**STUDY *XXXX***

**Randomization Test report**

**Version x.x**

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Title | Reason for signing | Signature |
|  | Senior Statistician | Study Statistician |  |

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**Document history**

|  |  |  |
| --- | --- | --- |
| Version | Date approved | Reason for modification |
|  |  |  |

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# Purpose

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

This document describes the test result of the Medidata randomization process implementation test for *XXXX*.

# 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 |

# Test results

## Functional testing

*Describe the test result.*

|  |  |  |  |
| --- | --- | --- | --- |
| Randomization Parameter | Protocol | Medidata Randomization Process | Result |
| study design:  Basic, Cohort, Treatment Period | *NA* | *Basic* | *OK* |
| Method: “Dynamic Allocation” or “Permuted Blocks” |  |  |  |
| treatment arm: name, ratio and description |  |  |  |
| stratification factors: name, values, description and weight |  |  |  |
| Complete Randomization Probability |  |  |  |
| Block length and size |  |  |  |
| … |  |  |  |

Resulting modifications:

*List any relevant modifications if any.*

Notes:

*Describe any relevant results or comments.*

## User acceptance testing

*Describe the test result.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Strata** | **Patient ID** | **Patient data** | Medidata Randomization Process **log** |
| *F1,F2,F3* |  |  |  |
| *F1,F2,F4* |  |  |  |
| *…* |  |  |  |

Resulting modifications:

*List any relevant modifications if any.*

Notes:

*Describe any relevant results or comments.*

## Performance testing

*Describe the test result.*

Modified patient

|  |  |  |
| --- | --- | --- |
| **Patient ID** | **Strata at time of randomization** | **Modified strata** |
|  | *F1,F2,F3* | *F1,F2,F3* |

Result after new randomization:

|  |  |  |  |
| --- | --- | --- | --- |
| **Patient ID** | **Strata at time of randomization** | **Modified strata** | **Strata in** Medidata Randomization Process **log** |
|  | *F1,F2,F3* | *F1,F2,F3* | *F1,F2,F3* |

Resulting modifications:

*List any relevant modifications if any.*

Notes:

*Describe any relevant results or comments.*

# Conclusion

|  |  |  |  |
| --- | --- | --- | --- |
|  | Functional Testing | UAT | Performance Testing |
| CRF version used for the tests |  |  |  |
| The environment(s) used |  |  |  |
| The date of finalization |  |  |  |
| Test results and Medidata Randomization Process modifications (if any). |  |  |  |