

CONFIDENTIAL

Data testing summary

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(Sign and print name)	
Dates (YYYY-MM-DD)	

Testing log

RID	Topic	Test ID	Step Description	Expected Result	Qualification Note(s)	Pass/Fail
3	NONMEM run data (tab and partab files) can be read, displayed, and summarized	1	Upload run data 0069 into /data via Rstudio	Upload successful	Upload successful <Screencaps>	Pass
		2	Load run data into the application	Screenshot of Data Input -> Model info and Data Input -> Change E-R SSAP Defaults	Input specified <Screencaps>	Pass
		3	View the data	Screenshot of Data -> Run Data, showing data contents	Screenshot shows data <Screencaps>	Pass
		4	View the data summary	Screenshot of Data -> Run Data Summary, showing data summary	Data summary appears for run data <Screencaps>	Pass
4	Run data can be manipulated using the code parser	1	Input parsing code: enter the following into Data Input -> Modify Data -> Table data manipulation code: ROUTF <- factor(ROUT, c(1,2), c("IV","SC")) subset(\$DATA, ID == 1, select=c(ID,TIME,EVID,STUD,ROUTF))	Input	Input allowed	Pass
		2	Screenshot of Run Data view	Screenshot shows the selected subset of patients and variables, with the renamed Route factor	Data view shows ROUTEF for factored route and only patient 1 <Screencaps>	Pass
5	Source data can be read, displayed, and summarized	1	Uplaod source data 0069/source.csv into /data	Upload successful	Upload successful	Pass
		2	Load source data into the application	Screenshot of Data Input -> Model info and Data Input -> Change E-R SSAP Defaults	Input allowed <Screencaps>	Pass
		3	View the data	Screenshot of Data -> Source Data, showing data contents	Source data view shows data <Screencaps>	Pass
		4	View the data summary	Screenshot of Data -> Source Data Summary, showing data summary	Source data summar view appears <Screencaps>	Pass

6	Source data can be manipulated using the code parser	1	Input parsing code: enter the following into Data Input -> Modify Data -> Source data manipulation code: ROUTF <- factor(ROUT, c(1,2), c("IV","SC")) subset(\$DATA, ID == 1, select=c(ID,TIME,EVID,STUD,ROUTF))	Input	Input allowed	Pass
		2	Screenshot of Source Data view	Screenshot shows the selected subset of patients and variables, with the renamed Route factor	Screenshot shows only patient 1 and updated Route <Screencaps>	Pass
7	Analysis data can be created by merging run data and source data	1	Remove data parsing subsets, but leave ROUTEF. Take screenshots of data summaries for run and source data	Screencaps show that other patients beside subject 1 have been added back in to the datasets	Data summaries show many subjects in run and source data <Screencaps>	Pass
		2	Merge the datasets by selecting Data -> Analysis Data	Screencap of analysis data shows merged data	Analysis data view shows merged data <Screencaps>	Pass
		3	Confirm merge is a full merge by subsetting to study 183 and verifying that all values of WGT are missing	Screencap of summary shows all studies are 183 and no values for WGT	Summary shows all STUDY 183 and WGT is all missing <Screencaps>	Pass
8	Analysis data can be manipulated using the code parser	1	Enter the following in Data Input -> Modify Data -> Analysis data manipulation code: SEXF <- factor(SEX, c(0,1), c("Female","Male"))	Screencap of analysis data summary shows SEXF factor with Male and Female	SEXF created <Screencaps>	Pass
9	Analysis data can be viewed and summarized	1	View the analysis data	Screencap of analysis data view shows data	Showed previously in 7.1-3	Pass

10	Subject level exclusions can be specified and viewed	1	Create subject and observation level exceptions indicator column. In Data Input -> Modify Data -> Analysis data manipulation code enter: SUBJEXC = "Keep" SUBJEXC[RACE==88] = "Missing race" OBSEXC = "Keep" OBSEXC[EVID==0 & DV<0.05] = "BQL"	Code is input, new column is created in analysis data	New columns shown in analysis data summary <Screencaps>	Pass
		2	From Data Exclusions -> Subject exclusions -> Subject exclusion specification enter: Keep:: Missing race::No race information for subject Press "Generate subject exclusions" button	Input allowed, no errors	Input allowed, no errors given	Pass
		3	View subject exclusions: Data Exclusions -> Subject exclusion specification -> Subject Exclusion Data	Screencap of data showing missing race for all patients	Data shows all Race==88, missing value for 0069 data <Screencaps>	Pass
		4	Verify that exclusions are no longer in analysis data	Screencap of analysis data summary shows that no patients with missing race are present	No missing race present <Screencaps>	Pass
11	Observation level exclusions can be specified and viewed	1	From Data Exclusions -> Observation exclusions -> Observatoin exclusion specification enter: BQL::Concentration BQL Keep:: Press "Generate observation exclusions" button	Input allowed, no errors	Input allowed without errors	Pass
		2	View observation exclusions: Data Exclusions -> Observation exclusion specification -> Observation Exclusion Data	Screencap of data showing BQL for all observations	BQL shown for all patients <Screencap>	Pass
		3	Verify that exclusions are no longer in analysis data	Screencap of analysis data summary shows that no patients with missing race are present	Expected result is mispecified, intention is for no BQL patients to be shown. None are (all OBSEXC are "Keep") <Screencaps>	Pass

12	Data cache can be cleared from the app	1	Clear cache: Data input -> Model info -> Clear cached data Reset Model Input filenames to point to nothing	Screencap shows no observation, source, or analysis data	All data viewers show either nothing or present error <Screencaps>	Pass

Appendix

Screenshots

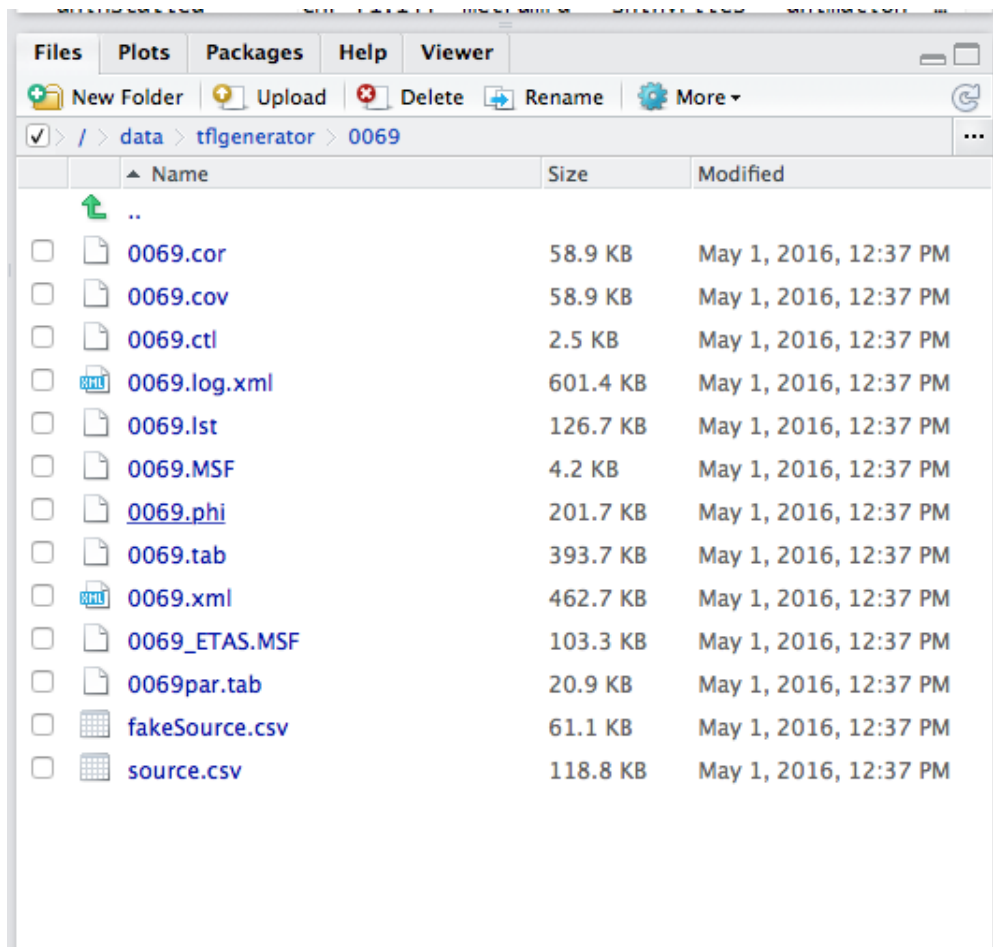


Figure 1: RID: 3 Topic ID: 1

Data Input

[Project Information](#)
[Model Info](#)
[Modify Data](#)
[Change E-R SSAP Defaults](#)

Parent working directory:

NONMEM source data:

Run Number:

File Extensions:

☒ Header?

Skip Lines:

Figure 2: RID: 3 Topic ID: 2

Data Input

[Project Information](#)
[Model Info](#)
[Modify Data](#)

Change E-R SSAP Defaults

DV Column

DV

TAFD Column

TIME

STUDY Column

STUD

NMID Column

ID

IPRED Column

IPRE

PRED Columns

PRED

Subject exclusion column (analysis dataset)

SUBJEXC

Observation exclusion column (analysis dataset)

OBSEXC

Figure 3: RID: 3 Topic ID: 2

Data

Run Data Run Data Summary Source Data Source Data Summary Analysis Data Analysis Data Summary

Show 10 entries Search:

	ID	TIME	EVID	STUD	COHO	SEX	ROUT	VISIT	DOSE
1	1	0.00000	1	620	2	0	2	1	7
2	1	0.16875	0	620	2	0	2	1	7
3	1	0.33333	0	620	2	0	2	1	7
4	1	1.00210	0	620	2	0	2	2	7
5	1	2.00000	0	620	2	0	2	3	7
6	1	2.96740	0	620	2	0	2	4	7
7	1	3.93120	0	620	2	0	2	5	7
8	1	4.94930	0	620	2	0	2	6	7
9	1	5.93330	0	620	2	0	2	7	7
10	1	9.95070	0	620	2	0	2	11	7

Showing 1 to 10 of 1,901 entries Previous 1 2 3 4 5 ... 191 Next

Figure 4: RID: 3 Topic ID: 3

Data			
Run Data	Run Data Summary	Source Data	Source Data Summary
Analysis Data	Analysis Data Summary		
ID (integer)	TIME (numeric)	EVID (integer)	STUD (integer)
Min. : 1.00	Min. : 0.00	Min. :0.00000	Min. :183.0
1st Qu.: 29.00	1st Qu.: 2.00	1st Qu.:0.00000	1st Qu.:390.0
Median : 54.00	Median : 16.90	Median :0.00000	Median :620.0
Mean : 56.41	Mean : 33.39	Mean :0.07838	Mean :474.3
3rd Qu.: 87.00	3rd Qu.: 56.12	3rd Qu.:0.00000	3rd Qu.:620.0
Max. :111.00	Max. :182.94	Max. :1.00000	Max. :620.0
COHO (integer)	SEX (integer)	ROUT (integer)	VISIT (integer)
Min. :1.000	Min. :0.0000	Min. :1.000	Min. : 1.00
1st Qu.:1.000	1st Qu.:0.0000	1st Qu.:1.000	1st Qu.: 3.00
Median :4.000	Median :0.0000	Median :2.000	Median : 16.00
Mean :4.036	Mean :0.2788	Mean :1.549	Mean : 34.13
3rd Qu.:6.000	3rd Qu.:1.0000	3rd Qu.:2.000	3rd Qu.: 57.00
Max. :9.000	Max. :1.0000	Max. :2.000	Max. :174.00
DOSE (numeric)	DAY (numeric)	WGTE (numeric)	RACE (integer)
Min. : 2.1	Min. : 0.00	Min. : 50.20	Min. : 0.000
1st Qu.: 70.0	1st Qu.: 2.00	1st Qu.: 66.40	1st Qu.: 0.000
Median :210.0	Median : 17.00	Median : 75.50	Median : 1.000
Mean :359.3	Mean : 33.36	Mean : 76.12	Mean : 3.136
3rd Qu.:700.0	3rd Qu.: 56.00	3rd Qu.: 83.10	3rd Qu.: 3.000
Max. :700.0	Max. :173.00	Max. :111.50	Max. :88.000
AGE (integer)	DIS (integer)	HGTB (numeric)	IPRE (numeric)
Min. :18.00	Min. :0.0000	Min. :150.1	Min. : 0
1st Qu.:28.00	1st Qu.:0.0000	1st Qu.:165.0	1st Qu.: 1804
Median :33.00	Median :0.0000	Median :171.0	Median : 18170
Mean :33.14	Mean :0.4529	Mean :171.5	Mean : 52927
3rd Qu.:37.00	3rd Qu.:1.0000	3rd Qu.:178.0	3rd Qu.: 76802
Max. :60.00	Max. :2.0000	Max. :194.0	Max. :580840
IRES (numeric)	IWRE (numeric)	MDV (integer)	CL (numeric)
Min. : -237140.0	Min. : -0.99999	Min. :0.00000	Min. :0.09041
1st Qu.: -789.9	1st Qu.: -0.06845	1st Qu.:0.00000	1st Qu.:0.13937
Median : 0.0	Median : 0.00000	Median :0.00000	Median :0.16012
Mean : -1391.8	Mean : -0.01980	Mean :0.09363	Mean :0.17725
3rd Qu.: 1036.2	3rd Qu.: 0.07109	3rd Qu.:0.00000	3rd Qu.:0.20613
Max. : 95782.0	Max. : 0.56770	Max. :1.00000	Max. :0.39005
V2 (numeric)	Q (numeric)	V3 (numeric)	KA (numeric)
Min. : 1.449	Min. :0.7244	Min. :2.227	Min. :0.07869
1st Qu.: 2.379	1st Qu.:0.7244	1st Qu.:2.227	1st Qu.:0.32942
Median : 3.123	Median :0.7244	Median :2.227	Median :0.32942
Mean : 3.300	Mean :0.7244	Mean :2.227	Mean :0.34844
3rd Qu.: 3.802	3rd Qu.:0.7244	3rd Qu.:2.227	3rd Qu.:0.34304
Max. :10.537	Max. :0.7244	Max. :2.227	Max. :1.30820
R2 (numeric)	F1 (numeric)	THAL (numeric)	SBWCL (numeric)
Min. : 0.00000	Min. :0.00000	Min. :14.000	Min. :0.00000
1st Qu.:0.00000	1st Qu.:0.00000	1st Qu.:14.000	1st Qu.:0.00000
Median :0.00000	Median :0.00000	Median :14.000	Median :0.00000
Mean :0.00000	Mean :0.00000	Mean :14.000	Mean :0.00000
3rd Qu.:0.00000	3rd Qu.:0.00000	3rd Qu.:14.000	3rd Qu.:0.00000
Max. :0.00000	Max. :0.00000	Max. :14.000	Max. :0.00000

Figure 5: RID: 3 Topic ID: 4

Data

Run Data Run Data Summary Source Data Source Data Summary Analysis Data Analysis Data Summary

Show 10 entries Search:

	ID	TIME	EVID	STUD	ROUTF
	All	All	All	All	All
1	1	0.00000	1	620	SC
2	1	0.16875	0	620	SC
3	1	0.33333	0	620	SC
4	1	1.00210	0	620	SC
5	1	2.00000	0	620	SC
6	1	2.96740	0	620	SC
7	1	3.93120	0	620	SC
8	1	4.94930	0	620	SC
9	1	5.93330	0	620	SC
10	1	9.95070	0	620	SC

Showing 1 to 10 of 17 entries Previous 1 2 Next

Figure 6: RID: 4 Topic ID: 2

Data Input

[Project Information](#) [Model Info](#) [Modify Data](#) [Change E-R SSAP Defaults](#)

Parent working directory:

NONMEM source data:

Run Number:

File Extensions:

☒ Header?

Skip Lines:

Figure 7: RID: 5 Topic ID: 2

Data

Run Data Run Data Summary **Source Data** Source Data Summary Analysis Data Analysis Data Summary

Show 10 entries Search:

	ID	TIME	EVID	STUD	COHO	SEX	ROUT	VISIT	DOSE	DAY
	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
1	1	0.00000	1	620	2	0	2	1	7	0.00000
2	1	0.16875	0	620	2	0	2	1	7	0.16667
3	1	0.33333	0	620	2	0	2	1	7	0.33333
4	1	1.00210	0	620	2	0	2	2	7	1.00000
5	1	2.00000	0	620	2	0	2	3	7	2.00000
6	1	2.96740	0	620	2	0	2	4	7	3.00000
7	1	3.93120	0	620	2	0	2	5	7	4.00000
8	1	4.94930	0	620	2	0	2	6	7	5.00000
9	1	5.93330	0	620	2	0	2	7	7	6.00000
10	1	9.95070	0	620	2	0	2	11	7	10.00000

Showing 1 to 10 of 1,901 entries

Previous 1 2 3 4 5 ... 191 Next

Figure 8: RID: 5 Topic ID: 3

Data

Run Data Run Data Summary **Source Data** Source Data Summary Analysis Data Analysis Data Summary

ID (numeric)	TIME (numeric)	EVID (numeric)	STUD (numeric)
Min. : 1.00	Min. : 0.00	Min. : 0.00000	Min. : 183.0
1st Qu.: 29.00	1st Qu.: 2.00	1st Qu.: 0.00000	1st Qu.: 390.0
Median : 54.00	Median : 16.90	Median : 0.00000	Median : 620.0
Mean : 56.41	Mean : 33.39	Mean : 0.07838	Mean : 474.3
3rd Qu.: 87.00	3rd Qu.: 56.12	3rd Qu.: 0.00000	3rd Qu.: 620.0
Max. : 111.00	Max. : 182.94	Max. : 1.00000	Max. : 620.0

COHO (numeric)	SEX (numeric)	ROUT (numeric)	VISIT (numeric)
Min. : 1.000	Min. : 0.0000	Min. : 1.000	Min. : 1.00
1st Qu.: 1.000	1st Qu.: 0.0000	1st Qu.: 1.000	1st Qu.: 3.00
Median : 4.000	Median : 0.0000	Median : 2.000	Median : 16.00
Mean : 4.036	Mean : 0.2788	Mean : 1.549	Mean : 34.13
3rd Qu.: 6.000	3rd Qu.: 1.0000	3rd Qu.: 2.000	3rd Qu.: 57.00
Max. : 9.000	Max. : 1.0000	Max. : 2.000	Max. : 174.00

DOSE (numeric)	DAY (numeric)	WGTB (numeric)	RACE (numeric)
Min. : 2.1	Min. : 0.00	Min. : 50.20	Min. : 0.000
1st Qu.: 70.0	1st Qu.: 2.00	1st Qu.: 66.40	1st Qu.: 0.000
Median : 210.0	Median : 17.00	Median : 75.50	Median : 1.000
Mean : 359.3	Mean : 33.36	Mean : 76.12	Mean : 3.136
3rd Qu.: 700.0	3rd Qu.: 56.00	3rd Qu.: 83.10	3rd Qu.: 3.000
Max. : 700.0	Max. : 173.00	Max. : 111.50	Max. : 88.000

AGE (numeric)	DIS (numeric)	HGTB (numeric)	MDV (numeric)
Min. : 18.00	Min. : 0.0000	Min. : 150.1	Min. : 0.00000
1st Qu.: 28.00	1st Qu.: 0.0000	1st Qu.: 165.0	1st Qu.: 0.00000
Median : 33.00	Median : 0.0000	Median : 171.0	Median : 0.00000
Mean : 33.14	Mean : 0.4529	Mean : 171.5	Mean : 0.09363
3rd Qu.: 37.00	3rd Qu.: 1.0000	3rd Qu.: 178.0	3rd Qu.: 0.00000
Max. : 60.00	Max. : 2.0000	Max. : 194.0	Max. : 1.00000

WGT (numeric)

Min. : 51.31

1st Qu.: 72.56

Median : 79.14

Mean : 80.10

3rd Qu.: 86.70

Max. : 122.68

NA's : 356

Figure 9: RID: 5 Topic ID: 4

Data

Run Data Run Data Summary **Source Data** Source Data Summary Analysis Data Analysis Data Summary

Show 10 entries Search:

	ID	TIME	EVID	STUD	ROUTF
	All	All	All	All	All
1	1	0.00000	1	620	SC
2	1	0.16875	0	620	SC
3	1	0.33333	0	620	SC
4	1	1.00210	0	620	SC
5	1	2.00000	0	620	SC
6	1	2.96740	0	620	SC
7	1	3.93120	0	620	SC
8	1	4.94930	0	620	SC
9	1	5.93330	0	620	SC
10	1	9.95070	0	620	SC

Showing 1 to 10 of 17 entries Previous 1 2 Next

Figure 10: RID: 6 Topic ID: 2

Data

Run Data

Run Data Summary

Source Data

Source Data Summary

Analysis Data

Analysis Data Summary

ID (integer)	TIME (numeric)	EVID (integer)	STUD (integer)
Min. : 1.00	Min. : 0.00	Min. :0.00000	Min. :183.0
1st Qu.: 29.00	1st Qu.: 2.00	1st Qu.:0.00000	1st Qu.:390.0
Median : 54.00	Median : 16.90	Median :0.00000	Median :620.0
Mean : 56.41	Mean : 33.39	Mean :0.07838	Mean :474.3
3rd Qu.: 87.00	3rd Qu.: 56.12	3rd Qu.:0.00000	3rd Qu.:620.0
Max. :111.00	Max. :182.94	Max. :1.00000	Max. :620.0
COHO (integer)	SEX (integer)	ROUT (integer)	VISIT (integer)
Min. :1.000	Min. :0.0000	Min. :1.000	Min. : 1.00
1st Qu.:1.000	1st Qu.:0.0000	1st Qu.:1.000	1st Qu.: 3.00
Median :4.000	Median :0.0000	Median :2.000	Median : 16.00
Mean :4.036	Mean :0.2788	Mean :1.549	Mean : 34.13
3rd Qu.:6.000	3rd Qu.:1.0000	3rd Qu.:2.000	3rd Qu.: 57.00
Max. :9.000	Max. :1.0000	Max. :2.000	Max. :174.00
DOSE (numeric)	DAY (numeric)	WGTV (numeric)	RACE (integer)
Min. : 2.1	Min. : 0.00	Min. : 50.20	Min. : 0.000
1st Qu.: 70.0	1st Qu.: 2.00	1st Qu.: 66.40	1st Qu.: 0.000
Median :210.0	Median : 17.00	Median : 75.50	Median : 1.000
Mean :359.3	Mean : 33.36	Mean : 76.12	Mean : 3.136
3rd Qu.:700.0	3rd Qu.: 56.00	3rd Qu.: 83.10	3rd Qu.: 3.000
Max. :700.0	Max. :173.00	Max. :111.50	Max. :88.000
AGE (integer)	DIS (integer)	HGTB (numeric)	IPRE (numeric)
Min. :18.00	Min. :0.0000	Min. :150.1	Min. : 0
1st Qu.:28.00	1st Qu.:0.0000	1st Qu.:165.0	1st Qu.: 1804
Median :33.00	Median :0.0000	Median :171.0	Median : 18170
Mean :33.14	Mean :0.4529	Mean :171.5	Mean : 52927
3rd Qu.:37.00	3rd Qu.:1.0000	3rd Qu.:178.0	3rd Qu.: 76802
Max. :60.00	Max. :2.0000	Max. :194.0	Max. :580840
IRES (numeric)	IWRE (numeric)	MDV (integer)	CL (numeric)
Min. : -237140.0	Min. : -0.99999	Min. :0.00000	Min. :0.09041
1st Qu.: -789.9	1st Qu.: -0.06845	1st Qu.:0.00000	1st Qu.:0.13937
Median : 0.0	Median : 0.00000	Median :0.00000	Median :0.16012
Mean : -1391.8	Mean : -0.01980	Mean :0.09363	Mean :0.17725
3rd Qu.: 1036.2	3rd Qu.: 0.07109	3rd Qu.:0.00000	3rd Qu.:0.20613
Max. : 95782.0	Max. : 0.56770	Max. :1.00000	Max. :0.39005
V2 (numeric)	Q (numeric)	V3 (numeric)	KA (numeric)
Min. : 1.449	Min. :0.7244	Min. :2.227	Min. :0.07869
1st Qu.: 2.379	1st Qu.:0.7244	1st Qu.:2.227	1st Qu.:0.32942
Median : 3.123	Median :0.7244	Median :2.227	Median :0.32942
Mean : 3.300	Mean :0.7244	Mean :2.227	Mean :0.34844
3rd Qu.: 3.802	3rd Qu.:0.7244	3rd Qu.:2.227	3rd Qu.:0.34304
Max. :10.537	Max. :0.7244	Max. :2.227	Max. :1.30820
R2 (numeric)	F1 (numeric)	THAL (numeric)	SBWCL (numeric)
Min. : 0	Min. :0.698	Min. :14.01	Min. :0.75

Figure 11: RID: 7 Topic ID: 1

Data				
Run Data	Run Data Summary	Source Data	Source Data Summary	Analysis Data
Analysis Data Summary				
ID (numeric)	TIME (numeric)	EVID (numeric)	STUD (numeric)	
Min. : 1.00	Min. : 0.00	Min. :0.00000	Min. :183.0	
1st Qu.: 29.00	1st Qu.: 2.00	1st Qu.:0.00000	1st Qu.:390.0	
Median : 54.00	Median : 16.90	Median :0.00000	Median :620.0	
Mean : 56.41	Mean : 33.39	Mean :0.07838	Mean :474.3	
3rd Qu.: 87.00	3rd Qu.: 56.12	3rd Qu.:0.00000	3rd Qu.:620.0	
Max. :111.00	Max. :182.94	Max. :1.00000	Max. :620.0	
COHO (numeric)	SEX (numeric)	ROUT (numeric)	VISIT (numeric)	
Min. :1.000	Min. :0.0000	Min. :1.000	Min. : 1.00	
1st Qu.:1.000	1st Qu.:0.0000	1st Qu.:1.000	1st Qu.: 3.00	
Median :4.000	Median :0.0000	Median :2.000	Median : 16.00	
Mean :4.036	Mean :0.2788	Mean :1.549	Mean : 34.13	
3rd Qu.:6.000	3rd Qu.:1.0000	3rd Qu.:2.000	3rd Qu.: 57.00	
Max. :9.000	Max. :1.0000	Max. :2.000	Max. :174.00	
DOSE (numeric)	DAY (numeric)	WGTB (numeric)	RACE (numeric)	
Min. : 2.1	Min. : 0.00	Min. : 50.20	Min. : 0.000	
1st Qu.: 70.0	1st Qu.: 2.00	1st Qu.: 66.40	1st Qu.: 0.000	
Median :210.0	Median : 17.00	Median : 75.50	Median : 1.000	
Mean :359.3	Mean : 33.36	Mean : 76.12	Mean : 3.136	
3rd Qu.:700.0	3rd Qu.: 56.00	3rd Qu.: 83.10	3rd Qu.: 3.000	
Max. :700.0	Max. :173.00	Max. :111.50	Max. :88.000	
AGE (numeric)	DIS (numeric)	HGTB (numeric)	MDV (numeric)	
Min. :18.00	Min. :0.0000	Min. :150.1	Min. :0.00000	
1st Qu.:28.00	1st Qu.:0.0000	1st Qu.:165.0	1st Qu.:0.00000	
Median :33.00	Median :0.0000	Median :171.0	Median :0.00000	
Mean :33.14	Mean :0.4529	Mean :171.5	Mean :0.09363	
3rd Qu.:37.00	3rd Qu.:1.0000	3rd Qu.:178.0	3rd Qu.:0.00000	
Max. :60.00	Max. :2.0000	Max. :194.0	Max. :1.00000	
WGT (numeric)	ROUTF (factor)			
Min. : 51.31	IV: 858			
1st Qu.: 72.56	SC:1043			
Median : 79.14				
Mean : 80.10				
3rd Qu.: 86.70				
Max. :122.68				
NA's :356				

Figure 12: RiD: 7 Topic ID: 1

Data

Run Data Run Data Summary Source Data Source Data Summary Analysis Data Analysis Data Summary

Show 10 entries Search:

	NMID	TAFD	EVID	STUDY	COHO	SEX	ROUT	VISIT	DOSE	DAY
1584	86	0.000000	0	183	1	0	1	1	700	0.000000
1585	86	0.046528	1	183	1	0	1	1	700	0.000000
1586	86	0.088194	0	183	1	0	1	1	700	0.041667
1587	86	0.213190	0	183	1	0	1	1	700	0.166670
1593	86	2.925000	0	183	1	0	1	4	700	3.000000
1603	86	6.945100	0	183	1	0	1	8	700	7.000000
1589	86	13.982000	0	183	1	0	1	15	700	14.000000
1591	86	28.008000	0	183	1	0	1	29	700	28.000000
1592	86	28.050000	1	183	1	0	1	29	700	28.042000
1594	86	40.907000	0	183	1	0	1	41	700	40.000000

Showing 1 to 10 of 1,901 entries Previous 1 2 3 4 5 ... 191 Next

Figure 13: RID: 7 Topic ID: 2

Data

Run Data Run Data Summary Source Data Source Data Summary Analysis Data Analysis Data Summary

NMID (numeric)	TAFD (numeric)	EVID (numeric)	STUDY (numeric)	
Min. : 86.00	Min. : 0.000	Min. : 0.0000	Min. : 183	
1st Qu.: 89.00	1st Qu.: 6.927	1st Qu.: 0.0000	1st Qu.: 183	
Median : 95.00	Median : 41.897	Median : 0.0000	Median : 183	
Mean : 94.05	Mean : 45.220	Mean : 0.1264	Mean : 183	
3rd Qu.: 98.00	3rd Qu.: 63.028	3rd Qu.: 0.0000	3rd Qu.: 183	
Max. : 102.00	Max. : 182.940	Max. : 1.0000	Max. : 183	
COHO (numeric)	SEX (numeric)	ROUT (numeric)	VISIT (numeric)	DOSE (numeric)
Min. : 1	Min. : 0.0000	Min. : 1	Min. : 1	Min. : 700
1st Qu.: 1	1st Qu.: 0.0000	1st Qu.: 1	1st Qu.: 8	1st Qu.: 700
Median : 1	Median : 1.0000	Median : 1	Median : 42	Median : 700
Mean : 1	Mean : 0.6264	Mean : 1	Mean : 46	Mean : 700
3rd Qu.: 1	3rd Qu.: 1.0000	3rd Qu.: 1	3rd Qu.: 64	3rd Qu.: 700
Max. : 1	Max. : 1.0000	Max. : 1	Max. : 169	Max. : 700
DAY (numeric)	WGTB (numeric)	RACE (numeric)	AGE (numeric)	
Min. : 0.00	Min. : 50.20	Min. : 0.0000	Min. : 18.00	
1st Qu.: 7.00	1st Qu.: 62.90	1st Qu.: 0.0000	1st Qu.: 22.00	
Median : 41.00	Median : 66.00	Median : 0.0000	Median : 28.00	
Mean : 44.94	Mean : 72.26	Mean : 0.2247	Mean : 30.64	
3rd Qu.: 63.00	3rd Qu.: 82.73	3rd Qu.: 0.0000	3rd Qu.: 35.00	
Max. : 168.00	Max. : 104.40	Max. : 2.0000	Max. : 50.00	
DIS (numeric)	HGTB (numeric)	MDV (numeric)	ROUTF (factor)	WGT (numeric)
Min. : 2	Min. : 156.0	Min. : 0.0000	IV: 356	Min. : NA
1st Qu.: 2	1st Qu.: 163.0	1st Qu.: 0.0000	SC: 0	1st Qu.: NA
Median : 2	Median : 165.0	Median : 0.0000		Median : NA
Mean : 2	Mean : 169.2	Mean : 0.1713		Mean : NaN
3rd Qu.: 2	3rd Qu.: 180.0	3rd Qu.: 0.0000		3rd Qu.: NA
Max. : 2	Max. : 188.0	Max. : 1.0000		Max. : NA
				NA's : 356

Figure 14: RID: 7 Topic ID: 3

SEXF (factor)
Female:1371
Male : 530

Figure 15: RID: 8 Topic ID: 1

Data exclusions

Subject exclusions [Observation exclusions](#)

[Subject exclusion specification](#) [Subject Exclusion Data](#)

Search:

SEX	ROUT	VISIT	DOSE	DAY	WGTB	RACE	AGE	DIS	HGTB
0	2	1	210	0.00000	61.1	88	32	0	169
0	2	1	210	0.16667	61.1	88	32	0	169
0	2	1	210	0.33333	61.1	88	32	0	169
0	2	2	210	1.00000	61.1	88	32	0	169
0	2	3	210	2.00000	61.1	88	32	0	169
0	2	4	210	3.00000	61.1	88	32	0	169
0	2	5	210	4.00000	61.1	88	32	0	169

Figure 16: RID: 10 Topic ID: 3

Data

Run Data Run Data Summary Source Data Source Data Summary Analysis Data Analysis Data Summary

NMID (numeric)	TAFD (numeric)	EVID (numeric)	STUDY (numeric)
Min. : 1.00	Min. : 0.00	Min. : 0.00000	Min. : 183.0
1st Qu.: 29.00	1st Qu.: 2.00	1st Qu.: 0.00000	1st Qu.: 390.0
Median : 55.00	Median : 19.98	Median : 0.00000	Median : 620.0
Mean : 56.79	Mean : 33.64	Mean : 0.07891	Mean : 471.3
3rd Qu.: 87.00	3rd Qu.: 56.18	3rd Qu.: 0.00000	3rd Qu.: 620.0
Max. : 111.00	Max. : 182.94	Max. : 1.00000	Max. : 620.0

COHO (numeric)	SEX (numeric)	ROUT (numeric)	VISIT (numeric)
Min. : 1.000	Min. : 0.0000	Min. : 1.000	Min. : 1.00
1st Qu.: 1.000	1st Qu.: 0.0000	1st Qu.: 1.000	1st Qu.: 3.00
Median : 4.000	Median : 0.0000	Median : 2.000	Median : 16.00
Mean : 3.982	Mean : 0.2732	Mean : 1.551	Mean : 34.38
3rd Qu.: 6.000	3rd Qu.: 1.0000	3rd Qu.: 2.000	3rd Qu.: 57.00
Max. : 9.000	Max. : 1.0000	Max. : 2.000	Max. : 174.00

DOSE (numeric)	DAY (numeric)	WGTB (numeric)	RACE (numeric)
Min. : 2.1	Min. : 0.00	Min. : 50.20	Min. : 0.000
1st Qu.: 70.0	1st Qu.: 2.00	1st Qu.: 66.40	1st Qu.: 0.000
Median : 210.0	Median : 20.00	Median : 75.50	Median : 1.000
Mean : 356.8	Mean : 33.61	Mean : 76.21	Mean : 1.405
3rd Qu.: 700.0	3rd Qu.: 56.00	3rd Qu.: 84.10	3rd Qu.: 3.000
Max. : 700.0	Max. : 173.00	Max. : 111.50	Max. : 3.000

Figure 17: RID: 10 Topic ID: 4

Data exclusions

Subject exclusions Observation exclusions

Observation exclusion specification Observation Exclusion Data

	DV	PRED	RES	WRES	NPDE	Run	SEXF	SUBJEXC	OBSEXC	excl_reasons
										All
0	0	0	0	0	-1.3597011	0069	Female	Keep	BQL	Concentration BQL
0	0	0	0	0	0.9282008	0069	Female	Keep	BQL	Concentration BQL
0	0	0	0	0	0.7226767	0069	Male	Keep	BQL	Concentration BQL
0	0	0	0	0	-0.6675164	0069	Male	Keep	BQL	Concentration BQL
0	0	0	0	0	-1.2873751	0069	Male	Keep	BQL	Concentration BQL
0	0	0	0	0	-0.6264489	0069	Male	Keep	BQL	Concentration BQL
0	0	0	0	0	-1.2628056	0069	Female	Keep	BQL	Concentration BQL
0	0	153710	0	0	1.5558875	0069	Male	Keep	BQL	Concentration R01

Figure 18: RID: 11 Topic ID: 2

Data

Run Data Run Data Summary Source Data Source Data Summary Analysis Data Analysis Data Summary

ETA7	ETA8	DV	PRED	RES	WRES	NPDE	Run	SEXF	SUBJEXC	OBSEXC
0	0	0	0	0	0.00000	0.39865010	0069	Female	Keep	Keep
0	0	148000	172210	-24210	0.42434	0.36999052	0069	Female	Keep	Keep
0	0	141000	167410	-26413	0.28900	1.23464984	0069	Female	Keep	Keep
0	0	74700	109720	-35024	-1.08180	-0.42986685	0069	Female	Keep	Keep
0	0	58500	84585	-26085	-0.95998	-0.96928669	0069	Female	Keep	Keep
0	0	46300	66000	-19700	-0.66365	0.33528069	0069	Female	Keep	Keep
0	0	29900	42027	-12127	-0.18607	0.51775691	0069	Female	Keep	Keep
0	0	0	41971	0	0.00000	-0.07011567	0069	Female	Keep	Keep
0	0	72900	96130	-23230	-0.14814	0.32303107	0069	Female	Keep	Keep
0	0	65500	93082	-27582	-0.48908	0.64838833	0069	Female	Keep	Keep

Figure 19: RID: 11 Topic ID: 3

Data

Run Data Run Data Summary Source Data Source Data Summary Analysis Data Analysis Data Summary

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Figure 20: RID: 12 Topic ID: 1

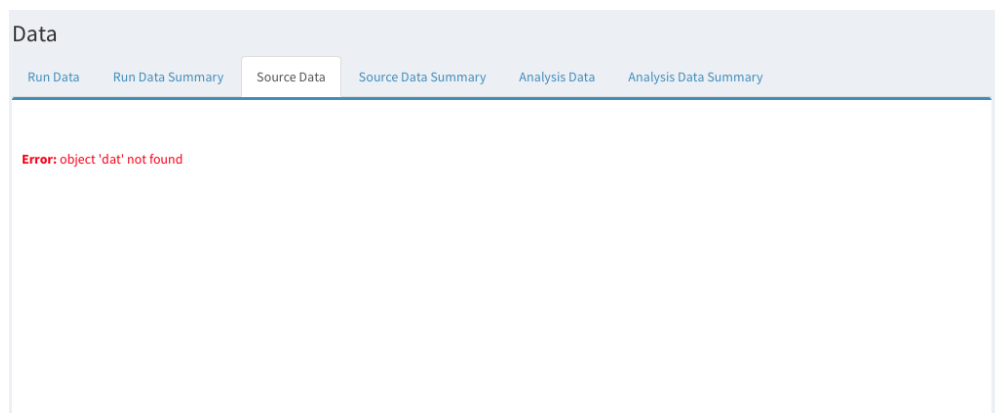


Figure 21: RID: 12 Topic ID: 1

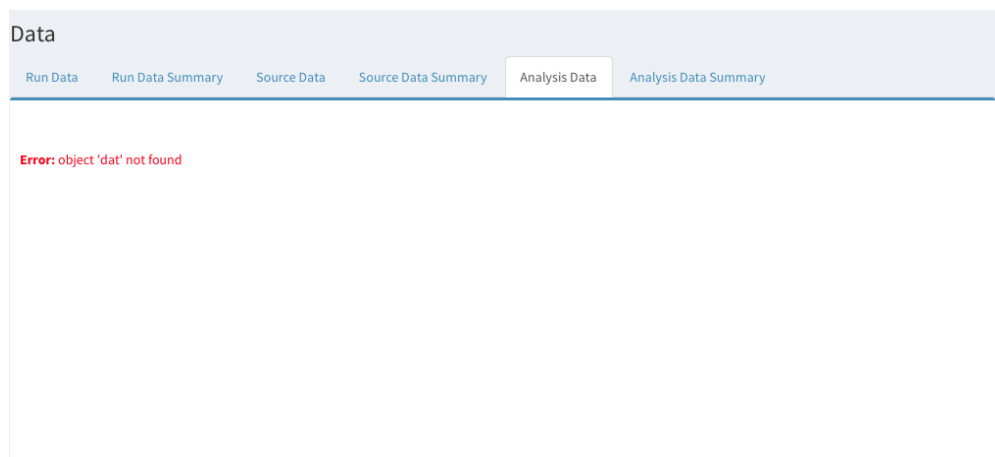


Figure 22: RID: 12 Topic ID: 1