

# StudyDoc™

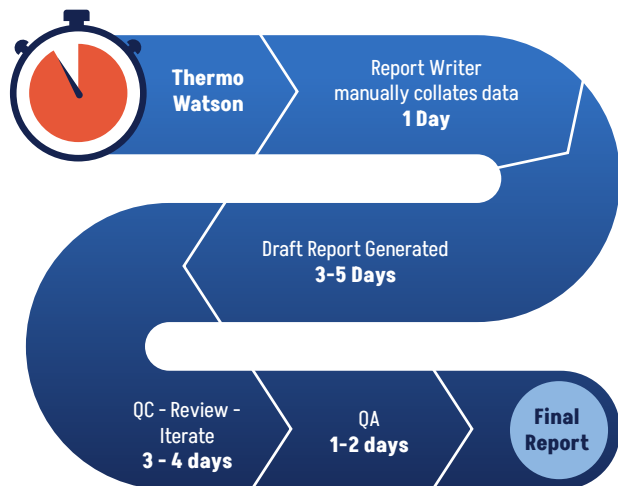
Rapid, Automated Reporting System for your GLP Bioanalysis Lab

StudyDoc is a robust data reporting software that is built to fit your needs and improve your process.

## Processing Clinical Data

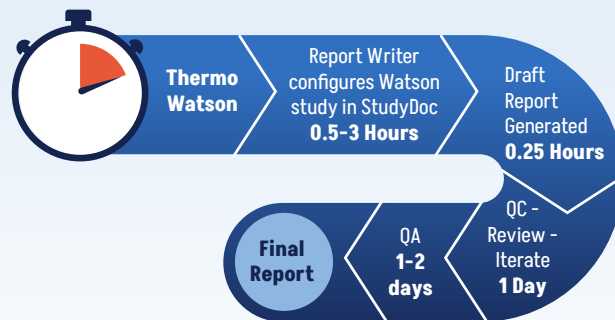
### Problem - Current Day

Today's GLP Final Report generation workflow relies heavily on manual copying/pasting/formatting/hyperlinking processes to compile and generate a draft GLP Final Report. These manual processes by nature are lengthy and consume valuable FTE resources. This limits the number of studies that can be completed in a given time frame.



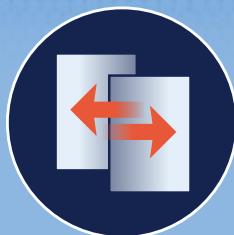
### Solution - StudyDoc™

StudyDoc retrieves all study-related data from the Thermo Scientific Watson database and produces GLP Final Reports in a fast, efficient, accurate and consistent manner allowing labs to complete more studies in the same given time frame.



#### Automated

Seamlessly assign and compile report data from Thermo Scientific Watson database.



#### Adaptable

StudyDoc field codes allow a single template to be used for single- or multi-analyte studies. Unlimited number of templates allowed.



#### Compliant

Provides full or partial 21 CFR Part 11 support (security, electronic signatures, and audit trails).



#### Save Time + Money

Cut unnecessary cost by reducing manual processes, minimizing chance of human error, and eliminating redundant review.

## StudyDoc provides a robust set of features to improve your work process. With efficiency and compliance in mind, StudyDoc is built to completely optimize your lab report writing.

- 
**Regulatory Support**  
 Complete support for GLP/ICH Small Molecule and Large Molecule assay table formats, including China regulatory body NMPA Small Molecule table formats
- 
**Application Portability**  
 Sponsors can send clients StudyDoc Word Templates and StudyDoc Study Templates to configure in the client StudyDoc system, ensuring that client reports are exactly as defined by sponsor.
- 
**Field Code Generator**  
 Provides complete control over how the text sections of reports are generated such that the complete section of tables, any individual table, or any table-specific statistical data can be put anywhere in the final document template. Specific references to tables in the form of hyper-links are also available.
- 
**Document Content Management and Version Control**  
 All document modifications are version controlled. Users may compare versions of documents, make modifications as necessary and save as a new version.
- 
**21 CFR Part 11 Compliance**  
 Audit trails keep track of any changes made in the report generation process. Electronic signatures allow the software to restrict any fraudulent StudyDoc changes. The compliance feature can be configured as a silent audit trail without an electronic signature prompt.
- 
**Locked Tables**  
 Users may choose to generate reports or tables in which the table raw data and statistics sections are locked.
- 
**Lock Sections Field Code**  
 Table creation field codes can be preceded and followed by the field codes [LOCKSECTION] and [UNLOCKSECTION], respectively. The portion of the document enclosed by these field codes are then locked using Word's 'Restrict Editing' feature. A random password (unknown to anyone) is created and applied to the section.
- 
**Automatic Method Validation Sample Assignment**  
 Allows users to assign and/or exclude Sample Name and Analytical Run Description text fragments to specific tables, which allows StudyDoc to automatically assign samples to specific assay tables.
- 
**User Groups and Permissions**  
 Permissions allow for strict access-and control of reporting features, including the ability to adjust the types of tables in a report, and the ability to create newer versions of the report templates. Permission Groups are configured by an administrator; groups are then assigned to individual user accounts.
- 
**Report Writer Aids**  
 StudyDoc notifies user if any field code has not been configured after the generation of the report.
- 
**Watson Check**  
 When a study is opened in StudyDoc, StudyDoc checks to ensure that any reported concentrations have not been changed since the last time a Final Report has been generated in StudyDoc. If a concentration is found to have been changed, StudyDoc displays a constant warning message with a blinking red dot.
- 
**Automated Formatting**  
 StudyDoc automatically hyperlinks table/appendix/figure references in the report body section and replaces spaces with non-breaking spaces in such items as Compound Name. In addition, there is a Non-Breaking Space field code to hard code needed formatting.
- 
**Built In Study and Table Specific Field Codes**  
 StudyDoc has over 1,000 available Study- and Table-specific field codes. Every QC table statistics section parameter (mean, SD, Precision, Accuracy and [n]) are available to be reported in the Report Body section of the report. In addition, all temperature and time parameters for stability QC tables are available for reporting.

LabIntegrity is not only here to support your report writing success, but provide unparalleled service after you have been onboarded. We offer 2 service plans to choose from.

	Pro Service Plan	Premium Service Plan
Priority Support Response (1-2 Business Days)		
Upgrades and Bug Fixes Yearly		
Report Template Configuration		
Microsoft Word Report Template Configuration		
StudyDoc Custom Report Writing		
StudyDoc Feature Customization Consideration		