



datainnovations.com

EP Evaluator 12.0 – What's New

11-2017

Enhancements in release 12.0

- **New Statistical Module EP09-A3**

- New statistical module designed for CLSI protocol EP09-A3 (2013) "Measurement Procedure Comparison and Bias Estimation Using Patient Samples".
- Method comparison using multiple replicates using advanced regression algorithms.
- Primarily for vendors and LDT (Lab Developed Test). Can be used in place of Method Comparison (EP9)

- **Licensing and versions streamlined**

- Help file has been enhanced to more clearly mark the additional functionality that is available with EE Professional version.
- Trial Version is 30 days rather than 14.

- **EE 12.0 compatible with Microsoft Edge and Windows 10**

- **Multifunction desktop quick help buttons added**

- New help buttons added to Statistical Modules overview screen access EE File Manager, EE Help, and EE resources on the Data Innovations website.

New Screen Features

The screenshot shows the EP Evaluator software interface. The title bar reads "EP Evaluator [AACC/Demo 2016]". The menu bar includes "File", "Edit", "Module", "Experiment", "RRE", "ERI View", "Utilities", "Tools", "Help", and "Debug". The toolbar contains various icons for file operations and analysis. The main window title is "Project- AACC/Demo 2016".

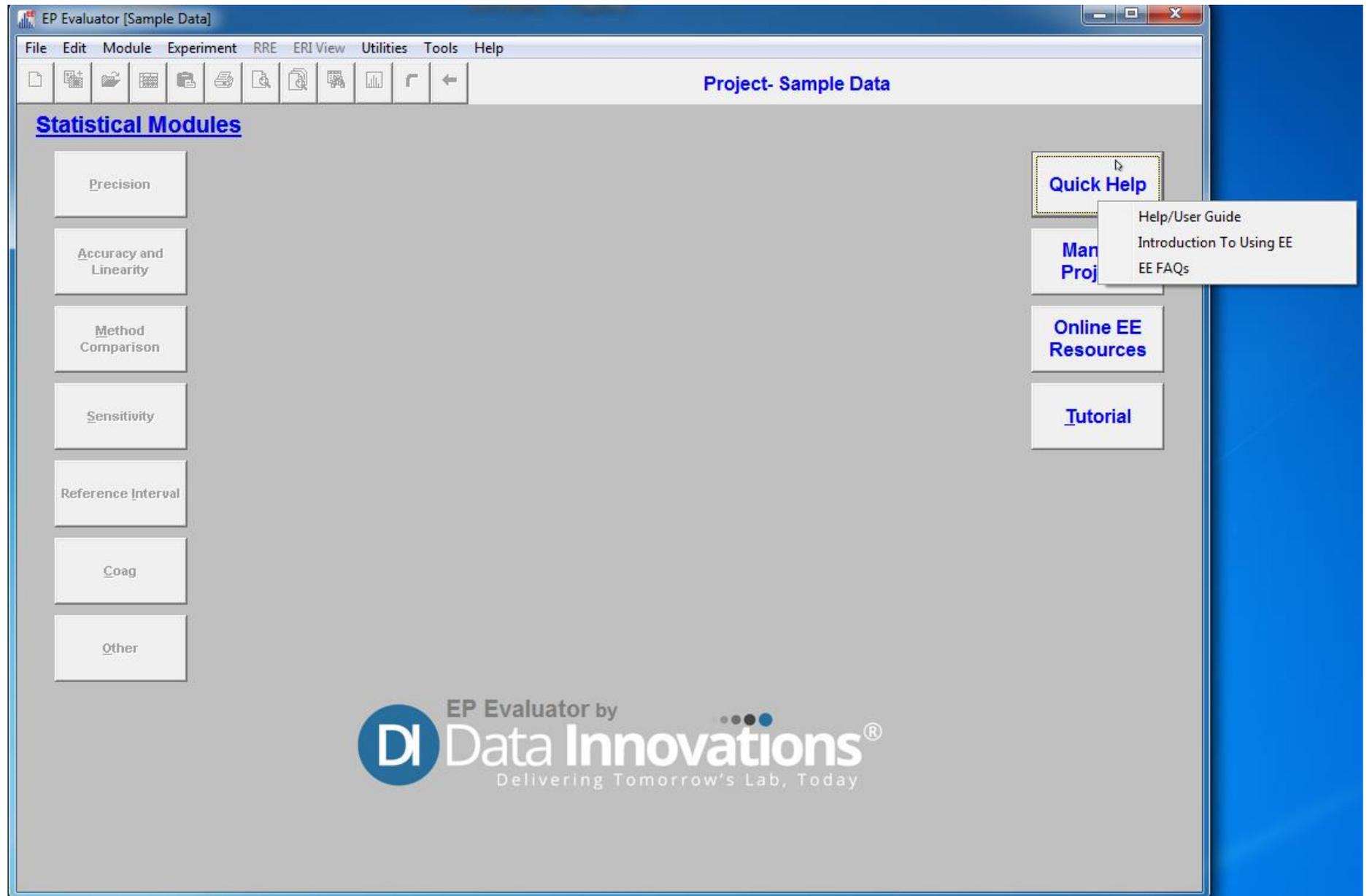
The "Statistical Modules" section is highlighted. It contains several buttons: "Precision", "Accuracy and Linearity", "Method Comparison", "Sens", "Refer Inte", "Coag", and "Other". The "Sens" button is selected, and a dropdown menu is open, listing the following options: "Alternate (Quantitative)", "CLSI EP9", "CLSI EP9A3" (highlighted in yellow), "Qualitative and SemiQuant", "2-Instrument Comparison", "Multiple Instrument Comparison", "Glucose POC Instrument Evaluation", and "Hematology Studies".

Three red arrows with the word "NEW" are overlaid on the interface, pointing to the "Sens" button, the "CLSI EP9A3" option in the dropdown menu, and the "Method Comparison" button.

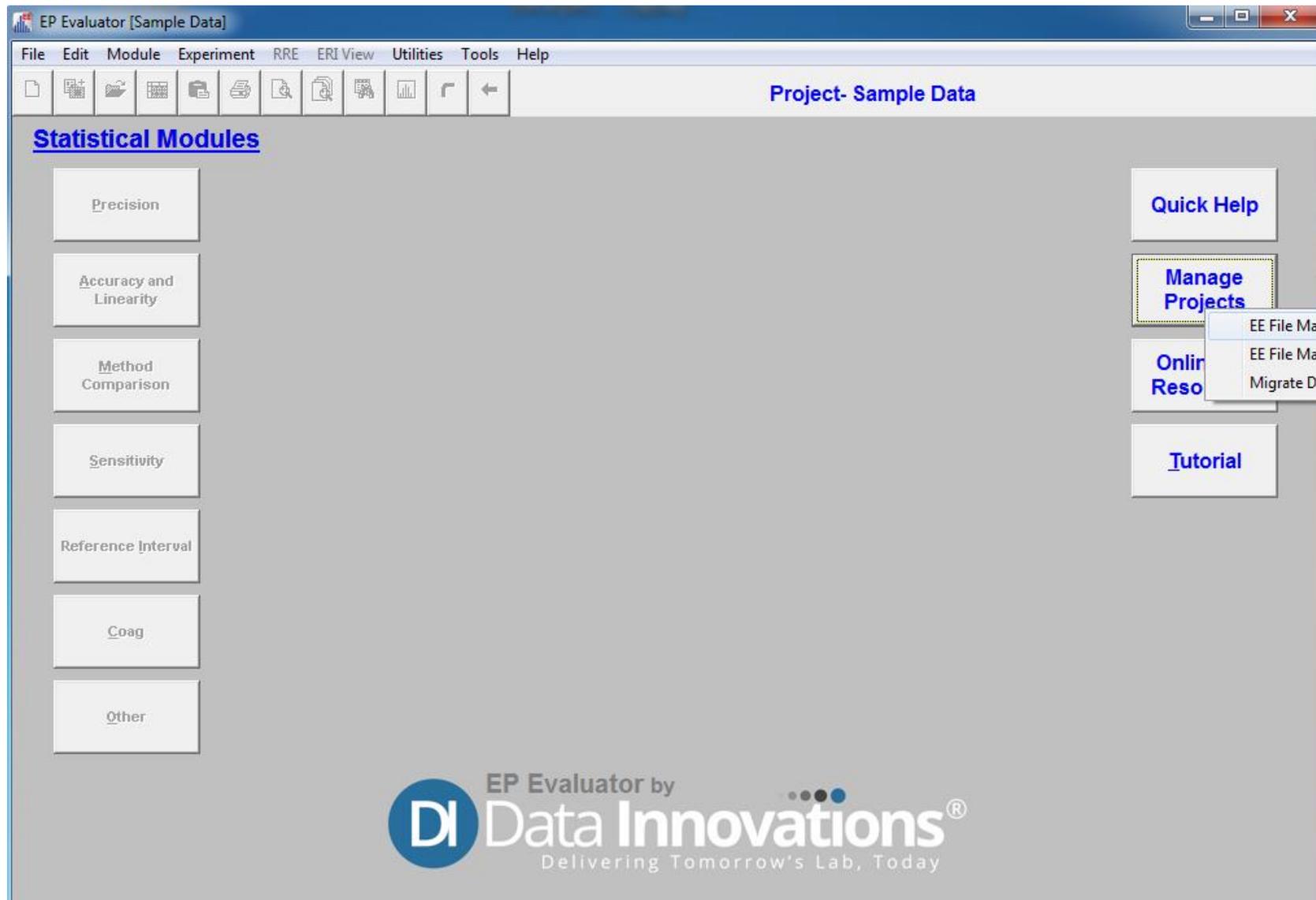
On the right side of the interface, there are four buttons: "Quick Help", "Manage Projects", "Online EE Resources", and "Tutorial".

The logo for "EP Evaluator by Data Innovations" is located at the bottom right of the interface, with the tagline "Delivering Tomorrow's Lab, Today".

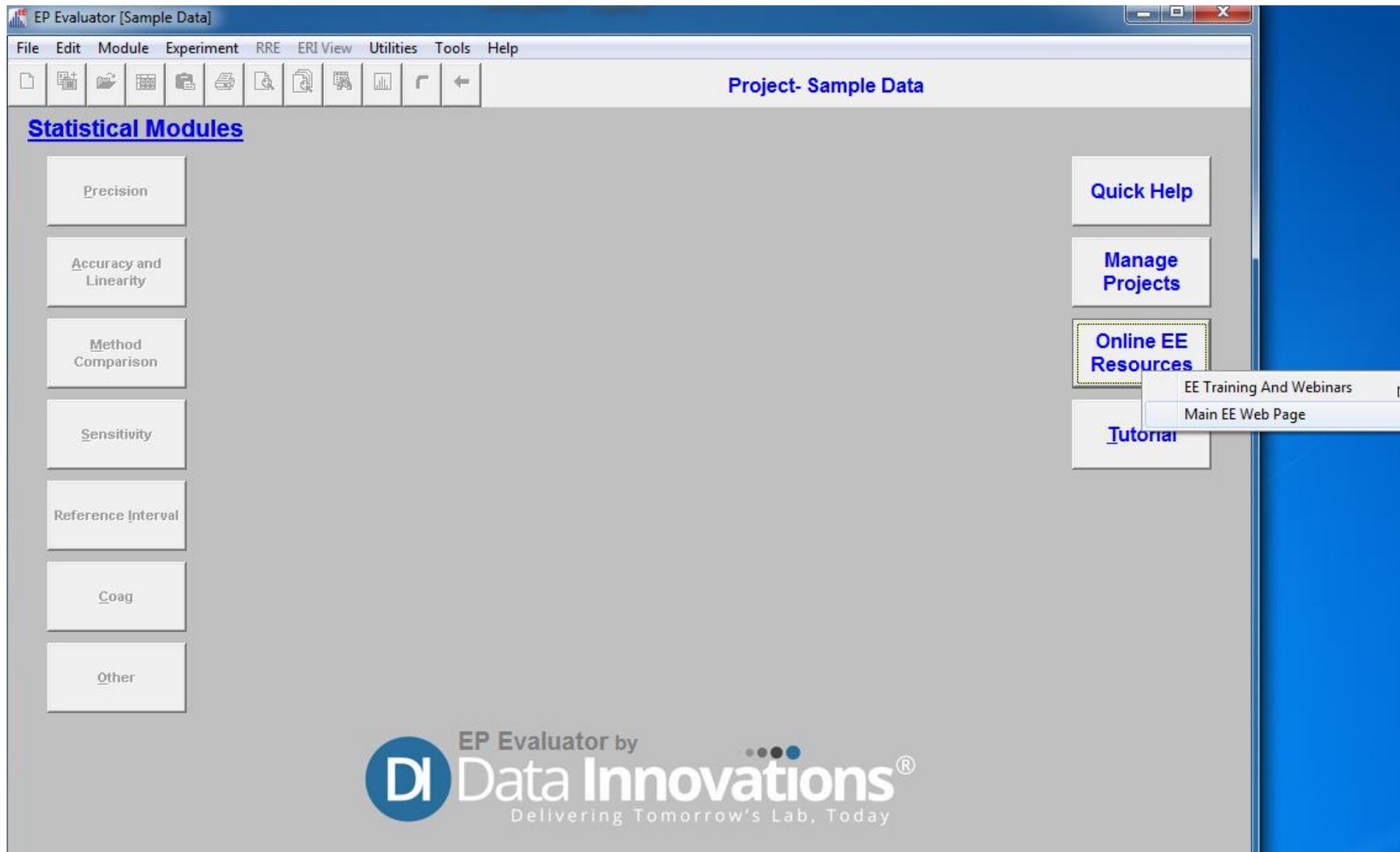
Links for Quick Help



Links for Manage Projects

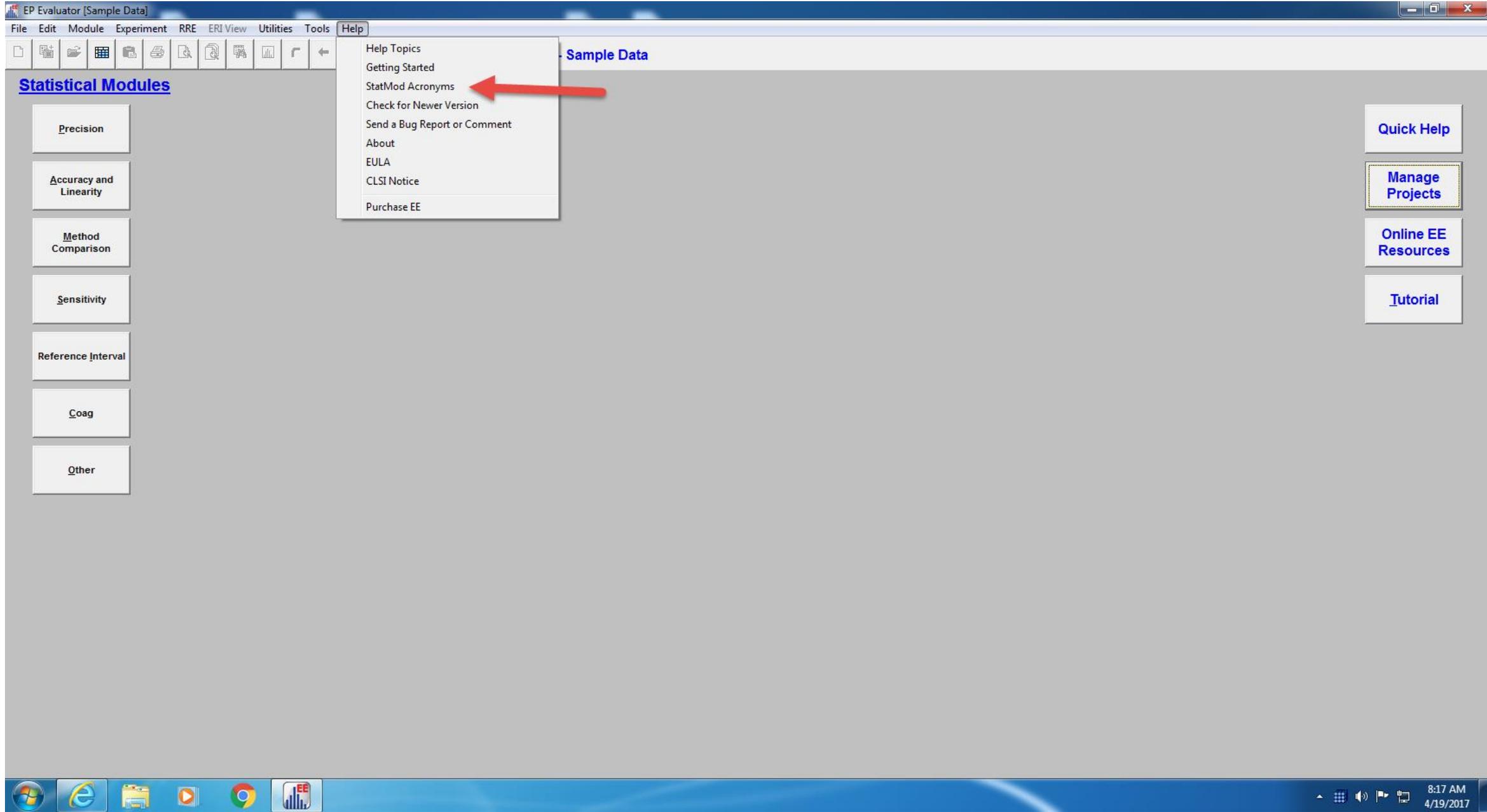


Links for Online EE Resources



Enhancements in release 12.0

- **Warning when entering organization details at registration**
 - When entering unlock codes to activate the software, users are now informed that they must enter accurate default user Organization, Institution and Location details.
- **Auto-correction of non-standard dash characters at unlock**
 - When entering unlock codes, EP Evaluator now auto-corrects the character type for dashes used in the text of the codes.
- **Help system enhancements including reference list of statistical modules and acronyms**
 - Users can now access a list of all the statistical modules available and the acronyms used, directly from the interface itself through the Help menu



Contents

- Welcome to EP Evaluator®
- Introduction to Using EP Evaluator
- FAQs for IT Administrators
- What's New in Release 12
- List of Statistical Modules & Acronyms**
- Resources Spreadsheets
- Terms of use, trademarks, and copyright
- Interface Overview
- Common Operations
- Statistical Modules
- Projects
- Reports
- Lab Management Modules
- Data Management
- Translation into non-English Languages
- Professional Version Overview
- Professional Version: Security and Passwords
- Professional Version: AuditVu
- Professional Version: ODBC
- Zipper
- Other Tools
- Ordering and Activating EE
- Contacting Data Innovations
- EULA
- Glossary

The list of statistical modules arranged as per the overview screen

[Click here to see the list ordered alphabetically](#) See the Statistical Modules help chapters for full details of each module. The section is marked with a sigma sign in the table of contents. This list is also accessible from the EE interface **Help** option on the main menu bar.

Precision (Click for module page)	Title of Module and Description (Hover over for summary)
SP	Simple
CP	Complex (incl CLSI EP5)
Accuracy and Linearity	
LIN	Linearity and Calibration Verification
SA	Simple Accuracy
EP6	EP6 Linearity
TRU	Trueness
Method Comparison	
AMC	Alternate (Quantitative)
EP9	CLSI EP9
EP9A3	CLSI EP9A3
QMC	Qualitative and SemiQuant
2IC (or SMC)	2-Instrument Compare
MIC (or MMC)	Multiple Instrument Comparison
ERG (or POC, GLUPOC)	Glucose POC Instrument Evaluation
HMC	Hematology Studies
Sensitivity	
LOB	Limit of Blank
LOQ	Limit of Quantitation
Reference Interval	
VRI	Verify Reference Interval
ERI/ROC	Establish Reference Interval/ROC

-  Welcome to EP Evaluator®
-  Introduction to Using EP Evaluator
-  FAQs for IT Administrators
-  What's New in Release 12
-  **List of Statistical Modules & Acronyms**
-  Resources Spreadsheets
-  Terms of use, trademarks, and copyright
-  Interface Overview
-  Common Operations
-  **Statistical Modules**
-  Projects
-  Reports
-  Lab Management Modules
-  Data Management
-  Translation into non-English Languages
-  Professional Version Overview
-  Professional Version: Security and Passwords
-  Professional Version: AuditVu
-  Professional Version: ODBC
-  Zipper
-  Other Tools
-  Ordering and Activating EE
-  Contacting Data Innovations
-  EULA
-  Glossary



The list of statistical modules arranged as per the overview screen

[Click here to see the list ordered alphabetically](#) See the Statistical Modules help chapters for full details of each module. The section is marked with a sigma sign  in the table of contents. This list is also accessible from the EE interface **Help** option on the main menu bar.

Precision (Click for module page) **Title of Module and Description** (Hover over for summary)

[SP](#)

Simple

[CP](#)

[Complex \(incl CLSI EP5\)](#)

Accuracy and Linearity

[LIN](#)

Complex Precision calculates within run, between run, between day, and total precision. The CLSI EP5 protocol is a subset of this statistical module.

[SA](#)

Verification

[EP6](#)

[TRU](#)

Method Comparison

[AMC](#)

Alternate (Quantitative)

[EP9](#)

CLSI EP9

[EP9A3](#)

CLSI EP9A3

[QMC](#)

Qualitative and SemiQuant

[2IC \(or SMC\)](#)

2-Instrument Compare

[MIC \(or MMC\)](#)

Multiple Instrument Comparison

[ERG \(or POC, GLUPOC\)](#)

Glucose POC Instrument Evaluation

[HMC](#)

Hematology Studies

Sensitivity

[LOB](#)

Limit of Blank

New Help Design

Statistical Modules Grouped

Pro Features are highlighted as such

DI Data Innovations®
Delivering Tomorrow's Lab, Today

Contents

- Welcome to EP Evaluator®
- Introduction to Using EP Evaluator
- FAQs for IT Administrators
- What's New in Release 12
- List of Statistical Modules & Acronyms
- Resources Spreadsheets
- Terms of use, trademarks, and copyright
- Interface Overview
- Common Operations
- Statistical Modules**
- Projects
- Reports
- Lab Management Modules
- Data Management
- Translation into non-English Languages
- Professional Version Overview**
- Professional Version: Security and Passwords**
- Professional Version: AuditVu**
- Professional Version: ODBC**
- Zipper
- Other Tools
- Ordering and Activating EE
- Contacting Data Innovations
- EULA
- Glossary

EE EP Evaluator®
Quality Assurance ... Simplified™

Welcome to EP Evaluator® 12.0

Congratulations you have successfully installed EP Evaluator. Thank you for choosing this [Data Innovations](#) laboratory test equipment using EP Evaluator's powerful suite of statistical modules. Your methods will

Enter your data in a variety of ways according to your requirements. EP Evaluator will analyze your data complete, EP evaluator will present your data in professionally designed and formatted reports.

Sample reports are available from the [EP Evaluator](#) resources page online.

This help guide provides the detailed information you need to navigate through the different processes.

New in EP Evaluator version 12.0 is a [module dedicated to the CLSI protocol EP9A3 \(2013\)](#) "Measurement of Total Error Allowable (TEa) for common clinical lab test analytes, on the program interface and in this help guide.

[The full list of Statistical Modules](#) and the acronyms used to referred to them is now accessible from the

For real-world instrument/patient sample applications, users may obtain key statistics from the following:

ONLINE: [Total Error Allowable \(TEa\)](#) table for all common clinical lab test analytes, taken from approved

ONLINE: [Reference Interval Ranges](#) for common clinical lab test analytes, taken from approved referen

NOTE: these values are for guidance and customers must check manufacturer's values supplied with in

In addition to the statistical modules, EP Evaluator provides a set of Lab Management Programs accessi

A Lab [Incident Tracking](#) database, an [Inventory Management](#) tool and a [Competency Assessment](#) system

History of EP Evaluator

Statistical Modules

Within Each Module is an Experiment Design Tab

DI Data Innovations®
Delivering Tomorrow's Lab, Today

Contents

- Resources Spreadsheets
- Terms of use, trademarks, and copyright
- Interface Overview
- Common Operations
- Statistical Modules
 - Simple Precision
 - SP: Overview
 - SP: Experiment Design**
 - SP: Parameters
 - Complex Precision
 - Linearity and Calibration Verification
 - Simple Accuracy
 - EP6 Linearity
 - Trueness
 - Alternate Method Comparison
 - EP9 Method Comparison
 - EP9A3 Advanced Method Comparison
 - Qualitative Method Comparison
 - 2-Instrument Comparison
 - Multiple Instrument Comparison
 - Glucose POC Instrument Evaluation
 - Hematology Method Comparison
 - Sensitivity-Limit of Blank
 - Sensitivity-Limit of Quantitation
 - Verify Reference Interval
 - ERI/ROC
 - COAG/INR Modules
 - Factor Sensitivity
 - EP10 Preliminary Evaluation
 - Carryover
 - Six Sigma Metrics
 - Performance Standards
 - Interference
 - Average of Normals
 - Histogram and Descriptive Statistics
 - Stability
- Projects
- Reports
- Lab Management Modules
- Data Management

Simple Precision Experiment Design

A minimum of 3 results are required to display the graph on the screen and to generate a report. A good precision study should include 20-50 replicates. The maximum number of results is 10,000. NOTE: In the Simple Precision module there is no requirement nor provision for replicate results or multiple

Experiment Detail Screen

The Experimental Detail Screen displays a wealth of detail about this experiment. Experimental Results are displayed on the left side. They are identified by [redacted] were entered. Results can be entered manually, pasted here from spreadsheets, or brought in using [RRE](#) (Rapid Results Entry). The Levey-Jennings chart is [redacted] SDI (standard deviation index) is plotted on the Y axis. Index number along the X axis.

Key statistics are displayed on the information bar along the lower part of the screen (Observed Mean, Target Mean, Observed SD, etc.). The status of the [redacted] green, Fail in red, and Uncertain in yellow.

Index	Value
1	21
2	19
3	22
4	20
5	18
6	20
7	15
8	20
9	21
10	19
11	22
12	20
13	18
14	20
15	15
16	20
17	21
18	19
19	22
20	20
21	18
22	20
23	15
24	20
25	21
26	15
27	17

BUI: Simple Precision

SD Index (Target)

Specimen Index

Key Statistics

Pass/Fail/Uncertain

Data

Enhancements in release 12.0

- **New networking path log**
 - New networking path log installed to facilitate troubleshooting of network/licensing issues with multiple networked workstations.
- **Installation information messages on About screen**
 - The installation license type (standard, professional) is now easily visible in the About

Known Issues corrected in release 12.0

- **Missing project overwriting change**

- Previously, the logic in EE was that if any one of the standard projects was absent (Default, Sample Data, Master, etc), then all of the standard projects would be recreated. In fact only the missing project should have been recreated. This has now been rectified.

- **New Barcode Reader support**

- New Barcode Reader support has been added since the Motorola Symbol CS-1504 which EE previously used is no longer available. The Motorola Symbol CS3070 is now the standard device used with EE [See Barcode Scanner Setup](#) pages for details.

- **Content Sensitive Help for RRE improved**

- Content sensitive Help system is now better integrated with the interface in Rapid Results Entry screens.

- **ODBC Data Acquisition running warning**

- Any active ODA (ODBC Data Acquisition) will be brought on top if it is already running in the background yet the user attempts to open a new one. This will reduce user confusion in this event.

Known Issues corrected in release 12.0

- **Accented characters accommodated**
 - Accented characters are now allowed in data entered for the X-Methods in Method Comparison statistical modules so that non-English instrument names may be entered.
- **Warning when long project names truncated**
 - A warning now displays when excessively long project names are entered, before truncation.
- **Tutorial language default settings fixed**
 - Tutorial language defaults to English to avoid issues with language locales, while content for languages other than ENG and FR is not yet available.
- **PDF Report printing improved**
 - Issue with printing reports as PDFs have been resolved.
- **Default language settings fixed**
 - Users can now select ENG as the operating language of EE even if their operating system is in a different language.
- **LIN History**
 - Known issue with entering dates before today resolved for LIN module history.

Common features to EP09A2

- Scatter plots with Deming regression.
 - Automatic calculation of rep SD to determine Deming Statistics.
 - Scatter plots on reports for both individual pairs and specimen mean
- Medical Decision Point analysis
 - Partitioned bias technique when R less than Preferences' choice
- Preliminary Data Evaluation
 - Assessment of uniform scatter – but overall only
 - Adequate results range : $R >$ preference choice
 - Check for adequate number of results
 - Outlier detection (but different technique)

Feature Comparison

EP09A2

1. Duplicate measurements required
2. 2 types of Regression
3. 4 types of bias plots
4. Outlier Detection for reps within method and across method
5. Conventional confidence Interval Calculations

EP09A3

1. Replicate results from 1 to 5, flexible within the experiment
2. 6 types of regression
3. 8 types of bias plots
4. Outlier Detection by Grubbs method (Extreme Studentized Deviate)
5. 5 ways to calculate confidence intervals

More Features of CLSI EP09 A3

- Mean or median overall bias calculation
- Estimated Medical Decision Point calculation
- Regressions and Scatter plots
 - Weighted and unweighted Original Least Squares (OLS) Regression
 - Weighted and unweighted Deming Regression
 - Passing Bablok - 2 types (as selected by user)
- Difference (Bias) plots with optional mini-histogram
- Confidence intervals (CI) by 5 different techniques including Jackknife and Bootstrap

4 Analytical modes (AM)

All with Single or multiple reps allowed for both X and Y

- **MER** – *Manufacturer's establish relationship in assay development*
 - At least 100 different specimens - to not be preliminary
- **MCV** -*Manufacturer's claims Validations*
 - At least 100 different specimens - to not be preliminary
- **CCL** – *Clinical Laboratory: New method introduction per CLIA*
 - At least 40 different specimens - to not be preliminary
- **WMC** - *within a measurement procedure Comparisons*
 - At least 40 different specimens - to not be preliminary

Note: For all, at least 20 different specimens for subrange or outlier detection

Parameters Screen

EP9A3 Method Comparison Experimental Parameters

Analyte: **AppA** Clear Lot Info

X (Comp) Method Method 1
Units: ng/dL
Date: 03 May 2016
Analyst: DINA crl
Comment:
Analytical Range: 1 to 60
Rep SD: 1
Max Results: 1 2 3 4 5

Y (Test) Method Method 2
Units: ng/dL
Date: 03 May 2016
Analyst: DINA crl
Comment:
Analytical Range: 1 to 60
Rep SD: 1
Max Results: 1 2 3 4 5

The X and Y values will be used **11**

Bias Claim Conc: 2 Pct: 5 **2**

Medical Decision Points: 20 (X) 20 (Y) **3**

X Results Distribution # Bins: 4 Upper limit of bins: 15.8 30.5 45.3 **10**

Max Decimal Places: Auto

Analysis Mode **1**
 MER
 MCV
 CLL
 WMC

Scatter Plot Bounds **4**
 None
 Bias Claim
 Confidence Interval

Scatter CI Criterion
 95% 99%

Bias Plot Bounds **5**
 None
 Bias Claim
 Confidence Interval

Bias CI Criterion
 95% 99%

Reagents & Calibrators

X Method	Lot	Source	Exp. Date
Reagent	bbb	bbb	1/1/2013
Calibrators	fred	fred	1/1/2001

Y Method

Reagent	Lot	Source	Exp. Date
Reagent	bbb	bbb	1/1/2013
Calibrators	fred	fred	1/1/2001

Mean/Median for Reps **6**
 Mean Median

Bias Histograms
 Never Use Weighted Regression

Mean/Median for Bias Est **7**
 Mean Median

Passing Bablok **8**
 None MC Regression

Outlier Sig Lev **9**
 1% 5%

OK
Cancel
Help

Experiment Detail Screen with Data

Spec ID	Results	
SPEC01A	80 130	82 30
SPEC02A	158 155	158 165
SPEC03A	194 202	208 197
SPEC04A	50 47	45 43
SPEC05A	72 72	70 68
SPEC06A	177 176	180 184
SPEC07A	222 218	220 227
SPEC08A	138 136	140 140
SPEC09A	170 175	173 168
SPEC10A	78 79	86 87
SPEC11A	150 147	152 144
SPEC12A	245 250	248 264
SPEC13A	44 45	49 45
SPEC14A	96 98	87 92
SPEC15A	73 69	73 74

glucose: Scatter Plot (Spec)

Deming
Slope 1.026
Intercept -4.8
R 0.9744 (RSQ 0.9495)
SEE 9.796

Alerts

X Rep SD was calculated

Y Rep SD was calculated

Your data does not have Constant CV.

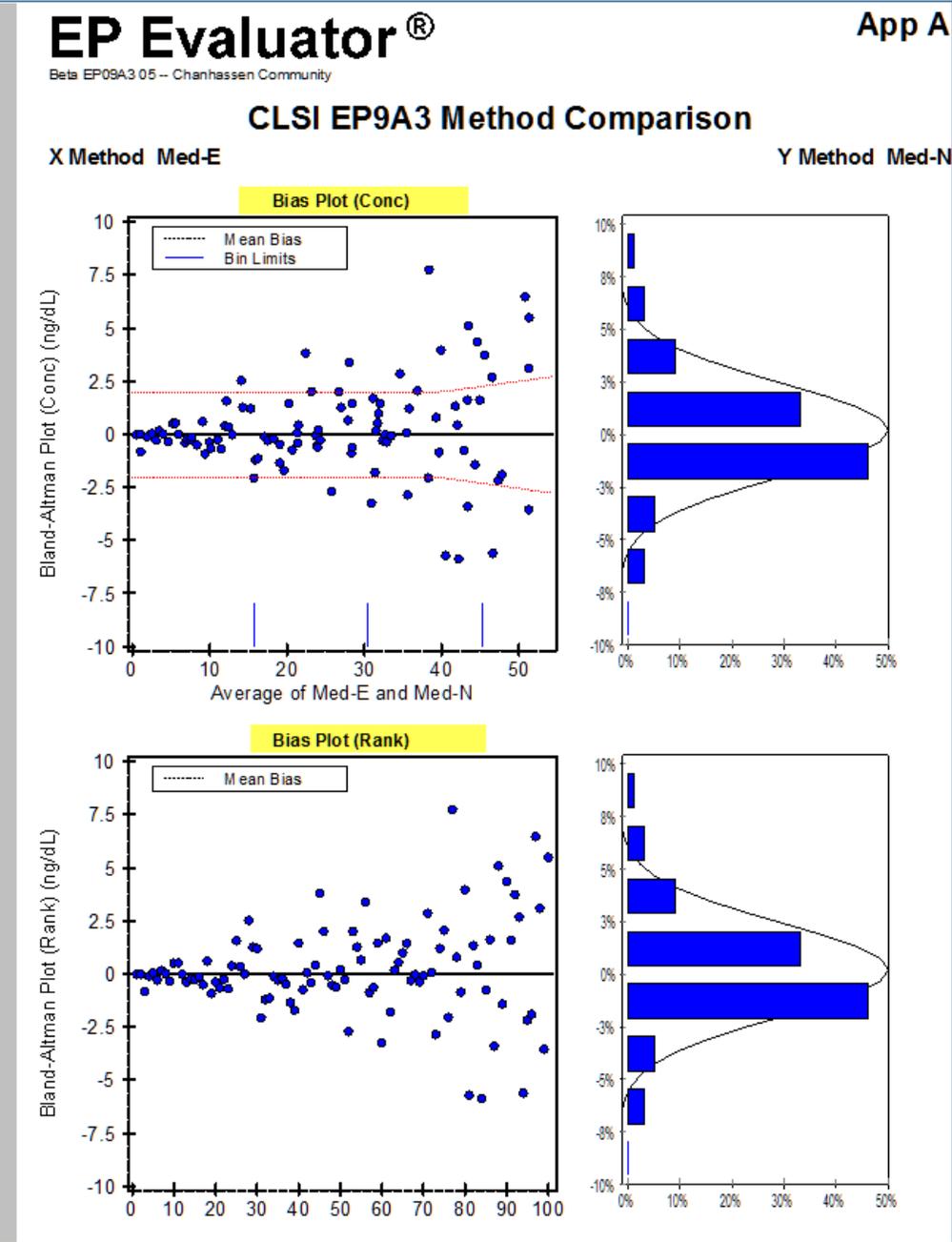
You need a minimum of 100 specimens after exclusions, orphans, and outliers are removed (because AM = MER). You have only 40. Your report will be stamped PRELIMINARY.

Subrange: None Const SD is True (0.67) SpecID Sort: N: 40 of 40 Specs All complete replicate pairs will be used

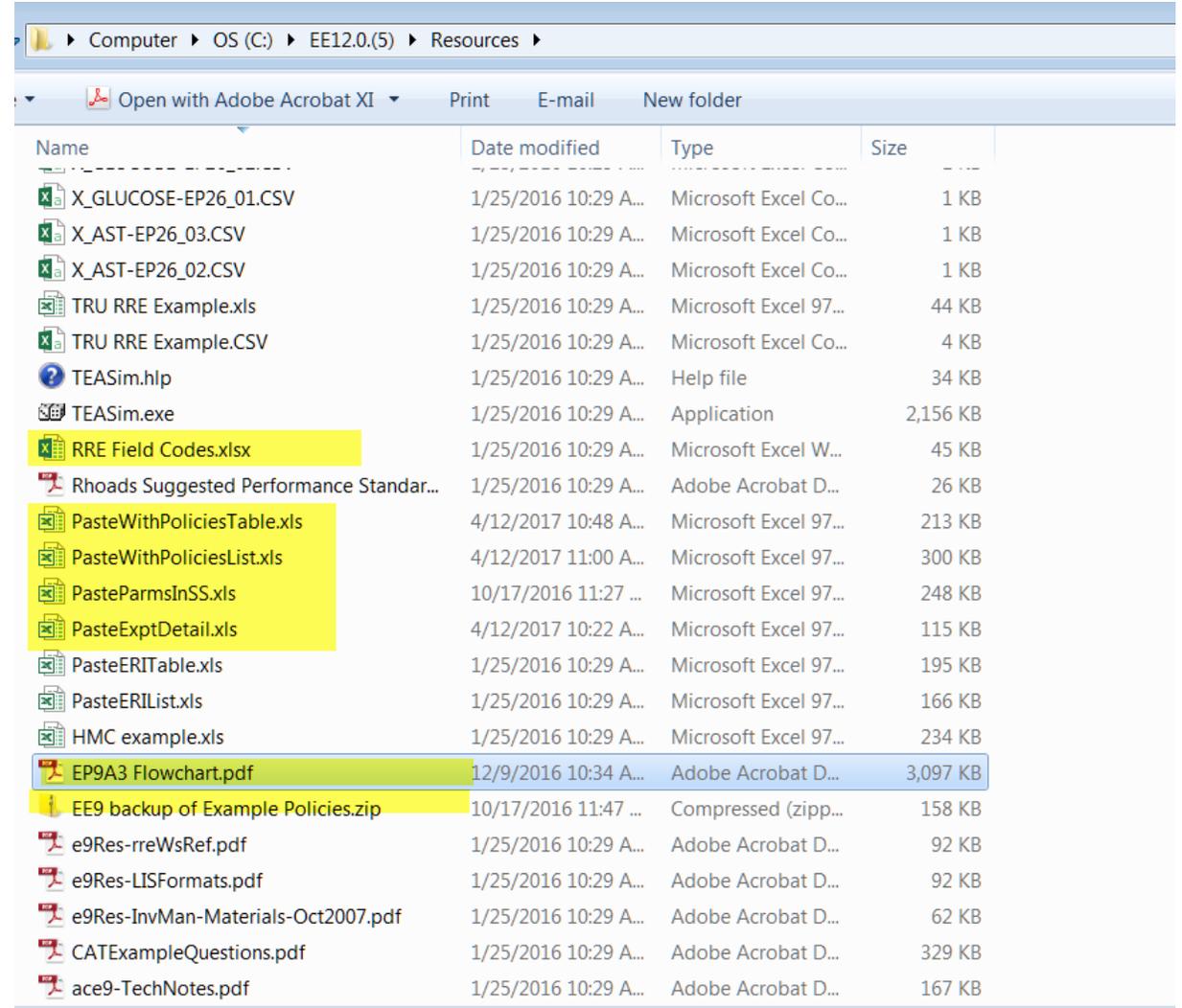
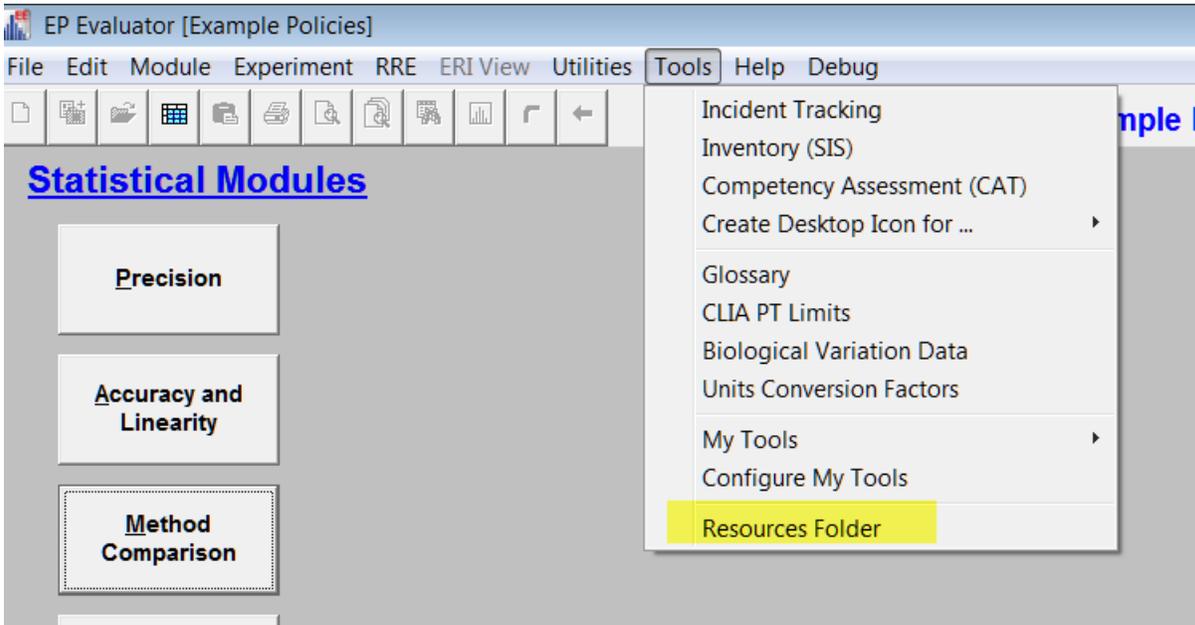
Const CV is False (2.06) Remove Outliers? R: 0.9744 User asserts data appears to be linear

F3 Add F4 Delete F5 Exclude F6 Clear Flags F7 Parameters F8 ID Access Record 1 of 40 Scatter (Spec) / Scatter (Pair) / Bland-Altman (Conc) / % Bland-Altman (Conc) / Bland-Altman (Rank) / % Bland-Altman (Rank) / Statistics /

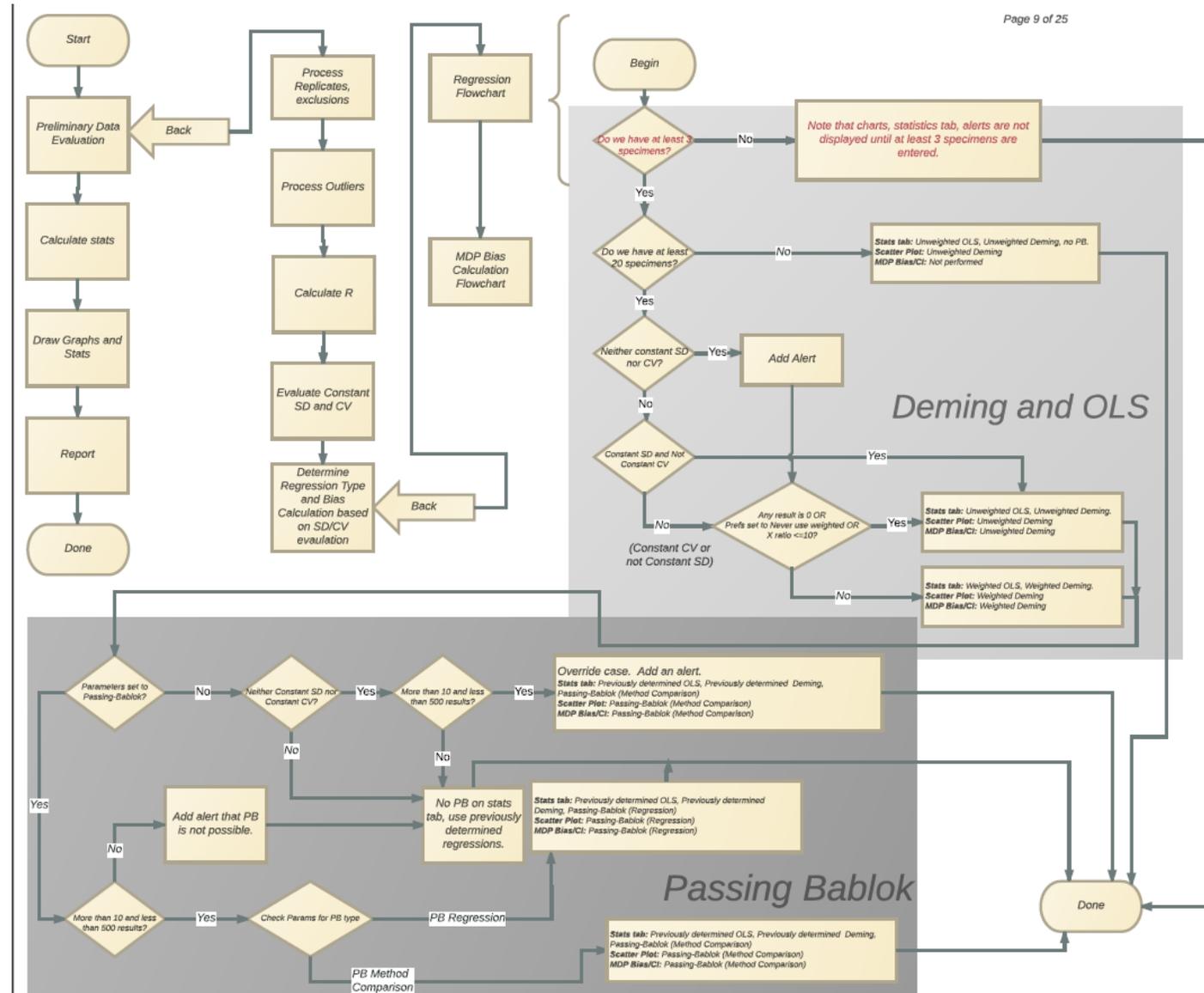
Bias Plots on Reports



Resources Folder



The Decision Tree Flowchart in the resources folder.



Why Upgrade?

- The changes in this CLSI document were aimed at the needs of IVD vendors and laboratories validating Lab Developed Tests (LDT's)
- EP09-A3 has the advantage of
 - being able to use mean or median in calculations as well as
 - utilizing more complex algorithms for those calculations.
 - provides greater flexibility with the number of replicates used
 - greater variety of possible regression models used.
- The EP09 module (based on EP09-A2) remains valid and suitable for general laboratory use if the additional features and flexibility of EP09-A3 is not required as determined by that laboratory.

Thank You for Your Time