

CONFIDENTIAL

## Listings 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
30	Concentration vs Time Multipanel Plots	1	Create listing panel: Analysis Selection -> Listings -> Serum Concentration Versus Time-Multipanel to 1	ConcvTimeMult panel created in Listings	Panel created	Pass
		2	Figure renders and respects inputs for specific ID's	Plot is updated, respecting inputs. Screenshot(s) as evidence	3 pages shown for patients 1-36 <Screenshots>	Pass
		3	Figure renders and respects input for all ID's	Plot is updated, respecting inputs. Screenshot(s) as evidence	All ID's print, first and last page shown <Screenshots>	Pass
		4	Figure renders and respects input for rows, columns, and page to display	Plot is updated, respecting inputs. Screenshot(s) as evidence	Inputs are respected <Screenshots>	Pass
		5	Figure renders and respects input for Plots Details	Plot is updated, respecting inputs. Screenshot(s) as evidence	Plot is updated, inputs respected <Screenshots>	Pass
		6	Figure renders and respects input for Change Defaults	Plot is updated, respecting inputs. Screenshot(s) as evidence	Plot updated, inputs respected <Screenshots>	Pass
		7	Figure renders and respects input for Manipulate data	Plot is updated, respecting inputs. Screenshot(s) as evidence	Plot updated, inputs respected <Screenshots>	Pass
		8	Reset button resets defaults	Options are updated, respecting inputs. Screenshot(s) as evidence	Plot updated, inputs respected <Screenshots>	Pass
31	Image listing from disk	1	Create table panel: Analysis Selection -> Listings -> Listing from disk (table or figure as png) to 1	inputTable panel created in Tables	Panel created	Pass
		2	Table image is read from disk and displayed. Enter File location: /data/tfgenerator/NMStorage/table.png	Image from disk is rendered	Plot updated, inputs respected <Screenshots>	Pass
		3	Reset button clears selections	Plot is updated, respecting inputs. Screenshot as evidence	Plot updated, inputs respected <Screenshots>	Pass
32	Text listing from disk	1	Create table panel: Analysis Selection -> Listings -> Listing from disk (text file) to 1	inputTable_text panel created in Tables	Panel created	Pass
		2	Text file is read from disk and displayed. Enter File location: /data/tfgenerator/NMStorage/0069/0069.ctf	Control file is read and rendered as verbatim text	Plot updated, inputs respected <Screenshots>	Pass
		3	Reset button clears selections	Plot is updated, respecting inputs. Screenshot as evidence	Plot updated, inputs respected <Screenshots>	Pass
33	Subject exclusions table	1	Create table panel: Analysis Selection -> Listings -> Subject exclusions listing to 1	subjectExclusionsTab panel created in Tables	Panel created	Pass

RID	Topic	Test ID	Step Description	Expected Result	Qualification Note(s)	Pass/Fail
		2	Additional columns are displayed when requested. Enter into "Columns" box:  STUDY;Study DOSE;Dose ROUTE;Route	Extra columns rendered in display	Plot updated, inputs respected <Screencaps>	Pass
		3	Reset button clears selections	Plot is updated, respecting inputs. Screencap as evidence	Plot updated, inputs respected <Screencaps>	Pass
34	Observation exclusions table	1	Create table panel:  Analysis Selection -> Listings -> Subject exclusions listing to 1	observationExclusionsTab panel created in Tables	Panel created	Pass
		2	Additional columns are displayed when requested. Enter into "Columns" box:  STUDY;Study DOSE;Dose ROUT;Route DV;DV	Extra columns rendered in display	Plot updated, inputs respected <Screencaps>	Pass
		3	Reset button clears selections	Plot is updated, respecting inputs. Screencap as evidence	Plot updated, inputs respected <Screencaps>	Pass

## Appendix

### Screenshots

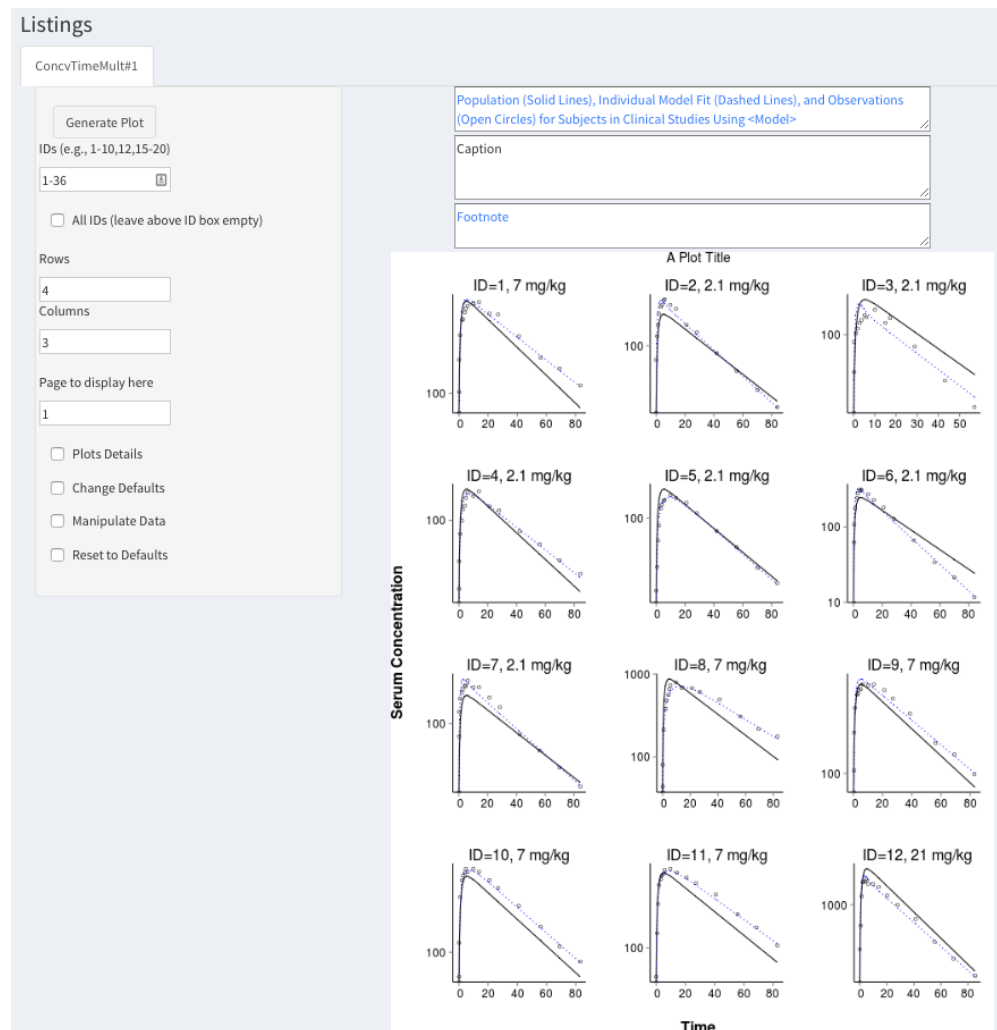


Figure 1: RID: 30 Test ID: 2

## Listings

ConcVTimeMult#1

Generate Plot

IDs (e.g., 1-10,12,15-20)

1-36

☐ All IDs (leave above ID box empty)

Rows

4

Columns

3

Page to display here

2

☐ Plots Details

☐ Change Defaults

☐ Manipulate Data

☐ Reset to Defaults

Population (Solid Lines), Individual Model Fit (Dashed Lines), and Observations (Open Circles) for Subjects in Clinical Studies Using <Model>

Caption

Footnote

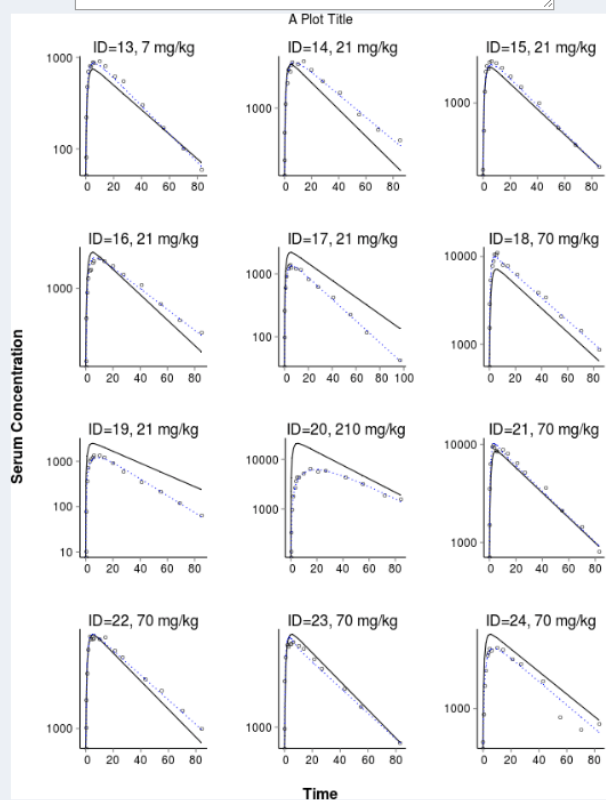


Figure 2: RID: 30 Test ID: 2

## Listings

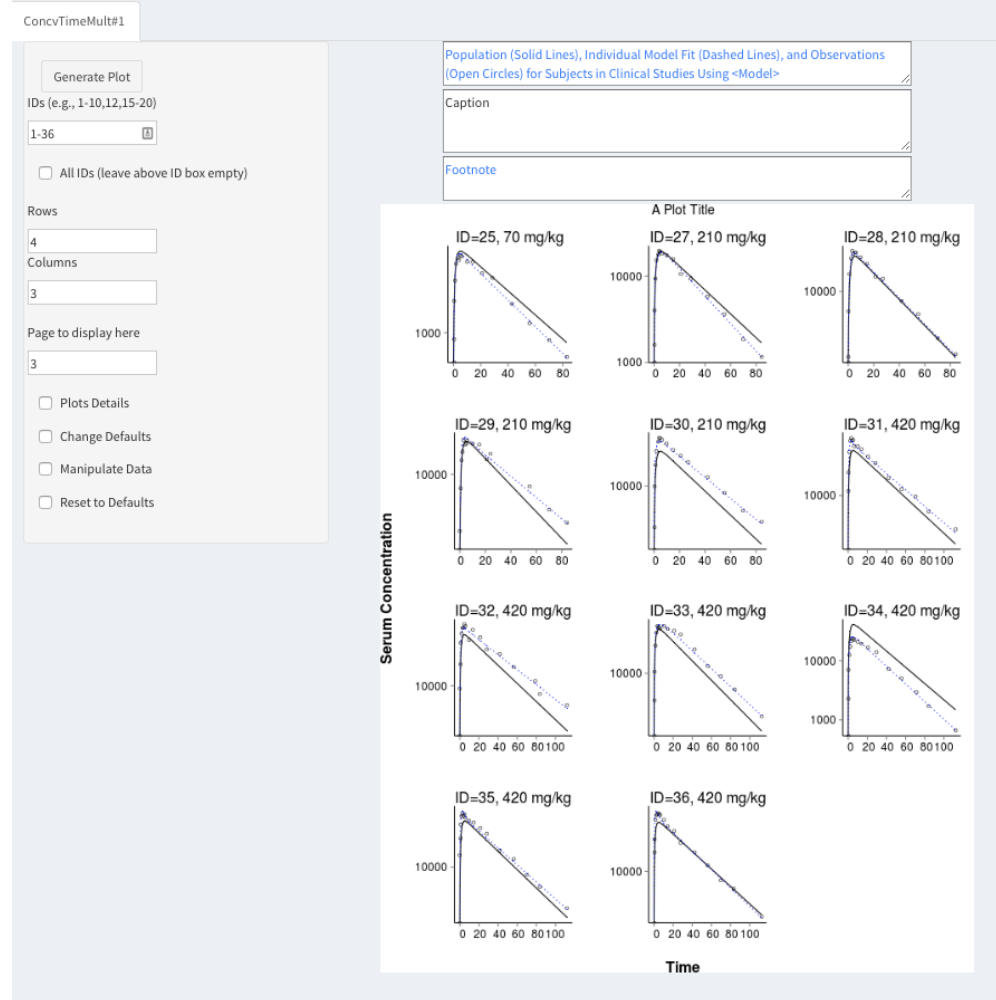


Figure 3: RID: 30 Test ID: 2



## Listings

ConcVTimeMult#1

Generate Plot

IDs (e.g., 1-10,12,15-20)

☒ All IDs (leave above ID box empty)

Rows

Columns

Page to display here

☐ Plots Details

☐ Change Defaults

☐ Manipulate Data

☐ Reset to Defaults

Population (Solid Lines), Individual Model Fit (Dashed Lines), and Observations (Open Circles) for Subjects in Clinical Studies Using <Model>

Caption

Footnote

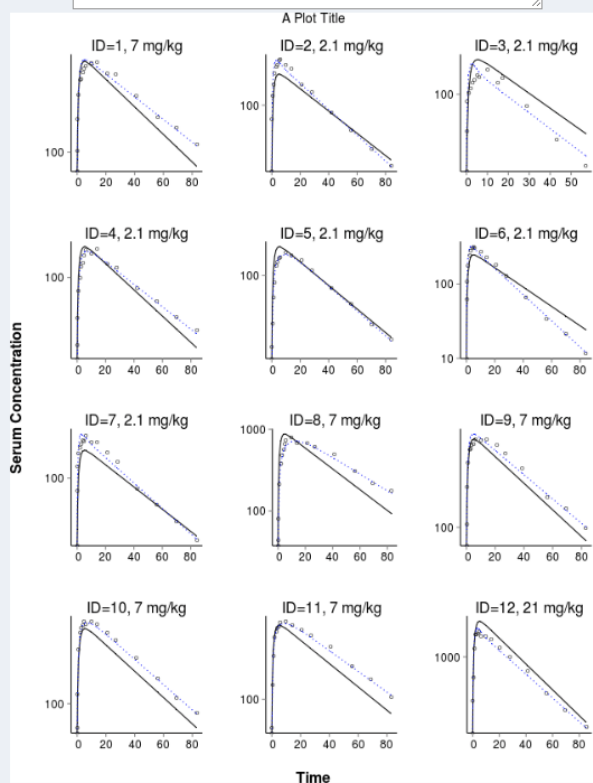


Figure 4: RID: 30 Test ID: 3

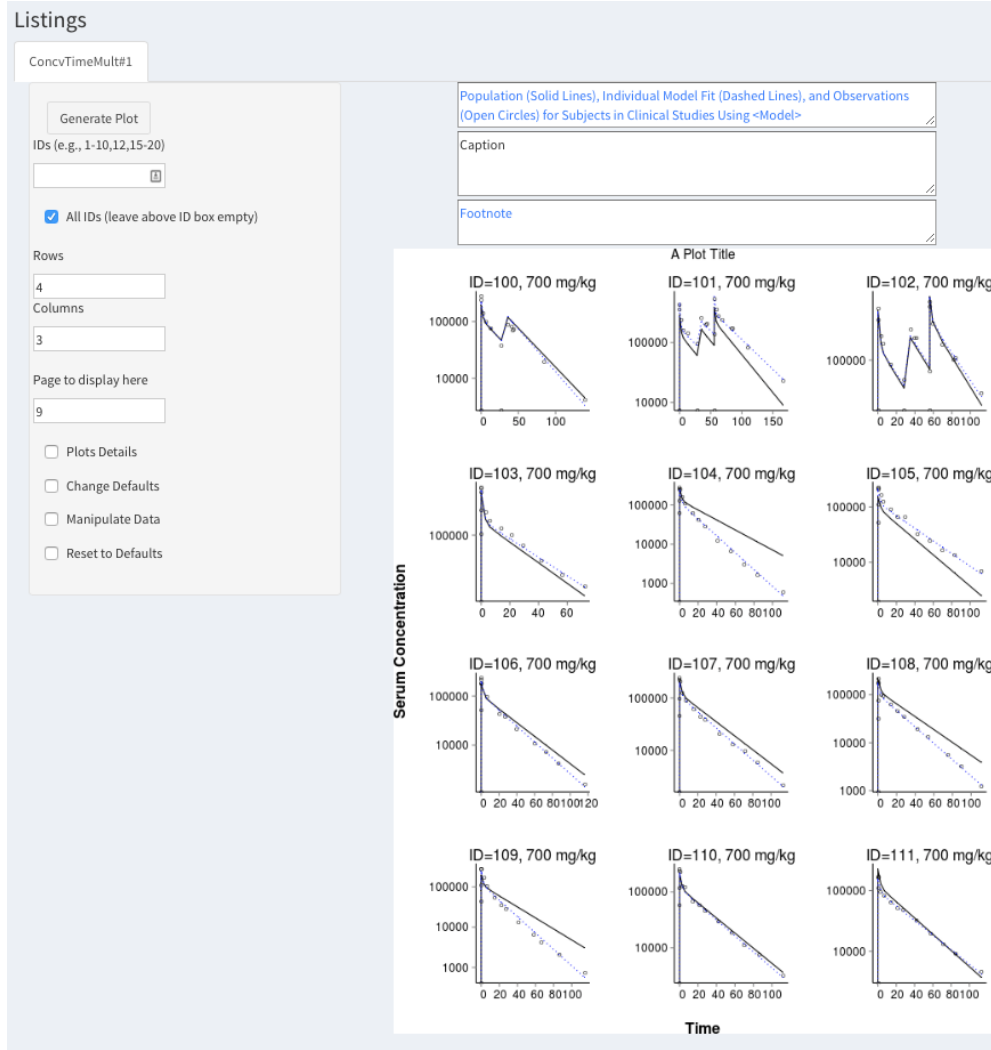


Figure 5: RID: 30 Test ID: 3

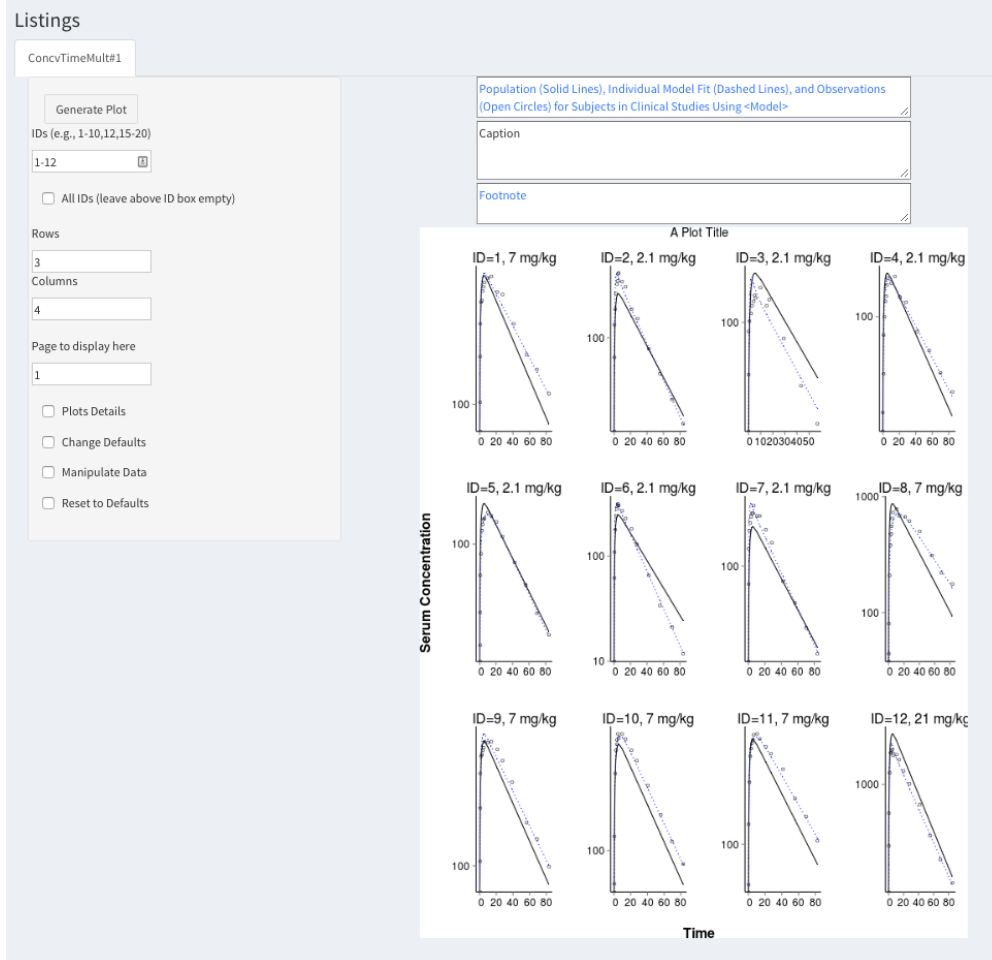


Figure 6: RID: 30 Test ID: 4

## Listings

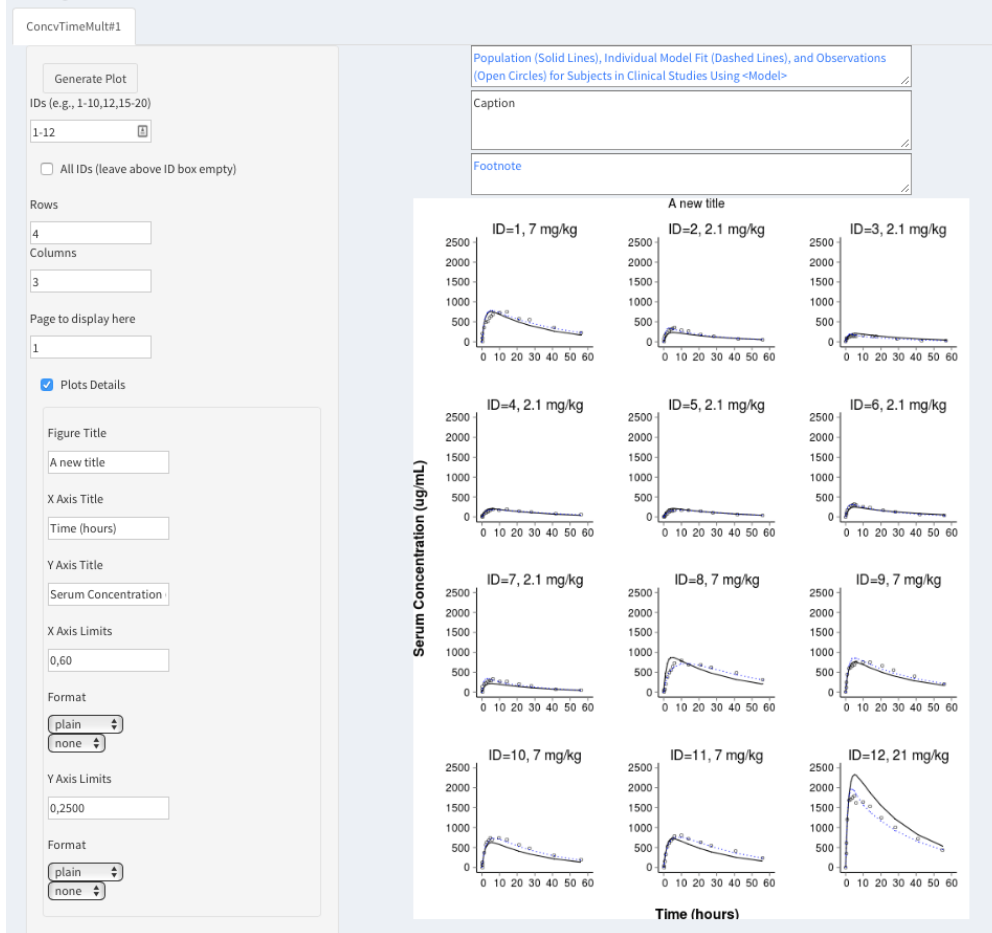


Figure 7: RID: 30 Test ID: 5

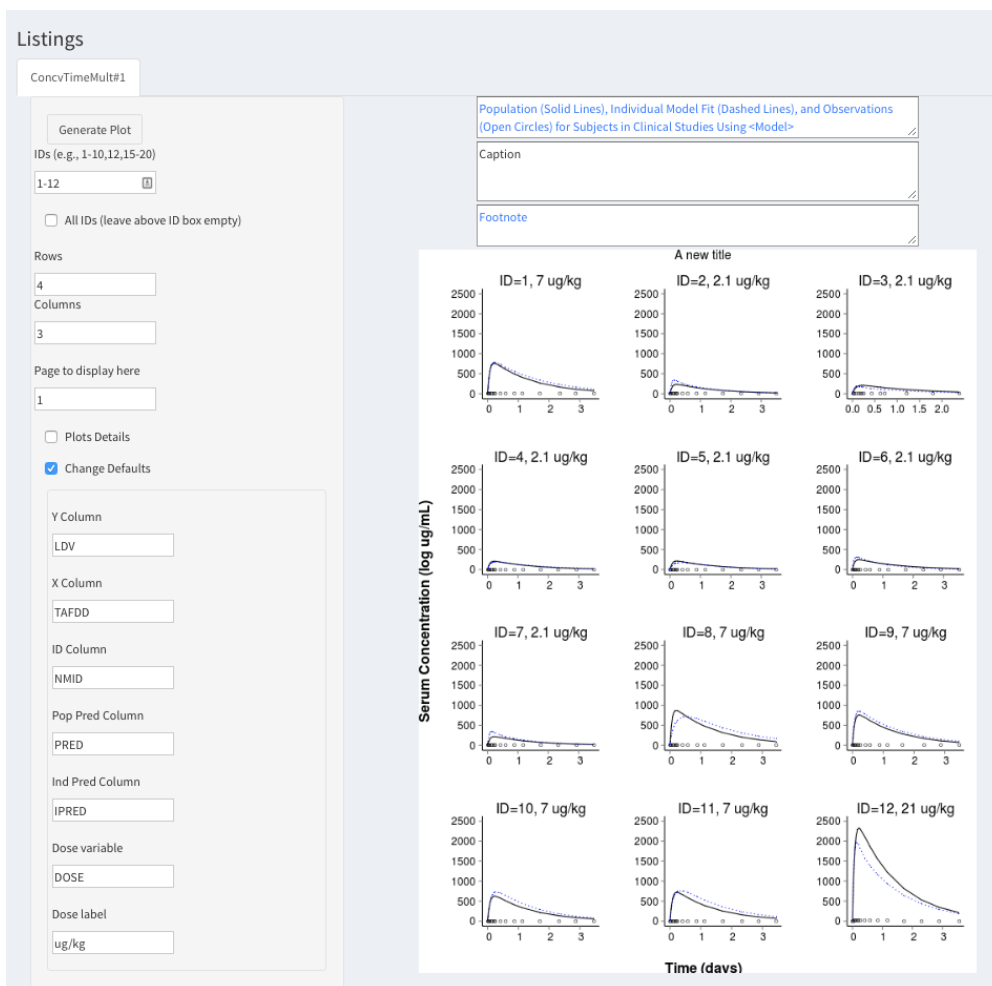


Figure 8: RID: 30 Test ID: 6

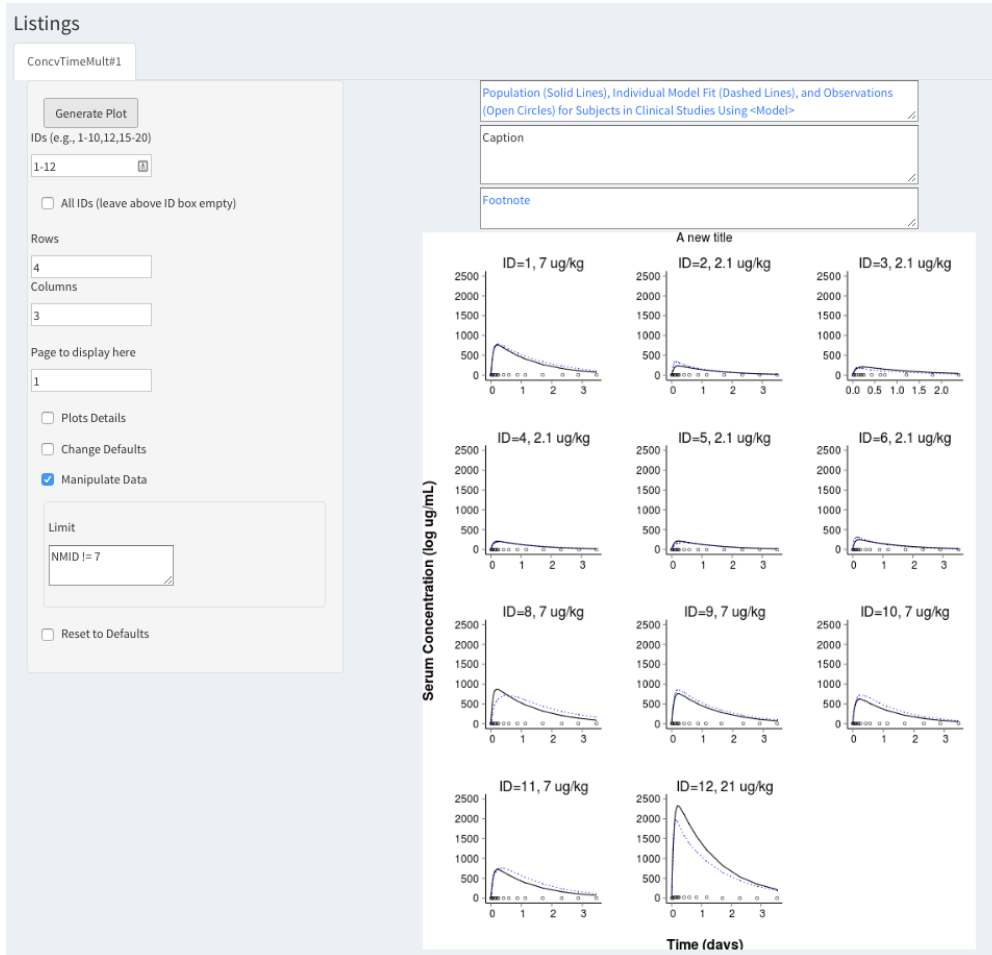


Figure 9: RID: 30 Test ID: 7

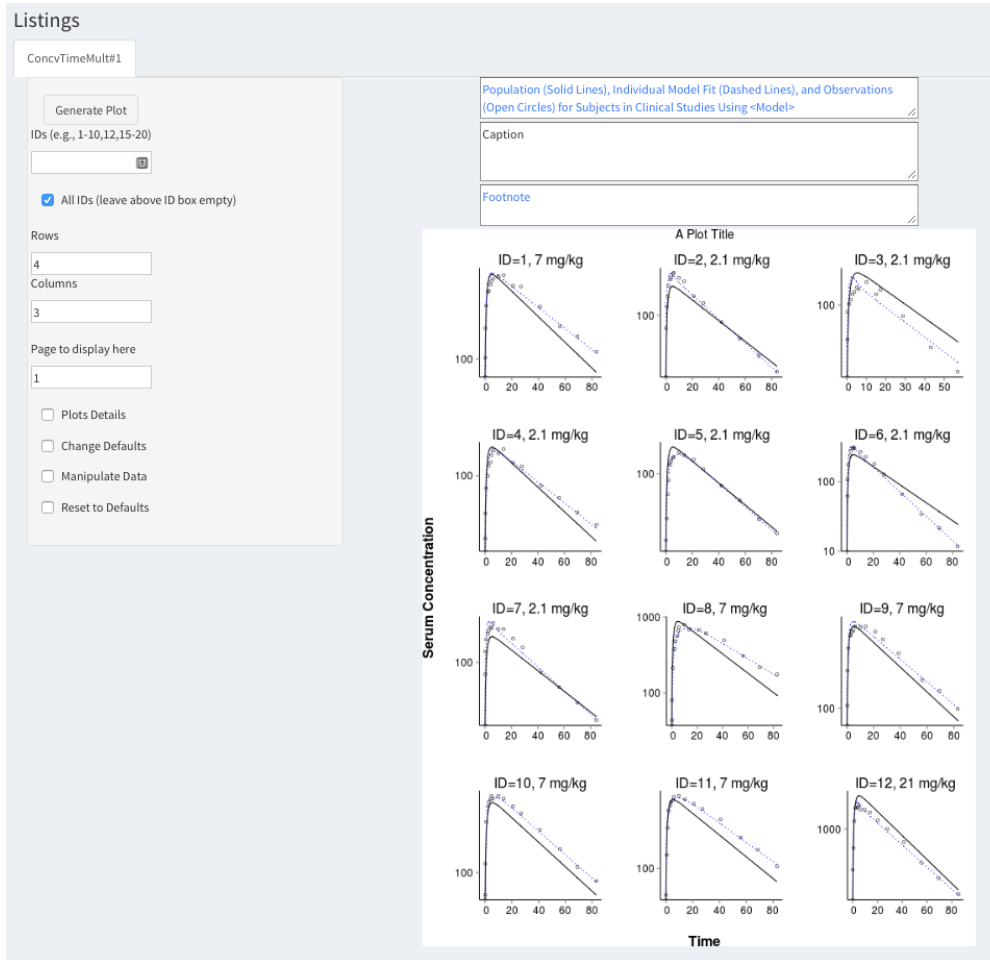


Figure 10: RID: 30 Test ID: 8

**Listings**

ConcVTimeMult#1 inputListing#1

Generate Plot

File location: /data/demotable.png

☐ Reset to Defaults

Listing Title

Listing caption

Listing footnote

Study	n	Age (years)	Height (cm)	Weight (kg)
<b>Disease: 0</b>				
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]
<b>Disease: 1</b>				
620	9	48.1 (11.3) [28-60]	173 (7.97) [163-183]	79.5 (17.8) [52.5-112]
<b>Disease: 2</b>				
183	16	30.8 (10.9) [18-50]	169 (10.2) [156-188]	71.8 (15.9) [50.2-104]
<b>Disease: Total</b>				
<b>Total</b>	110	33.4 (8.51) [18-60]	171 (9.55) [150-194]	76.3 (11.8) [50.2-112]

Figure 11: RID: 31 Test ID: 2

**Listings**

ConcVTimeMult#1   inputListing#1

Generate Plot

**File location:**

/data

☐ Reset to Defaults

Listing Title

Listing caption

Listing footnote

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

Figure 12: RID: 31 Test ID: 3

ConcVTimeMult#1   inputListing#1   inputListing\_text#1

Generate Plot

**File location:**

/data/tflgenerator/0069/0069.cti

**Number of lines to preview:**

20

☐ Reset to Defaults

Listing Title

Listing caption

Listing footnote

```
[1] "$PROB RUN# 0069 ; 0028 but THETA 7, THETA 8, OM7, OM8 estimated."
[2] "$INPUT C STUD ID COHO SEX ROUT VISIT DOSE DV HALD INFDR DAY TIME WGTB RACE HGTB AGE D
    IS MDV EVID AMT RATE ADDL II CMT"
[3] "$DATA ../183_6209_620_390.csv IGNORE=C"
[4] "\\tIGNORE=(ID.EQ.91)"
[5] " ; 1015=91 in Study 183 is a placebo "
[6] ""
[7] "$SUBROUTINES ADVAN4 TRANS4"
[8] ""
[9] "$PK"
[10] " BWAvg = 76.5 \\t; kg. mean for the three studies,"
[11] ""
[12] " MU_1=LOG(THETA(1))"
[13] " TVCL=EXP(MU_1+ETA(1))\\t; L/day"
[14] ""
[15] " MU_7=LOG(THETA(7))"
[16] " SBWCL=EXP(MU_7+ETA(7))"
[17] " "
[18] " CL=TVCL*(WGTB/BWAvg)**SBWCL\\t; L/day"
[19] " "
[20] " MU_2=LOG(THETA(2))"
```

Figure 13: RID: 32 Test ID: 2



istings

ConcvTimeMult#1   inputListing#1   inputListing\_text#1

Generate Plot

**File location:**

/data

**Number of lines to preview:**

20

☐ Reset to Defaults

Listing Title

Listing caption

Listing footnote

character(0)

Figure 14: RID: 32 Test ID: 3

Listings

ConcvTimeMult#1   inputListing#1   inputListing\_text#1   subjectExclusionsTab#1

Generate Plot

Columns (ID, exclusion reason, and time included by default)

DOSE;Dose

ROUT;Route

**Number of ID's listed in ID column**

5

**Number of lines to preview**

30

☐ Reset to Defaults

Subject Exclusion

Caption

Reason for exclusion	Study	Dose	Route	ID
Missing race information (N=2)	620	210	2	26
	620	700	1	47

Footnote

Figure 15: RID: 33 Test ID: 2

**Listings**

ConcVTimeMult#1   inputListing#1   inputListing\_text#1   **subjectExclusionsTab#1**

Generate Plot

Columns (ID, exclusion reason, and time included by default)

STUDY;Study  
DOSE;Dose

Number of ID's listed in ID column

5

Number of lines to preview

30

☐ Reset to Defaults

Subject Exclusion

Caption

Reason for exclusion	Study	Dose	ID
Missing race information (N=2)	620	210	26
	620	700	47

Footnote

Figure 16: RID: 33 Test ID: 3

**Listings**

ConcVTimeMult#1   inputListing#1   inputListing\_text#1   subjectExclusionsTab#1   **observationExclusionsTab#1**

Generate Plot

Additional columns: (ID, exclusion reason, time by default)

ROUT;Route  
DV;DV

Number of lines to preview

30

☐ Reset to Defaults

Observation Exclusion

Caption

Reason for exclusion	ID	TIME	Study	Dose	Route	DV
Concentration is BQL (N=29)	3	77.949000	620	2.1	2	0
	3	85.006000	620	2.1	2	0
	48	68.819000	620	700.0	1	0
	86	0.000000	183	700.0	1	0
	87	0.000000	183	700.0	1	0
	88	0.000000	183	700.0	1	0
	89	0.000000	183	700.0	1	0
	90	0.000000	183	700.0	1	0
	92	0.000000	183	700.0	1	0
	93	0.000000	183	700.0	1	0
	94	0.023611	183	700.0	1	0
	95	0.000000	183	700.0	1	0
	96	0.000000	183	700.0	1	0
	97	0.000000	183	700.0	1	0
	98	0.000000	183	700.0	1	0
	99	0.000000	183	700.0	1	0
	100	0.000000	183	700.0	1	0
	101	0.000000	183	700.0	1	0
	102	0.000000	183	700.0	1	0
	103	0.000000	620	700.0	1	0
	104	0.000000	620	700.0	1	0
	105	0.000000	620	700.0	1	0
	106	0.000000	620	700.0	1	0
	107	0.000000	620	700.0	1	0
	108	0.000000	620	700.0	1	0
	109	0.000000	620	700.0	1	0
	110	0.000000	620	700.0	1	0
	111	0.000000	620	700.0	1	0
	111	0.031250	620	700.0	1	0

Footnote

Figure 17: RID: 34 Test ID: 2

**Listings**

ConcVTimeMult#1   inputListing#1   inputListing\_text#1   subjectExclusionsTab#1   **observationExclusionsTab#1**

Generate Plot

Additional columns: (ID, exclusion reason, time by default)

STUDY;Study  
DOSE;Dose

Number of lines to preview

30

☐ Reset to Defaults

Observation Exclusion

Caption

Reason for exclusion	ID	TIME	Study	Dose
Concentration is BQL (N=29)	3	77.949000	620	2.1
	3	85.006000	620	2.1
	48	68.819000	620	700.0
	86	0.000000	183	700.0
	87	0.000000	183	700.0
	88	0.000000	183	700.0
	89	0.000000	183	700.0
	90	0.000000	183	700.0
	92	0.000000	183	700.0
	93	0.000000	183	700.0
	94	0.023611	183	700.0
	95	0.000000	183	700.0
	96	0.000000	183	700.0
	97	0.000000	183	700.0
	98	0.000000	183	700.0
	99	0.000000	183	700.0
	100	0.000000	183	700.0
	101	0.000000	183	700.0
	102	0.000000	183	700.0
	103	0.000000	620	700.0
	104	0.000000	620	700.0
	105	0.000000	620	700.0
	106	0.000000	620	700.0
	107	0.000000	620	700.0
	108	0.000000	620	700.0
	109	0.000000	620	700.0
	110	0.000000	620	700.0
	111	0.000000	620	700.0
	111	0.031250	620	700.0

Footnote

Figure 18: RID: 34 Test ID: 3