



## iStudyReporter Study Archiving Module



### Features:

- Supports Thermo Scientific™ Watson LIMS™
- Cover requirements of 21 CFR Part 11 (11.10 (b) and 11.50)
- Complete human-readable study data documentation in PDF/A format
- No knowledge of Thermo Watson LIMS™ or iStudyReporter required for review
- Supplementary CSV and XML file sets for further processing

Thermo Scientific™ Watson LIMS™ is the industry standard in handling regulatory bioanalytical studies, and covers most of the important requirements from regulatory agencies.

Thermo Watson supports study archiving, but 21 **CFR Part 11 (11.10 (b) and 11.50)** requires electronic records to be archived in human-readable format (Draft Guidance, 21 CFR Part 11; Electronic Records; Electronic Signatures – Maintenance of Electronic Records).

The **Watson Study Archiving Module** generates a complete set of human-readable study data documents in PDF/A format from the Thermo Watson study database. The resulting structured documentation is reviewable without any knowledge of, or access to, Watson or iStudyReporter.

The documentation comes with a full set of supplemental CSV and XML files with the exported study data for further processing and future analysis without reliance on any specific tool.

The module supports attaching other files to the archive before transfer to a long-term corporate archiving solution; as an example, Thermo Watson exports Sciex Analyst files and any other study-relevant information for inclusion in the study archive generated.

Apart from long-term study data archiving, this provides an ideal solution for CROs to submit study data to a study sponsor.

The module slashes processing times by eliminating almost all manual activities in creating archives including hard copy, consistency checks with study submissions already created, and manually compiling the resulting documents.

The Watson Study Data Archiving Module was developed in close cooperation with global pharmaceutical corporations based on regulatory requirements.

The module's large number of interfaces allows for integration into any existing IT environment while supporting major systems such as LIMS, ELN, SAP, SDMS and legacy systems.

iStudyReporter Bioanalytics bridges this gap with a specialized Watson Study Archiving Module similar to automated submission documentation generation.