



Automating TLG Generation for Clinical Trials Leveraging R/R Shiny Technology

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PHUSE US CONNECT 2024

Agenda

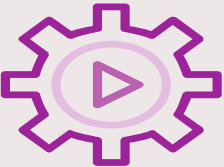


Data Visualization

TLG Automation



Mission: Provide a tool to **empower data driven** decisions through the life of a clinical trial, to **uncover new insights** utilizing **cutting edge** technologies, by generating interactive and static outputs for exploratory and regulatory needs.

Use Case	Objective	Benefits
 TLG Automation	• Provide stakeholders access to Near Real-Time (NRT) data for informed decision making • Solution to representing complex information in a consistent format with enhanced technologies • Reduce the data review time for study teams while providing greater insights	• An in-house solution to data visualization allows for tools and outputs to be customizable to targeted end user • Proactively empower faster informed data driven decision-making • Reduce the number of CSR outputs required due to the dynamic and interactive features of the tool

Governance Team

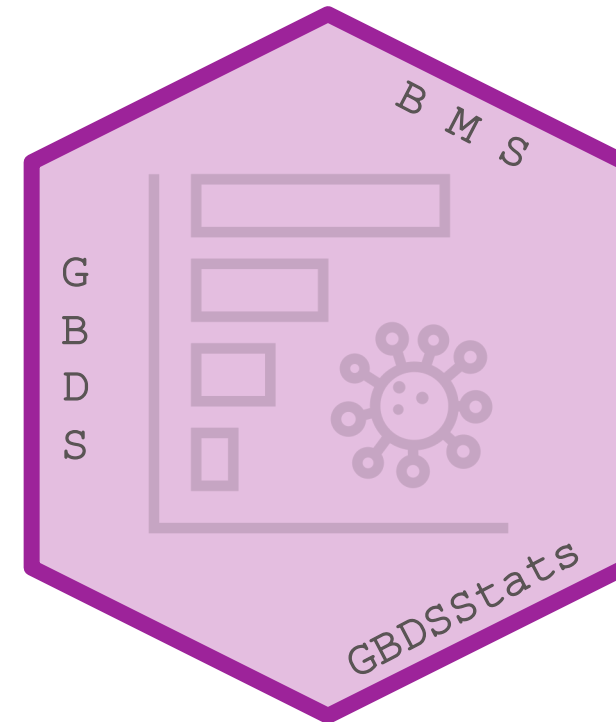
Standards

R Statistical Package

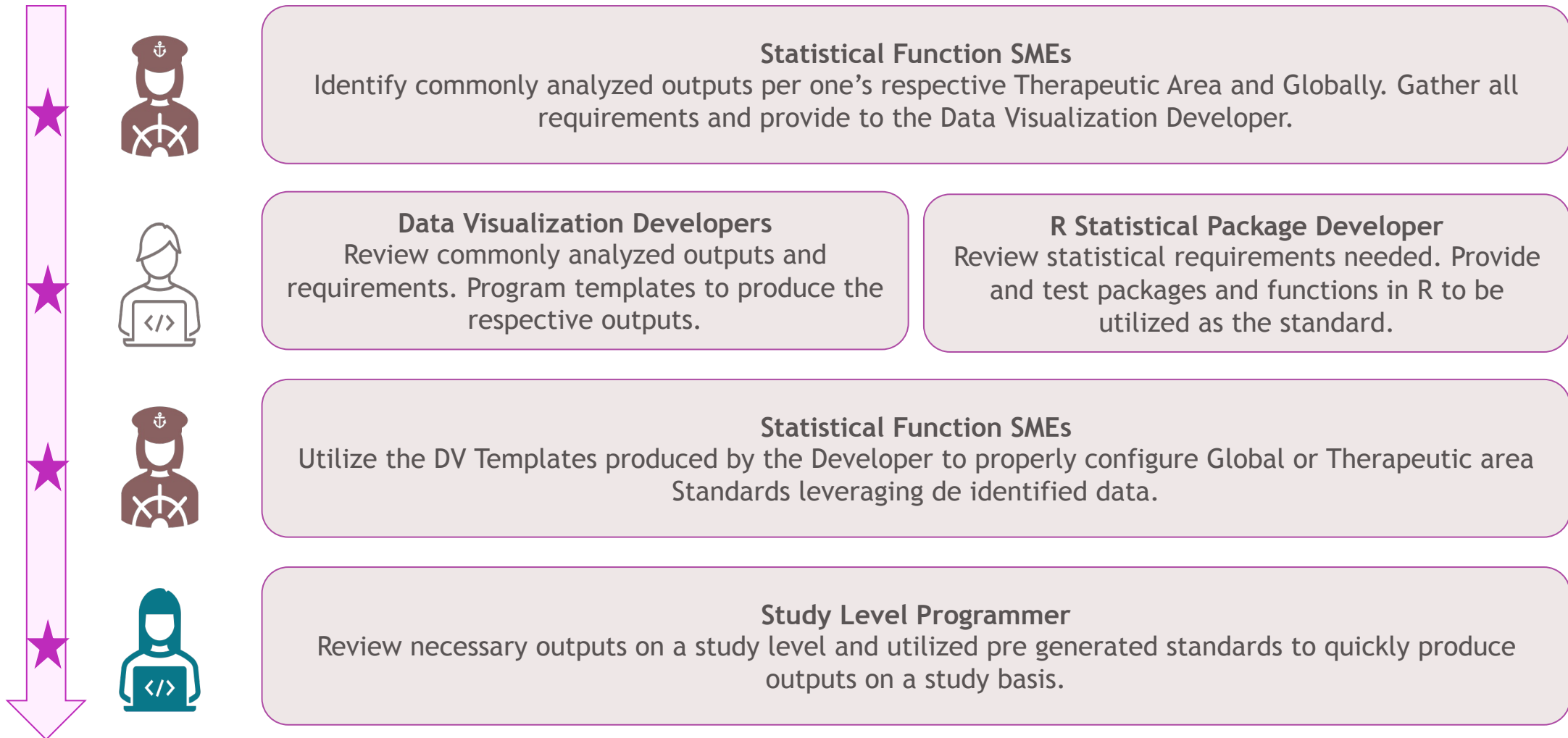


Goal: to create standards for R statistical methods within BMS GBDS. **Develop R Packages** containing statistical methods for analysis.

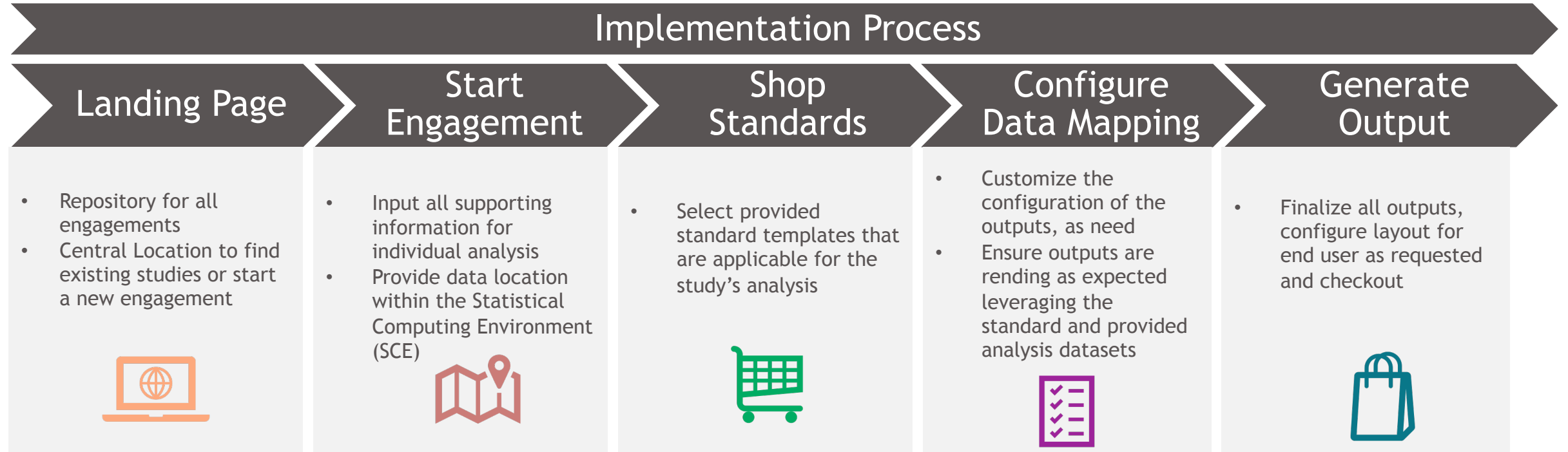
- Development of standard functions using opensource R packages, conducted by an **experienced statistician versed in R.**
- Ensuring that the statistical methods produced are not only **technically sound** but also **methodologically robust**
- Statisticians to be the **owner and maintainer** of these packages
- **Cross collaboration between functions:** Statisticians, Statistical Programmers and Data Visualization Developers



Roles and Responsibilities



Implementation



Shop the Standards

- Display all standard templates available, allowing end users to add to their engagement
- Add selected panels to new engagement
 - Choose/inherit from Global or TA Standards set of panels
 - Choose/inherit from other Study panel layouts (eg: Study B wants to replicate what Study A generated)

The screenshot shows the DaVinci Shop interface. On the left is a sidebar with the following sections:

- DaVinci Shop v1.1.1**
- Select Use Case**: A dropdown menu showing "TLG - Toplines/TLGs".
- Select Engagement to View**: A dropdown menu showing "Global-TLG-Sandbox".
- Global-TLG-Sandbox Reports**: A section with a "Debugger OFF ?" button.
- Tables**: A list of table templates, with "GS_CSR_DM_T_003" selected and highlighted in grey. Other tables listed include GS_CSR_DS_T_003, GS_CSR_DS_T_007, GS_CSR_PD_T_001, GS_CSR_AE_T_001, and GS_CSR_AE_T_002.

The main area displays the selected table, "GS_CSR_DM_T_003". At the top of this area, it says "You are editing engagement [Demo-TLG-Stable](#)". Below this, the table is titled "Table 14.1.2.x Demographic Characteristics Summary - Randomized Subjects". The table has columns for "ARM A N = 325", "ARM B N = 321", "ARM C N = 324", and "Total N = 970". The rows include "AGE (YEARS)" with statistics (N, MEAN, SD, MEDIAN, Q1, Q3, MIN, MAX) and "AGE CATEGORIZATION n(%)" with categories "< 65" and ">= 65". The "SEX n(%)" section shows "FEMALE" and "MALE" counts and percentages.

A purple arrow points to a shopping cart icon in the top right corner of the main area, which is also highlighted with a purple box.

Configure Data Mapping

- Display standard DataSpecs of selected panels
- Map DataSpecs to study datasets
- Preview outputs while configuring mapping to ensure accuracy

Engagement Name: Demo-TLG-Stable

Data Folder: /cdscs/dss/bmsprod/zz/dataviz-stable/data/stable/blinded/adam/DV_mock_ADaM_BMS_subset/

Panel Name (editable): GS_CSR_DM_T_003

Package Version (editable): TLGStandards.v2.0.0

Template: tlg_basic_table

☐ Panel validated for regulatory use

Validation Summary Report with full path

- Invalid

- Editable

- Editable JSON

Create New Datasets (Optional)

DV Parameter	Variables	Defaults	Input Datasets	Output Datasets	Is Required	Notes
No data available in table						

Select Valid Panel Inputs (Required)

DV Parameter	Variables	Defaults	Input Datasets	Is Required	Notes	
1	PARAM_POPFL	"%FL"	RANDFL	ads1	Y	
2	PARAM_GROUPVAR	{ "1": { "var": "TRTNP", "sort": "TRTNP" }, "2": { "var": "TRTNA", "sort": "TRTNA" } }	TRT01P	ads1	Y	
3	PARAM_SUMMARY	{ "1": { "var": "AGEGR1", "text": "AGE CATEGORIZATION n(%)", "sort": "AGEGR1" }, "2": { "var": "ASEX", "text": "SEX n(%)", "sort": "ASEX" }, "3": { "var": "RACE", "text": "RACE n(%)", "sort": "RACE" } }	AGEGR1:1,ASEX:2,RACE:3	ads1	Y	
4	PARAM_GROUP_ROWS	"USUBJID"	-	-	Y	
5	CORE_TITLE	-	Demographic Characteristics Summary	-		
6	CORE_TABLE_NUMBER	-	Table 14.1.2.x	-		
7	PARAM_SUBGROUPVAR	""				

Select Study Dataset:

ads1

Metadata

Data

Panel Preview

Table 14.1.2.x
Demographic Characteristics Summary
Randomized Subjects

	ARM A N = 20	ARM B N = 19	ARM C N = 23	Total N = 62
AGE CATEGORIZATION n(%)				
< 65	9 (45.0)	7 (36.8)	5 (21.7)	21 (33.9)
>= 65	11 (55.0)	12 (63.2)	18 (78.3)	41 (66.1)
SEX n(%)				
FEMALE	3 (15.0)	5 (26.3)	2 (8.7)	10 (16.1)
MALE	17 (85.0)	14 (73.7)	21 (91.3)	52 (83.9)
RACE n(%)				
ASIAN INDIAN	0	1 (5.3)	0	1 (1.6)
JAPANESE	20 (100.0)	18 (94.7)	22 (95.7)	60 (96.8)
OTHER	0	0	1 (4.3)	1 (1.6)

→ Run

← Copy

For Exploratory Use Only

Configure Data Mapping Cont.

DV Parameter	Variables	Defaults	Input Datasets
1	PARAM_POPFL	"%FL"	RANDFL
2	PARAM_GROUPVAR	{ "1": { "var": "TRT%P", "sort": "TRT%PN" }, "2": { "var": "TRT%AN", "sort": "TRT%AN" } }	ads1
3	PARAM_SUMMARY	{ "1": { "var": "AAGE", "text": "AGE", "units": "AAGEU", "stats": ["N", "MEAN", "SD", "MEDIAN", "Q1", "Q3", "MIN", "MAX"] }, "2": { "var": "AGEGR1", "text": "AGE CATEGORIZATION n(%)", "sort": "AGEGR1N" }, "3": { "var": "ASEX", "text": "SEX n(%)", "sort": "ASEXN" }, "4": { "var": "RACE", "text": "RACE n(%)", "sort": "RACEN" }, "5": { "var": "ETHNIC", "text": "ETHNICITY n(%)", "sort": "ETHNICN" }, "6": { "var": "REGION1", "text": "COUNTRY BY GEOGRAPHIC REGION n(%)", "sub": { "var": "COUNTRYL" } } }	ads1
4	PARAM_GROUP_ROWS	"SUBJID"	-
5	CORE_TITLE	-	Demographic Characteristics Summary
6	CORE_TABLE_NUMBER	-	Table 14.1.2.x
7	PARAM_SUBGROUPVAR	""	-
8	CORE_HEADER	-	-
9	CORE_FOOTER	-	-
10	CORE_EXTRACT	-	-
11	PARAM_TOTAL_COLUMN	-	TRUE
12	PARAM_N_LOCATION	-	BOTTOM

GS_CSR_DM_T_003

Table 14.1.2.x
Demographic Characteristics Summary
Randomized Subjects

	ARM A N = 20	ARM B N = 19	ARM C N = 23
AGE (YEARS)			
N	20	19	23
MEAN	62.4	69.3	67
SD	9.77	8.08	6
MEDIAN	65.5	65.0	70
Q1	56	60	65
Q3	70	75	72
MIN	44	55	54
MAX	79	86	78
AGE CATEGORIZATION n(%)			
< 65	9 (45.0)	7 (36.8)	8 (34.8)
>= 65	11 (55.0)	12 (63.2)	15 (65.2)
SEX n(%)			
FEMALE	8 (40.0)	8 (42.1)	2 (8.7)
MALE	12 (60.0)	11 (57.9)	21 (91.3)
RACE n(%)			
ASIAN INDIAN	0	1 (5.3)	0
JAPANESE	20 (100.0)	18 (94.7)	22 (95.7)
OTHER	0	0	1 (4.3)
ETHNICITY n(%)			
NON-HISPANIC WHITE	12 (60.0)	12 (63.2)	15 (65.2)

Population

Randomized Population Flag (RANDFL)

Group Variable

Planned Treatment for Period 01 (TRT01P)

Sub-Group Variable

Summary Variables

AAGE:1 AGEGR1:2
ASEX:3 RACE:4
ETHNIC:5 REGION1:6

✓ Show Total Columns

Exporting Outputs

DaVinci: Demo-TLG-Stable

GS_CSR_DM_T_003

Table 14.1.2.x
Demographic Characteristics Summary
Randomized Subjects

	ARM A N = 20	ARM B N = 19	ARM C N = 23	Total N = 62
AGE (YEARS)				
N	20	19	23	62
MEAN	63.4	63.3	67.3	66.7
SD	8.77	9.08	8.83	8.44
MEDIAN	65.5	65.0	70.0	67.5
Q1	56	63	65	63
Q3	70	75	72	72
MIN	44	55	54	44
MAX	79	86	78	86
AGE CATEGORIZATION n(%)				
< 45	9 (45.0)	7 (36.8)	5 (21.7)	21 (33.9)
≥ 45	11 (55.0)	12 (63.2)	18 (78.3)	41 (66.1)
SEX n(%)				
FEMALE	3 (15.0)	5 (26.3)	2 (8.7)	10 (16.3)
MALE	17 (85.0)	14 (73.7)	21 (91.3)	52 (83.7)

v1.0.8
b307ada
2024-01-08

Application is deployed per individual study. End-user can interactively explore outputs.

DaVinci: Demo-TLG-Stable

GS_CSR_DM_T_003

Table 14.1.2.x
Demographic Characteristics Summary
Randomized Subjects

	ARM A N = 20	ARM B N = 19	ARM C N = 23	Total N = 62
AGE (YEARS)				
N	20	19	23	62
MEAN	63.4	63.3	67.3	66.7
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v1.0.8
b307ada
2024-01-08

<https://davinci-qc-gxp.web.bms.com/Demo-TLG-Stable/w-Ba5a56a/session/7f0b0b154bb6731128227101a2f6c2/download/export-generate-report?w-Ba5a56a>

End-users have the ability to export outputs as an rtf.

Protocol: Demo

Table 14.1.2.x
Demographic Characteristics Summary
Randomized Subjects

	ARM A N = 20	ARM B N = 19	ARM C N = 23	Total N = 62
AGE (YEARS)				
N	20	19	23	62
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SD	8.77	9.08	8.83	8.44
MEDIAN	65.5	65.0	70.0	67.5
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MALE	17 (85.0)	14 (73.7)	21 (91.3)	52 (83.7)
RACE n(%)				
0	0	1 (5.3)	0	1 (1.6)
ASIAN INDIAN	0	18 (94.7)	0	18 (94.7)
JAPANESE	20 (100.0)	0	22 (95.7)	42 (95.7)
OTHER	0	0	1 (4.3)	1 (1.6)
ETHNICITY n(%)				
NOT REPORTED	10 (50.0)	10 (52.6)	12 (52.2)	32 (51.6)
HISPANIC OR LATINO	0	0	1 (4.3)	1 (1.6)
NOT HISPANIC OR LATINO	10 (50.0)	9 (47.4)	10 (43.5)	29 (46.8)
COUNTRY BY GEOGRAPHIC REGION n(%)				
J/K/T	20 (100.0)	19 (100.0)	22 (95.7)	61 (98.4)
JAPAN	20 (100.0)	19 (100.0)	22 (95.7)	61 (98.4)
ROW	0	0	1 (4.3)	1 (1.6)
MEXICO	0	0	1 (4.3)	1 (1.6)

Program Path: develop:0805Data/Demo-TLG-Stable/commit/b307ada29a2b45a1817ca3175550b692fc090156
Program Name: panel_11801:TLGStandard.v1.7.0:tlg_basic_table

08JAN2024:14:12:47

Consistency

Flexibility

Conclusion

Efficiency

**Cost-
effectiveness**

Q&A | Any questions?





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