Submission 28: Integration of non-compartmental analysis and biological equivalence test using EDISON Science Apps

Table 1. An example of the concentration-time data used for EDISON Apps.

SUBJ	GRP	PRD	TRT	nTIME	TIME	CONC
1	RT	1	R	0	0	0
1	RT	1	R	0.25	0.26	511.3
1	RT	1	R	0.5	0.46	678.79
1	RT	1	R	...	...	...
1	RT	2	T	0	0	0
1	RT	2	T	0.25	0.25	487.62
1	RT	2	T	0.5	0.48	769.6
...	...	...	...	...	...	...
5	TR	1	T	0	0	0
5	TR	1	T	0.25	0.23	382.79
5	TR	1	T	0.5	0.45	477.03
5	TR	1	T	...	...	...
5	TR	2	R	0	0	0
5	TR	2	R	0.25	0.28	596.98
5	TR	2	R	0.5	0.47	832.76
5	TR	2	R	...	...	...
...	...	...	...	...	...	...

Table 2. The raw pharmacokinetic data calculated by NonCompartEdison App

SUBJ	GRP	PRD	TRT	AUClast	Cmax	Tmax
1	RT	1	R	5018.927	1043.13	1.04
1	RT	2	T	6737.507	894.21	1.03
2	TR	1	T	4373.97	447.26	1.01
2	TR	2	R	6164.276	783.92	1.98
4	TR	1	T	5592.993	824.42	1.97
4	TR	2	R	5958.16	646.31	0.97
5	TR	1	T	3902.59	803.7	0.8
5	TR	2	R	4620.156	955.3	0.74

Table 3. Comparison of 90% confidence interval for the ratio of the geometric means

(A)

Analysis	Lower Limit	Point Estimate	Upper Limit
EDISON Science App	0.88944	0.95408	1.02341
SAS: PROC GLM	0.88944	0.95408	1.02341
SAS: PROC MIXED	0.88944	0.95408	1.02341

(B)

Analysis	Lower Limit	Point Estimate	Upper Limit
EDISON Science App	0.90136	0.97984	1.06515
SAS: PROC GLM	0.90136	0.97984	1.06515
SAS: PROC MIXED	0.90136	0.97984	1.06515

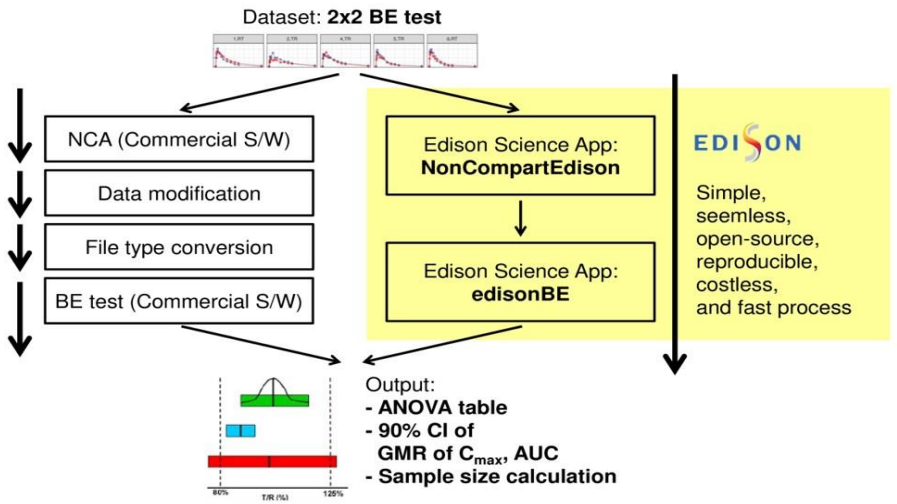

Figure 1. Comparison between a traditional analysis process (left boxes) and the proposed process (right boxes) using EDISON Science Apps.