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EP Evaluator 12.0 – What's New

11-2017

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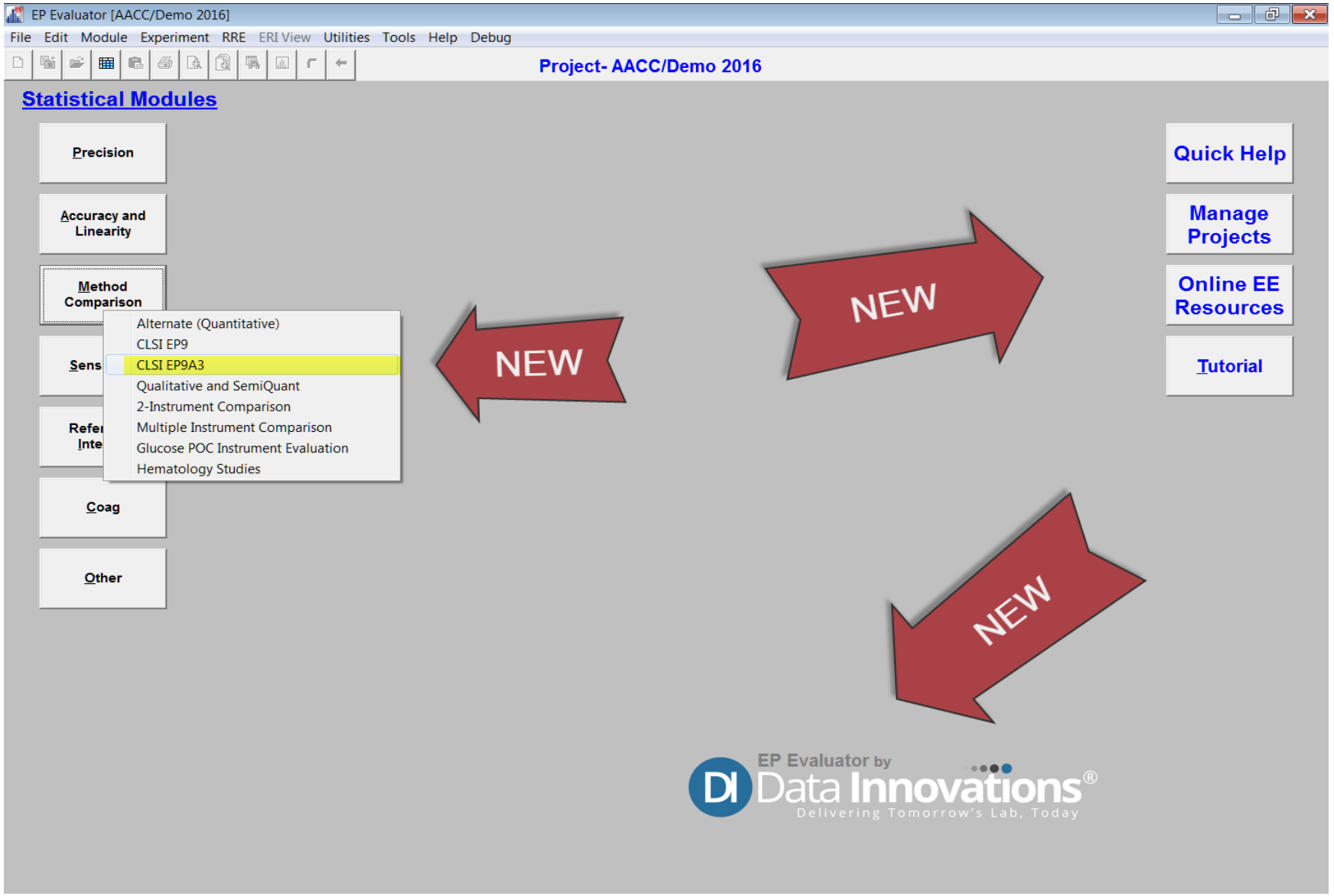
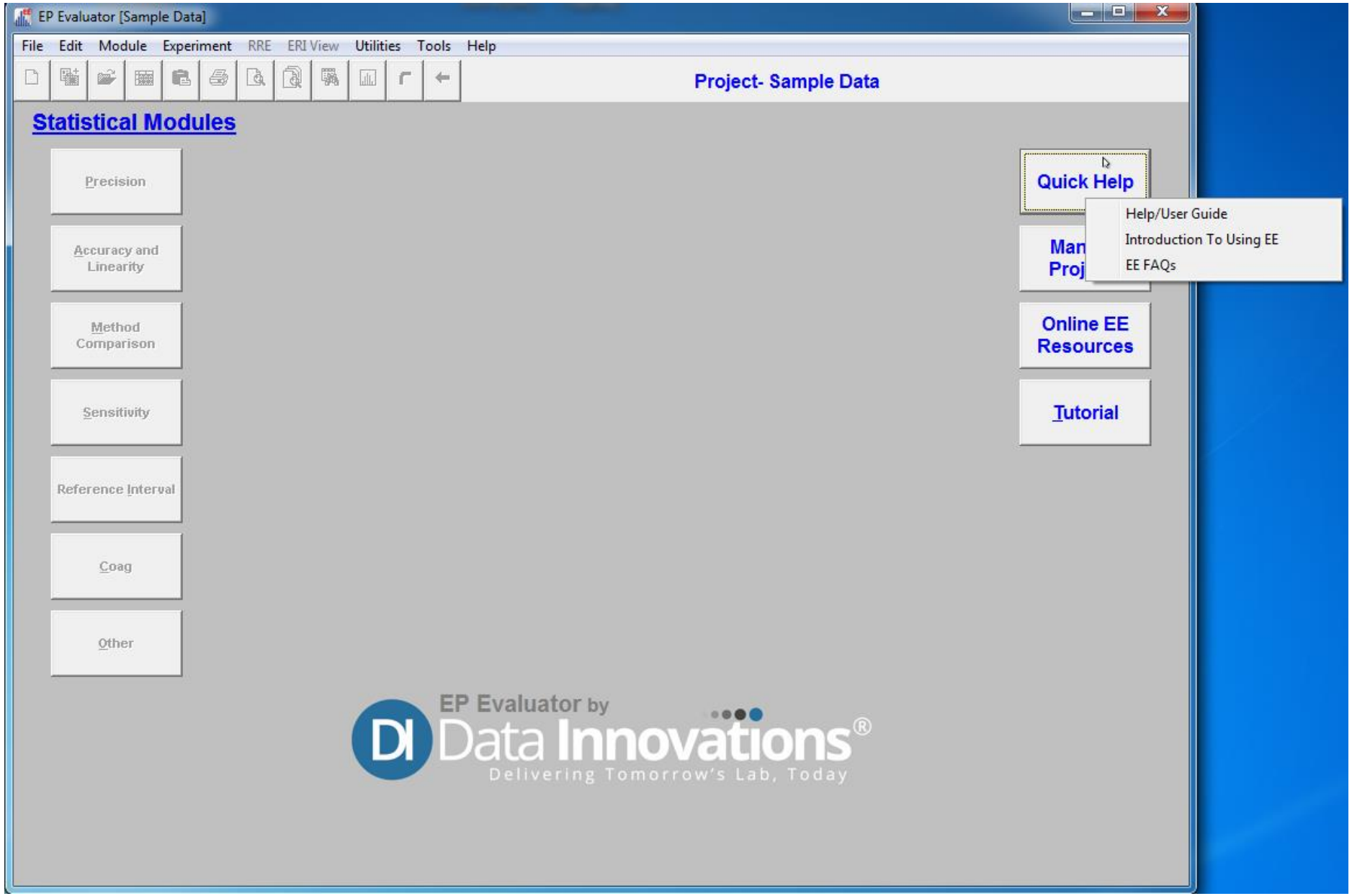
Enhancements in release 12.0

- **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.

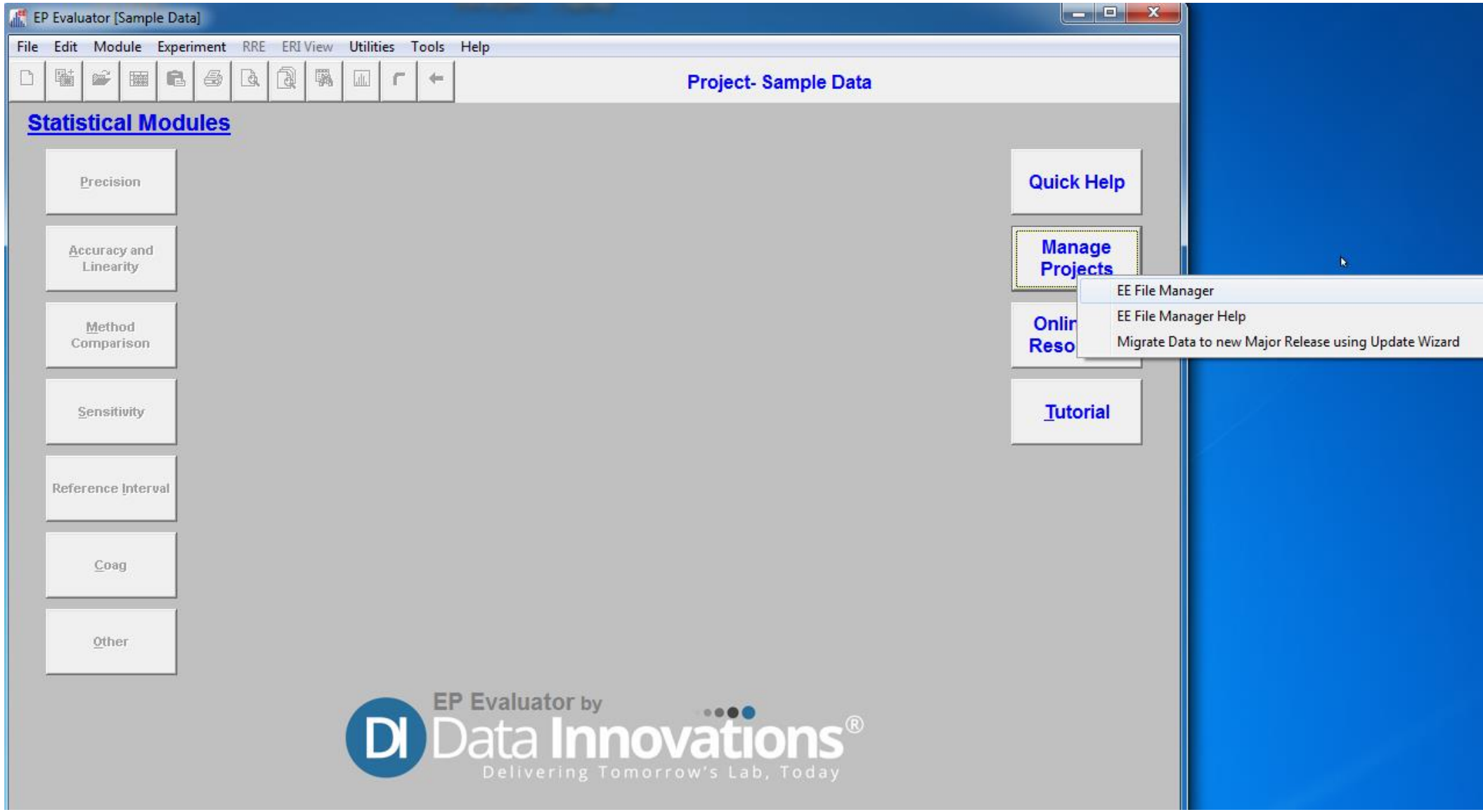
New Screen Features



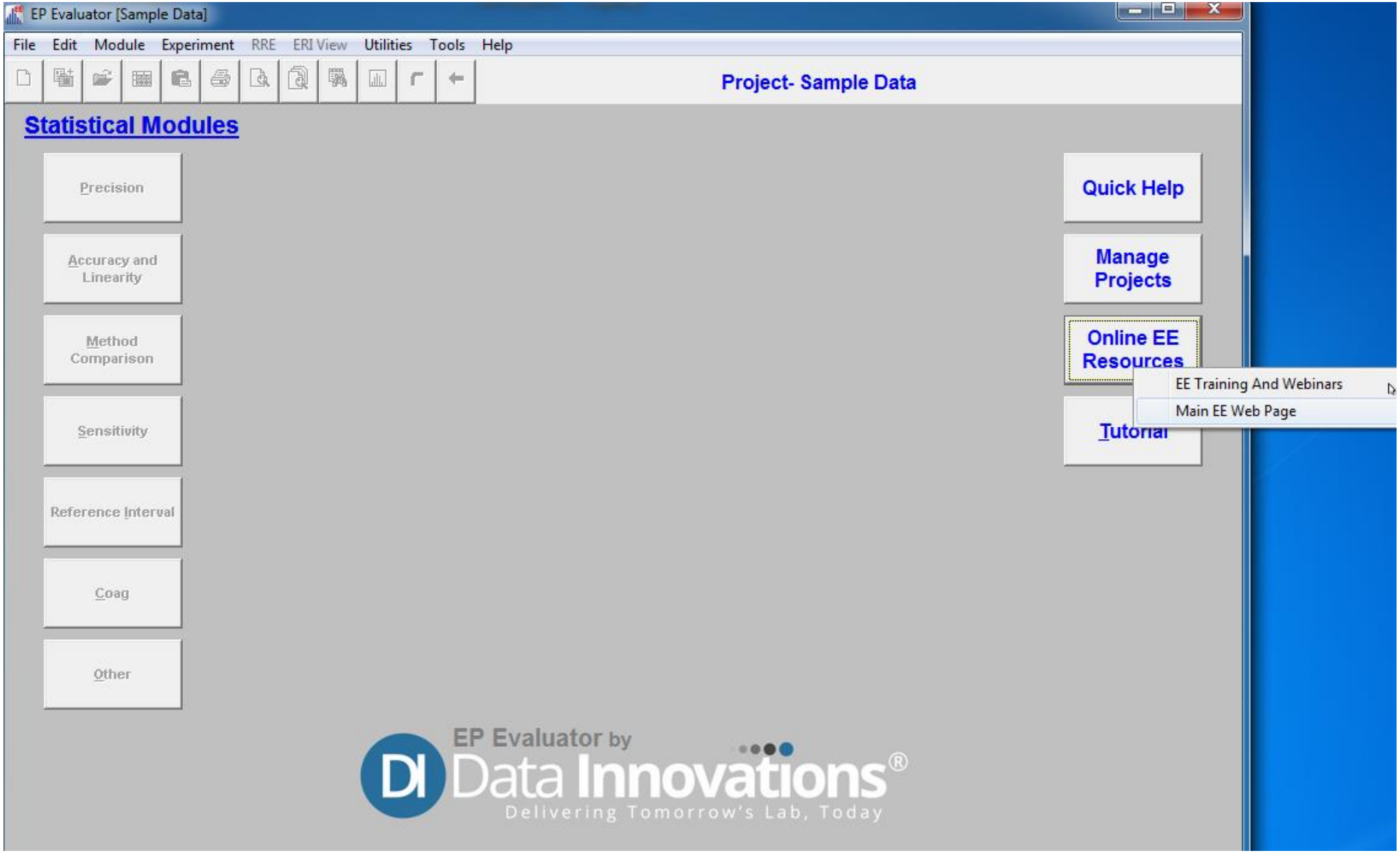
Links for Quick Help



Links for Manage Projects

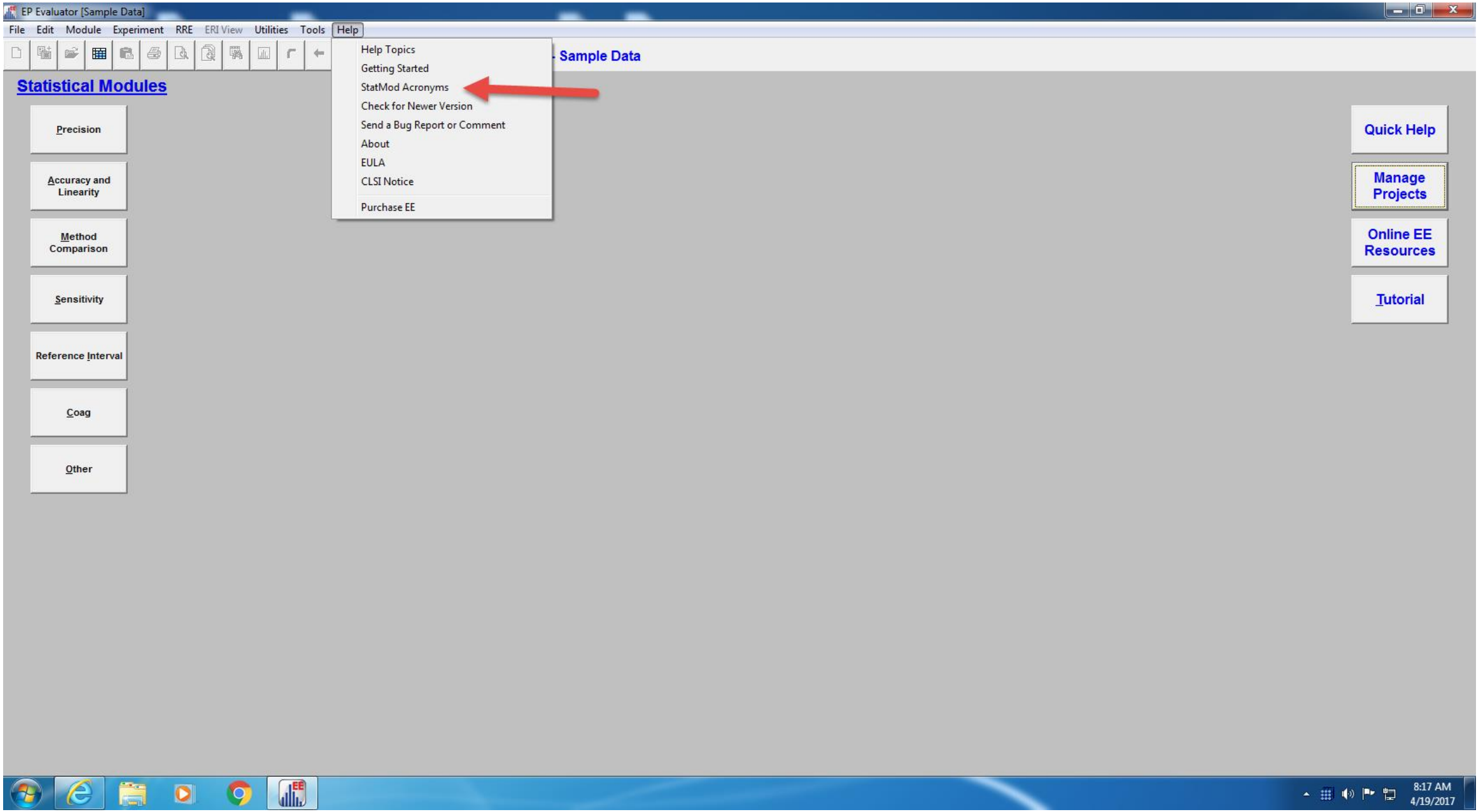


Links for Online EE Resources



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


EP Evaluator [Sample Data]
File Edit Module Experiment RRE ERI View Utilities Tools Help
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Method Comparison
Sensitivity
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Coag
Other
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Manage Projects
Online EE Resources
Tutorial
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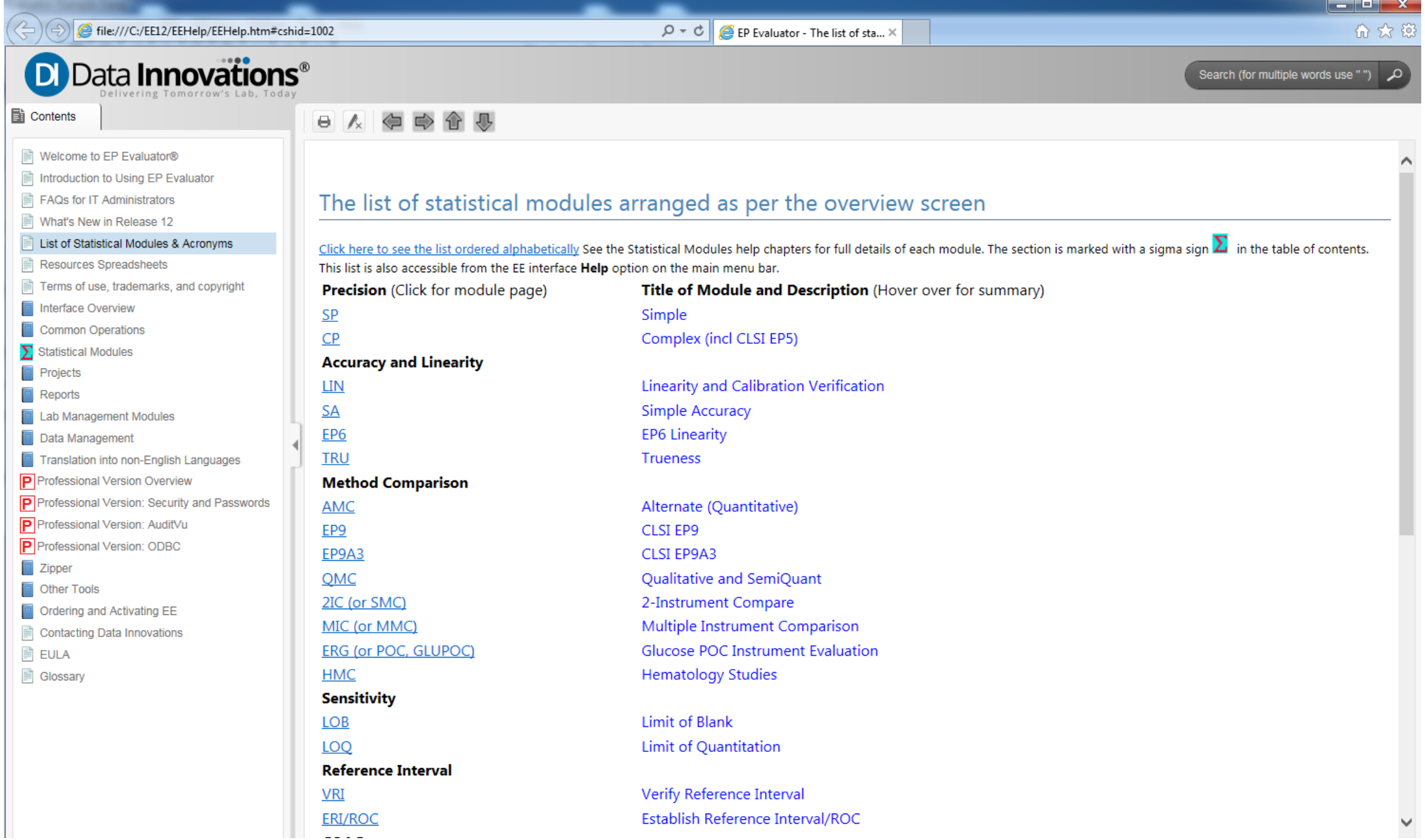
file:///C:/EE12/EEHelp/EEHelp.htm#cshid=1002
EP Evaluator - The list of sta...
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Glossary
The list of statistical modules arranged as per the overview screen
Click here to see the list ordered alphabetically See the Statistical Modules help chapters 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

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Search (for multiple words use " ")

Contents

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 Σ in the table of contents. This list is also accessible from the EE interface **Help** option on the main menu bar.

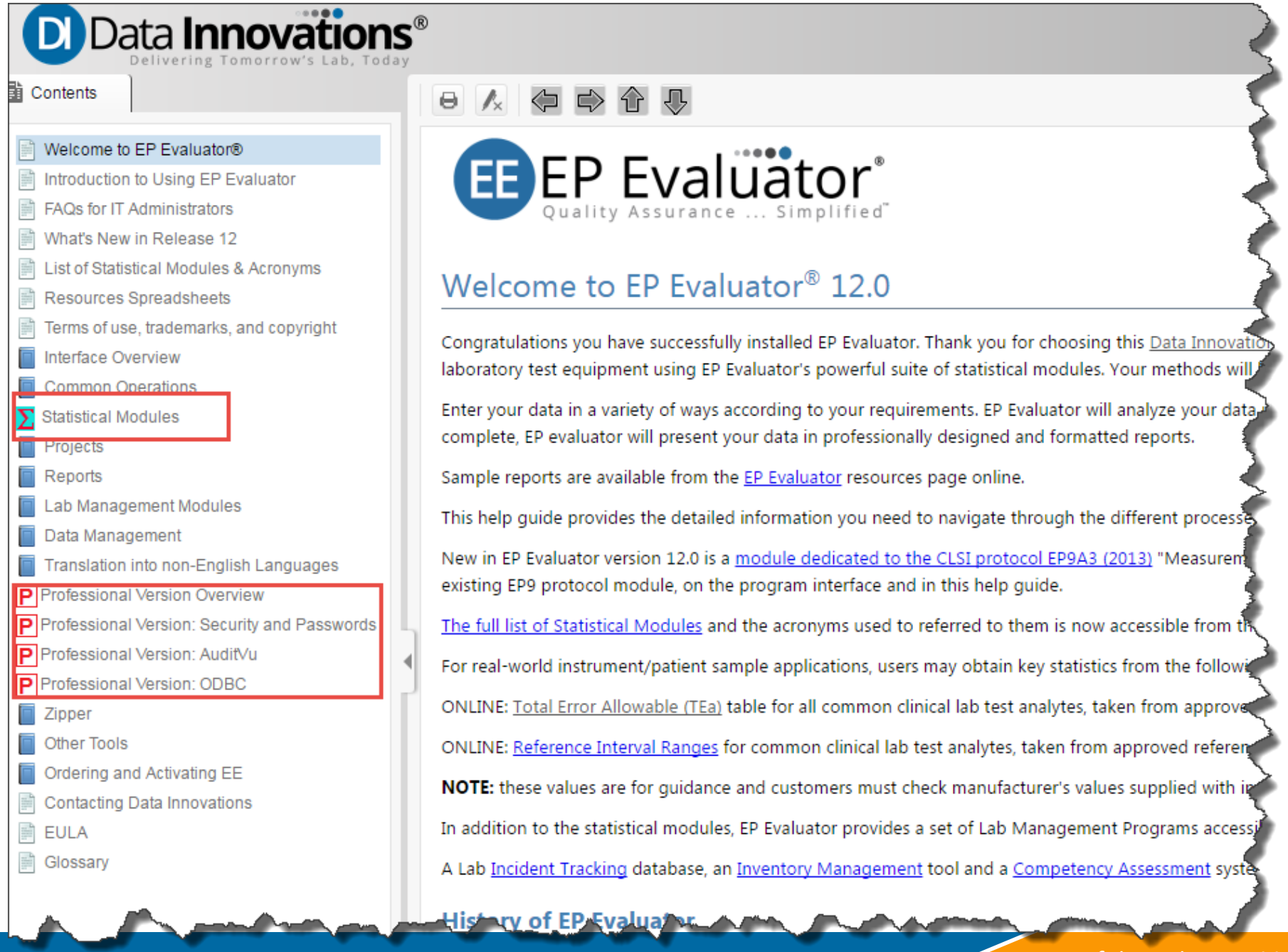
Precision (Click for module page)	**Title of Module and Description** (Hover over for summary)
SP	Simple
CP	Complex (incl CLSI EP5)
Accuracy and Linearity	
LIN	Verification
SA	
EP6	
TRU	
Method Comparison	
AMC	Alternate (Quantitative)
EP9	CLSI EP9
EP9A3	CLSI EP9A3
QMC	Qualitative and SemiQuant
2IC (or 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

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

New Help Design

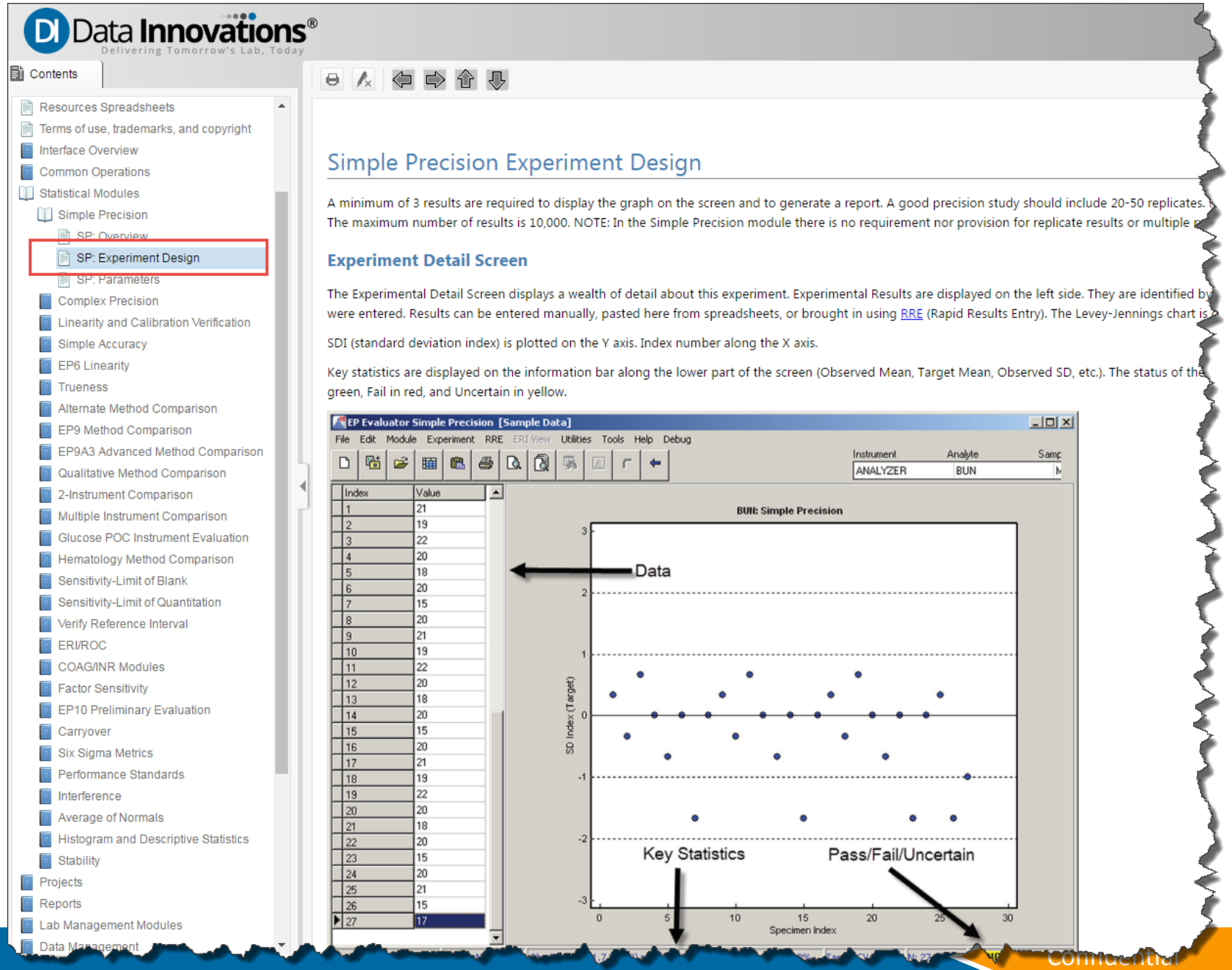
Statistical Modules Grouped

Pro Features are highlighted as such



Statistical Modules

Within Each Modules is an Experiment Design Tab



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

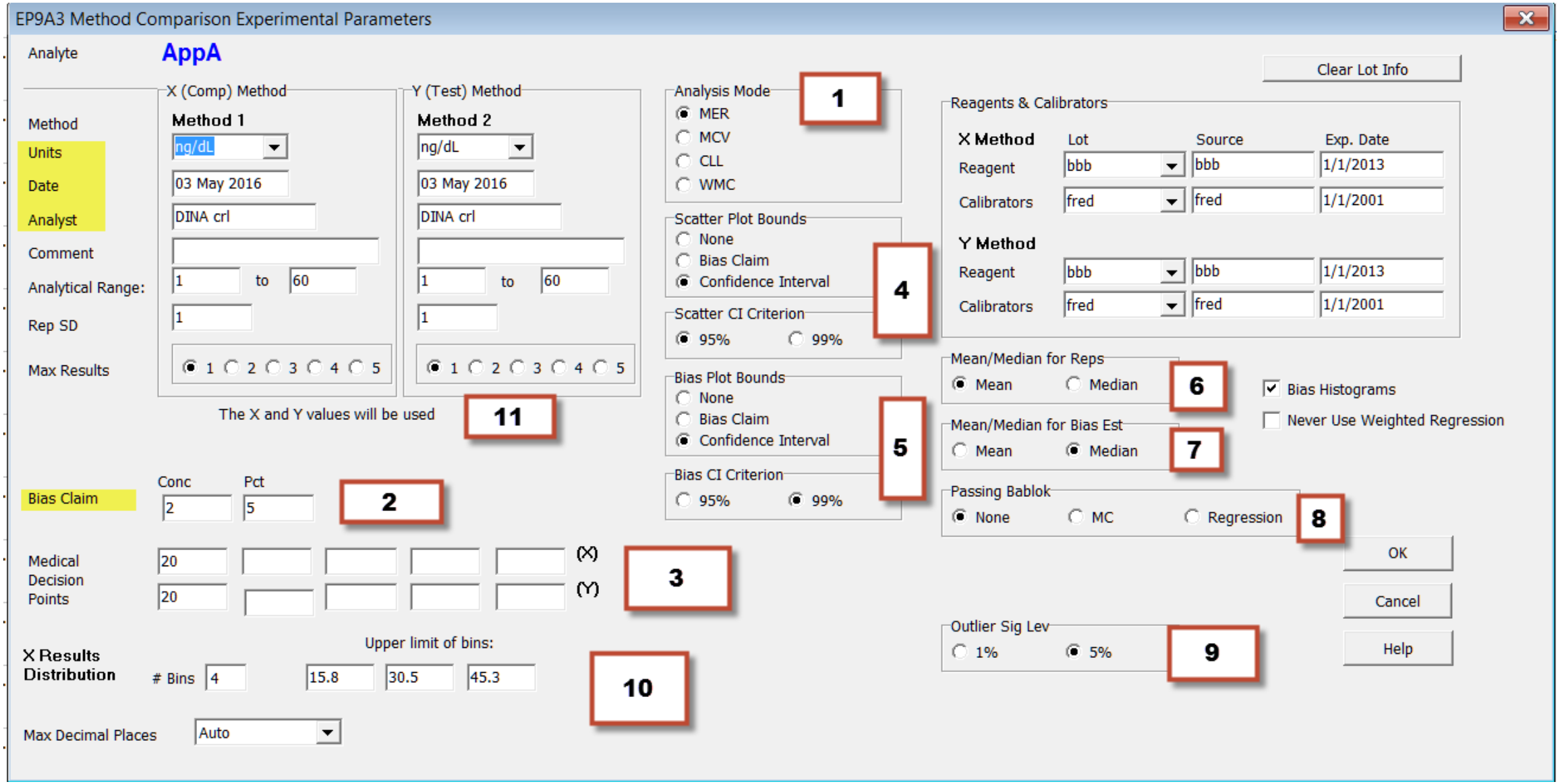
4 Analytical modes (AM)

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

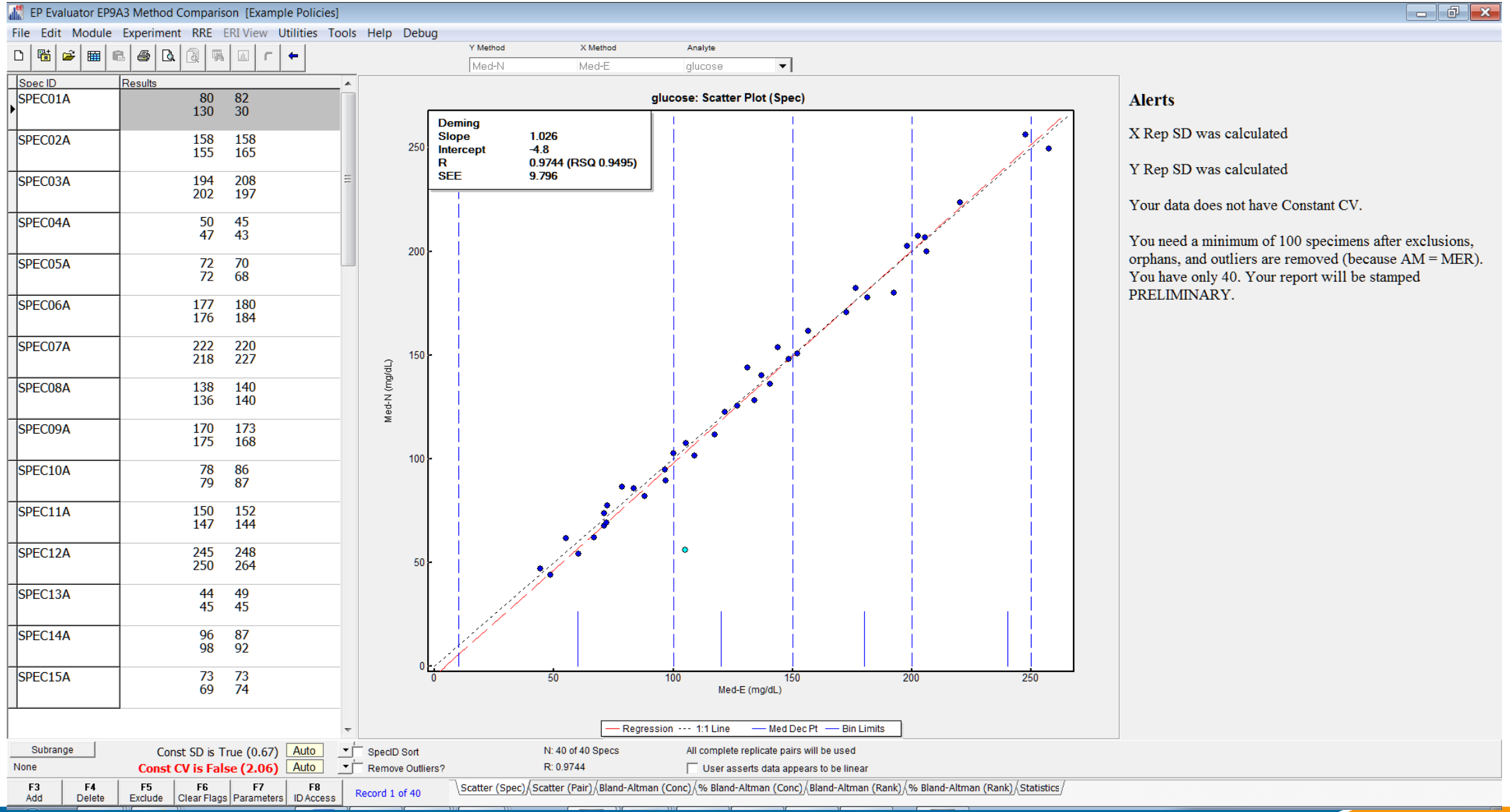
- **MER** – *Manufacturer's establish relationship in assay development*
  - At least 100 different specimens - to not be preliminary
- **MCV** -*Manufacturer's claims Validations*
  - At least 100 different specimens - to not be preliminary
- **CCL** – *Clinical Laboratory: New method introduction per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

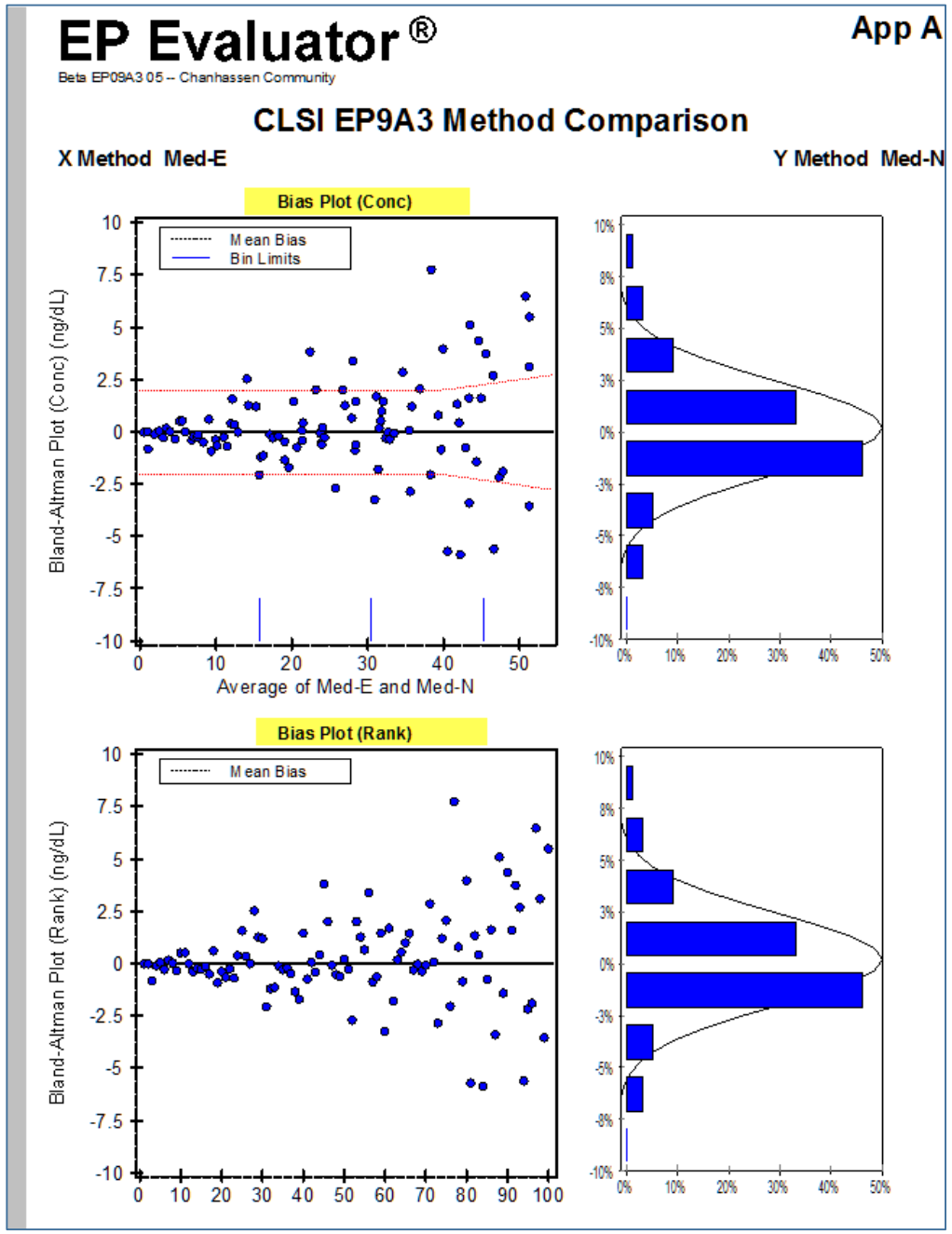
Parameters Screen



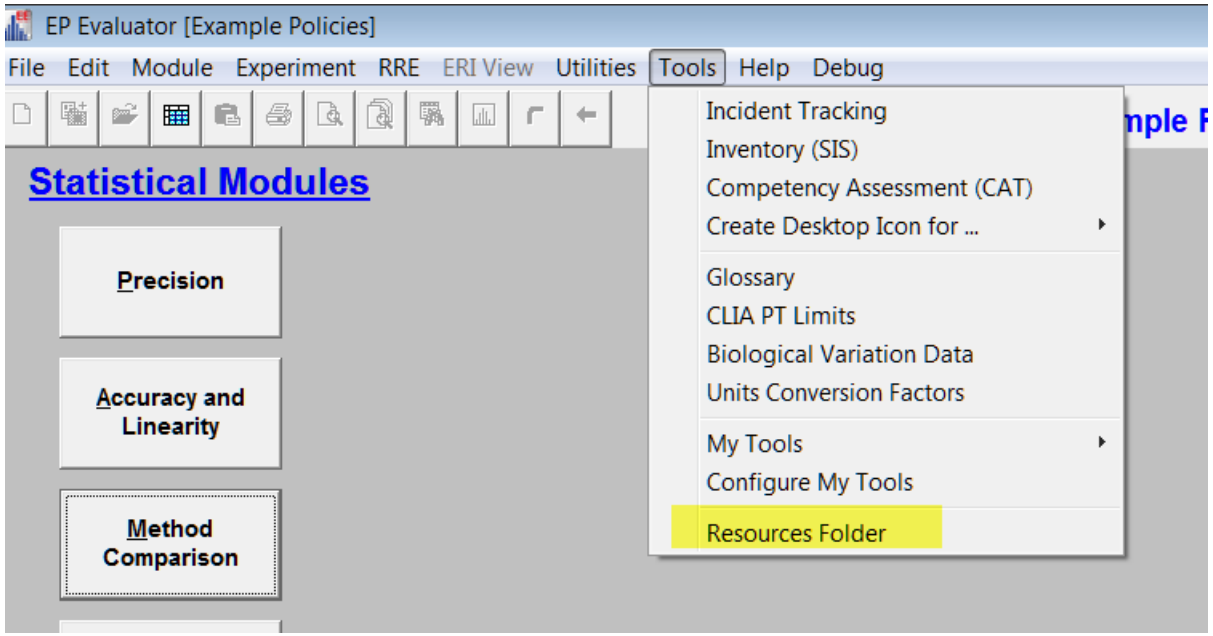
Experiment Detail Screen with Data

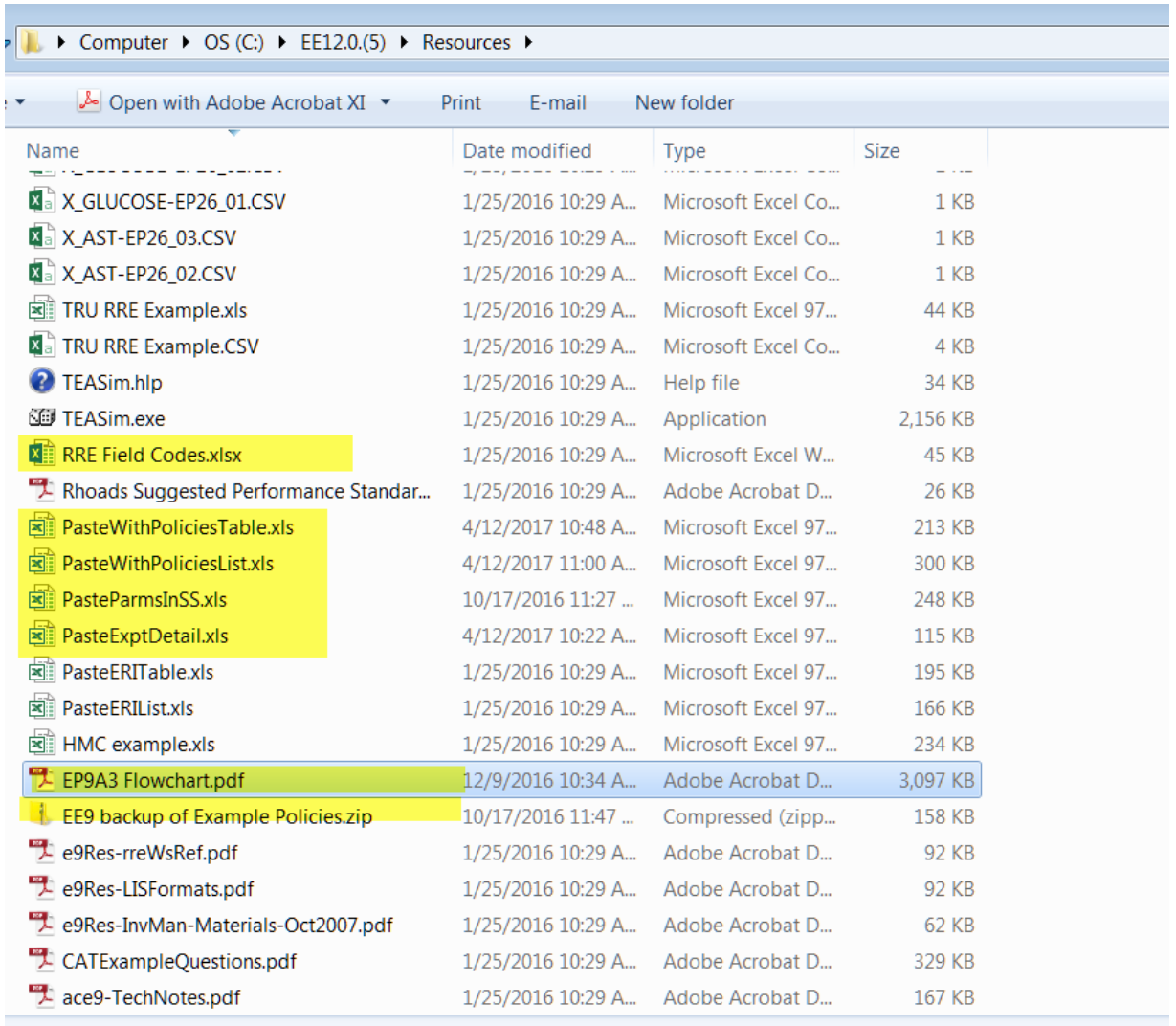


Bias Plots on Reports

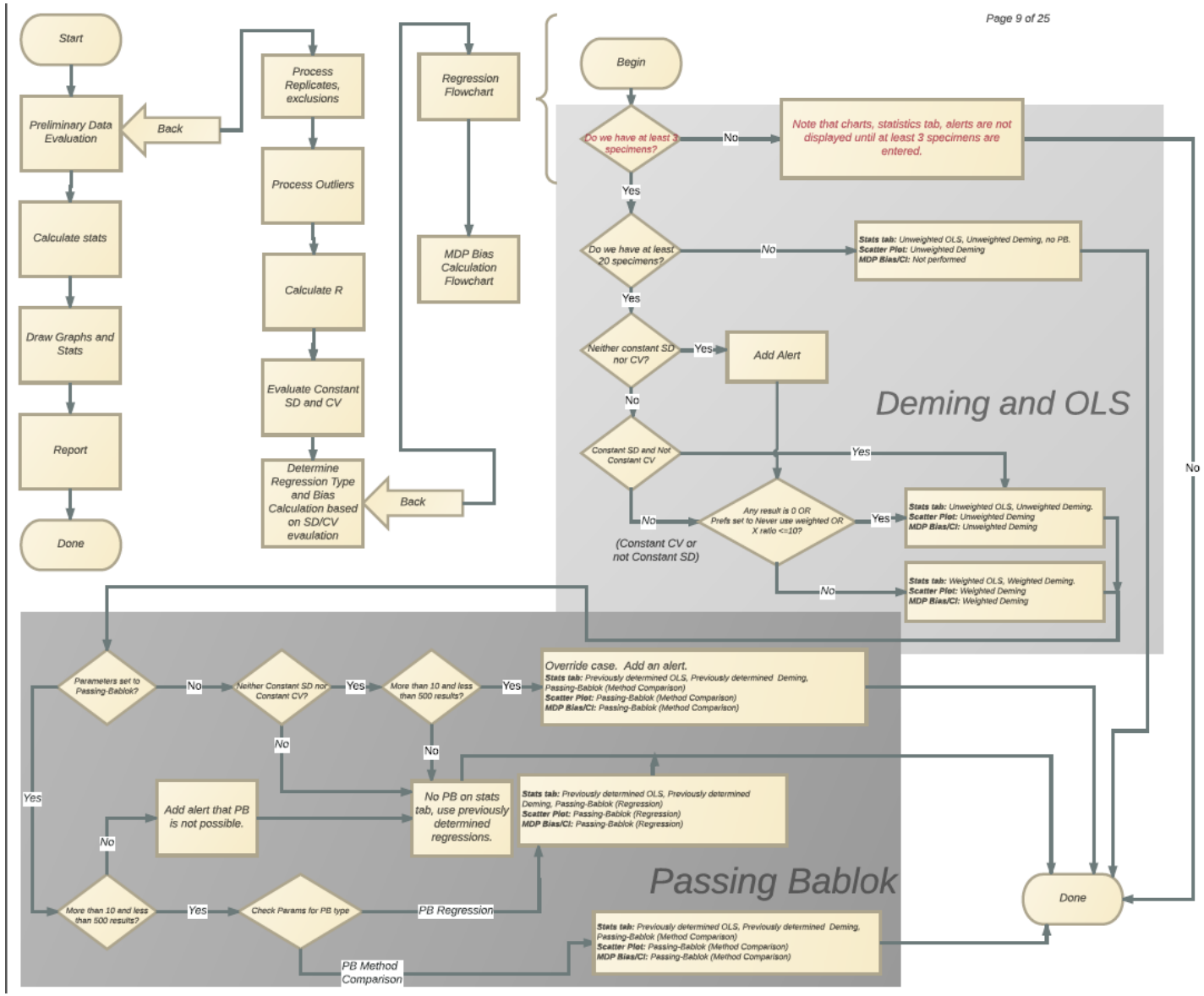


Resources Folder





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

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