

Pirana

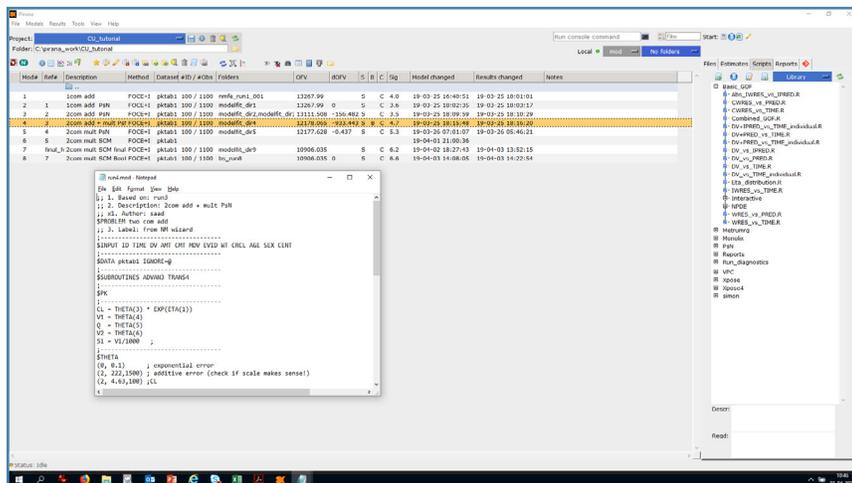
The Premier Workbench for Optimizing Pharmacometric Workflows

Pirana is a flexible and extendible modeling workbench that provides a graphical user interface (GUI) for NONMEM, PsN, Xpose/R, and more, facilitating the management of pharmacometric workflows¹.

Population PK/PD (Pop PK/PD), a powerful tool used by modelers in the pharmaceutical industry and regulatory agencies to analyze drug safety and efficacy, has become the norm for regulatory submissions. Organizing and managing pharmacometric models can be an inefficient and time-consuming process. Pirana's research tools provide modelers with structure to facilitate the iterative processes used to create Pop PK/PD models and perform simulations resulting in better organization and more efficient analysis of Pop PK/PD results.

Optimize Pharmacometric Workflows with Pirana

Pirana delivers faster, more efficient modeling and simulation by connecting multiple tools for optimizing a pharmacometrics workflow. A graphical user interface provides an automated folder structure for the storage of analytical results, adding order and traceability to complex analyses.



- Pirana provides modelers a wide range of critical structure, tools and graphics pivotal to validating modeling results for traceability and reproducibility:
 - Model templates and wizards
 - Library of goodness-of-fit plots (R)
 - Model translation tools
 - Built-in support for version control and audit trails
- Seamless access to open source tools in order to interface with Pop PK/PD modeling tools for visual predictive check, covariate modeling, and bootstraps
- Runs on all major operating systems including Windows®, macOS®, and Linux®

Organize and manage models

Analogous to a lab notebook, Pirana creates the necessary infrastructure to manage, create, track, and perform simulations.

Pirana provides an intuitive interface to manage models when selected in the lab notebook area:

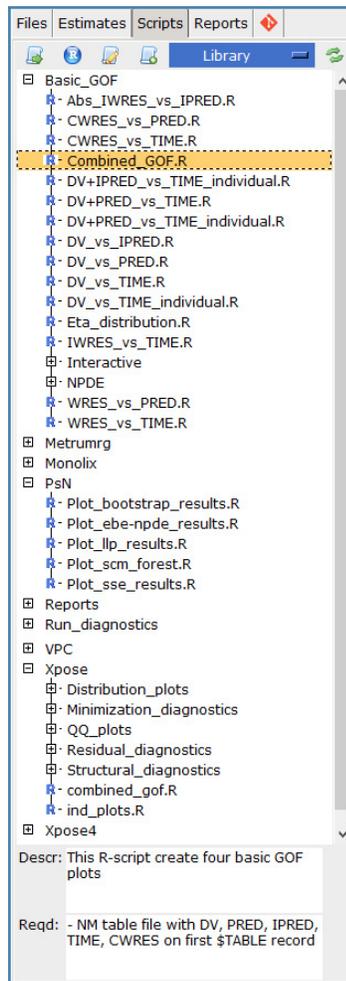
- The Estimates tab contains model results displaying summaries of estimated model parameters
- A library of scripts provides options to run, generate plots and analyses, create, review or modify R code and run additional scripts by other integrated software, e.g., PsN or Xpose
- Basic summaries of results and reports and generated plots of the scripts in PDF format can be easily accessed from the Results tab

Pirana Graphical User Interface

The Pirana modeling workbench provides a flexible and intuitive graphical user interface for the management of pharmacometric workflows using NONMEM and other analysis software.

Pirana provides functionality for model management, model execution, output generation, and interpretation of results:

- Models can be read from a folder or created in Pirana
- Analyses are automatically managed using a basic command line tool
- Post-processing work can be performed on models executed in Pirana



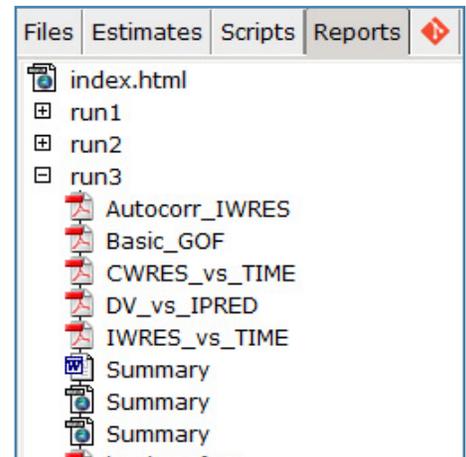
The screenshot shows the 'Estimates' tab in the Pirana GUI. It displays parameter estimates for three components: Theta, Omega, and Sigma. Each parameter is listed with its name, value, a progress bar, and a percentage. A legend explains the symbols used in the estimates.

Theta			
1	exponenti	0.126	(3%)
2	additive	0	
3	CL	5.1	(4%)
4	V1	98.5	(4%)
5	Q	7.59	(3%)
6	V2	97.7	(9%)
7	CLWT1	0.009	(22%)
8	V1SEX1	-0.171	(30%)
9	V1WT1	0.0144	(9%)
10	CLCRCL1	0.0172	(23%)
11	CLCRCL2	0.0031	(170%)
Omega			
1	IIV C	0.0387	(21%) [6%]
2,1	cov	0.026	
2	IIV V	0.0509	(15%) [4%]
Sigma			
1	residual	1	[8%]

Legend:
 (%) = RSE
 [%] = Shr.
 = Fixed
 = Bound.
 = Etabar

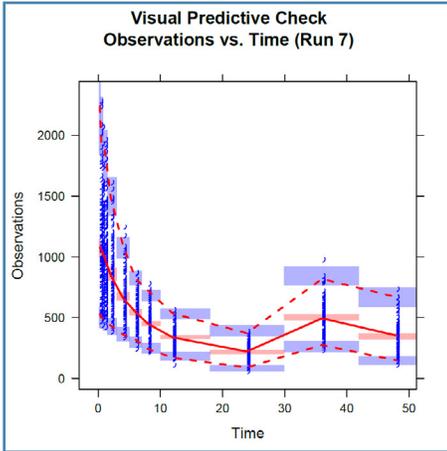
Untransformed exp(TH)

minimization successful
 no. of function evaluations used: 474
 no. of sig. digits in final est.: 6.2



Data Visualization

Pirana provides a quick and easy graphical interface to R plotting tools and supports the generation of plots in R using PSN and Xpose or custom user scripts.



Parameter	Description	run1	run2
OPV	Objective function	12205.445	11140.326
dOPV	OPV diff (with run1)	0	-1165.119
TH 1	CL	7.07 (2.6%)	4.76 (0.2%)
TH 2	V1	97.7 (3.3%)	90 (3.0%)
TH 3	Q		7.32 (2.7%)
TH 4	V2		109 (6.0%)
OM 1	TIIV C1	0.0406 (21.2%)	0.161 (1.8%)
OM 2	TIIV V2	0.117 (13.1%)	0.131 (17.5%)
SI 1	Additive error PK	17300 (8.2%)	5430 (5.2%)

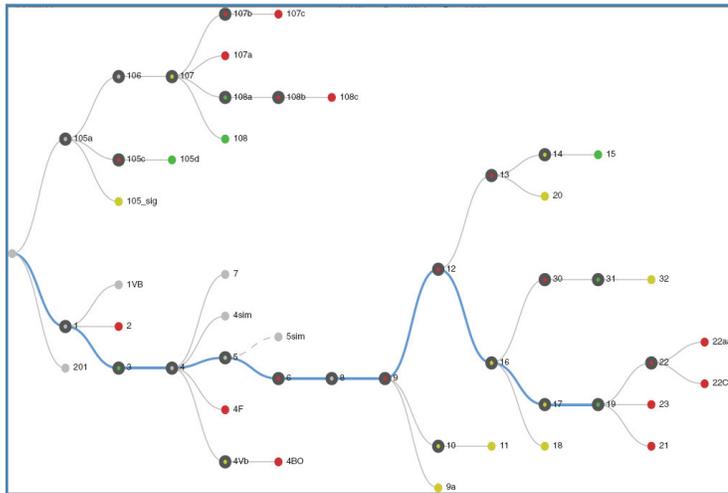
Run statistics	run1
Reference model	run1
Description	2 comp add err
NONMEM version	version 7.4.0
Author	NAME
Dataset	pk001
Records	0L,TH1B,PK,AMT,CONC,MT,PL,LEVEL,V1, V2, C1, C2, SIG, SE, CONT
Ignored rows	
Accepted rows	100
# Individuals	100
# Observations	1100
Output file date	2016-1-26, 13:30:53
Run started	
Run finished	
Table file:	pk002
Table file:	pk002
Attached files:	
Notes in Pirana:	
Comments on model:	None
Model:	E3

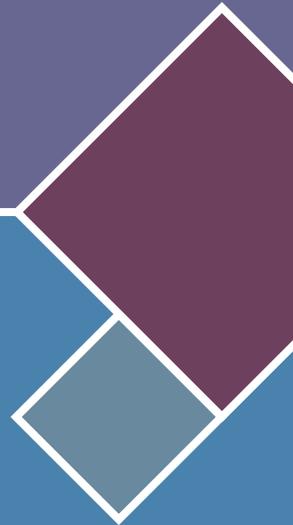
Compare model diagnostics

Pirana provides faster, easier model evaluation and side-by-side model diagnostics to aid in the model development process.

Report and summarize model results

Pirana's powerful reporting tools provide options to run reports in various formats, including Word, html, plain text, LaTeX, and Excel.





About Certara

Certara is a leading provider of decision support technology and consulting services for optimizing drug development and improving health outcomes. Certara's solutions, which span the drug development and patient care lifecycle, help increase the probability of regulatory and commercial success by using the most scientifically advanced modeling and simulation technologies and regulatory strategies. Its clients include hundreds of global biopharmaceutical companies, leading academic institutions and key regulatory agencies.

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