

CONFIDENTIAL

Data testing summary

Testing performed by	Dan Polhamus Senior Scientist Metrum Research Group LLC 2 Tunxis Road, Suite 112 Tariffville, CT Phone: Fax: 860-372-7988 Email:
(Sign and print name)	
Dates (YYYY-MM-DD)	

Testing log

RID	Topic	Test ID	Step Description	Expected Result	Qualification Note(s)	Pass/Fail
24	Tabulated NONMEM run summary	1	Create table panel: Analysis Selection -> Tables -> Tabulated NM Diagnostic to 1	ConcvTime panel created in Tables	NMTab panel is created (not ConcvTime), but this is expected	Pass
		2	Figure renders and respects inputs for all boxes	Plot is updated, respecting inputs. Screenshot(s) as evidence	Significant figures, CI, displaying off diagonals, removing fixed values all work as intended <Screenscaps>	Pass
		3	Figure footnote LaTeX rendering works as expected. Enter: $\$omega\$$ is IIV	Footnote renders correctly. Screenshot as evidence	Footnote renders correctly (different text entered, but several greek letters and apostrophes tested as well <Screenscaps>	Pass
		4	Reset button clears selections	Plot is updated, respecting inputs. Screenshot as evidence	Cleared back to defaults <Screenscaps>	Pass
25	Demographics tables (categorical)	1	Create table panel: Analysis Selection -> Tables -> Demographic tables (categorical) to 1	demogTabCat panel created in Tables	Panel created	Pass
		2	Figure renders and respects inputs for all "Change Defaults" boxes	Plot is updated, respecting inputs. Screenshot as evidence	All inputs passed through correctly to output <Screenscaps>	Pass
		3	Limits work to restrict data: Enter RACE != 3	Plot is updated, respecting inputs. Screenshot as evidence	Race 3 successfully subset out <Screenscaps>	Pass
		4	Figure renders and respects inputs for all "Adjust margins" boxes	Plot is updated, respecting inputs. Screenshot as evidence	Adding on another column, it's necessary to increase the right margin. After doing so, complete table is visible. See 25-3-1. <Screenscaps>	Pass
		5	Figure footnote LaTeX rendering works as expected. Enter: Subjects with RACE value 3 excluded	Footnote renders correctly. Screenshot as evidence	Footnote works as expected <Screenscaps>	Pass
		6	Reset button clears selections	Plot is updated, respecting inputs. Screenshot as evidence	All defaults cleared to original <Screenscaps>	Pass
26	Demographics tables (continuous)	1	Create table panel: Analysis Selection -> Tables -> Demographic tables (continuous) to 1	demogTabCont panel created in Tables	Panel created	Pass
		2	Figure renders and respects inputs for all "Change Defaults" boxes	Plot is updated, respecting inputs. Screenshot as evidence	Plot is updated, all inputs respected <Screenscaps>	Pass
		3	Limits work to restrict data: Enter DIS == 0	Plot is updated, respecting inputs. Screenshot as evidence	Plot is updated, all inputs respected <Screenscaps>	Pass
		4	Figure renders and respects inputs for all "Adjust margins" boxes	Plot is updated, respecting inputs. Screenshot as evidence	This is evidenced in 26-2	Pass

RID	Topic	Test ID	Step Description	Expected Result	Qualification Note(s)	Pass/Fail
		5	Figure footnote LaTeX rendering works as expected. Enter: Mild severity patients at baseline excluded	Footnote renders correctly. Screenshot as evidence	Footnote render correctly <Screenshots>	Pass
		6	Reset button clears selections	Plot is updated, respecting inputs. Screenshot as evidence	All defaults cleared to original <Screenshots>	Pass
27	Table file from disk	1	Create table panel: Analysis Selection -> Tables -> Table from disk to 1	inputTable panel created in Tables	Panel created	Pass
		2	Table image is read from disk and displayed. Enter File location: /data/tfigenerator/NMStorage/table.png	Image from disk is rendered	Table image is rendered (/data/demotable.png) <Screenshots>	Pass
		3	Reset button clears selections	Plot is updated, respecting inputs. Screenshot as evidence	All defaults cleared to original <Screenshots>	Pass
28	Observation exclusions summary	1	Create table panel: Analysis Selection -> Tables -> Observation exclusions summary to 1	observationExclusionsSummaryTab panel created in Tables	Panel created	Pass
		2	Exclusions table is created. Note that this uses exclusions defined in RID 3.10	Verbatim text preview is shown	Text preview of table is shown <Screenshots>	Pass
29	Subject exclusions summary	1	Create table panel: Analysis Selection -> Tables -> Subject exclusions summary to 1	subjectExclusionsSummaryTab panel created in Tables	Panel created	Pass
		2	Exclusions table is created. Note that this uses exclusions defined in RID 3.10	Verbatim text preview is shown	Text preview shown <Screenshots>	Pass

Appendix

Screenshots

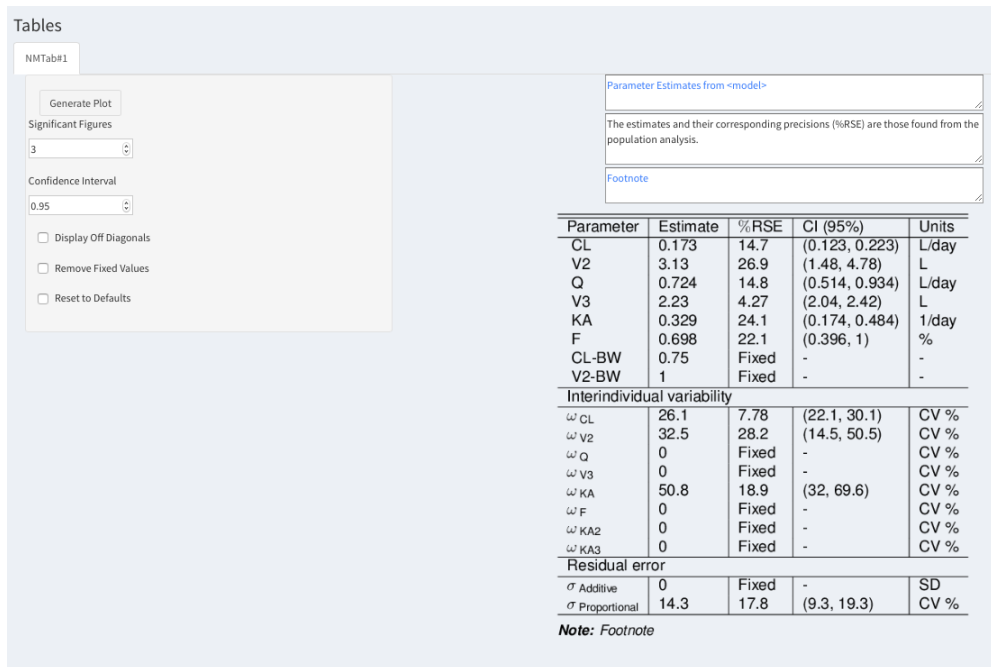


Figure 1: RID: 24 Test ID: 2

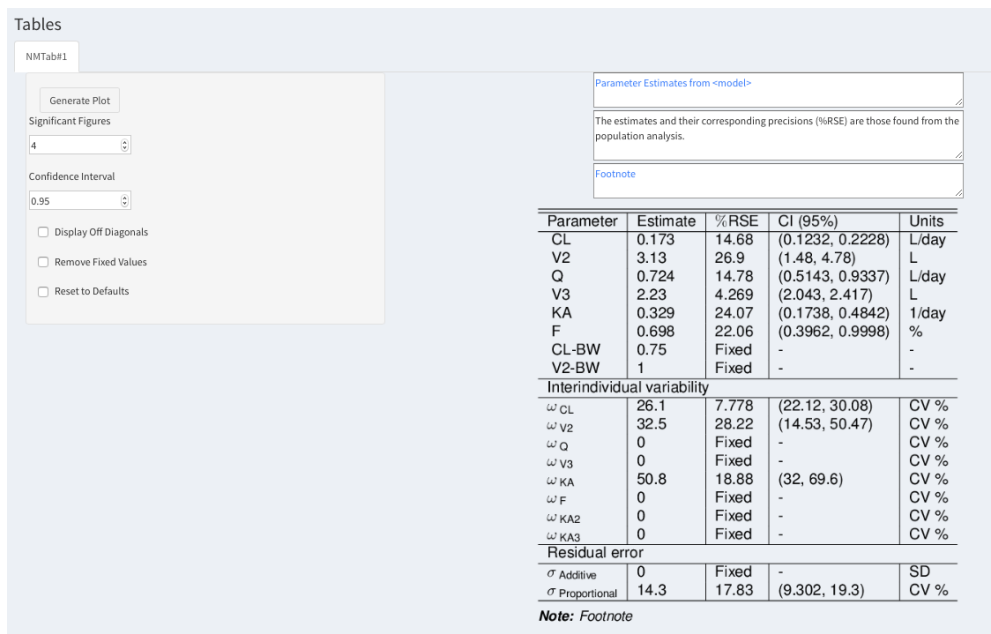


Figure 2: RID: 24 Test ID: 2

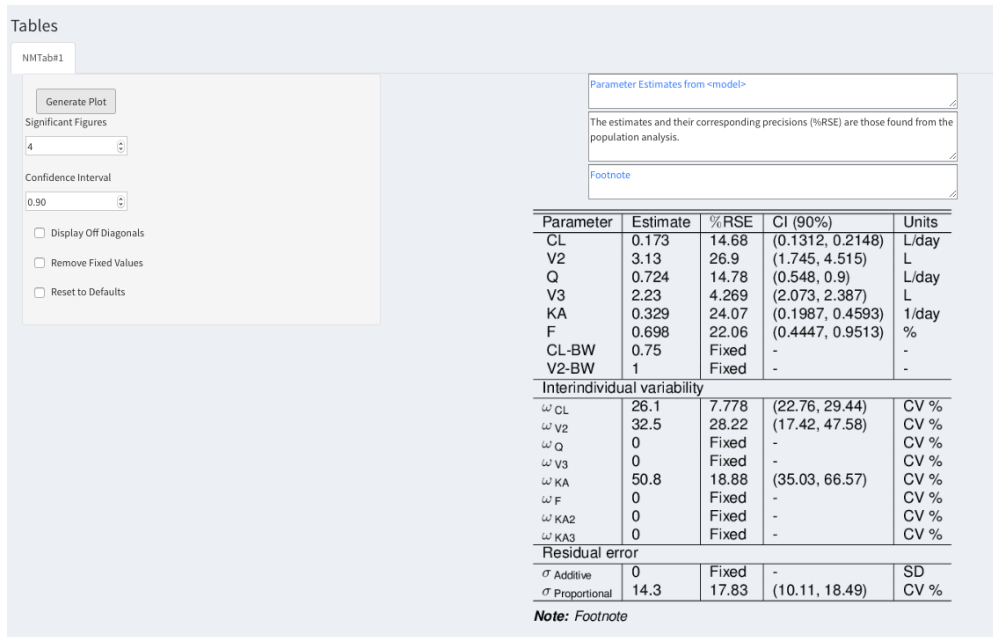


Figure 3: RID: 24 Test ID: 2

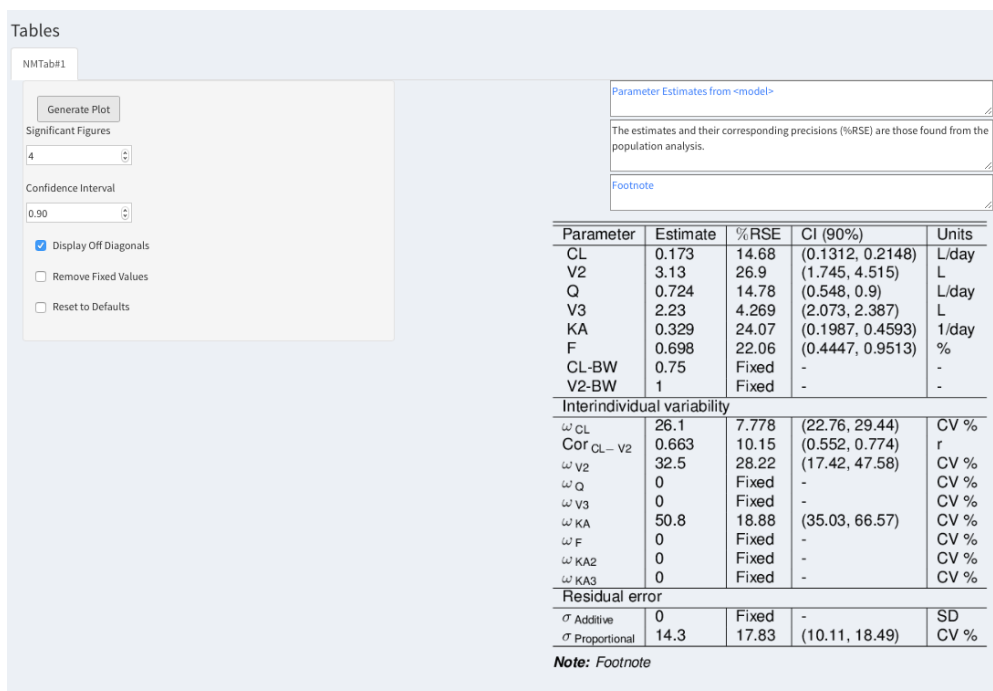


Figure 4: RID: 24 Test ID: 2

Tables

NMTab#1

Generate Plot

Significant Figures
4

Confidence Interval
0.90

☒ Display Off Diagonals

☒ Remove Fixed Values

☐ Reset to Defaults

Parameter Estimates from <model>

The estimates and their corresponding precisions (%RSE) are those found from the population analysis.

Footnote

Parameter	Estimate	%RSE	CI (90%)	Units
CL	0.173	14.68	(0.1312, 0.2148)	L/day
V2	3.13	26.9	(1.745, 4.515)	L
Q	0.724	14.78	(0.548, 0.9)	L/day
V3	2.23	4.269	(2.073, 2.387)	L
KA	0.329	24.07	(0.1987, 0.4593)	1/day
F	0.698	22.06	(0.4447, 0.9513)	%
CL-BW	0.75	Fixed	-	-
V2-BW	1	Fixed	-	-
Interindividual variability				
ω_{CL}	26.1	7.778	(22.76, 29.44)	CV %
Cor_{CL-V2}	0.663	10.15	(0.552, 0.774)	r
ω_{V2}	32.5	28.22	(17.42, 47.58)	CV %
ω_{KA}	50.8	18.88	(35.03, 66.57)	CV %
Residual error				
σ Proportional	14.3	17.83	(10.11, 18.49)	CV %

Note: Footnote

Figure 5: RID: 24 Test ID: 2

Tables

NMTab#1

Generate Plot

Significant Figures
3

Confidence Interval
0.95

☐ Display Off Diagonals

☐ Remove Fixed Values

☐ Reset to Defaults

Parameter Estimates from <model>

The estimates and their corresponding precisions (%RSE) are those found from the population analysis.

We only remove fixed θ 's, ω 's, and σ 's that are non-zero

Parameter	Estimate	%RSE	CI (95%)	Units
CL	0.173	14.7	(0.123, 0.223)	L/day
V2	3.13	26.9	(1.48, 4.78)	L
Q	0.724	14.8	(0.514, 0.934)	L/day
V3	2.23	4.27	(2.04, 2.42)	L
KA	0.329	24.1	(0.174, 0.484)	1/day
F	0.698	22.1	(0.396, 1)	%
CL-BW	0.75	Fixed	-	-
V2-BW	1	Fixed	-	-
Interindividual variability				
ω_{CL}	26.1	7.78	(22.1, 30.1)	CV %
ω_{V2}	32.5	28.2	(14.5, 50.5)	CV %
ω_Q	0	Fixed	-	CV %
ω_{V3}	0	Fixed	-	CV %
ω_{KA}	50.8	18.9	(32, 69.6)	CV %
ω_F	0	Fixed	-	CV %
ω_{KA2}	0	Fixed	-	CV %
ω_{KA3}	0	Fixed	-	CV %
Residual error				
σ Additive	0	Fixed	-	SD
σ Proportional	14.3	17.8	(9.3, 19.3)	CV %

Note: We only remove fixed θ 's, ω 's, and σ 's that are non-zero

Figure 6: RID: 24 Test ID: 3

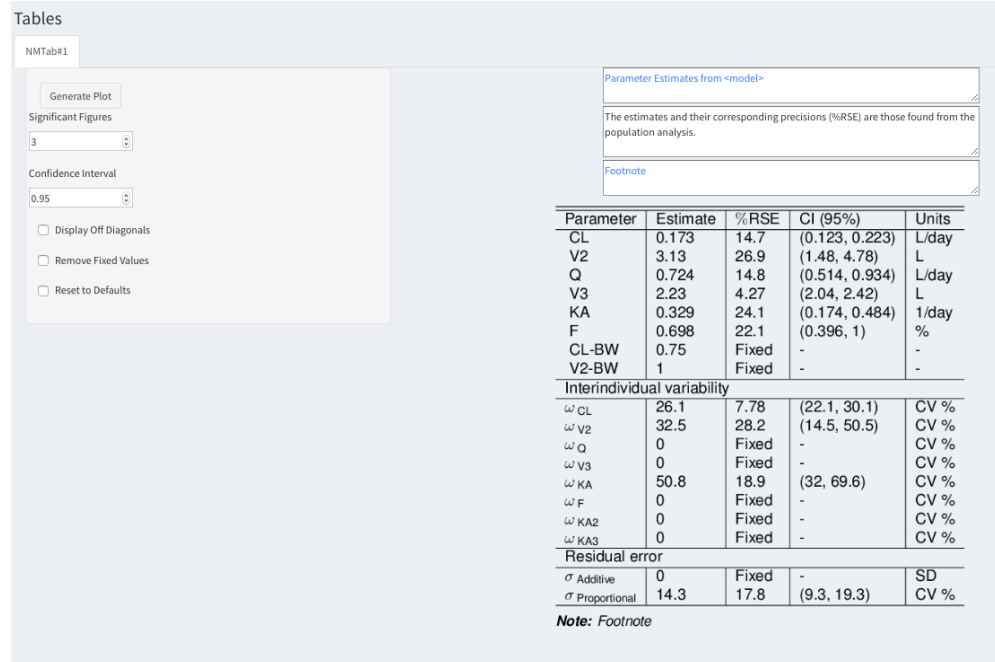


Figure 7: RID: 24 Test ID: 4

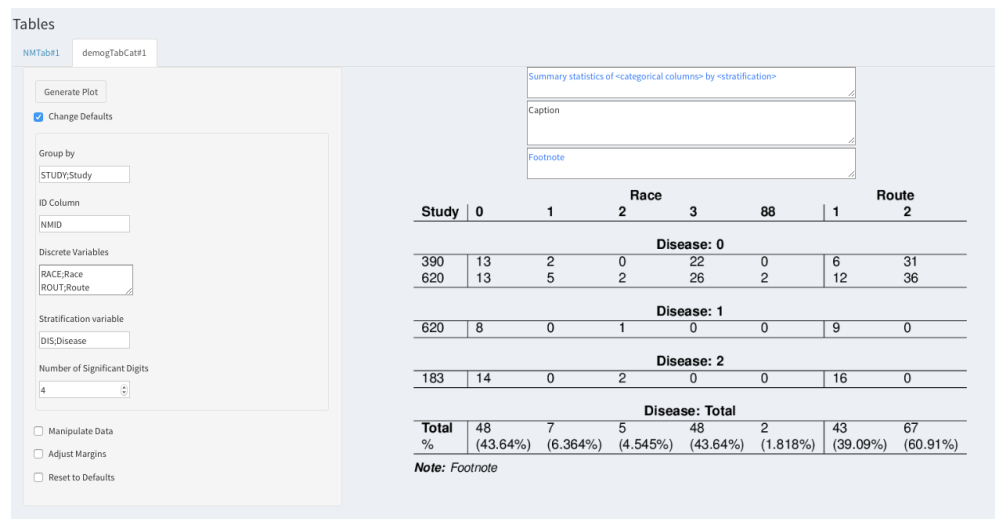


Figure 8: RID: 25 Test ID: 2



Figure 9: RID: 25 Test ID: 2

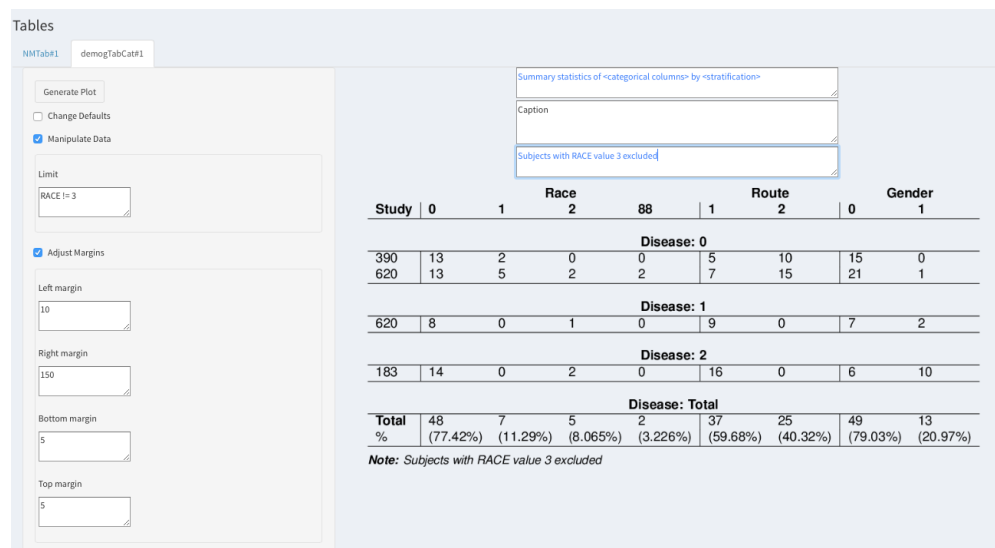


Figure 10: RID: 25 Test ID: 3

Tables

NMTab#1 demogTabCat#1

Generate Plot

☐ Change Defaults

☒ Manipulate Data

Limit

RACE != 3

☒ Adjust Margins

Left margin

10

Right margin

150

Bottom margin

5

Top margin

5

Summary statistics of <category columns> by <stratification>

Caption

Footnote

Study	0	1	Race 2	88	1	Route 2	0	Gender 1
Disease: 0								
390	13	2	0	0	5	10	15	0
620	13	5	2	2	7	15	21	1
Disease: 1								
620	8	0	1	0	9	0	7	2
Disease: 2								
183	14	0	2	0	16	0	6	10
Disease: Total								
Total	48	7	5	2	37	25	49	13
%	(77.42%)	(11.29%)	(8.065%)	(3.226%)	(59.68%)	(40.32%)	(79.03%)	(20.97%)

Note: Footnote

Figure 11: RID: 25 Test ID: 4

Tables

NMTab#1 demogTabCat#1

Generate Plot

☐ Change Defaults

☐ Manipulate Data

☐ Adjust Margins

☐ Reset to Defaults

Summary statistics of <category columns> by <stratification>

Caption

Footnote

Study	0	Sex 1	0	1	Race 2	3	88
Disease: 0							
390	32	5	13	2	0	22	0
620	37	11	13	5	2	26	2
Disease: 1							
620	7	2	8	0	1	0	0
Disease: 2							
183	6	10	14	0	2	0	0
Disease: Total							
Total	82	28	48	7	5	48	2
%	(74.5%)	(25.5%)	(43.6%)	(6.36%)	(4.55%)	(43.6%)	(1.82%)

Note: Footnote

Figure 12: RID: 25 Test ID: 6

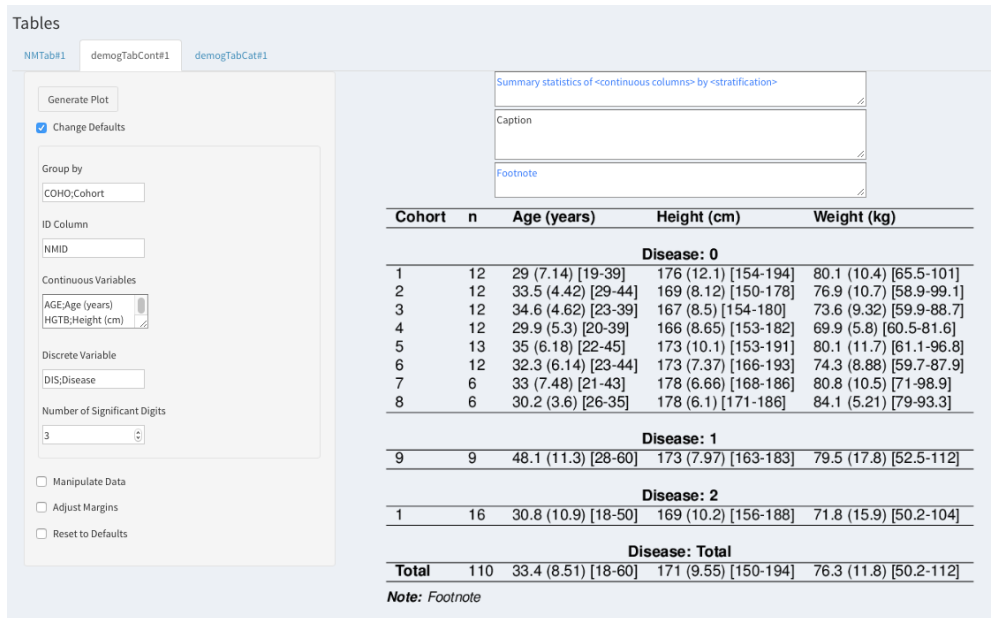


Figure 13: RID: 26 Test ID: 2

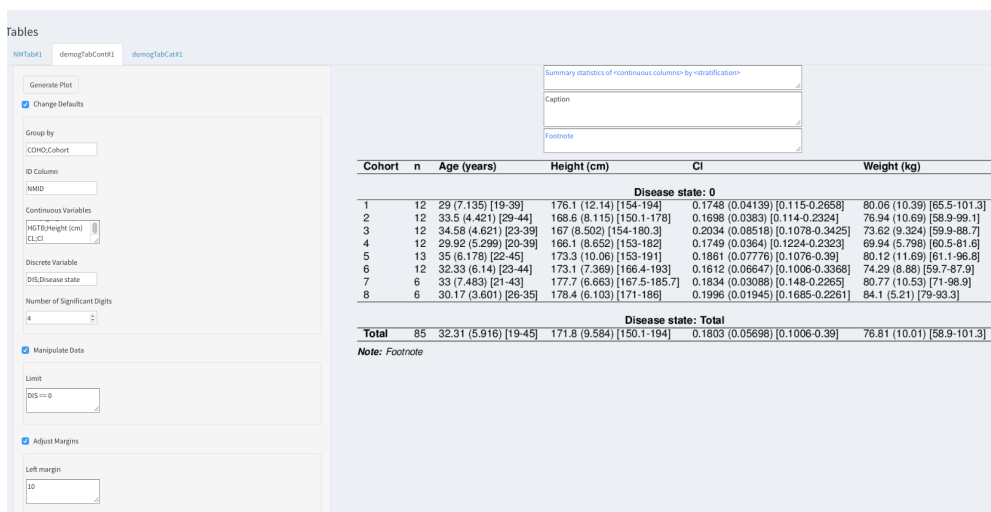


Figure 14: RID: 26 Test ID: 3

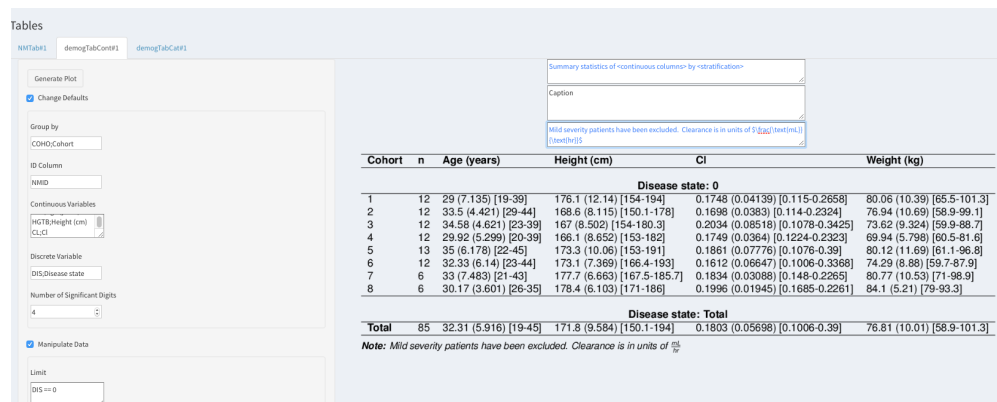


Figure 15: RID: 26 Test ID: 5

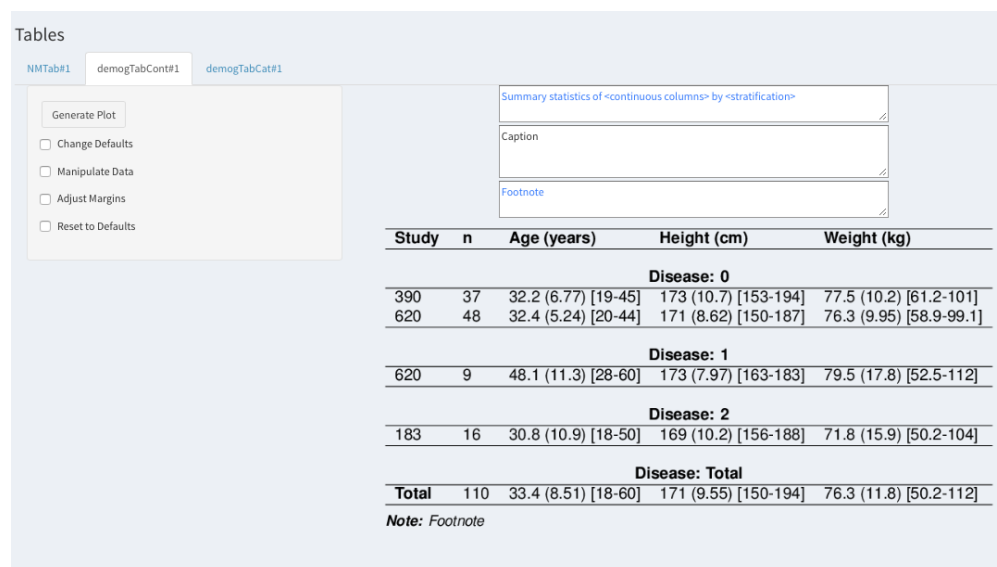


Figure 16: RID: 26 Test ID: 6

ables

NMTab#1 demogTabCont#1 demogTabCat#1 inputTable#1

Generate Plot

File location:

/data/demotable.png

☐ Reset to Defaults

Table Title

Table caption

Table footnote

Study	n	Age (years)	Height (cm)	Weight (kg)
Disease: 0				
390	37	32.2 (6.77) [19-45]	173 (10.7) [153-194]	77.5 (10.2) [61.2-101]
620	48	32.4 (5.24) [20-44]	171 (8.62) [150-187]	76.3 (9.95) [58.9-99.1]
Disease: 1				
620	9	48.1 (11.3) [28-60]	173 (7.97) [163-183]	79.5 (17.8) [52.5-112]
Disease: 2				
183	16	30.8 (10.9) [18-50]	169 (10.2) [156-188]	71.8 (15.9) [50.2-104]
Disease: Total				
Total	110	33.4 (8.51) [18-60]	171 (9.55) [150-194]	76.3 (11.8) [50.2-112]

Figure 17: RID: 27 Test ID: 2

Tables

NMTab#1 demogTabCont#1 demogTabCat#1 inputTable#1

Generate Plot

File location:

☐ Reset to Defaults

Table Title

Table caption

Table footnote

Error: length(n) == 1L is not TRUE

Figure 18: RID: 27 Test ID: 3

Tables

NMTab#1 demogTabCont#1 demogTabCat#1 inputTable#1 observationExclusionsSummaryTab#1

Generate Plot

Number of lines to preview

30

☐ Reset to Defaults

Summary of Observation Exclusions by Reason for Exclusion

Caption

Reason for exclusion	N	% of Exclusions
Concentration is BQL	29	100
Total	29	100.0

Footnote

Figure 19: RID: 28 Test ID: 2

Tables

[NMTab#1](#)
[demogTabCont#1](#)
[demogTabCat#1](#)
[inputTable#1](#)

subjectExclusionsSummaryTab#1

[observationExclusionsSummaryTab#1](#)

Generate Table

Number of lines to preview

30

☐ Reset to Defaults

Summary of Subject Exclusions by Reason for Exclusion

Caption

Reason for exclusion	N	% of Exclusions
Missing race information	2	100
Total	2	100.0

Footnote

Figure 20: RID: 29 Test ID: 2