StudyGen 360

StudyGen 360 StudyLab
Smart Sample Lifecycle Management for Bioanalytical Science



Study Lab

- 21 CFR Part 11-aligned sample pipeline
- Automated manifestreconciliation & discrepancy flagging
- 2D/1D barcode scanning & cryo-storage rack mapping
- Dilution & aliquot tracking to the parent sample
- Automated CAL/QC-sequence construction
- Native worklist export to LC-MS/MS & LBA platforms
- Automated 4-6-20 rule and ISR-evaluation
- Role-based access, including real-time sponsor visibility
- Organized by project and study
- Direct feed into StudyGen 360 reporting

From Specimen Receipt to Audited Bioanalytical Report

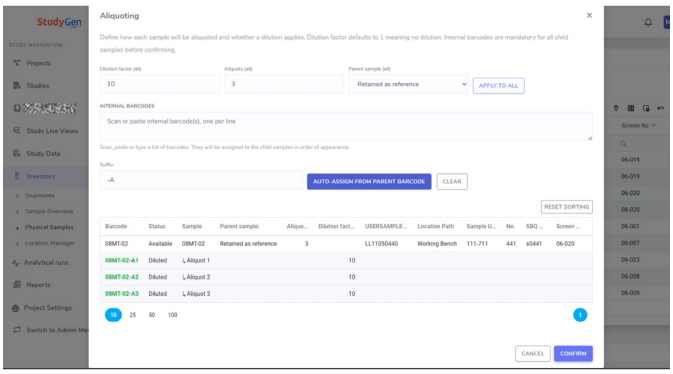
StudyLab is the core operational module within StudyGen 360, engineered to manage the bioanalytical sample lifecycle. From clinical and preclinical accessioning and reconciliation to automated analytical batch creation and direct instrument communication, StudyLab enforces a complete chain of custody and data integrity. By capturing sample metadata and analytical results in a single, GLP-aligned database, StudyLab feeds validated data into StudyGen 360's automated report-generation engine.

Built Around the Full Chain of Custody

The same system tracks every stage. Incoming shipments are automatically matched to their manifests upon arrival, and the system flags any discrepancy or temperature excursion immediately, not after the fact. Samples are identified throughout by 2D or 1D barcodes and mapped in real time across freezers, racks, boxes, and well positions, so cryo-storage location is always known. When a sample is diluted or aliquoted for further testing, the derivative is automatically linked back to its parent sample, so the full history of a specimen, not just its original tube, remains traceable. When it's time to analyze, StudyLab builds the full run layout, including standards and calibrators, quality controls, blanks, and randomized study samples, and exports a native worklist directly to the analyzing instrument, whether that's an LC-MS/MS platform or an LBA-reader.

Organized by Project and Study

StudyLab's data structure mirrors how a CRO works: everything is organized by project and, within it, by study, so samples, runs, and results are always seen in the context of the work they belong to rather than as one undifferentiated pool of data. The same structure controls access, so a user or sponsor only sees the projects and studies they've been granted access to.



Eliminates Post-Hoc Data Reconstruction

Traditional workflows rely on disjointed spreadsheets, paper shipping manifests, and isolated freezer logs. StudyLab replaces this fragmented chain with a single, 21 CFR Part 11-aligned pipeline. StudyLab logs every sample status update, storage transfer, and freeze-thaw cycle in real time, eliminating the manual reconciliation typically required to assemble the final study report.

Streamlined Analytical Sequence Construction

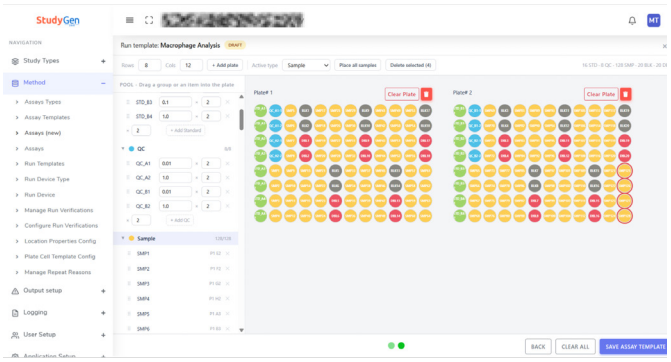
Building complex analytical runs for PK, ADA, or biomarker assays require precise placement of calibration curves and quality control samples. StudyLab automatically generates complete analytical sequence layouts, reduces setup time, and exports native worklists directly to your analytical software.

Automated Run Evaluation and Reanalysis Tracking

After batch completion, StudyLab ingests raw and processed data and automatically evaluates them against predefined bioanalytical acceptance criteria, including the 4-6-20 rule and calibration curve acceptance. If a run or sample fails or requires Incurred Sample Reanalysis or repeat testing, StudyLab logs the exact reanalysis reason code, such as exceeding the upper limit of quantitation or an internal standard response failure and tracks the repeat sample through final resolution.

Role-Based Access, Including the Sponsor

As a cloud-based system, StudyLab gives every user access level matched to their role, from lab technicians and analysts through to lab management and QA. Where appropriate, sponsors can be given their own access to connect directly to the system and follow their study's data in real time, rather than waiting for a scheduled update. Every action any user takes, regardless of role, is captured in the audit trail, so the system stays fully traceable end to end. StudyLab is configurable to the compliance level a lab actually needs, whether that's a fully regulated GLP-environment or a simpler R&D setting, without forcing either one into a workflow built for the other.



At a Glance

- Clinical & preclinical accessioning
- Manifest reconciliation & discrepancy logging
- Barcode scanning & cryo-storage mapping
- Dilution & aliquot tracking
- Automated CAL/QC-sequence building
- LC-MS/MS & LBA instrument interfacing
- 4-6-20 rule & ISR-tracking
- Role-based access & real-time sponsor visibility
- Organized by project & study
- Full audit trail traceability
- Configurable: GLP through R&D
- Draft, staging & final report generation

Ready to Experience the Power and Efficiency of StudyGen 360?