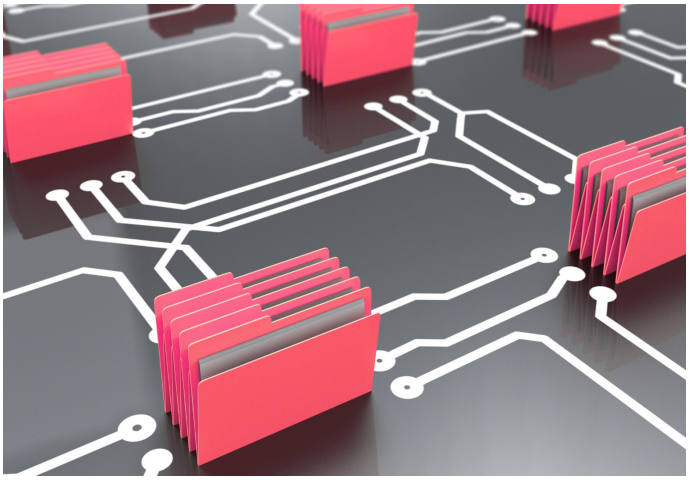
StudyGen 360

StudyGen 360 Plus
Archiving Solution - From Active Study to Long-Term Retention



Study Plus

- Three-stage lifecycle: Active, Archived, Deactivated
- Automatic read-only enforcement
- Single-click, machine-readable archive export
- PDF/A, CSV & XML output (StudyPlus Archive)
- Human-readable archive, no proprietary viewer needed
- SHA-256 tamper-evident integrity
- Validation support aligned with GAMP 5 principles
- Build to 21 CFR Part 11 & EU GMP Annex 11 principles

Three Lifecycle States, One Compliant Pipeline

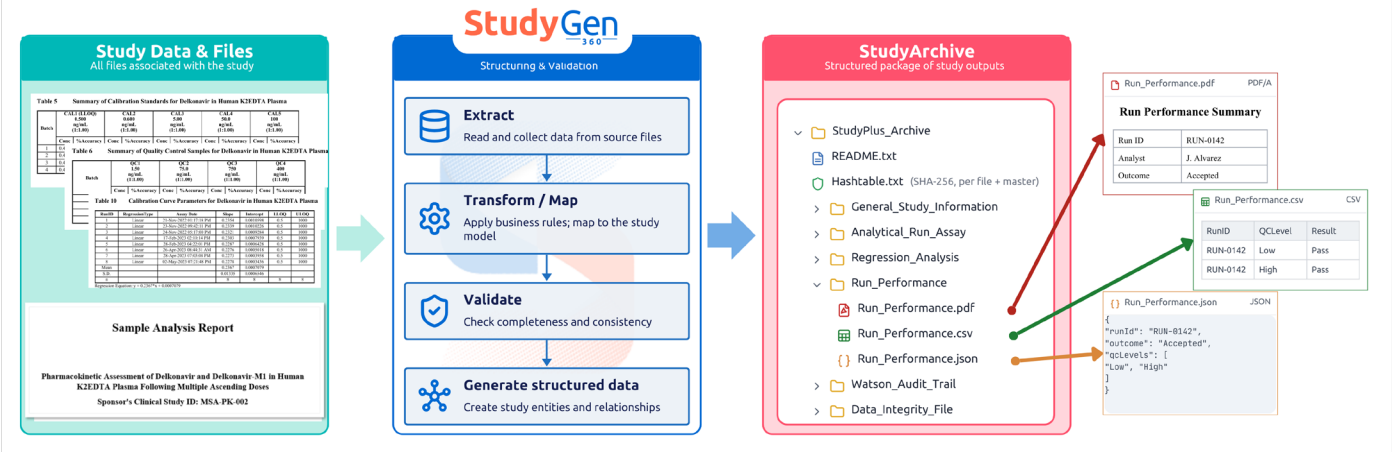
Every study in StudyGen 360 moves through three lifecycle states: active while it's being worked on, with full edit access; archived once it's complete and preserved for regulatory compliance; and deactivated when it's removed from active use. Archived and deactivated studies are automatically enforced as read-only to prevent accidental modifications, and every status change, including who made it, when, and why, is captured in the audit trail. A single click then generates a tamper-proof, machine-readable export package containing the complete study data, its full context, and metadata, structured to plug into enterprise document management systems.

StudyPlus Archive: Independence from Watson LIMS™

For labs running Thermo Scientific Watson LIMS™, StudyPlus Archive builds a complete, human-readable archive of Watson™ study data with no dependency on Watson™ once the archive is generated. It's designed to remain accessible for a twenty-five-year-plus retention period using only standard tools, which matters most in two situations: decommissioning Watson™ in favor of a newer LIMS platform, or consolidating systems after a merger or acquisition, when two Watson™ instances end up doing the same job, and neither can be retired without a compliant archive already in place.

Six Report Types, Inspection-Ready

Every archive run generates the same six structured report types, each delivered in PDF/A for human reading, CSV for Excel-based analysis, and XML for system-to-system import: general study information, analytical run assay details, regression analysis, run performance statistics, the complete Watson LIMS™ audit trail, and a dedicated data integrity file. Once an authorized inspector has access, no Watson login, specialist software, or someone in the room is needed to



navigate it: calibration parameters, QC performance, the audit history, every layer of the study is already there, readable as-is. That's what ALCOA+ means by a record staying enduring and available: readable on its own, for as long as it needs to be, without depending on the system that created it.

Tamper-Evident by Design

Every archived file gets its own SHA-256 hash, tied together by a master checksum and a hash of hashes, so any change to any byte is detectable within seconds. The archiving process itself is built to ISO 9001:2015 and GAMP 5 principles, and we provide full documentation and support for your own validation effort, rather than a pre-qualified package.

Why This Matters

For small CROs, moving to this kind of automated, compliant archiving typically cuts manual archiving effort by 70 to 80 percent and enables a lab to manage a much larger portfolio of completed studies without adding headcount. For enterprise customers, the machine-readable format cuts custom integration effort with corporate archiving systems and data lakes by about 60 percent and turns audit preparation from days of manual compilation into instant retrieval of a complete study package.

Two Moments This Becomes Strategic

The value shows up most clearly in two situations. The first is LIMS decommissioning, especially after a merger, when an old Watson™ instance is still consuming license, infrastructure, and IT support costs for studies nobody is actively working on anymore. The second is a compliance review, where 21 CFR Part 11 and EU GMP Annex 11 both require accurate, complete, human-readable records to be available throughout the full retention period, not just for as long as the originating software happens to still be supported.

At a Glance

- Three-state study lifecycle: Active, Archived, Deactivated
- Automatic read-only enforcement
- Full audit trail: who, when, why
- Machine-readable, enterprise DMS-ready export
- PDF/A, CSV and JSON from a single archive run
- Human-readable, no proprietary viewer needed
- Designed for 25+ year retention: enduring and available, in ALCOA+ terms
- SHA-256 hash-of-hashes integrity
- Documentation and support for your own GAMP 5 validation

Ready to Experience the Power and Efficiency of StudyGen 360?