**STUDY *XXXX***

**Randomization Test Plan**

**Version x.x**

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| --- | --- | --- | --- |
| Name | Title | Reason for signing | Signature |
|  | Senior Statistician | Study Statistician |  |
|  | Lead Statistician | Tester |  |
|  | CDM | Study Designer |  |

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**Document history**

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| Version | Date approved | Reason for modification |
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# Purpose

*Define the features to be tested and the features not to be tested.*

The document describes the testing and validation of the Medidata Randomization Process implementation for *XXXX*.

The following features will be tested:

- Randomization Method specified according to protocol

- Treatment Arms specified according to protocol.

- Stratification Factors specified according to protocol.

*- Random component specified in accordance with the protocol.*

*- Block size and length specified in accordance with the protocol.*

The following features will not be tested:

- Capping

- Site list

- Blinding restrictions

- Email alerts

# Testers

*The specific staff involved is listed in the test plan with name, test role (e.g. user test writing, user test execution, functional test execution,...) and function.*

|  |  |  |
| --- | --- | --- |
| Name | Test role | Function |
|  | Tester | Lead Statistician |
|  | Study Statistician | Senior Statistician |
|  | Medidata Randomization Process expert | Lead Statistician |
|  | Study Designer | CDM |

# Methodology

*Indicate the type of testing that will be applied; document the environment and the specific test approach (mandatory for functional testing).*

|  |  |  |
| --- | --- | --- |
| Type of testing | Environment | Specific test approach |
| Functional testing | *NA* | *Verify that the features to be tested listed in section 1 as completed in Medidata Randomization Process are in accordance with the protocol.* |
| UAT | *UAT* | *Export the Medidata Randomization Process log of randomized subjects and verify export in accordance with the test data in the database.* |
| Performance testing | *UAT* | *Verify that the results in the log are in accordance with the hypothesized algorithm.* |

## Functional testing

*Describe the test to be performed.*

The tester downloads the “configuration report” from the “Randomization Design” page.

The tester consults the randomization description according to the latest (major) version of the protocol.

The tester verifies that the Medidata Randomization Process parameters match the protocol randomization description. If a Medidata Randomization Process parameter is not specified in the protocol, it cannot violate the EORTC SOP on trial design and randomization.

If a parameter is unclear is ambiguously defined in the protocol or Medidata Randomization Process implementation, the tester should first clarify the intended value with the study statistician.

## User acceptance testing

*Describe the test to be performed.*

The User Acceptance Test can be done when at least one patient is entered within each distinct stratum (excluding site/country) of the study. The strata for the XXXX study are:

Complete the table using the Medidata Randomization Process configuration report

|  |  |
| --- | --- |
| **Nbr** | **Strata** |
| 1 | *F1,F2,F3* |
| 2 | *F1,F2,F4* |
| … | *…* |

The tester exports the Medidata Randomization Process log of the randomized subjects. This is done via the Subjects Tab, choosing “Donwload Subject List” from the Subject Downloads drop-down menu. The file becomes available as an Excel file for download.

For each stratum, the Tester verifies for a patient within that stratum if the stratum assigned at time of randomization matches the data as entered in the database.

The verification can be done by either:

* comparing manually via RAVE
* exporting the trial database via SAS On Demand. Reading both the Medidata Randomization Process log and the SAS export files into one software package where an automated comparison can be made (eg. SAS, Excel).

## Performance testing

The Performance Test can be done when the User Acceptance Test has been successfully completed. After the User Acceptance Test has been successfully completed, the Tester requests the Study Designer to modify the data of an already randomized patient so that the patient is in a different stratum. After this data modification has been done, a new patient has to be subsequently randomized.

The tester needs to verify that “Stratum at time of Randomization” and “Current Stratum” remain the original stratum for the modified patient.

# Issue reporting plan

After each of the three test steps, the Tester analyzes the results and considers if the Medidata Randomization Process implementation needs modification. The Tester informs the Study Statistician of these findings. The Study Statistician is responsible for implementing the necessary modifications.

# **Test cases**

## User acceptance testing

For the user acceptance testing, a number of patients need to be randomized so that within each distinct stratum (excluding site/country) at least one patient is present. The strata for the *XXXX* study are:

|  |  |
| --- | --- |
| **Nbr** | **Strata** |
| 1 | *F1,F2,F3* |
| 2 | *F1,F2,F4* |
| … | *…* |

The Study Designer informs the Tester and the Study Statistician when the required number of patients have been entered and successfully randomized.

*Insert other UAT scenarios if needed.*

## Performance testing

For the performance testing, the data of a randomized patient needs to be modified so that the resulting stratum of the patient is changed.

Action steps (in order):

* Select a randomized patient (at random)
* Verify the stratum of the patient
* Modify the *stratification factor states* data points.
* Verify that the stratum of the patient after this modification is different from the stratum the patient belonged to at time of randomization.
* A new patient needs to be entered and successfully randomized.

The Study Designer informs the Tester and the Study Statistician when these action points have been successfully performed.

*Insert other Performance Test scenarios if needed.*

# Test report documentation

At the end of the testing, when the Tester considers the Medidata Randomization Process implementation needs no modifications, the test report is finalized and signed by the Study Statistician.

This test report contains:

* the CRF version used for the tests
* the environment used
* the date of execution
* the test results and Medidata Randomization Process modifications (if any).
* the final configuration report

The signed test report is stored in the study TMF.