



Accomplish More with Phoenix 8.1

Powers Easy Validation and One-step Calculation of Parameter Ratios

Phoenix 8.1 has new features that can simplify processes and can be automated to save you time.

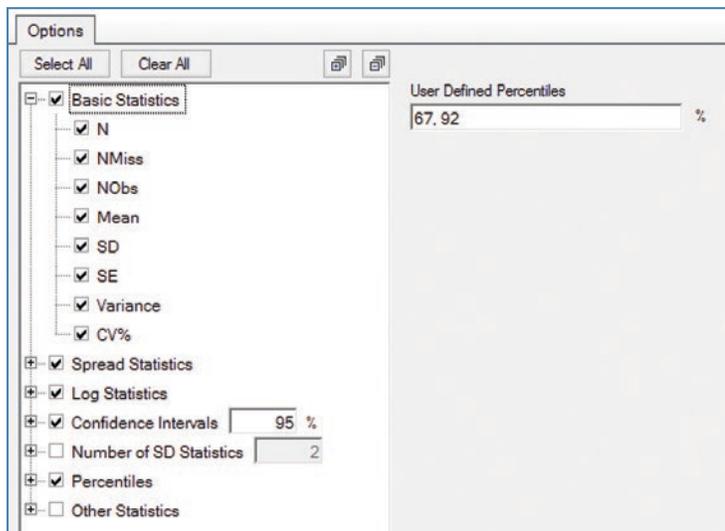
New Ratios and Differences plugin within Phoenix delivers one-step calculation ratios such as renal clearance, accumulation ratio, linearity index, bioavailability, and parent/metabolite comparisons from PK or PD parameters from NCA or compartmental modeling outputs. Our new ratios plugin simplifies the workflow so that users can calculate ratio/difference readily to create report ready tables.

Example Table of Ratio Output: Gender Differences in Cmax and AUClast

Analyte	Day	Dose	Gender	Cmax (µg/mL)	AUClast (hr*µg/mL)	Ratio Cmax F/M	Ratio AUClast F/M
TA	1	1 mg/kg	F	0.83	9.16	1.48	1.23
		1 mg/kg	M	0.57	7.42		
	10	10 mg/kg	F	5.31	41.00	0.98	1.08
		10 mg/kg	M	5.44	37.87		
	60	60 mg/kg	F	17.07	160.89	1.53	1.45
		60 mg/kg	M	11.13	110.66		

F: Female; M: Male

Additional Descriptive Statistics in Phoenix 8.1 include sums, user-specified percentiles, range, min and max when weighting is used, and an option to select statistics for outputs.

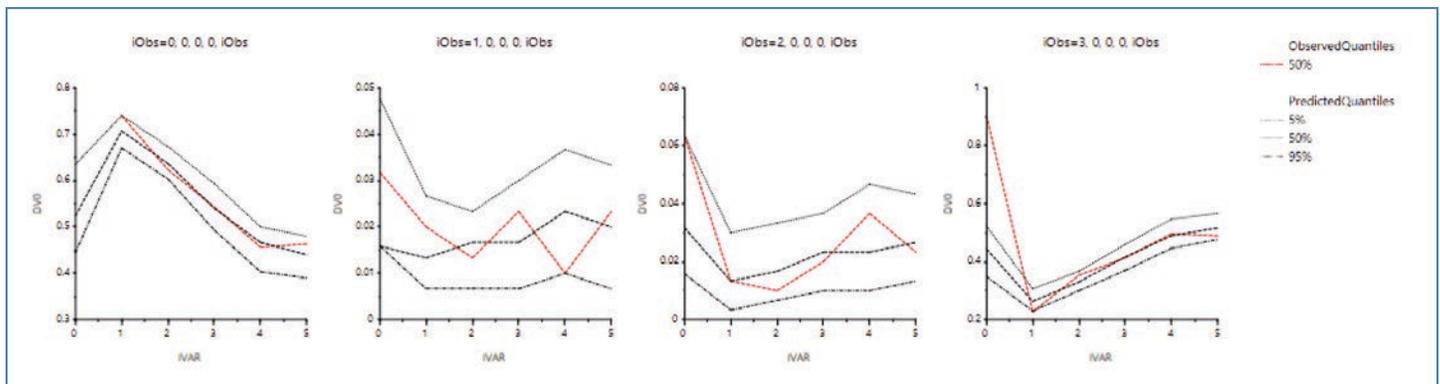


New Dialog Box for Descriptive Statistics with User Defined Percentiles

Enhanced Phoenix WinNonlin Validation Suite has locked PDF reports with links to saved reference files, user output files, and difference files. Plus, we have updated, ready-to-use validation template documents aligned with regulatory guidance for computer system validation such as ICH E6 Good Clinical Practice (GCP) R2. Validate your WinNonlin software in under 30 minutes while working on other applications.

Test Case	Status	Results Worksheet	Reference	Run	Difference
WNL Bioeq Average Crossover 2x2	Passed	Average Bioequivalence	Reference	Run	Difference
		Ratios Test <test formulation name>	Reference	Run	Difference
		Diagnostics	Reference	Run	Difference
		Final Fixed Parameters	Reference	Run	Difference
		Final Variance Parameters	Reference	Run	Difference
		Least Squares Means	Reference	Run	Difference
		LSM Differences	Reference	Run	Difference
		Partial SS	Reference	Run	Difference
		Partial Tests	Reference	Run	Difference
		Residuals	Reference	Run	Difference
		Sequential SS	Reference	Run	Difference
Sequential Tests	Reference	Run	Difference		

Improved Visual Predictive Check in Phoenix NLME offers separate analyses for different types of data such as continuous data with BQLs, categorical data, and time to event data .



Furthermore, we are adding charting capabilities that enable users to order the presentation of categorical axes and profiles in XY plots, utilize the offset function left or right on X-axis, add line to XY (X-categorical), and more. These enhancements will provide more flexibility for customization of charts and plots.

Stay tuned for more updates on Phoenix!

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