Study management in late stage discovery and preclinical research

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Abstract

Increasingly organizations need to streamline their operations by managing the entire lifecycle of an experiment - from design, through data capture and analysis and study report creation to final publication of data - all within one environment. Organizations require the full benefits of IP protection, with the ability to access a solution for data capture, reduction, statistical analysis, charting and data curation. Researchers want a familiar notebook interface that they can use to create and manage study reports and publish data to corporate warehouses and document systems. IDBS introduces BioBook™, addressing these researchers' needs.

Introduction

There are some similarities and, conversely, differences between late stage discovery and preclinical areas of pharmaceutical research. Similarities exist between research processes and the types of experiments conducted. Differences lie in the specifics of how the research is conducted and the regulation of the research.

Late Stage Research

- Efficacy testing
- Early ADME & DMPK
- PK/PD (Pharmacokinetics and Pharmacodynamics)
- Non-GLP safety
- Toxicology and side effect profiling

→ Typically *in vitro* and *in vivo* assays
→ Typically do not work to GLP standards
→ Flexibility may not be as important as compliance and validation
→ Assays often more dynamic or 'loosely' defined
→ Researchers work within the project group

Pre-clinical Development

- Toxicology
- Safety sciences
- Pharmaceutical sciences (formulation)
- Pharmacokinetics
- Metabolism

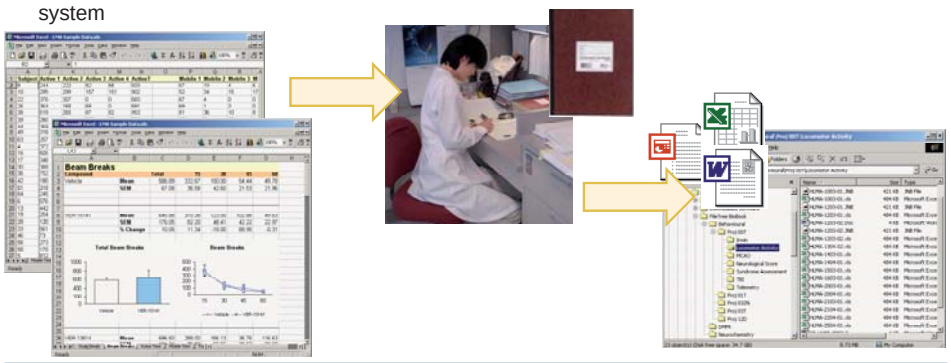
→ Typical *in vivo* assays
→ Typically work to GLP standards
→ Assays are more routine and prescribed
→ Compliance and validation critical
→ Researchers work within a specific area, e.g. safety sciences

BioBook is a solution that works in both of these areas, providing the flexibility required for late stage discovery researchers, while allowing the process and validation to be regulated in the preclinical area with additional 'compliance options'.

Currently

Typical workflow for experimental data management

→ Capture and analyze data using multiple applications, such as Microsoft® Excel, Prism or SAS/JMP
→ Print, cut and paste selected data into a paper lab notebook
→ Transcribe selected data into summary 'reports' in Excel, Word or PowerPoint for dissemination via email
→ Save both the source and report files on a shared fileserver
→ Upload selected results to corporate data warehouse, and reports to document management system



Solution to the problem - BioBook

User interface designed to look like a notebook

→ Experiments organized using a configurable hierarchical structure
→ 'Lab notebook' editor for experiment data collection & curation
→ Ideal for contextual data entry
→ E-signature and witnessing framework for 21 CFR Part 11 compliance
→ Report creation

Biologically 'intelligent' spreadsheets

→ Data capture, reduction, statistics, charting and data curation
→ Rapid creation of flexible templates without the need for programming

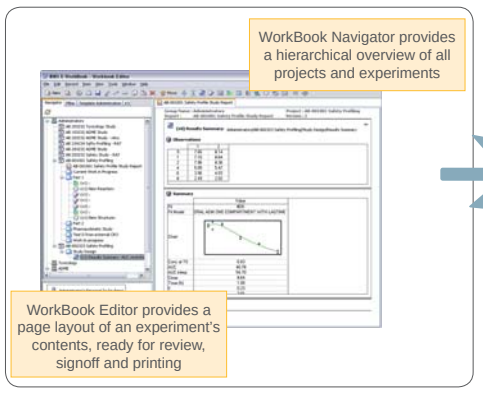
Oracle database

→ Security, compliance, data storage and search capabilities

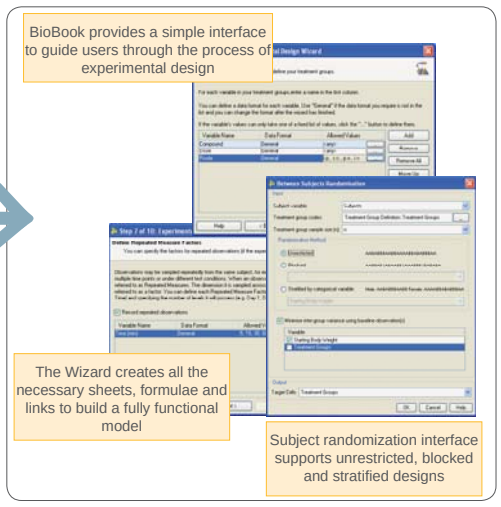
Components for integration with third party corporate databases/warehouses

→ Integration with compound registry and dictionaries. Publication of selected data to corporate data

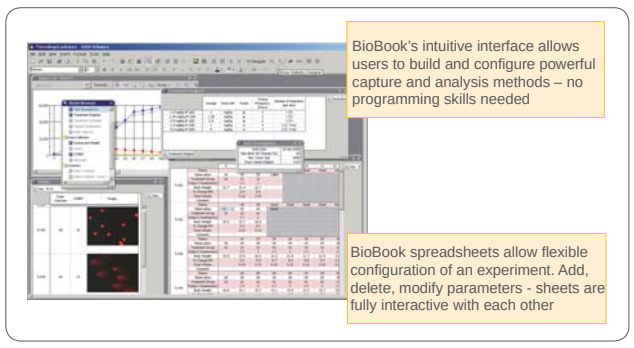
BioBook supports the workflows associated with complex studies in one integrated environment



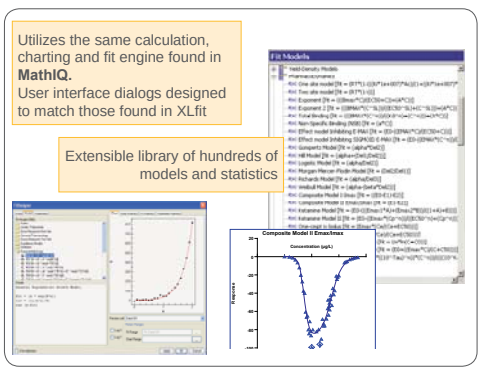
Study Management



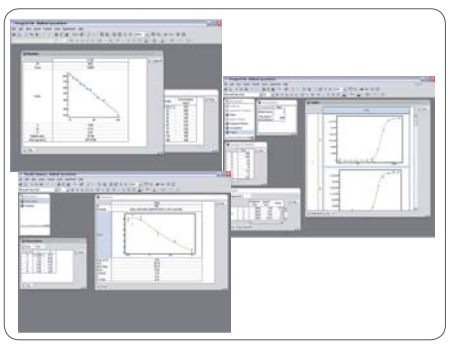
Experimental Design Features



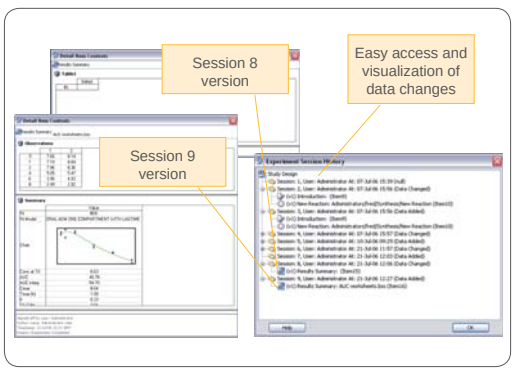
BioBook Spreadsheet interface



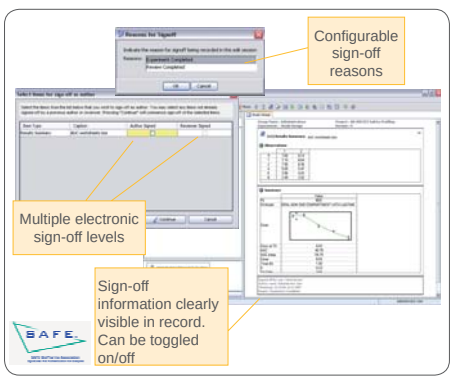
Integrated Statistics and Data Analysis



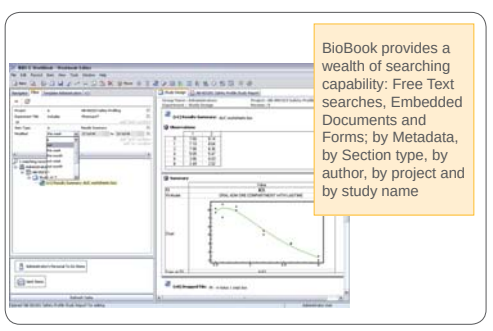
Graphing and Visualization



Compliance and Auditing



Study Report and Signoff



Data and Knowledge Mining

Conclusion

BioBook delivers complete late stage discovery and early preclinical research data management.

- **Bench Scientists:** Increase bench and library time by reducing data analysis and lab notebook write up burden
- **Team Leaders:** Reduce time spent preparing reports. Strengthen decision-making support. Facilitate report creation
- **IT:** Reduce infrastructure cost and complexity
- **Business:** Improve security, integrity and organization of data. Provide data store of knowledge of late stage compounds as a resource to facilitate clinical candidate selection

One integrated framework for all your discovery data

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