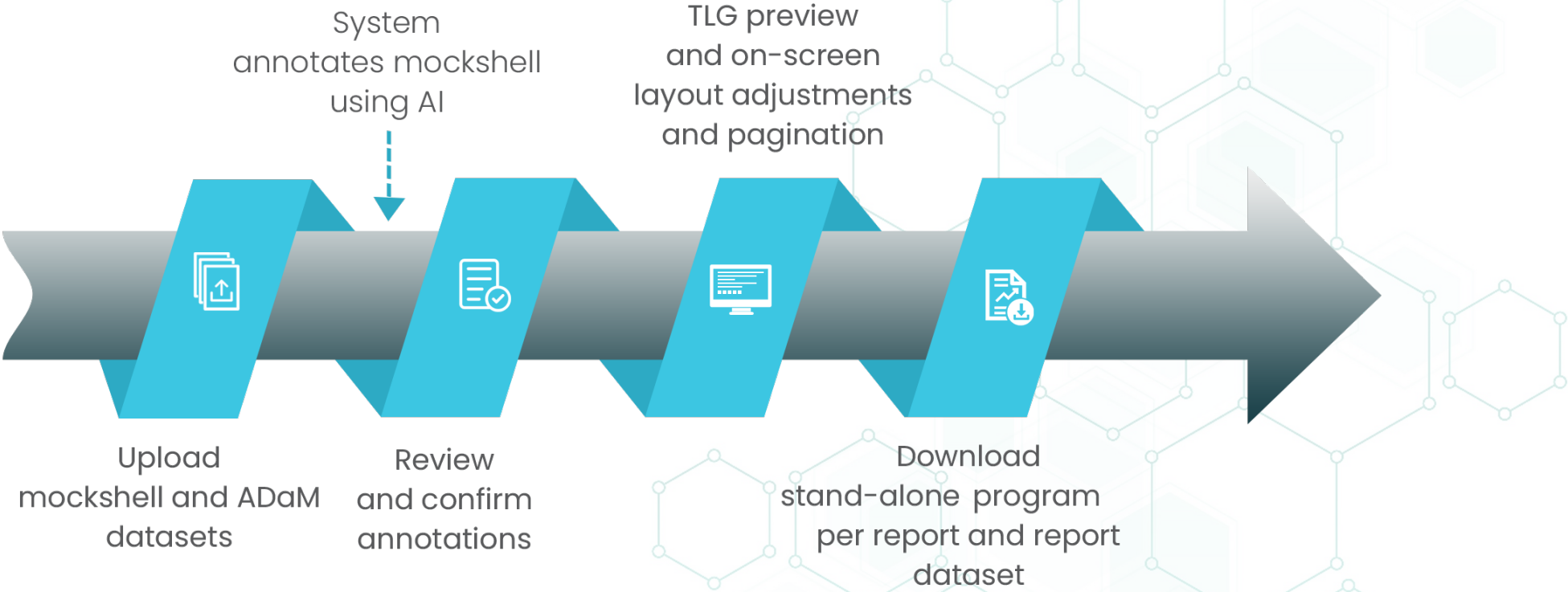
WHY AI TOOL?

- Significant reduction of programming efforts
- Easy adaption to any sponsor's TLG mock shells
- Quick & Flexible to re-do TLGs towards mock shell and ADaM data changes
- Down-loadable Stand-alone programs without Macros

USE OF ML, DL & NLP FOR TLG GENERATION



OVERALL PROCESS



UPLOAD

UploadsMockshell AnnotationDownloadVersion History

MockShell

Upload File

.docx

Mockshell-001.docx

ADaM Datasets

Upload File

.sas7bdat

adae.sas7bdat

adcm.sas7bdat

adds.sas7bdat

adlb.sas7bdat

admh.sas7bdat

adsl.sas7bdat

adv.sas7bdat

Version : 1

23-03-2022 12:10:17 PM

Study Lead

jey A

Step 1: Upload TLG Mock Shell & ADaM Datasets

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ANNOTATION & USER REVIEW

Uploads

Mockshell Annotation

Download

Version History

Tables

Q Search

Table 14.1.4.1.1

Demographic and Baseline Characteristics

Table 14.1.3

Analysis Sets

Table 14.1.4.1.2.1

Demography and Baseline Characteristics by Age Group (1)

Table 14.1.1.3

Subject Disposition and Primary Reason for Discontinuation from Study

Table 14.1.4.1.5

Medical History by System Organ Class and Preferred Term

Table 14.1.4.2

Prior Medications

Listings

Figures

Shell View

Table 14.1.4.1.1

Mixed

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Table 14.1.4.1.1

Demographic and Baseline Characteristics

Safety Analysis Set

ADSL TRT01A == 'Plac'

ADSL TRT01A == 'Drug'

ADSL TRT01A == 'P1'

Category

Placebo

Drug01

Combined Total

(N=xx)

(N=xx)

(N=xx)

Age (year) a

n

xx

xx

xx

missing

xx

xx

xx

mean (SD)

xx.xx (xx.xx)

xx.xx (xx.xx)

xx.xx (xx.xx)

median

xx.xx

xx.xx

xx.xx

min,max

xx.xx,xx.xx

xx.xx,xx.xx

xx.xx,xx.xx

Age group 1, n (%)

2-<7 years

7-<12 years

12-<17 years

>=17 to <65 years

>=65 years

Missing

xx (xx.x)

xx (xx.x)

xx (xx.x)

xx (xx.x)

xx (xx.x)

xx (xx.x)

Age group 2, n (%)

2-<7 years

7-<12 years

12-<18 years

xx (xx.x)

xx (xx.x)

xx (xx.x)

xx (xx.x)

xx (xx.x)

xx (xx.x)

List of tables from the uploaded
TLG Mock Shell

Step 2: Annotations &
User Review

ON-SCREEN REPORT & COLUMN RESIZING

UploadsMockshell AnnotationDownloadVersion History

Tables

Search

Table 14.1.4.1.1

Demographic and Baseline Characteristics

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Demography and Baseline Characteristics by Age Group (1)

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TLF View

Table 14.1.4.1.1

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Demo001-001

Table 14.1.4.1.1

Demographic and Baseline Characteristics

Safety Analysis Set

Category	Placebo (N=6)	Drug01 (N=26)	Combined Total (N=32)
Age (year)*			
n	6	26	32
missing	0	0	0
mean(SD)	17.50(10.63)	12.77(8.44)	13.66(8.90)
median	17.50	10.50	11.00
min,max	6.00,35.00	2.00,35.00	2.00,35.00
Age group 1, n (%)			
2-<7 years	1(16.67)	6(23.08)	7(21.88)
7-<12 years	1(16.67)	9(34.62)	10(31.25)
12-<17 years	1(16.67)	4(15.38)	5(15.62)
>=17 to <65 years	3(50.00)	7(26.92)	10(31.25)
>=65 years	0	0	0
Age group 2, n (%)			
2-<7 years	1(16.67)	6(23.08)	7(21.88)
7-<12 years	1(16.67)	9(34.62)	10(31.25)
12-<18 years	1(16.67)	4(15.38)	5(15.62)

« Prev

1

2

3

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Step 3: On-Screen Report

REALTIME COLUMN RESIZING

UploadsMockshell AnnotationDownloadVersion History

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Demographic and Baseline Characteristics

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Analysis Sets

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Demography and Baseline Characteristics by Age Group (1)

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Subject Disposition and Primary Reason for Discontinuation from Study

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Medical History by System Organ Class and Preferred Term

Table 14.1.4.2

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TLF View

Table 14.1.4.1.1

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Demo001-001

Table 14.1.4.1.1

Demographic and Baseline Characteristics

Safety Analysis Set

Category	Placebo (N=6)	Drug01 (N=26)	Combined Total (N=32)
Age (year) ^a			
n	6	26	32
missing	0	0	0
mean (SD)	17.50 (10.63)	12.77 (8.44)	13.66 (8.90)
median	17.50	10.50	11.00
min,max	6.00,35.00	2.00,35.00	2.00,35.00
Age group 1, n (%)			
2-<7 years	1 (16.67)	6 (23.08)	7 (21.88)
7-<12 years	1 (16.67)	9 (34.62)	10 (31.25)
12-<17 years	1 (16.67)	4 (15.38)	5 (15.62)
>=17 to <65 years	3 (50.00)	7 (26.92)	10 (31.25)
>=65 years	0	0	0
Age group 2, n (%)			
2-<7 years	1 (16.67)	6 (23.08)	7 (21.88)
7-<12 years	1 (16.67)	9 (34.62)	10 (31.25)
12-<18 years	1 (16.67)	4 (15.38)	5 (15.62)

« Prev123Next »

Column resizing changes will be reflected in the downloadable stand-alone program

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8

LISTING

Listing Annotation

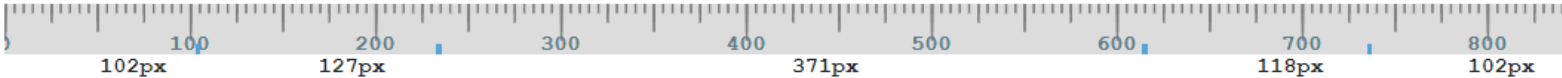
Demo_0106

Page x of y

Listing 16.2.4.3
Medical History and Current Medical Conditions
All Randomized Subjects

Treatment Group:Xxx					
ADSL SUBJID ADSL ASR	ADSL TRT01A	ADMH MHBODSYS	ADMH MHDECOD ADMH MHTERM	ADMH MHSTDTC	ADMH MHENDTC
Age(y) , Sex, Race		System Organ Class	Medical History Preferred Term / Investigator Term	Date of Diagnosis, Surgical Procedure or Onset of Symptoms	End Date or Ongoing
00100110 25, M, W			Hypertension / Hypertension	2005-11-05	2006-01---
00100111 26, W, W			Parkinson's disease / Parkinson's disease	2007-03---	ONGOING

LISTING PREVIEW



Listing 16.2.4.3

Medical History and Current Medical Conditions

All Randomized Subjects

Treatment Group: Placebo

Subject ID Age(y) , Sex, Race	System Organ Class	Medical History or Current Medical Condition Preferred Term / Investigator Term	Date of Diagnosis, Surgical Procedure or Onset of Symptoms	End Date or Ongoing
30011001 22, F, W	Surgical and medical procedures	Brain tumour operation/Excision of Right fronto-temporal neuroepithelial tumor	1965-06-23	1965-06-23
30011001 22, F, W	Endocrine disorders	Hypopituitarism/Hypopituitarism	1965-06-23	
30011001 22, F, W	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Medulloblastoma/Medulloblastoma	1965-06-24	1965-06-24
30011001 22, F, W	Nervous system disorders	Narcolepsy/Narcolepsy	1965-06-27	
30011001 22, F, W	Psychiatric disorders	Hallucination, auditory/Auditory hallucinations	1965-07-03	
30011001 22, F, W	Endocrine disorders	Hypothyroidism/hypothyroidism		
	Injury, poisoning			

DOWNLOAD PROGRAM PER REPORT & REPORT DATASET

UploadsMockshell AnnotationDownloadVersion History

TablesListingFiguresMockshell

Table Name

☒ Table 14.1.4.1.1- Demographic and Baseline Characteristics

☐ Table 14.1.3- Analysis Sets

☐ Table 14.1.4.1.2.1- Demography and Baseline Characteristics by Age Group (1)

☐ Table 14.1.1.3- Subject Disposition and Primary Reason for Discontinuation from Study

☐ Table 14.1.4.1.5- Medical History by System Organ Class and Preferred Term

☐ Table 14.1.4.2- Prior Medications

☐ Table 14.3.1.3.1- Overview of Treatment-Emergent Adverse Events

☐ Table 14.3.1.1- Treatment-Emergent Adverse Events by Decreasing Frequency

☐ Table 14.3.1.2- Treatment-Related, Treatment-Emergent Adverse Events by System Organ Class and Preferred Term

☐ Table 14.3.1.3- Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Maximum Severity

Dataset

SAS Code

Downloadable Stand-alone program per report & Report Dataset (before final output)

SAS PROGRAM & REPORT DATASET

```
1 *****  
2 Study      : demo006  
3 Program Name : Table 14.1.4.1.1.sas  
4 Table      : Demographic and Baseline Characteristics  
5 Author     : jey A  
6 Date Created : 2022-03-30  
7 *****  
8 libname source ".\adam";  
9 data ADSL;  
10     set source.ADSL;  
11     keep SAFFL TRT01A AGE AGEGR01 AGEGR02 SEXC RACE ETHNIC WEIGHT HEIGHT BMI TRT01AN AGEGR01N AGEGR02N RACEN ETHNICN USUBJID ;  
12 run;  
13  
14  
15 proc sort data =ADSL out= final (keep = SAFFL TRT01A AGE AGEGR01 AGEGR02 SEXC RACE ETHNIC WEIGHT HEIGHT BMI TRT01AN AGEGR01N AGEGR02N RACEN  
16     by USUBJID ;  
17 run;  
18  
19  
20 data population_filter_1_1;  
21     set final;  
22     where SAFFL = "Y";  
23 run;  
24  
25  
26 data cohort_filter1_1;  
27     length TRTGRP_ $100;  
28     set population_filter_1_1;  
29     where TRT01A = "Placebo";  
30     TRTGRP_ = "cohort1";  
31     TRTGRPN_ = 1;  
32 run;  
33  
34  
35 data cohort_filter2_1;  
36     length TRTGRP_ $100;  
37     set population_filter_1_1;
```

table 14.1.4.1.1 (4).xpt

Library Properties DATASET

Freeze Hide Show... Format Filter... Font... Find

Table View

	column1	column2	column3	column4	pageno
1	Age (year)<sup>a				1
2	n	6	26	32	1
3	missing	0	0	0	1
4	mean(SD)	17.50(10.63)	12.77(8.44)	13.66(8.90)	1
5	median	17.50	10.50	11.00	1
6	min,max	6.00,35.00	2.00,35.00	2.00,35.00	1
7	Age group 1, n (%)				1
8	2 to <7 years	1(16.67)	6(23.08)	7(21.88)	1
9	7 to <12 years	1(16.67)	9(34.62)	10(31.25)	1
10	12 to <17 years	1(16.67)	4(15.38)	5(15.62)	1
11	17 to <65 years	3(50.00)	7(26.92)	10(31.25)	1
12	Age group 2, n (%)				2
13	2-<7 years	1(16.67)	6(23.08)	7(21.88)	2
14	7-<12 years	1(16.67)	9(34.62)	10(31.25)	2
15	12-<18 years	1(16.67)	4(15.38)	5(15.62)	2
16	>=18 to <65 ye...	3(50.00)	7(26.92)	10(31.25)	2
17	>=65 years	0	0	0	2
18	Sex, n (%)				2
19	Female	1(16.67)	10(38.46)	11(34.38)	2
20	Male	5(83.33)	16(61.54)	21(65.62)	2
21	Male	0	0	0	2
22	Female	0	0	0	2
23	Missing	0	0	0	2

Rows 1-56 of 56 Filter: Off Sort: none 1,1

c:\users\jeyantharkumara\downloads\table 14.1.4.1.1 (4).xpt