

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

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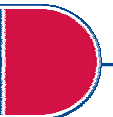
**Oct 10, 2007**



# 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.

# 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**

# Re-Randomization – Pre-check

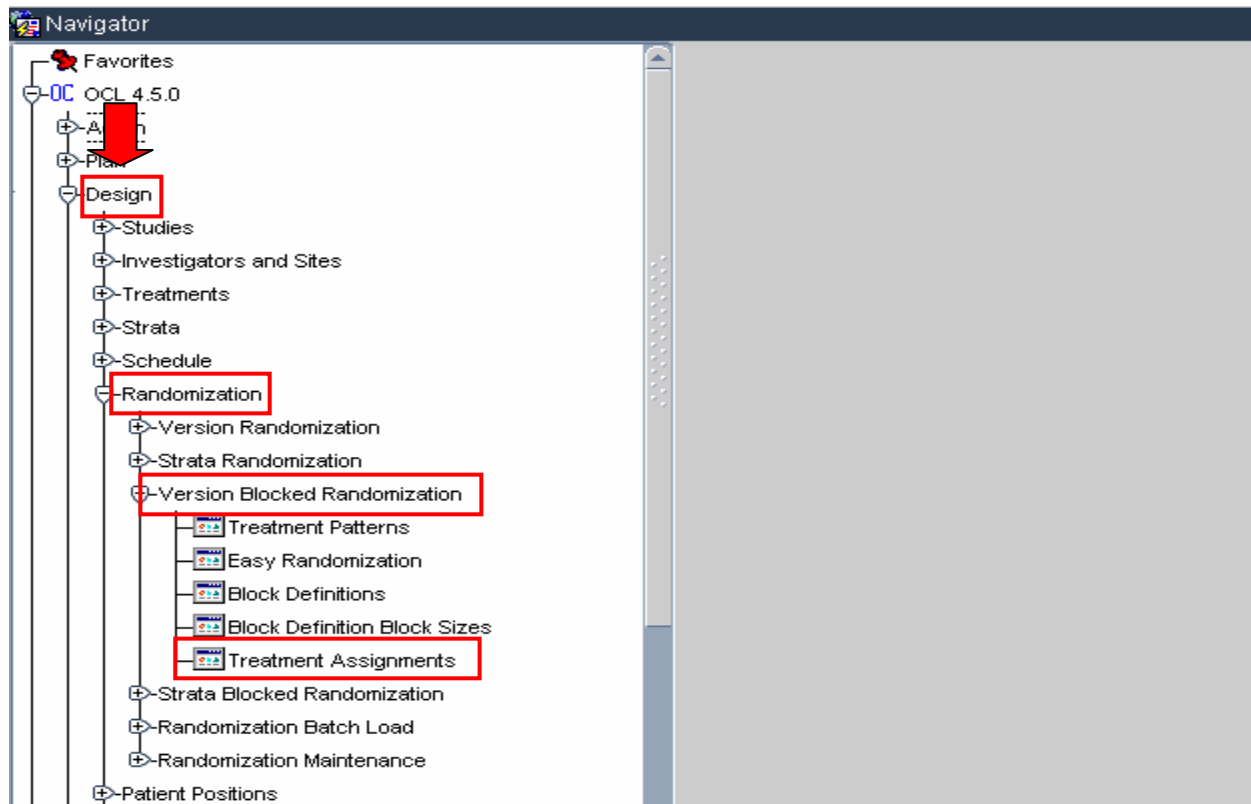
- **In the development instance check**
  - 1. Randomization existence.**
  - 2. Type of Randomization.**
    - Whether it is Easy Randomization, Cohort Randomization or a combination of Easy and Cohort Randomization.
  - 3. Existence of Mirror Randomization.**
    - Exact copy of Randomization. 1 –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

# 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

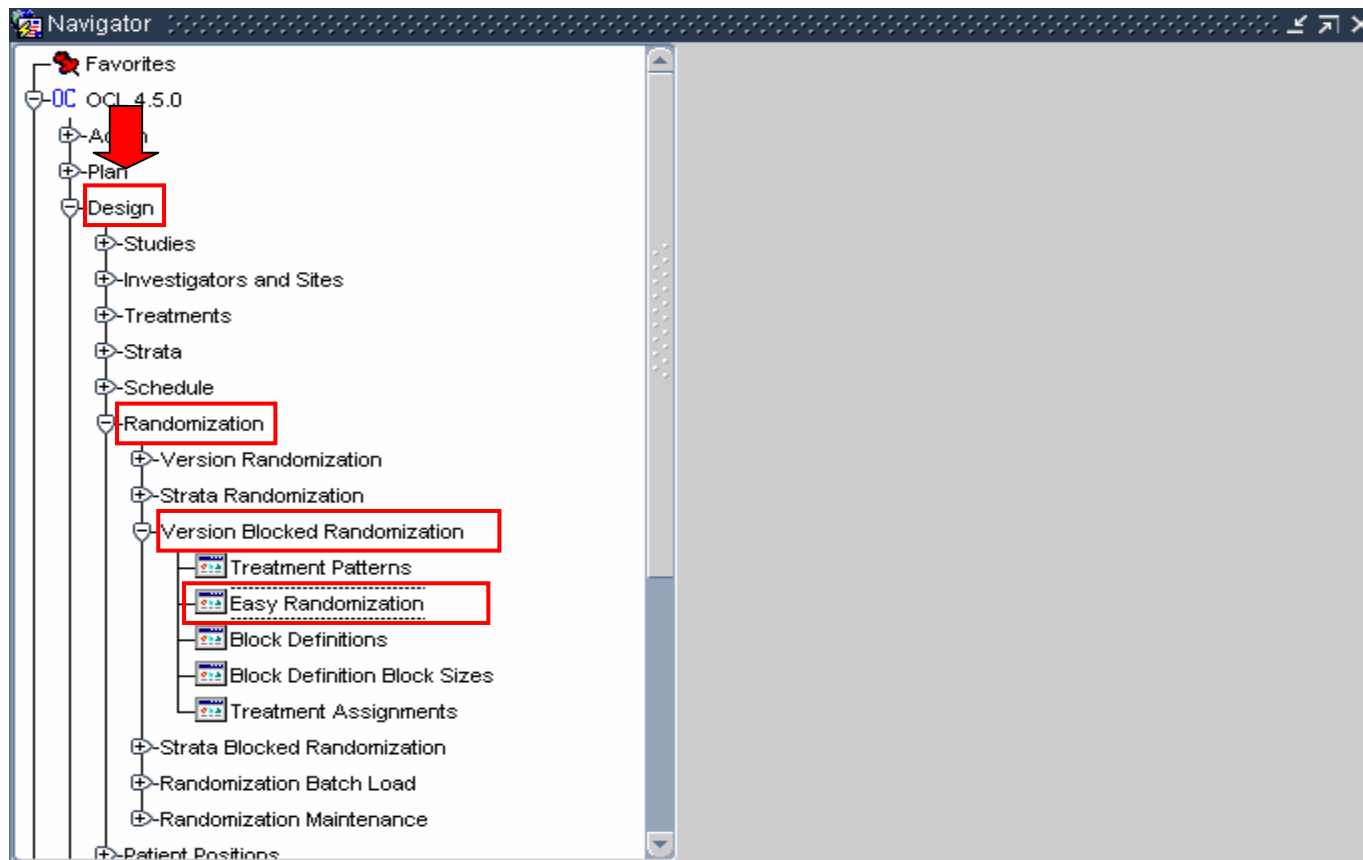
1. Check whether Randomization is Locked. If it is Locked, unlock the Randomization.

Type	Performed By	Time	Seed	Locked
ESVBD	OPS\$REYNOL1	26-JUL-2007 15:25:15	1185477918	<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>

Buttons: Back, Delete Randomization, Lock Randomization, Unlock Randomization, Verify

# Re-Randomization – Easy Randomization

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





# Re-Randomization – Easy Randomization

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

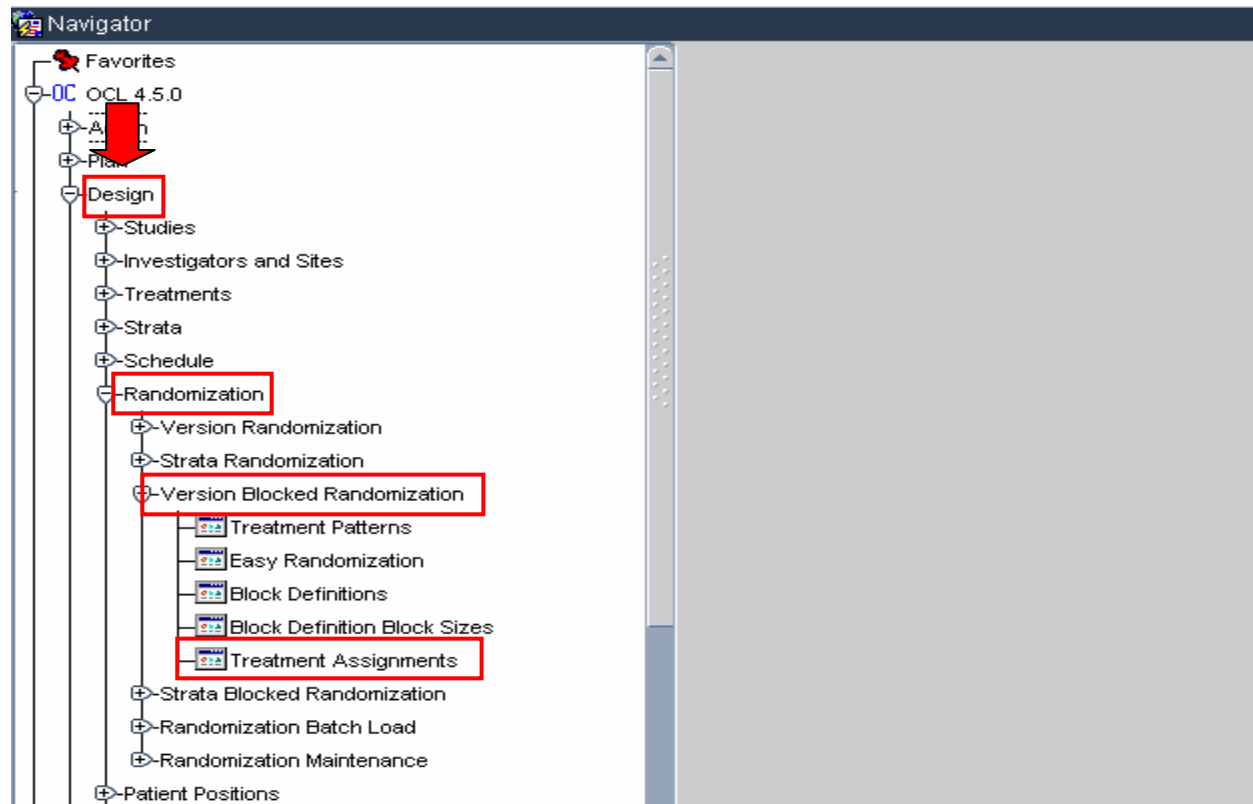
Randomizations for Study TEST, Version 1

Type	Performed By	Time	Seed	Locked
ESVBD	OPS\$VENKAK1	13-AUG-2007 12:24:41	1187022283	

Back Delete Randomization Lock Randomization Unlock Randomization Verify

# 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.

Type	Performed By	Time	Seed	Locked
SVBD	OPS\$VENKAK1	05-JUL-2007 11:31:27	1183649490	<input type="checkbox"/>
SVBD	OPS\$VENKAK1	05-JUL-2007 11:31:33	1183649496	<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>

Buttons: Back, Delete Randomization, Lock Randomization, Unlock Randomization, Verify



# 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.

Create Version Level Blocked Randomizations

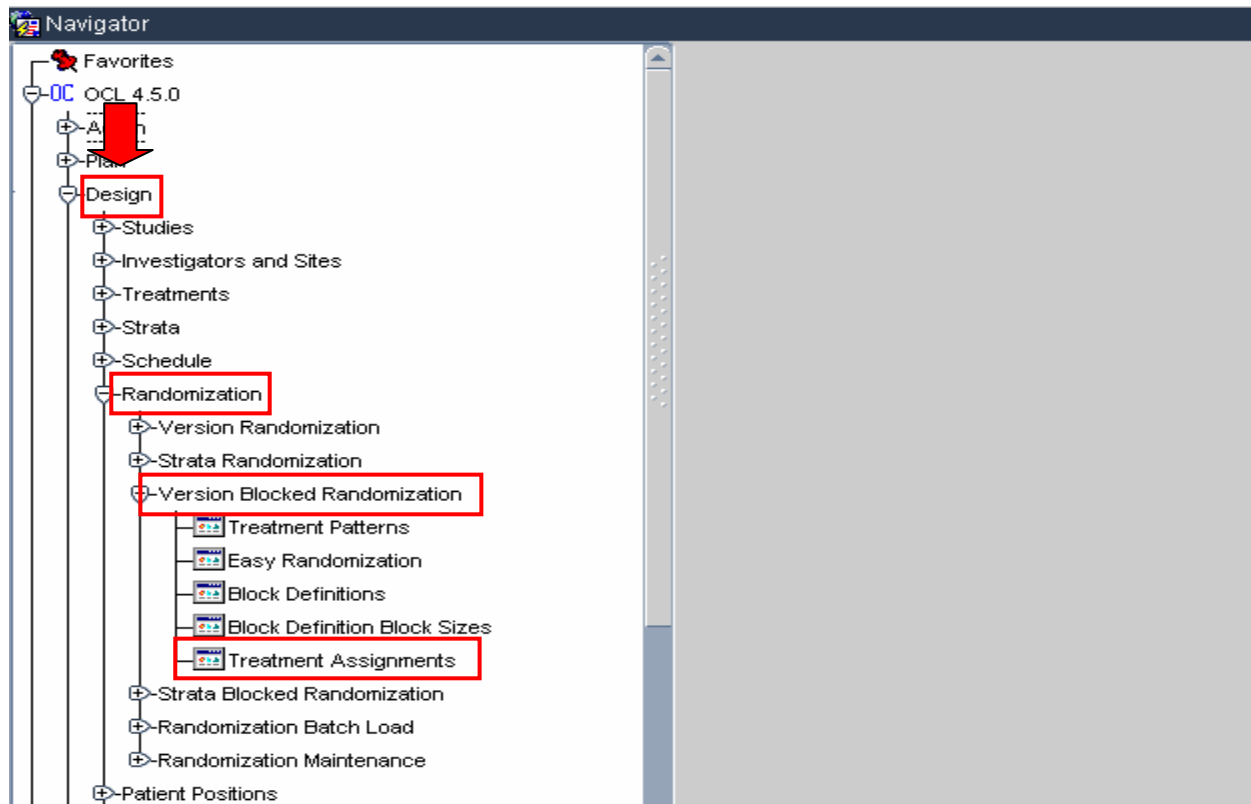
Randomizations for Study TEST, Version 1

Type	Performed By	Time	Seed	Locked
SVBD	OPS\$VENKAK1	13-AUG-2007 12:39:00	1187023142	<input type="checkbox"/>
SVBD	OPS\$VENKAK1	13-AUG-2007 12:39:27	1187023169	<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>

Back Delete Randomization Lock Randomization Unlock Randomization Verify

# 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.

The screenshot shows a software window titled "Create Version Level Blocked Randomizations" with a sub-header "Clinical Study Versions". It contains a table with the following columns: "Study", "Version", "Title", and "Live?". The first row is populated with "TEST", "1", and "Live Version of TEST", and its "Live?" checkbox is checked. Below the table are three buttons: "Exit", "Block Definitions", and "Show Randomizations". The "Show Randomizations" button is highlighted with a red rectangular border.

Study	Version	Title	Live?
TEST	1	Live Version of TEST	<input checked="" type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>

Exit   Block Definitions   **Show Randomizations**

# Re-Randomization – Mirror Ranomization.

1. Unlock the “Mirror” Randomization by clicking **Unlock Randomization**.

The screenshot shows a software window titled "Create Version Level Blocked Randomizations" with a subtitle "Randomizations for Study TEST, Version 1". The window contains a table with the following data:

Type	Performed By	Time	Seed	Locked
ESVBD	OPS\$REYNOL1	20-SEP-2006 22:31:34	1158805898	<input type="checkbox"/>
MIRROR	OPS\$REYNOL1	04-OCT-2006 11:37:12	1158805898	LOCKED
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>

Below the table are several buttons: "Back", "Delete Randomization", "Lock Randomization", "Unlock Randomization" (highlighted with a red box), and "Verify". A "Forms" dialog box is overlaid on the table, displaying a yellow sticky note icon and the text "169700: Randomization has been Unlocked", with an "OK" button at the bottom right.

# Re-Randomization – Mirror Ranomization.

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

Create Version Level Blocked Randomizations

Randomizations for Study TEST Version 1

Type	Performed By	Time	Seed	Locked
ESVBD	OPS\$REYNOL1	20-SEP-2006 22:31:34	1158805898	

Back Delete Randomization Lock Randomization Unlock Randomization Verify

# Re-Randomization – Mirror Ranomization.

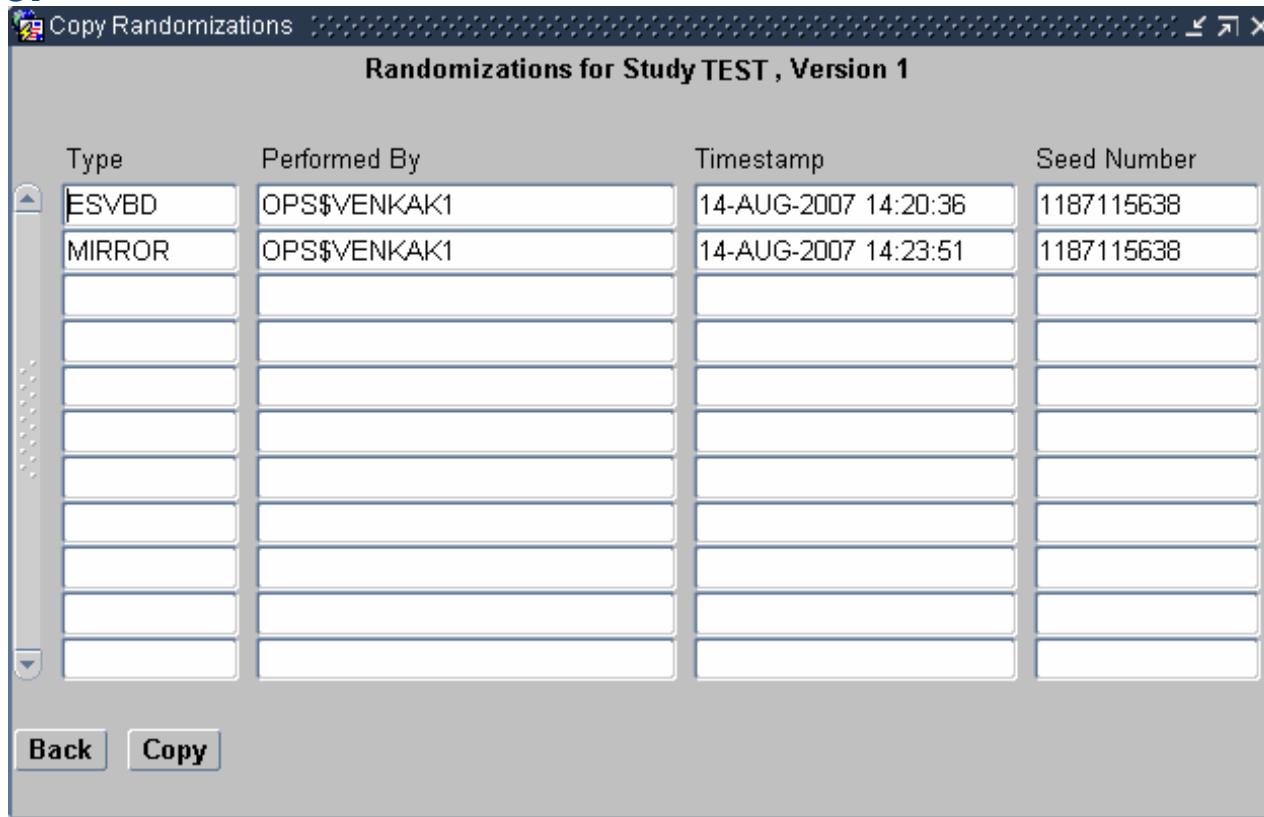
1. Note down the Randomization number for the Mirrored Randomization.
2. Follow the path and note down the Randomization number.

Description	Block Size	No. of Kits	Start Kit Code	No of Repl kits	Start Repl Kit Code
Quick Randomization Block	12	276	1001		
Copy of Quick Randomization Blo	12			276	2001

Back Save Single Treatment Patterns

# 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.

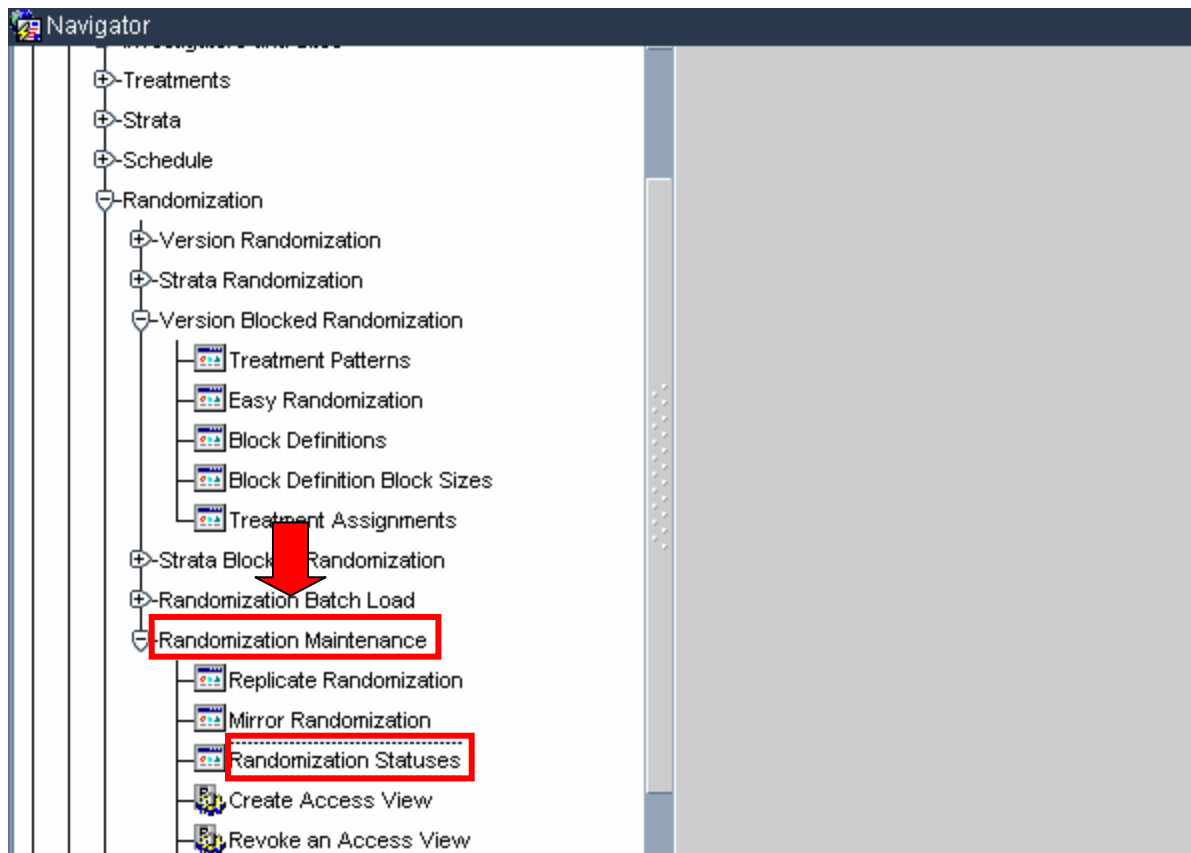


The screenshot shows a software window titled "Copy Randomizations" with a subtitle "Randomizations for Study TEST , Version 1". The window contains a table with four columns: "Type", "Performed By", "Timestamp", and "Seed Number". The first two rows of the table are populated with data, while the remaining rows are empty. At the bottom of the window, there are two buttons: "Back" and "Copy".

Type	Performed By	Timestamp	Seed Number
ESVBD	OPS\$VENKAK1	14-AUG-2007 14:20:36	1187115638
MIRROR	OPS\$VENKAK1	14-AUG-2007 14:23:51	1187115638

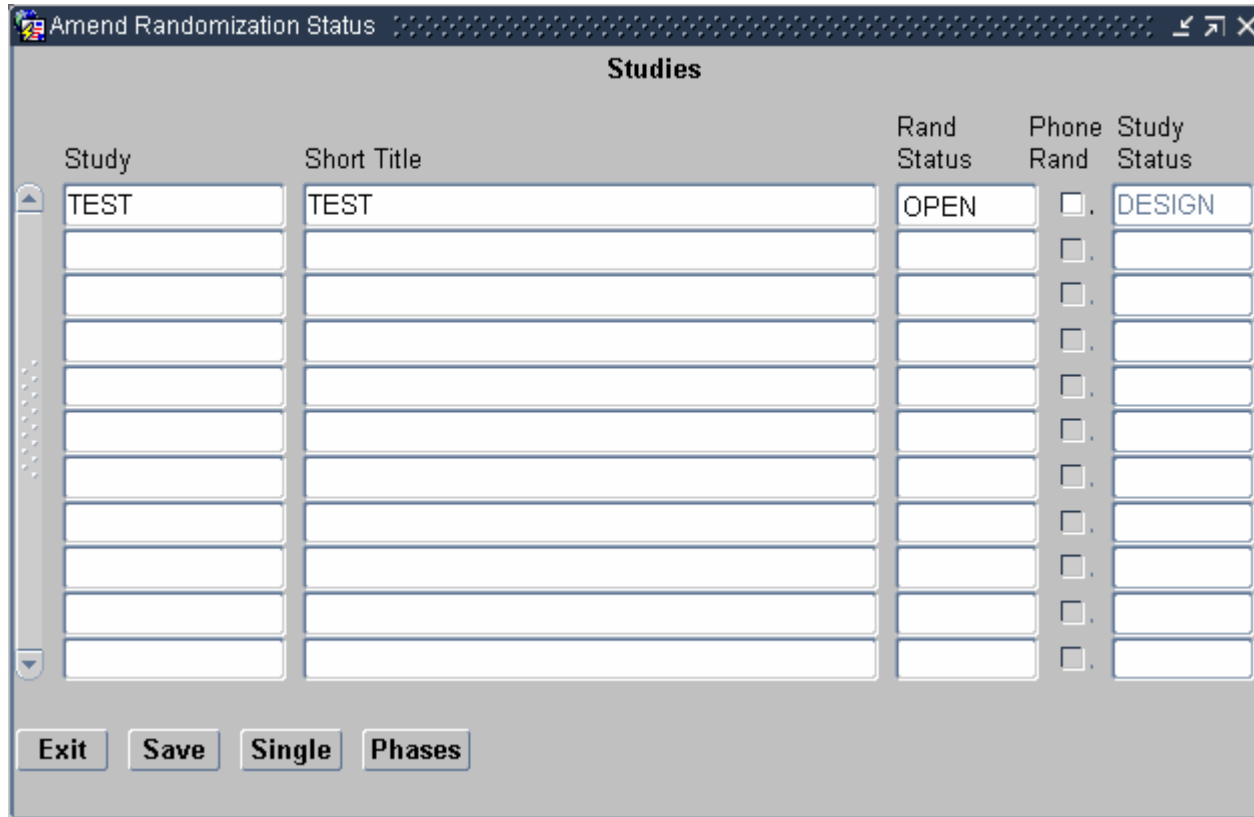
# Re-Randomization – Changing Status

Click exit and follow the path.



# Re-Randomization – Changing Status

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



The screenshot shows a software window titled "Amend Randomization Status" with a sub-header "Studies". The window contains a table with the following columns: "Study", "Short Title", "Rand Status", "Phone Rand", and "Study Status". The first row is populated with "TEST", "TEST", "OPEN", an unchecked checkbox, and "DESIGN". Below the table are buttons for "Exit", "Save", "Single", and "Phases".

Study	Short Title	Rand Status	Phone Rand	Study Status
TEST	TEST	OPEN	<input type="checkbox"/>	DESIGN
			<input type="checkbox"/>	
			<input type="checkbox"/>	
			<input type="checkbox"/>	
			<input type="checkbox"/>	
			<input type="checkbox"/>	
			<input type="checkbox"/>	
			<input type="checkbox"/>	
			<input type="checkbox"/>	
			<input type="checkbox"/>	
			<input type="checkbox"/>	
			<input type="checkbox"/>	

Find

OK

Cancel

PREMIER  
RESEARCH

# 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 is up and running.

Questions?

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