

The Platform of Choice for Drug Metabolism, Pharmacokinetics, (DMPK) and Bioanalysis Study Management

BioBook (E-WorkBook for Biology) is a data management framework that combines the best features of an electronic lab notebook, data analysis tools and LIMS to enhance the productivity of DMPK teams working in an R&D setting. Adept alone or integrated with other industry-standard tools, BioBook provides the platform of choice for study management within one compliant environment.



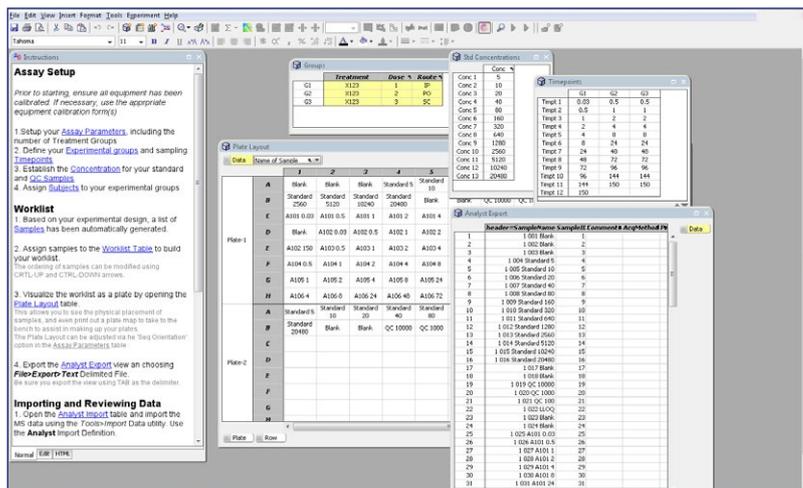
Pharmacokinetics

BioBook has been designed from the ground up to support preclinical research, making it a natural fit for managing pharmacokinetic studies. Its intuitive interface allows for flexible configuration of different study designs: you can add additional dosing arms, sampling times or subjects with a few easy clicks. BioBook's

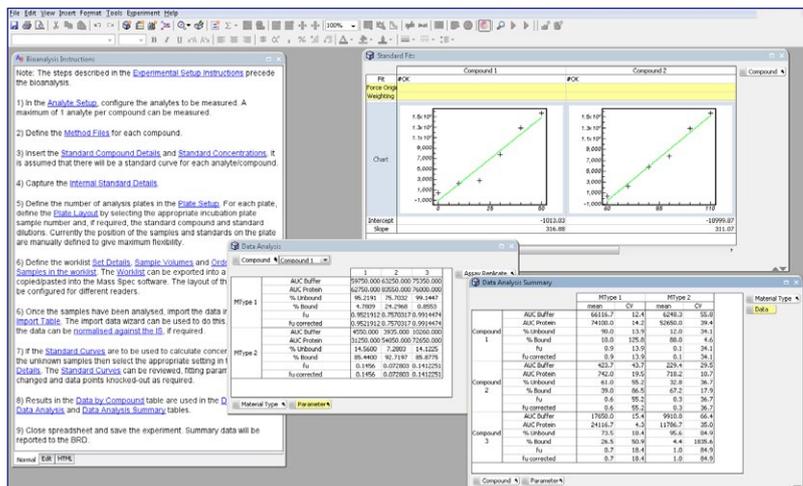
relational model can easily handle complex designs such as multiday dosing, cassette studies and both serial sampling from single subjects or sample pooling from multiple subjects at each time point. Once a study design is complete, BioBook can prepare your dosing and sampling schedule and facilitate sample collection.

Drug Metabolism

As well as delivering advanced preclinical data management BioBook is also a serious in vitro tool that manages plate-based assays just as deftly. BioBook is a proven workhorse when it comes to managing cell permeability, CYP inhibition and stability assays, and can be easily configured for other assay types too. Its multi-dimensional spreadsheets represent plate data with finesse, allowing transparent management of plate layouts, direct instrument data capture and automatic deconvolution of well contents. Its native statistical engine is based on over 15 years of expertise at IDBS, with a library of over 100+ curve-fitting models to leverage. The curve-fitting engine is highly extensible and provides an easy-to-use interface for end users. BioBook is also chemistry intelligent and can be used to define and visualize metabolic pathways derived from metabolite identification studies.



Instruction sheet allows for uncomplicated experimental set up



Advanced and highly extensible in-built statistical analysis and graphing

Bioanalysis

BioBook can either supplement your current LIMS system or provide native functionality of its own. BioBook's inbuilt notebook and analysis tools facilitate the preparation of standards and samples, track your instrument settings and record your analytical methods. Once you are ready for an analytical run, BioBook can translate your study design into a plate map and worklist for export to common platforms such as Analyst®, TurboQuan™

or MassLynx™. When you are finished, quickly load your MS analytical results back into BioBook to take advantage of non-compartmental modeling, or use the fit engine to automate compartmental analyses. Do you work with pharmacologists or toxicologists? BioBook can also help your colleagues with their data management needs and provide a groundbreaking platform for driving PKPD analysis within your business.

Perform non-compartmental analysis within BioBook

The screenshot displays the BioBook software interface. On the left, the 'Assay Setup' panel provides instructions for setting up assays, defining experimental groups, and assigning subjects. The main 'Analysis' window shows a table of parameters for six experimental groups (S-1 to S-6). Below this, a 'Subject Calculations' window displays a 'Subject Data' plot of Log Concentration versus Time (hours) for six subjects (S-1 to S-6). A 'NCA Summary' table is also visible, providing statistical data for three groups: X123 (1 mg/kg by IP), X123 (2 mg/kg by PO), and X123 (3 mg/kg by SC).

	X123 (1 mg/kg by IP)		X123 (2 mg/kg by PO)		X123 (3 mg/kg by SC)	
	Mean	SD	Mean	SD	Mean	SD
Lambda _z	0	0	0	0	0	0
t _{1/2}	31	21	53	9	26	7
C _{max}	8955	387	4638	581	4126	426
C ₀	0	0	0	0	0	0
t ₀	123	38	147	4	123	38
Cl _{CR}	9	6	7	0	5	2
AUC _{0-∞}	68555	2393	66508	8860	51023	7912
AUC _{0-t}	66555	2393	66508	8860	51023	7913
V _{z_obs}	667	473	2312	708	2157	280
V _{z_pred}	15	1	30	4	59	9
V _{z_obs}	667	473	2314	709	2159	283
V _{z_pred}	15	1	30	4	59	9
V _{ss_obs}	185	12	448	55	677	3
V _{ss_pred}	185	11	442	53	668	15

Faster Studies, Quicker Report Turnaround Time

BioBook organizes and stores data in a secure, 21 CFR Part 11, GxP-compliant environment. What's even better is the ease at which this data can be pulled together for fast reporting. BioBook will allow your organization to reduce the cycle time from study inception to report creation, and create a secure searchable archive that will become an invaluable asset for your entire R&D organization.

The screenshot displays the BioBook software interface. On the left, a 'Navigator' tree shows a hierarchical view of the study data. The main window shows a 'PK Chart' with a linear plot of Log Concentration versus Time (hours). Below this, a 'Subject Calculations' window displays a 'Subject Data' plot of Log Concentration versus Time (hours) for six subjects (S-1 to S-6). At the bottom, an 'Analysis' window shows a table of parameters for six experimental groups (S-1 to S-6).

	S-1	S-2	S-3	S-4	S-5	S-6
Extravascular	Extravascular	Extravascular	Extravascular	Extravascular	Extravascular	Extravascular
AUC Method	Linear	Linear	Linear	Linear	Linear	Linear
Weighting	Uniform	Uniform	Uniform	Uniform	Uniform	Uniform
Lambda _z Start	72	72	72	72	72	72
Lambda _z End	1000	1000	1000	1000	1000	1000
Dose	2	2	2	2	2	2
Group ID	X123 (1 mg/kg bX123 (1 mg/kg bX123 (2 mg/kg bX123 (2 mg/kg bX123 (3 mg/kg bX123 (3 mg/kg b					
Lambda _z Fit	#OK	#OK	#OK	#OK	#OK	#OK
C ₀ Fit	#OK	#OK	#OK	#OK	#OK	#OK
Rsq	1.0000	0.2903	0.7649	0.6517	0.6673	1.0000
Rsq_adj	#DIV/0!	0.5075	0.5297	0.4775	0.5009	#DIV/0!
Corr_XY	-1.0000	-0.9687	-0.8746	-0.8073	-0.8169	-1.0000
Number of Points	2	4	3	4	4	2

Study reports can be generated in a matter of minutes – giving users more time to focus on decision-making



About IDBS

IDBS is a leading global provider of advanced software for research and development (R&D) organizations to securely capture, manage, share and exploit structured and unstructured data.

Our technology and domain expertise enables users to link data to data, data to people and people to people to drive innovation, achieve faster time to market and improve margins.

Our diverse customer list includes R&D driven international companies in pharmaceuticals, biotechnology, agricultural sciences, chemicals, consumer goods, energy, engineering, food and beverage, and healthcare.

Founded in 1989 and privately held, IDBS is headquartered in the United Kingdom with offices across Europe, Asia and the United States.