Blinded Pre-testing of an Oracle Clinical study closeout using a development instance

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Scope

- Scope

  Test the OC setup, unblinded views, data entry, breakblind processes and randomization in a development instance while the study is up and running in a production instance.

Introduction to Randomization

- **Documents needed for Randomization.**
  - **Final Protocol/ Synopsis.**
    - For setting up the Regimens and Intervals.
  - **Randomization Request Form.**
    - For setting up the Treatment Patterns.

Dummy Randomization & Benefits

- What is Dummy Randomization?
  - Randomization done on the development Instance to make sure that proper testing is done while the study is still ongoing.
- Requirements
  - An instance which is a copy of the production instance, without transferring the Randomization of studies.
- Benefits of Dummy Randomization
  - To break the blind without touching the original patient data.
  - To make sure that the Intervals, CPE's, DCM's, Regimens, Data Entry and the reports are setup properly.
  - To make sure that data is extracted without any problems.

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Types of Randomization

- **Three types of Randomization**
  - **Easy Randomization.**
    - Randomization done on the whole study.
  - **Cohort Randomization.**
    - Randomizing the study based on certain conditions
    - Example: Cohort 1 – Male, Cohort 2 – Female.
  - **Conversion Randomization.**
    - Randomization transferred from External Sources.
- **Any Combination can exist**

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Re-Randomization – Pre-check

- **In the development instance check**
  1. **Randomization existence.**
  2. **Type of Randomization.**
     - **Whether it is Easy Randomization, Cohort Randomization or a combination of Easy and Cohort Randomization.**
  3. **Existence of Mirror Randomization.**
     - **Exact copy of Randomization. 1 – 10 Normal and 101 – 110 Mirror Randomization. Maintains Balance in study's randomization if a patient drops out in-between the study.**

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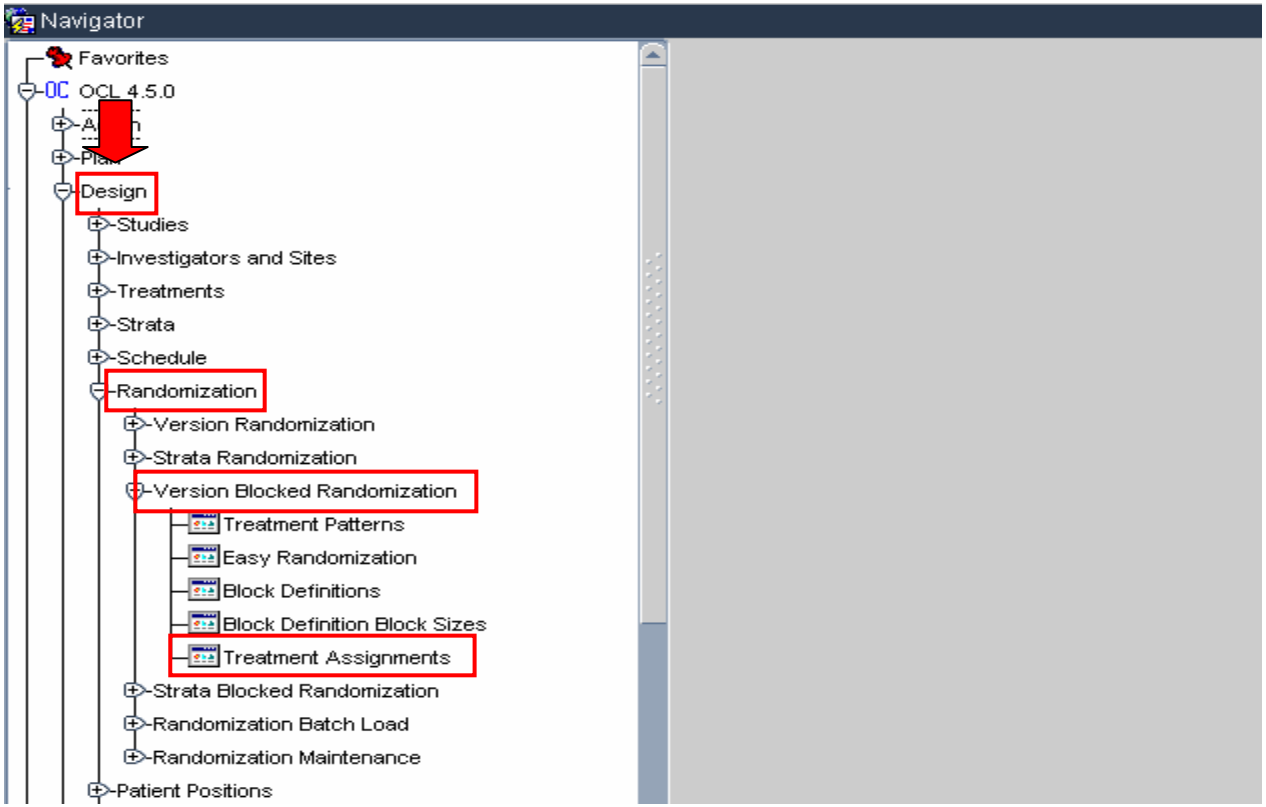
Re-Randomization Pre-Check

- **Randomization Existence in Development Instance**
  - Randomization does not come across when development instance is refreshed, since it is important to preserve blinding.
  - Check whether there is any existence of Mirror Randomization.

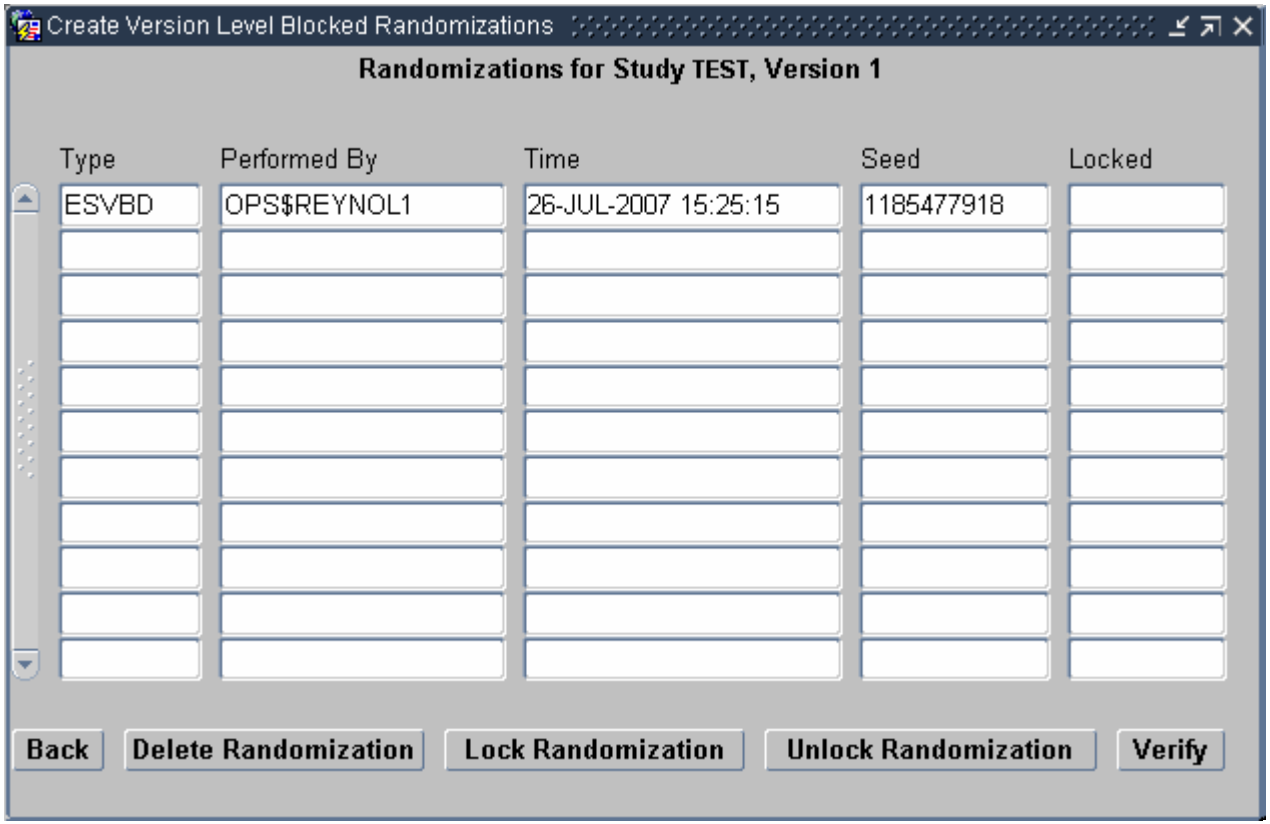
Re-Randomization – Easy Randomization

In order to view the type of Randomization, Follow the path:



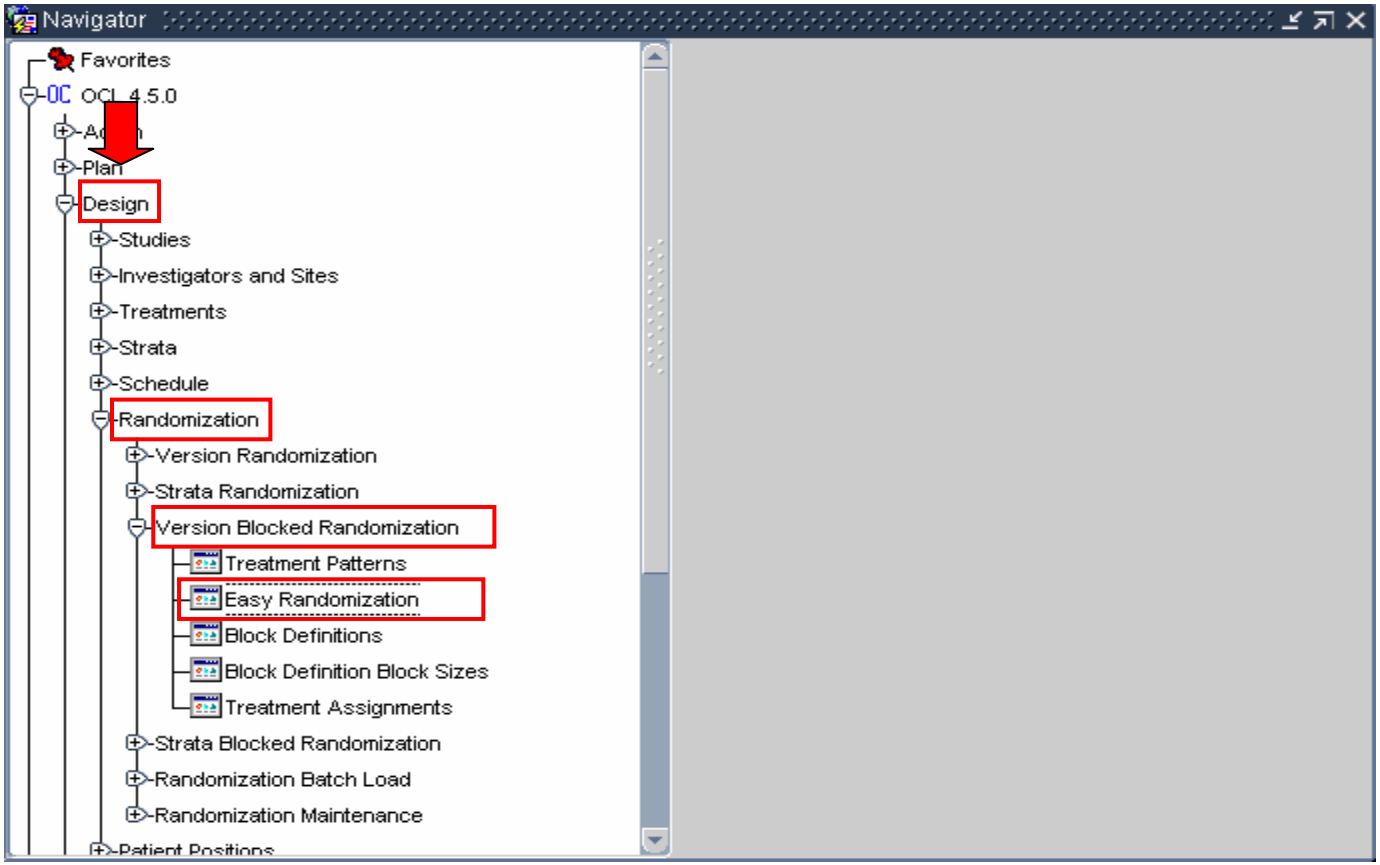
Re-Randomization – Easy Randomization

1. **Check whether Randomization is Locked. If it is Locked, unlock the Randomization.**



Re-Randomization – Easy Randomization

1. **After unlocking the Randomization, Click Back and exit**
2. **To Re-Randomize, follow the path.**



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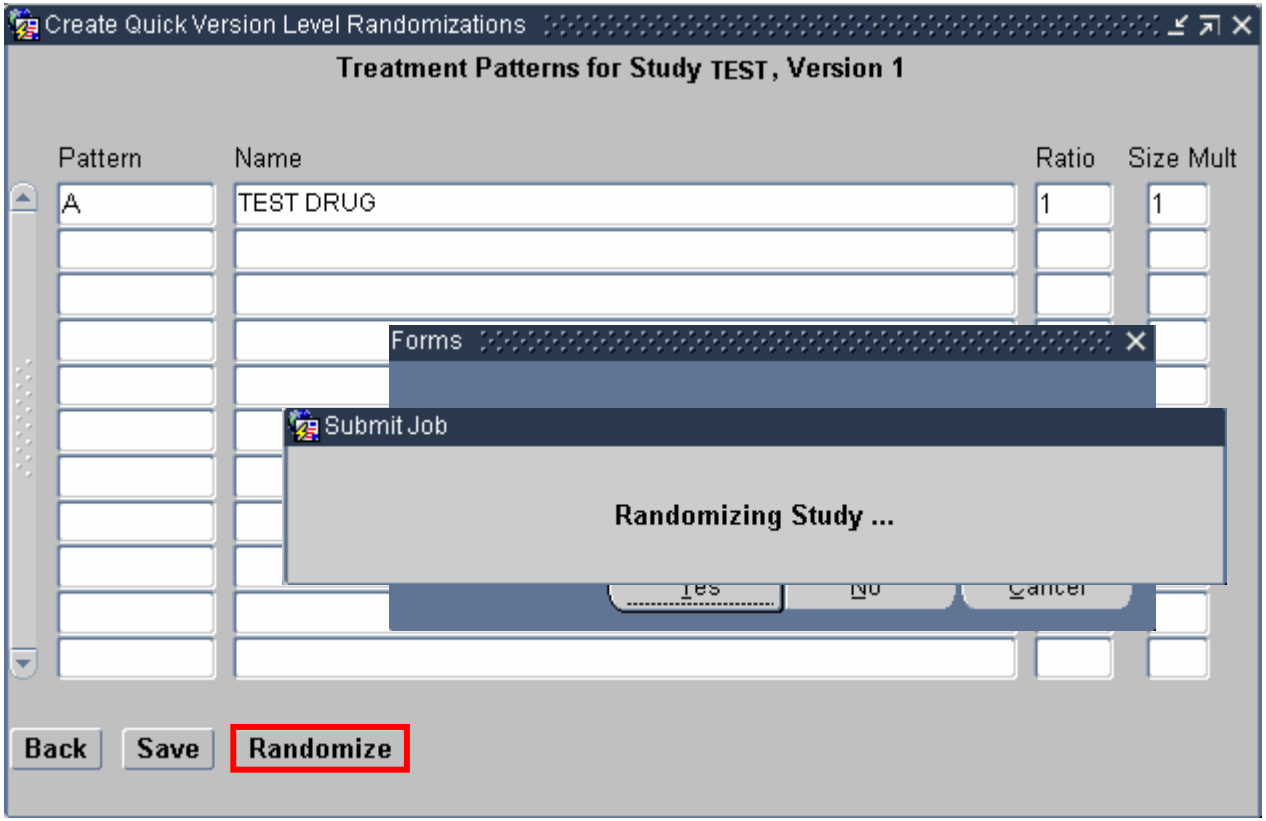
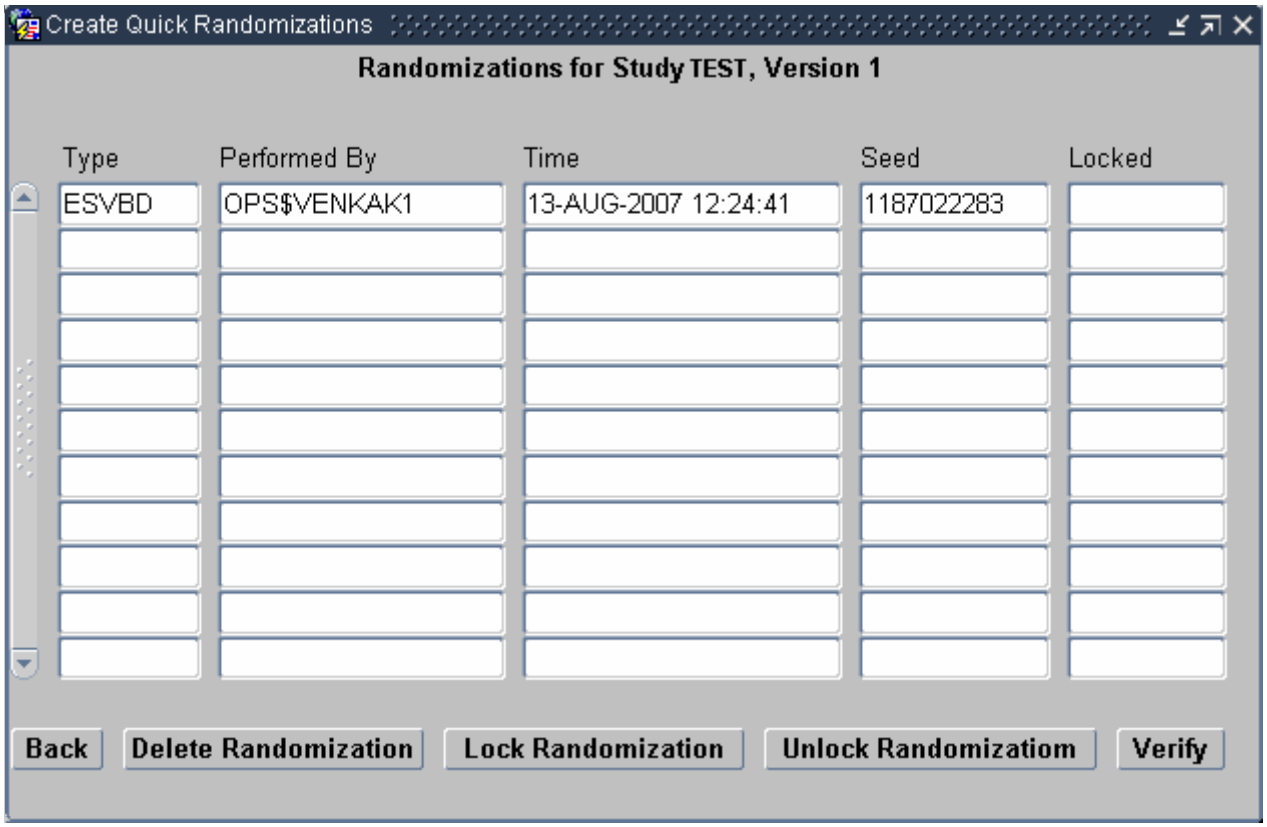
Re-Randomization – Easy Randomization

1. **Click Treatment patterns button and the Randomize button.**



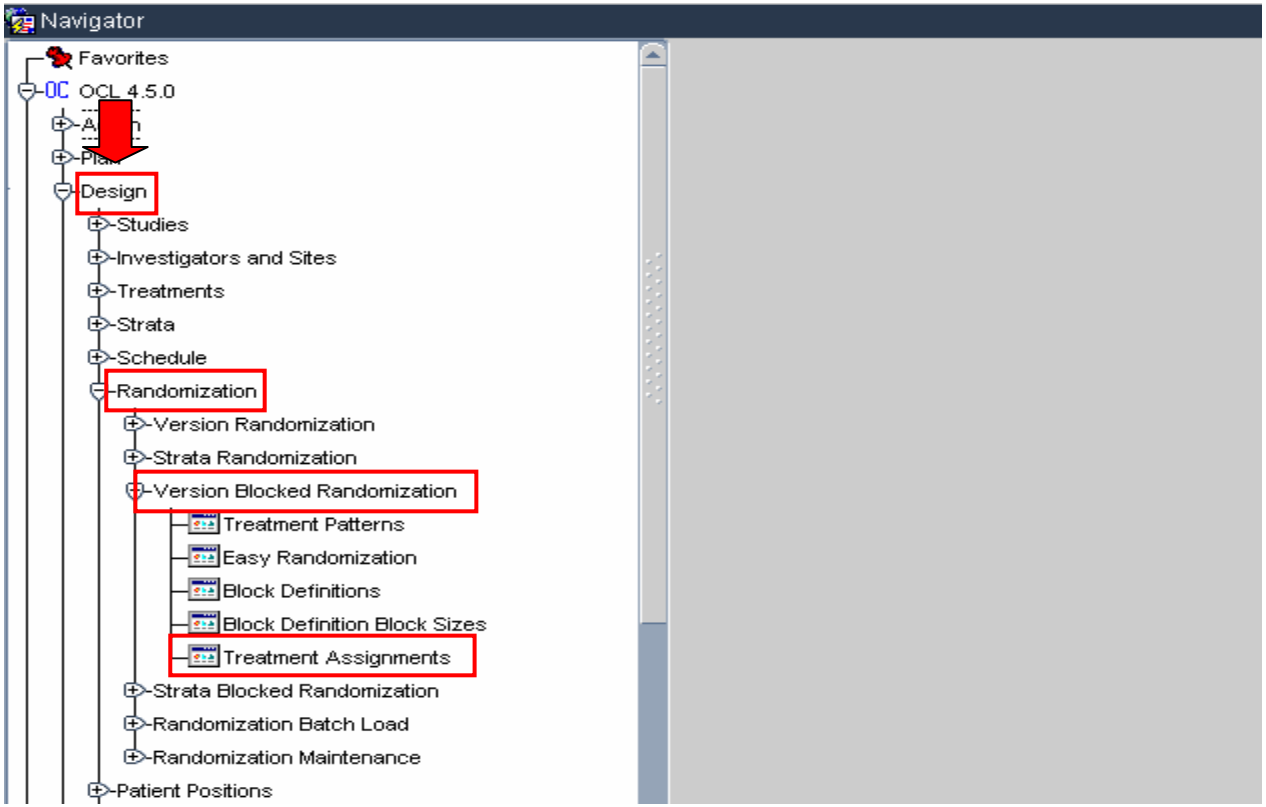
Re-Randomization – Easy Randomization

1. Click Show Randomization button on the bottom.
2. Notice that the Seed number is different.



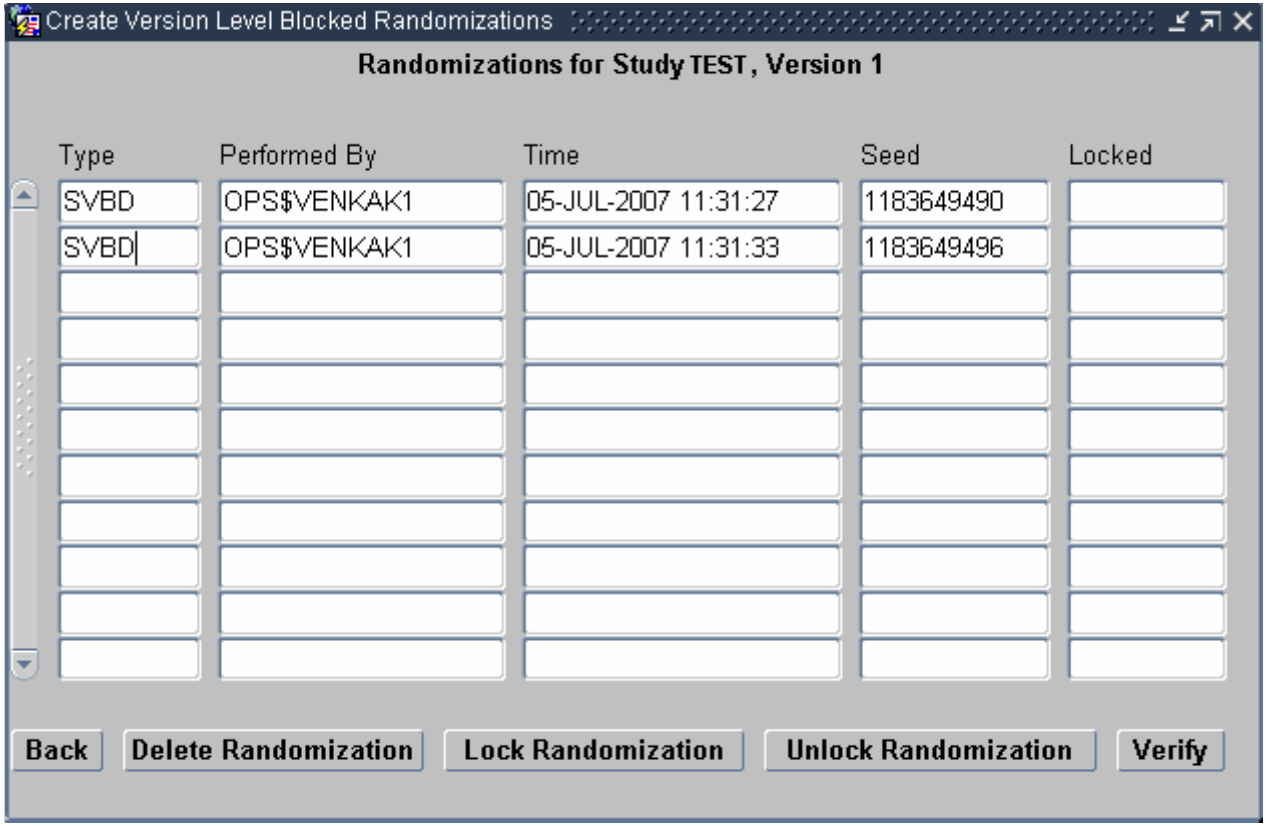
Re-Randomization - Cohort Randomization

In order to view the type of Randomization, Follow the path:



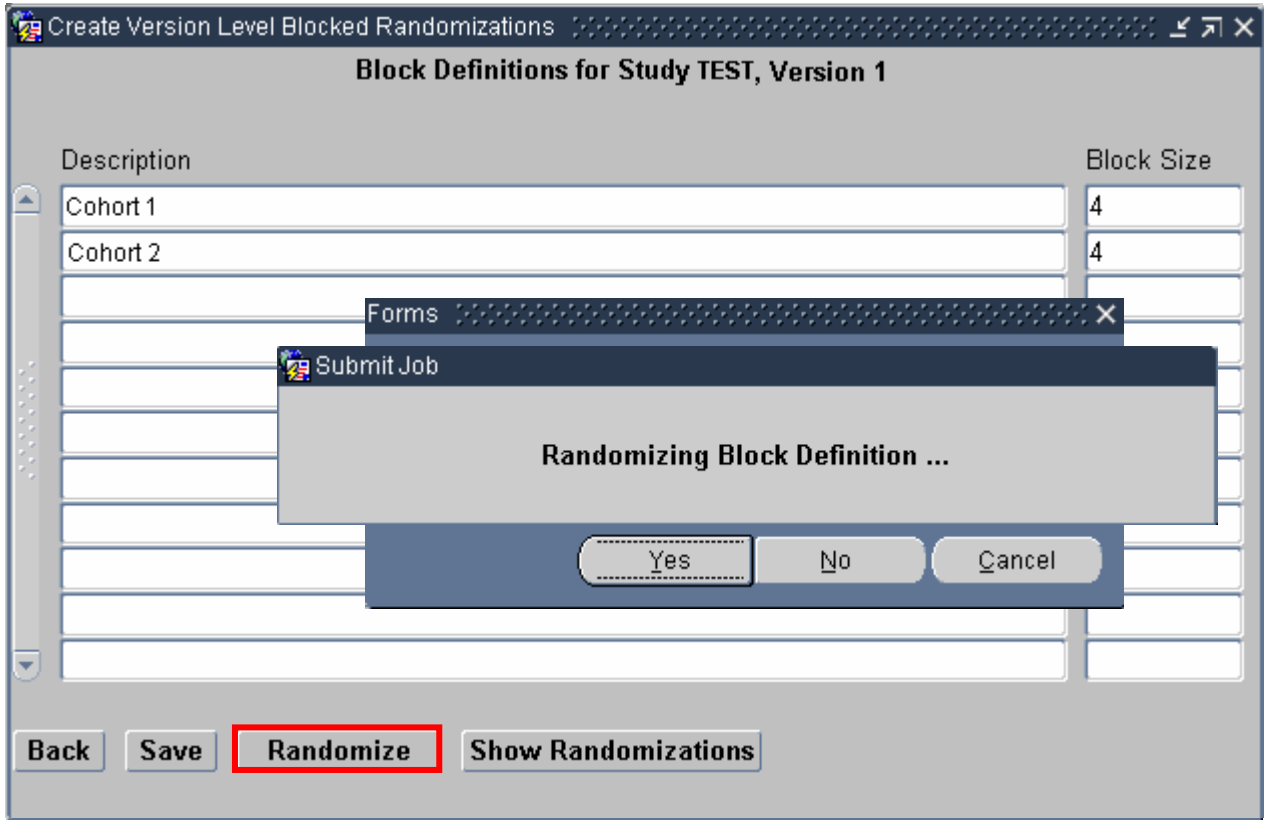
Re-Randomization - Cohort Randomization

1. Choose the appropriate study and click the show randomizations button.
2. Click the Unlock randomization button for all the randomizations one at a time.



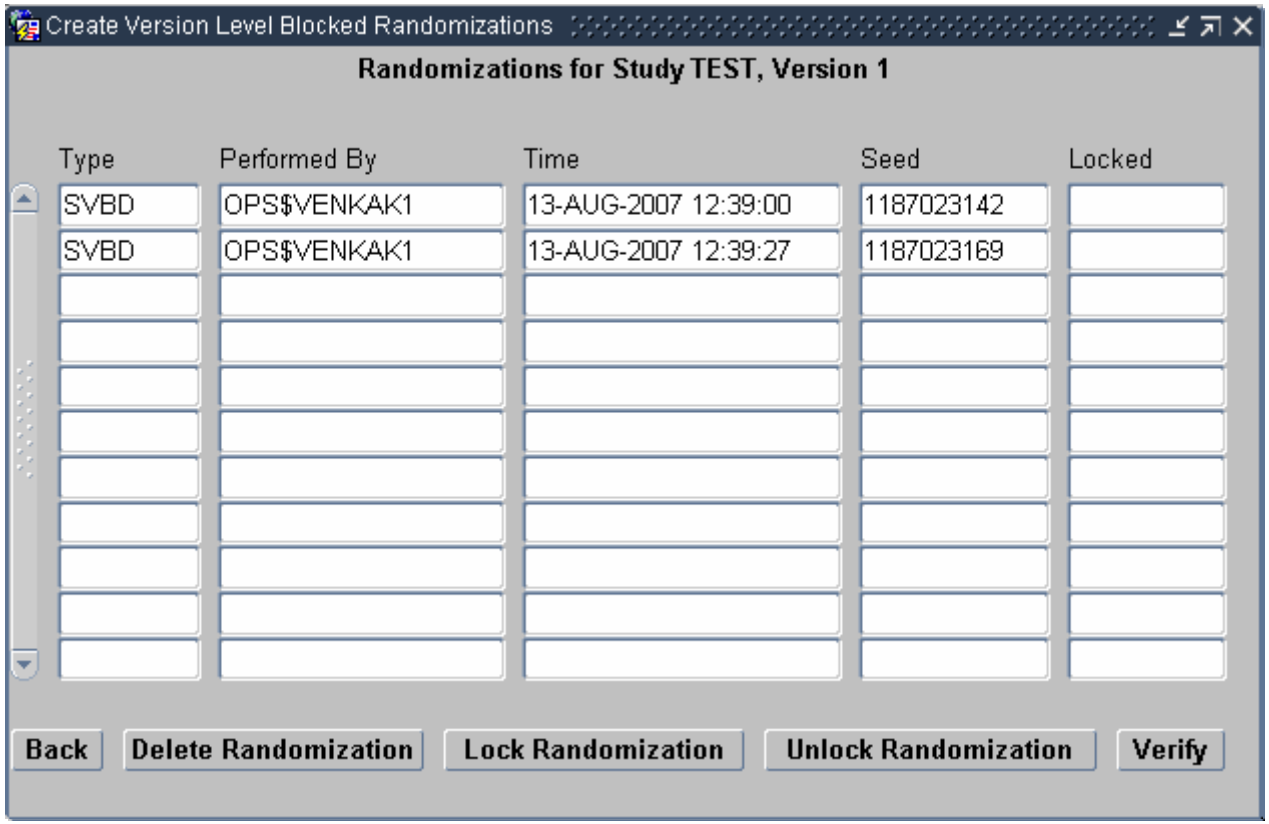
Re-Randomization - Cohort Randomization

1. **Go to the previous screen and click Block Definitions button on the bottom.**
2. **Click Randomize for all the block's present.**



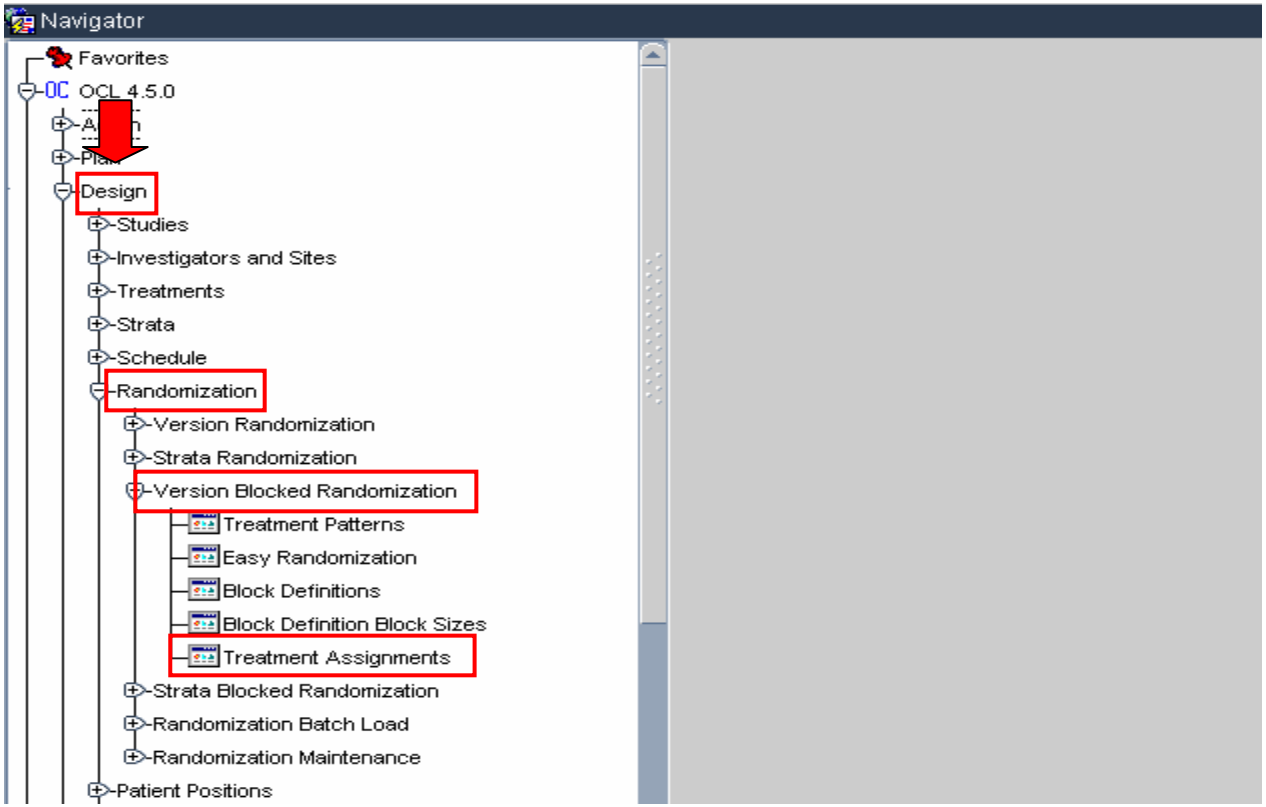
Re-Randomization - Cohort Randomization

1. **Go to the previous screen and click Show Randomization button on the bottom.**
2. **Notice the Seed number that is different.**



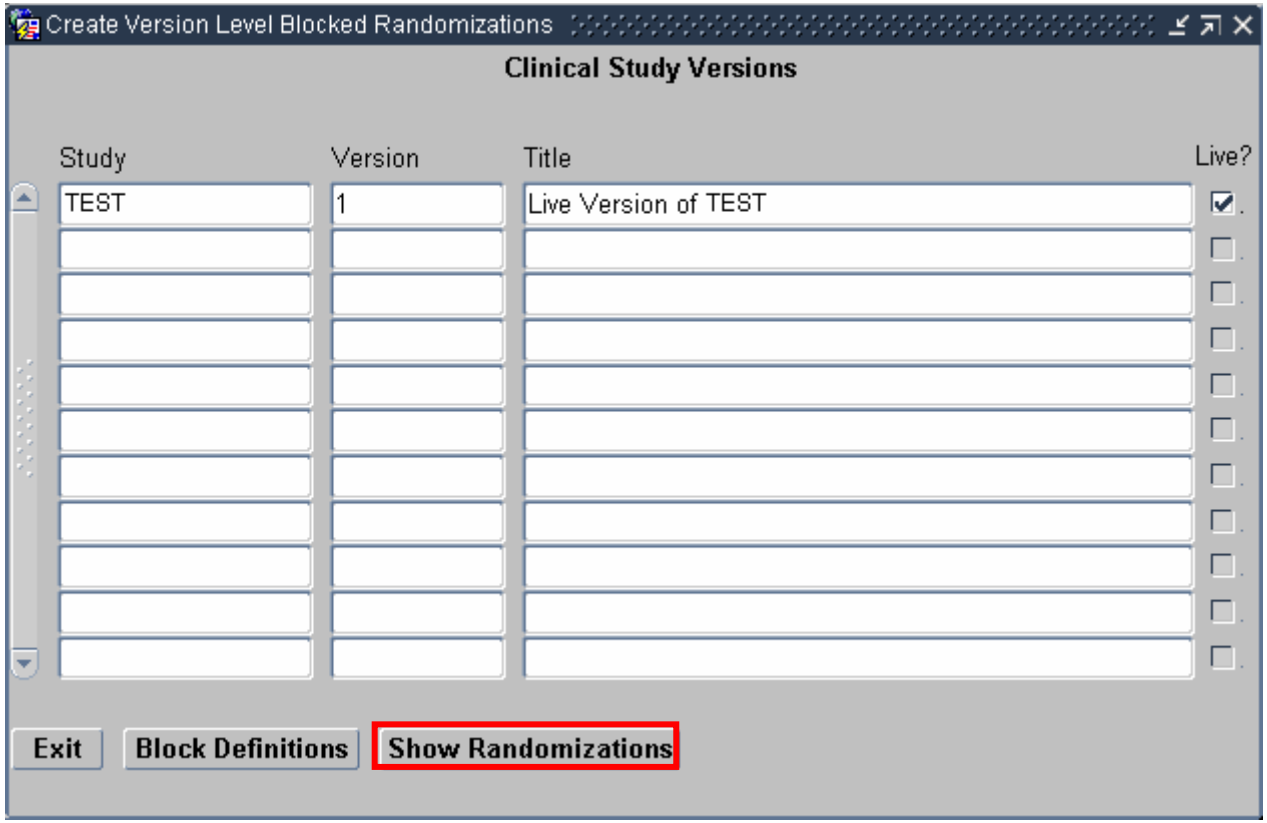
Re-Randomization – Mirror Ranomization.

In order to view the type of Randomization, Follow the path:



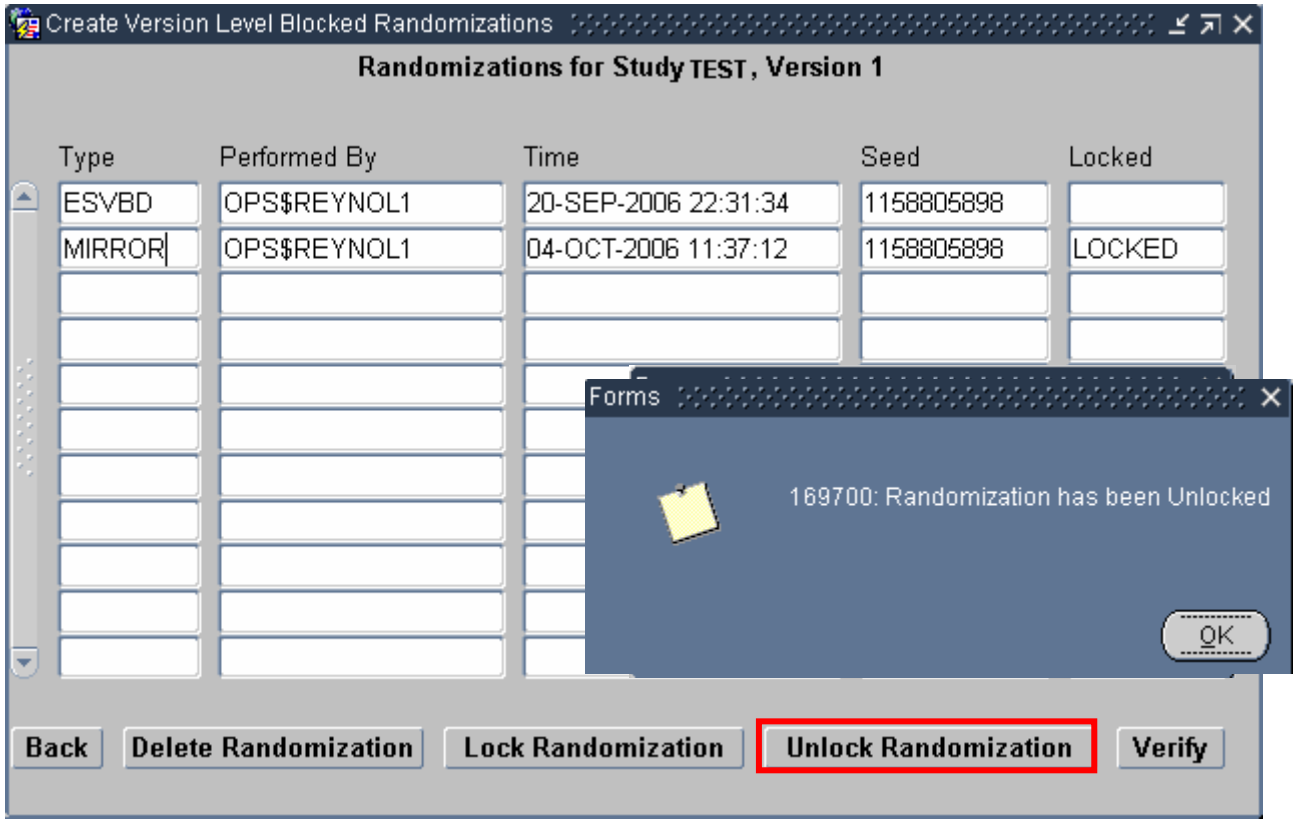
Re-Randomization – Mirror Ranomization.

- Click Show **Randomization** button at the bottom.



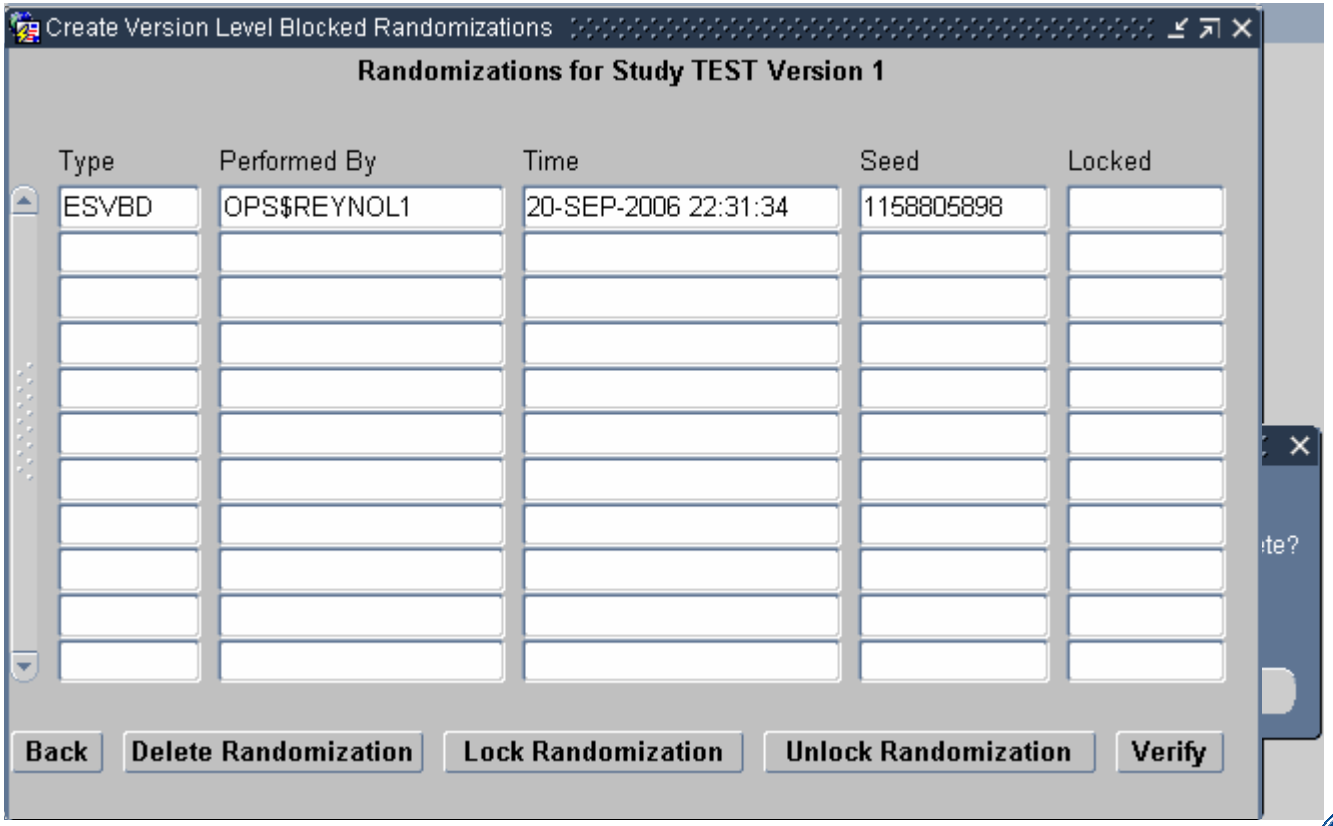
Re-Randomization – Mirror Ranomization.

1. **Unlock the "Mirror" Randomization by clicking Unlock Randomization.**



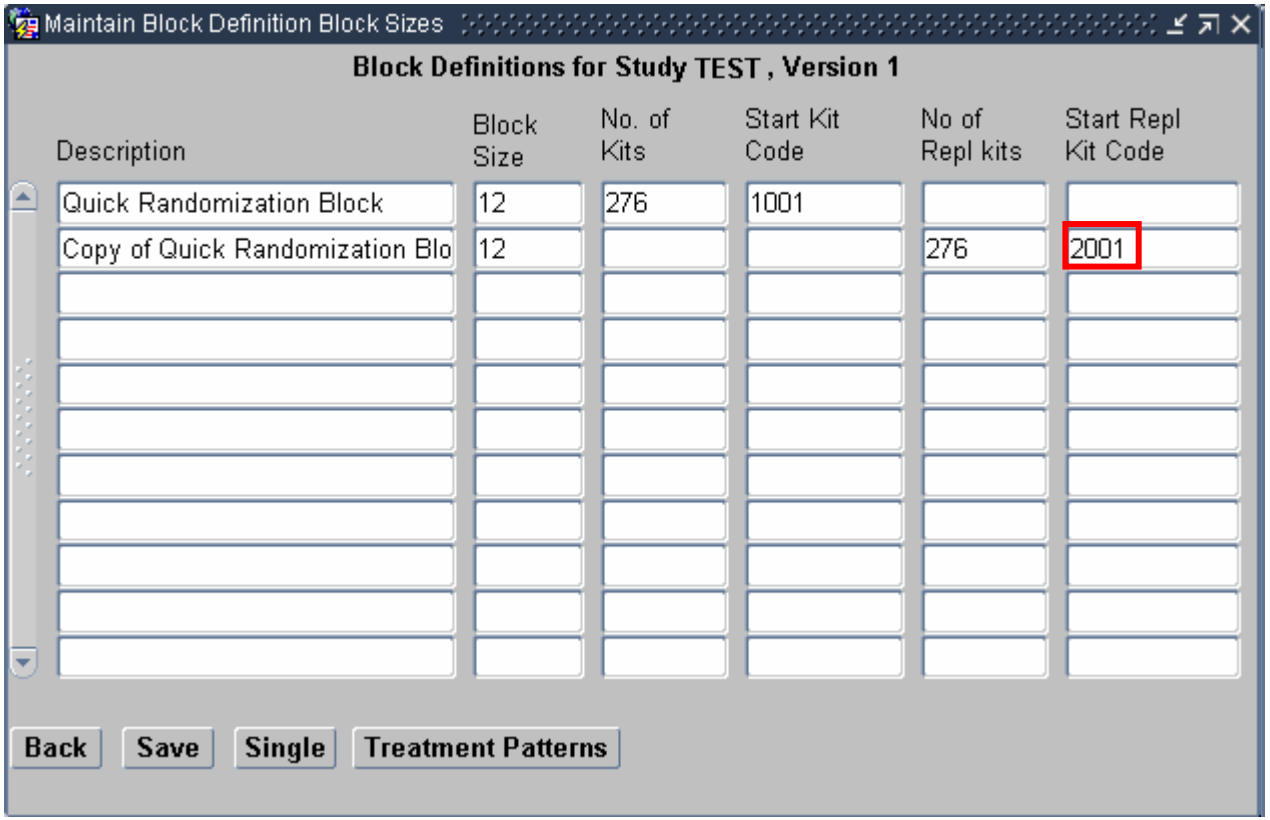
Re-Randomization – Mirror Ranomization.

1. **Delete the "Mirror" Randomization by clicking delete randomization on the bottom.**
2. **Re-randomize using the Easy Randomization.**



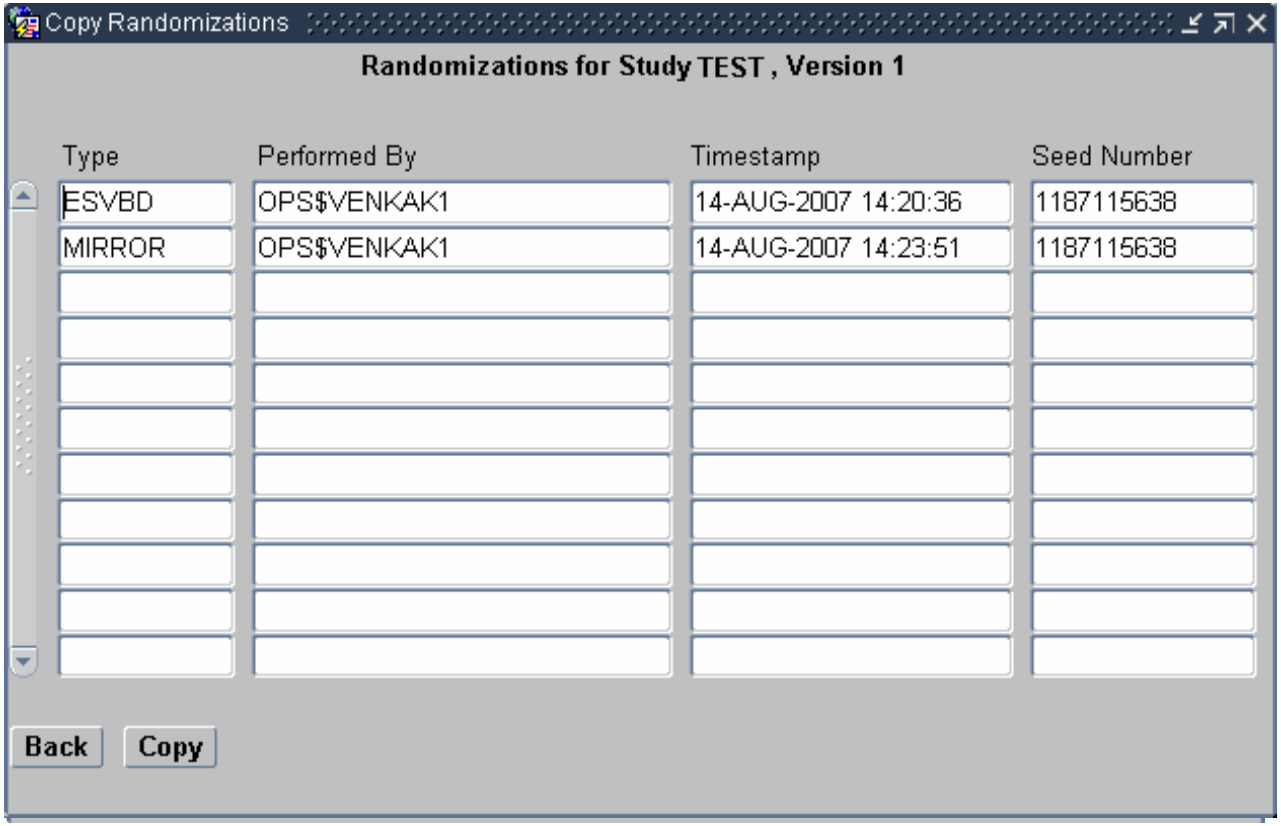
Re-Randomization – Mirror Ranomization.

1. **Note down the Randomization number for the Mirrored Randomization.**
2. **Follow the path and note down the Randomization number.**



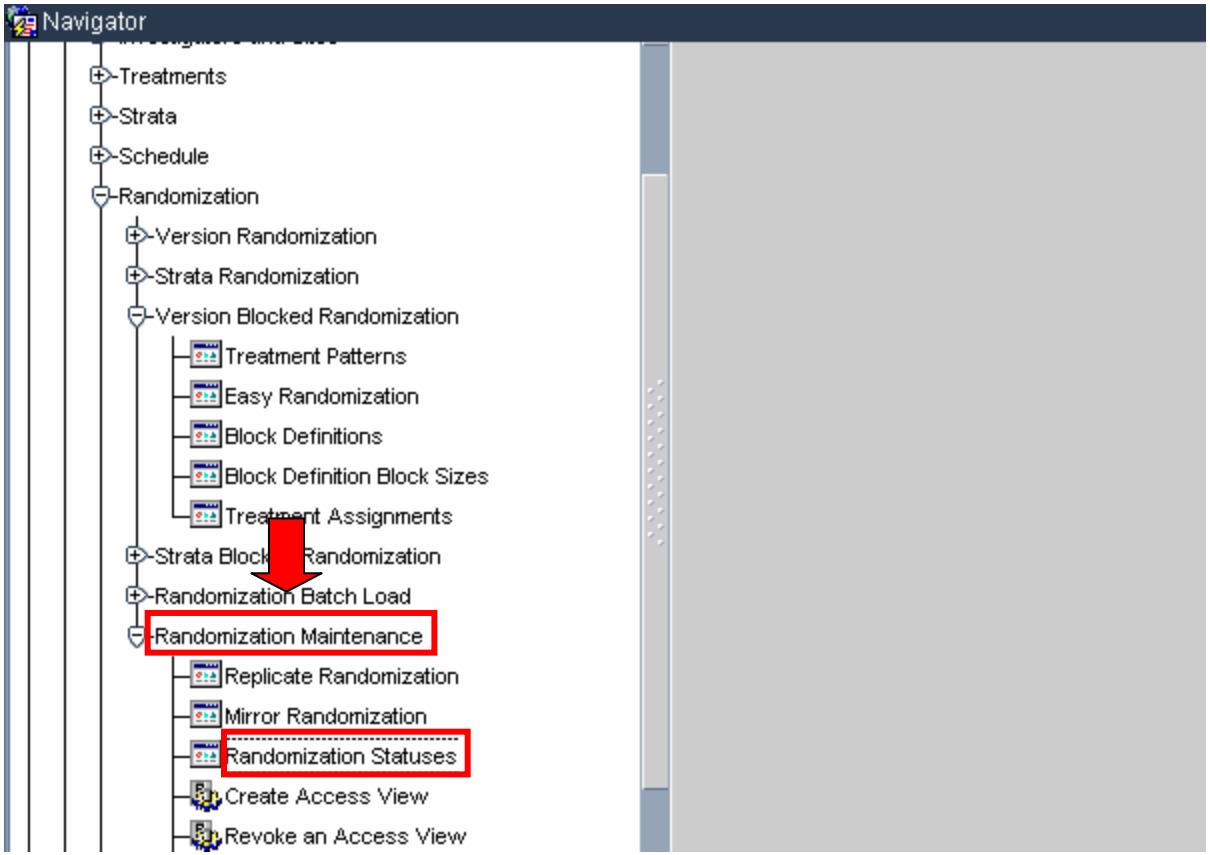
Re-Randomization – Mirror Ranomization.

1. **Follow the path to Mirror Randomization and click Show Randomization.**
2. **Click Copy at the bottom and enter the Randomization number from before.**



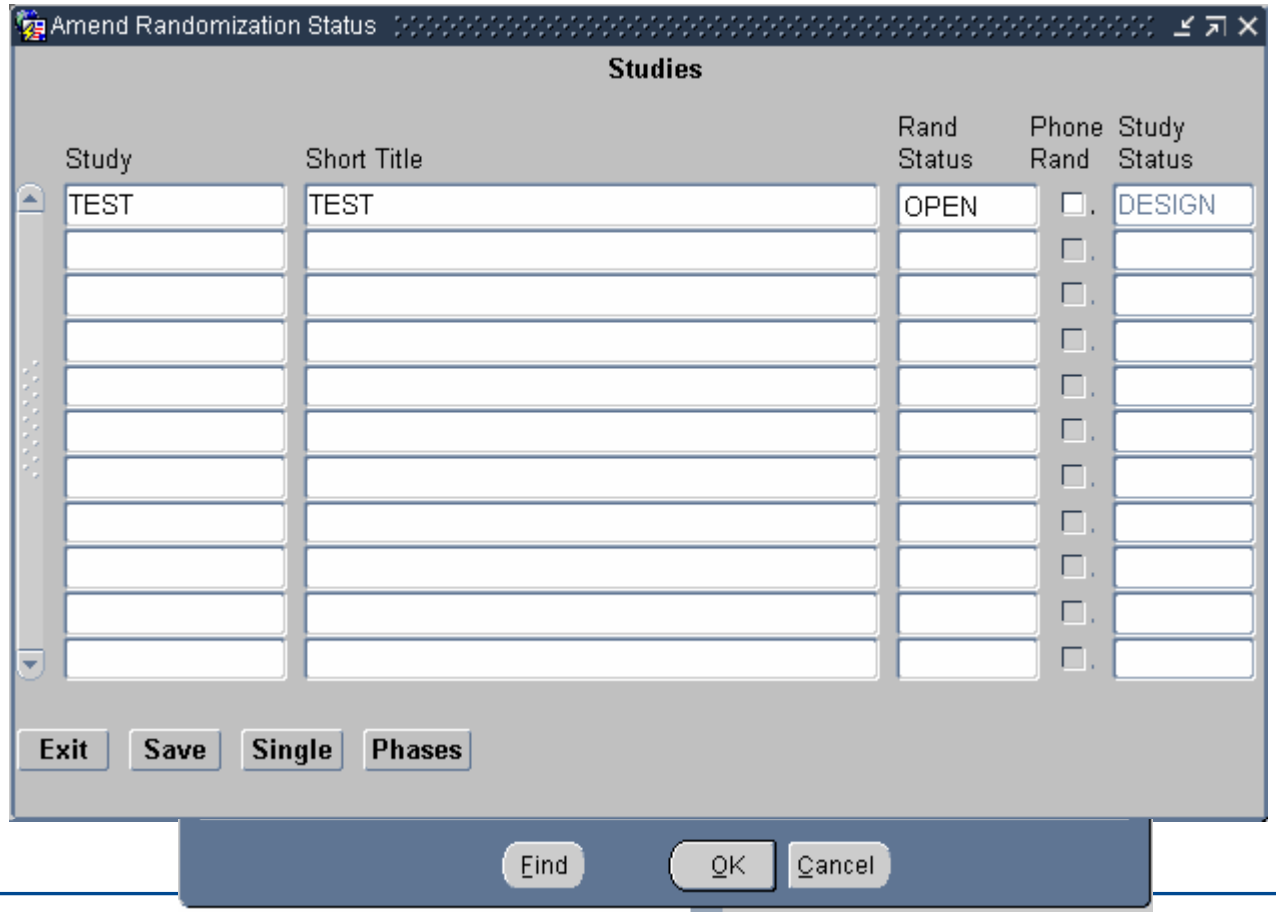
Re-Randomization – Changing Status

Click exit and follow the path.



Re-Randomization – Changing Status

1. **Press “F9” on the Rand status and choose OPEN.**



After Re-Randomization

- **Export the Re-Rand for testing.**
- **Make sure that the Rand is OPENED in order to for testing.**
- **Make sure that you are using a testing instance for re-randomization.**

Summary

- **Advantages of using Development Instance for test Randomization**
  - **You don’t have to touch the production Instance.**
  - **No Unblinding is done on the production data.**
  - **Make sure that everything is setup properly on the production Instance while the production Instance in up and running.**

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Questions?

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