StudyGen 360

StudyGen 360 Reporter
The Standard Reporting for Watson LIMS™



Study Reporter

- Support for Watson™ 7.7.X
- Seemless integration with MS SHAREPOINT
- Watson™ study archiving
- Enhanced sample reconciliation
- Flexible template builder
- Improved integration and performance
- Solution catalogue of experiments
- Traceability, eSignatures and AuditTrails
- CRO specific workflow support

Automate Watson LIMS™ Reporting — GxP-compliant Reports at the Push of a Button

Increasing reporting efficiency is the most promising approach to realize the greatest potential savings in bioanalytical laboratories. The creation of bioanalytical study reports for submission today is tedious and time-consuming. It requires a severe amount of manual processes. Most information in these reports has to be copied manually from data management LIMS Systems (e.g. Thermo Scientific™ Watson LIMS™) and supporting systems such as ELN, SDMS, MS EXCEL into the final document, and it then has to be double-checked line by line to ensure data integrity, a task just as time-consuming as the copying itself.

StudyReporter Bioanalytics improves time-to-market by delivering submission-ready reports through an automated process, directly interfacing with the various lab data management and supporting sytems.

ICH M10-ready Reports within Minutes

By making use of StudyReporter Bioanalytics almost all manual activities, including the time-consuming data recheck, are eliminated and thus, the processing time is reduced significantly. As a result tox-, analytic- and validation GxP-study reports are available within minutes; laboratory resources will be used in an optimal way. An integrated interface to *Sciex Analyst© Software* allows an automated embedding of relevant chromatograms into the final MS WORD report as protected graphics. These can be selected flexibly per report. To ensure consistency between the submission report and the CDISC "Standard for Exchange of Nonclinical Data" (SEND), an export interface is provided.

Intuitive Guidance Through The Report Creation Process

The application is designed similar to the MS-Windows Explorer to guarantee an intuitive handling of the software. The ability to create an individual structure, based on report

properties, ensures that it fits to any personal needs and preferences. An easy to use wizard supports the definition of the specific content and intuitively guides the user through the report creation process.
StudyReporter Bioanalytics relies on the MS Office Suite. This allows leveraging established operations, which ensures a high user acceptance and a reduction of training effort for any new user.

Secure and Traceable to the Origin

Each report created with StudyReporter Bioanalytics is reproducible. Well-established document management functionalities, such as versioning, audit trails and eSignatures, ensure that any item of information on the report is easily traceable to its origin. Unintended changes are avoided entirely.
An integrated "Document-Life-Cycle" feature guarantees that business and QA demands for the document review, the finalization, and approval workflow can be mapped easily.

Seamless Integration of IT

By providing an easy to use wizard, all aspects of the report purpose are defined at creation time (e.g. specification to use). The report is based on customer defined MS WORD templates that meet the demands of latest regulatory guidelines, while addressing individualized client requirements.
The solution ensures the valid transfer of data to MS WORD and provides integrity by protecting data sections against unintentional changes, while allowing an option for manual amendments.

StudyReporter Bioanalytics integrates with any IT environment due to its innovative *RemoteCollector* technology. Established systems like LIMS, ELN, SAP, SDMS, and legacy systems can be integrated and linked to each other, while addressing common issues using the integrated Master-Data Management functionalities. As a result data from a multitude of IT systems is seamlessly combined into a submission-ready bioanalytical study report.

Human-Readable Archiving Option

StudyPlus Archive delivers a human-readable study archiving mechanism, strictly based on regulatory authority requirements, allowing long-term data access and processing without special knowledge or access to the Watson™ software.

Established in Regulatory Lab Environment

StudyReporter Bioanalytics has been developed in close co-operation with global pharmaceutical companies and CROs based on market-specific requirements.
Thus, a lot of leading enterprises around the world rely on the StudyGen 360 product family.

At a Glance

- Automated "out of the box" regulatory reporting
- Comprehensive set of bioanalytical standard tables
- ICH M10-readiness in bioanalytic reports
- Protected tables supporting graphics, statistical calculations, and multi-analyte layouts
- Scientific amendments can be included easily
- Validated data transfer from bioanalytical data management systems; Thermo Scientific™ Watson LIMS™ access is available as a standard interface
- No manual steps, no transcription errors: a controlled process that substantially reduces the data cross-check required
- Secure and fully auditable through eSignatures and audit trails
- Seamless integration with IT infrastructure and document management systems
- *Sciex Analyst© Software* interface to easily integrate chromatograms
- Human-readable study archiving with full lifecycle management and built-in integrity protection

Ready to Experience the Power and Efficiency of StudyGen 360?