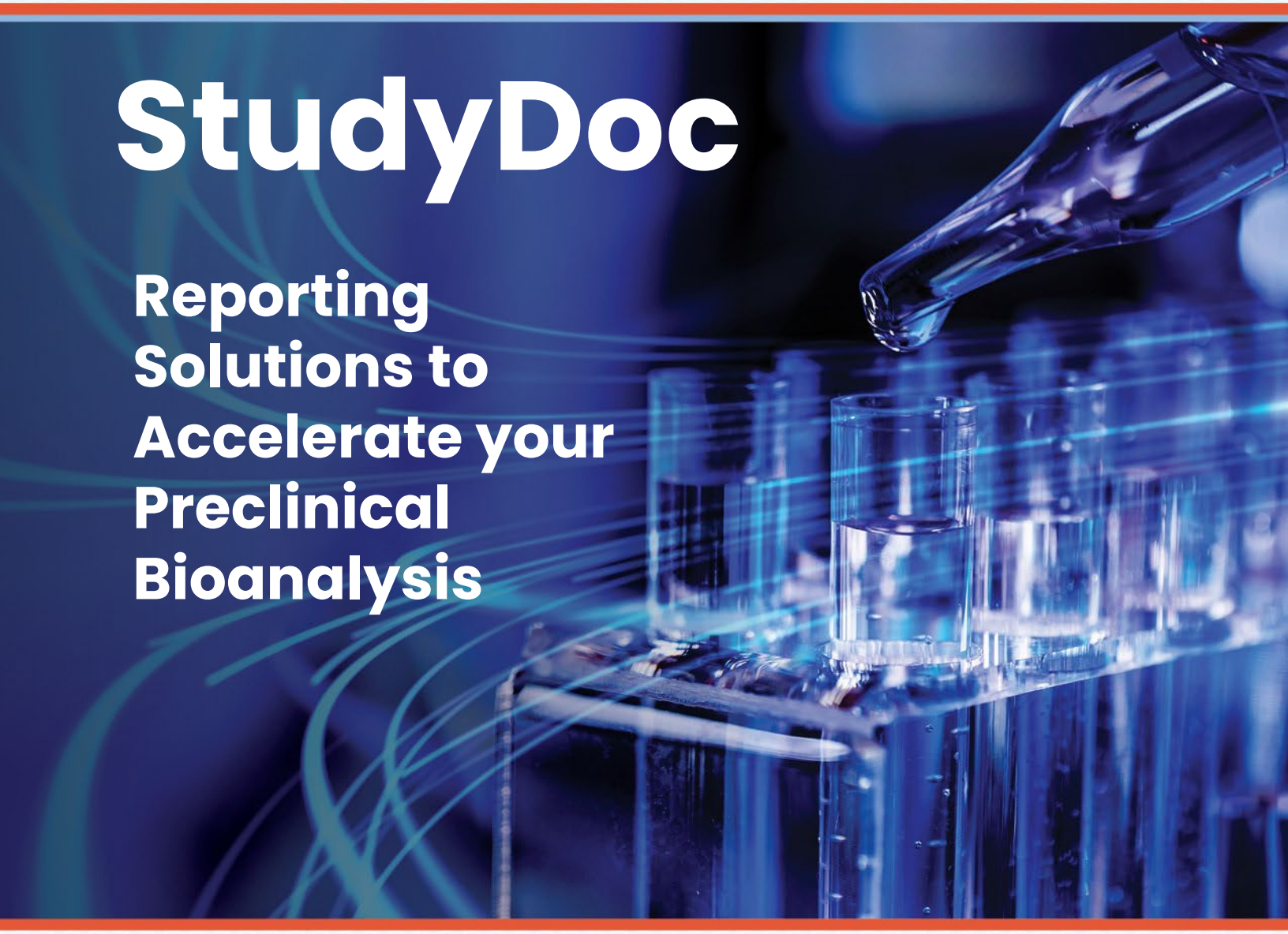
LABIntegrity

Rapid, Automated Reporting System for your GLP Bioanalysis Lab

StudyDoc

Reporting Solutions to Accelerate your Preclinical Bioanalysis



www.labintegrity.com

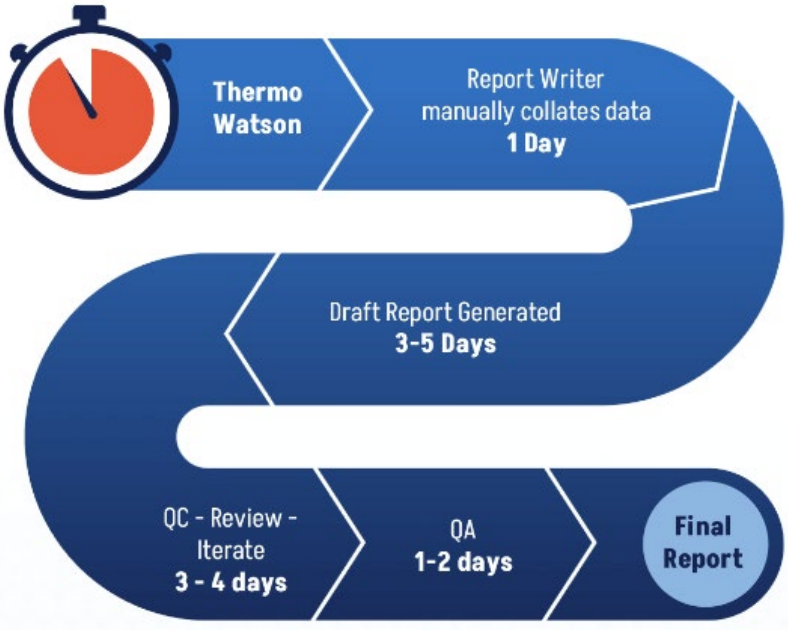
Current Day

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.

Current Day – Work Flow

These manual processes

- Are **lengthy** and time consuming exhausting valuable FTE resources
  - Formatting tables, table titles, table captions
  - Hyperlinking tables, figures, appendices
  - Accurately and completely searching, replacing, entering Study and Table specific variables
  - Inserting metadata information
  - Cleaning up the report and making sure there are no unwanted line wraps
- **Limit** the number of studies that can be completed in a given time frame
- Increase **risk** of human **error** and require a significant amount of QA/QC accuracy checking
- Average 8-12+ days to complete



Current Day – During Inspections

Four harmful behaviors cited by FDA representative*:

1. Delaying or refusing inspections
2. Altering records to confound inspectors
3. Refusing to correct objectionable conditions
4. Cut-and-paste errors

* Michael Skelly, FDA speaking at Applied Pharmaceutical Analysis conference, Sept 14, 2014 Cambridge, MA. These views are his personal opinion, and do not represent the official views of the FDA.

GOAL - Issue Report in a Timely Manner

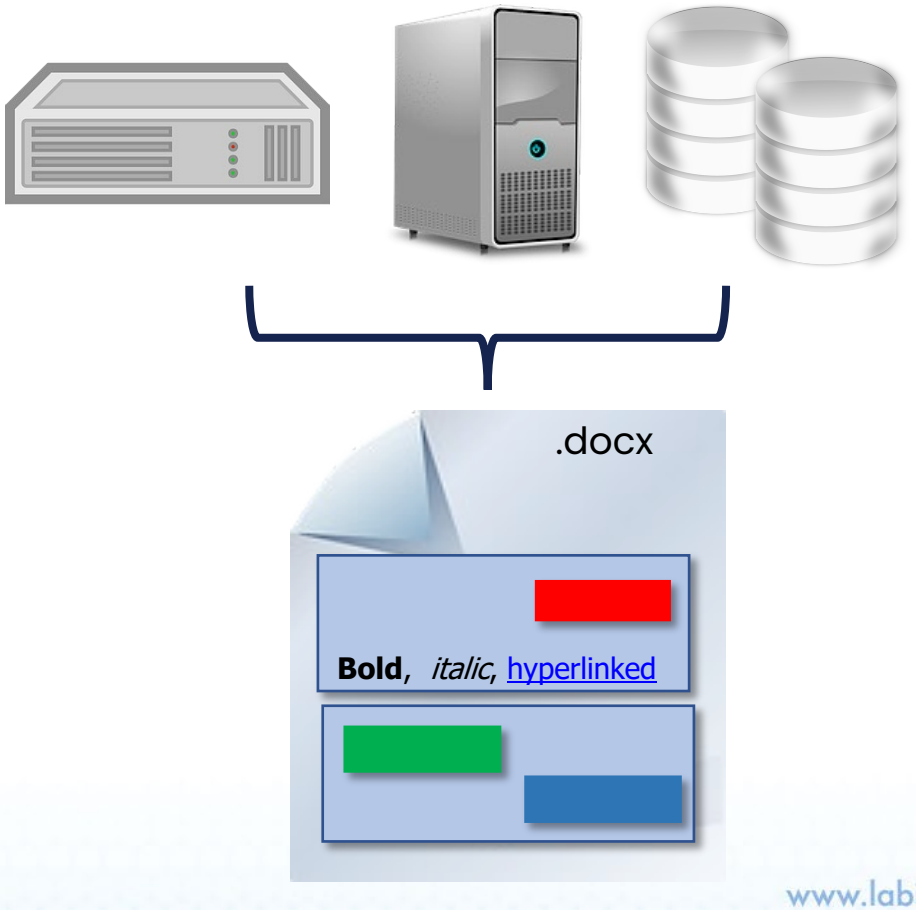
- The goal of every Laboratory Director is to issue the Final Report in a timely manner

Timely reporting

- Allows resources to proceed uninhibited to next project
- The study is still fresh in the minds of lab personnel in case QA Findings need resolution
- Project managers can accept and complete more projects in a given period of time

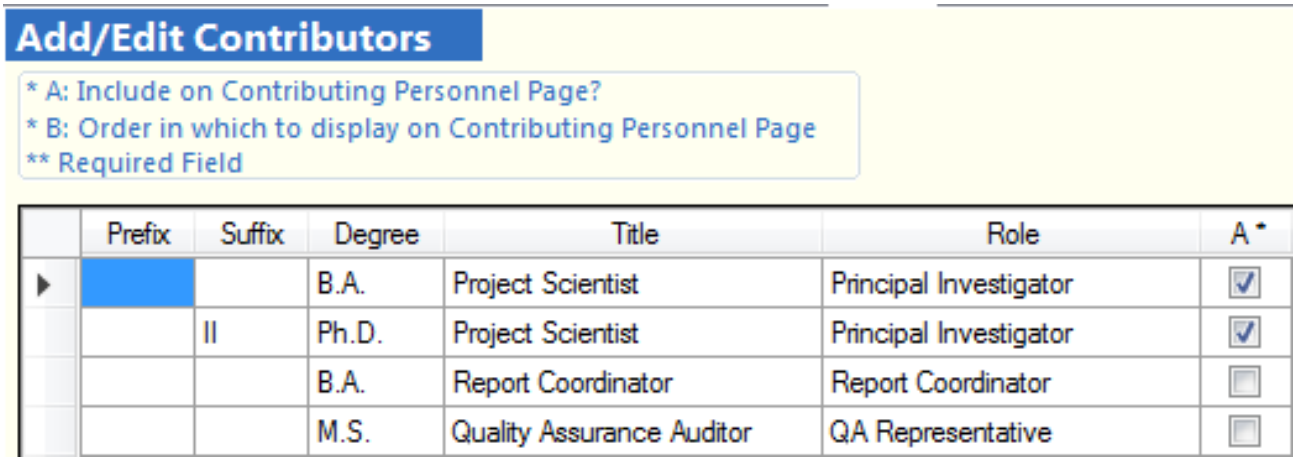
What should a Report Writing System do?

- Gather data needed to create the report
- Create standard sections of report with gathered data
  - Descriptive Sections (with hyperlinks to tables)
  - Data Tables (correctly titled, populated and formatted)
  - Figures and Appendices
- Insert variables into the report body
- Format any items within the report



What should a Report Writing System do?

- Report "metadata"
  - Analytical Reference Standard Information
  - Sample Receipt Information
  - Contributing Personnel Table
  - Signature Blocks
  - QA Events Table



Add/Edit Contributors

* A: Include on Contributing Personnel Page?
* B: Order in which to display on Contributing Personnel Page
** Required Field

	Prefix	Suffix	Degree	Title	Role	A *
▶			B.A.	Project Scientist	Principal Investigator	☑
		II	Ph.D.	Project Scientist	Principal Investigator	☑
			B.A.	Report Coordinator	Report Coordinator	☐
			M.S.	Quality Assurance Auditor	QA Representative	☐

Introducing

StudyDoc™

- LABIntegrity Inc. focuses on the growing need for automated software solutions in the FDA-regulated bioanalytical laboratory

- **StudyDoc™ Manager** is an established software solution that helps lab managers to not only create the Final Report, but to help manage the report writing process

Why StudyDoc ™?

Automated

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

Compliant

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

Adaptable

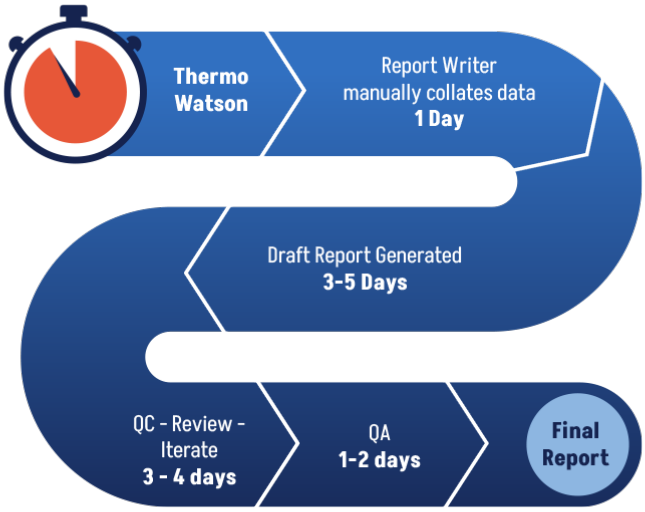
Final Reports created from user-provided Microsoft Word templates. StudyDoc™ field codes allow a single template to be used for single- or multi-analyte studies. Unlimited number of templates allowed.

Save Time + Money

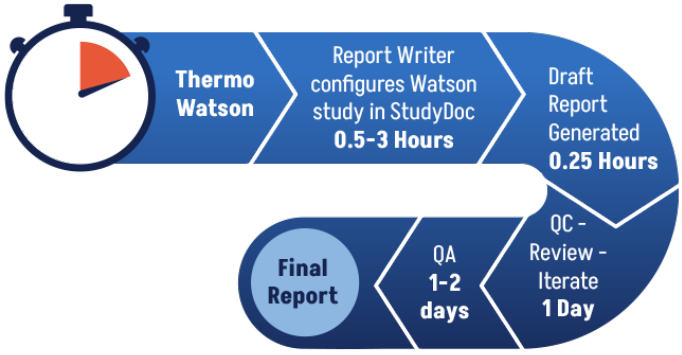
Cut unnecessary cost by reducing manual processes, minimizing chance of human error, and eliminating redundant review.

Improve Your Process

Problem
Current Day



Solution
StudyDoc™



Cost Benefit

Cost benefits of report writing automation can be up to **$2 million / year**

Reports/Year		Cost Savings		
Method Validation	Sample Analysis	Method Validation	Sample Analysis	Total Savings/ Year
3	7	$ 28,980	$ 32,830	$ 61,810
7	13	$ 67,620	$ 60,970	$ 128,590
13	26	$ 125,580	$ 121,940	$ 247,520
26	52	$ 251,160	$ 243,880	$ 495,040
52	104	$ 502,320	$ 487,760	$ 990,080
78	156	$ 753,480	$ 731,640	$ 1,485,120
104	208	$1,004,640	$ 975,520	$ 1,980,160

Based on $140/hr FTE, 2-week and 1-week studies

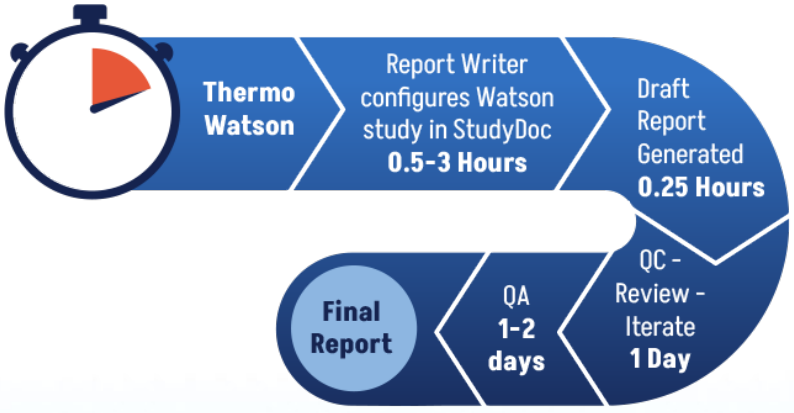
StudyDoc™ gets you from Data to Report **in minutes**

Generates Tables

- Retrieves relevant sample data from Watson databases.
- Organizes the data into the relevant tables.
- Performs calculations and reports statistical information needed for tables
- Formats tables in a pre-defined manner (according to user options).

Generates Text

- Combines Watson data with information saved in StudyDoc
- Replaces study-specific and table-specific variables within the report body
- Formats report based on user-defined settings and user-defined Microsoft Word Template



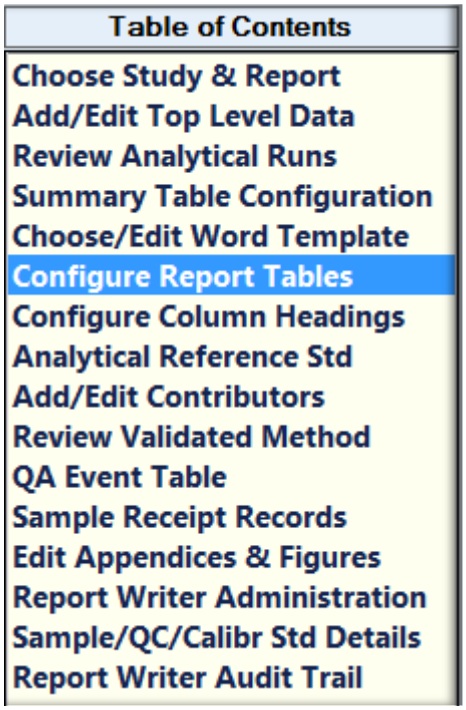
Manage the Entire Report Writing Process

Process Management

- Watson analytical run progress
- Contributing Personnel and QA Events
- Samples Receipt information (or it can upload from Watson)

Flexible Template Management

- Each type of Study (e.g. Method Development vs. Sample Analysis) has a **StudyDoc™** Template for its own table/report setup.
- **StudyDoc™** Templates contain defaults:
  - Microsoft® Word Report Templates (for formatting)
  - Table types and configurations
  - Global settings (e.g. Significant Figures, rounding preferences, etc)



Automated Report Writing Solution Requirements

Report Management

Manages the Report Creation Process.

Report Generation

Contains a comprehensive set of features to create Microsoft® Word templates.

Data Integrity

Contains features to allow managers the ability to monitor the progress of the report itself.

Notifies users if/when underlying Watson data has been changed.

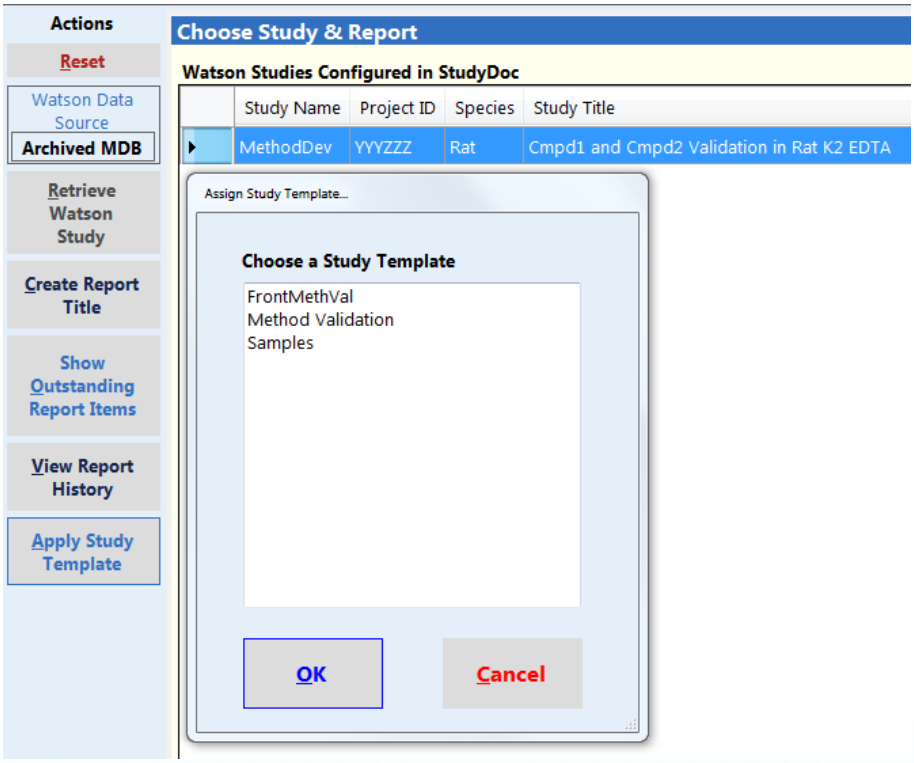
Report Management Requirements

An automated report writing solution should allow management of the Report Creation Process.

Controlled Flexibility: Choose a StudyDoc™ Template

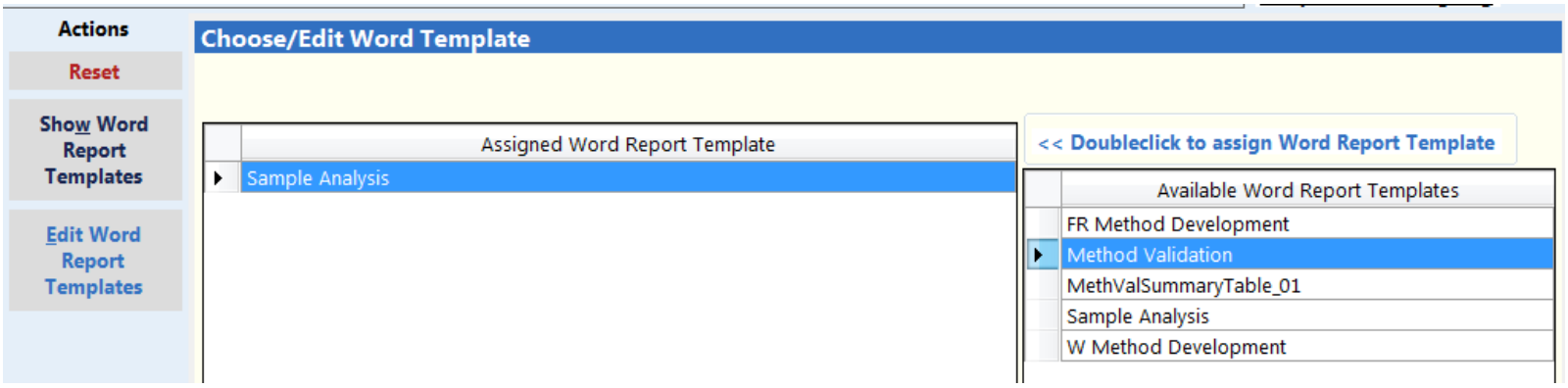
The StudyDoc Template is:

- List of tables to be included in the report
- Table configuration specifics
- Study configuration specifics
- Custom Field Code values
- Word™ Report Template
- Contributing Personnel



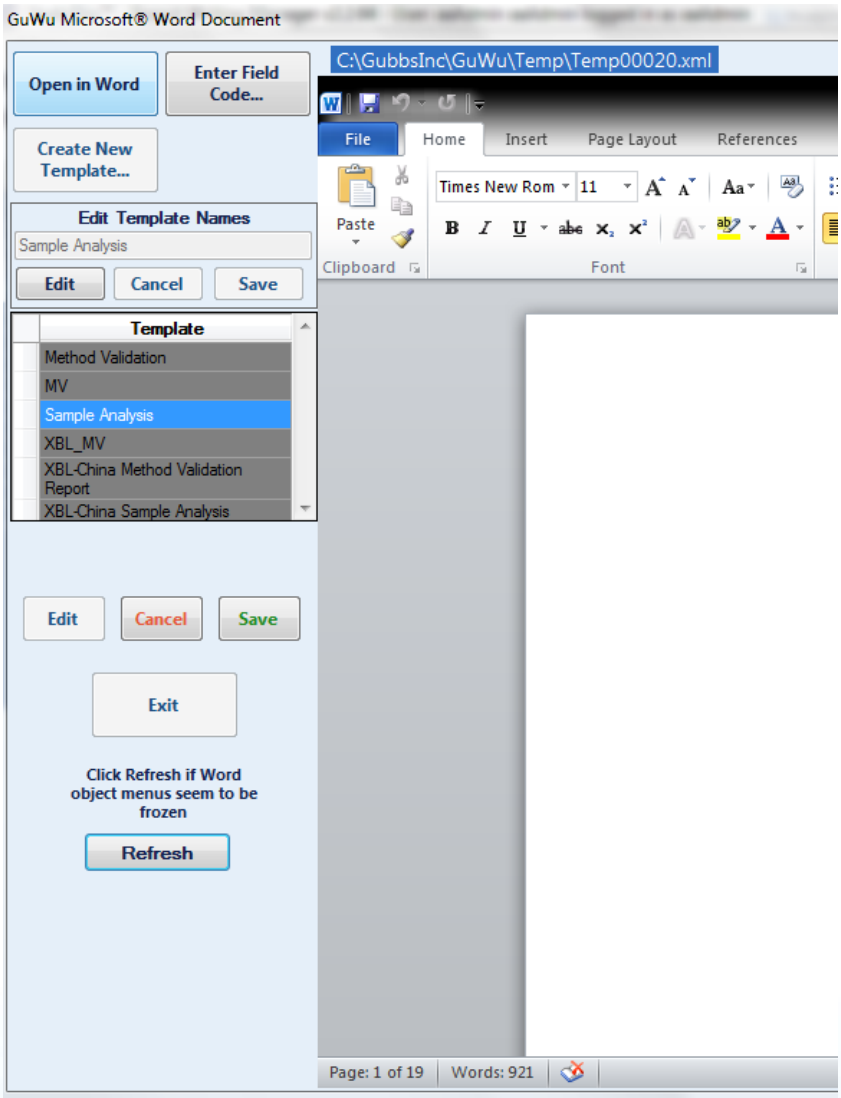
Controlled Flexibility: Secure Template Management

- Allows users to securely manage Microsoft® Word Report Templates
- Click on the 'Edit Word Report Templates' button to edit a template within Word, but controlled by StudyDoc



Controlled Flexibility: Secured Word™ Template Editing

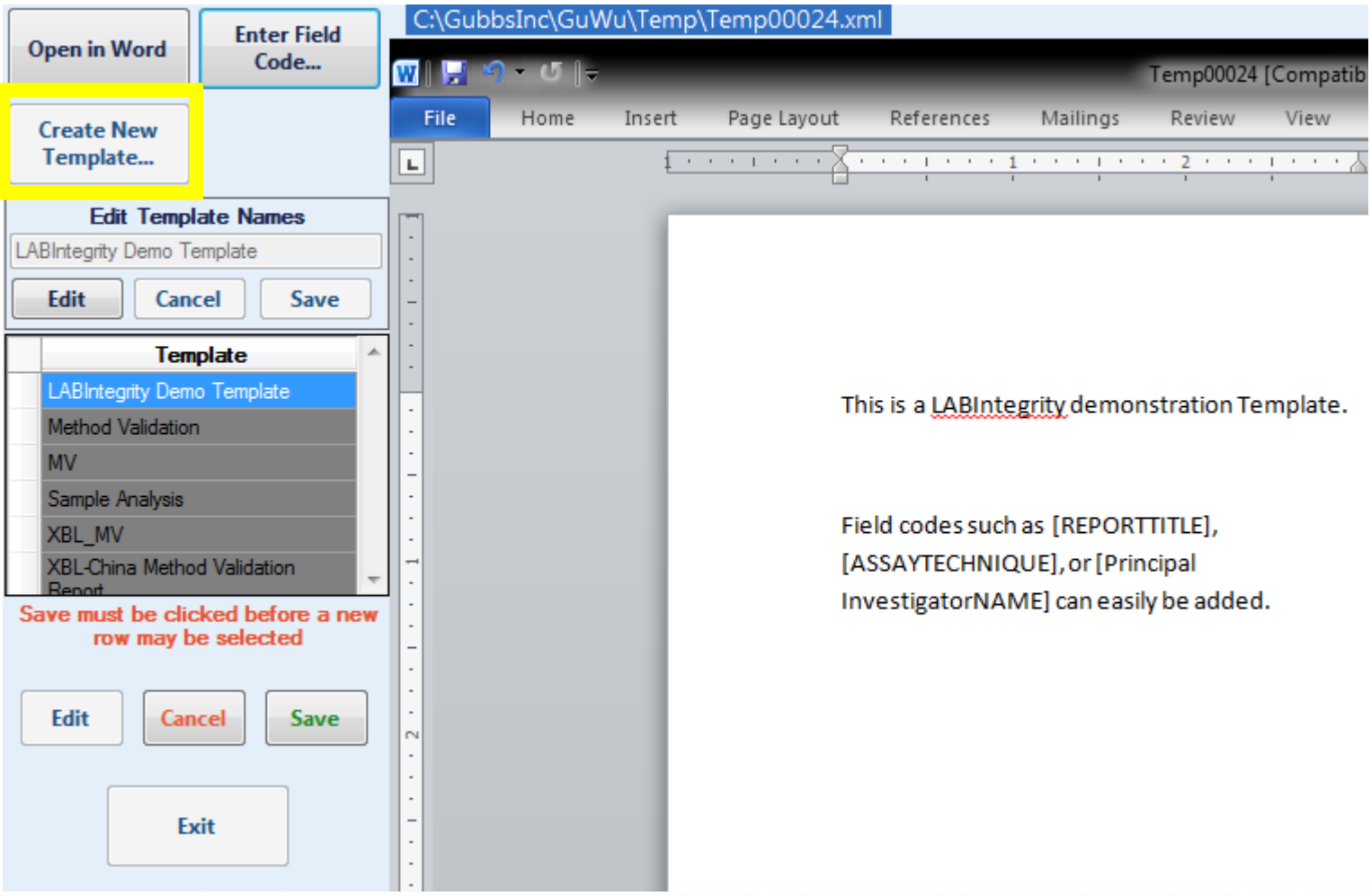
- Securely edit and store the Word™ Report Templates
- The Word™ Report Template is stored in the StudyDoc database



Controlled Flexibility: Configured Word Template

As easy as opening a Word™ document

1. Click ‘Create New Template’
2. Open Word document in StudyDoc Word Viewer
3. Click StudyDoc ‘Save’ button



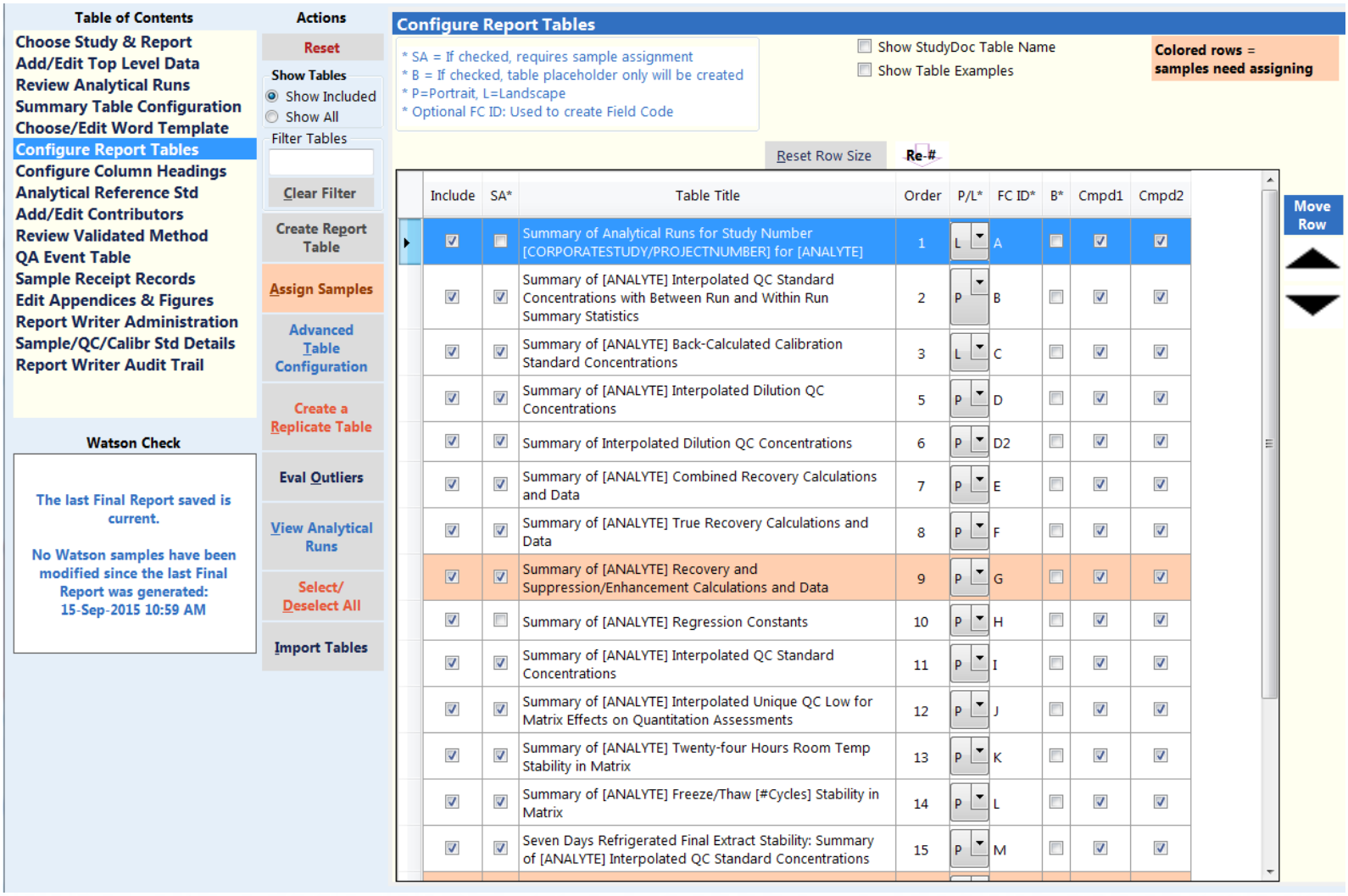
Controlled Flexibility: Template Document Styles

StudyDoc™ works integrally with Microsoft® Word

- Document “Styles” are managed by the user, not StudyDoc™
  - Fonts
  - Margins
  - Line Spacing
- Styles Saved with the Word™ Template when stored in StudyDoc™

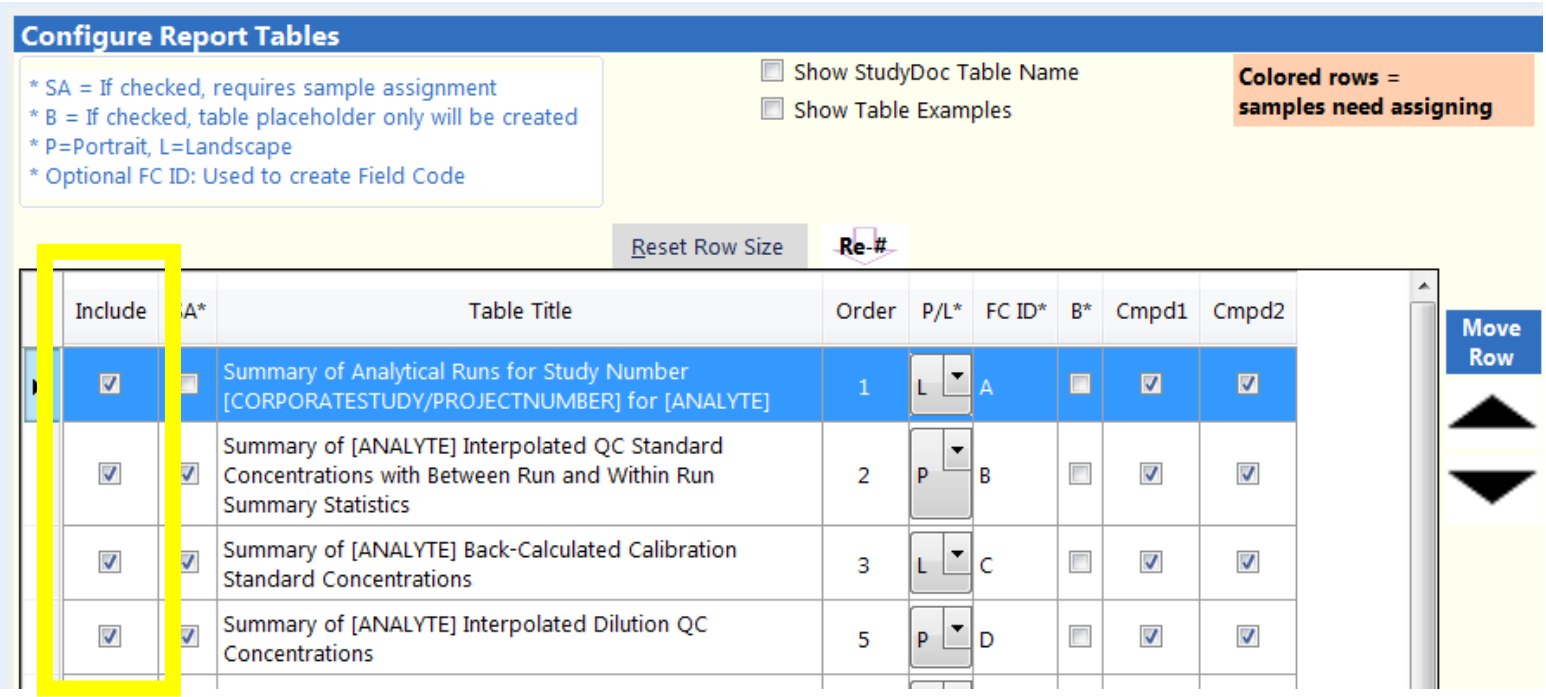
Controlled Flexibility: Table Assignment

- Features to allow users to decide which Tables are included in the Report
- Each Table can be individually pre-configured within the StudyDoc™ Template



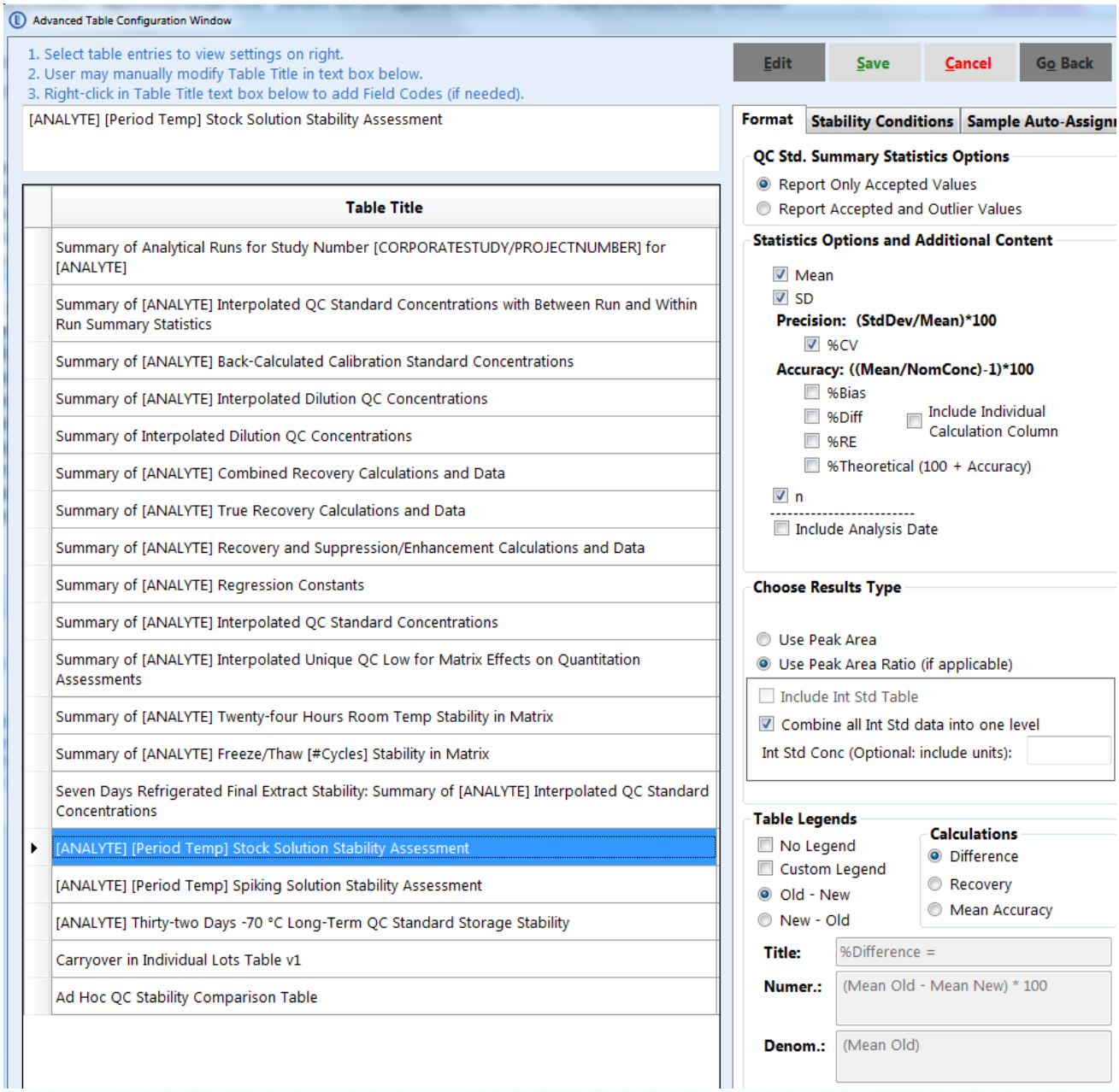
Controlled Flexibility: Table Assignment

- Features to allow users to decide which Tables are included in the Report
- Each Table can be individually pre-configured within the StudyDoc™ Template using the "Advanced Table Configuration"



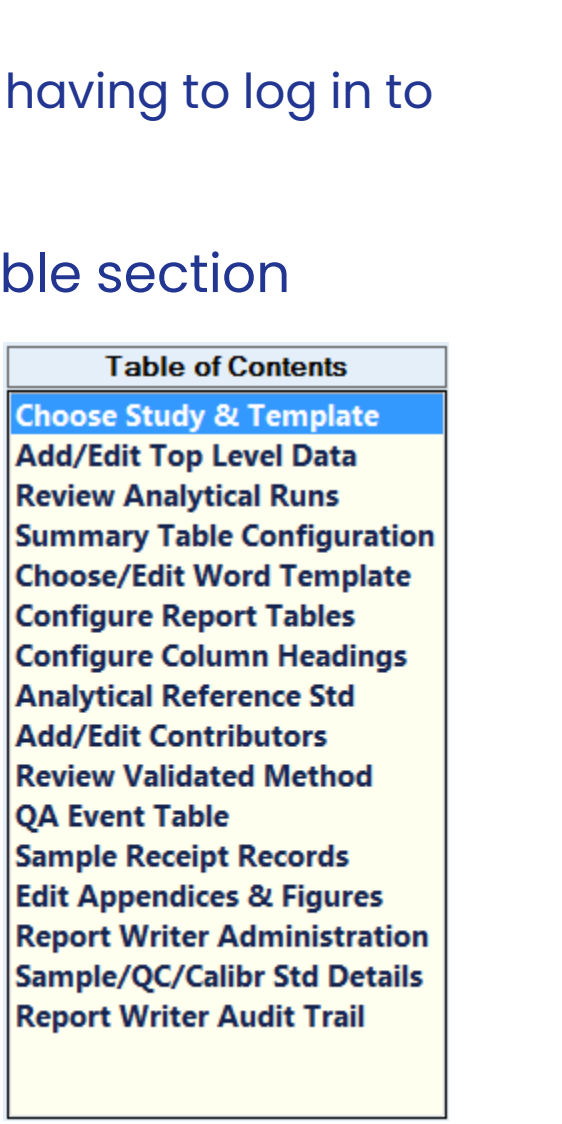
Controlled Flexibility: Table Parameters

- Features to allow users to modify specific table parameters if needed



Additional Management Features

- Analytical Run Summary
  - Real-time study progress without having to log in to Watson
- Study Summary Table section
- Analytical Reference Standard Table section
- Contributing Personnel section
  - Including signature blocks
- Linked Method Validation section
- QA Event Table section
- Sample Receipt section
- Appendices and Figures section
- Sample/QC/Calibr Std Details



Report Generation Requirements

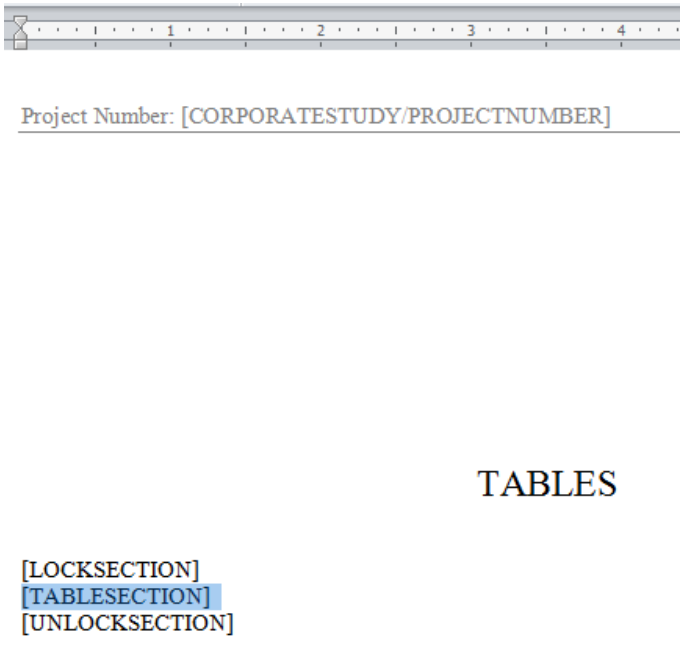
An automated report writing solution should contain a comprehensive set of features to create Microsoft® Word templates

Report Generation: Inserting Tables

StudyDoc utilizes field codes to allow placement of tables in the report

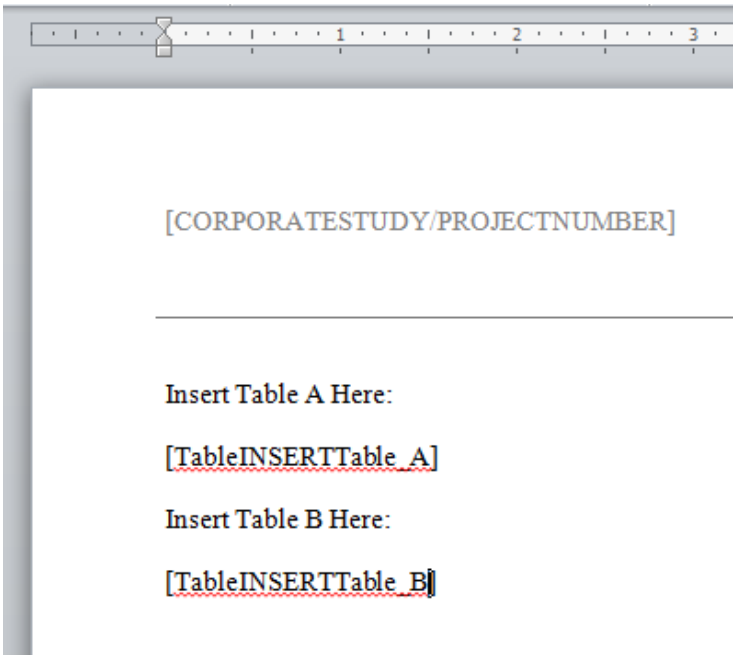
All tables can be placed in one section

- [TABLESECTION]



And/Or Individual tables in specific locations

- [TableINSERTTable_]



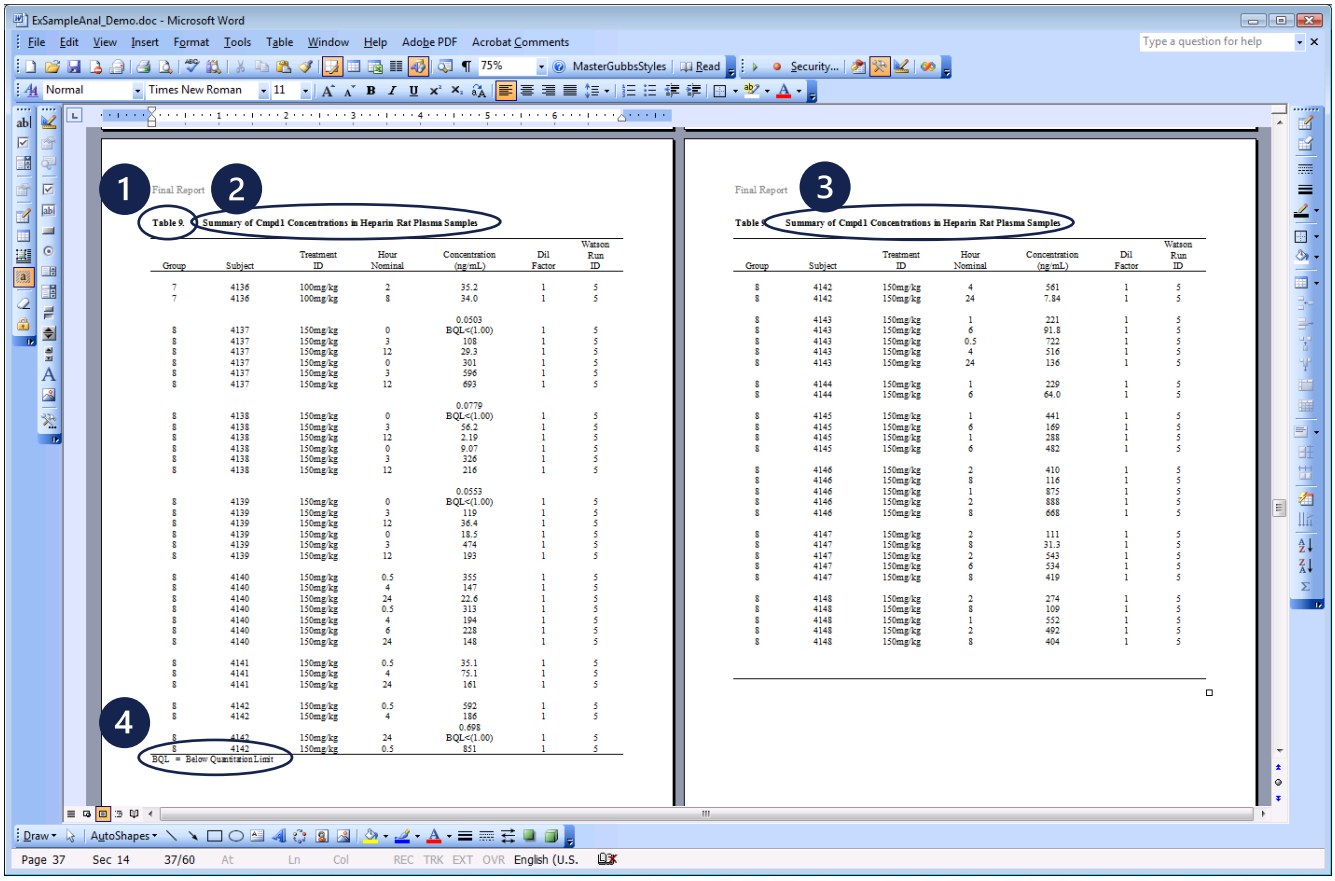
Report Generation: Table Creation Features

Automatically Adds:

1. Table Number
2. Table Title
3. Table Title Repeat

Generates:

4. Page Specific Footnotes/Legends



Report Generation:
Automatically Generated Tables - Back Calculated Standard Concentrations

Summary of Cmpd1 Back-Calculated Calibration Standard Concentrations

Watson Run ID	Nominal Concentrations 1.00 ng/mL	2.00 ng/mL	5.00 ng/mL	10.0 ng/mL	50.0 ng/mL
1	1.12	1.96	4.93	10.4	49.2
	0.931	1.90	4.74	9.60	51.2
2	0.935	1.98	4.96	10.3	49.3
	1.08	1.93	4.97	10.6	51.4
3	1.19	2.00	5.59	10.6	51.9
	0.860	1.79	4.26	10.3	52.9
Mean	1.02	1.93	4.91	10.30	50.98
S.D.	0.129	0.0758	0.429	0.369	1.47
%CV	12.7	3.9	8.7	3.6	2.9
n	6	6	6	6	6

NRB = Not Reported: Value outside of acceptance criteria (± 15% theoretical) and excluded from regression and summary statistics.

Report Generation:
Automatically Generated Tables - Interpolated QC Standards

Summary of Cmpd1 Interpolated QC Standard Concentrations

Watson Run ID	Nominal Concentrations QC Low 3.00 ng/mL	QC Mid 30.0 ng/mL	QC High 800 ng/mL
1	3.25	33.5 [a]	794
	3.00	33.4	803
2	3.10	32.5	778
	3.05	31.6	803
	[...]	[...]	[...]
Summary Statistics Excluding Outlier Values			
Mean	3.17	32.2	804
S.D.	0.274	0.998	23.0
%CV	8.7	3.1	2.9
Summary Statistics Including Outlier Values			
Mean	3.16	32.7	805
S.D.	0.274	0.981	23.0
%CV	8.7	3.0	2.9

[a] = Value outside of acceptance criteria (± 15% theoretical) and excluded from summary statistics because the value is a statistical outlier according to the Grubbs Test.

[b] = Value outside of acceptance criteria (± 15% theoretical) but included in summary statistics.

Report Generation:
Automatically Generated Tables - Regression Constants

Summary of Cmpd1 Regression Constants

Watson Run ID	A [a]	B [a]	R-Squared
1	2.6933E-2	2.0024E-3	9.9728E-1
2	2.7440E-2	1.0743E-3	9.9786E-1
3	2.4572E-2	-1.6091E-3	9.9052E-1
5	2.4052E-2	-6.3360E-4	9.9609E-1
6	2.4396E-2	2.1584E-3	9.9800E-1
Mean	2.5479E-2	5.9848E-4	9.9595E-1
SD	1.5805E-3	1.6600E-3	3.1275E-3
%CV	6.2	277.4	0.3
n	5	5	5

[a] = Linear Regression: y = Ax + B where y is the peak area ratio of Cmpd1 to Int. Std., x is the concentration of Cmpd1, and A and B are regression constants. Regression weighted 1/x^2.

Report Generation:
Automatically Generated Tables - Method Validation: Freeze/Thaw Stability

Table 16. Summary of Cmpd1 Twenty-four Hours Room Temp Stability in Matrix

	Nominal Concentrations	
Watson Run ID	QC Low 3.00 ng/mL	QC High 800 ng/mL
5	3.61 [a]	802
	3.28	780
	3.38	777
	3.29	806
	3.38	802
	3.13	771
Mean	3.35	790
S.D.	0.159	15.3
%CV	4.7	1.9
%Bias	11.7	-1.3
n	6	6

[a] = Value outside of acceptance criteria (± 15% theoretical) but included in summary statistics.

Report Generation: Automatically Generated Tables - Method Validation: QC Inter/Intra-Run Precision

Table 8. Summary of Cmpd02 in Human K_2-EDTA Plasma Interpolated QC Standard Concentrations with Between Run and Within Run Summary Statistics

Here's some extra header information

	Nominal Concentration							
Watson Run ID	QC LLOQ 1.00 ng/mL	%Bias	QC Low 3.00 ng/mL	%Bias	QC Mid 30.0 ng/mL	%Bias	QC High 800 ng/mL	%Bias
3	1.03	3.0	3.34	11.3	33.9	13.0	831	3.9
	1.10	10.0	3.32	10.7	34.0	13.3	802	0.3
	1.06	6.0	3.36	12.0	34.3	14.3	842	5.3
	1.10	10.0	3.38	12.7	**34.7** [a]	**15.7** [a]	840	5.0
	0.972	-2.8	3.19	6.3	33.9	13.0	828	3.5
	1.02	2.0	3.08	2.7	**25.8** [b]	**-14.0** [b]	829	3.6
Intra-run Mean	1.05		3.28		34.2 (32.8)		829	
Intra-run S.D.	0.0499		0.118		0.344 (3.43)		14.3	
Intra-run %CV	4.8		3.6		1.0 (10.5)		1.7	
Intra-run %Bias	5.0		9.3		14.0 (9.3)		3.6	
n	6		6		5 (6)		6	
4	1.03	3.0	3.31	10.3	**34.6** [a]	**15.3** [a]	784	-2.0
	0.922	-7.8	3.30	10.0	33.9	13.0	794	-0.8
	0.932	-6.8	3.08	2.7	33.4	11.3	805	0.6
	1.09	9.0	3.31	10.3	33.9	13.0	826	3.3
	0.962	-3.8	3.39	13.0	33.9	13.0	832	4.0
	0.874	-12.6	3.24	8.0	**35.0** [a]	**16.7** [a]	819	2.4
Intra-run Mean	0.968		3.27		34.1		810	
Intra-run S.D.	0.0788		0.105		0.578		18.9	
Intra-run %CV	8.1		3.2		1.7		2.3	
Intra-run %Bias	-3.2		9.0		13.7		1.3	
n	6		6		6		6	
5	1.19	19.0	3.31	10.3	33.6	12.0	839	4.9
	1.13	13.0	3.43	14.3	34.0	13.3	814	1.8
	1.15	15.0	3.36	12.0	34.3	14.3	831	3.9
	0.884	-11.6	3.11	3.7	33.9	13.0	819	2.4
	0.982	-1.8	3.09	3.0	33.3	11.0	813	1.6
	1.03	3.0	3.20	6.7	33.5	11.7	823	2.9
Intra-run Mean	1.06		3.25		33.8		823	
Intra-run S.D.	0.117		0.138		0.368		10.2	
Intra-run %CV	11.0		4.2		1.1		1.2	
Intra-run %Bias	6.0		8.3		12.7		2.9	
Summary Statistics Section								
Inter-run Mean	1.03		3.27		34.0 (33.6)		821	
Inter-run S.D.	0.0911		0.115		0.458 (1.98)		16.1	
Inter-run %CV	8.8		3.5		1.3 (5.9)		2.0	
Inter-run %Bias	3.0		9.0		13.3 (12.0)		2.6	
n	18		18		17 (18)		18	
Intra-run Mean	1.03		3.27		34.0 (33.6)		821	
Intra-run S.D.	0.0505		0.0153		0.208 (0.681)		9.71	
Intra-run %CV	4.9		0.5		0.6 (2.0)		1.2	
Intra-run %Bias	3.0		9.0		13.3 (12.0)		2.6	
n	3		3		3 (3)		3	

[a] = Value outside of acceptance criteria (± 15% theoretical) but included in summary statistics.

[b] = Value excluded from summary statistics because the value is a statistical outlier according to the SD Test. The statistical results within parentheses were calculated including the outlier value.

Report Generation:
Automatically Generated Tables - Matrix Factor

Table 1: Internal Standard-Normalized Matrix Factor Summary for Cmpd 1 in Rat K3EDTA Plasma

Watson Run ID (Analysis Date)	QC ID	Theoretical Nominal Concentration (ng/mL)	Recovery Solution Analyte Peak Area	Recovery Solution Internal Standard Peak Area	Post Extraction Spike Solution Peak Area	Post Extraction Spike Solution Internal Standard Peak Area	Analyte Matrix Factor [a]	Internal Standard Matrix Factor [b]	Internal Standard Normalized Matrix Factor [c]
8 (29-Oct-2015)	QC Low	50.0	57600	128100	27640	59820	0.480	0.467	1.03
			85810	192500	28060	61870	0.327	0.321	1.02
			90950	207800	27840	62360	0.306	0.300	1.02
			94140	224800	28700	62420	0.305	0.278	1.10
			98210	225600	28230	59200	0.287	0.262	1.10
			101300	225400	28000	58960	0.276	0.262	1.06
		Mean	88000	200700	28080	60770	0.330	0.315	1.06
		S.D.	15850	37950	364.7	1619	0.0755	0.0779	0.0378
		%CV	18.0	18.9	1.3	2.7	22.9	24.7	3.6
		n	6	6	6	6	6	6	6
	QC High	2000	16820000	122300	8499000	54980	0.505	0.450	1.12
			20500000	154400	8873000	59380	0.433	0.385	1.13
			21770000	181000	8337000	52820	0.383	0.292	1.31
			22420000	187700	7941000	52090	0.354	0.278	1.28
			22490000	192400	8784000	59570	0.391	0.310	1.26
			23100000	184700	9117000	59770	0.395	0.324	1.22
		Mean	21180000	170400	8592000	56440	0.410	0.340	1.22
		S.D.	2313000	27090	421600	3569	0.0529	0.0655	0.0792
		%CV	10.9	15.9	4.9	6.3	12.9	19.3	6.5
		n	6	6	6	6	6	6	6
								Mean	1.14
								S.D.	NA
								%CV	NA
								n	2

NA = Not Applicable

Report Generation:
Automatically Generated Tables - Plus Many Others

Table Title
Summary of Analytical Runs for Study Number [CORPORATESTUDY/PROJECTNUMBER] for [ANALYTE]
Summary of Interpolated QC Std Conc Intra- and Inter-Run Precision
Summary of [ANALYTE] Interpolated QC Standard Concentrations with Between Run and Within Run Summary Statistics
Summary of [ANALYTE] Back-Calculated Calibration Standard Concentrations
Summary of Back-Calculated Calibration Std Conc
Summary of [ANALYTE] Interpolated Dilution QC Concentrations
Summary of Interpolated Dilution QC Concentrations
Summary of [ANALYTE] Combined Recovery Calculations and Data
Summary of Samples
Summary of [ANALYTE] True Recovery Calculations and Data
Summary of Reassayed Samples
Summary of [ANALYTE] Recovery and Suppression/Enhancement Calculations and Data
Summary of [ANALYTE] Regression Constants
Summary of Repeat Samples
Summary of [ANALYTE] Interpolated QC Standard Concentrations
Summary of [ANALYTE] Interpolated Unique QC Low for Matrix Effects on Quantitation Assessments
Incurred Samples
Summary of [ANALYTE] Twenty-four Hours Room Temp Stability in Matrix
Summary of [ANALYTE] Freeze/Thaw [#Cycles] Stability in Matrix
Seven Days Refrigerated Final Extract Stability: Summary of [ANALYTE] Interpolated QC Standard Concentrations
[ANALYTE] [Period Temp] Stock Solution Stability Assessment
[ANALYTE] [Period Temp] Spiking Solution Stability Assessment
[ANALYTE] Thirty-two Days -70 °C Long-Term QC Standard Storage Stability
System Suitability Table v1
Selectivity in Individual Lots Table v1
Carryover in Individual Lots Table v1

Report Generation:
Automatic Hyperlinking

- Report body table references should be automatically hyperlinked
- Hyperlink color should be configurable as Blue or Black
- Space between 'Table' and '#' should be automatically converted to non-breaking space
- Prevents unwanted line-wrap

16.1.1.2 Between Run QC Accuracy

Between run QC accuracy was acceptable for the assay of Cmpd1 and Cmpd2 in K2-EDTA rat plasma. The overall mean concentrations across these runs were compared to theoretical nominal concentrations and the difference was expressed as %bias. Refer to Table 3 and Table 4 for summaries of between run accuracy results for Cmpd1 and Cmpd2, respectively.

16.1.1.3 Between Run Calibration Standard Accuracy

Between run calibration standard accuracy was acceptable for the assay of Cmpd1 and Cmpd2 in K2-EDTA rat plasma. The between run accuracy statistics for the backcalculated calibration standard concentrations are also represented by %bias. Refer to Table 5 and Table 6 for summaries of the between run calibration standard accuracy results for d3 IS.

Report Generation:
Eliminate Line-Wraps

StudyDoc automatically converts report body instances to:

- Nonbreaking hyphens
- Nonbreaking spaces

Examples of unwanted line-wrap

16.1.1.3 Between Run Calibration Standard Accuracy

Between run calibration standard accuracy was acceptable for the assay of Cmpd One and Cmpd Two in K2-EDTA rat plasma. Statistics for the back-calculated calibration standard concentrations are presented for Cmpd One. Maybe you should also try representing things by writing numbers upside down and aligned. Refer to Table 5 and Table 6 for summaries of the between run calibration standard accuracy results for d3 IS.

- Hyphens
- Compound names
- Table numbers

Report Generation:
Field Codes

StudyDoc has a comprehensive set of over **200** field codes to insert information into a report

Study-Specific
Variables that are specific to the study itself

E.g. Study Name, Study Number, etc.

Table-Specific
Variables that are specific to individual tables within a study

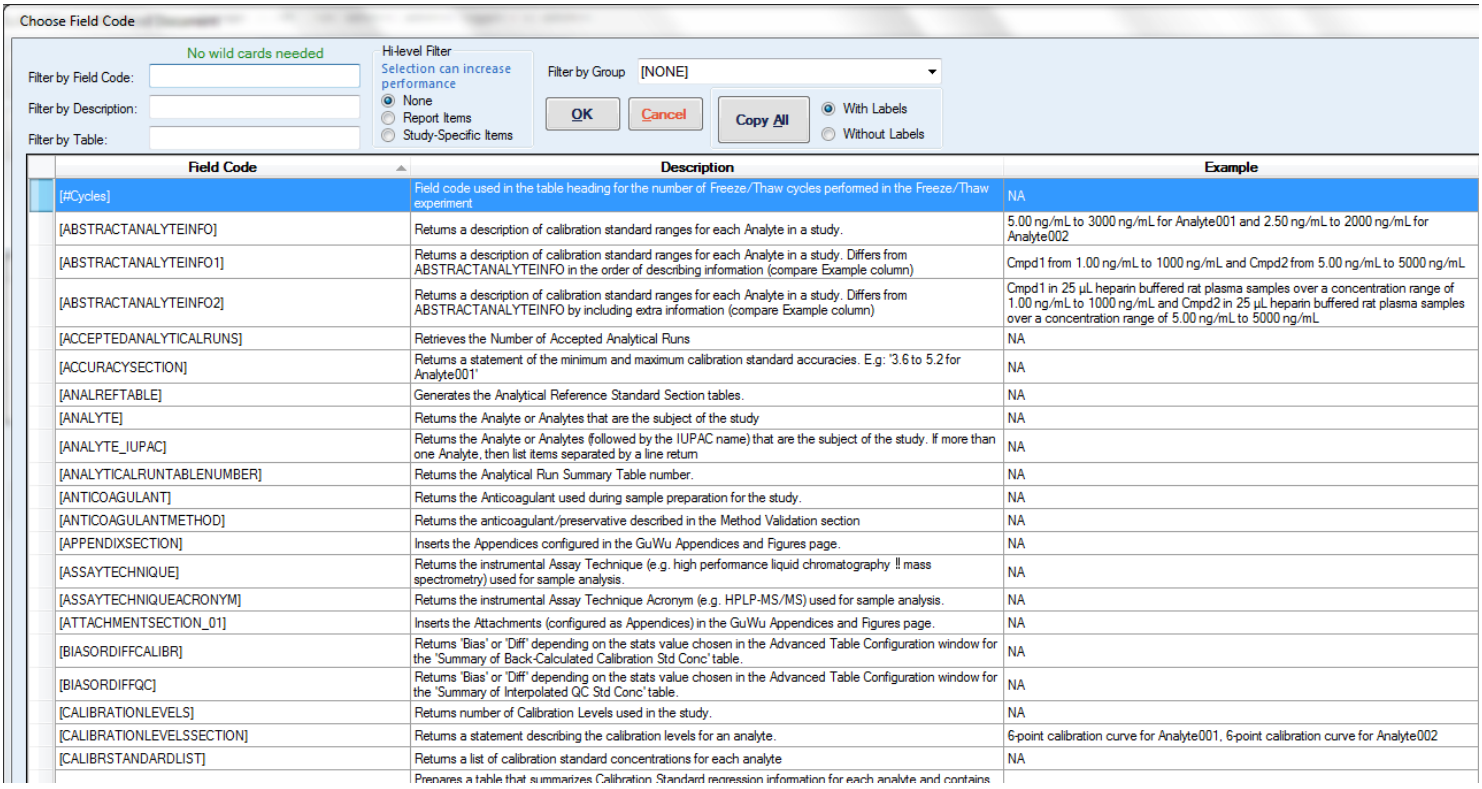
E.g. Maximum precision of the stats section of a given table, Maximum accuracy of the stats section of a given table

Custom Field Codes
Administrators can create custom field codes

Users are encouraged to use Field Codes in the report template to automatically enter study-specific and table-specific information in the report body.

Report Generation:
Field Codes

Field codes can be hand-entered or inserted using the Field Code Window.



Field Code	Description	Example
[#Cycles]	Field code used in the table heading for the number of Freeze/Thaw cycles performed in the Freeze/Thaw experiment	NA
[ABSTRACTANALYTEINFO]	Returns a description of calibration standard ranges for each Analyte in a study.	5.00 ng/mL to 3000 ng/mL for Analyte001 and 2.50 ng/mL to 2000 ng/mL for Analyte002
[ABSTRACTANALYTEINFO1]	Returns a description of calibration standard ranges for each Analyte in a study. Differs from ABSTRACTANALYTEINFO in the order of describing information (compare Example column)	Cmpd1 from 1.00 ng/mL to 1000 ng/mL and Cmpd2 from 5.00 ng/mL to 5000 ng/mL
[ABSTRACTANALYTEINFO2]	Returns a description of calibration standard ranges for each Analyte in a study. Differs from ABSTRACTANALYTEINFO by including extra information (compare Example column)	Cmpd1 in 25 µL heparin buffered rat plasma samples over a concentration range of 1.00 ng/mL to 1000 ng/mL and Cmpd2 in 25 µL heparin buffered rat plasma samples over a concentration range of 5.00 ng/mL to 5000 ng/mL
[ACCEPTEDANALYTICALRUNS]	Retrieves the Number of Accepted Analytical Runs	NA
[ACCURACYSECTION]	Returns a statement of the minimum and maximum calibration standard accuracies. E.g: '3.6 to 5.2 for Analyte001'	NA
[ANALREFTABLE]	Generates the Analytical Reference Standard Section tables.	NA
[ANALYTE]	Returns the Analyte or Analytes that are the subject of the study	NA
[ANALYTE_IUPAC]	Returns the Analyte or Analytes (followed by the IUPAC name) that are the subject of the study. If more than one Analyte, then list items separated by a line return	NA
[ANALYTICALRUNTABLENUMBER]	Returns the Analytical Run Summary Table number.	NA
[ANTICOAGULANT]	Returns the Anticoagulant used during sample preparation for the study.	NA
[ANTICOAGULANTMETHOD]	Returns the anticoagulant/preservative described in the Method Validation section	NA
[APPENDIXSECTION]	Inserts the Appendices configured in the GuWu Appendices and Figures page.	NA
[ASSAYTECHNIQUE]	Returns the instrumental Assay Technique (e.g. high performance liquid chromatography ‼ mass spectrometry) used for sample analysis.	NA
[ASSAYTECHNIQUEACRONYM]	Returns the instrumental Assay Technique Acronym (e.g. HPLP-MS/MS) used for sample analysis.	NA
[ATTACHMENTSECTION_01]	Inserts the Attachments (configured as Appendices) in the GuWu Appendices and Figures page.	NA
[BIASORDIFFCALIBR]	Returns 'Bias' or 'Diff' depending on the stats value chosen in the Advanced Table Configuration window for the 'Summary of Back-Calculated Calibration Std Conc' table.	NA
[BIASORDIFFQC]	Returns 'Bias' or 'Diff' depending on the stats value chosen in the Advanced Table Configuration window for the 'Summary of Interpolated QC Std Conc' table.	NA
[CALIBRATIONLEVELS]	Returns number of Calibration Levels used in the study.	NA
[CALIBRATIONLEVELSSECTION]	Returns a statement describing the calibration levels for an analyte.	6-point calibration curve for Analyte001, 6-point calibration curve for Analyte002
[CALIBRSTANDARDLIST]	Returns a list of calibration standard concentrations for each analyte	NA
	Prepares a table that summarizes Calibration Standard regression information for each analyte and contains	

Report Generation:
Study-Specific Field Codes

Red font items below show study-specific variables

26 study-specific variables in this single paragraph below

11.2 Method Summary

Samples in this project were analyzed for [ANALYTE] according to [SUBMITTEDBY] Laboratory Method (LM) "[LABMETHODNAME]", [LABMETHODNUMBER]. A copy of the most recent LM is included in [LMAPPENDIXNUMBER]. This method employs [METHODASSAYPROCEDUREDESCRIPTION]. This method was validated for the analysis of [ANALYTE] in [SAMPLESIZE] [SAMPLESIZEUNITS] [ANTICOAGULANT] buffered [SPECIES] [MATRIX] over a concentration range of [LLOQ] [LLOQUNITS] to [ULOQ] [ULOQUNITS]. A complete description of the assay and summaries of its performance during validation can be found in the report for [SUBMITTEDBY] validation study [METHODCORPORATESTUDY/PROJECTNUMBER].[METHODSUMMARYSTATEMENT]

Sample extraction for this project was initiated on [INITIALEXTRACTIONDATE] and completed on [LASTEXTRACTIONDATE]. See [ANALYTICALRUNTABLENUMBER] for a list of the analytical runs and extraction dates for the sample analysis of this project. [WATSONREPCHROMSECTION].

One Field Code expands to n-number of Analytes

11.2 Method Summary

Samples in this project were analyzed for Verapamil and Reserpine according to Gubbs Inc Bioanalysis R & D Division Laboratory Method (LM) "LM [illegible]". A copy of the most recent LM is included in Appendix C and Appendix D. This method employs protein precipitation. This method was validated for the analysis of Verapamil and Reserpine in 20 µL K2-EDTA buffered rat plasma over a concentration range of 1.00 ng/mL to 1000 ng/mL. A complete description of the assay and summaries of its performance during validation can be found in the report for Gubbs Inc Bioanalysis R & D Division validation study AXWV.

Sample extraction for this project was initiated on January 5, 2007 and completed on January 20, 2007. See Table 1 and Table 2 for a list of the analytical runs and extraction dates for the sample analysis of this project. Representative raw chromatographic data from Watson Run ID 5 for Verapamil and Reserpine are provided in Appendix B.

Report Generation:
Table-Specific Field Codes

Red font items below show table-specific variables

7.5 Quality Control Standard Accuracy and Precision

[QCSECTION] [DILUTIONQCSECTION] Summaries of interpolated QC standard concentrations are provided in [QCTABLENUMBERSECTION]. Mean accuracy, expressed as %[BIASORDIFFQC], ranged between [QCACCURACYSECTION] across concentrations and analytical runs. Precision, as measured by percent coefficient of variation (%CV), ranged between [QCPRECISIONSECTION] across concentrations and analytical runs.

[Or stats summary may be shown as a table – LabIntegrity]

[QCTABLE1]

11.5 Quality Control Standard Accuracy and Precision

provided in Table 7 for Verapamil and Table 8 for Reserpine.

concentrations and analytical runs. Precision, as measured by percent coefficient of variation (%CV), ranged between 2.9 to 8.7 for Verapamil and 1.9 to 5.3 for Reserpine across concentrations and analytical runs.

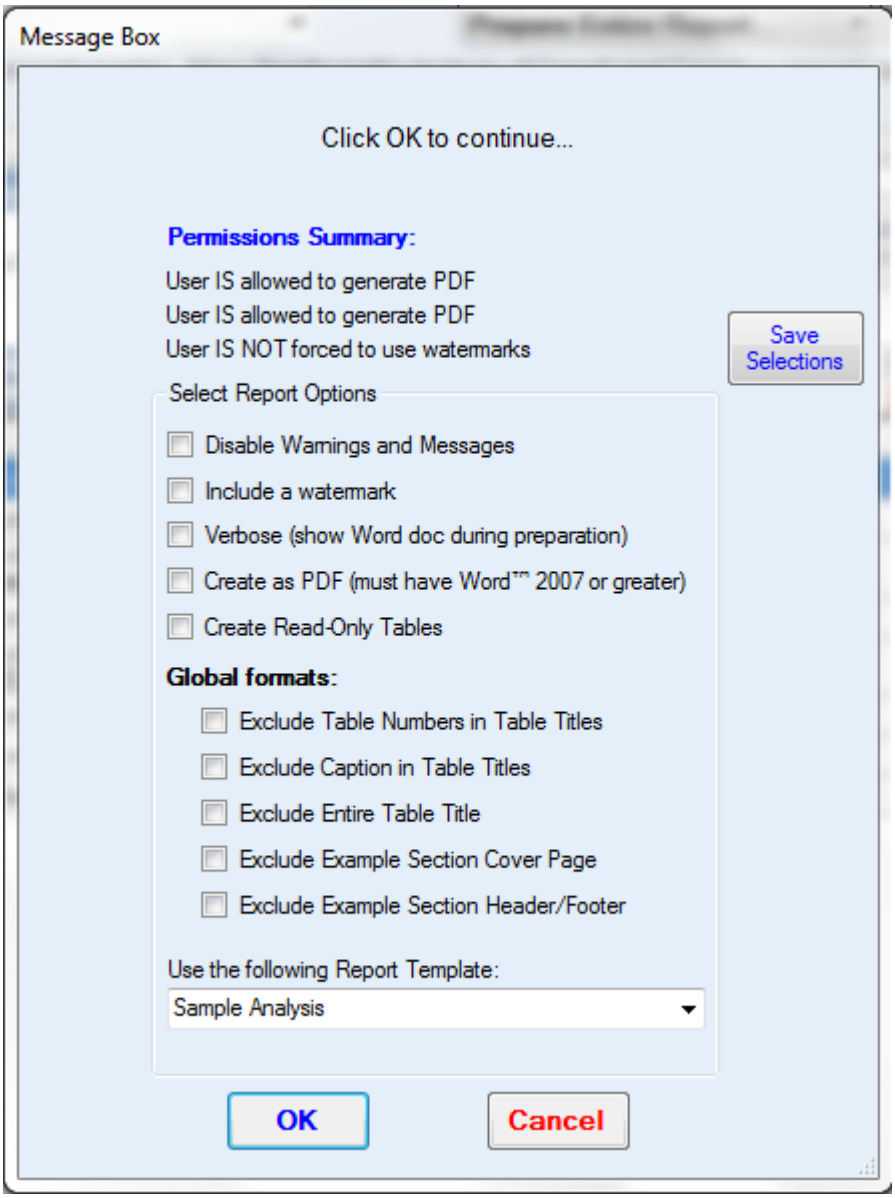
[Or stats summary may be shown as a table – LabIntegrity]

	Mean Accuracy (%Bias)			Precision (%CV)		
Analyte	Min	Max	Table #	Min	Max	Table #
Verapamil	0.6	8.7	Table 7	2.9	8.7	Table 7
Reserpine	1.7	6.0	Table 8	1.9	5.3	Table 8

Min and Max Accuracy and Precision QC Values

Report Generation:
Prepare Reports

- Report can be configured:
  - Include watermark
    - Or be forced to include watermark depending on user permissions
  - Create directly as PDF
    - Or be forced to create directly as PDF depending on user permissions



Report Generation:
Hooks and Custom Reports

StudyDoc™ supports 'Hooks'

- Retrieve information from other data stores
  - Analytical Reference Standards
  - Electronic notebooks
  - Enabled with StudyDoc™ customization

StudyDoc™ supports Custom Reports

- Some customers tables are completely different than those produced by StudyDoc™
  - Not feasible to write code for a complete set of tables specific to one client
  - Instead, use Custom Reports

Report Generation:
Custom Reports

- **A Custom Report is a Microsoft® Word report template**
  - Contains embedded VBA code that generates report and tables as required by customer
    - VBA code can be written by customer or LabIntegrity
    - VBA code is essentially customer-specific extension of StudyDoc™

- **Code is completely owned by customer**

- **Code is maintained outside the auspices of StudyDoc™**
  - No StudyDoc™ modification required

Data Integrity Requirements

An automated report writing solution should contain features to allow managers the ability to monitor the progress of the report itself.

Data Integrity:
Report Requirements

Follow progress of study by viewing Analytical Run Summary

Review Analytical Runs

*A = Include in Run Summary Table
*B = Include in Regression, Calibr, and QC Tables
B NOTE: If the analytical run has no calibration information, that run will not be reported, even if checked

Analytical Run Summary Table Options

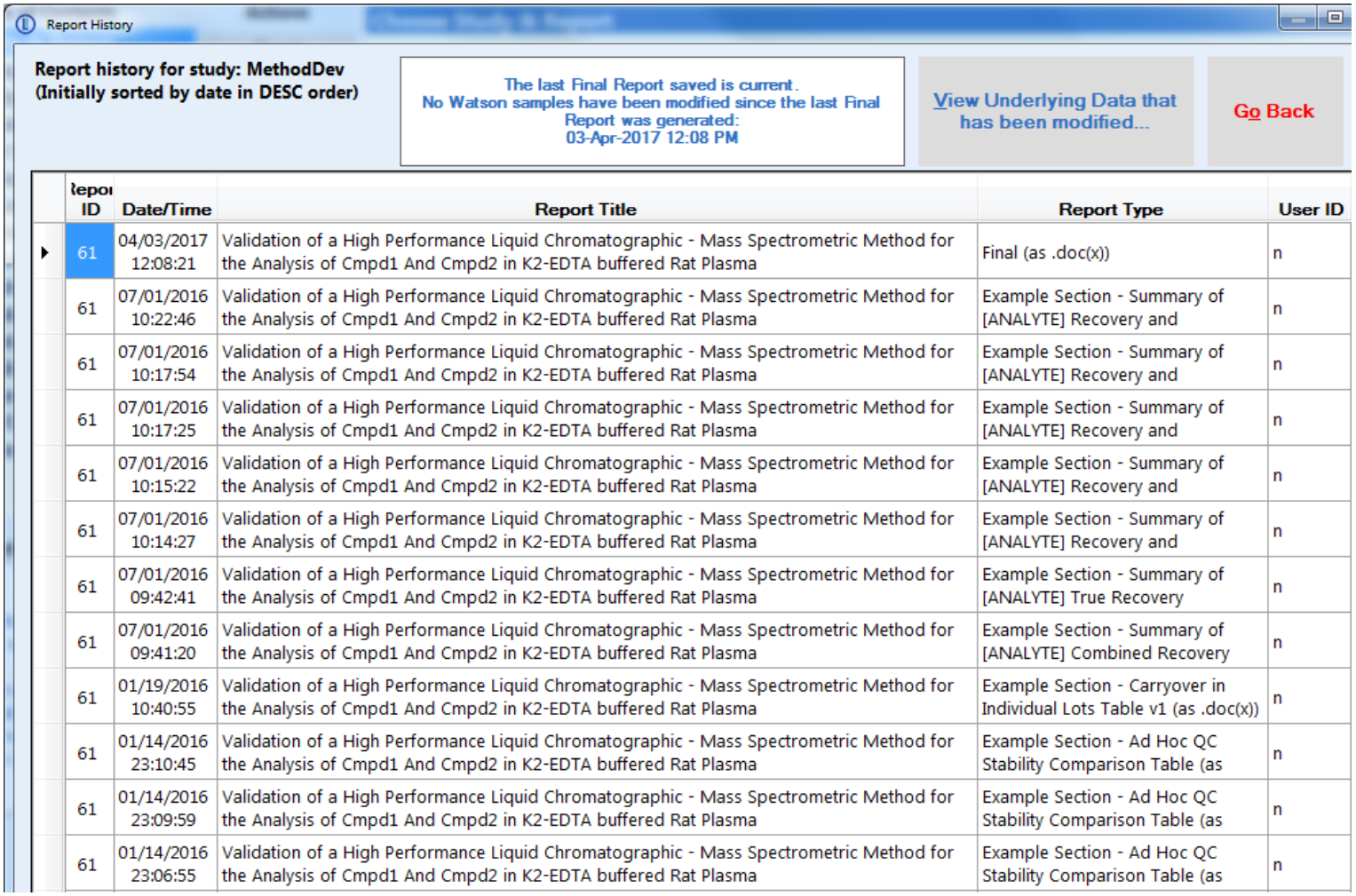
Include the following run/regression types:
- [x] All Analytical Runs
- [ ] Accepted Regression
- [ ] Rejected Regression
- [ ] Regression Performed
- [ ] NO Regression Performed
- [ ] Include PSAE Runs

- ( ) Use Watson Comments
- (•) Use User Comments

	A *	B *	Watson Run ID	Analyte	Run Type	Notebook ID	Extraction Date	Analysis Date	Pass/Fail	Run Description	Watson Comments
1	☑	☑	1	Cmpd1	VALIDATION	MethDev-008	12/12/2012	12/13/2012	NO Regression Performed	STK CHK	
2	☑	☑	2	Cmpd1	PSAE	MethDev-010-1	12/14/2012	12/14/2012	Accepted	Test batch	OK
3	☑	☑	3	Cmpd1	VALIDATION	MethDev-1-014	12/15/2012	12/15/2012	Accepted	Accuracy, Precision, Matrix effects	OK
4	☑	☑	4	Cmpd1	VALIDATION	MethDev-1-015	12/15/2012	12/16/2012	Accepted	Accuracy, precision, dilution, recovery	OK
5	☑	☑	5	Cmpd1	VALIDATION	MethDev-1-016	12/18/2012	12/23/2012	Accepted	Accuracy and Precision, 4 Cycles F/T, 24h RT	OK
	☐	☐									
1	☑	☑	1	Cmpd2	VALIDATION	MethDev-008	12/12/2012	12/13/2012	NO Regression Performed	STK CHK	
2	☑	☑	2	Cmpd2	PSAE	MethDev-010-1	12/14/2012	12/14/2012	Accepted	Test batch	OK
3	☑	☑	3	Cmpd2	VALIDATION	MethDev-1-014	12/15/2012	12/15/2012	Accepted	Accuracy, Precision, Matrix effects	OK
4	☑	☑	4	Cmpd2	VALIDATION	MethDev-1-015	12/15/2012	12/16/2012	Accepted	Accuracy, precision, dilution, recovery	OK
5	☑	☑	5	Cmpd2	VALIDATION	MethDev-1-016	12/18/2012	12/23/2012	Accepted	Accuracy and Precision, 4 Cycles F/T, 24h RT	OK

Data Integrity:
Report Requirements

View Report Generation History with 'View Report History…' button



Report History

Report history for study: MethodDev
(Initially sorted by date in DESC order)

The last Final Report saved is current.
No Watson samples have been modified since the last Final Report was generated:
03-Apr-2017 12:08 PM

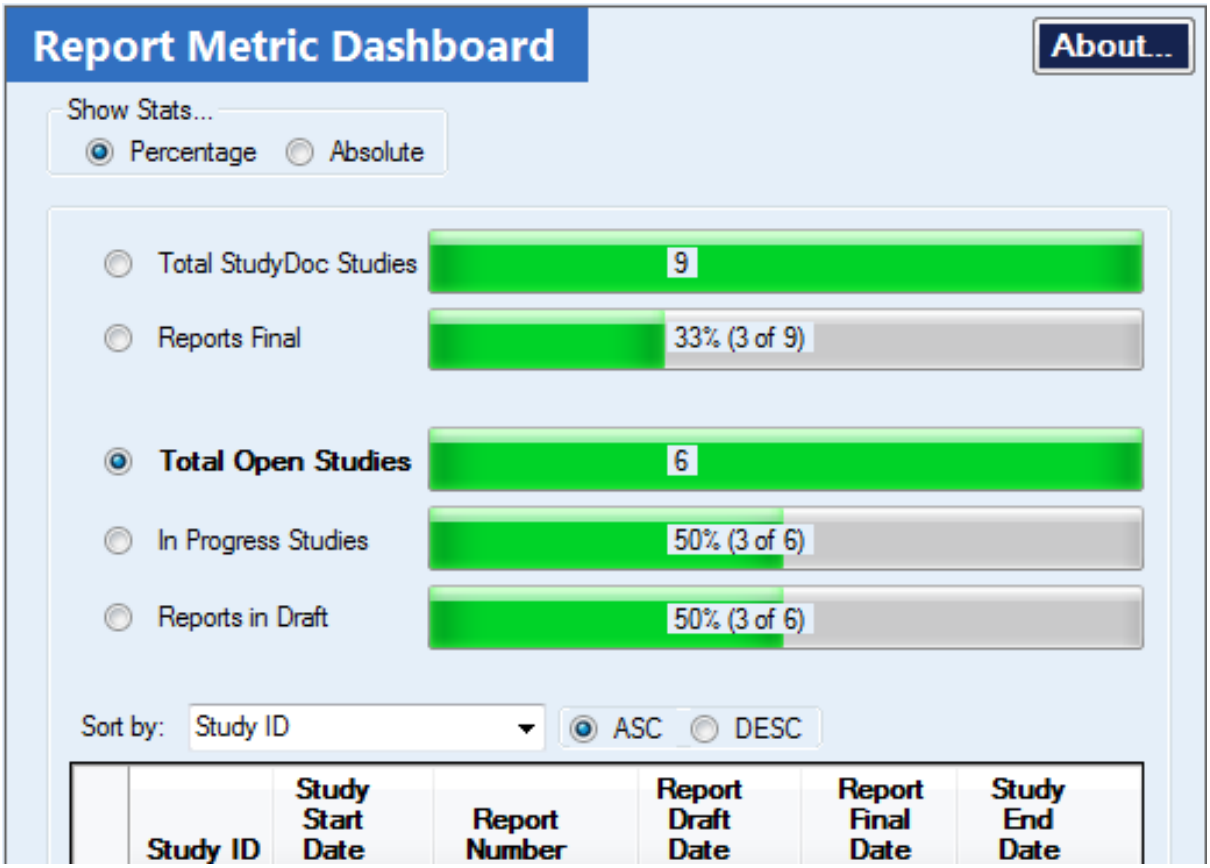
View Underlying Data that has been modified...

Go Back

Report ID	Date/Time	Report Title	Report Type	User ID
61	04/03/2017 12:08:21	Validation of a High Performance Liquid Chromatographic - Mass Spectrometric Method for the Analysis of Cmpd1 And Cmpd2 in K2-EDTA buffered Rat Plasma	Final (as .doc(x))	n
61	07/01/2016 10:22:46	Validation of a High Performance Liquid Chromatographic - Mass Spectrometric Method for the Analysis of Cmpd1 And Cmpd2 in K2-EDTA buffered Rat Plasma	Example Section - Summary of [ANALYTE] Recovery and	n
61	07/01/2016 10:17:54	Validation of a High Performance Liquid Chromatographic - Mass Spectrometric Method for the Analysis of Cmpd1 And Cmpd2 in K2-EDTA buffered Rat Plasma	Example Section - Summary of [ANALYTE] Recovery and	n
61	07/01/2016 10:17:25	Validation of a High Performance Liquid Chromatographic - Mass Spectrometric Method for the Analysis of Cmpd1 And Cmpd2 in K2-EDTA buffered Rat Plasma	Example Section - Summary of [ANALYTE] Recovery and	n
61	07/01/2016 10:15:22	Validation of a High Performance Liquid Chromatographic - Mass Spectrometric Method for the Analysis of Cmpd1 And Cmpd2 in K2-EDTA buffered Rat Plasma	Example Section - Summary of [ANALYTE] Recovery and	n
61	07/01/2016 10:14:27	Validation of a High Performance Liquid Chromatographic - Mass Spectrometric Method for the Analysis of Cmpd1 And Cmpd2 in K2-EDTA buffered Rat Plasma	Example Section - Summary of [ANALYTE] Recovery and	n
61	07/01/2016 09:42:41	Validation of a High Performance Liquid Chromatographic - Mass Spectrometric Method for the Analysis of Cmpd1 And Cmpd2 in K2-EDTA buffered Rat Plasma	Example Section - Summary of [ANALYTE] True Recovery	n
61	07/01/2016 09:41:20	Validation of a High Performance Liquid Chromatographic - Mass Spectrometric Method for the Analysis of Cmpd1 And Cmpd2 in K2-EDTA buffered Rat Plasma	Example Section - Summary of [ANALYTE] Combined Recovery	n
61	01/19/2016 10:40:55	Validation of a High Performance Liquid Chromatographic - Mass Spectrometric Method for the Analysis of Cmpd1 And Cmpd2 in K2-EDTA buffered Rat Plasma	Example Section - Carryover in Individual Lots Table v1 (as .doc(x))	n
61	01/14/2016 23:10:45	Validation of a High Performance Liquid Chromatographic - Mass Spectrometric Method for the Analysis of Cmpd1 And Cmpd2 in K2-EDTA buffered Rat Plasma	Example Section - Ad Hoc QC Stability Comparison Table (as	n
61	01/14/2016 23:09:59	Validation of a High Performance Liquid Chromatographic - Mass Spectrometric Method for the Analysis of Cmpd1 And Cmpd2 in K2-EDTA buffered Rat Plasma	Example Section - Ad Hoc QC Stability Comparison Table (as	n
61	01/14/2016 23:06:55	Validation of a High Performance Liquid Chromatographic - Mass Spectrometric Method for the Analysis of Cmpd1 And Cmpd2 in K2-EDTA buffered Rat Plasma	Example Section - Ad Hoc QC Stability Comparison Table (as	n

Data Integrity:
Report Requirements

StudyDoc opening Console window contains a metrics table



All Watson Studies are listed in this table

Data Integrity:
Features

Data Integrity is of utmost concern in the Report Generation Process

While the Word™ final report document is open and being modified with study-specific metadata information, the raw data tables are unprotected and open to unintentional modification

StudyDoc contains features to help ensure the integrity of raw data tables

Data Integrity:
Features

- **[LOCKSECTION]** Field Code can be used for any section
- Uses Word™ 'Restrict Editing' feature to render defined sections as Read-Only
- See example (below): all tables will be unable to edit

Project Number: [CORPORATESTUDY/PROJECTNUMBER]

TABLES

[LOCKSECTION]
[TABLESECTION]
[UNLOCKSECTION]

Data Integrity:
Features

- Option to add table-specific page numbering
- Option to add date/time stamp to table

Table 1. → Summary of Cmpd1 Regression Constants

Watson Run ID	A[a]	B[a]	R-Squared
1	2.6933E-2	2.0024E-3	9.9728E-1
2	2.7440E-2	1.0743E-3	9.9786E-1
3	2.4572E-2	-1.6091E-3	9.9052E-1
4	2.5061E-2	-5.3021E-4	9.4446E-1
5	2.4052E-2	-6.3360E-4	9.9609E-1
6	2.4396E-2	2.1584E-3	9.9800E-1
Mean	2.5409E-2	4.1037E-4	9.8737E-1
SD	1.4239E-3	1.5546E-3	2.1206E-2
%CV	5.6	378.8	2.1
n	6	6	6

[a] = Linear Regression: y = Ax + B where y is the peak area ratio of Cmpd1 to Int. Std., x is the concentration of Cmpd1, and A and B are regression constants. Regression weighted 1/x^2.

Page 1 of 1
06/12/2012 13:48:20 PM

Data Integrity:
Features

Can insert tables as figures (to prevent editing)

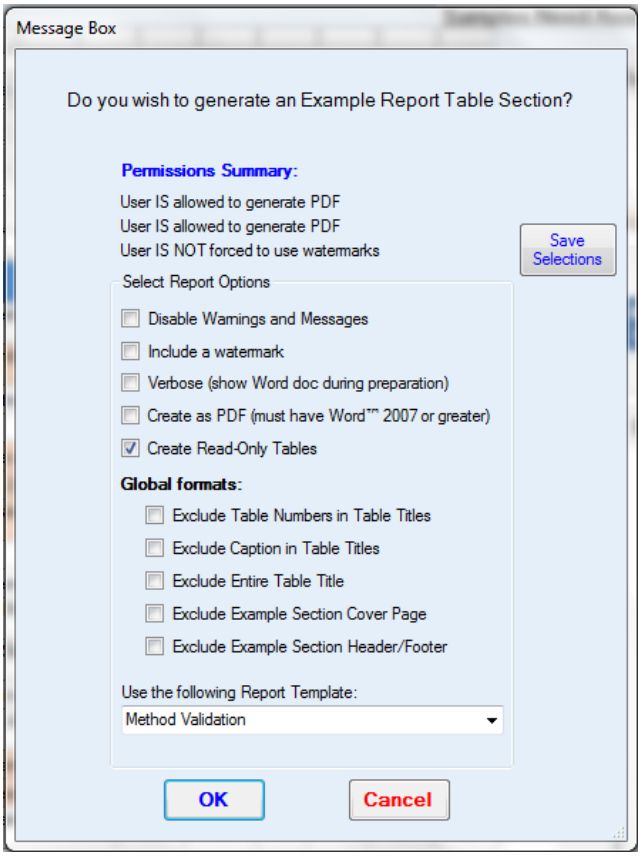


Table is an embedded Figure

Table 1. → Summary of Cmpd1 Regression Constants

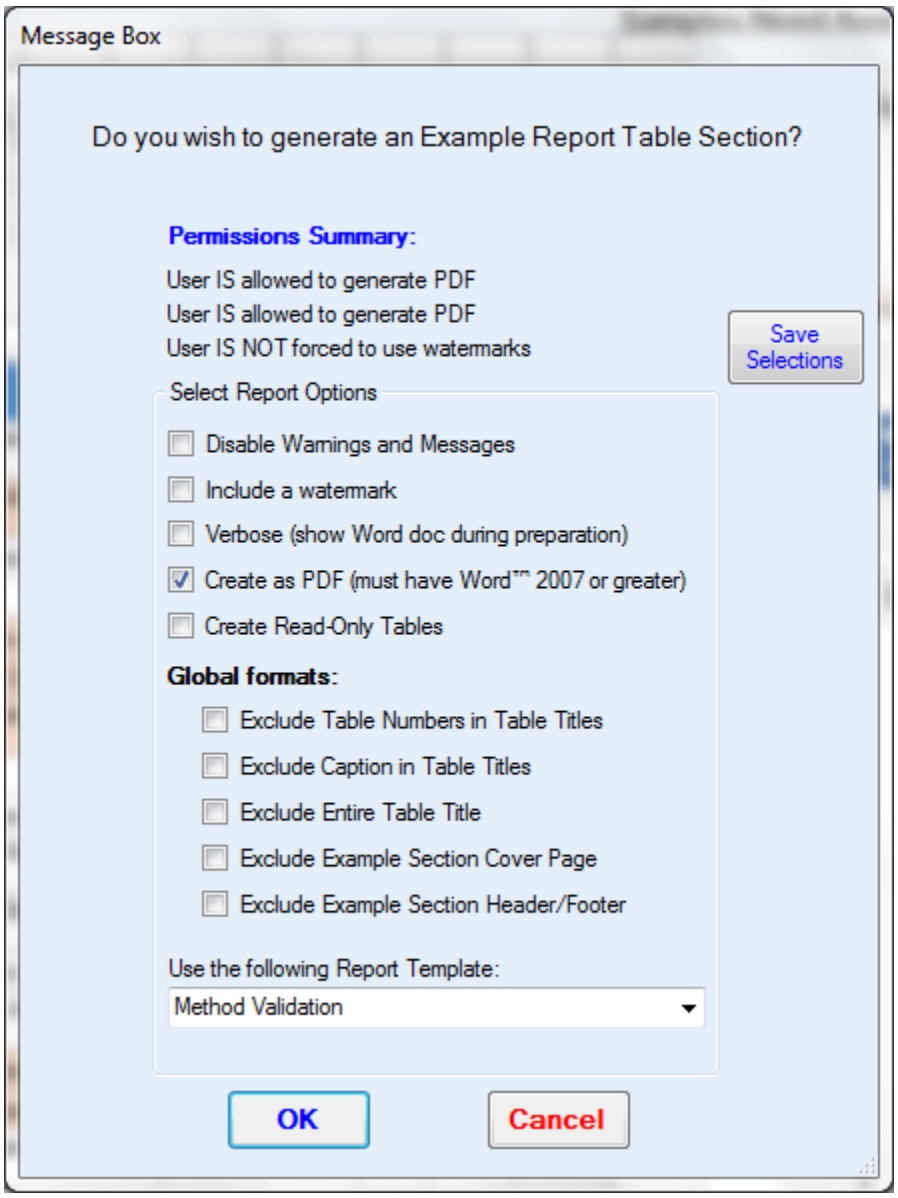
Watson Run ID	A[a]	B[a]	R-Squared
1	2.6933E-2	2.0024E-3	9.9728E-1
2	2.7440E-2	1.0743E-3	9.9786E-1
3	2.4572E-2	-1.6091E-3	9.9052E-1
4	2.5061E-2	-5.3021E-4	9.4446E-1
5	2.4052E-2	-6.3360E-4	9.9609E-1
6	2.4396E-2	2.1584E-3	9.9800E-1
Mean	2.5409E-2	4.1037E-4	9.8737E-1
SD	1.4239E-3	1.5546E-3	2.1206E-2
%CV	5.6	378.8	2.1
n	6	6	6

[a] = Linear Regression: y = Ax + B where y is the peak area ratio of Cmpd1 to Int. Std., x is the concentration of Cmpd1, and A and B are regression constants. Regression weighted 1/x^2.

Page 1 of 1
06/12/2012 13:48:20 PM

Data Integrity:
Features

- Create entire report as PDF
- User can be restricted to only PDF



LabIntegrity Validation Services

StudyDoc Scripts available for purchase

- End User scripts
- Unit Testing scripts

StudyDoc Validation Services

- LabIntegrity personnel can assist in the Validation Project at contracted levels

StudyDoc™ Evaluation

- StudyDoc is available as a fully-functional trial three-month license (extendable upon request)
- Trial version communicates with Watson archived .mdb studies
- Validated Watson™ instance untouched
- StudyDoc™ validation services and/or test scripts can also be provided

StudyDoc™ Service Plans

We are here to support your report writing success every step of the way even long after you have been onboarded with the StudyDoc Solution. We offer two service plans for you 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		✓

StudyDoc™ Solution

StudyDoc is unmatched in providing a solution with features that address as much as possible
ALL aspects of the preparation of the GLP Final Report

StudyDoc has 21 CFR Part 11 Compliant features (Audit Trail, ESig, Security)

StudyDoc is available as a fully-functional trial version that can be installed and evaluated without the need of IT interaction or Watson database connection.

Thank You

Contact Us:

Info@labintegrity.com

770-573-0169