

Data Management Platform for Clinical Studies



up to data

StudyGen 360 – From Lab Data to Submission. In One Platform.

StudyGen 360 unites all study data in one compliant platform, from sample to submission-ready report. StudyLab controls, documents, and automates the entire sample lifecycle at the lab level, while StudyConnect links LIMS, ELN, CDS, and Instruments. StudyReporter turns data into submission-ready reports in minutes. And with StudyAI, you create custom tables on the fly, simply by asking. The result: no copy-paste, end-to-end data integrity, full 21 CFR Part 11 alignment, seamless sponsor-CRO collaboration, and up to 70% less time per study.

Connectivity

- Connects LIMS, ELN, CDS, SAP, and instruments.
- Works with or without a LIMS.
- No spreadsheet calculations, no copy-paste.

Time-Saving

- End-to-end traceability in line with ALCOA+.
- No copy-paste, far fewer manual cross-checks.
- Full audit trail and e-signatures.

Compliance

- 21 CFR Part 11 alignment with GAMP 5 validation support.
- ICH M10- and FDA-ready templates.
- SEND export included.

Collaboration

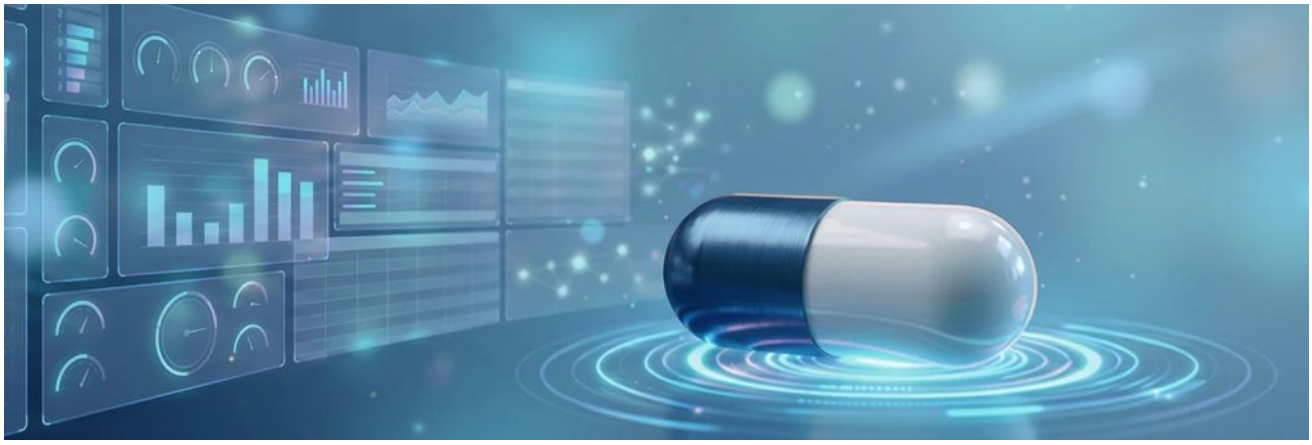
- Transparent sponsor-CRO data exchange.
- Sponsor template management.
- Simplified sponsor audits.

Flexibility

- SaaS, cloud, hybrid, or on-premises.
- Pay only for what you use.
- Think big, work smart.

Speed

- Reports in minutes, not days.
- Up to 70% faster study completion.
- Study results available on demand.



The StudyGen 360 Modules

Six Applications – One Platform

Study Lab

StudyLab follows every sample from shipment receipt through barcode identification, storage, and aliquoting, with a complete chain of custody in one compliant system. Assay layouts and sequence files can be created and sent directly to the instrument, and each finalized run is automatically checked against its acceptance criteria before its data flows into StudyGen 360's reporting.

Study Reporter

Every successful clinical trial ends with a high-quality, compliant study report, yet meeting regulatory standards still costs the industry valuable time and resources. StudyReporter transforms this by digitalizing and automating study report generation, removing manual steps and significantly shortening time to market.

Study AI

StudyAI, the built-in assistant of StudyGen 360, turns plain-language requests into tables, graphs, and report structures, in real time and without a developer. Each configuration is verified against an anonymized seed data set, and source data stays visible for fast, audit-trailed human review. The AI builds from the structure of the data, such as column names and formats, while the results themselves stay inside StudyGen 360.

Study Insight

StudyInsight is a shared environment where sponsor and CRO contribute to and review the same study data. Sponsors see quality across the whole study instead of batch by batch, with trends across studies and over time, guided by a risk-based oversight plan for each CRO, while every issue is tracked to resolution with an auditable history per CRO. Every oversight decision and exchange is documented.

Study Plus

StudyPlus Archive converts Watson LIMS™ study data into a human-readable archive in open formats (PDF, CSV and JSON), fully independent from the source system, so Watson™ itself can be retired. Aligned with FDA 21 CFR Part 11, all study data and metadata remain complete, traceable, and audit-ready. SHA-256 hashing makes any change detectable, in an archive designed to last 25+ years.

Study Connect

StudyConnect brings data from LIMS, ELN, CDS, SAP, files, and analytical instruments together in one platform, in the cloud or on-premises, transferring it securely and without manual re-entry. Analytical parameters are checked in real time as the data arrives, and every connection is recorded in an immutable audit trail, in line with ALCOA+ principles, so lineage stays traceable from source to report.

About

up to data, founded in 1992, is an international provider of innovative, customizable IT solutions for the Life Sciences, pharmaceutical, chemical, and biotech industries, with offices in Europe, North America, and Asia-Pacific. Its product offerings include lab data management and data review applications, as well as report-writing solutions, brought together on its data management platform, StudyGen 360. The platform delivers GxP-compliant study reporting, helping labs meet pharmaceutical regulatory requirements.

Through long-term partnerships with industry leaders, up to data ensures that its solutions support the latest technologies while meeting each customer's requirements. Whether working on early-stage drug development, vaccine research, or stability studies, up to data delivers solutions that integrate seamlessly into existing workflows and support individual processes, helping significantly improve time-to-market through automated workflows.

Compliance & Security

Security and data integrity are essential to good scientific and laboratory practice. Our solutions support compliance with GxP requirements, ISO 17025, and FDA 21 CFR Part 11. up to data's quality management system is certified by DQS according to DIN EN ISO 9001:2015.

Standard DIN EN ISO 9001: 2015 certified

GxP-validatable solutions & GxP-validation support

GMP, ISO 17025 & FDA 21 CFR Part 11 compliant

Partners

We maintain long-term partnerships and work with the best in the industry. This ensures our solutions support the latest technologies and meet our customer's individual requirements.

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