

ReadMe Notes

East 5.2

1. What's New in East 5.2

A new module "Exact Tests" has been added in this version, which includes:

A. Design, simulation and monitoring of the following **exact inference** tests suitable for binomial responses, especially when the total sample size of the trial is small and/or the binomial proportions involved are close to zero or one:

1. Binomial – Superiority – One Sample – Single Proportion

The preceding test is available as a group sequential procedure.

The following features are based on unconditional test procedures for single look fixed sample designs:

2. Binomial – Superiority – One Sample – Paired Proportions.
3. Binomial – Superiority – Two Samples – Difference of Proportions..
4. Binomial – Superiority – Two Samples – Ratio of Proportions
5. Binomial – Noninferiority – Two Samples – Difference of Proportions
6. Binomial – Noninferiority – Two Samples – Ratio of Proportions
7. Binomial – Equivalence – Two Samples – Proportions

B. Design and simulation of Phase II studies using the optimal "Simon's Two-Stage Design for Single Proportion"

2. Improvements from East 5.1 to East 5.2

1. East 5.2 is compatible with Microsoft Excel 2007.
2. East 5.2 is also compatible with Microsoft Vista operating system.
3. Haybittle-Peto (HP) Boundary designs: In Interim Monitoring computations, the design p-values of HP boundaries are now used as discrete p-values without any interpolation, even if interim looks frequency and intervals differ from design specification.
4. Binomial non-inferiority designs- interim monitoring-test statistic calculator: Now it is possible to enter the basic data on sample sizes and number of responses.

5. Binomial non-inferiority design-Ratio-Farrington-Manning: Now variance of standardized test statistic can be specified to be computed either under null hypothesis or under empirical estimate. The variance is computed using proper restricted maximum likelihood method.
6. Simulation: Currently after a set of simulations are run with a specified initial seed, and if a new set of simulations is added, the second set starts with the same initial seed of the first set. This is incorrect. Now in this version, the second set starts with the last seed of the first set of simulations.
7. Binomial Equivalence: In East 5.1, the equivalence design is essentially 1-sided, though the display indicates it as 2-sided. This has been corrected now in this version.
8. It is possible to export East design details to an XML file.

3. Bug-Fixes in East 5.2

1. Normal - Superiority - 2 Sample - t Test for Difference of Independent Means (and for one-sample t-test): For certain input parameter values, the program hangs. This has been fixed now.
2. In survival enhanced simulation, if user specified a value for assigned fraction different from the design value, the simulation process ignored the new value and used only the design value. This has been corrected in this version.
3. In Binomial non-inferiority boundary chart, the read-out box did not display the negative sign of negative numbers. This has been corrected now.
4. When computing a design based on user input parameters, East displayed an error message that the parameters of the design were too extreme whenever one or more output values were incalculable. In East 5.2, the design is produced anyway, without an error message, and with the value "N/A" in any fields where a solution is not available.

4. Installing East 5.2

System Requirements to run East 5.2

The minimum hardware/operating system/software requirements for East 5.2 are:
A system running one of the following operating systems:

- Windows 2000/XP or Vista
 - A minimum of 256 MB RAM (512 MB recommended)
 - A hard disk with at least 25 MB of free disk space
 - Microsoft Excel 2000 SR-1 or 2002 or 2003 or 2007 version.

Installation

You can install East 5.2 in different ways:

- 1) If you are a new user and you have Excel 2003 as your default Excel version program in your computer, use East 5.2 CD for Excel 2003 and follow instructions under 'Installation using CD'.
- 2) If you are a new user and you have Excel 2007 as your default Excel version program in your computer, use East 5.2 CD for Excel 2007 and follow instructions under 'Installation using CD'.
- 3) If you are currently using East 5.0 or 5.1 and would like to install East 5.2 using CD, then completely uninstall your current version and then install East 5.2 from CD like a new user as per step 1) or 2) shown above.
- 4) If you are currently using East 5.0 or 5.1 and would like to upgrade to East 5.2 using upgrade module available in Cytel website, then follow the instructions given in the website.

Installation using CD

To install East 5.2, please follow these steps:

- i) If an earlier (including beta and demo) version of East 5 is currently installed on your PC, please uninstall it or else the installation of the current version will not proceed correctly. To uninstall the earlier version of East 5, go to the Start Menu and select:

Programs-> East 5-> Uninstall East 5

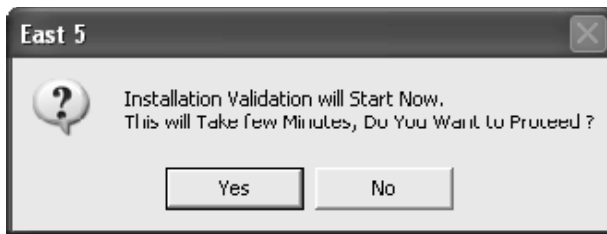
- ii) Insert the East 5.2 CD into your CD-drive.
 - (a) If your Windows Auto run Default is already active, you'll see an installation screen similar to what is shown below. Follow the instructions that will appear on the screen.



- (b) If your Windows Autorun Default is not active, you won't see any installation screen. In that case, open your Windows Explorer, click on the CD Drive, and double-click on Setup. Then you will see the installation screen. Follow the instructions that will appear on the screen.

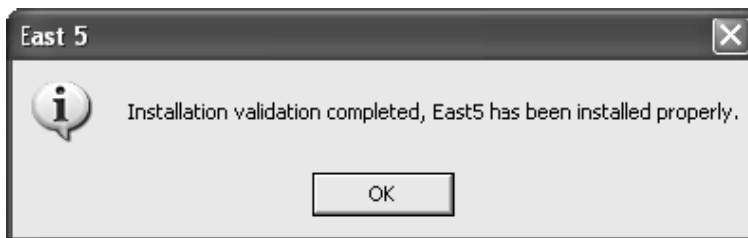
5. Validating Installation

To validate installation of East 5.2, go to the Start Menu and select **Programs-> East 5.2-> Validate Installation**. You will be presented with the following dialog box.



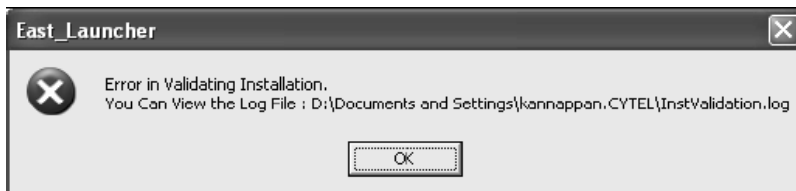
Click on Yes.

If the installation validation is successful, you will get the following message box



Click on OK.

If the installation validation is not successful, you will get a message similar to the one shown in the following message box.



Click on OK and then send the log file InstValidation.log to support@cytel.com for getting help on the installation validation failure.

For more information:

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