StudyGen 360

StudyGen 360 Reporter
Automated Bioanalytical Reporting – GxP-Ready, Regardless of Data Source



Study Reporter

- One platform for any data source, whether your lab runs a LIMS or not
- GxP-compliant management of study-related data
- Report-generator for submission-ready bioanalytical reports
- Preconfigured tables aligned with ICH M10 and FDA guidance
- Protected tables, supporting graphics, statistical calculations, and multi-analyte data
- End-to-end solution: no manual copy-and-paste or formatting work
- Support for LC-MS and LBA studies, including PK, ADA, biomarker, and immunogenicity assays
- 21 CFR Part 11 compliant: versioning, audit trails, eSignatures, and CDISC SEND export
- Full sample management available through StudyLab, including direct instrument integration

The Cost of Manual Reporting

Handling study sample data and preparing bioanalytical study reports for submission is extremely tedious and time-consuming. Most incoming sample and study-related information end up in MS EXCEL spreadsheets, collected by hand and copied from various sources into the final MS WORD document. Because that data is copied and re-entered manually, the final report must be double-checked line by line, and special precautions must be taken into account to keep those MS EXCEL sheets safe and traceable.

One Reporting Platform, Any Data Source

Whatever your lab already has in place - an existing Watson™ LIMS, a different LIMS, or no LIMS at all, StudyReporter Bioanalytics can take that data and turn it into a submission-ready report.Labs running Watson™ are connected to StudyReporter. Labs using any other LIMS bring their data in through StudyConnect. Labs without a LIMS have two options: a simple Excel upload for straightforward cases, or StudyLab, our integrated application for full sample management and tighter control.As a result, a compliant report can be generated end-to-end, whatever the starting point is.

Consistency by Design

Reports, tables, and graphs in StudyGen 360 are built on configuration, not fixed templates. Once you define and save a configuration, you can reuse it for any report that needs it, so a validated setup always produces the same result and speeds up QC-checks. Configurations can include protected tables for graphics, statistics, and multi-analyte data, with a preconfigured ICH M10- and FDA-aligned set as a starting point; you can add new tables as a study evolves without rebuilding what already works. This same configuration model is what makes StudyAI possible, generating new tables and graphs from a plain-language request rather than a manual build.

ICH M10 Ready Reports Within Minutes

With study-relevant data already captured, whichever path it took to get there, StudyReporter Bioanalytics removes the manual activities that would otherwise sit between that data and the final report. This end-to-end handling protects data integrity and significantly reduces the need for additional manual cross-checks. As a result, processing time for study reports drops dramatically, with full reports available within minutes rather than days. An export interface is also provided to keep the submission report consistent with CDISC's Standard for Exchange of Nonclinical Data (SEND files).

One System, Every Study Type

Whether the work is a PK, ADA, biomarker, immunogenicity, or stability study, StudyReporter Bioanalytics supports it on both LC-MS and LBA platforms. Because reporting is built on configuration rather than fixed templates, the same engine adapts to whatever combination of study type, platform, and assay a lab is actually working with, and new configurations can be added as that work evolves, rather than waiting on a fixed list of what's supported.

Intuitive Guidance Through the Report Creation Process

The application is designed to guarantee intuitive handling. An easy-to-use report creation dialog lets users define specific content and guides them through the process. The report is based on customer-defined MS WORD templates that meet the latest regulatory guidelines while addressing individual client requirements.

StudyReporter Bioanalytics provides a valid and secure transfer of study data to MS WORD, ensuring data integrity by protecting results tables against unintentional changes while still allowing manual amendments below the table sections.

Human-Readable Archiving Option

Each activity in the StudyGen 360 application family is reproducible. All data functionalities rely on versioning, audit trails, and eSignatures, so any item of information stays easily traceable to its origin, and unintended changes are prevented from happening in the first place.

As a cloud-based platform, StudyGen 360 gives each user a level of access matched to their role and, where appropriate, lets a sponsor connect directly to follow a study's data in real time. The platform is administered in a GxP-compliant manner, and we provide full documentation and support for your own validation effort, significantly reducing the work required on your side.

StudyLab: Full Sample Management for Labs That Want More

StudyLab adds full sample management on top of the reporting engine: shipment reconciliation against the expected manifest, barcode-based sample identification, cryo-storage location mapping, and dilutions or aliquots linked back to the parent sample. It also builds the analytical run layout for a batch and exports it directly to the instrument, then follows reanalysis and incurred sample repeats through to resolution. Every step is captured in a 21 CFR Part 11-aligned audit trail, so physical sample handling stays just as traceable as the report it feeds into. It's there for labs that need that level of physical sample control, optional for everyone else.

At a Glance

- Watson™, another LIMS, or none at all - one platform either way
- MS EXCEL upload, or full sample management through StudyLab
- Configurations save and reuse, so QC-checks deliver the same validated setup every time
- StudyAI builds new tables and reports directly from a plain-language request
- Full reports in minutes, not days, with CDISC SEND export built in
- 21 CFR Part 11: versioning, audit trails, eSignatures; all captured automatically
- Cloud-based, with role-based access and real-time sponsor visibility

Ready to Experience the Power and Efficiency of StudyGen 360?