



Innovation Never Sleeps

M&I
(Methodology & Innovation)

DPS Helper: a Web Application to Create the **Data Presentation Specifications** Word Document in Clinical Trials

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Outline

- Background
- Quick Look
- Key Features
- Technical Stack and Challenge
- Demo
- Q&A

Background

- In Janssen, Data Presentation Specifications has two separated documents:
 - DPS Part 1
 - Mockup Tables
 - Mockup Listings
 - Mockup Graphs
 - DPS Part 2
 - ...
- It's the statistician's responsibility to create these two documents.

Background

- Concerns:
 - the DPS document usually has more than two hundreds pages.
 - the statisticians are not the Microsoft Word experts.
 - it takes a statistician's so much time to draft a high quality DPS document.
- Facts:
 - The DPS documents are with all kinds of discrepancies and flaws.
 - A lot of back-and-forth communications

Background

- For DPS Part 1
 - In-house
 - Statisticians and SAS programmers
 - Outsourced
 - Janssen and CRO

**A Picture
is worth
a thousand words.**

**A good mockup TLG
is worth
a thousand words.**

Background

- In Janssen, we have an Autocode Project to target generating SAS/R codes automatically
 - There's plenty of information in mockup tables, listings and graphs and this could be leveraged from DPS document (.docx) to develop the code.

Quick Look

Application Layout

janssen

AUTOCODE

Links

DPS Helper

ADaM Planning

Study DPS Reference

All

Type to Search

Search Box

User

Home >

Breadcrumb

▶ Standards

▶ JNJ-56021927

▶ Standards_Dev

▶ Test

Tree View

COMPOUND

STUDY

REPORTING EFFORT

Standards

Global

Master

Standards

DAS01

Standards

DAS02

Standards

Study_S_C

dbr_Master

JNJ-56021927

PCR3002

RE_CSR

JNJ-56021927

PCR3002

RE_CSR1

JNJ-56021927

PCR3002

RE_CSR2

Standards_Dev

Global

Master

Standards_Dev

Global

RE_CSR

Standards_Dev

Global

MMY

Previous

Page 1 of 6

10 rows

Next

Main Body

Tree hierarchy

- ▼ TSample02
 - ▼ Column Header
 - blank
 - ▼ Treatment A
 - Male
 - Female
 - ▼ Treatment B
 - Male
 - Female
 - Analysis set: [Analysis set]
 - ▼ Char Var
 - N
 - Category1
 - Category 2
 - ▼ Num Var
 - N
 - Mean (SD)
 - Median
 - Range
 - ▼ Footnotes
 - footnote1

TSample02: Table Title; Safety Analysis Set (Study dbr_RE_01)				
	Treatment A		Treatment B	
	Male	Female	Male	Female
Analysis set: Safety	###	###	###	###
Char Var				
N	###	###	###	###
Category1	###(xx.x%)	###(xx.x%)	###(xx.x%)	###(xx.x%)
Category 2	###(xx.x%)	###(xx.x%)	###(xx.x%)	###(xx.x%)
Num Var				
N	###	###	###	###
Mean (SD)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x	xx.x
Range	(xx; xx)	(xx; xx)	(xx; xx)	(xx; xx)
footnote1				
[Output Identifier] [Program Location] [Date/Time of output]				

Tree hierarchy

- ▼  LSample01
 - ▼ Column Header
 - Subject ID
 - Treatment Arm
 - Sex
 - Age (years)
 - ▼  Footnotes
 - Footnote1

[illegible]

Tree hierarchy

▼ GSample01

Graph Title

▼ Axis

X

Y

▼ Groups

▶ Group 1

▶ Group 2

▶ Group 3

Legend

▼ Reference Line

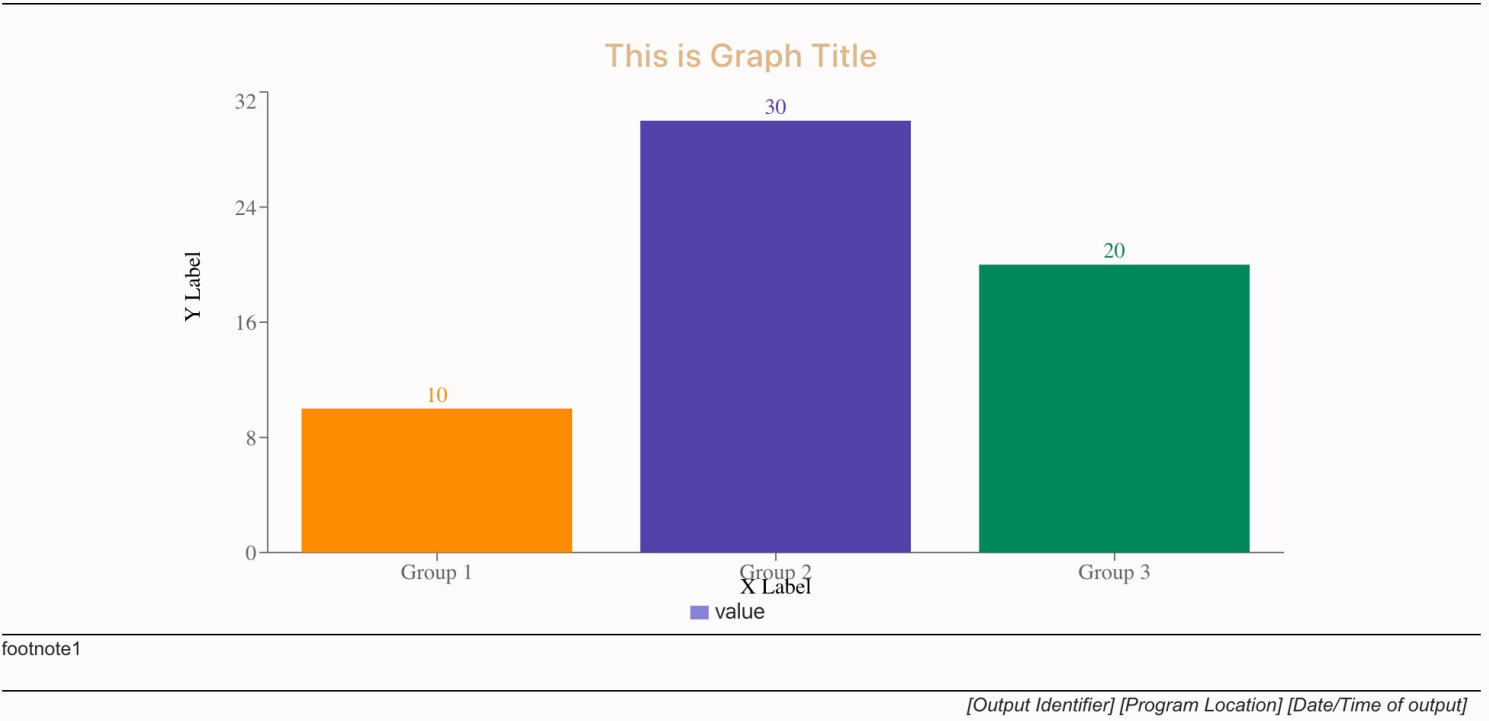
Vertical

Horizontal

▼ Footnotes

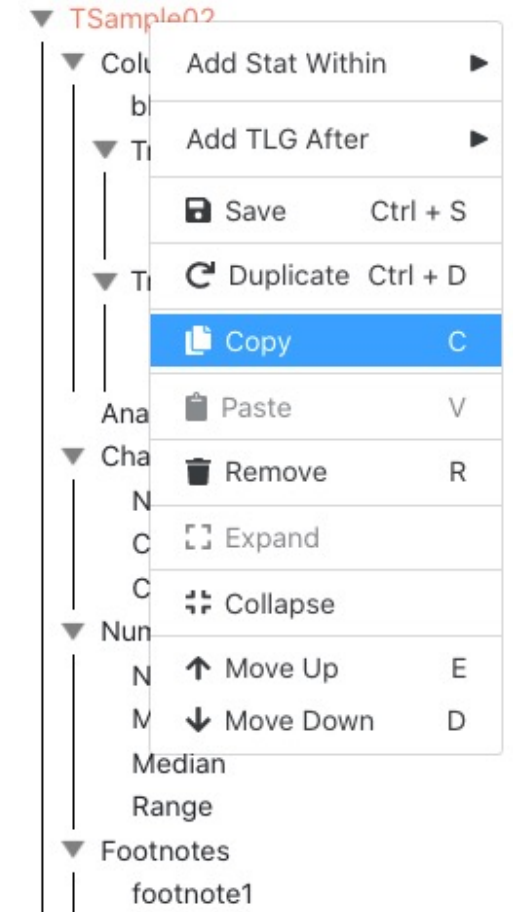
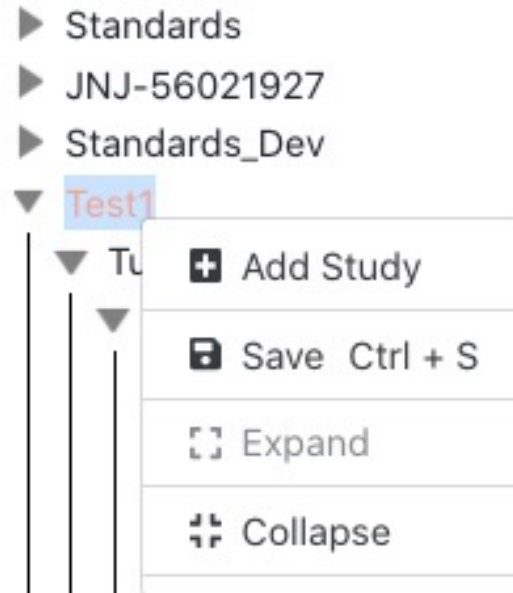
footnote1

GSample01: Graph Title; Safety Analysis Set (Study Safety)



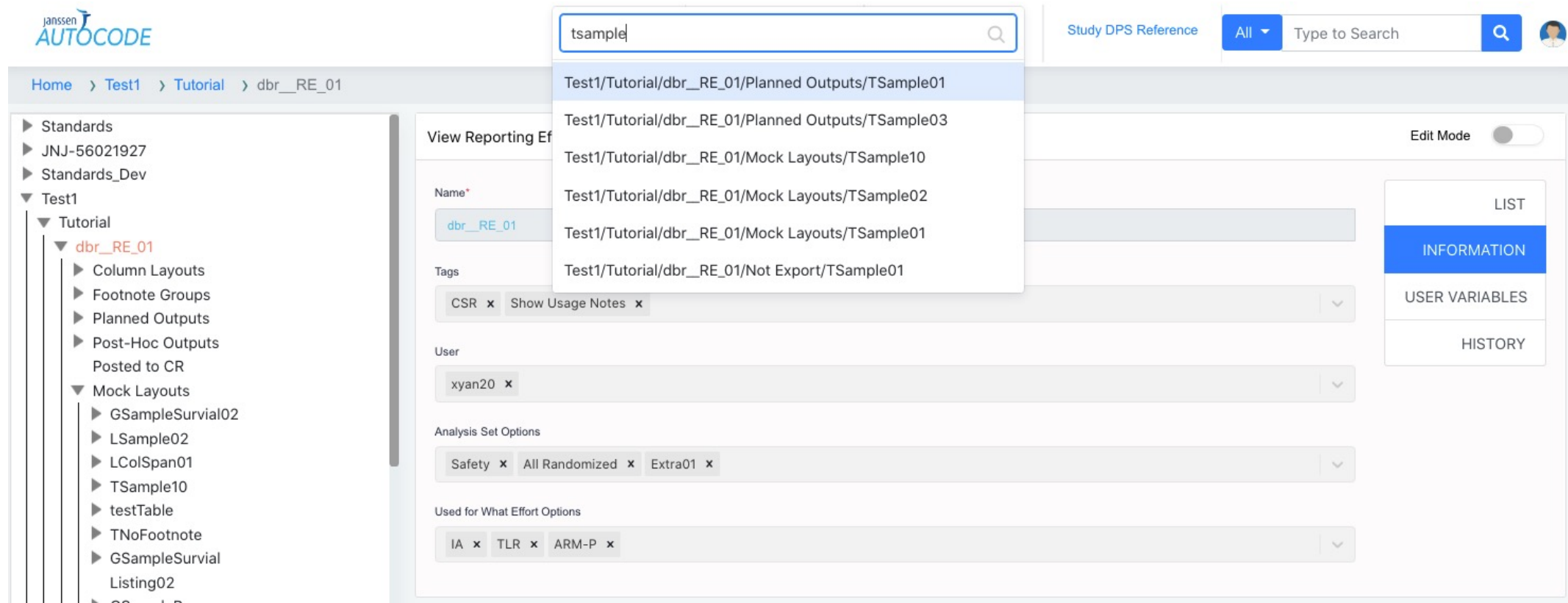
Key UI component and operation

- **Right click on the tree node**, you can do a lot of action from the context menu, such as copy, paste, remove, and save, etc.



Key UI component and operation

- The most important shortcut key is **ESC**. It allows you to quickly jump to any TLG or RE locally.



Key Features

- Central repository
 - Global and TA standards
 - All the clinical trial studies
- Orientated to Copy and Paste design to reuse similar items
 - Reporting effort
 - Table/listing/graph/column layout/footnote group
- Export to .docx and .xlsx
- User defined variables
 - Report effort
 - Table/listing/graph/column layout/footnote group

Key Features

- Shortcut keys to improve efficiency
- Multiple ways to create a TLG
 - Copy from similar TLG
 - Create from sample
 - Create from scratch
- Global search to find specific TLG quickly
- Mockup Graph
 - Upload PNG file
 - Interactive graph design

Technical Stack and Challenge

- Backend
 - Python
 - Django web framework
 - PostgreSQL
- Frontend
 - HTML + CSS
 - JavaScript
 - React UI library

Technical Stack and Challenge

- Challenge
 - One mockup layout used by several TLGs
 - Keep the TLG layout in exported .docx document the same as on web page

Demo

Demo

Create a new DPS word document based on a Standard study

Outline

- Create a new study
- Copy a Reporting Effort to Your Study
- Modify a Column Layout
- Copy and Modify a Column Layout
- Copy and Modify a Footnote Group
- Copy and Modify a table
- Export Word Document

Create a new Study

Create a New Study

Copy a Reporting Effort to Your Study

Copy a Reporting Effort to Your Study

Modify a Column Layout

Modify a Column Layout

Copy and Modify a Column Layout

Copy and Modify a Column Layout

Copy and Modify a Footnote Group

Copy and Modify a Footnote Group

Copy and Modify a table

Copy and Modify a table

Export Word Document

Export Word Document

Demo

Create a Table from Scratch

Let's create a table like below

TSIDEM-ST01: Summary of Demographics and Baseline Characteristics at [Time Point]; [Analysis Set] (Study [Study ID])					
	[Active Study Agent]				
	[Placebo]	[Treatment Group A]	[Treatment Group B]	Combined	Total
Analysis set: [Analysis set]	###	###	###	###	###
Age, [years]					
N	###	###	###	###	###
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Range	(xx;xx)	(xx;xx)	(xx;xx)	(xx;xx)	(xx;xx)
IQ range	(xx;xx)	(xx;xx)	(xx;xx)	(xx;xx)	(xx;xx)
[Age category 1]	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
[Age category 2]	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Sex					
N	###	###	###	###	###
Female	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Male	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Undifferentiated	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Unknown	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Key: IQ = interquartile Note: N's for each parameter reflect non-missing values.					
[Output Identifier] [Program Location] [Date/Time of output]					

Create the Table tree structure

Create a Table from Scratch Part 1

Add Identifier, Title and Analysis set

Create a Table from Scratch Part 2

Add the Column Headers

Create a Table from Scratch Part 3

Add Age

Create a Table from Scratch Part 4

Add Sex

Create a Table from Scratch Part 5

Add the footnote

Create a Table from Scratch Part 6

Q&A

Thanks