InSilicoMinds

In Silico Bioequivalence – Non-Proportional Formulation

In Silico trial to replace Bioequivalence trial for non-proportional formulation

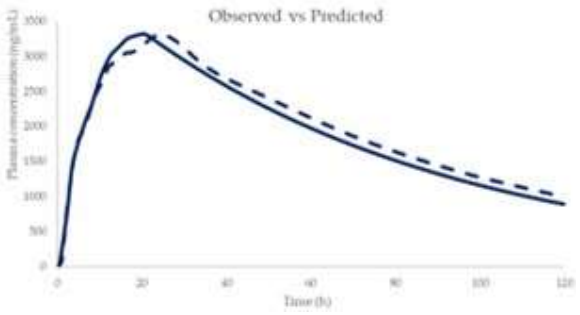
August 2020 | In Silico Bioequivalence, Non-Proportional Formulation, Clinical Development

Background: The Sponsor intended to have a biowaiver for the non-proportional lower strength. The Sponsor had performed a BA BE study with the higher strength.

Question of Interest: Could Modeling and Simulation replace the BA BE trial by an in silico BA BE?

Methods: BA BE data of the higher strength and PK data of the reference for the lower strength were used in the analysis.
The in-silico BA BE trial was performed by means of IVIVC modeling.

Results:
A validated IVIVC model (see figure) was developed and used to simulate the BA BE trial.



Impact:

- The Agency accepted the Sponsor's clinical development program including the in-silico BA BE study.
- The Sponsor reduced costs and timelines by waiving off the BA BE study for lower strengths.