**STUDY *XXXX***

**Randomization User requirements**

**Version x.x**

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

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**Document history**

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

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# Purpose

The document describes the user requirements for the randomization implementation for *XXXX*.

# Randomization Parameters

## Design

|  |  |
| --- | --- |
| **Study design:** | *Basic, Cohort, Treatment Period* |
| **Method:** | *Dynamic Allocation or Permuted Blocks* |

Notes:

*Describe any relevant comments.*

## Treatment arms

|  |  |  |
| --- | --- | --- |
| **Name** | **Ratio** | **Description** |
| *Standard arm* | *1* | *Standard chemotherapy for 6 weeks (during radiotherapy) then (after 4-week break) up to 6 cycles or PD.* |
|  |  |  |

Notes:

*Describe any relevant comments.*

## Stratification Factors

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Weight** | **State** | **Description** |
| *Site* | *1* | *(NA)* | *(NA)* |
| *Stratum* | *1* | *(NA)* | *(NA)* |
| *Study* | *1* | *(NA)* | *(NA)* |
| *STRT\_AGE* | *1* | *<=55 years, >55years* | *Age* |
|  |  |  |  |

Notes:

*Describe any relevant comments.*

## Probability of Complete Randomization

|  |  |
| --- | --- |
| **Probability of Complete Randomization** | *0 %* |

Notes:

*Describe any relevant comments.*

## Block Size/Lengths

|  |  |
| --- | --- |
| **Randomization List Name:** | *[name]* |
| **Randomization ID** | *Sequential or Random* |
| **Acceptable Block Sizes** | *Size 2 = 100 Blocks*  *Size 4 = 100 Blocks*  *Size 6 = 100 Blocks* |

Notes:

*Describe any relevant comments.*

# Other parameters

*In case of deviation of the default values, list any relevant parameter setting for:*

*- Capping*

*- Site list*

*- Blinding restrictions*

*- Email alerts*

*Otherwise state “All other parameters kept to default setting”.*