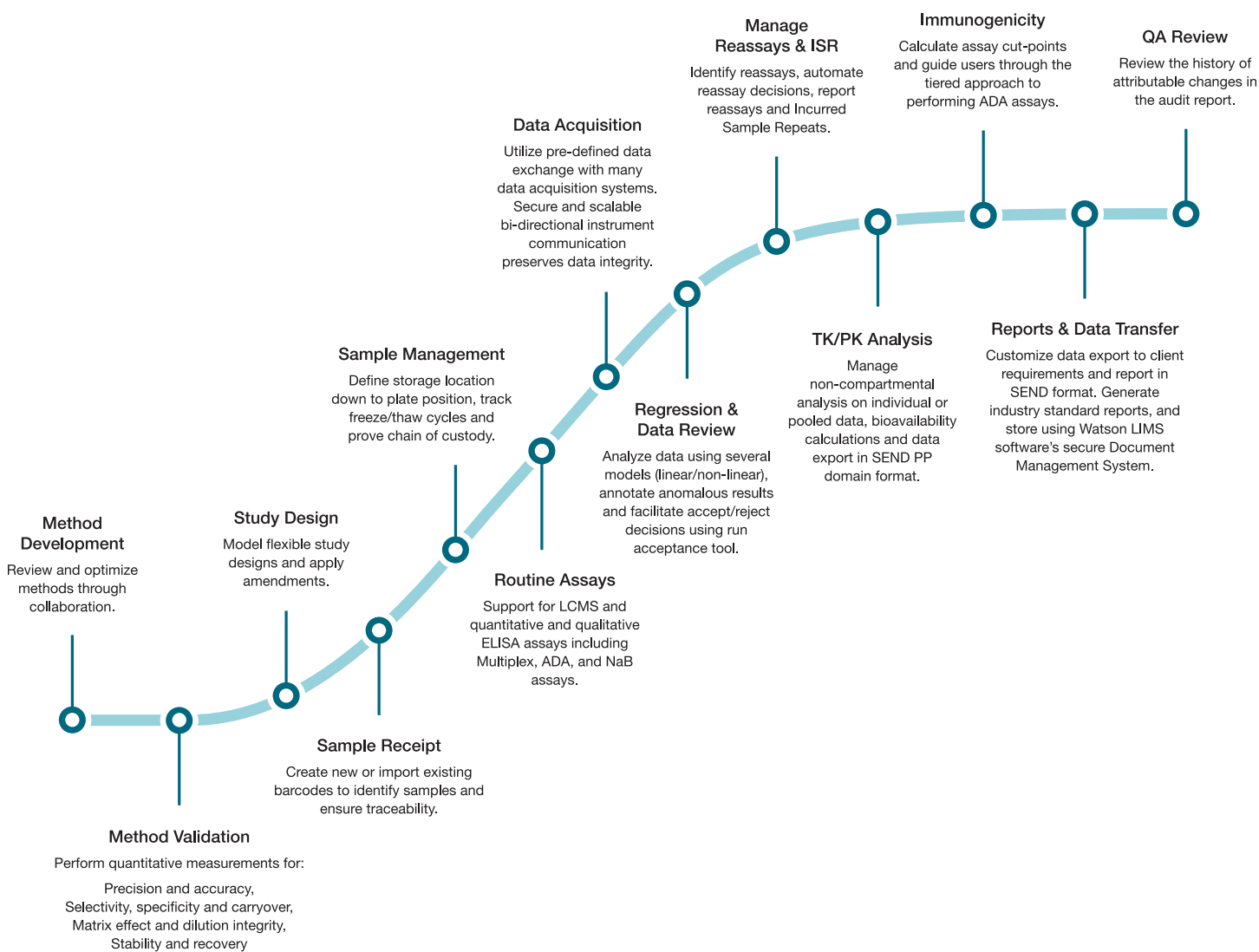


Thermo Scientific Watson LIMS software

Built for bioanalysis

Watson LIMS software is specifically designed and built to support the bioanalytical workflow, allowing users to:

- Harmonize laboratory processes across all sites
- Ease exchange of information between sponsors and contract labs
- Increase throughput by automating data handling and reporting tasks
- Promote compliance throughout the workflow
- Implement quantitative concentration assays or qualitative immunogenicity assays
- Track study sample history from receipt to disposal



Compliance throughout the entire workflow

- The **Reassay Decision Matrix and Run Acceptance Template** assist users to comply with SOPs, reducing the risk of non-compliance. Decisions are automated according to pre-configured criteria, but allow the user to override when required.
- System and study access is granted to authorized users only. Role-based access ensures only authorized actions can be performed by users, in accordance with Good Laboratory Practices.
- Audit trail records are stored in the database, readily retrievable for review and outlining all events performed in the system.
- Electronic signatures record user identity, time/date stamp and reason for save, as required by 21 CFR Part 11.
- Lockout/logout timers are configurable for periods of inactivity, requiring a user to reenter their username and password to regain system access.
- Watson LIMS software was designed to enable compliance with 21CFR58, FDA Bioanalytical Method Validation guidance documents, and EMA guidance documents.

Watson LIMS software is ready to help manage bioanalytical studies, from initiation through archival, working to industry and regulatory standards. The software was designed with a deep understanding of the bioanalytical workflow and regulations. Principal Investigators, scientists and analysts are all able to move logically through each step in their workflow, simplifying bioanalytical support for nonclinical and clinical studies.

Study design and sample management

Dynamic study design simplifies study setup with groups, treatments and biological matrices, for both blinded and unblinded studies, modeling the preclinical and clinical trial process. Since bioanalytical studies evolve around real world incidents, studies can easily be amended by adding or removing samples as required to reflect protocol amendments or unscheduled events. The **Design Reconciliation** feature also provides a way for Principal Investigators to document and correct sample manifest discrepancies all within one software system.

Pharmaceutical companies and CROs worldwide adopt Watson LIMS software as it provides a standardized way to work, ensuring seamless data collaboration and reporting.

Compliance checks and audits are made easier, since a sample is easily identified using barcodes, which can be added from external sources as well as created by the system. Location changes can be tracked using barcodes and electronic signatures. The product facilitates the creation of labels according to study requirements, and storage facilities can be displayed and barcoded to ease identification and traceability. The product also supports the use of 2D barcodes.

Analysts can quickly and easily move samples from a sample manifest into a new storage location. Principal Investigators can recreate the lifecycle of a sample in Watson LIMS software using various entities to see where the sample was stored, who handled the sample, report freeze/thaw cycles, demonstrating a complete chain of custody from sample receipt to archival and disposal.

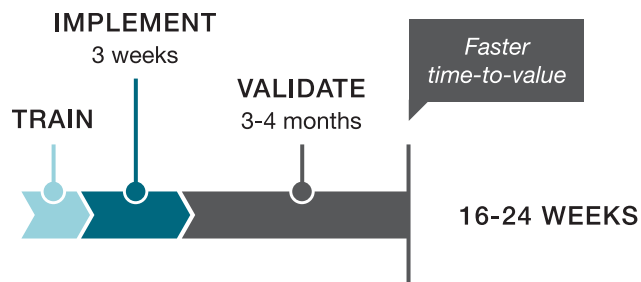
“Watson [LIMS software] is an essential element to providing a quality bioanalytical service. It is the single point of control, ensuring that samples received have a chain of custody and an unambiguous analysis pathway to deliver the final concentration results.”

– Stuart McDougall, Bioanalysis Leader, Arcinova

Fast implementation and expert support

Laboratories installing the software get more than just an industry-proven software package. Our team of experts not only understand the complex requirements of a bioanalytical lab, they also have the knowledge and experience required to ensure every implementation is a success.

Established processes and templates mean that customers are up and running far faster than you might expect. Typically, implementation projects take only four months from initial install to go live, which is impressive in such a highly regulated environment. This short implementation period is due to our teams' extensive experience in risk-based validation approaches and minimal configuration required to fit Watson LIMS software into the bioanalytical workflow.



Watson LIMS Software



Traditional Analytical LIMS

“Watson [LIMS software] is unique in its ability to maintain the data for a bioanalytical laboratory in a compliant way so that we meet all of our sponsors’ expectations.”

– Chad Briscoe, Executive Director of Global Bioanalytical Science, PRA Health Sciences

Streamlining method validation and data analysis

Watson LIMS software supports method validation and data analysis for LCMS and ELISA assays including Multiplex, ADA, and NaB assays. Providing scientists, the ability to perform method validation and data analysis for many different assay types all within one system.

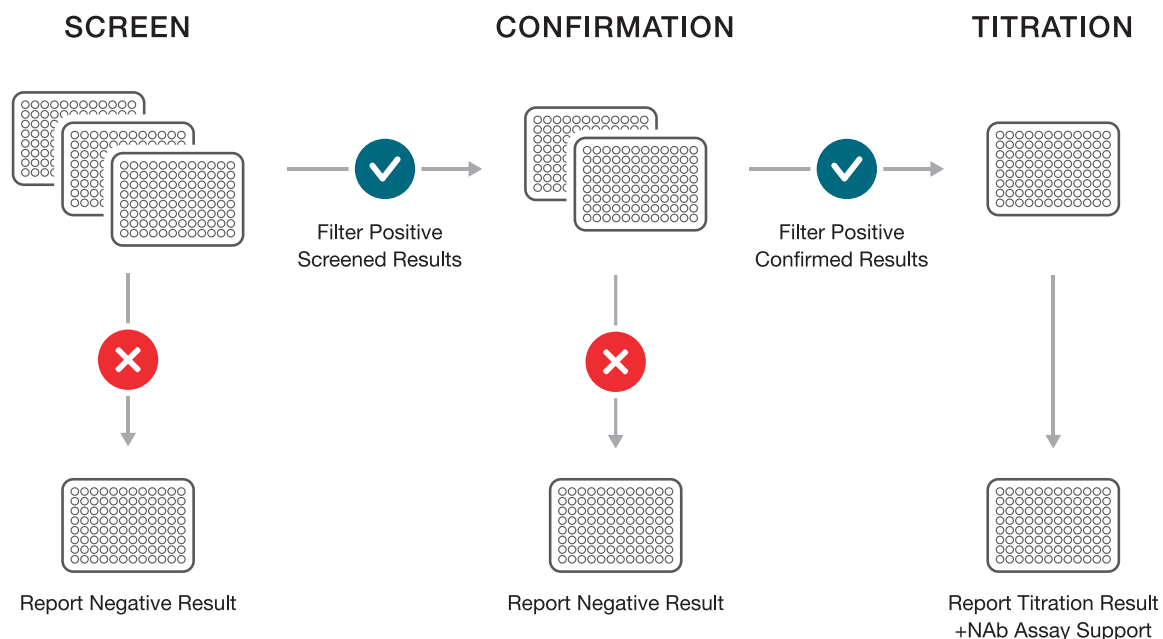
Method Validation support enables scientists to evaluate their methods for reliability and reproducibility. Predefined reports include precision and accuracy, specificity, selectivity, carryover, dilution integrity, stability (including benchtop, freeze/thaw and long-term stability), recovery and matrix effect.

The configurable **Run Acceptance Template** provides a tool to assess run performance against an SOP with defined acceptance criteria.

The integrated **Pharmacokinetics Module (PK)** allows the user to perform non-compartmental pharmacokinetic and toxicokinetic calculations within Watson LIMS software.

Enabling testing for immunogenicity

Immunogenicity assays protect patients from potentially harmful anti-drug antibodies and provide insights into neutralizing antibodies that may inhibit the biologic activity of a drug. The **Immune Response Module (IRM)** enables a tiered approach to performing immunogenicity assessments. IRM guides its users through the tiered approach of performing screening, confirmatory, and neutralizing assays. Scientists utilize the IRM to calculate assay cut-points, create automated flags for samples outside of the cut-point and to determine if there is a reactive sample. New study-level control reports include intra/inter-run statistics, flag limits, and cut-point values reported, providing valuable data in one location.



“Watson [LIMS software] is essential for a CRO, as it allows us to import samples and output data in a variety of ways to meet our clients needs.”

– Stuart McDougall, Bioanalysis Leader, Arcinova

Reassays and ISR

Reassays can be queued both from the PK and IRM modules and on review of statistical study data. Results are linked to the original for comparison, including the reason for reassay and reanalysis. The user is easily able to view the impact of the reassay result on the overall data.

The **Reassay Decision Matrix** enables the user to create a graphical workflow which emulates a decision tree defined in a reassay SOP.

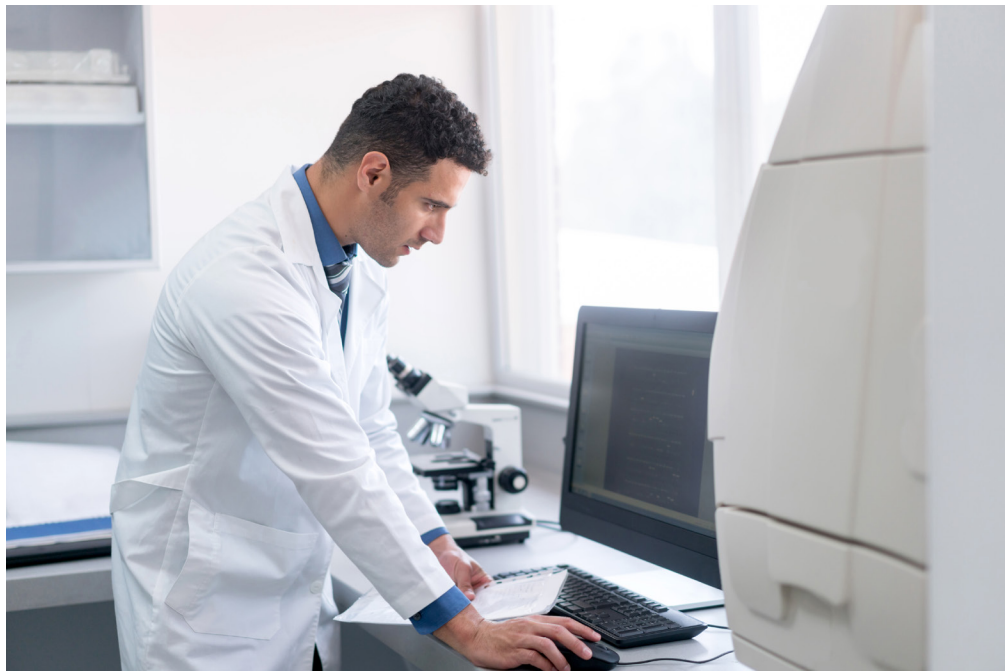
Built in calculations and configurable reporting support **Incurred Sample Reanalysis**. The report can be quickly and easily configured from a set template.

Watson LIMS software provides users the ability to report data in SEND format, based on the SEND Implementation Guide.

Instrument and system interfacing

With an extensive library of bidirectional interfaces to commonly used bioanalytical instruments, no matter what hardware and equipment you use or might add to your lab in future, Watson LIMS software can speak its language.

Once an analytical run has been acquired, the raw data is transferred from the data acquisition software back into the system for review and processing. Secure connections eliminate transcription errors and preserve data integrity.



Data processing and reports

Watson LIMS software's unrivaled data processing capability easily generates a variety of graphs, tables and statistical calculations from study data. Easily sort, find, filter, and reorder grid contents enabling a quick way to review a particular sample's data.

Regression Analysis is centralized and automated supporting linear and non-linear models.

Considerable time is saved in collating and reporting results compared to other LIMS or laboratory data management solutions.

Quality review time is minimized using Watson LIMS software—the gallery of **pre-defined assay performance and summary tables** are a major benefit since the precision and accuracy of study data is very quickly demonstrated. Any new data added is automatically taken into account—providing a real-time snapshot of data quality. Standard data exchange enables easy transfer of study data between sponsor and CRO.

The powerful **Document Management System** enables you to select the documents, tables and graphs to quickly build a full study report. All results, raw data, graphs and reports are held in one database which is controlled securely by user access and system roles.

Find out more at thermofisher.com/watson