

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 <Screenscaps>	Pass
		2	Load run data into the application	Screenshot of Data Input -> Model info and Data Input -> Change E-R SSAP Defaults	Input specified <Screenscaps>	Pass
		3	View the data	Screenshot of Data -> Run Data, showing data contents	Screenshot shows data <Screenscaps>	Pass
		4	View the data summary	Screenshot of Data -> Run Data Summary, showing data summary	Data summary appears for run data <Screenscaps>	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:  ROUTE <- factor(ROUT, c(1,2), c("IV","SC")) subset(\$DATA, ID == 1, select=c(ID,TIME,EVID,STUD,R OUTF))	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 <Screenscaps>	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 <Screenscaps>	Pass
		3	View the data	Screenshot of Data -> Source Data, showing data contents	Source data view shows data <Screenscaps>	Pass
		4	View the data summary	Screenshot of Data -> Source Data Summary, showing data summary	Source data summar view appears <Screenscaps>	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,R OUTF))	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 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 -> Observatoion 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	Screenshot shows no observation, source, or analysis data	All data viewers show either nothing or present error <Screenshots>	Pass