

Analysis Studio

A Tool Framework for Supporting Regulatory Review

PhUSE US Connect

March 10, 2020

SD10



Disclaimer

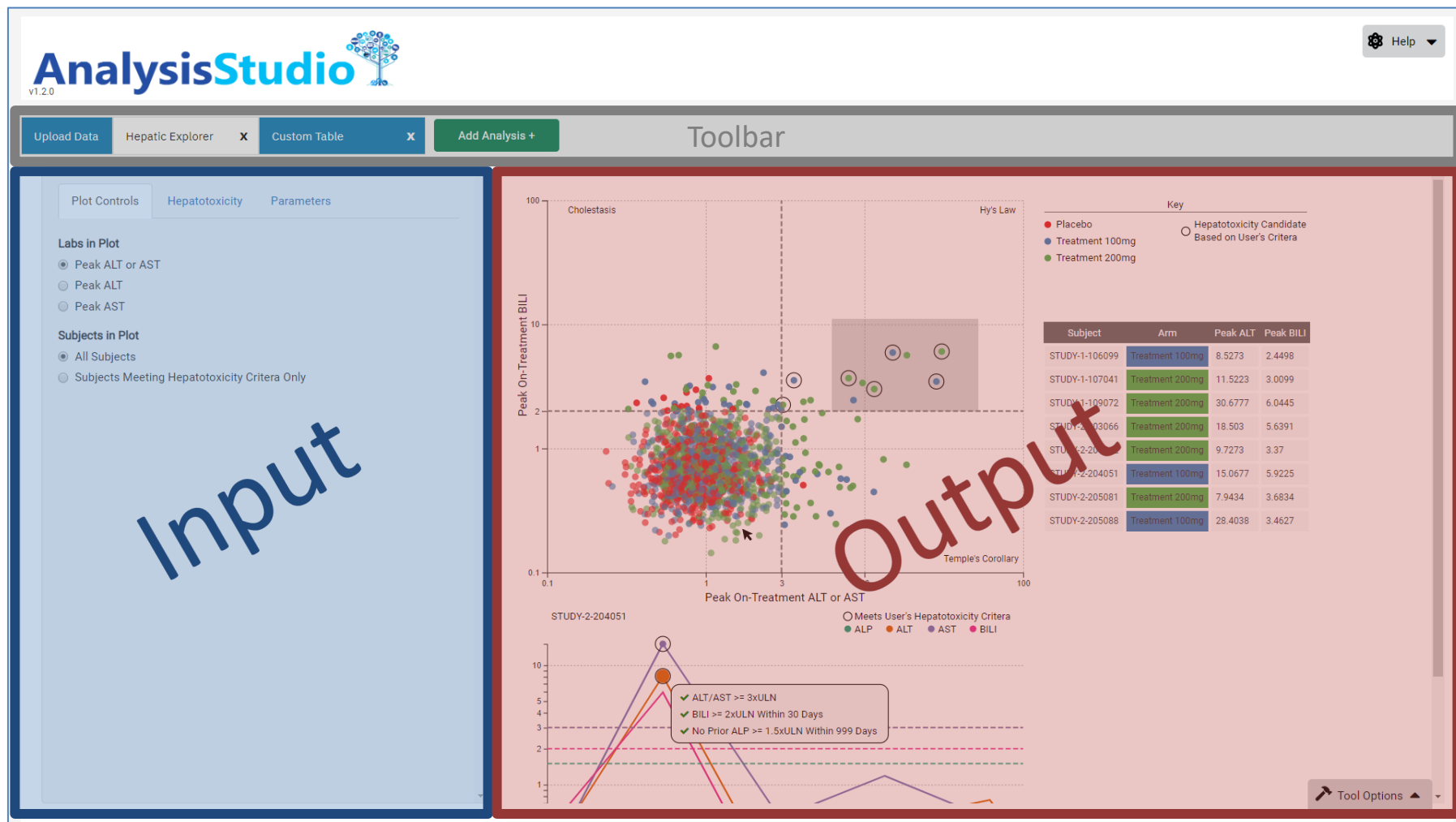
The views and opinions expressed in this presentation are those of the authors and do not represent official policy or position of the FDA or other organizations.

Office of Computational Science (OCS)

- The mission of OCS is to make the review process more thorough and efficient *via* innovative and reliable solutions
- OCS provides a variety of services and tools to assist clinical reviewers and statisticians in the regulatory review process



Analysis Studio: A Novel Tool Framework



Analysis Studio: A Programmer's Perspective

- Developed entirely using **open-source** programming languages

- Web-based framework
- Many useful libraries
- No licensing costs



- Updates are continuous, allowing for new tools and features to be incorporated **quickly**
- Easily **accessible** through a web browser – users never have to wait for IT to get software installed or updated
- Leverages a **uniform user interface** (UI) across all tools, drastically reducing development time

Analysis Studio: A Reviewer's Perspective

- A **uniform user interface** (UI) across tools decreases learning time as all tools look, feel, and work the same
- The tools are **interactive** – reviewers' input selections modify the output in real time, resulting in a clearer association between the inputs chosen and the analytical output created
- Allows for creation of **tables and figures** formatted in alignment with OND standard review guidance. These outputs can be downloaded as Word documents for easy transfer to review documents
- Generates an **audit trail** in Word downloads for transparency and replicability

Custom Table and Hepatic Explorer

WALKTHROUGH OF TOOL FUNCTIONALITY

Analysis Studio: Custom Table Demo

AnalysisStudio 1.2.0

Help

Upload Data Add Analysis +

Which datasets do I need to upload?

Demographic
Browse... No file selected

Adverse Event
Browse... No file selected

Concomitant Medications
Browse... No file selected

Disposition
Browse... No file selected

Exposure
Browse... No file selected

Laboratory
Browse...

Medical History
Browse... No file selected

Upload data using the panel on the left.

To load data, select 'Browse' next to the type of data you wish to upload.

AnalysisStudio 1.2.0

Add Analysis +

Browse... No file selected

Open

Navigation: << GIT > Analysis_Studio_GIT_Lab > analysis-studio > TestData > deidentified

Search: deidentified

Organize ▾ New folder

Name	Date modified	Type	Size
adsl_demo.sas7bdat	2/4/2020 4:19 PM	SAS Data Set	1,280 KB
lb_demo.sas7bdat	2/4/2020 4:19 PM	SAS Data Set	14,016 KB

File name: adsl_demo.sas7bdat

File type: Custom Files (*.xpt;*.sas7bdat;*)

Buttons: Open, Cancel

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Analysis Studio: Custom Table Demo



 Help

Upload Data

Add Analysis +

Which datasets do I need to upload?

Demographic

Browse... adsl.sas7bdat

Upload complete

Adverse Event

Browse... adae.sas7bdat

Upload complete

Concomitant Medications

Browse... No file selected

Disposition

Browse... No file selected

Exposure

Browse... No file selected

Laboratory

Browse... lb.sas7bdat

Upload complete

Medical History

Browse... No file selected

Demographic

Adverse Event

Laboratory

Columns

STUDYID (Study Identifier)

USUBJID (Unique Subject Identifier)

SITEID (Study Site Identifier)

SEX (Sex)

RACE (Race)

ETHNIC (Ethnicity)

ARM (Description of Planned Arm)

ACTARM (Description of Actual Arm)

TRT01P (Planned Treatment for Period 01)

TRT01A (Actual Treatment for Period 01)

Show 5 entries

Search:

	STUDYID	USUBJID	SITEID	SEX	RACE	ETHNIC	ARM	ACTARM	TRT01P	TRT01A
1	STUDY-1	STUDY-1-101001	101	M	WHITE	HISPANIC OR LATINO	Treatment 100mg	Treatment 100mg	Treatment 100mg	Treatment 100mg
2	STUDY-1	STUDY-1-101002	101	M	BLACK OR AFRICAN AMERICAN	HISPANIC OR LATINO	Treatment 100mg	Treatment 100mg	Treatment 100mg	Treatment 100mg
3	STUDY-1	STUDY-1-101003	101	M	BLACK OR AFRICAN AMERICAN	HISPANIC OR LATINO	Placebo	Placebo	Placebo	Placebo
4	STUDY-1	STUDY-1-101004	101	M	ASIAN	NOT HISPANIC OR LATINO	Screen Failure	Screen Failure	Screen Failure	Screen Failure
5	STUDY-1	STUDY-1-101005	101	M	WHITE	NOT HISPANIC OR LATINO	Screen Failure	Screen Failure	Screen Failure	Screen Failure

Showing 1 to 5 of 2,000 entries

Previous

1

2

3

4

5

...

400

Next

 Tool Options

The data viewer on the right side of the screen can be used to explore your data.

Analysis Studio: Custom Table Demo

Help

Upload Data
Add Analysis +

Which datasets do I need to upload?

Demographic
Browse... adsl.sas7bdat
Upload complete

Adverse Event
Browse... adae.sas7bdat
Upload complete

Concomitant Medications
Browse... No file selected

Disposition
Browse... No file selected

Exposure
Browse... No file selected

Laboratory
Browse... lb.sas7bdat
Upload complete

Medical History
Browse... No file selected

Demographic
Adverse Event
Laboratory

Columns
STUDYID (Study Identifier) USUBJID (Unique Subject Identifier) SITEID (Study Site Identifier) SEX (Sex) RACE (Race) ETHNIC (Ethnicity)
ARM (Description of Planned Arm) ACTARM (Description of Actual Arm) TRT01P (Planned Treatment for Period 01) TRT01A (Actual Treatment for Period 01)

Show 5 entries
Search:

	STUDYID	USUBJID	SITEID	SEX	RACE	ETHNIC	ARM	ACTARM	TRT01P	TRT01A
1	STUDY-1	STUDY-1-101001	101	M	WHITE	HISPANIC OR LATINO	Treatment 100mg	Treatment 100mg	Treatment 100mg	Treatment 100mg
2	STUDY-1	STUDY-1-101002	101	M	BLACK OR AFRICAN AMERICAN	HISPANIC OR LATINO	Treatment 100mg	Treatment 100mg	Treatment 100mg	Treatment 100mg
3	STUDY-1	STUDY-1-101003	101	M	BLACK OR AFRICAN AMERICAN	HISPANIC OR LATINO	Placebo	Placebo	Placebo	Placebo
4	STUDY-1	STUDY-1-101004	101	M	ASIAN	NOT HISPANIC OR LATINO	Screen Failure	Screen Failure	Screen Failure	Screen Failure
5	STUDY-1	STUDY-1-101005	101	M	WHITE	NOT HISPANIC OR LATINO	Screen Failure	Screen Failure	Screen Failure	Screen Failure

Showing 1 to 5 of 2,000 entries

Previous
1
2
3
4
5
...
400
Next

Tool Options

To add an analysis, click the “Add Analysis +” button in the toolbar.

Analysis Studio: Custom Table Demo

The screenshot displays the Analysis Studio v1.2.0 interface. On the left, a sidebar contains sections for uploading data: Demographic (adsl.sas7bdat), Adverse Event (adae.sas7bdat), Concomitant Medications (No file selected), Disposition (No file selected), Exposure (No file selected), Laboratory (lb.sas7bdat), and Medical History (No file selected). The main area shows a table with columns for STUDY-1, STUDY-1-101004, 101, M, ASIAN, NOT HISPANIC OR LATINO, Screen Failure, Screen Failure, Screen Failure, and Screen Failure. A modal titled 'Add Analysis to Dashboard' is open, listing options: Table Builders, Custom Table (highlighted with an orange arrow), Listing Table, Review Division-Specific Tools, and Exploratory Visualizations. The modal also includes 'Cancel' and 'Create Analysis' buttons.

Add Analysis to Dashboard

- Table Builders
- Custom Table
- Listing Table
- Review Division-Specific Tools
- Exploratory Visualizations

Cancel Create Analysis

	SEX (Sex)	RACE (Race)	ETHNIC (Ethnicity)	TRT01A (Actual Treatment for Period 01)						
4	STUDY-1	STUDY-1-101004	101	M	ASIAN	NOT HISPANIC OR LATINO	Screen Failure	Screen Failure	Screen Failure	Screen Failure
5	STUDY-1	STUDY-1-101005	101	M	WHITE	NOT HISPANIC OR LATINO	Screen Failure	Screen Failure	Screen Failure	Screen Failure

Showing 1 to 5 of 2,000 entries

Previous 1 2 3 4 5 ... 400 Next

Tool Options

Tools are organized by type.

Analysis Studio: Custom Table Demo

The screenshot shows the Analysis Studio interface. At the top left is the "AnalysisStudio" logo with version "1.2.0". To the right is a "Help" button with a gear icon. Below the logo is a navigation bar with "Upload Data", "Custom Table" (selected), and "Add Analysis +". The main area is split into a left sidebar and a right canvas. The sidebar contains tabs for "Column Inputs", "Rename/Group", "Order/Sort", and "Row Inputs". Under "Column Inputs", there are sub-tabs for "Formatting" and "Footnotes". The "Column Inputs" section includes: "Name of Table" (text input), "Column Dataset" (dropdown menu with "Required" selected), "Column Filter" (text input), "Column Variable 1" (dropdown menu with "Required" selected), "Column Variable 2" (dropdown menu), "Include Total Column" (radio buttons for "Yes" and "No", with "Yes" selected), and "Total Column Name" (text input with "Total" entered). The right canvas is empty. At the bottom right is a "Tool Options" button with a wrench icon.

This is the Custom Table canvas. A user selects their inputs on the left side and output is generated on the right side.

Analysis Studio: Custom Table Demo

AnalysisStudio 1.2.0

Help

Upload Data Custom Table x Add Analysis +

Column Inputs Rename/Group Order/Sort Row Inputs

Formatting Footnotes

Name of Table

PhUSE Example Table

Column Dataset ?

Required

Column Filter ?

Column Variable 1 ?

Required

Column Variable 2 ?

Include Total Column ?

☒ Yes ☐ No

Total Column Name

Total

Tool Options

First, we give the table a title. This will output on the top of the table.

Analysis Studio: Custom Table Demo

AnalysisStudio 1.2.0

Help

Upload Data Custom Table x Add Analysis +

Column Inputs Rename/Group Order/Sort Row Inputs

Formatting Footnotes

Name of Table
PhUSE Example Table

Column Dataset ?
Required
Demographics

Column Variable 1 ?
Required

Column Variable 2 ?

Include Total Column ?
☒ Yes
☐ No

Total Column Name
Total

Tool Options

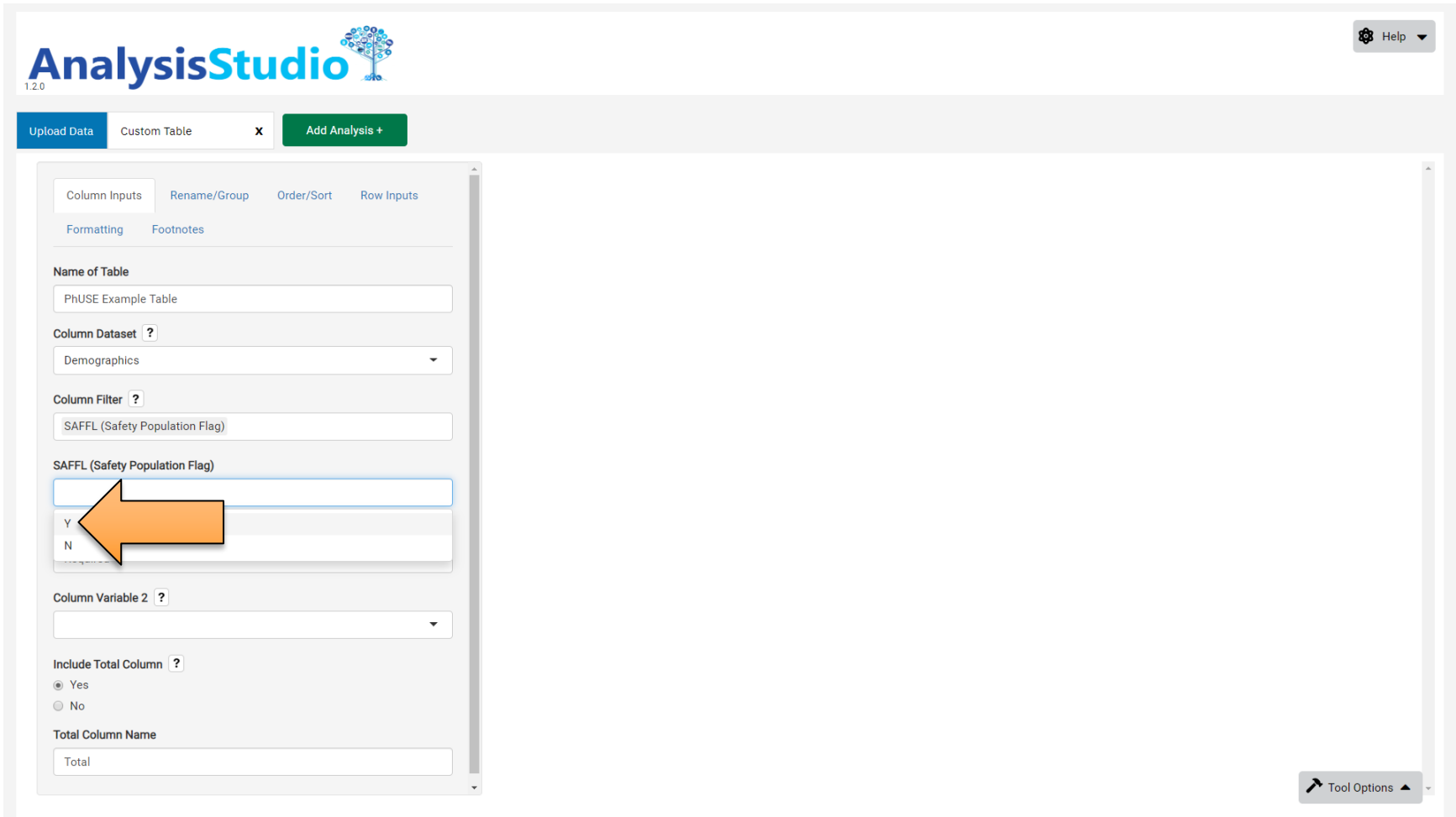
Then we select the dataset used to build the columns.

AnalysisStudio 1.2.0



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Analysis Studio: Custom Table Demo



AnalysisStudio 1.2.0 Help

Upload Data Custom Table x **Add Analysis +**

Column Inputs Rename/Group Order/Sort Row Inputs

Formatting Footnotes

Name of Table
PhUSE Example Table

Column Dataset ?
Demographics

Column Filter ?
SAFFL (Safety Population Flag)

SAFFL (Safety Population Flag)
Y
N

Column Variable 2 ?

Include Total Column ?
☒ Yes
☐ No

Total Column Name
Total

Tool Options

This table will include only the safety population.

Analysis Studio: Custom Table Demo

AnalysisStudio 1.2.0

Help

Upload Data Custom Table x Add Analysis +

Column Inputs Rename/Group Order/Sort Row Inputs

Formatting Footnotes

Name of Table
PhUSE Example Table

Column Dataset ?
Demographics

Column Filter ?
SAFFL (Safety Population Flag)

SAFFL (Safety Population Flag)
Y

Column Variable 1 ?
Required

- ARM (Description of Planned Arm)
- ACTARM (Description of Actual Arm)
- TRT01P (Planned Treatment for Period 01)
- TRT01A (Actual Treatment for Period 01)
- STUDYID (Study Identifier)
- USUBJID (Unique Subject Identifier)
- SUBJID (Subject Identifier for the Study)
- SITEID (Study Site Identifier)

Total

Tool Options

A user selects which variable's values will be used to populate the column names.

Analysis Studio: Custom Table Demo

AnalysisStudio v1.2.0   Help

Upload Data Custom Table x Add Analysis +

Column Inputs Rename/Group Order/Sort Row Inputs

Formatting Footnotes

Name of Table
PhUSE Example Table

Column Dataset ?
Demographics

Column Filter ?
SAFFL (Safety Population Flag)

SAFFL (Safety Population Flag)
Y

Column Variable 1 ?
STUDYID (Study Identifier)

Column Variable 2 ?

Include Total Column ?
☒ Yes
☐ No

Total Column Name
Total

PhUSE Example Table

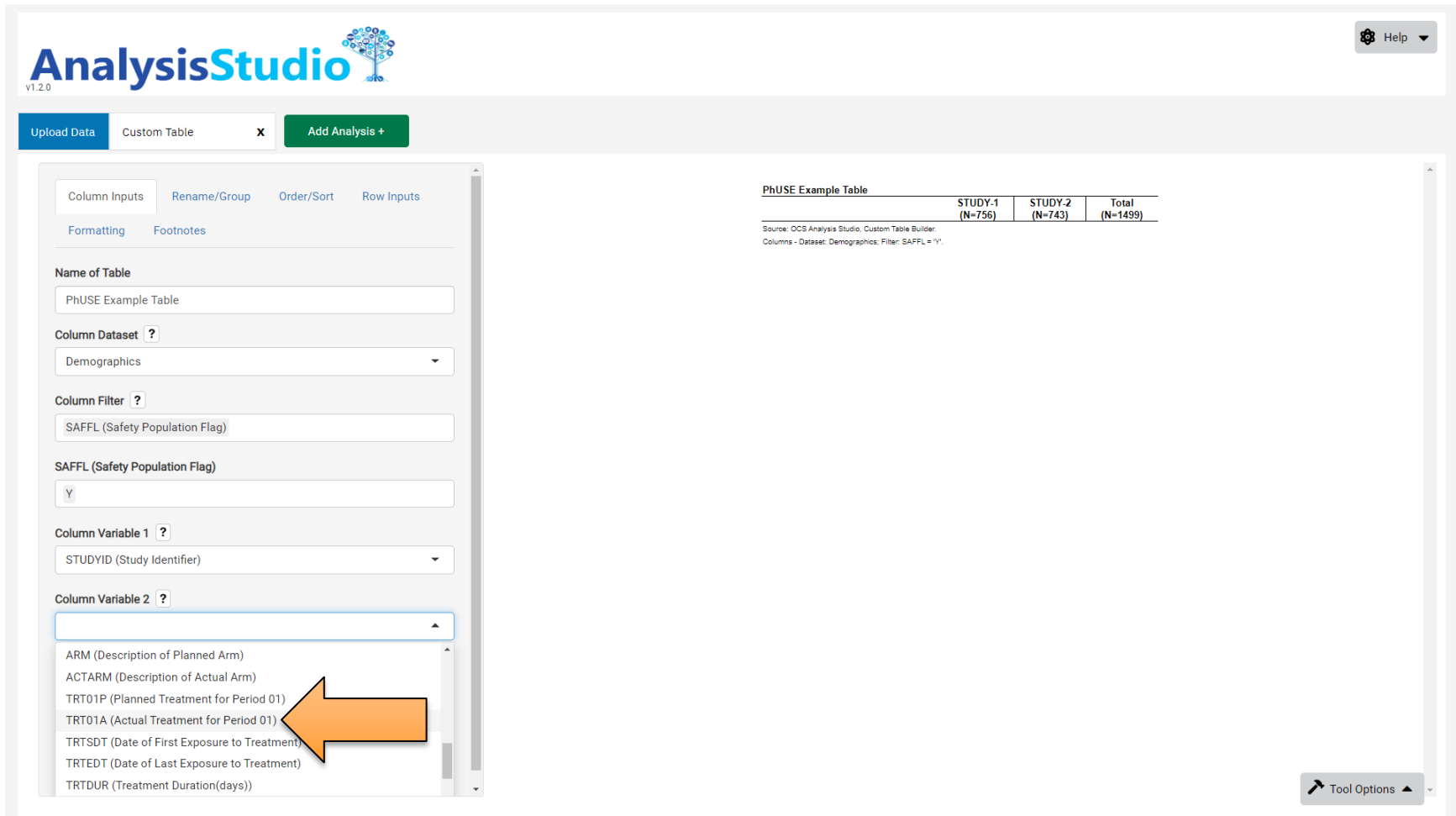
	STUDY-1 (N=756)	STUDY-2 (N=743)	Total (N=1499)
--	--------------------	--------------------	-------------------

Source: OCS Analysis Studio, Custom Table Builder.
Columns - Dataset: Demographics; Filter: SAFFL = "Y".

Tool Options

Here we have selected STUDYID. This completes the needed variables to build the column header of the table so output is generated. The names of the studies are listed across the top of the table.

Analysis Studio: Custom Table Demo



AnalysisStudio v1.2.0

Upload Data Custom Table x Add Analysis +

Column Inputs Rename/Group Order/Sort Row Inputs

Formatting Footnotes

Name of Table

PhUSE Example Table

Column Dataset ?

Demographics

Column Filter ?

SAFFL (Safety Population Flag)

SAFFL (Safety Population Flag)

Y

Column Variable 1 ?

STUDYID (Study Identifier)

Column Variable 2 ?

ARM (Description of Planned Arm)
ACTARM (Description of Actual Arm)
TRT01P (Planned Treatment for Period 01)
TRT01A (Actual Treatment for Period 01)
TRTSDT (Date of First Exposure to Treatment)
TRTEDT (Date of Last Exposure to Treatment)
TRTDUR (Treatment Duration(days))

PhUSE Example Table

	STUDY-1 (N=756)	STUDY-2 (N=743)	Total (N=1499)
--	--------------------	--------------------	-------------------

Source: OCS Analysis Studio, Custom Table Builder.
Columns - Dataset: Demographics; Filter: SAFFL = "Y".

Tool Options

A second column variable can be added to stratify the first into smaller subsets.

Analysis Studio: Custom Table Demo

Analysis Studio v1.2.0

Upload Data Custom Table x Add Analysis +

Column Inputs Rename/Group Order/Sort Row Inputs

Formatting Footnotes

Name of Table
PhUSE Example Table

Column Dataset ?
Demographics

Column Filter ?
SAFFL (Safety Population Flag)

SAFFL (Safety Population Flag)
Y

Column Variable 1 ?
STUDYID (Study Identifier)

Column Variable 2 ?
TRT01A (Actual Treatment for Period 01)

Include Total Column ?
☒ Yes ☐ No

Total Column Name
Total

PhUSE Example Table

STUDY-1			STUDY-2			Total		
Placebo (N=249)	Treatment 100mg (N=254)	Treatment 200mg (N=253)	Placebo (N=252)	Treatment 100mg (N=240)	Treatment 200mg (N=251)	Placebo (N=501)	Treatment 100mg (N=494)	Treatment 200mg (N=504)

Source: OCS Analysis Studio, Custom Table Builder.
Columns - Dataset: Demographics; Filter: SAFFL = "Y".

Tool Options

Now each study's treatments are listed under that study. The total column pools like treatment names together. This can be removed if desired.

Analysis Studio: Custom Table Demo

Upload Data

Custom Table x

Add Analysis +

Column Inputs

Rename/Group

Formatting

Footnotes

Rename or Group Column Variable 1

Current Value	New Value
STUDY-1	Enter text to rename value
STUDY-2	Enter text to rename value

Rename or Group Column Variable 2

Current Value	New Value
Placebo	Enter text to rename value
Treatment 100mg	Enter text to rename value
Treatment 200mg	Enter text to rename value

Apply Rename To

☒ Entire Table
 ☐ Just Total Column

PHUSE Example Table

	STUDY-1			STUDY-2			Total		
	Placebo (N=249)	Treatment 100mg (N=254)	Treatment 200mg (N=253)	Placebo (N=252)	Treatment 100mg (N=240)	Treatment 200mg (N=251)	Placebo (N=501)	Treatment 100mg (N=494)	Treatment 200mg (N=504)

Source: OCS Analysis Studio, Custom Table Builder.
Columns - Dataset: Demographics; Filter: SAFFL = "Y".

Columns can be given new names under the 'Rename/Group' tab.

Analysis Studio: Custom Table Demo

Help

Upload Data
Custom Table x
Add Analysis +

Column Inputs
Rename/Group
Order/Sort
Row Inputs

Formatting
Footnotes

Rename or Group Column Variable 1

Current Value	New Value
STUDY-1	Enter text to rename value
STUDY-2	Enter text to rename value

Rename or Group Column Variable 2

Current Value	New Value
Placebo	Enter text to rename value
Treatment 100mg	Trt. 100 mg
Treatment 200mg	Trt. 200 mg

Apply Rename To
☒ Entire Table
☐ Just Total Column

PhUSE Example Table

	STUDY-1		STUDY-2		Total		
	Placebo (N=249)	Trt. 100 mg (N=254)	Trt. 100 mg (N=240)	Trt. 200 mg (N=251)	Placebo (N=501)	Trt. 100 mg (N=494)	Trt. 200 mg (N=504)

Source: OCS Analysis Studio, Custom Table Builder.
Columns - Dataset: Demographics; Filter: SAFFL = "Y".

Tool Options

New names are reflected instantly in the output.

Analysis Studio: Custom Table Demo

AnalysisStudio v1.2.0

Upload Data Custom Table x Add Analysis +

Column Inputs Rename/Group Order/Sort Row Inputs

Formatting Footnotes

Rename or Group Column Variable 1

Current Value	New Value
STUDY-1	Enter text to rename value
STUDY-2	Enter text to rename value

Rename or Group Column Variable 2

Current Value	New Value
Placebo	Enter text to rename value
Treatment 100mg	Treatment
Treatment 200mg	Treatment

Apply Rename To

☒ Entire Table

☐ Just Total Column

PhUSE Example Table

STUDY-1		STUDY-2		Total	
Placebo (N=249)	Treatment (N=507)	Placebo (N=252)	Treatment (N=491)	Placebo (N=501)	Treatment (N=998)

Source: OCS Analysis Studio, Custom Table Builder.
Columns - Dataset: Demographics Filter: SAFFL = "Y".

Tool Options

If the same name is given to multiple treatments, those columns are grouped together.

Analysis Studio: Custom Table Demo

Help

Upload Data
Custom Table x
Add Analysis +

Column Inputs
Rename/Group
Order/Sort
Row Inputs

Formatting
Footnotes

Rename or Group Column Variable 1

Current Value	New Value
STUDY-1	Enter text to rename value
STUDY-2	Enter text to rename value

Rename or Group Column Variable 2

Current Value	New Value
Placebo	Enter text to rename value
Treatment 100mg	Treatment
Treatment 200mg	Treatment

Apply Rename To
☐ Entire Table
☒ Just Total Column

PhUSE Example Table

	STUDY-1			STUDY-2			Total	
	Placebo (N=249)	Treatment 100mg (N=254)	Treatment 200mg (N=253)	Placebo (N=252)	Treatment 100mg (N=240)	Treatment 200mg (N=251)	Placebo (N=501)	Treatment (N=998)

Source: OCS Analysis Studio, Custom Table Builder.
Columns - Dataset: Demographics; Filter: SAFPL = 'Y'.

Tool Options

A rename can be applied to only the total column if desired.

Analysis Studio: Custom Table Demo

AnalysisStudio v1.2.0

Upload Data Custom Table x Add Analysis +

Column Inputs Rename/Group Order/Sort **Row Inputs** Formatting Footnotes

Table Section 1

Title ?
Table Section 1

Row Dataset ?
Required

Analysis Filter ?

Row Variable 1 ?

Row Variable 2 ?

Percent Threshold Filter ?
0

Add Table Section

STUDY-1			STUDY-2			Total	
Placebo (N=249)	Treatment 100mg (N=254)	Treatment 200mg (N=253)	Placebo (N=252)	Treatment 100mg (N=240)	Treatment 200mg (N=251)	Placebo (N=501)	Treatment (N=998)
Source: OCS Analysis Studio, Custom Table Builder. Columns - Dataset: Demographics; Filter: SAFFL = 'Y'.							

Tool Options

The body of the table is built in the 'Row Inputs' tab.

Analysis Studio: Custom Table Demo

AnalysisStudio
v1.2.0

Help

Upload Data Custom Table x Add Analysis +

Column Inputs Rename/Group Order/Sort Row Inputs

Formatting Footnotes

Table Section 1

Title ?
Any TEAE

Row Dataset ?
Required

Analysis Filter ?

Row Variable 1 ?

Row Variable 2 ?

Percent Threshold Filter ?
0

Add Table Section

PhUSE Example Table

STUDY-1			STUDY-2			Total	
Placebo (N=249)	Treatment 100mg (N=254)	Treatment 200mg (N=253)	Placebo (N=252)	Treatment 100mg (N=240)	Treatment 200mg (N=251)	Placebo (N=501)	Treatment (N=998)
Source: OCS Analysis Studio, Custom Table Builder. Columns - Dataset: Demographics; Filter: SAFPL = "Y".							

Tool Options

A name is given to the table section. This will be shown when output is generated.

Analysis Studio: Custom Table Demo

AnalysisStudio
v1.2.0

Help

Upload Data Custom Table x Add Analysis +

Column Inputs Rename/Group Order/Sort Row Inputs

Formatting Footnotes

Table Section 1

Title ?
Any TEAE

Row Dataset ?
Required
Demographics
Adverse Events
Laboratory

Row Variable 1 ?

Row Variable 2 ?

Percent Threshold Filter ?
0

Add Table Section

PhUSE Example Table

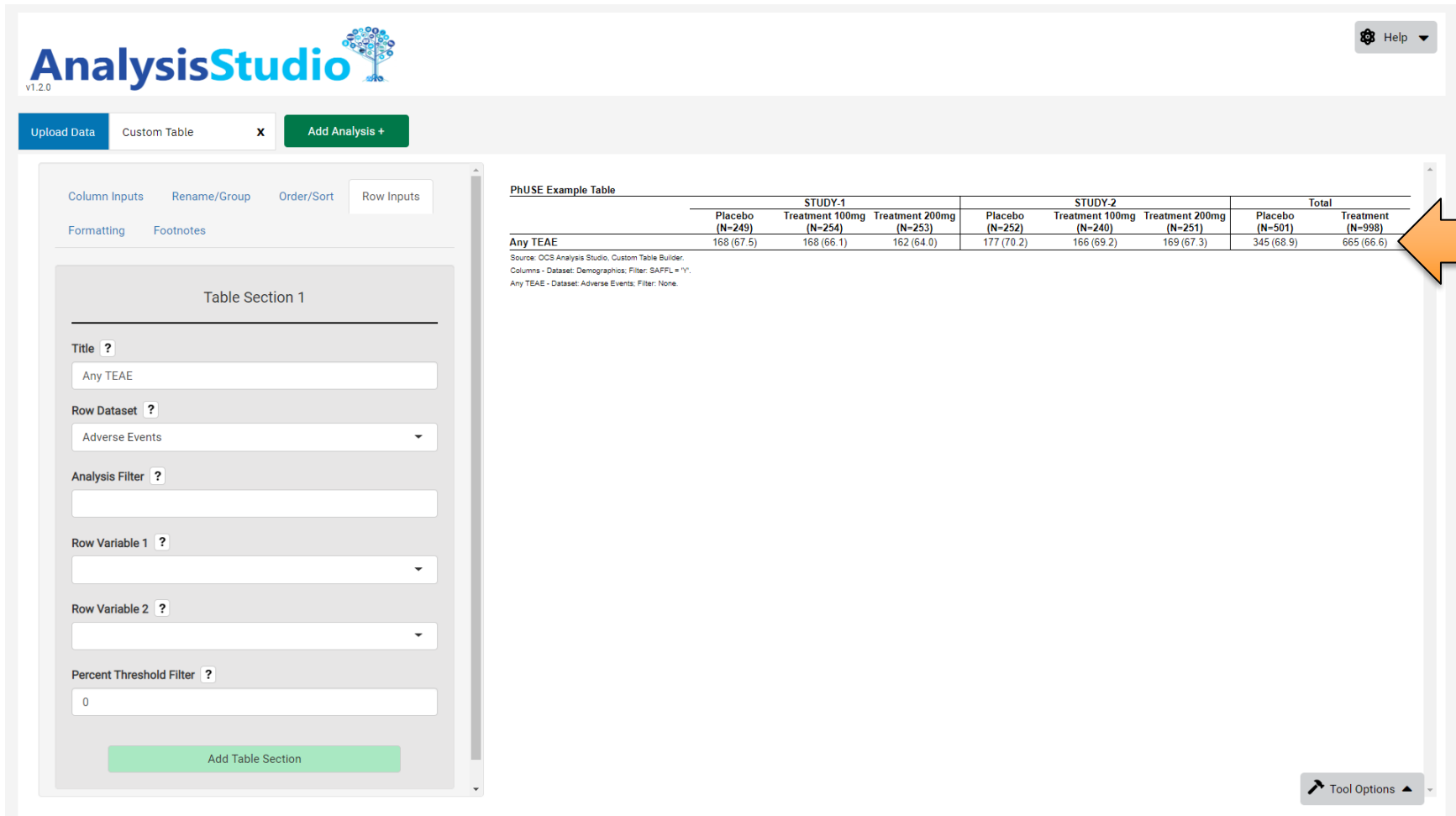
STUDY-1			STUDY-2			Total	
Placebo (N=249)	Treatment 100mg (N=254)	Treatment 200mg (N=253)	Placebo (N=252)	Treatment 100mg (N=240)	Treatment 200mg (N=251)	Placebo (N=501)	Treatment (N=998)
Source: OCS Analysis Studio, Custom Table Builder. Columns - Dataset: Demographics; Filter: SAFPL = "Y".							

Tool Options

The dataset used to build a table section is selected.

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Analysis Studio: Custom Table Demo



AnalysisStudio v1.2.0

Upload Data Custom Table x Add Analysis +

Column Inputs Rename/Group Order/Sort Row Inputs

Formatting Footnotes

Table Section 1

Title ?
Any TEAE

Row Dataset ?
Adverse Events

Analysis Filter ?

Row Variable 1 ?

Row Variable 2 ?

Percent Threshold Filter ?
0

Add Table Section

PhUSE Example Table

	STUDY-1			STUDY-2			Total	
	Placebo (N=249)	Treatment 100mg (N=254)	Treatment 200mg (N=253)	Placebo (N=252)	Treatment 100mg (N=240)	Treatment 200mg (N=251)	Placebo (N=501)	Treatment (N=998)
Any TEAE	168 (67.5)	168 (66.1)	162 (64.0)	177 (70.2)	166 (69.2)	169 (67.3)	345 (68.9)	665 (66.6)

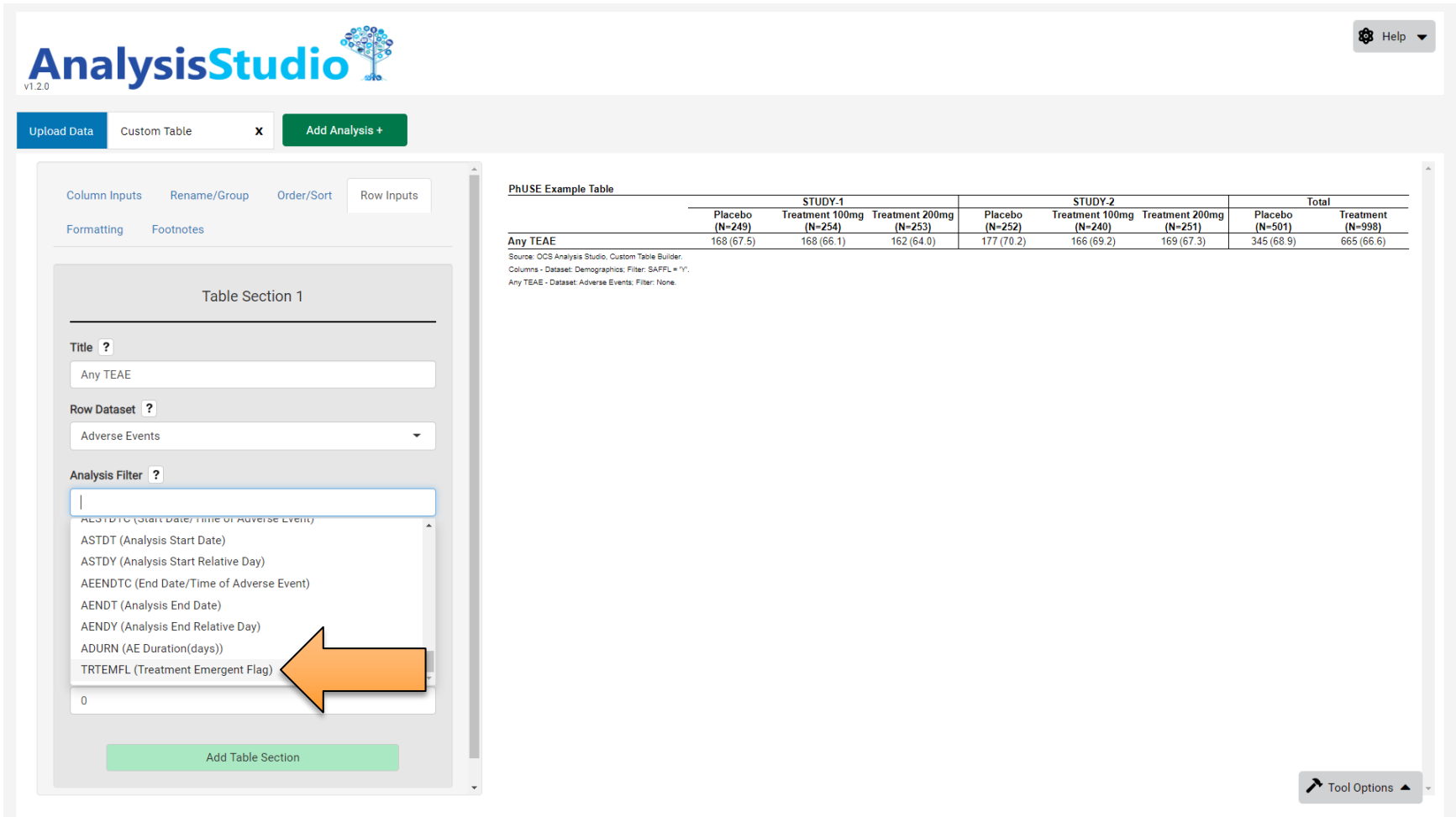
Source: OCS Analysis Studio, Custom Table Builder.
Columns - Dataset: Demographics; Filter: SAFPL = "Y".
Any TEAE - Dataset: Adverse Events; Filter: None.

Help

Tool Options

Output is generated. Subjects appearing in the 'Adverse Events' dataset are summarized by study and treatment. Only subjects that are in the safety population are counted based on filters previously applied.

Analysis Studio: Custom Table Demo



AnalysisStudio v1.2.0

Upload Data Custom Table x Add Analysis +

Column Inputs Rename/Group Order/Sort Row Inputs

Formatting Footnotes

Table Section 1

Title ?
Any TEAE

Row Dataset ?
Adverse Events

Analysis Filter ?
ASTDTC (Start Date/Time of Adverse Event)
ASTDT (Analysis Start Date)
ASTDY (Analysis Start Relative Day)
AEENDTC (End Date/Time of Adverse Event)
AENDT (Analysis End Date)
AENDY (Analysis End Relative Day)
ADURN (AE Duration(days))
TRTEMFL (Treatment Emergent Flag)
0

Add Table Section

PhUSE Example Table

	STUDY-1			STUDY-2			Total	
	Placebo (N=249)	Treatment 100mg (N=254)	Treatment 200mg (N=253)	Placebo (N=252)	Treatment 100mg (N=240)	Treatment 200mg (N=251)	Placebo (N=501)	Treatment (N=998)
Any TEAE	168 (67.5)	168 (66.1)	162 (64.0)	177 (70.2)	166 (69.2)	169 (67.3)	345 (68.9)	665 (66.6)

Source: OCS Analysis Studio, Custom Table Builder.
Columns - Dataset: Demographics; Filter: SAFPL = "Y".
Any TEAE - Dataset: Adverse Events; Filter: None.

Tool Options

The dataset being used to create the table section can be filtered. For example, the Adverse Events dataset can be filtered to events that were treatment emergent.

Analysis Studio: Custom Table Demo

AnalysisStudio v1.2.0

Upload Data Custom Table x Add Analysis +

Column Inputs Rename/Group Order/Sort Row Inputs

Formatting Footnotes

Table Section 1

Title ?
Any TEAE

Row Dataset ?
Adverse Events

Analysis Filter ?
TRTEMFL (Treatment Emergent Flag)

TRTEMFL (Treatment Emergent Flag)
Y

Row Variable 1 ?

Row Variable 2 ?

Percent Threshold Filter ?
0

PhUSE Example Table

	STUDY-1			STUDY-2			Total	
	Placebo (N=249)	Treatment 100mg (N=254)	Treatment 200mg (N=253)	Placebo (N=252)	Treatment 100mg (N=240)	Treatment 200mg (N=251)	Placebo (N=501)	Treatment (N=998)
Any TEAE	164 (65.9)	165 (65.0)	158 (62.5)	176 (69.8)	163 (67.9)	166 (66.1)	340 (67.9)	652 (65.3)

Source: OCS Analysis Studio, Custom Table Builder.
Columns - Dataset: Demographics; Filter: SAFPL = "Y".
Any TEAE - Dataset: Adverse Events; Filter: TRTEMFL = "Y".

Tool Options

The table updates instantaneously to user's input. The footnotes below the table display the filters used.

Analysis Studio: Custom Table Demo

AnalysisStudio v1.2.0

Help

Upload Data Custom Table x Add Analysis +

Table Section 1

Title ?

Any TEAE

Row Dataset ?

Adverse Events

Analysis Filter ?

TRTEMFL (Treatment Emergent Flag)

TRTEMFL (Treatment Emergent Flag)

Y

Row Variable 1 ?

Row Variable 2 ?

Percent Threshold Filter ?

0

Add Table Section

PhUSE Example Table

	STUDY-1			STUDY-2			Total	
	Placebo (N=249)	Treatment 100mg (N=254)	Treatment 200mg (N=253)	Placebo (N=252)	Treatment 100mg (N=240)	Treatment 200mg (N=251)	Placebo (N=501)	Treatment (N=998)
Any TEAE	164 (65.9)	165 (65.0)	158 (62.5)	176 (69.8)	163 (67.9)	166 (66.1)	340 (67.9)	652 (65.3)

Source: OCS Analysis Studio, Custom Table Builder.
Columns - Dataset: Demographics; Filter: SAFPL = "Y".
Any TEAE - Dataset: Adverse Events; Filter: TRTEMFL = "Y".

Tool Options

Table sections can be stacked on top of one another to create a more robust analysis.

Analysis Studio: Custom Table Demo

Upload Data

Custom Table x

Add Analysis +

Add Table Section

Table Section 2

Table Section Sub-header ?

Table Section 2

Row Dataset ?

Required

Analysis Filter ?

Row Variable 1 ?

Row Variable 2 ?

Percent Threshold Filter ?

0

Add Table Section

Delete Table Section

PhUSE Example Table

	STUDY-1			STUDY-2			Total	
	Placebo (N=249)	Treatment 100mg (N=254)	Treatment 200mg (N=253)	Placebo (N=252)	Treatment 100mg (N=240)	Treatment 200mg (N=251)	Placebo (N=501)	Treatment (N=998)
Any TEAE	164 (65.9)	165 (65.0)	158 (62.5)	176 (69.8)	163 (67.9)	166 (66.1)	340 (67.9)	652 (65.3)

Source: OCS Analysis Studio, Custom Table Builder.

Columns - Dataset: Demographics; Filter: SAFPL = "Y".

Any TEAE - Dataset: Adverse Events; Filter: TRTEMPL = "Y".

Inputs for a new table section are added. The previous steps are repeated to create additional output.

Analysis Studio: Custom Table Demo


Help

Upload Data
Custom Table x
Add Analysis +

Table Section 2

Table Section Sub-header ?

TEAEs by SOC/PT

Row Dataset ?

Adverse Events

Analysis Filter ?

TRTEMFL (Treatment Emergent Flag)

TRTEMFL (Treatment Emergent Flag)

Y

Row Variable 1 ?

Row Variable 2 ?

Percent Threshold Filter ?

0

Add Table Section
Delete Table Section

PhUSE Example Table

	STUDY-1			STUDY-2			Total	
	Placebo (N=249)	Treatment 100mg (N=254)	Treatment 200mg (N=253)	Placebo (N=252)	Treatment 100mg (N=240)	Treatment 200mg (N=251)	Placebo (N=501)	Treatment (N=998)
Any TEAE	164 (65.9)	165 (65.0)	158 (62.5)	176 (69.8)	163 (67.9)	166 (66.1)	340 (67.9)	652 (65.3)
TEAEs by SOC/PT	164 (65.9)	165 (65.0)	158 (62.5)	176 (69.8)	163 (67.9)	166 (66.1)	340 (67.9)	652 (65.3)

Source: OCS Analysis Studio, Custom Table Builder.
Columns - Dataset: Demographics; Filter: SAFFL = "Y".
Any TEAE - Dataset: Adverse Events; Filter: TRTEMFL = "Y".
TEAEs by SOC/PT - Dataset: Adverse Events; Filter: TRTEMFL = "Y".

Tool Options

Above, the analysis in the first table section is replicated. However, this analysis will be further subset by System Organ Classes and Preferred Terms.

Analysis Studio: Custom Table Demo


v1.2.0

Help ▾

Upload Data
Custom Table x
Add Analysis +

Table Section 2

Table Section Sub-header ?

TEAEs by SOC/PT

Row Dataset ?

Adverse Events

Analysis Filter ?

TRTEMFL (Treatment Emergent Flag)

TRTEMFL (Treatment Emergent Flag)

Y

Row Variable 1 ?

AEHLTCD (High Level Term Code)

AEHLGT (High Level Group Term)

AEHLGTC (High Level Group Term Code)

AEBODSYS (Body System or Organ Class)

AEBDSYCD (Body System or Organ Class Code)

AESEV (Severity/Intensity)

AESER (Serious Event)

AEQUIT (Outcome of Adverse Event)

Add Table Section
Delete Table Section

PhUSE Example Table

	STUDY-1			STUDY-2			Total	
	Placebo (N=249)	Treatment 100mg (N=254)	Treatment 200mg (N=253)	Placebo (N=252)	Treatment 100mg (N=240)	Treatment 200mg (N=251)	Placebo (N=501)	Treatment (N=998)
Any TEAE	164 (65.9)	165 (65.0)	158 (62.5)	176 (69.8)	163 (67.9)	166 (66.1)	340 (67.9)	652 (65.3)
TEAEs by SOC/PT	164 (65.9)	165 (65.0)	158 (62.5)	176 (69.8)	163 (67.9)	166 (66.1)	340 (67.9)	652 (65.3)

Source: OCS Analysis Studio, Custom Table Builder.
Columns - Dataset: Demographics; Filter: SAFFL = "Y".
Any TEAE - Dataset: Adverse Events; Filter: TRTEMFL = "Y".
TEAEs by SOC/PT - Dataset: Adverse Events; Filter: TRTEMFL = "Y".

Tool Options ▴ ▾

A row variable is selected. Events will be stratified by this variable's values.

Analysis Studio: Custom Table Demo



Upload Data

Custom Table x

Add Analysis +

Help ▼

Table Section 2

Table Section Sub-header ?

TEAEs by SOC/PT

Row Dataset ?

Adverse Events ▼

Analysis Filter ?

TRTEMFL (Treatment Emergent Flag)

TRTEMFL (Treatment Emergent Flag)

Y

Row Variable 1 ?

AEBODSYS (Body System or Organ Class) ▼

Row Variable 2 ?

Percent Threshold Filter ?

0

Add Table Section

Delete Table Section

PhUSE Example Table

	STUDY-1			STUDY-2			Total	
	Placebo (N=249)	Treatment 100mg (N=254)	Treatment 200mg (N=253)	Placebo (N=252)	Treatment 100mg (N=240)	Treatment 200mg (N=251)	Placebo (N=501)	Treatment (N=998)
Any TEAE	164 (65.9)	165 (65.0)	158 (62.5)	176 (69.8)	163 (67.9)	166 (66.1)	340 (67.9)	652 (65.3)
TEAEs by SOC/PT								
Blood and lymphatic system disorders	13 (5.2)	12 (4.7)	18 (7.1)	16 (6.3)	19 (7.9)	15 (6.0)	29 (5.8)	64 (6.4)
Cardiac disorders	34 (13.7)	43 (16.9)	39 (15.4)	33 (13.1)	41 (17.1)	35 (13.9)	67 (13.4)	158 (15.8)
Congenital, familial and genetic disorders	0	0	1 (0.4)	1 (0.4)	0	1 (0.4)	1 (0.2)	2 (0.2)
Ear and labyrinth disorders	8 (3.2)	8 (3.1)	4 (1.6)	5 (2.0)	8 (3.3)	6 (2.4)	13 (2.6)	26 (2.6)
Endocrine disorders	2 (0.8)	4 (1.6)	4 (1.6)	0	4 (1.7)	6 (2.4)	2 (0.4)	18 (1.8)
Eye disorders	12 (4.8)	13 (5.1)	15 (5.9)	12 (4.8)	17 (7.1)	12 (4.8)	24 (4.8)	57 (5.7)
Gastrointestinal disorders	62 (24.9)	74 (29.1)	73 (28.9)	63 (25.0)	50 (20.8)	63 (25.1)	125 (25.0)	260 (26.1)
General disorders and administration site conditions	41 (16.5)	37 (14.6)	41 (16.2)	39 (15.5)	38 (15.8)	42 (16.7)	80 (16.0)	158 (15.8)
Hepatobiliary disorders	4 (1.6)	1 (0.4)	5 (2.0)	3 (1.2)	4 (1.7)	7 (2.8)	7 (1.4)	17 (1.7)
Immune system disorders	2 (0.8)	2 (0.8)	3 (1.2)	1 (0.4)	6 (2.5)	0	3 (0.6)	11 (1.1)
Infections and infestations	73 (29.3)	78 (30.7)	82 (32.4)	73 (29.0)	70 (29.2)	85 (33.9)	146 (29.1)	315 (31.6)
Injury, poisoning and procedural complications	28 (11.2)	23 (9.1)	24 (9.5)	26 (10.3)	24 (10.0)	32 (12.7)	54 (10.8)	103 (10.3)
Investigations	36 (14.5)	29 (11.4)	42 (16.6)	37 (14.7)	31 (12.9)	45 (17.9)	73 (14.6)	147 (14.7)
Metabolism and nutrition disorders	29 (11.6)	33 (13.0)	31 (12.3)	30 (11.9)	40 (16.7)	29 (11.6)	59 (11.8)	133 (13.3)
Musculoskeletal and connective tissue disorders	46 (18.5)	57 (22.4)	53 (20.9)	44 (17.5)	46 (19.2)	37 (14.7)	90 (18.0)	193 (19.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	13 (5.2)	16 (6.3)	13 (5.1)	10 (4.0)	8 (3.3)	17 (6.8)	23 (4.6)	54 (5.4)
Nervous system disorders	50 (20.1)	41 (16.1)	46 (18.2)	51 (20.2)	45 (18.8)	27 (10.8)	101 (20.2)	159 (15.9)
Product issues	0	2 (0.8)	1 (0.4)	0	0	0	0	3 (0.3)
Psychiatric disorders	18 (7.2)	24 (9.4)	22 (8.7)	19 (7.5)	23 (9.6)	26 (10.4)	37 (7.4)	95 (9.5)
Renal and urinary disorders	24 (9.6)	13 (5.1)	22 (8.7)	25 (9.9)	21 (8.8)	22 (8.8)	49 (9.8)	78 (7.8)
Reproductive system and breast disorders	6 (2.4)	10 (3.9)	12 (4.7)	7 (2.8)	7 (2.9)	10 (4.0)	13 (2.6)	39 (3.9)
Respiratory, thoracic and mediastinal disorders	26 (10.4)	36 (14.2)	34 (13.4)	41 (16.3)	33 (13.8)	34 (13.5)	67 (13.4)	137 (13.7)
Skin and subcutaneous tissue disorders	24 (9.6)	25 (9.8)	12 (4.7)	27 (10.7)	18 (7.5)	23 (9.2)	51 (10.2)	78 (7.8)
Social circumstances	0	1 (0.4)	0	0	0	0	0	1 (0.1)
Surgical and medical procedures	0	3 (1.2)	6 (2.4)	2 (0.8)	3 (1.2)	2 (0.8)	2 (0.4)	14 (1.4)
Vascular disorders	22 (8.8)	17 (6.7)	24 (9.5)	18 (7.1)	16 (6.7)	21 (8.4)	40 (8.0)	78 (7.8)

Source: QOS Analysis Studio, Custom Table Builder.
Columns - Dataset: Demographics; Filter: SAFFL = "Y".
Any TEAE - Dataset: Adverse Events; Filter: TRTEMFL = "Y".
TEAEs by SOC/PT - Dataset: Adverse Events; Filter: TRTEMFL = "Y".

Tool Options ▲

Subjects are now counted by System Organ Class. Subjects can be counted in multiple rows if they have events in multiple System Organ Classes.

Analysis Studio: Custom Table Demo


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Help

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Add Analysis +

Table Section 2

Table Section Sub-header ?

TEAEs by SOC/PT

Row Dataset ?

Adverse Events

Analysis Filter ?

TRTEMFL (Treatment Emergent Flag)

TRTEMFL (Treatment Emergent Flag)

Y

Row Variable 1 ?

AEBODSYS (Body System or Organ Class)

Row Variable 2 ?

RFPENDTC (Date/Time of End of Participation)

AESEQ (Sequence Number)

AEDECD (Dictionary-Derived Term)

AEPTCD (Preferred Term Code)

AEHLT (High Level Term)

AEHLTCD (High Level Term Code)

AEHLGT (High Level Group Term)

AEHLGTCD (High Level Group Term Code)

PHUSE Example Table

	STUDY-1			STUDY-2			Total	
	Placebo (N=249)	Treatment 100mg (N=254)	Treatment 200mg (N=253)	Placebo (N=252)	Treatment 100mg (N=240)	Treatment 200mg (N=251)	Placebo (N=501)	Treatment (N=998)
Any TEAE	164 (65.9)	165 (65.0)	158 (62.5)	176 (69.8)	163 (67.9)	166 (66.1)	340 (67.9)	652 (65.3)
TEAEs by SOC/PT								
Blood and lymphatic system disorders	13 (5.2)	12 (4.7)	18 (7.1)	16 (6.3)	19 (7.9)	15 (6.0)	29 (5.8)	64 (6.4)
Cardiac disorders	34 (13.7)	43 (16.9)	39 (15.4)	33 (13.1)	41 (17.1)	35 (13.9)	67 (13.4)	158 (15.8)
Congenital, familial and genetic disorders	0	0	1 (0.4)	1 (0.4)	0	1 (0.4)	1 (0.2)	2 (0.2)
Ear and labyrinth disorders	8 (3.2)	8 (3.1)	4 (1.6)	5 (2.0)	8 (3.3)	6 (2.4)	13 (2.6)	26 (2.6)
Endocrine disorders	2 (0.8)	4 (1.6)	4 (1.6)	0	4 (1.7)	6 (2.4)	2 (0.4)	18 (1.8)
Eye disorders	12 (4.8)	13 (5.1)	15 (5.9)	12 (4.8)	17 (7.1)	12 (4.8)	24 (4.8)	57 (5.7)
Gastrointestinal disorders	62 (24.9)	74 (29.1)	73 (28.9)	63 (25.0)	50 (20.8)	63 (25.1)	125 (25.0)	260 (26.1)
General disorders and administration site conditions	41 (16.5)	37 (14.6)	41 (16.2)	39 (15.5)	38 (15.8)	42 (16.7)	80 (16.0)	158 (15.8)
Hepatobiliary disorders	4 (1.6)	1 (0.4)	5 (2.0)	3 (1.2)	4 (1.7)	7 (2.8)	7 (1.4)	17 (1.7)
Immune system disorders	2 (0.8)	2 (0.8)	3 (1.2)	1 (0.4)	6 (2.5)	0	3 (0.6)	11 (1.1)
Infections and infestations	73 (29.3)	78 (30.7)	82 (32.4)	73 (29.0)	70 (29.2)	85 (33.9)	146 (29.1)	315 (31.6)
Injury, poisoning and procedural complications	28 (11.2)	23 (9.1)	24 (9.5)	26 (10.3)	24 (10.0)	32 (12.7)	54 (10.8)	103 (10.3)
Investigations	36 (14.5)	29 (11.4)	42 (16.6)	37 (14.7)	31 (12.9)	45 (17.9)	73 (14.6)	147 (14.7)
Metabolism and nutrition disorders	29 (11.6)	33 (13.0)	31 (12.3)	30 (11.9)	40 (16.7)	29 (11.6)	59 (11.8)	133 (13.3)
Musculoskeletal and connective tissue disorders	46 (18.5)	57 (22.4)	53 (20.9)	44 (17.5)	46 (19.2)	37 (14.7)	90 (18.0)	193 (19.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	13 (5.2)	16 (6.3)	13 (5.1)	10 (4.0)	8 (3.3)	17 (6.8)	23 (4.6)	54 (5.4)
Nervous system disorders	50 (20.1)	41 (16.1)	46 (18.2)	51 (20.2)	45 (18.8)	27 (10.8)	101 (20.2)	159 (15.9)
Product issues	0	2 (0.8)	1 (0.4)	0	0	0	0	3 (0.3)
Psychiatric disorders	18 (7.2)	24 (9.4)	22 (8.7)	19 (7.5)	23 (9.6)	26 (10.4)	37 (7.4)	95 (9.5)
Renal and urinary disorders	24 (9.6)	13 (5.1)	22 (8.7)	25 (9.9)	21 (8.8)	22 (8.8)	49 (9.8)	78 (7.8)
Reproductive system and breast disorders	6 (2.4)	10 (3.9)	12 (4.7)	7 (2.8)	7 (2.9)	10 (4.0)	13 (2.6)	39 (3.9)
Respiratory, thoracic and mediastinal disorders	26 (10.4)	36 (14.2)	34 (13.4)	41 (16.3)	33 (13.8)	34 (13.5)	67 (13.4)	137 (13.7)
Skin and subcutaneous tissue disorders	24 (9.6)	25 (9.8)	12 (4.7)	27 (10.7)	18 (7.5)	23 (9.2)	51 (10.2)	78 (7.8)
Social circumstances	0	1 (0.4)	0	0	0	0	0	1 (0.1)
Surgical and medical procedures	0	3 (1.2)	6 (2.4)	2 (0.8)	3 (1.2)	2 (0.8)	2 (0.4)	14 (1.4)
Vascular disorders	22 (8.8)	17 (6.7)	24 (9.5)	18 (7.1)	16 (6.7)	21 (8.4)	40 (8.0)	78 (7.8)

Source: QOS Analysis Studio, Custom Table Builder.
Columns - Dataset: Demographics; Filter: SAFFL = "Y".
Any TEAE - Dataset: Adverse Events; Filter: TRTEMFL = "Y".
TEAEs by SOC/PT - Dataset: Adverse Events; Filter: TRTEMFL = "Y".

The analysis can be further subset by an additional row variable.

Analysis Studio: Custom Table Demo


v1.2.0

Help

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Custom Table x
Add Analysis +

Table Section 2

Table Section Sub-header ?

TEAEs by SOC/PT

Row Dataset ?

Adverse Events

Analysis Filter ?

TRTEMFL (Treatment Emergent Flag)

TRTEMFL (Treatment Emergent Flag)

Y

Row Variable 1 ?

AEBODSYS (Body System or Organ Class)

Row Variable 2 ?

AEDECOD (Dictionary-Derived Term)

Percent Threshold Filter ?

0

Add Table Section
Delete Table Section

PHUSE Example Table

	STUDY-1			STUDY-2			Total	
	Placebo (N=249)	Treatment 100mg (N=254)	Treatment 200mg (N=253)	Placebo (N=252)	Treatment 100mg (N=240)	Treatment 200mg (N=251)	Placebo (N=501)	Treatment (N=998)
Any TEAE	164 (65.9)	165 (65.0)	158 (62.5)	176 (69.8)	163 (67.9)	166 (66.1)	340 (67.9)	652 (65.3)
TEAEs by SOC/PT								
Blood and lymphatic system disorders	13 (5.2)	12 (4.7)	18 (7.1)	16 (6.3)	19 (7.9)	15 (6.0)	29 (5.8)	64 (6.4)
Anaemia	5 (2.0)	2 (0.8)	7 (2.8)	6 (2.4)	9 (3.8)	6 (2.4)	11 (2.2)	24 (2.4)
Febrile neutropenia	0	0	0	1 (0.4)	0	0	1 (0.2)	0
Hilar lymphadenopathy	0	1 (0.4)	0	0	0	0	0	1 (0.1)
Increased tendency to bruise	0	0	0	0	1 (0.4)	0	0	1 (0.1)
Iron deficiency anaemia	0	1 (0.4)	2 (0.8)	2 (0.8)	0	1 (0.4)	2 (0.4)	4 (0.4)
Leukocytosis	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	0	2 (0.8)	2 (0.4)	4 (0.4)
Leukopenia	0	1 (0.4)	2 (0.8)	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.2)	5 (0.5)
Lymph node pain	0	0	2 (0.8)	0	0	0	0	2 (0.2)
Lymphadenopathy	0	0	1 (0.4)	0	1 (0.4)	2 (0.8)	0	4 (0.4)
Lymphadenopathy mediastinal	1 (0.4)	0	0	0	0	0	1 (0.2)	0
Microcytic anaemia	0	0	0	0	0	1 (0.4)	0	1 (0.1)
Neutropenia	3 (1.2)	2 (0.8)	1 (0.4)	2 (0.8)	1 (0.4)	0	5 (1.0)	4 (0.4)
Neutrophilia	1 (0.4)	0	0	0	0	0	1 (0.2)	0
Normochromic normocytic anaemia	1 (0.4)	0	0	0	0	0	1 (0.2)	0
Normocytic anaemia	0	0	0	0	0	1 (0.4)	0	1 (0.1)
Sickle cell anaemia with crisis	1 (0.4)	1 (0.4)	0	1 (0.4)	0	0	2 (0.4)	1 (0.1)
Splenomegaly	0	0	0	0	2 (0.8)	0	0	2 (0.2)
Thrombocytopenia	2 (0.8)	5 (2.0)	4 (1.6)	3 (1.2)	3 (1.2)	1 (0.4)	5 (1.0)	13 (1.3)
Thrombocytosis	0	0	0	0	1 (0.4)	0	0	1 (0.1)
Cardiac disorders	34 (13.7)	43 (16.9)	39 (15.4)	33 (13.1)	41 (17.1)	35 (13.9)	67 (13.4)	158 (15.8)
Acute coronary syndrome	1 (0.4)	0	0	0	0	0	1 (0.2)	0
Acute left ventricular failure	0	1 (0.4)	0	0	1 (0.4)	0	0	2 (0.2)
Acute myocardial infarction	4 (1.6)	4 (1.6)	4 (1.6)	2 (0.8)	7 (2.9)	5 (2.0)	6 (1.2)	20 (2.0)
Angina pectoris	2 (0.8)	8 (3.1)	3 (1.2)	1 (0.4)	5 (2.1)	5 (2.0)	3 (0.6)	21 (2.1)
Angina unstable	2 (0.8)	4 (1.6)	4 (1.6)	5 (2.0)	2 (0.8)	3 (1.2)	7 (1.4)	13 (1.3)
Aortic valve incompetence	1 (0.4)	2 (0.8)	1 (0.4)	0	0	0	1 (0.2)	3 (0.3)
Aortic valve stenosis	0	0	0	1 (0.4)	0	1 (0.4)	1 (0.2)	1 (0.1)
Arrhythmia	0	0	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.2)	3 (0.3)
Atrial fibrillation	6 (2.4)	5 (2.0)	4 (1.6)	6 (2.4)	3 (1.2)	6 (2.4)	12 (2.4)	18 (1.8)
Atrial flutter	1 (0.4)	0	1 (0.4)	1 (0.4)	2 (0.8)	1 (0.4)	2 (0.4)	4 (0.4)
Atrial tachycardia	1 (0.4)	1 (0.4)	0	1 (0.4)	0	0	2 (0.4)	1 (0.1)
Atrial thrombosis	1 (0.4)	0	0	1 (0.4)	0	0	2 (0.4)	0
Atrioventricular block complete	0	2 (0.8)	0	0	0	2 (0.8)	0	2 (0.2)
Atrioventricular block first degree	0	0	0	0	2 (0.8)	1 (0.4)	0	3 (0.3)

Row Variable 2's values are shown indented under Row Variable 1's values.

Analysis Studio: Custom Table Demo

Help

Upload Data
Custom Table
Add Analysis +

Table Section 2

Table Section Sub-header ?

TEAEs by SOC/PT

Row Dataset ?

Adverse Events

Analysis Filter ?

TRTEMFL (Treatment Emergent Flag)

TRTEMFL (Treatment Emergent Flag)

Y

Row Variable 1 ?

AEBODSYS (Body System or Organ Class)

Row Variable 2 ?

AEDECOD (Dictionary-Derived Term)

Percent Threshold Filter ?

5

Add Table Section

Delete Table Section

PHUSE Example Table

	STUDY-1			STUDY-2			Total	
	Placebo (N=249)	Treatment 100mg (N=254)	Treatment 200mg (N=253)	Placebo (N=252)	Treatment 100mg (N=240)	Treatment 200mg (N=251)	Placebo (N=501)	Treatment (N=998)
Any TEAE	164 (65.9)	165 (65.0)	158 (62.5)	176 (69.8)	163 (67.9)	166 (66.1)	340 (67.9)	652 (65.3)
TEAEs by SOC/PT								
Gastrointestinal disorders	62 (24.9)	74 (29.1)	73 (28.9)	63 (25.0)	50 (20.8)	63 (25.1)	125 (25.0)	260 (26.1)
Nausea	14 (5.6)	25 (9.8)	20 (7.9)	16 (6.3)	12 (5.0)	19 (7.6)	30 (6.0)	76 (7.6)
Vomiting	2 (0.8)	10 (3.9)	14 (5.5)	8 (3.2)	14 (5.8)	5 (2.0)	10 (2.0)	43 (4.3)
Infections and infestations	73 (29.3)	78 (30.7)	82 (32.4)	73 (29.0)	70 (29.2)	85 (33.9)	146 (29.1)	315 (31.6)
Bronchitis	8 (3.2)	18 (7.1)	10 (4.0)	8 (3.2)	7 (2.9)	5 (2.0)	16 (3.2)	40 (4.0)
Nasopharyngitis	15 (6.0)	12 (4.7)	10 (4.0)	10 (4.0)	18 (7.5)	9 (3.6)	25 (5.0)	49 (4.9)
Pneumonia	3 (1.2)	7 (2.8)	14 (5.5)	3 (1.2)	9 (3.8)	10 (4.0)	6 (1.2)	40 (4.0)
Upper respiratory tract infection	13 (5.2)	11 (4.3)	19 (7.5)	11 (4.4)	19 (7.9)	18 (7.2)	24 (4.8)	67 (6.7)
Musculoskeletal and connective tissue disorders	46 (18.5)	57 (22.4)	53 (20.9)	44 (17.5)	46 (19.2)	37 (14.7)	90 (18.0)	193 (19.3)
Back pain	7 (2.8)	10 (3.9)	15 (5.9)	9 (3.6)	11 (4.6)	14 (5.6)	16 (3.2)	50 (5.0)
Nervous system disorders	50 (20.1)	41 (16.1)	46 (18.2)	51 (20.2)	45 (18.8)	27 (10.8)	101 (20.2)	159 (15.9)
Headache	17 (6.8)	7 (2.8)	3 (1.2)	10 (4.0)	9 (3.8)	6 (2.4)	27 (5.4)	25 (2.5)
Vascular disorders	22 (8.8)	17 (6.7)	24 (9.5)	18 (7.1)	16 (6.7)	21 (8.4)	40 (8.0)	78 (7.8)
Hypertension	8 (3.2)	9 (3.5)	14 (5.5)	3 (1.2)	6 (2.5)	11 (4.4)	11 (2.2)	40 (4.0)

Source: OCS Analysis Studio, Custom Table Builder.
Columns - Dataset: Demographics; Filter: SAFPL = "Y".
Any TEAE - Dataset: Adverse Events; Filter: TRTEMFL = "Y".
TEAEs by SOC/PT - Dataset: Adverse Events; Filter: TRTEMFL = "Y"; Percent Threshold: 5%.

Tool Options

A percent threshold can be added to show only the most frequently occurring events. Above, only rows that have at least one column meeting 5 percent are kept.

Analysis Studio: Custom Table Demo

Help

Upload Data
Custom Table
Add Analysis +

Column Inputs

Rename/Group

Order/Sort

Formatting

Footnotes

Order Column Variable 1 Values

Order Column Variable 2 Values

Order Total Column values

Select Analysis Sorting Method

Alphabetical

PhUSE Example Table

	STUDY-1			STUDY-2			Total	
	Placebo (N=249)	Treatment 100mg (N=254)	Treatment 200mg (N=253)	Placebo (N=252)	Treatment 100mg (N=240)	Treatment 200mg (N=251)	Placebo (N=501)	Treatment (N=998)
Any TEAE	164 (65.9)	165 (65.0)	158 (62.5)	176 (69.8)	163 (67.9)	166 (66.1)	340 (67.9)	652 (65.3)
TEAEs by SOC/PT								
Gastrointestinal disorders	62 (24.9)	74 (29.1)	73 (28.9)	63 (25.0)	50 (20.8)	63 (25.1)	125 (25.0)	260 (26.1)
Nausea	14 (5.6)	25 (9.8)	20 (7.9)	16 (6.3)	12 (5.0)	19 (7.6)	30 (6.0)	76 (7.6)
Vomiting	2 (0.8)	10 (3.9)	14 (5.5)	8 (3.2)	14 (5.8)	5 (2.0)	10 (2.0)	43 (4.3)
Infections and infestations	73 (29.3)	78 (30.7)	82 (32.4)	73 (29.0)	70 (29.2)	85 (33.9)	146 (29.1)	315 (31.6)
Bronchitis	8 (3.2)	18 (7.1)	10 (4.0)	8 (3.2)	7 (2.9)	5 (2.0)	16 (3.2)	40 (4.0)
Nasopharyngitis	15 (6.0)	12 (4.7)	10 (4.0)	10 (4.0)	18 (7.5)	9 (3.6)	25 (5.0)	49 (4.9)
Pneumonia	3 (1.2)	7 (2.8)	14 (5.5)	3 (1.2)	9 (3.8)	10 (4.0)	6 (1.2)	40 (4.0)
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Source: OCS Analysis Studio, Custom Table Builder.
Columns - Dataset: Demographics; Filter: SAFPL = "Y".
Any TEAE - Dataset: Adverse Events; Filter: TRTEMFL = "Y".
TEAEs by SOC/PT - Dataset: Adverse Events; Filter: TRTEMFL = "Y"; Percent Threshold: 5%.

Tool Options

Under the Order/Sort tab, the table sections can be sorted.

Analysis Studio: Custom Table Demo

Help

Upload Data
Custom Table
Add Analysis +

Column Inputs

Rename/Group

Order/Sort

Row Inputs

Formatting

Footnotes

Order Column Variable 1 Values

Order Column Variable 2 Values

Order Total Column values

Select Analysis Sorting Method

Alphabetical

By Total Across All Columns

By User Selected Column

PHUSE Example Table

	STUDY-1			STUDY-2			Total	
	Placebo (N=249)	Treatment 100mg (N=254)	Treatment 200mg (N=253)	Placebo (N=252)	Treatment 100mg (N=240)	Treatment 200mg (N=251)	Placebo (N=501)	Treatment (N=998)
Any TEAE	164 (65.9)	165 (65.0)	158 (62.5)	176 (69.8)	163 (67.9)	166 (66.1)	340 (67.9)	652 (65.3)
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Source: OCS Analysis Studio, Custom Table Builder.
Columns - Dataset: Demographics; Filter: SAFPL = "Y".
Any TEAE - Dataset: Adverse Events; Filter: TRTEMFL = "Y".
TEAEs by SOC/PT - Dataset: Adverse Events; Filter: TRTEMFL = "Y"; Percent Threshold: 5%.

Tool Options

Three sorting methods are currently available.

Analysis Studio: Custom Table Demo


Help ▾

Upload Data
Custom Table x
Add Analysis +

Column Inputs
Rename/Group
Order/Sort
Row Inputs

Formatting
Footnotes

Order Column Variable 1 Values

Order Column Variable 2 Values

Order Total Column values

Select Analysis Sorting Method

By User Selected Column
▾

Choose Sort Column

Total - Treatment
▾

PhUSE Example Table

	STUDY-1			STUDY-2			Total	
	Placebo (N=249)	Treatment 100mg (N=254)	Treatment 200mg (N=253)	Placebo (N=252)	Treatment 100mg (N=240)	Treatment 200mg (N=251)	Placebo (N=501)	Treatment (N=998)
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Source: OCS Analysis Studio, Custom Table Builder.
 Columns - Dataset: Demographics; Filter: SAFPL = "Y".
 Any TEAE - Dataset: Adverse Events; Filter: TRTEMFL = "Y".
 TEAEs by SOC/PT - Dataset: Adverse Events; Filter: TRTEMFL = "Y"; Percent Threshold: 5%.

Tool Options ▴ ▾

The rows of the table are now sorted by the Total – Treatment column. The rows are first sorted by System Organ Class. The Preferred Terms are then sorted within each System Organ Class.

Analysis Studio: Custom Table Demo

Help

Upload Data
Custom Table
Add Analysis +

Column Inputs

Rename/Group

Order/Sort

Row Inputs

Formatting

Footnotes

Order Column Variable 1 Values

Order Column Variable 2 Values

Order Total Column values

Select Analysis Sorting Method

By User Selected Column

Choose Sort Column

Total - Treatment

PhUSE Example Table

	STUDY-1			STUDY-2			Total	
	Placebo (N=249)	Treatment 100mg (N=254)	Treatment 200mg (N=253)	Placebo (N=252)	Treatment 100mg (N=240)	Treatment 200mg (N=251)	Placebo (N=501)	Treatment (N=998)
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Source: OCS Analysis Studio, Custom Table Builder.
Columns - Dataset: Demographics; Filter: SAFPL = "Y".
Any TEAE - Dataset: Adverse Events; Filter: TRTEMFL = "Y".
TEAEs by SOC/PT - Dataset: Adverse Events; Filter: TRTEMFL = "Y"; Percent Threshold: 5%.

Download Word Report

Download Template

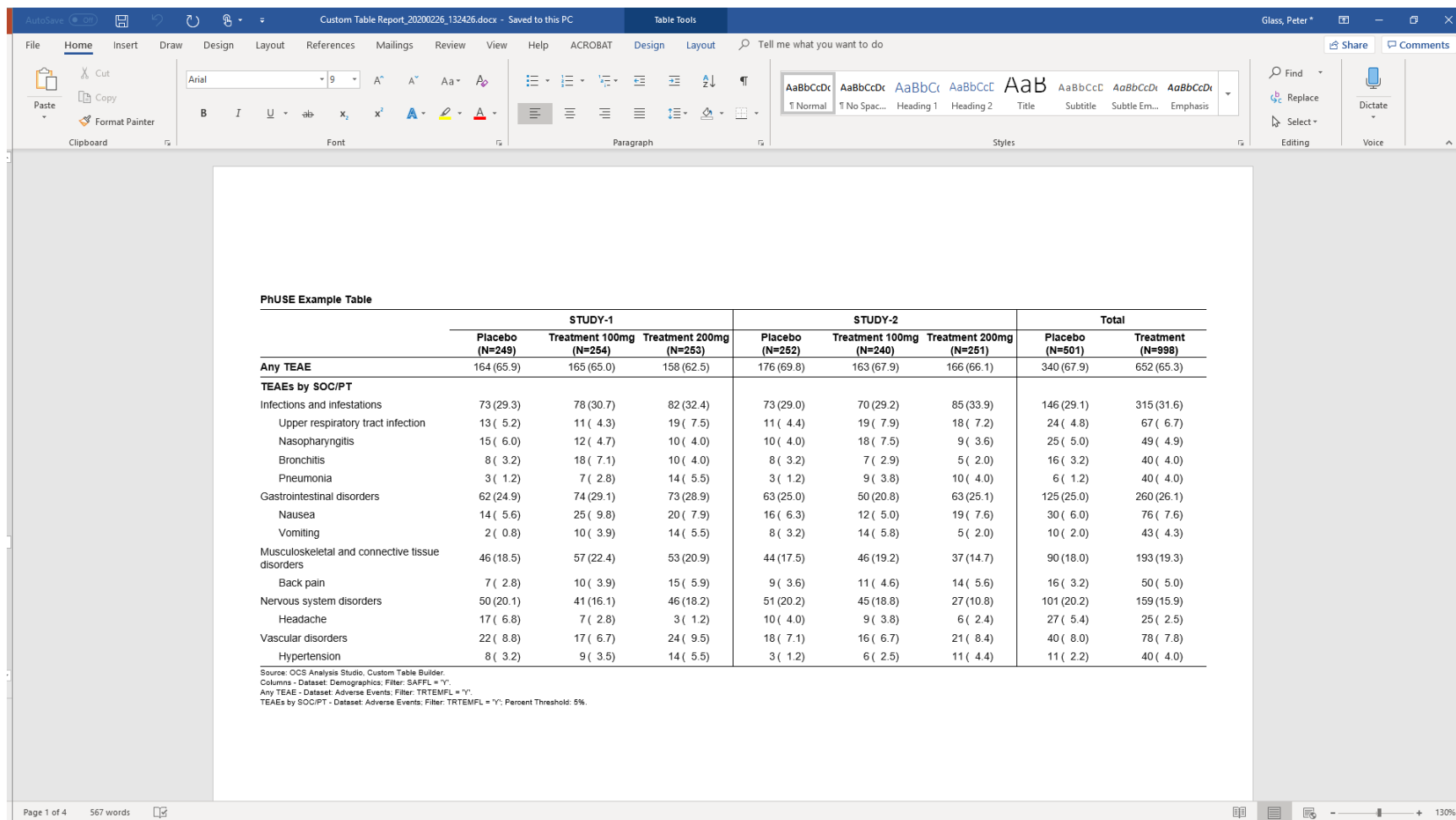
Restore Template

Reset All Inputs

Tool Options

Once a table is complete, it can be downloaded to Word using the Tool Options menu.

Analysis Studio: Custom Table Demo



PhUSE Example Table

	STUDY-1			STUDY-2			Total	
	Placebo (N=249)	Treatment 100mg (N=254)	Treatment 200mg (N=253)	Placebo (N=252)	Treatment 100mg (N=240)	Treatment 200mg (N=251)	Placebo (N=501)	Treatment (N=998)
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Source: OCS Analysis Studio, Custom Table Builder.
Columns - Dataset: Demographics; Filter: SAFFL = "Y".
Any TEAE - Dataset: Adverse Events; Filter: TRTEMFL = "Y".
TEAEs by SOC/PT - Dataset: Adverse Events; Filter: TRTEMFL = "Y"; Percent Threshold: 5%.

The table is downloaded exactly as it appears in the tool. The table can be further edited in Word as needed.

Analysis Studio: Custom Table Demo

The screenshot shows a Microsoft Word document titled 'Custom Table Report_20200226_132426.docx'. The document contains a custom table with the following data:

Parameters	Input
Additional Footnote Text 1	
Additional Footnote Text 2	
Adverse Events Dataset Unique Key (md5)	b76449e8ac2876257b72d929ba066e49
Apply Rename To	Just Total Column
Column Dataset	Demographics
Column Filter Values: SAFFL	Y
Column Filter Variables	SAFFL (Safety Population Flag)
Column Variable 1	STUDYID (Study Identifier)
Column Variable 1 Order	
Column Variable 2	TRT01A (Actual Treatment for Period 01)
Column Variable 2 Order	
Demographic Dataset Unique Key (md5)	6495f0548a9dc15c865f2495223d5f7d
First Column Size	2
Footer Font Size	6
Laboratory Dataset Unique Key (md5)	943fcc52fb0781ec24471a959950db2d
Lower Case All but First Letter in Rows	No
Missing Values Replacement	<NO DATA>
Number of Decimals	1
Other Column Size	1
Renamed STUDYID Column: STUDY-1	
Renamed STUDYID Column: STUDY-2	
Renamed TRT01A Column: Placebo	

The status bar at the bottom of the Word window shows 'Page 2 of 4' and '567 words'.

An audit trail appears with the table to ensure traceability.

Analysis Studio: Hepatic Explorer Demo

Help

Upload Data
Custom Table
Add Analysis +

Which datasets do I need to upload?

Demographic
 Browse... adsl.sas7bdat
 Upload complete

Adverse Event
 Browse... adae.sas7bdat
 Upload complete

Concomitant Medications
 Browse... No file selected

Disposition
 Browse... No file selected

Exposure
 Browse... No file selected

Laboratory
 Browse... lb.sas7bdat
 Upload complete

Medical History
 Browse... No file selected

Demographic
 Adverse Event
 Laboratory

STUDYID (Study Identifier) USUBJID (Unique Subject Identifier) SITEID (Study Site Identifier) SEX (Sex) RACE (Race) ETHNIC (Ethnicity)
 ARM (Description of Planned Arm) ACTARM (Description of Actual Arm) TRT01P (Planned Treatment for Period 01) TRT01A (Actual Treatment for Period 01)

Show 5 entries
 Search:

	STUDYID	USUBJID	SITEID	SEX	RACE	ETHNIC	ARM	ACTARM	TRT01P	TRT01A
1	STUDY-1	STUDY-1-101001	101	M	WHITE	HISPANIC OR LATINO	Treatment 100mg	Treatment 100mg	Treatment 100mg	Treatment 100mg
2	STUDY-1	STUDY-1-101002	101	M	BLACK OR AFRICAN AMERICAN	HISPANIC OR LATINO	Treatment 100mg	Treatment 100mg	Treatment 100mg	Treatment 100mg
3	STUDY-1	STUDY-1-101003	101	M	BLACK OR AFRICAN AMERICAN	HISPANIC OR LATINO	Placebo	Placebo	Placebo	Placebo
4	STUDY-1	STUDY-1-101004	101	M	ASIAN	NOT HISPANIC OR LATINO	Screen Failure	Screen Failure	Screen Failure	Screen Failure
5	STUDY-1	STUDY-1-101005	101	M	WHITE	NOT HISPANIC OR LATINO	Screen Failure	Screen Failure	Screen Failure	Screen Failure

Showing 1 to 5 of 2,000 entries
 Previous
 1
 2
 3
 4
 5
 ...
 400
 Next

Back on the front page of Analysis Studio, additional analyses can be added by selecting the 'Add Analysis +' button.

Analysis Studio: Hepatic Explorer Demo

Analysis Studio v1.2.0

Upload Data Custom Table X Add Analysis +

Which datasets do I need to upload?

Demographic
Browse... adsl.sas7bdat
Upload complete

Adverse Event
Browse... adae.sas7bdat
Upload complete

Concomitant Medications
Browse... No file selected

Disposition
Browse... No file selected

Exposure
Browse... No file selected

Laboratory
Browse... lb.sas7bdat
Upload complete

Medical History
Browse... No file selected

Add Analysis to Dashboard

- Table Builders
- Review Division-Specific Tools
- Exploratory Visualizations
- Hepatic Explorer**

Cancel Create Analysis

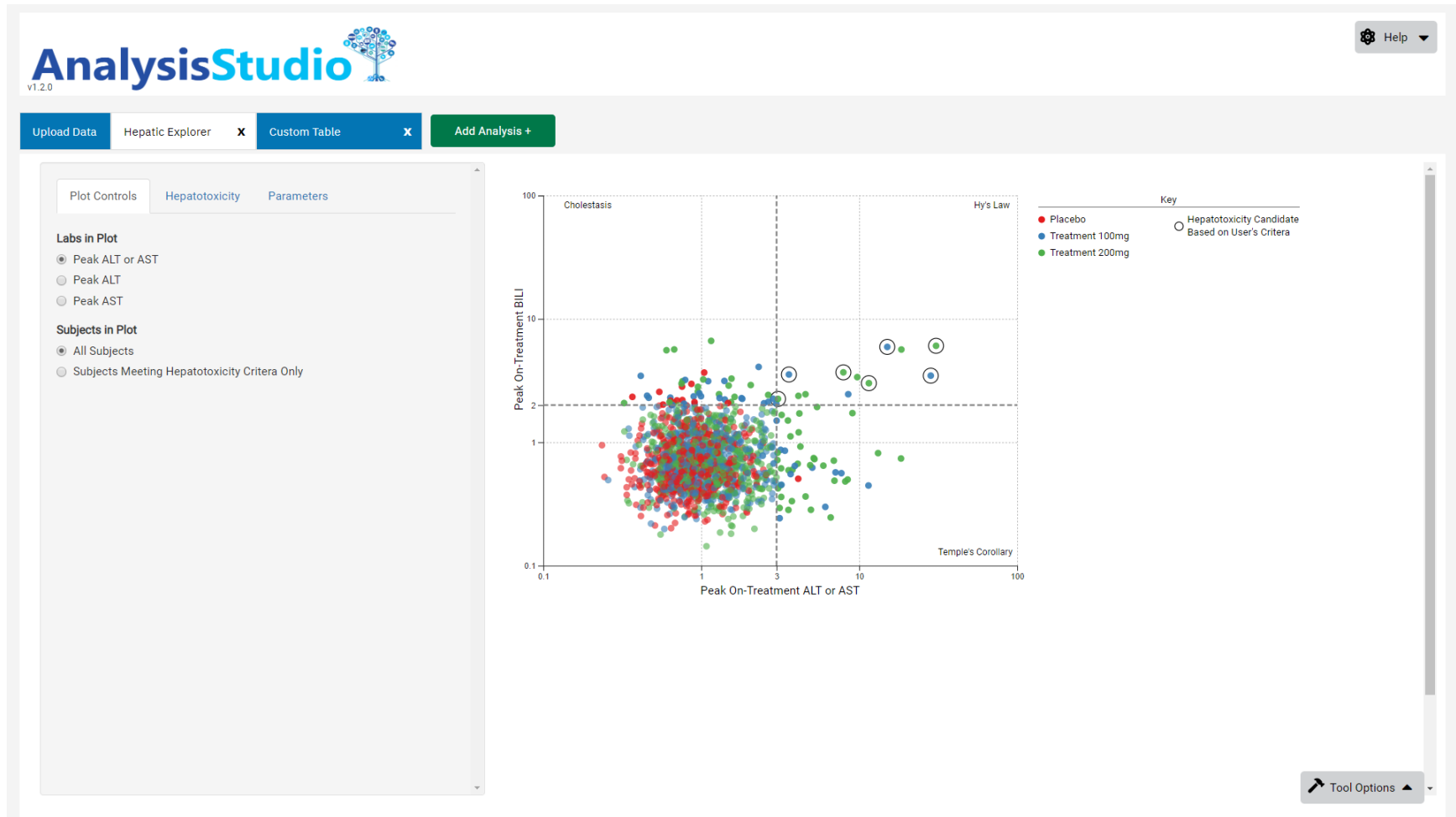
Showing 1 to 5 of 2,000 entries

	STUDY	ID	SEX	RACE	ETHNIC	ARM	ACTARM	TRT01P	TRT01A
2	STUDY-1	STUDY-1-101002	101	M	BLACK OR AFRICAN AMERICAN	HISPANIC OR LATINO	Treatment 100mg	Treatment 100mg	Treatment 100mg
3	STUDY-1	STUDY-1-101003	101	M	BLACK OR AFRICAN AMERICAN	HISPANIC OR LATINO	Placebo	Placebo	Placebo
4	STUDY-1	STUDY-1-101004	101	M	ASIAN	NOT HISPANIC OR LATINO	Screen Failure	Screen Failure	Screen Failure
5	STUDY-1	STUDY-1-101005	101	M	WHITE	NOT HISPANIC OR LATINO	Screen Failure	Screen Failure	Screen Failure

Previous 1 2 3 4 5 ... 400 Next

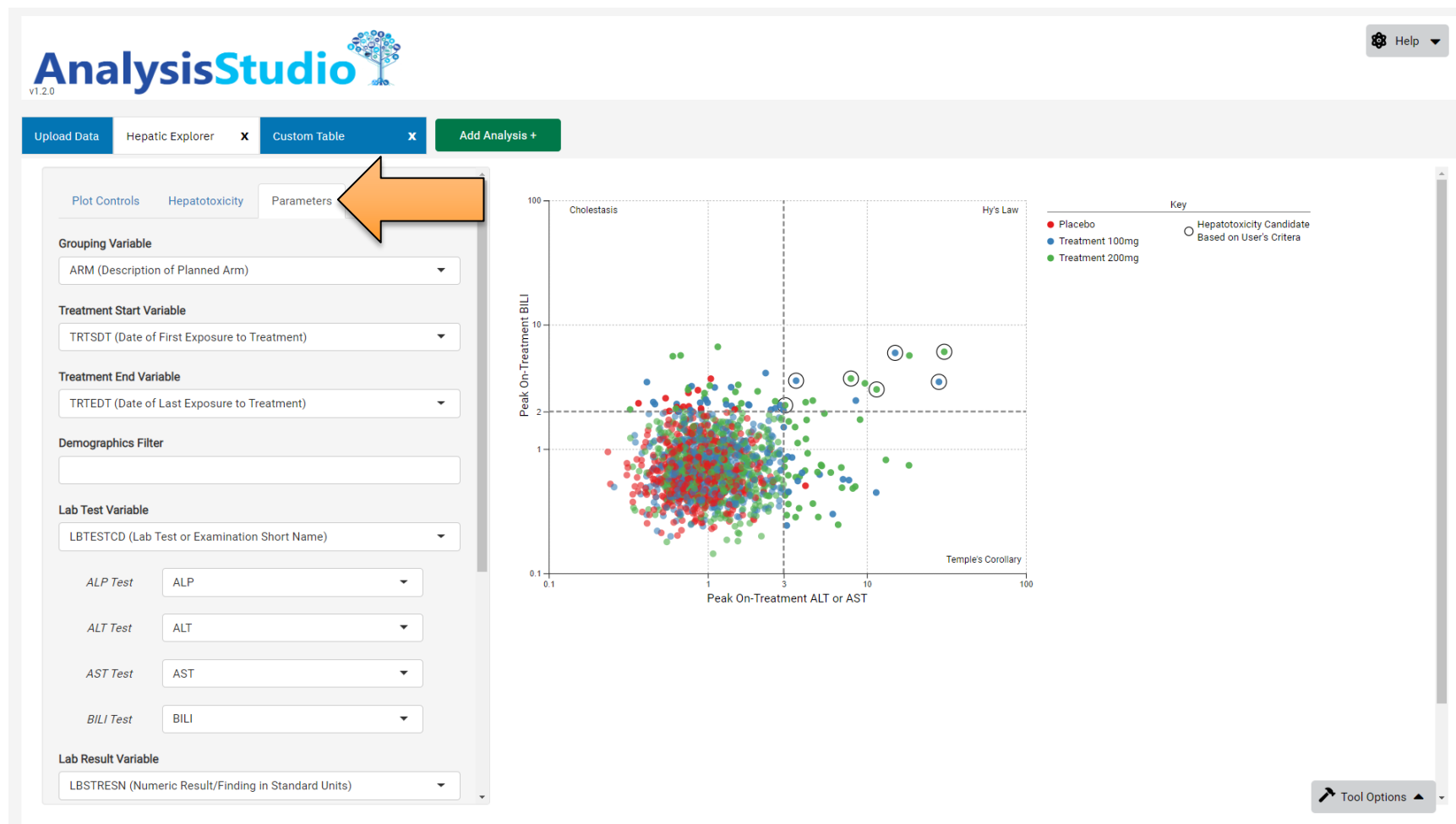
Hepatic Explorer is located under Exploratory Visualizations

Analysis Studio: Hepatic Explorer Demo



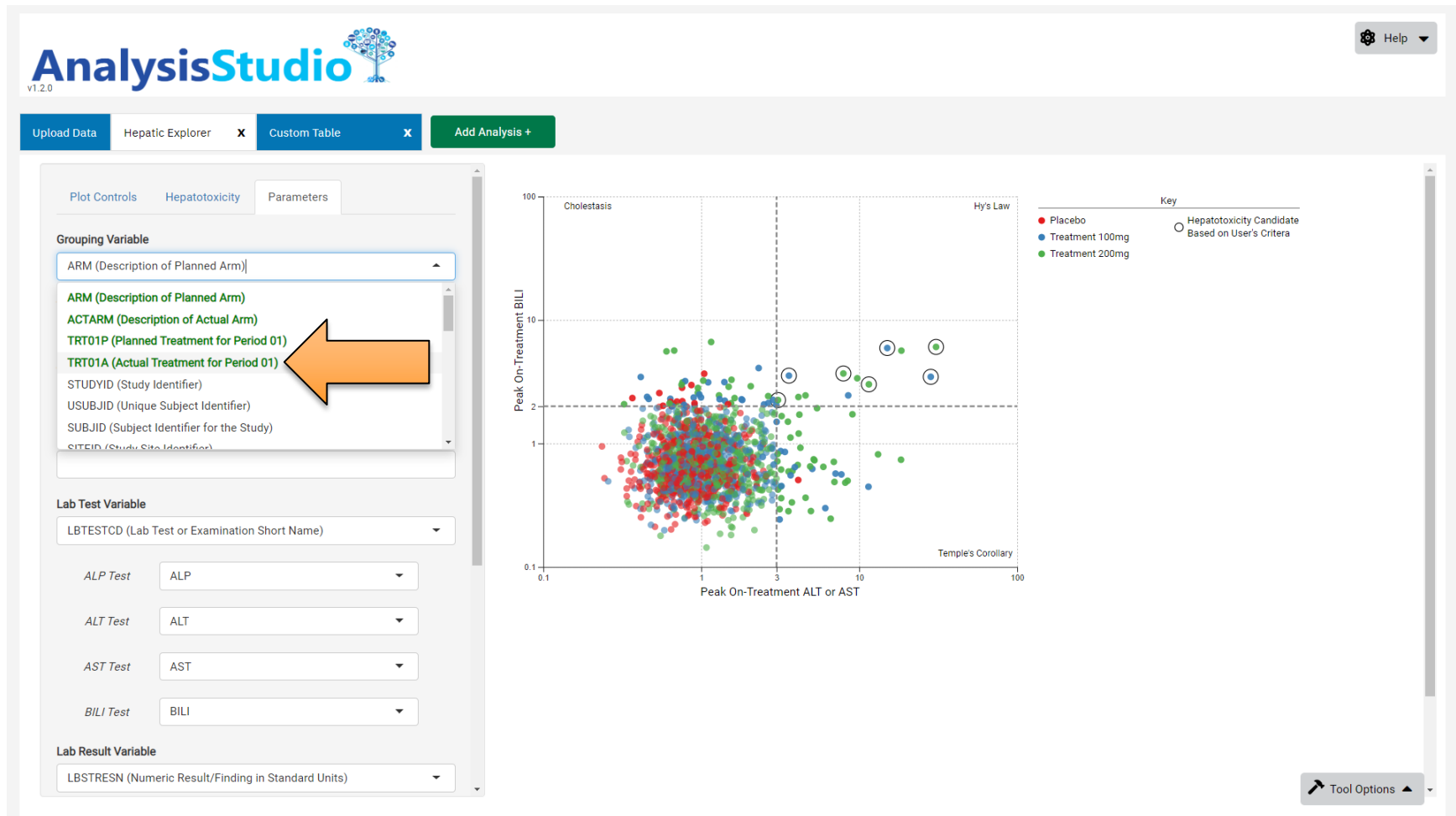
The Hepatic Explorer tool is constructed like other tools in Analysis Studio. If the user is familiar with one tool, they should be comfortable with all tools. If the needed parameters are available, the tool will automatically create output.

Analysis Studio: Hepatic Explorer Demo



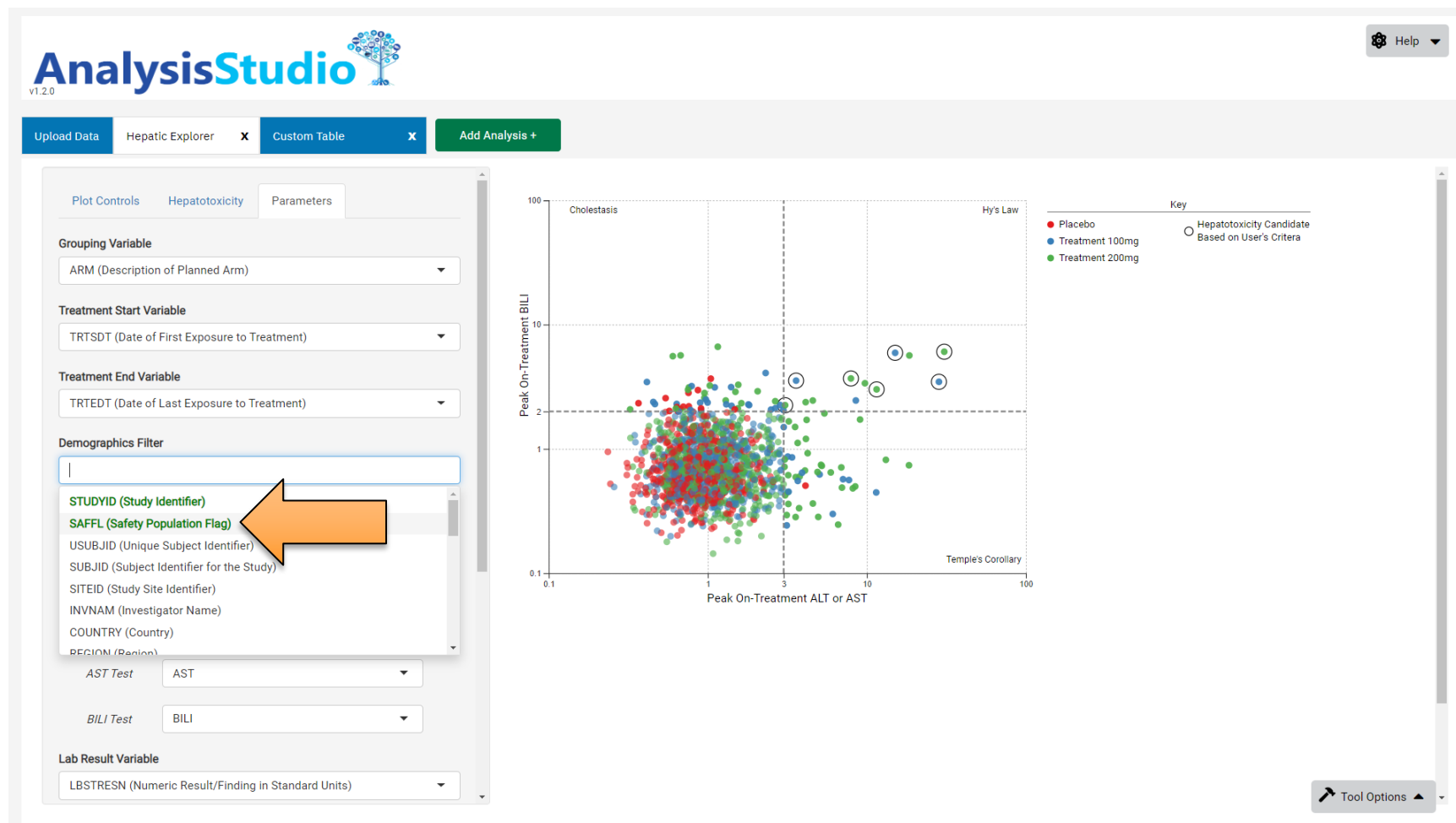
The user selects the variables needed to build or change the analysis under the Parameters tab.

Analysis Studio: Hepatic Explorer Demo



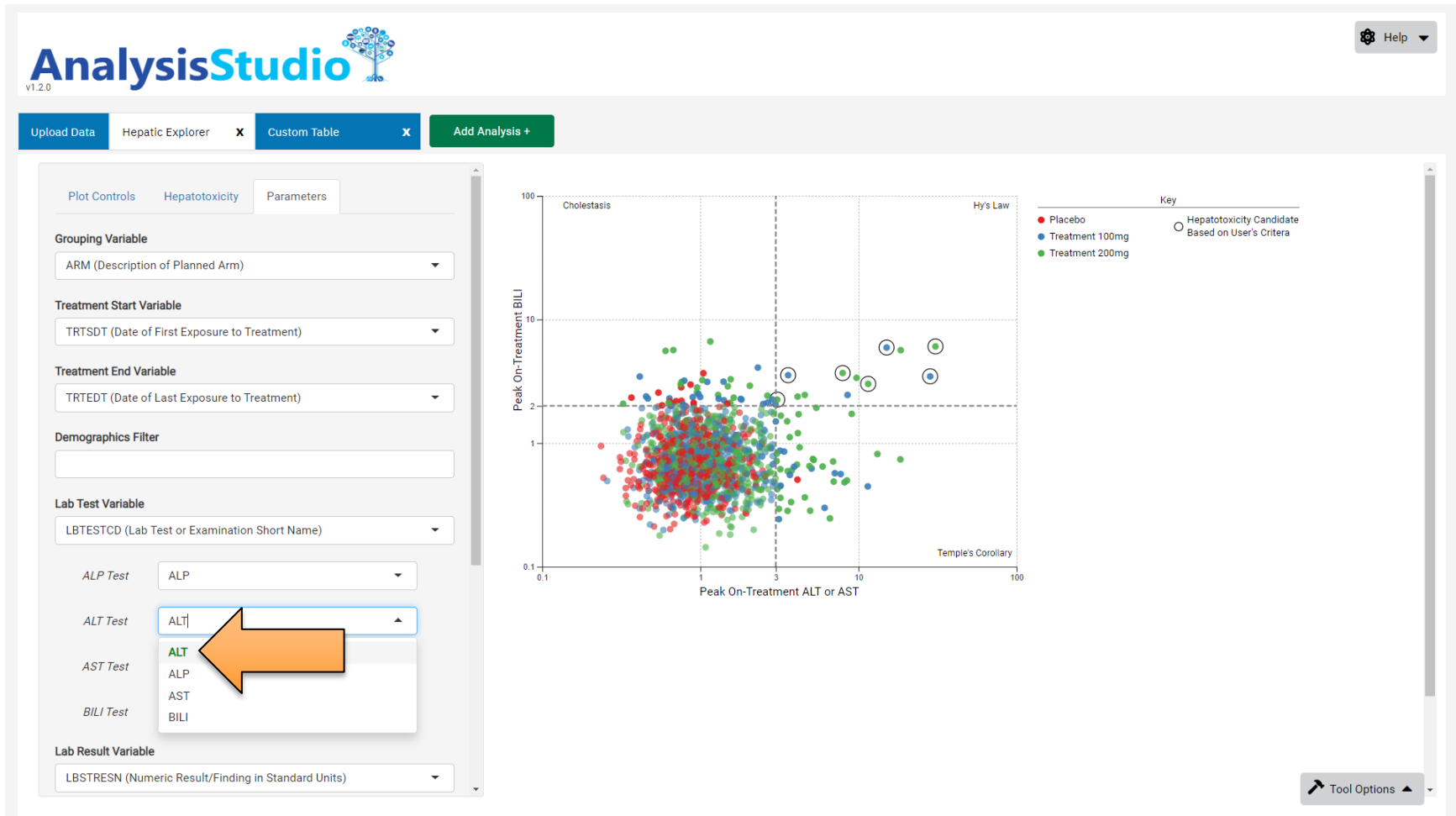
Like Custom Table, variables are selected from pulldowns. Because Hepatic Explorer is a more specific tool, suggested variables are highlighted and placed first.

Analysis Studio: Hepatic Explorer Demo



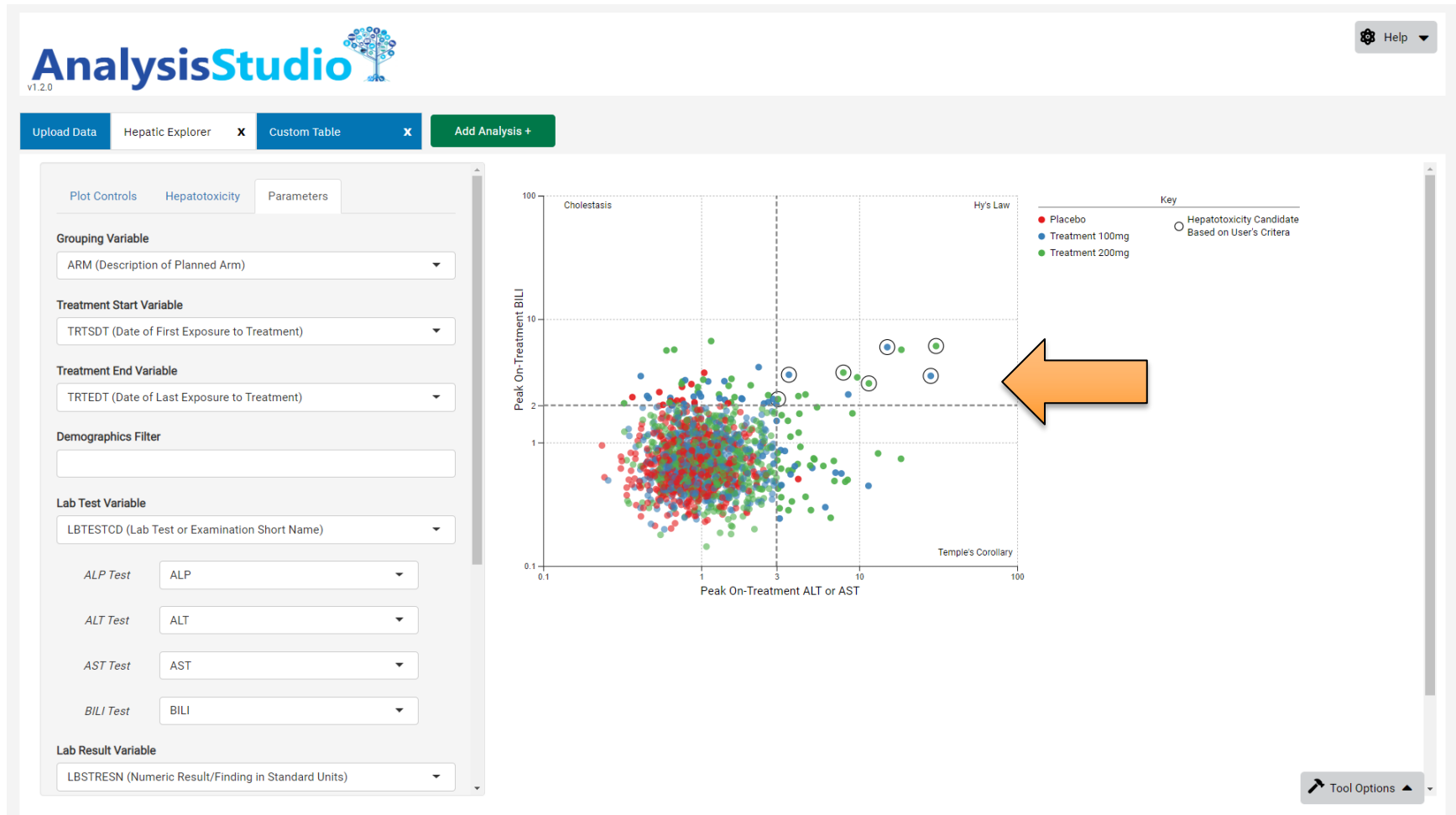
Variables and filters are selected as they are in Custom Table.

Analysis Studio: Hepatic Explorer Demo



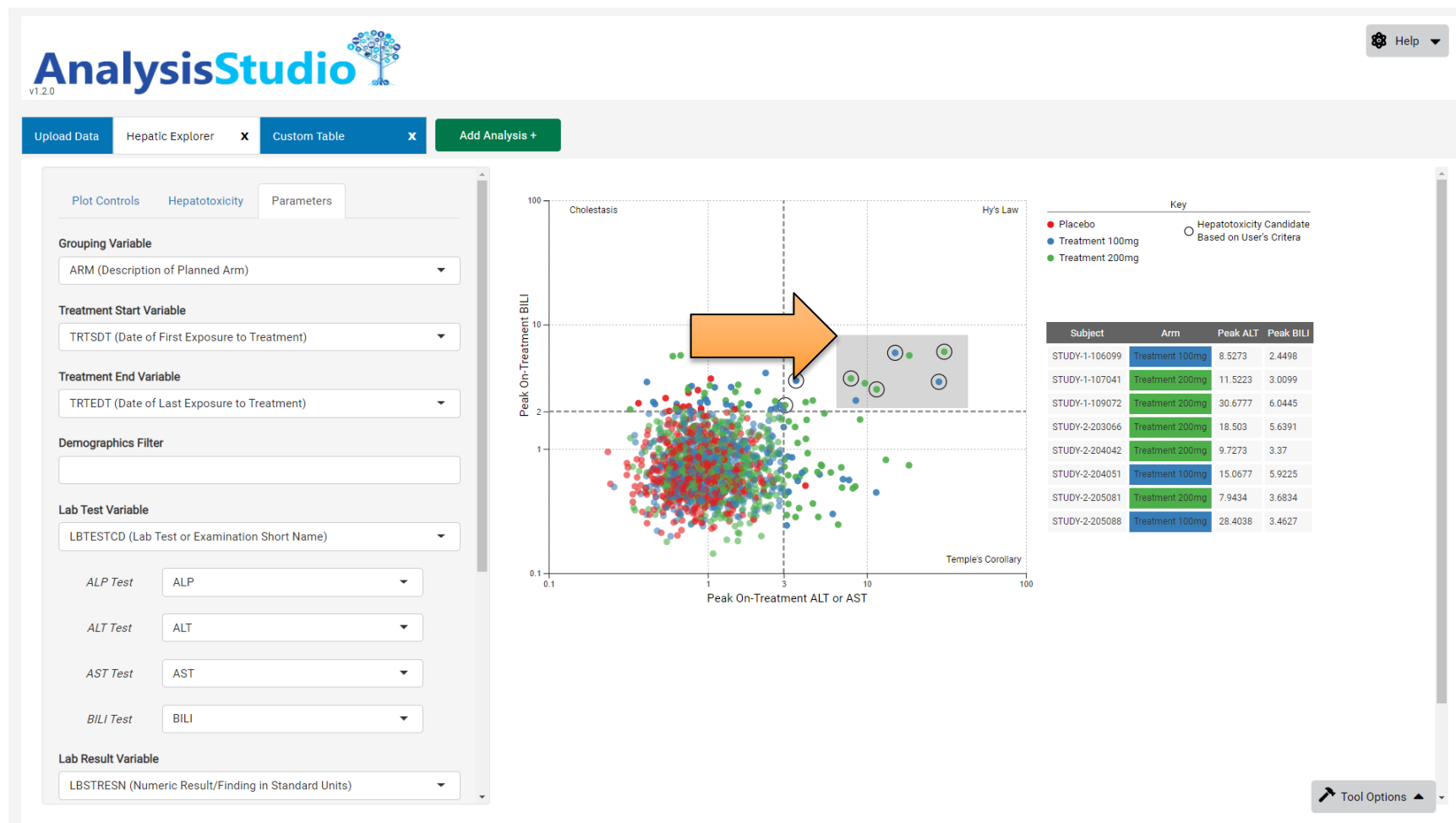
Similarly to how filters are created, the lab tests that will be used to create the output are chosen by the user.

Analysis Studio: Hepatic Explorer Demo



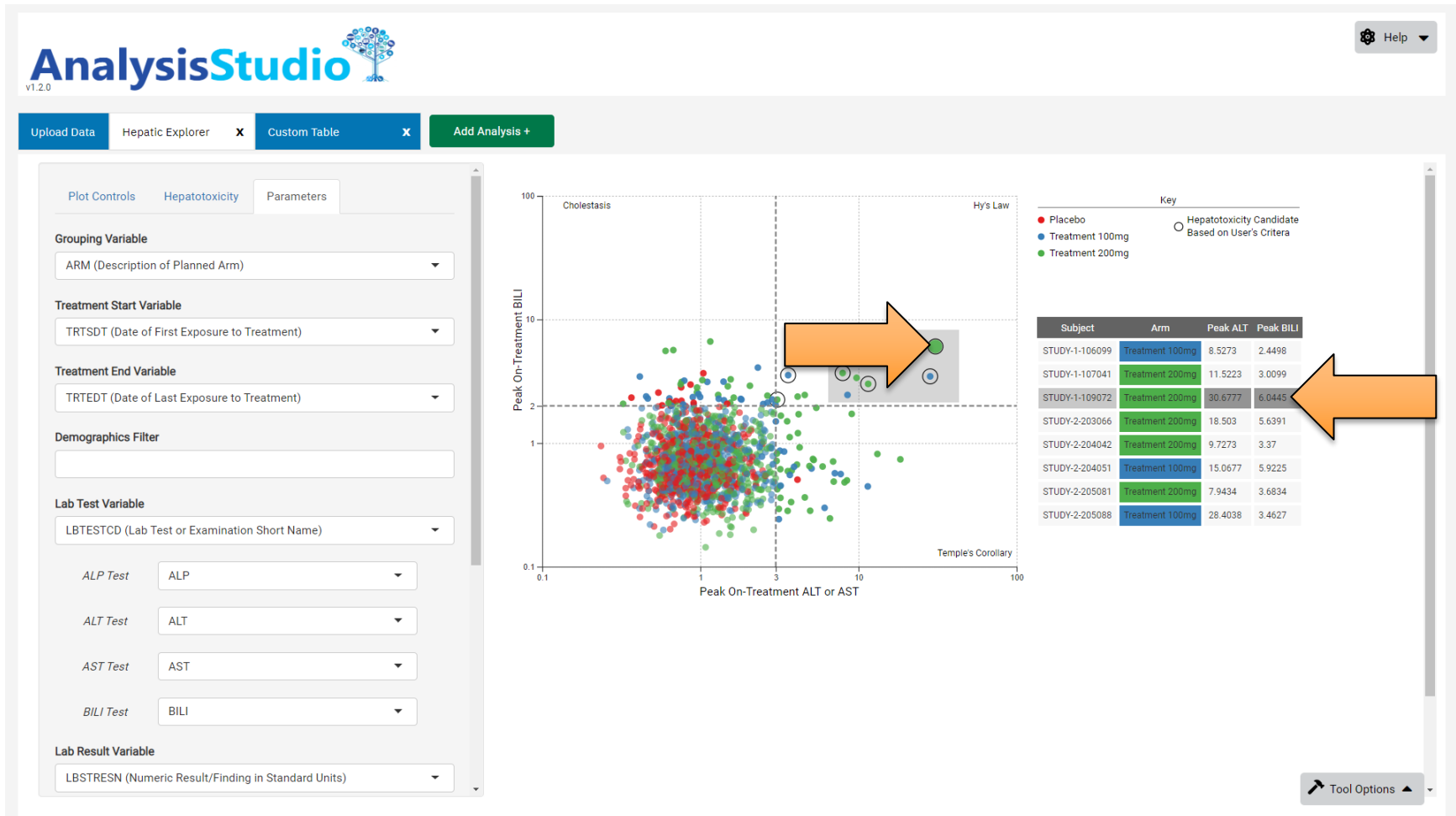
The plot depicts peak on-treatment ALT or AST on the x-axis and peak Bili on the y-axis. Both are normalized by Upper Limit of Normal.

Analysis Studio: Hepatic Explorer Demo



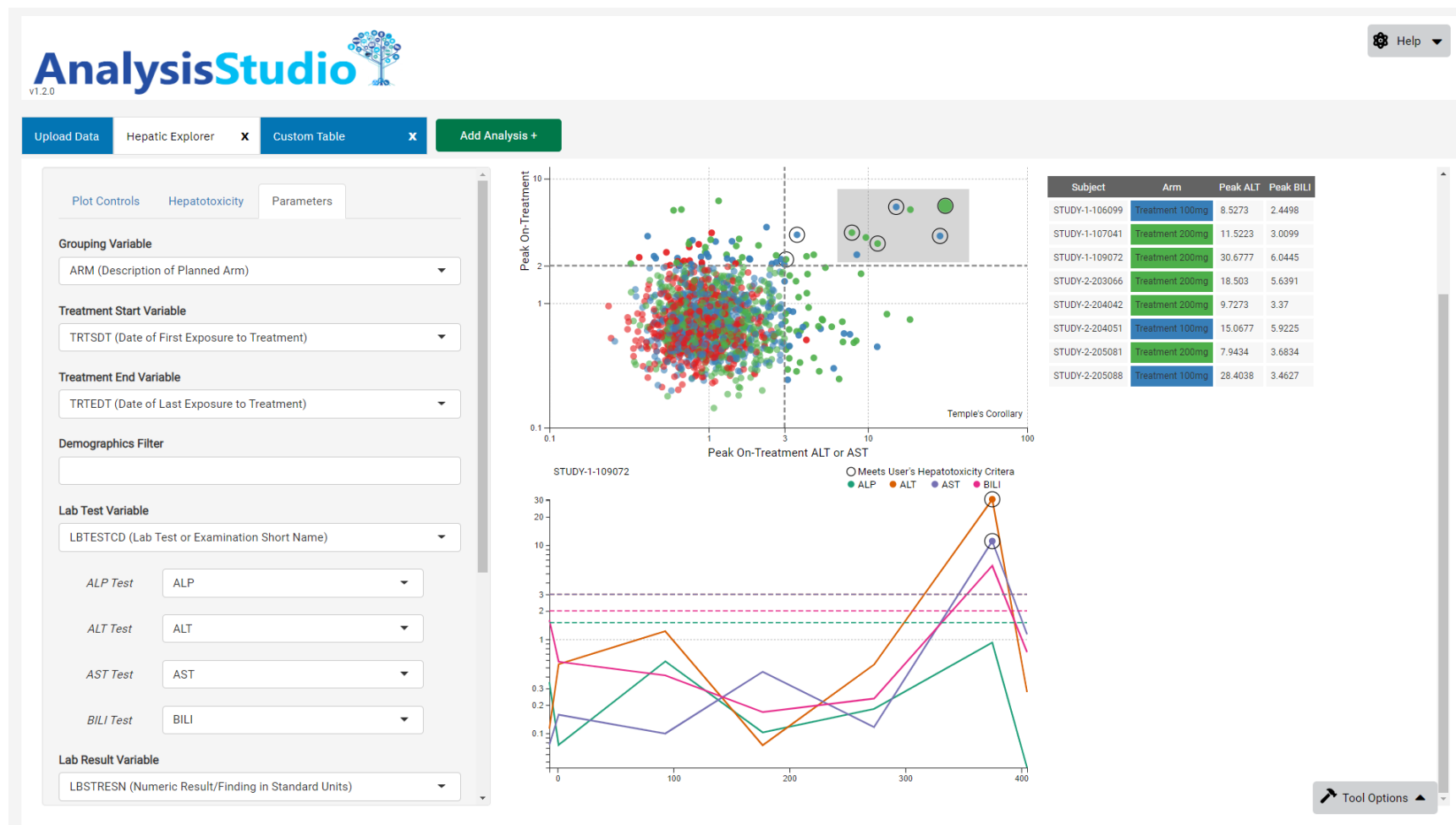
The plot is interactive. Here subjects are “lassoed” and appear in the table on the right.

Analysis Studio: Hepatic Explorer Demo



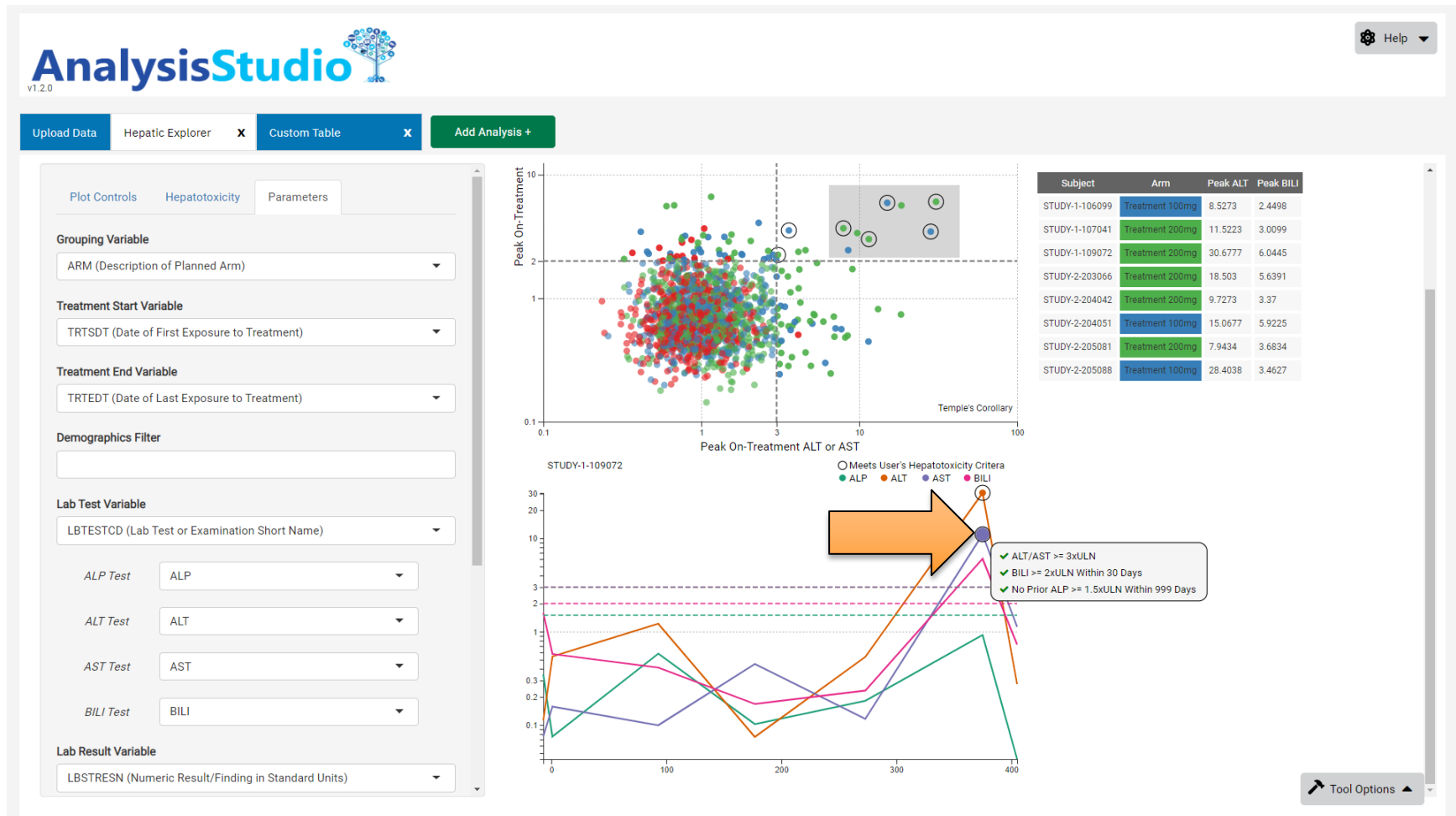
Clicking on a point in the plot or a row in the table will show a spaghetti plot for that subject.

Analysis Studio: Hepatic Explorer Demo



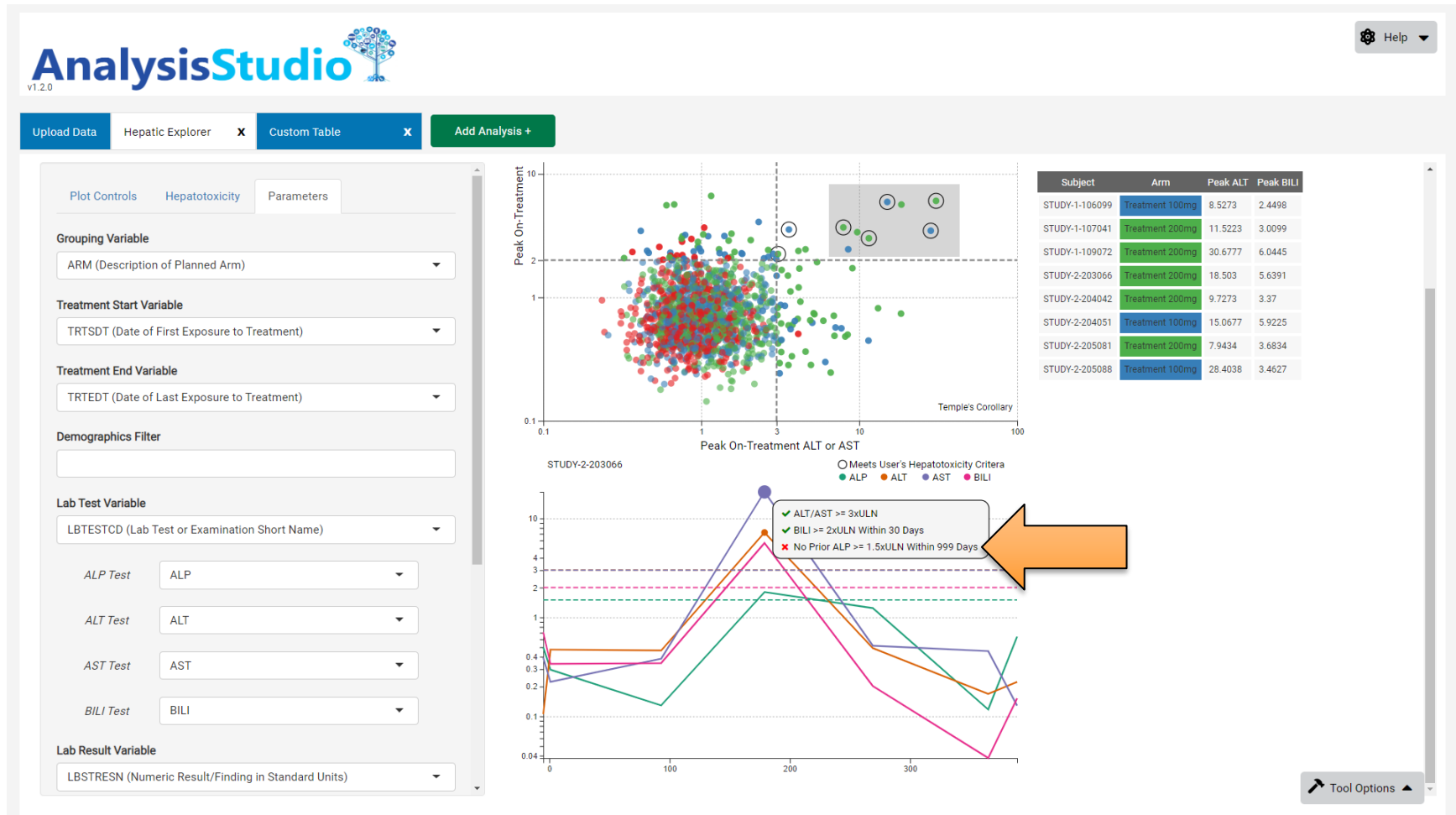
The spaghetti plot shows a subject's liver labs plotted by study day and normalized by Upper Limit of Normal. Elevated ALT or AST results show as interactive points.

Analysis Studio: Hepatic Explorer Demo



When hovering over a test result, a tool tip is shown. This contains information related to hepatotoxicity criteria set by the user in another tab. If a test meets all criteria, a circle is drawn around the point. 57

Analysis Studio: Hepatic Explorer Demo



The tool tip will identify criteria a result didn't meet with red X's.