SimulationsPlus

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GastroPlus® v9.7 Patch

October 2019

Dear GastroPlus® User,

Thank you for your interest in GastroPlus. The Simulations Plus development team has worked to ensure that GastroPlus remains the most advanced and reliable simulation of drug absorption, pharmacokinetics, and pharmacodynamics in the world today. Please find information for the October 2019 patch below:

1. Bug fixes in this patch

- ACAT™ Model:
    - Fixed issue with resetting temporary changes in Gut physiology parameters back to the default values after opening the enzyme or transporter tables
    - Synchronized setting for Zero-order gastric emptying between the Gut Physiology tab and the user-defined ACAT model
    - Fixed issue with saving enzyme and transporter names in lower case font when using a user-defined human ACAT model
- PBPKPlus™ Module:
    - If different tissue model types (perfusion- and permeability-limited) are used for parent and metabolite compounds or substrate and perpetrator, use the correct tissue concentration for the basolateral influx transporter located in PBPK tissue
    - Fixed muscle and adipose tissue volumes for infants less than 1-year-old
    - Updated phospholipid content in the human heart
    - Allow users to add clearance to the fetal blood compartment
    - Correctly load .pbk file saved in French to an English system
    - Updated the prevalence of 2D6 poor metabolizer in Asian population
- IVIVCPlus™ Module:
    - Allow the IVIVC module to load a .dsd file with more than 100 data points
    - Use correct dose level for IVIVC convolution step with dosing set up in MDD file
    - Fixed error in detecting observed Cmax in the IVIVC convolution step that occurred under certain conditions
- Population Simulation:
    - Correctly save the settings for variables with modified (non-default) distribution type in the result file
    - Show the correct enzyme expression level in gut physiology for pediatric subjects in the population simulation setup window
    - During population simulation with fed gut physiology, automatically set fed liver blood flow in PBPK physiology
    - Set the distribution type to Log-Normal for stomach transit time and stomach pH if baseline value is different from the default
    - Fixed the issue with generating the same population from different simulations under a specific condition
    - Fixed the issue with population simulation when the population included different phenotype of the Gut enzyme from the one defined in the enzyme table

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- DILIsym® Simulation:
    - Save the result in the correct format for DILIsym simulation
    - Fixed the issue of duplicated output points in the result file after certain DILIsym simulation
- General Features:
    - Increase the upper limit for Weibull time scale parameters to 1E23 to allow fitting the dissolution profiles for long acting injectables
    - Use "adjusted Fup" to calculate the liver clearance for a compartmental PK model when the structures are imported via the ADMET Predictor® module
    - Save Notes to the simulation output file
    - Added t1/2 output for Noncompartmental Analysis (NCA) in PKPlus module
    - Added a check for the value of Dose fraction of form 1 (between 0 and 1) during Import Drugs table
    - Fixed the issue with loading particle size distribution to Pulmonary dosage forms

2. Customer support

As part of our Personal Consultation Program, Simulations Plus has assigned scientists to specifically serve you in your use of GastroPlus. Feel free to contact them for advice on techniques for using the program better, for suggestions, and bug reports.

We stand ready to help you. If you need assistance in getting started, or if you would like advice on techniques for using the program most effectively in your research, please feel free to contact us.

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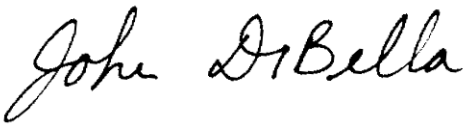
We look forward to serving you and assisting in any way we can.

Best regards,



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