datainnovations

EP Evaluator
Hematology Method Comparison

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DATA INNOVATIONS
Simple Ideas, Better Solutions

Session Objectives

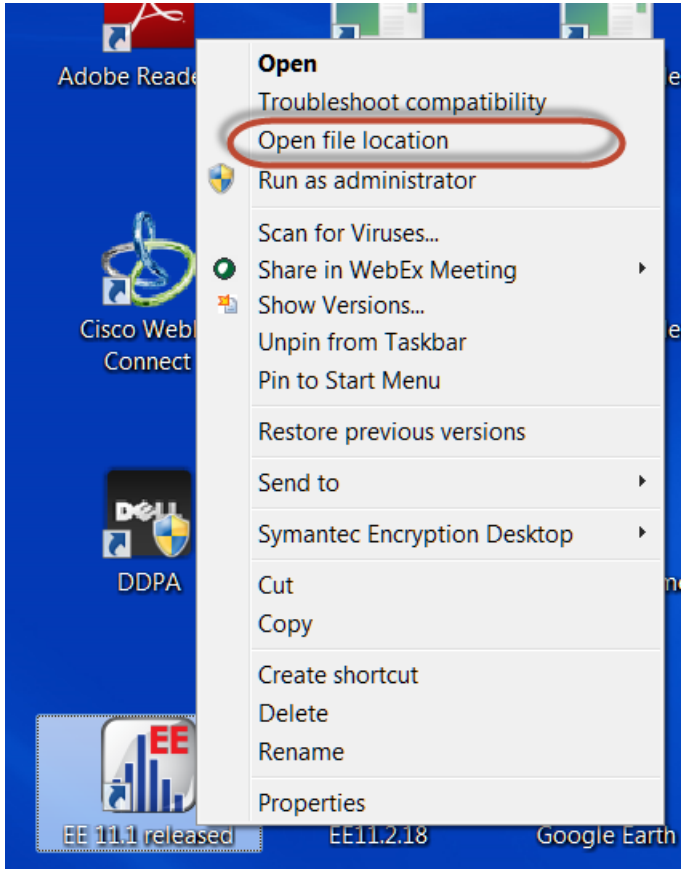
At the end of the session you should be able to:

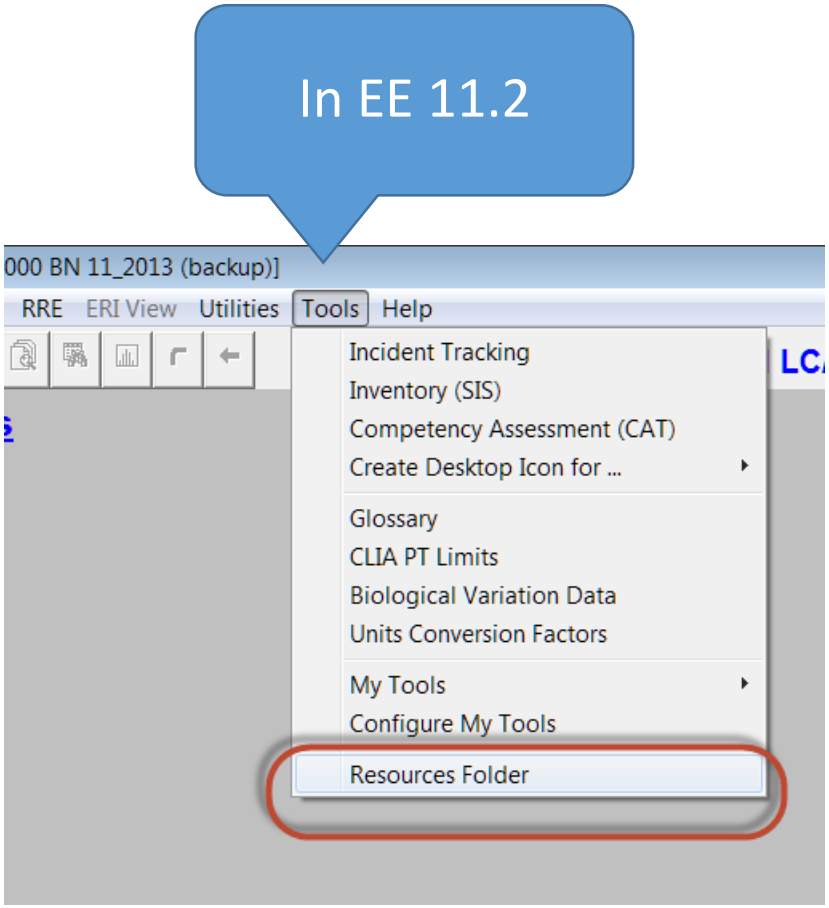
- Explain the purpose of the Hematology Method Comparison Module.
- Describe the benefits of using HMC vs AMC
- Use The HMC Example Project and spreadsheet “HMC example.xls” as a learning tool.
- Create new Studies: New with Policies
- Paste data into an experiment
- Review and Print Reports

Examples for this presentation

- Project “HMC example “
- Companion spreadsheet file:
  - **EE\resources\HMC example.xls**
- Project “EE9 backup of Example Policies.zip.”
  - The Backup project is present in the EE folder \data\backups and provides examples of parameters for several instrument classes
  - Restore using the Utilities \ file Manager

Find your Resource folder





Do you want to use AMC or HMC?

- Use AMC If your goal is:
  - **To only show method comparison of individual parameters**
  - **Compare Automated vs manual, or 2 automated methods.**
  - **Different patient specimens can be used for each parameter**
- Use HMC If your goal is to:
  - **Compare Morphology Assessment for up to 8 methods on a single set of specimens.**
  - **A truth table of Normal / Abnormal Morphology**
- Both modules provide
  - **Regression plots**
    - **Need at least 3 specimens to not be marked preliminary. Recommend at least 20 distributed across reportable range.**
  - **Medical Decision point (i.e. reference interval) analysis based on regression**

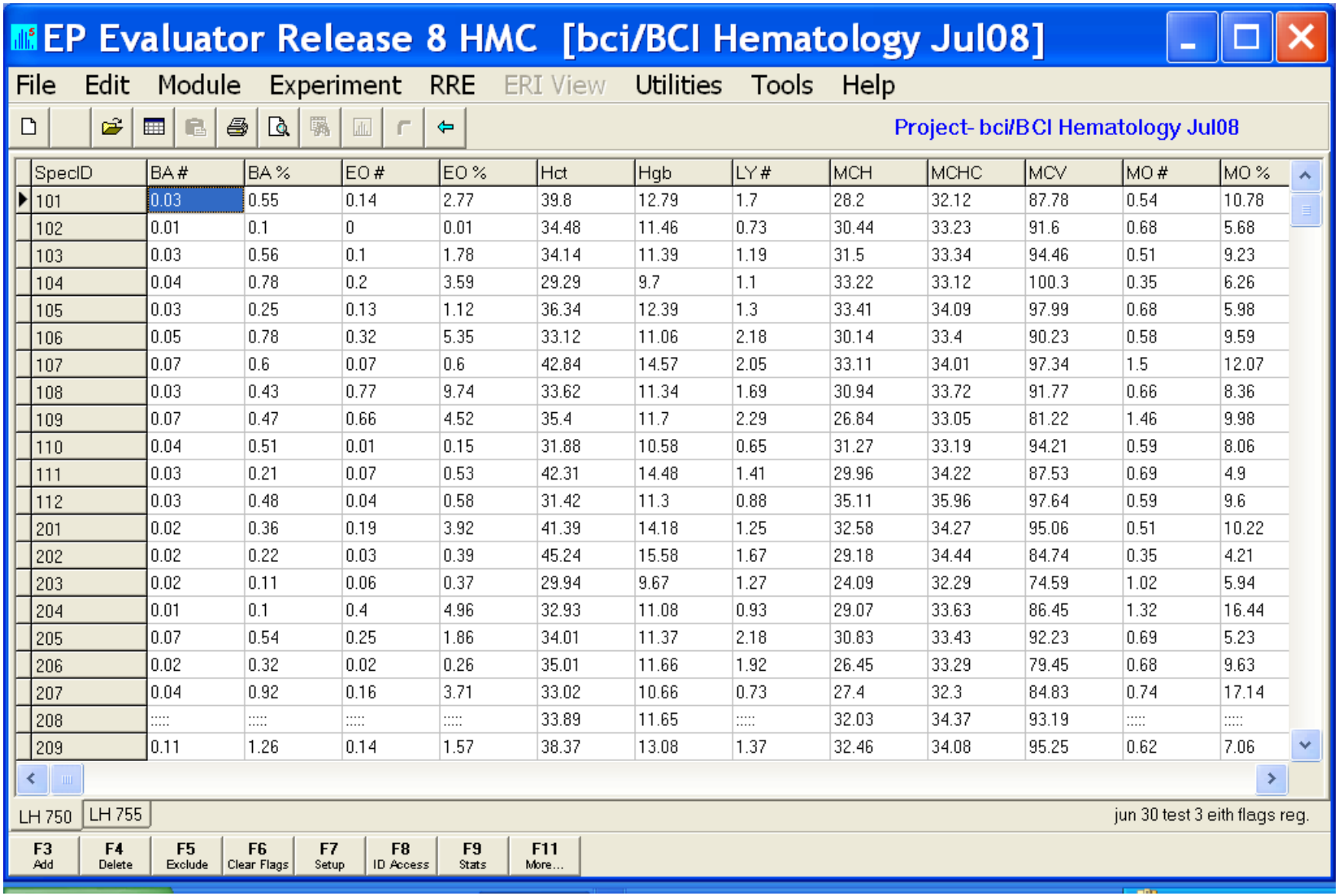
AMC Features for Hematology

- Compare specimen results for each parameter using linear, Deming or Passing Bablok Regression
  - **One experiment per parameter**
  - **No specimen morphology or flagging assessment**
  - **(No policies required) or use Non-hematology policies**
  - **Get slope, intercept, bias, etc.**
- In new experiment parameters screen you can
  - **Choose binomial scatter plot bounds**
  - **Enter cell counts**
- Confirm New method reference intervals
  - **Enter Medical Decision Point (MDP) reference values, and see Proposed Y values**

Hematology Method Comparison

- **Compare morphology / flag assessments for each specimen on up to 8 Analyzers in a single study / report**
- **Truth Tables for morphology vs. the manual method**
  - **Enabled by checking the "Gold standard" checkbox.**
  - **All parameters in a specimen are evaluated to determine positive / negative morphology when gold standard is checked**
  - **"flags" will print on report**
- **Scatter plots for selected parameters –**
  - **slope, intercept, bias, etc**
  - **Binomial scatter plot boundaries**
- **Policy Definitions are required**
- **Examples are provided:**
  - **Project "HMC example "**
  - **Companion spreadsheet file EE\resources\HMC example.xls**
  - **Backup Example Policies in EE\data\backups gives examples of parameters for several instrument classes**

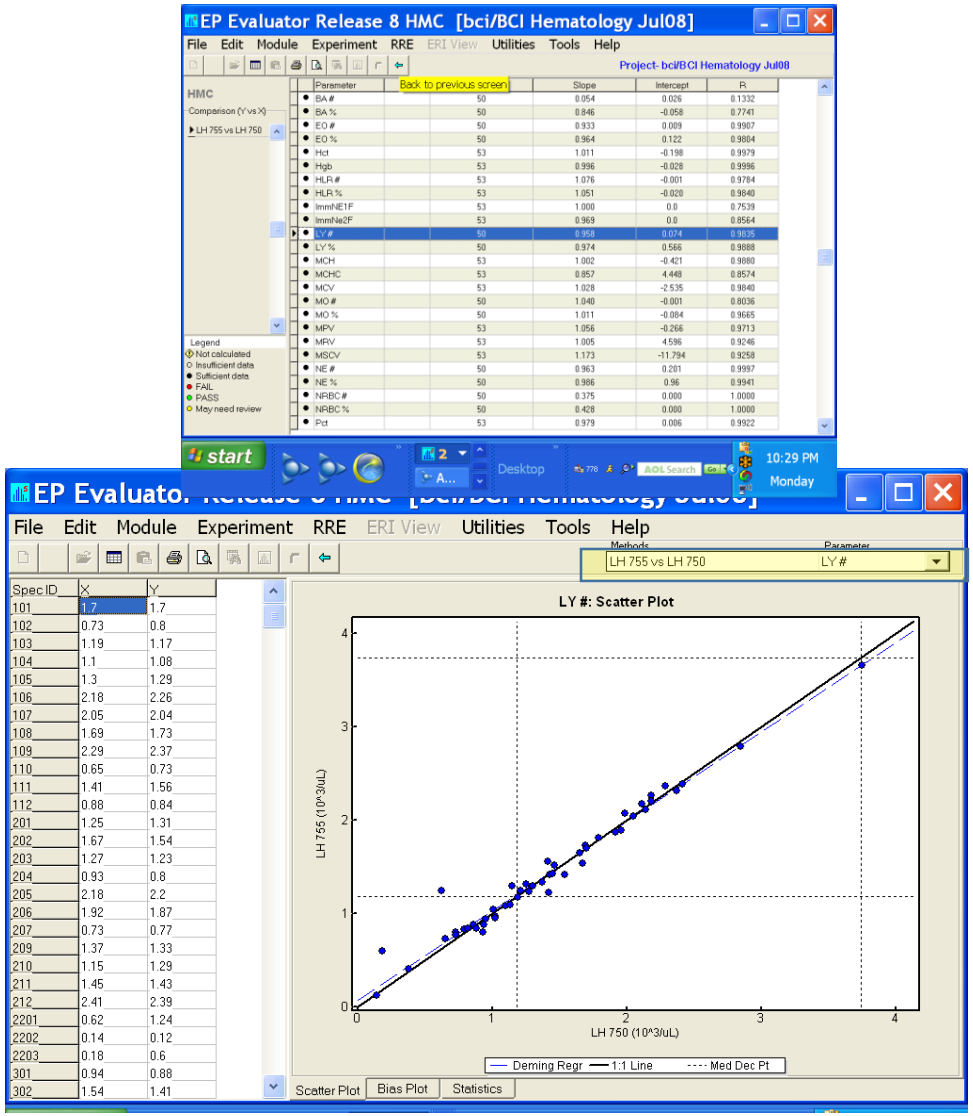
HMC Expt Detail screen: Methods Workbook



SpecID	BA #	BA %	EO #	EO %	Hct	Hgb	LY #	MCH	MCHC	MCV	MO #	MO %
101	0.03	0.55	0.14	2.77	39.8	12.79	1.7	28.2	32.12	87.78	0.54	10.78
102	0.01	0.1	0	0.01	34.48	11.46	0.73	30.44	33.23	91.6	0.68	5.68
103	0.03	0.56	0.1	1.78	34.14	11.39	1.19	31.5	33.34	94.46	0.51	9.23
104	0.04	0.78	0.2	3.59	29.29	9.7	1.1	33.22	33.12	100.3	0.35	6.26
105	0.03	0.25	0.13	1.12	36.34	12.39	1.3	33.41	34.09	97.99	0.68	5.98
106	0.05	0.78	0.32	5.35	33.12	11.06	2.18	30.14	33.4	90.23	0.58	9.59
107	0.07	0.6	0.07	0.6	42.84	14.57	2.05	33.11	34.01	97.34	1.5	12.07
108	0.03	0.43	0.77	9.74	33.62	11.34	1.69	30.94	33.72	91.77	0.66	8.36
109	0.07	0.47	0.66	4.52	35.4	11.7	2.29	26.84	33.05	81.22	1.46	9.98
110	0.04	0.51	0.01	0.15	31.88	10.58	0.65	31.27	33.19	94.21	0.59	8.06
111	0.03	0.21	0.07	0.53	42.31	14.48	1.41	29.96	34.22	87.53	0.69	4.9
112	0.03	0.48	0.04	0.58	31.42	11.3	0.88	35.11	35.96	97.64	0.59	9.6
201	0.02	0.36	0.19	3.92	41.39	14.18	1.25	32.58	34.27	95.06	0.51	10.22
202	0.02	0.22	0.03	0.39	45.24	15.58	1.67	29.18	34.44	84.74	0.35	4.21
203	0.02	0.11	0.06	0.37	29.94	9.67	1.27	24.09	32.29	74.59	1.02	5.94
204	0.01	0.1	0.4	4.96	32.93	11.08	0.93	29.07	33.63	86.45	1.32	16.44
205	0.07	0.54	0.25	1.86	34.01	11.37	2.18	30.83	33.43	92.23	0.69	5.23
206	0.02	0.32	0.02	0.26	35.01	11.66	1.92	26.45	33.29	79.45	0.68	9.63
207	0.04	0.92	0.16	3.71	33.02	10.66	0.73	27.4	32.3	84.83	0.74	17.14
208	.....	.....	.....	.....	33.89	11.65	.....	32.03	34.37	93.19	.....	.....
209	0.11	1.26	0.14	1.57	38.37	13.08	1.37	32.46	34.08	95.25	0.62	7.06

HMC Study – Scatter plots

- The second layer of the HMC study contains the regression plots that are checked “Yes” in policies
  1. An overview screen summary. Click on each comparison to calculate and open it
  2. X-Y Data display area is non-editable.
  3. Using dropdown box, page down and view any scatter plots, bias plots, and statistics.
  4. Blue back arrow goes to Prev screen



EP Evaluator®

Webinar -- Kennett Community Hospital

Hematology Method Comparison

Methods Evaluated:

Manual
Eximer 100
Eximer 500

Study prepared for:

My Community Hospital

Prepared by:

Inez Kruse

Accepted by: _____ _____
Signature Date

EP Evaluator 11.3.0.23

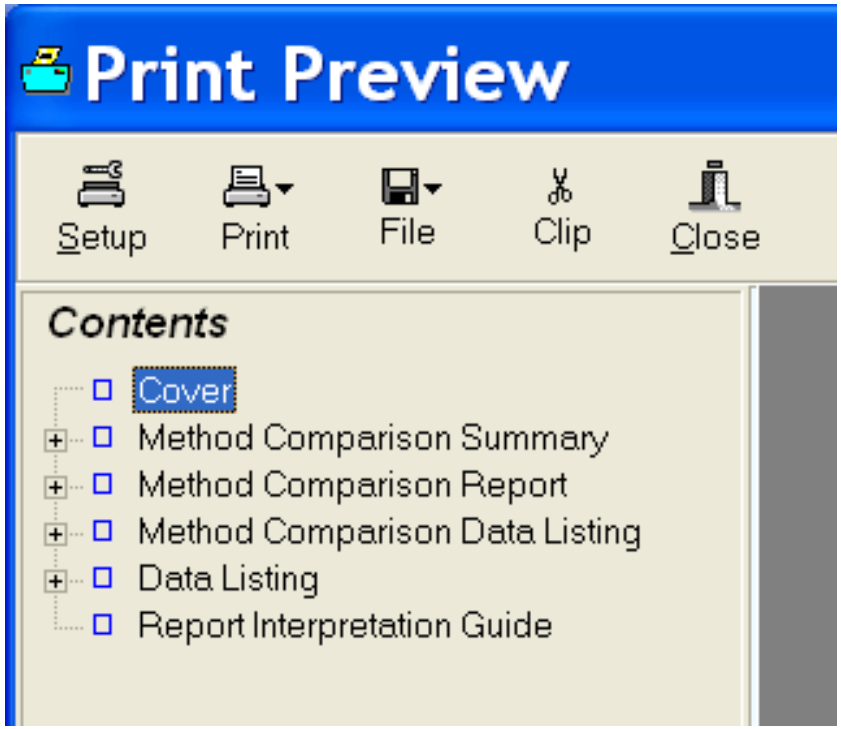
Hematology reports

- Could be dozens of pages (After EE10.1, sections selectable in F7)
  - **Cover page for the entire report**
  - **Methods Listing page**
  - **Method Comparison Summary Report – Key Regression Statistics – All Parameters for each pair of methods compared**
  - *** Morphology discrepancy page – for each pair of methods**
  - **Method Comparison Report of individual parameters - with plots for each pair of methods**
  - **Data Listing – Method bias for parameters used in regression analysis – each method pair**
  - *** Data Listing for differential Count Parameters by specimen for all methods**
  - **Data Listing for complete CBC - by specimen for all methods**

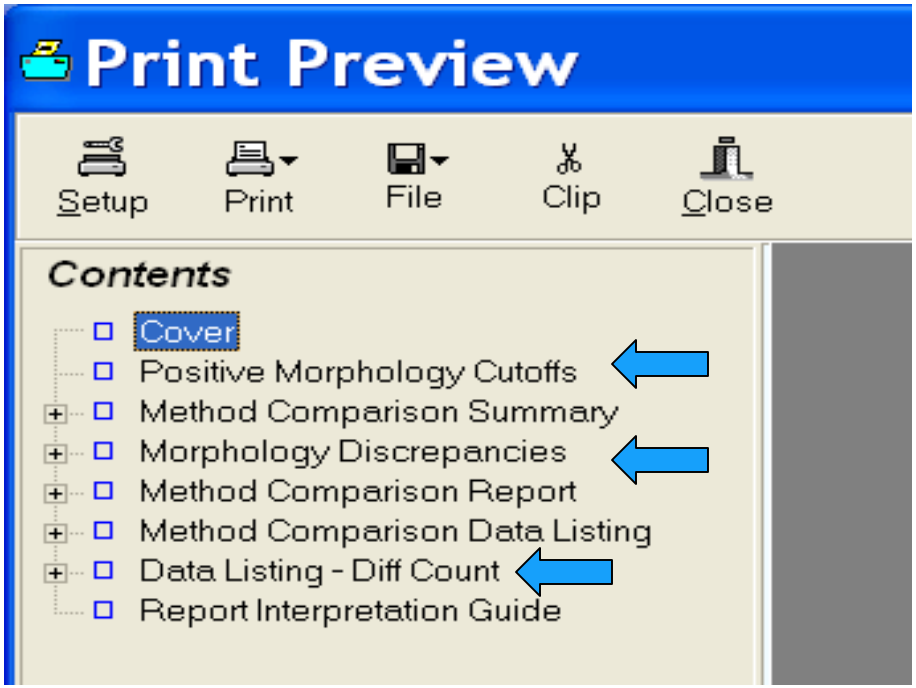
* Gold standard

Report Components

- **Not gold standard**



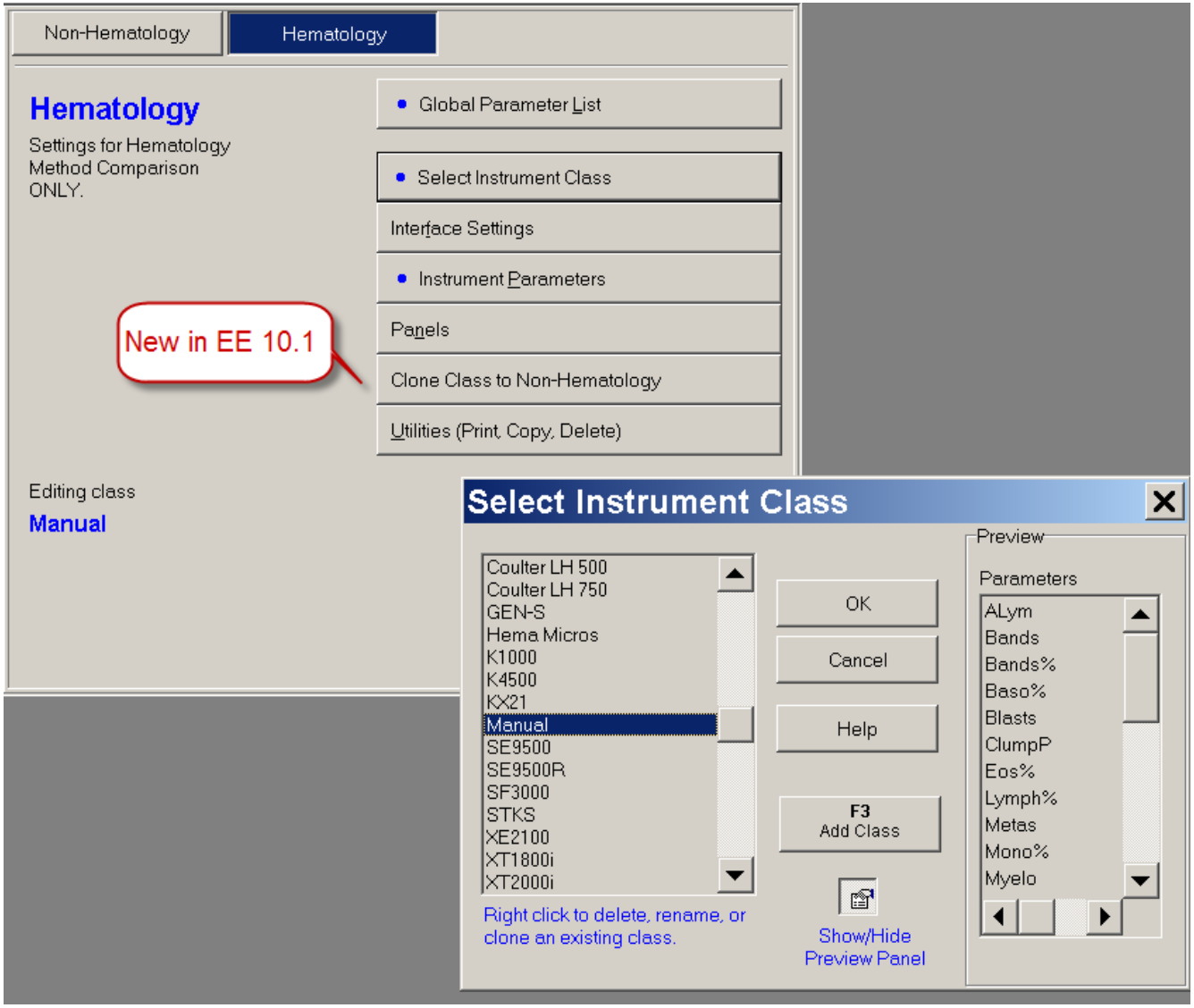
- **Gold Standard**



Policy Definitions

- Projects:
  - **ExamplePolicies**
  - **HMC Example**
- Example Spreadsheet
  - **C:EE9\resources\HMC example.xls**
- Required parameters
  - **Global Parameter names and units**
  - **Instrument classes (peer groups)**
- Optional
  - **Specify regression if you want regression plots**
  - **Input flag cutoffs if you want to evaluate morphology and see a clinical utility (truth) table**

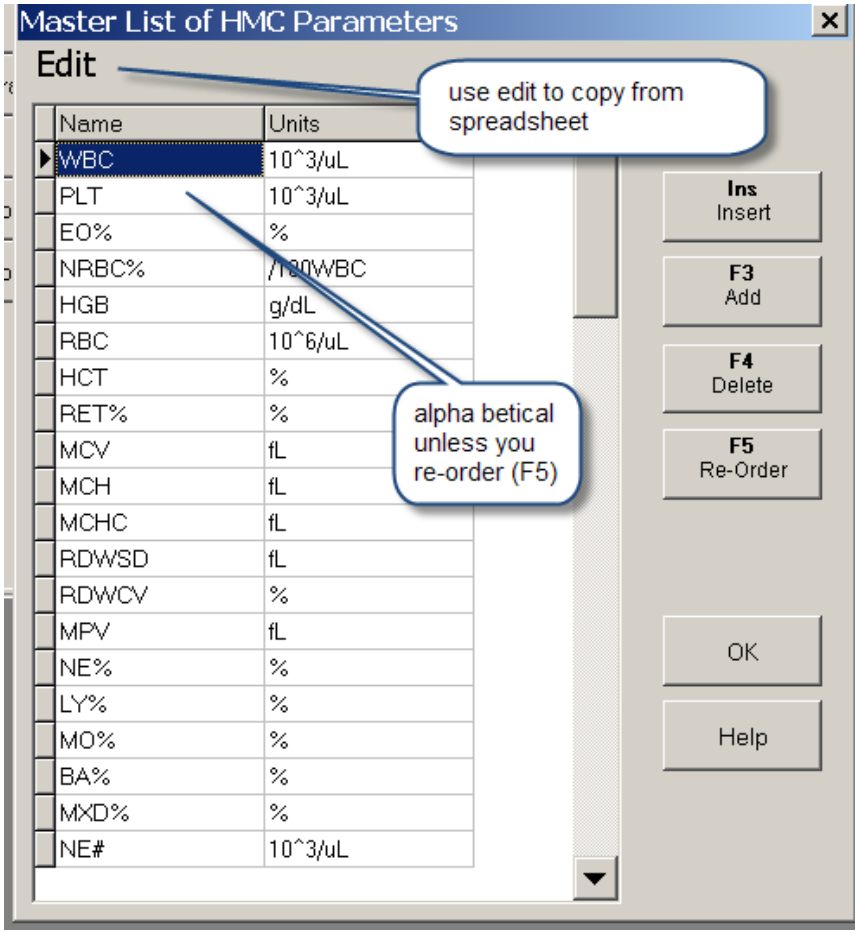
Policy Definitions are required

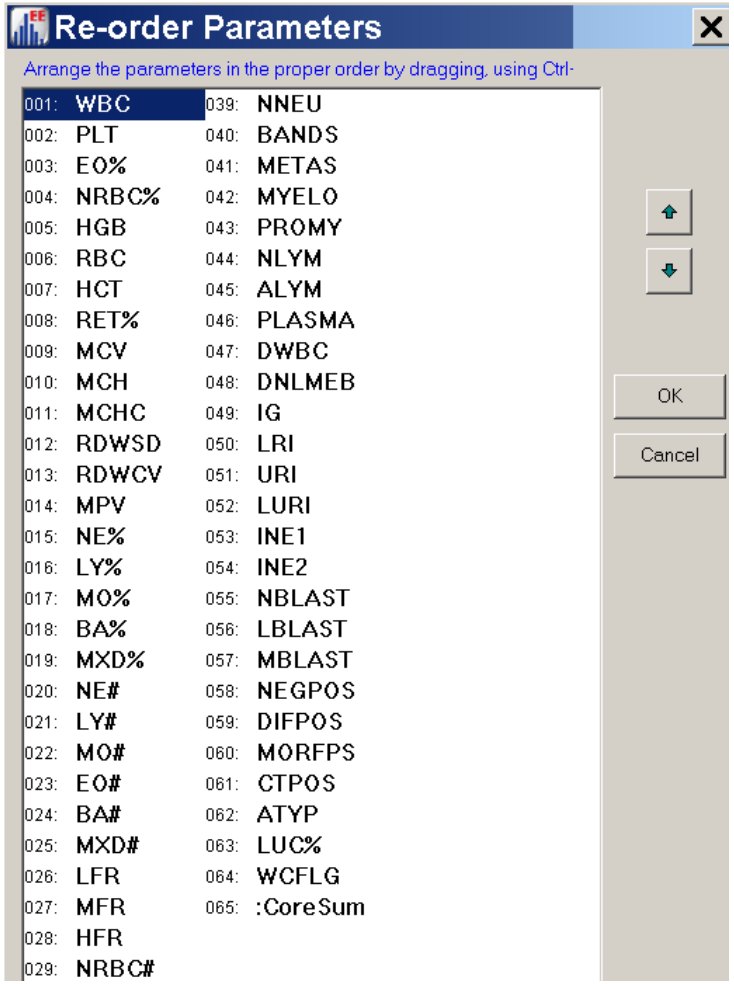


Setting up Hematology Policies

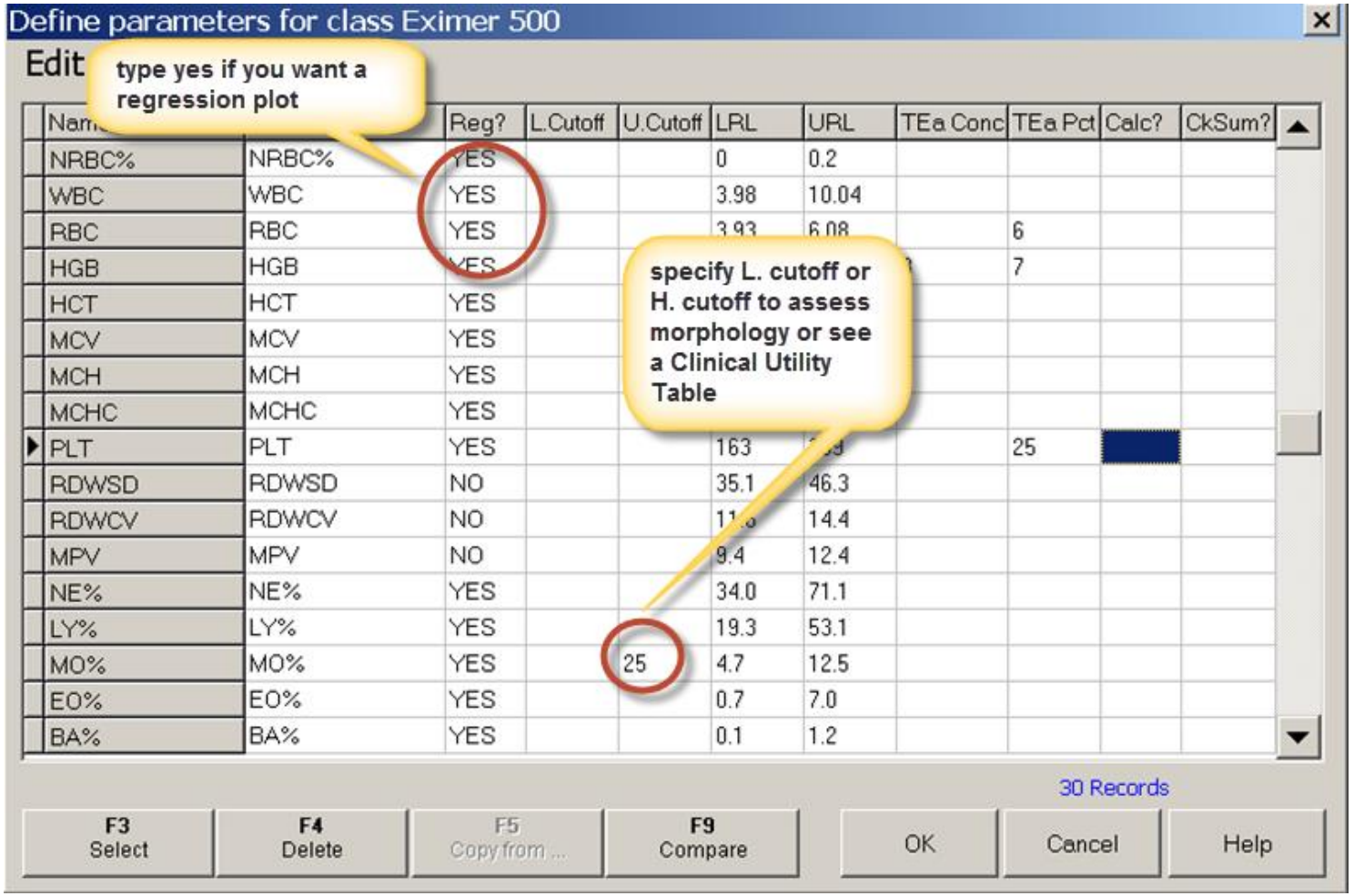
- Parameter names, spellings, etc are common to all classes in the project.
- Instrument classes are specific to instrument platform
  - **Interface settings, cell counts, gold standard choice**
  - **Panels**
  - **Selection of parameters from the global list**
  - **Characteristics like Flags, Cutoffs, ref ranges, calculated parameters.**

Global Parameters – the first step

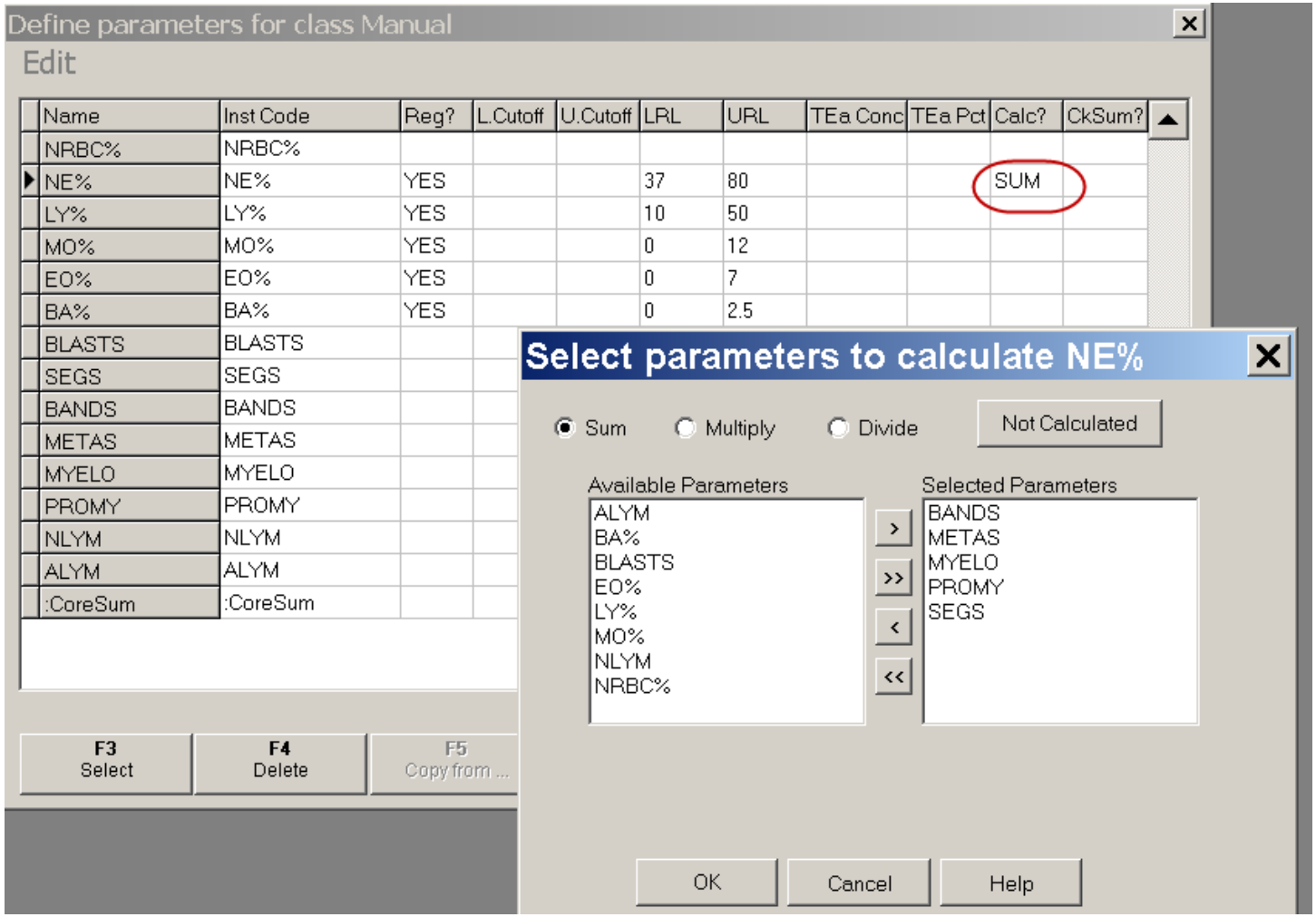




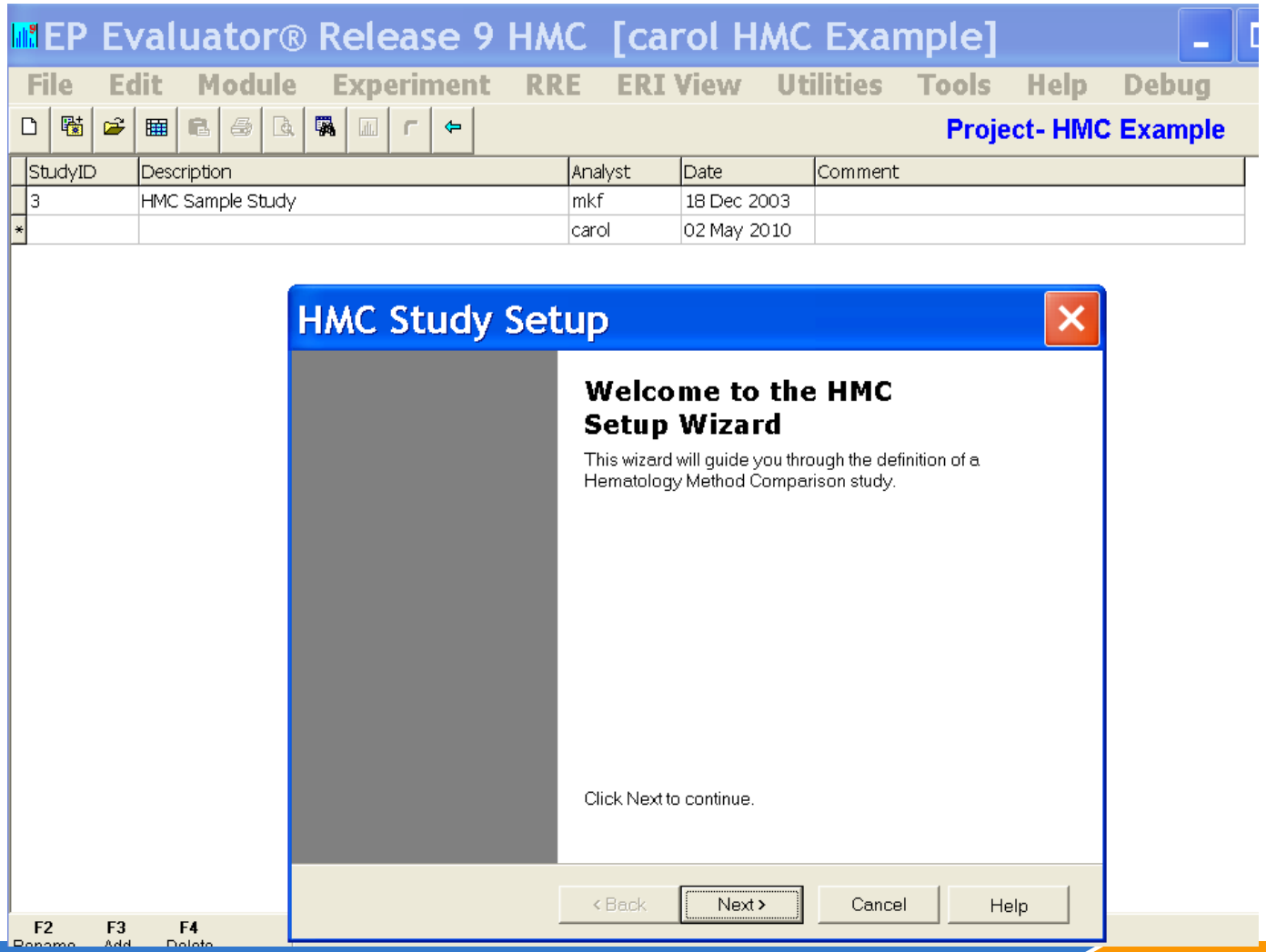
Policy definition – Instrument Parameters Screen



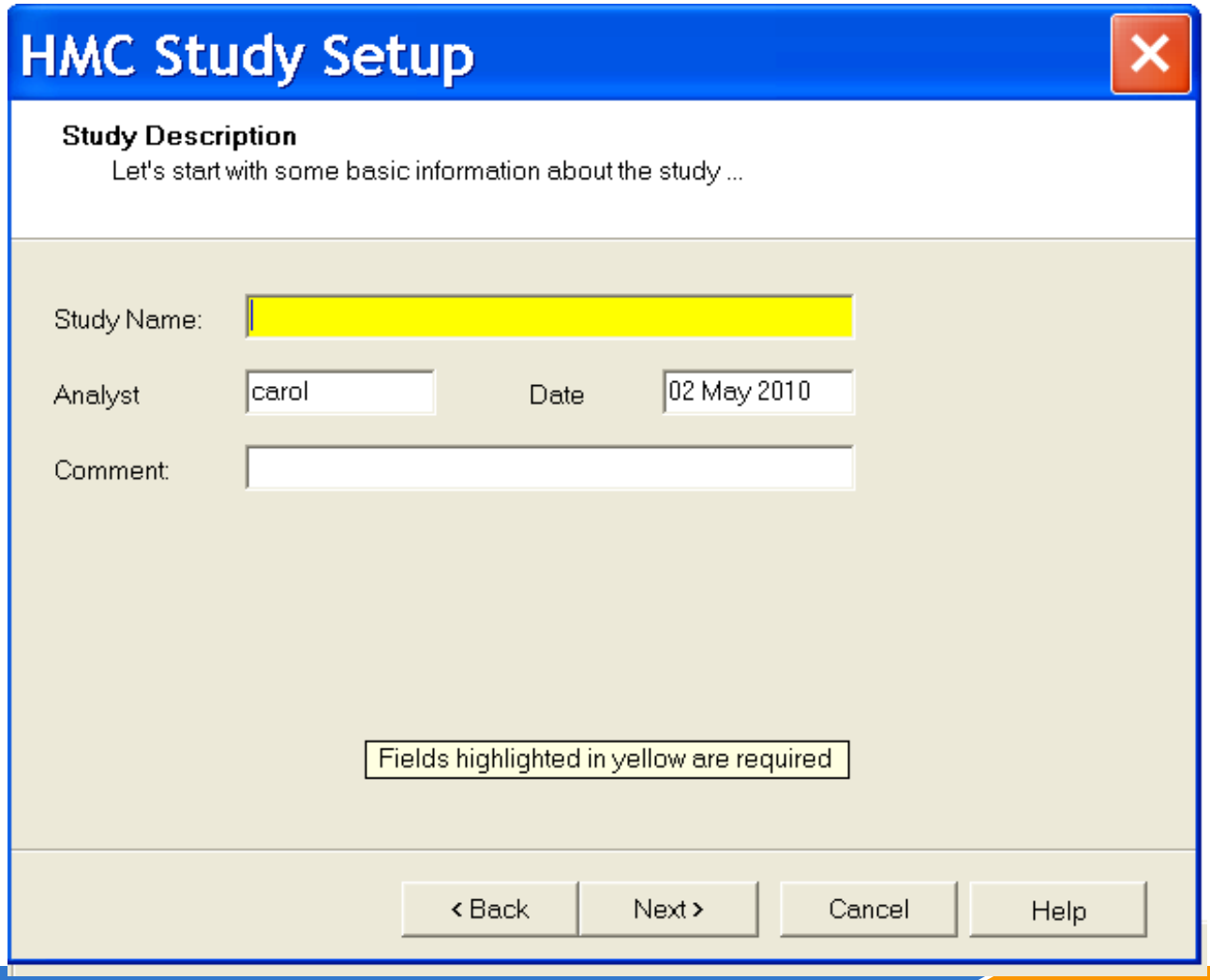
Calculated parameters



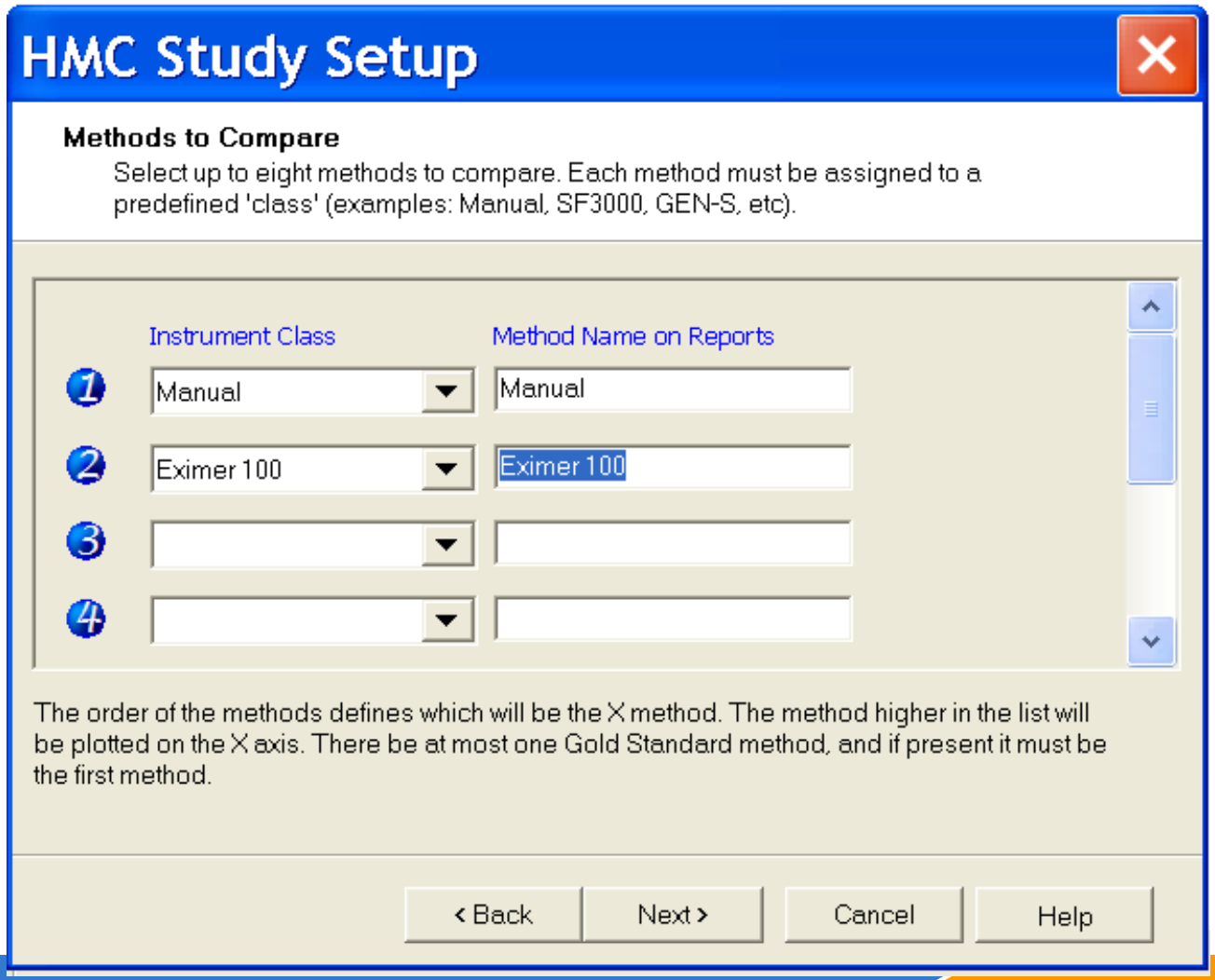
Creating a new study. Experiment\New from policies



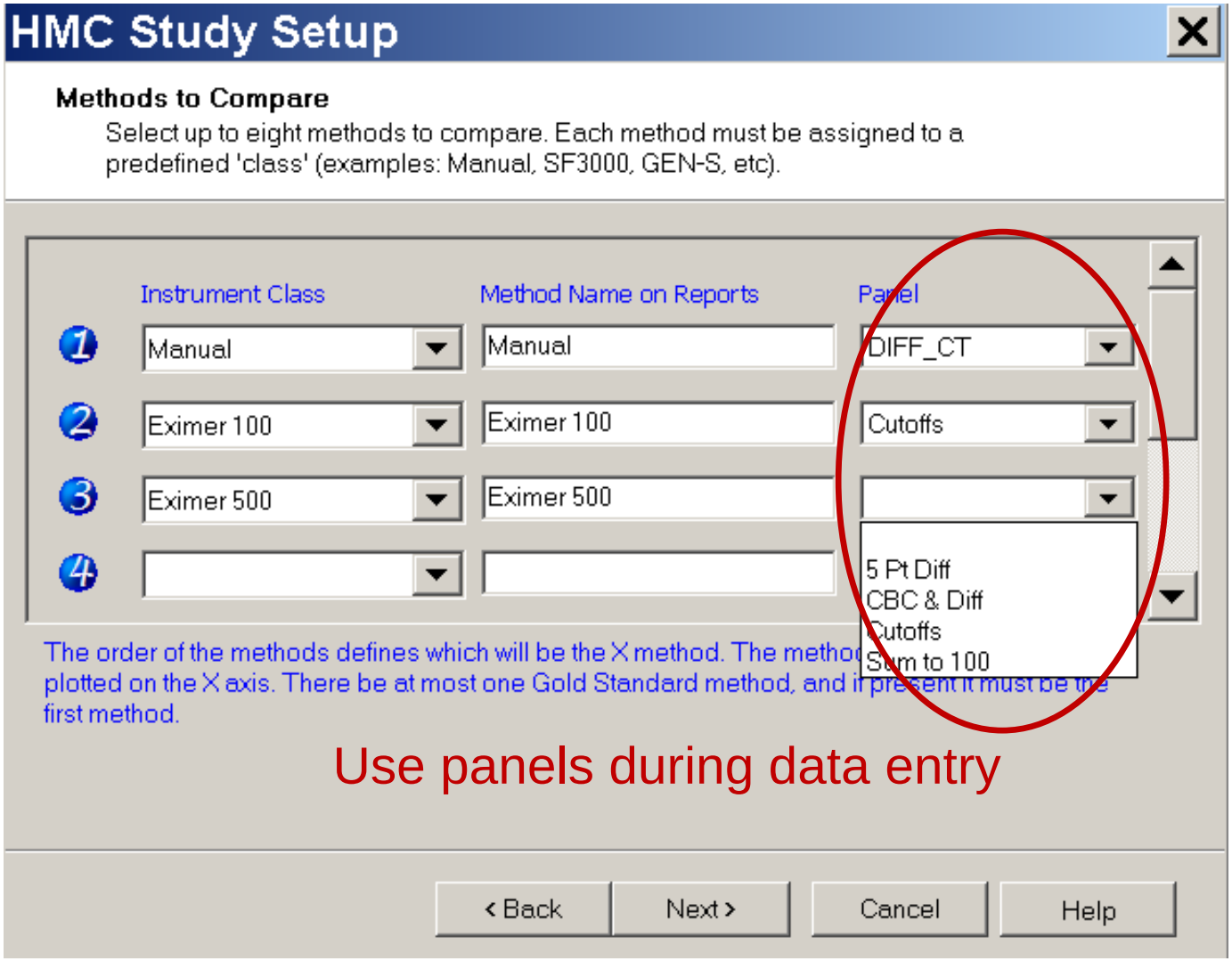
Creating the “Study”



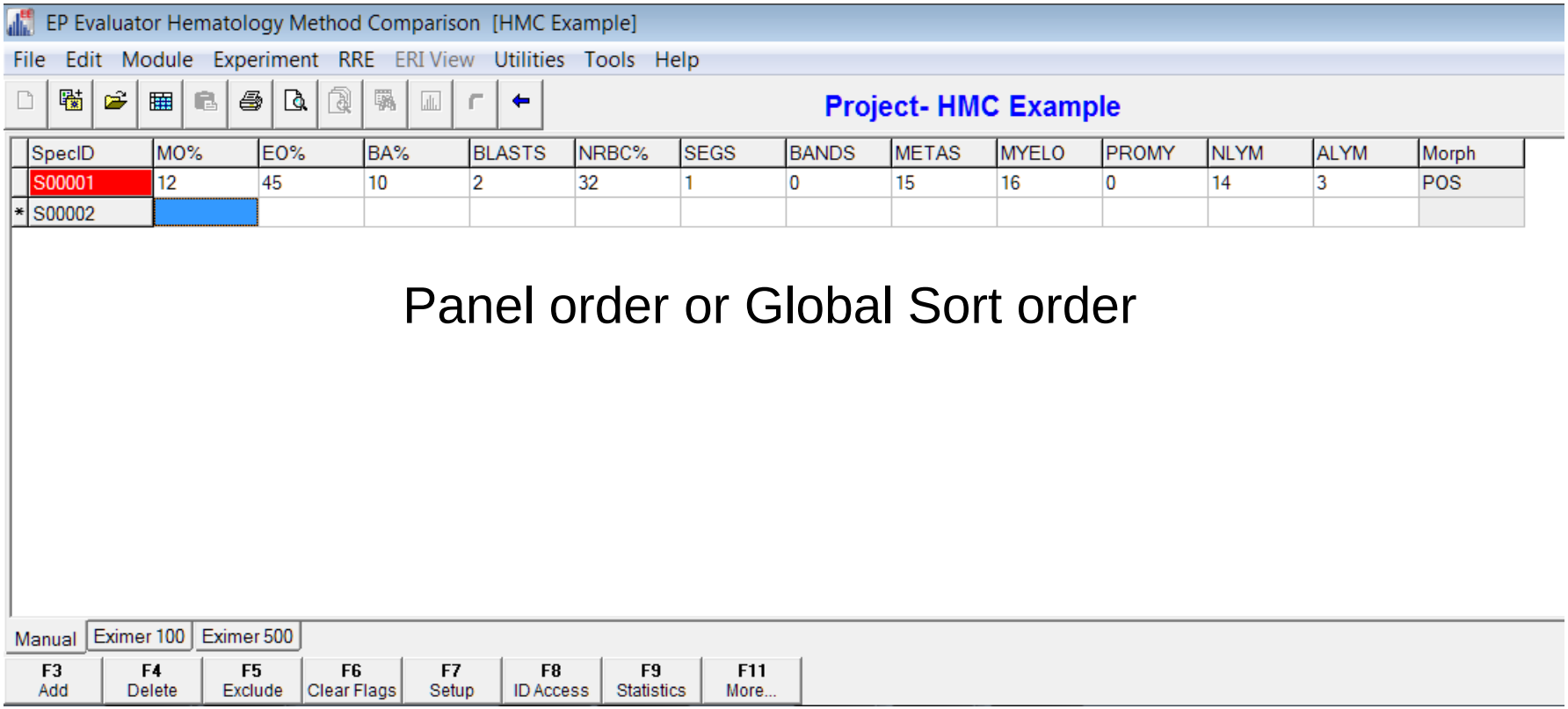
HMC Study setup
Prior to EE10.2



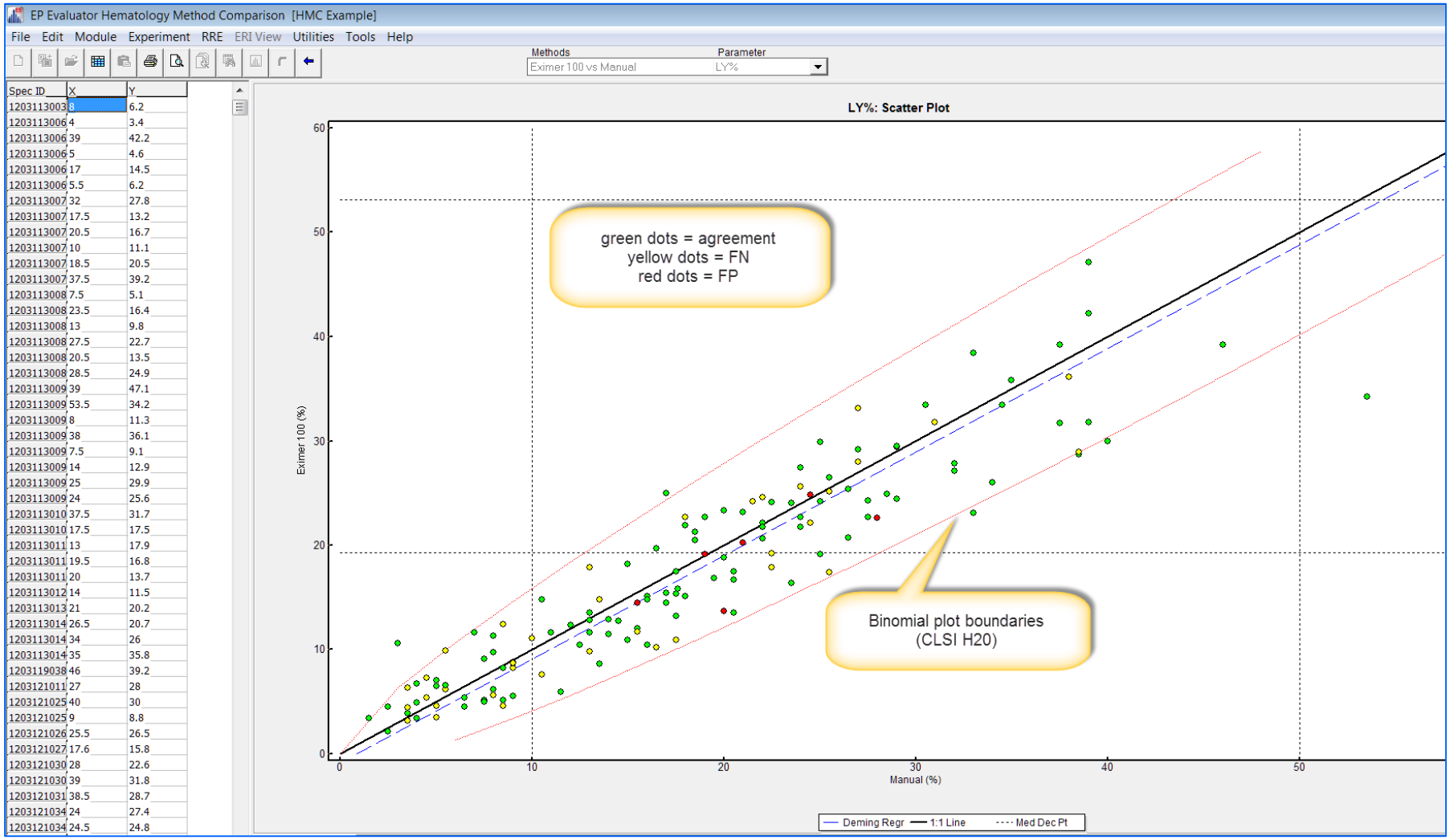
Study setup EE10.2



The HMC worksheets



F9: regression plots



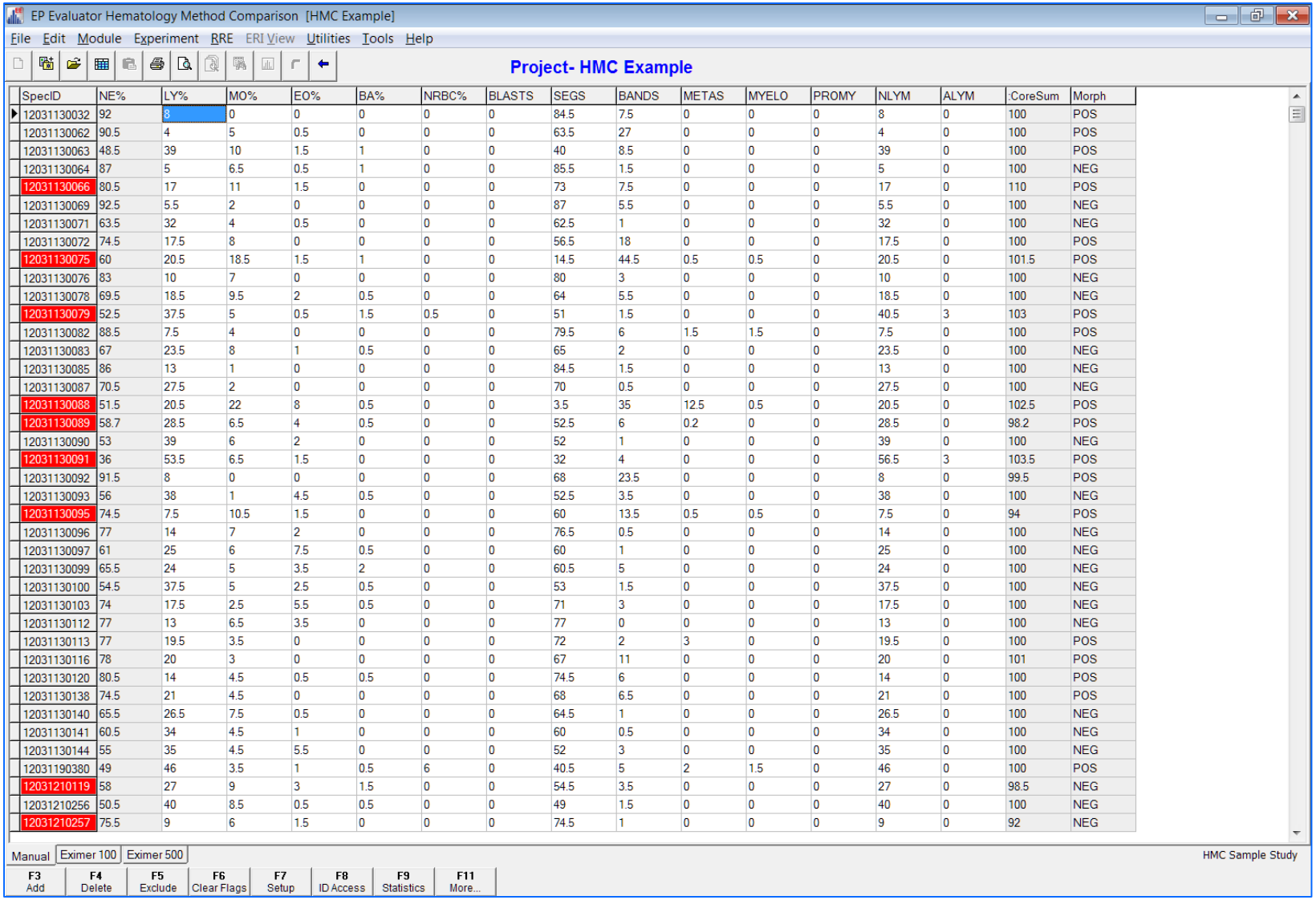
Hematology Method Comparison

- The study has 2 layers
  - **The first layer is a experimental data screen with tabs for entering each instrument method's data**
  - **The second layer contains the calculated regression plots for each parameter requested.**
- Function keys at bottom
  - **F9 gives access to mod overview screen for regression plots**
    - **Each regression plot has its own experimental detail screen showing X-Y data pairs and plot and statistics page.**
  - **F7 shows study design of Instruments being compared**
  - **F11 provides more useful tools**

HMC Experimental Detail Screen

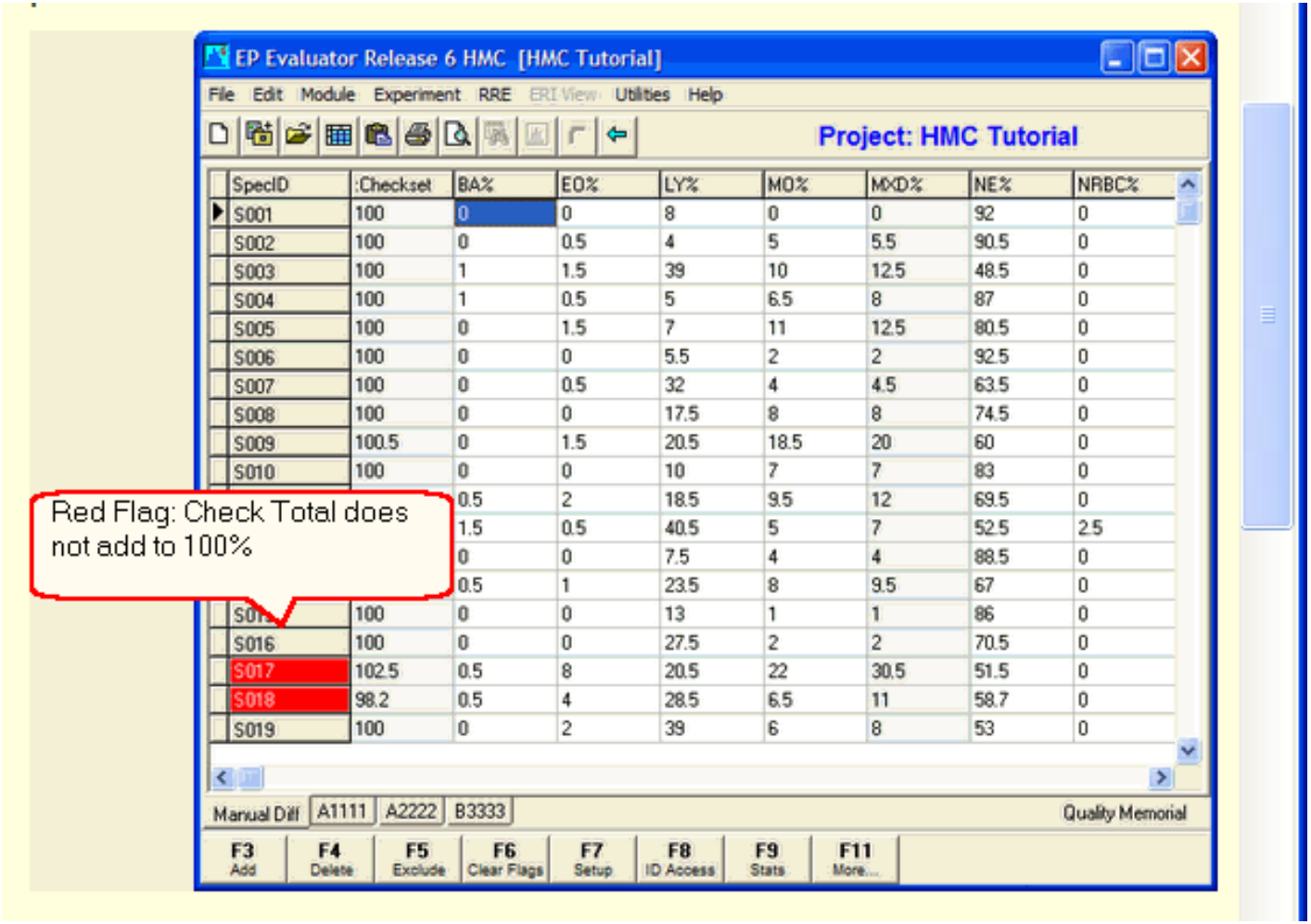
- Enter your data in this screen.
  - **It looks like an Excel Workbook, with a separate tab page for each method.**
  - **EE creates the column titles (parameter names) based on the instrument classes from your Policy definition.**
- The light blue shaded columns (MXD% and Checkset in the illustration) are computed parameters. You can't enter results in those columns.
- Red Spec IDs means you have defined a CheckSum parameter -- a set of parameters that should add to 100% -- and the checksum test failed.

HMC Expt Detail screen: Methods Workbook



SpecID	NE%	LY%	MO%	EO%	BA%	NRBC%	BLASTS	SEGS	BANDS	METAS	MYELO	PROMY	NLYM	ALYM	CoreSum	Morph
12031130032	92	8	0	0	0	0	0	84.5	7.5	0	0	0	8	0	100	POS
12031130062	90.5	4	5	0.5	0	0	0	63.5	27	0	0	0	4	0	100	POS
12031130063	48.5	39	10	1.5	1	0	0	40	8.5	0	0	0	39	0	100	POS
12031130064	87	5	6.5	0.5	1	0	0	85.5	1.5	0	0	0	5	0	100	NEG
12031130066	80.5	17	11	1.5	0	0	0	73	7.5	0	0	0	17	0	110	POS
12031130069	92.5	5.5	2	0	0	0	0	87	5.5	0	0	0	5.5	0	100	NEG
12031130071	63.5	32	4	0.5	0	0	0	62.5	1	0	0	0	32	0	100	NEG
12031130072	74.5	17.5	8	0	0	0	0	56.5	18	0	0	0	17.5	0	100	POS
12031130075	60	20.5	18.5	1.5	1	0	0	14.5	44.5	0.5	0.5	0	20.5	0	101.5	POS
12031130076	83	10	7	0	0	0	0	80	3	0	0	0	10	0	100	NEG
12031130078	69.5	18.5	9.5	2	0.5	0	0	64	5.5	0	0	0	18.5	0	100	NEG
12031130079	52.5	37.5	5	0.5	1.5	0.5	0	51	1.5	0	0	0	40.5	3	103	POS
12031130082	88.5	7.5	4	0	0	0	0	79.5	6	1.5	1.5	0	7.5	0	100	POS
12031130083	67	23.5	8	1	0.5	0	0	65	2	0	0	0	23.5	0	100	NEG
12031130085	86	13	1	0	0	0	0	84.5	1.5	0	0	0	13	0	100	NEG
12031130087	70.5	27.5	2	0	0	0	0	70	0.5	0	0	0	27.5	0	100	NEG
12031130088	51.5	20.5	22	8	0.5	0	0	3.5	35	12.5	0.5	0	20.5	0	102.5	POS
12031130089	58.7	28.5	6.5	4	0.5	0	0	52.5	6	0.2	0	0	28.5	0	98.2	POS
12031130090	53	39	6	2	0	0	0	52	1	0	0	0	39	0	100	NEG
12031130091	36	53.5	6.5	1.5	0	0	0	32	4	0	0	0	56.5	3	103.5	POS
12031130092	91.5	8	0	0	0	0	0	68	23.5	0	0	0	8	0	99.5	POS
12031130093	56	38	1	4.5	0.5	0	0	52.5	3.5	0	0	0	38	0	100	NEG
12031130095	74.5	7.5	10.5	1.5	0	0	0	60	13.5	0.5	0.5	0	7.5	0	94	POS
12031130096	77	14	7	2	0	0	0	76.5	0.5	0	0	0	14	0	100	NEG
12031130097	61	25	6	7.5	0.5	0	0	60	1	0	0	0	25	0	100	NEG
12031130099	65.5	24	5	3.5	2	0	0	60.5	5	0	0	0	24	0	100	NEG
12031130100	54.5	37.5	5	2.5	0.5	0	0	53	1.5	0	0	0	37.5	0	100	NEG
12031130103	74	17.5	2.5	5.5	0.5	0	0	71	3	0	0	0	17.5	0	100	NEG
12031130112	77	13	6.5	3.5	0	0	0	77	0	0	0	0	13	0	100	NEG
12031130113	77	19.5	3.5	0	0	0	0	72	2	3	0	0	19.5	0	100	POS
12031130116	78	20	3	0	0	0	0	67	11	0	0	0	20	0	101	POS
12031130120	80.5	14	4.5	0.5	0.5	0	0	74.5	6	0	0	0	14	0	100	POS
12031130138	74.5	21	4.5	0	0	0	0	68	6.5	0	0	0	21	0	100	POS
12031130140	65.5	26.5	7.5	0.5	0	0	0	64.5	1	0	0	0	26.5	0	100	NEG
12031130141	60.5	34	4.5	1	0	0	0	60	0.5	0	0	0	34	0	100	NEG
12031130144	55	35	4.5	5.5	0	0	0	52	3	0	0	0	35	0	100	NEG
12031190380	49	46	3.5	1	0.5	6	0	40.5	5	2	1.5	0	46	0	100	POS
12031210119	58	27	9	3	1.5	0	0	54.5	3.5	0	0	0	27	0	98.5	NEG
12031210256	50.5	40	8.5	0.5	0.5	0	0	49	1.5	0	0	0	40	0	100	NEG
12031210257	75.5	9	6	1.5	0	0	0	74.5	1	0	0	0	9	0	92	NEG

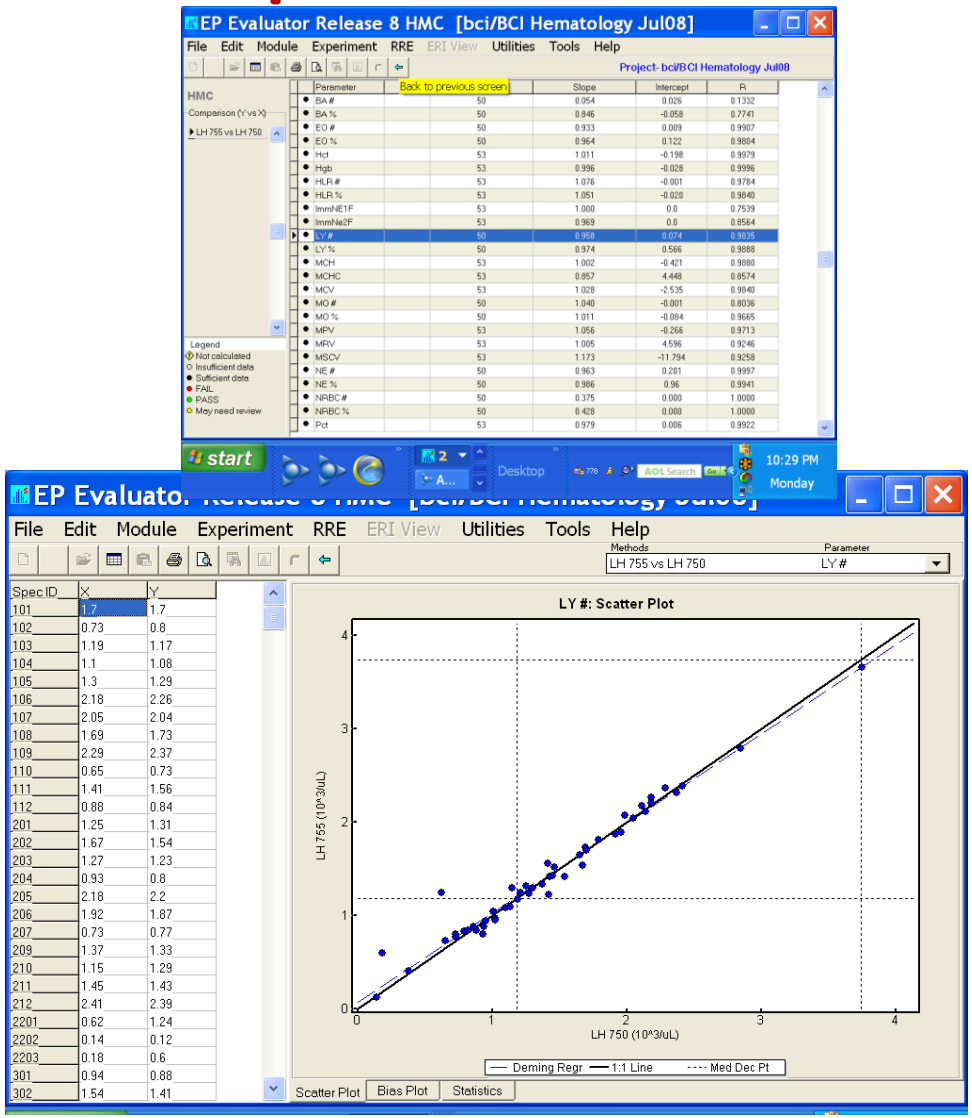
HMC Experimental detail screen 2



SpecID	:Checkset	BA%	EO%	LY%	MO%	MXD%	NE%	NRBC%
S001	100	0	0	8	0	0	92	0
S002	100	0	0.5	4	5	5.5	90.5	0
S003	100	1	1.5	39	10	12.5	48.5	0
S004	100	1	0.5	5	6.5	8	87	0
S005	100	0	1.5	7	11	12.5	80.5	0
S006	100	0	0	5.5	2	2	92.5	0
S007	100	0	0.5	32	4	4.5	63.5	0
S008	100	0	0	17.5	8	8	74.5	0
S009	100.5	0	1.5	20.5	18.5	20	60	0
S010	100	0	0	10	7	7	83	0
		0.5	2	18.5	9.5	12	69.5	0
		1.5	0.5	40.5	5	7	52.5	2.5
		0	0	7.5	4	4	88.5	0
		0.5	1	23.5	8	9.5	67	0
S015	100	0	0	13	1	1	86	0
S016	100	0	0	27.5	2	2	70.5	0
S017	102.5	0.5	8	20.5	22	30.5	51.5	0
S018	98.2	0.5	4	28.5	6.5	11	58.7	0
S019	100	0	2	39	6	8	53	0

HMC Study – Scatter plots

- The second layer of the HMC study contains the regression plots that are checked “Yes” in policies
    1. An overview screen shows a summary of the comparison. Click on each comparison to calculate and open it
    2. Detail screen shows the X and Y data and is non-editable.
    3. At upper right of screen, can page down and open all scatter plots, bias plots, and statistics.
    4. The blue back arrow goes to Prev screen



HMC Module Specific Instructions

- New studies can only be created using “Experiment / New from policies”. To launch the New Studies Wizard.
- Some policy definitions are required in order to generate a new experiment.
  - global list parameter
  - At least 2 methods in at least 1 instrument/method class.
  - Selection of parameters for each method (Characteristics like reference intervals and morphology cutoffs are optional.
  - Enter YES if you want regression plots
- Excel spreadsheet format for copy/paste (It’s a SPELLING Test!!
  - Column headings Spelled the same as the parameters in policies.
  - Specimen ID column must be spelled “SpecID” with no spaces.
- Blank Cells are considered to have no reported data. If cells were counted, but no cells of that type were found, then the cell should have a result of zero (0). Specimens with blank cells are NOT included in the parameter regression reports or the Clinical Utility table unless you check the box: “Do not require a result for all methods” in the HMC Study setup wizard.

Preferences and F7 setup

- Preferences:
  - **Some check boxes can control your study**
    - during the copy/paste process.
      - **Interface: Initialize interfaced/ pasted blank HMC morphology parameters to zero (SO you don't have to type in the zeros!!)**
    - For any existing study Report generation:
      - **Omit Reference intervals from HMC reports**
      - **HMC Flag comparison report by default**
- F7 setup
  - **Customize some study settings after creation**
  - **Reveal the number of specimens in each method**
  - **"Show Study Design reveals parameters with flags and regression defined, and number of specimens entered**
  - **Select report sections**
  - **Customize report interpretive comments**

Steps to create a new HMC Experiment

Assumption: Your hematology instrument classes describe all of the instruments you want to compare.

1. Create a new project
   (File / New)
2. Review or Define your policies “My lab hematology”
   (RRE / Define policies / Hematology policies)
3. Create a New study:
   Method comparison /Hematology Module / Overview screen
4. Click Experiment “New from policies” or F3 “Add”
   This opens the New Study Wizard

New Study Wizard

- New Study Wizard
  1. **"Study Description" screen**
     - Study name, analyst, date
  2. **Method setup screen**
     - Choose 2 to 8 methods to compare
     - Chose "instrument class"
     - Type in specific method or Instrument name for report
     - Manual or "gold standard" must be first
  3. **Cover sheet Information – up to 250 characters each**
     - Prepared For:
     - Prepared By:

Getting your data

- When the New Study wizard is complete, a workbook appears with one tab for each Method.
- You are now ready to enter data
- Where is your data coming from?
  - **instrument printouts**
    - **Manual entry Directly into method tabs or**
  - **Spreadsheets:**
    - **copy data from spreadsheet. Edit\Paste into its instrument data sheet.**
    - **EE ignores extraneous columns of "stuff". Only cares about SPECID and header names to match parameter names set up in policies.**
  - **Data capture ODBC from Instrument Manager: Use RRE: Connect to Instrument Manager. (only with an EE data capture version)**

Data Entry Modes

Mode	Instruments	Data Source	EE import process	Data headers	Panels? comments
Paste into method Tabs	Any	Excel spreadsheet file with headers and specID,	In your method tabs, paste entire spreadsheet (edit/paste)	Match global parameter names, SPECID	column order doesn't matter. undefined columns ignored
Keyboard - Manual entry from printouts	Manual, or other as needed	Inst printouts	RRE Create experiment, keyboard entry, manual enter data & spec ids into RRE worksheet, F9 send to tabs	NA	yes - panel in order of inst printout
INST Capture (Vendor only)	Specific INST driver	Cable connection or instrument generated file	RRE Create experiment, inst capture,	NA	Panels yes.
ODBC from Instrument Manager	Any connected to IM	Filter by date and spec ID	RRE: connect to IM	NA	Panels yes.

Data Capture Keyboard entry

- Use this to manually enter data from printouts,
- Select the instrument tab where you want to enter data
  - **click RRE / Create Experiment**
  - **Select “2. keyboard entry” and follow the prompts**
  - **Check “Yes” to enter specIDs**
  - **Need a panel defined in policies**
  - **Manually enter your specID & data from instrument printouts.**
  - **When finished entering data:**
  - **Save the worksheet**
  - **Press F9 to send data to the instrument /method tab**

Hematology Method Comparison - Step-By-Step

1. Ensure that policy definitions are set up
    1. **Global parameter names and units**
    2. **Classes for each instrument or method type**
    3. **Specifications for each method class, including calculated parameters and checksum.**
2. Data Entry Modes
    1. **Manual entry from instrument printouts**
        1. **Create panels for each instrument in the order of printout**
        2. **Create new experiment using RRE Create experiment wizard. – Keyboard entry**
        3. **Choose to enter spec IDs**
    2. **Copy/paste from excel spreadsheet**
        1. **excel spreadsheet with separate tabs for each instrument's data.**
        2. **Ensure spelling of parameter names exactly matches header names in excel spreadsheet data. (or vice versa)**

Hematology Method Comparison
Step-By-Step Summary

1. Create “New Experiment from policies” or F3 add from Mod overview screen. And let Wizard create the Data Workbook
    1. **Switch to Excel, copy all data for instrument 1, paste into corresponding tab of EE workbook.**
        1. **Repeat for other instruments/ methods**
    2. **Can also use Instrument capture, keyboard entry, or ODBC from Instrument Manager.**
2. F9 STATS generates the method comparisons
3. Review the reports in “Print Preview”
4. Use F11 to Review and filter the data to identify areas needing attention.
5. Print the report

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Reasons to upgrade from EE9 or EE10

Many enhancements and “bug” fixes were provided in the releases of EE10 and EE11

Enhancements in Release 10.1

- Policies
  - **Number of Parameters in a class increased from 63 to 250**
  - **Copy/paste into the Policy Definition screens**
  - **Added Conc term to HMC TEa**
  - **Clone Hematology classes to non-hematology classes.**
- Reports
  - **Added Bias calculation to HMC Regression**
  - **User defined sub-title in report F7**
  - **New Interpretive Comments report F7**
  - **New Flag Comparison report F7**
  - **Handling of blank data can be managed via *PREFERENCES* for both interfacing and paste from spreadsheet.**
- Panels revealed on data tabs
- Recalculate now works from the Module menu
- ODBC_IM now works with HMC

Enhancements in EE 10.2

- Panels can be selected when HMC Studies are created
- Panels selected in HMC are remembered between uses of the Study
- HMC users can enable/disable each section of the HMC reports in Setup
- The global sort order of parameters is honored in all sections of the HMC reports. HMC classes display the global sort order instead of alphanumeric.

Improvements in EE11.0 /EE11.1

- 11.0
  - **The F11 "Show Positive Specimens" filter will show only positive specimens.**
- 11.1
  - **An error message appears if the user attempts to exclude an HMC parameter that is used to compute another HMC parameter.**
  - **HMC scatter plots show false negatives and false positives in red and yellow.**
- 11.2
  - **Able to change the REG? option in the F7 setup edit screen for the current study. Previously it was editable only in RRE Policy definition and did not apply to the current study.**

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Additional Training & Services

- Visit the DI website for information on free training. http://datainnovations.com/services/training/ep-evaluator-training-programs
  - **Overview and Getting Started with EP Evaluator**
  - **Project Management**
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  - **Hematology Method Comparison**
  - **Determining Performance standards**
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- For more in-depth training or consultation
  - **Contact the DI Sales organization for a quote**
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Thank you!