

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		
		2	Load run data into the application	Screenshot of Data Input -> Model info and Data Input -> Change E-R SSAP Defaults		
		3	View the data	Screenshot of Data -> Run Data, showing data contents		
		4	View the data summary	Screenshot of Data -> Run Data Summary, showing data summary		
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		
		2	Screenshot of Run Data view	Screenshot shows the selected subset of patients and variables, with the renamed Route factor		
5	Source data can be read, displayed, and summarized	1	Uplaod source data 0069/source.csv into /data	Upload successful		
		2	Load source data into the application	Screenshot of Data Input -> Model info and Data Input -> Change E-R SSAP Defaults		
		3	View the data	Screenshot of Data -> Source Data, showing data contents		
		4	View the data summary	Screenshot of Data -> Source Data Summary, showing data summary		

RID	Topic	Test ID	Step Description	Expected Result	Qualification Note(s)	Pass/Fail
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		
		2	Screenshot of Source Data view	Screenshot shows the selected subset of patients and variables, with the renamed Route factor		
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	Screen caps show that other patients beside subject 1 have been added back in to the datasets		
		2	Merge the datasets by selecting Data -> Analysis Data	Screen cap of analysis data shows merged data		
		3	Confirm merge is a full merge by subsetting to study 183 and verifying that all values of WGT are missing	Screen cap of summary shows all studies are 183 and no values for WGT		
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"))	Screen cap of analysis data summary shows SEXF factor with Male and Female		
9	Analysis data can be viewed and summarized	1	View the analysis data	Screen cap of analysis data view shows data		

RID	Topic	Test ID	Step Description	Expected Result	Qualification Note(s)	Pass/Fail
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		
		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		
		3	View subject exclusions: Data Exclusions -> Subject exclusion specification -> Subject Exclusion Data	Screenshot of data showing missing race for all patients		
		4	Verify that exclusions are no longer in analysis data	Screenshot of analysis data summary shows that no patients with missing race are present		
11	Observation level exclusions can be specified and viewed	1	From Data Exclusions -> Observation exclusions -> Observation exclusion specification enter:  BQL::Concentration BQL Keep::  Press "Generate observation exclusions" button	Input allowed, no errors		
		2	View observation exclusions: Data Exclusions -> Observation exclusion specification -> Observation Exclusion Data	Screenshot of data showing BQL for all observations		
		3	Verify that exclusions are no longer in analysis data	Screenshot of analysis data summary shows that no patients with missing race are present		

RID	Topic	Test ID	Step Description	Expected Result	Qualification Note(s)	Pass/Fail
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	Screen cap shows no observation, source, or analysis data		