**ORTA REGISTRATION/RANDOMIZATION PROGRAM: APPROVAL FORM**

|  |  |
| --- | --- |
| EORTC study number |  |
| Program Version number  ORTA Designer |  |

**To be completed for the first version of the ORTA program only:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Total number of steps in study:  | | | | |
| Is the study randomized:  YES  NO  If yes, (repeat for each randomization step)   * Institution is a stratification factor YES  NO * Stratification factors:  |  |  | | --- | --- | | Factor | Levels | |  |  | |  |  |  * Study arms and ratio:  |  |  | | --- | --- | | Arm | Ratio | |  |  | |  |  |   Is the study blinded:  YES  NO  If yes, Blinded step: Unblind step: | | | | **To be completed by the ORTA Designer** |
| Minimization:   * Threshold value:   : equal to the number of stratification factors.  : specify threshold value =   * Random element: YES  NO   if yes, specify random element (<0.5) =  Blocks  Block length is set to       (specify with relative frequencies) | | | | **To be completed by the ORTA Statistician** |
|  | Name | Date of approval | Signature | |
| ORTA Lead DM |  |  |  | |
| ORTA Statistician  *(if randomized step)* |  |  |  | |

**To be completed for each new minor version of the ORTA program:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Program version number  ORTA Designer  Study step(s) to approve (\*) | | **All** | | |
| Summary of changes  (indicate reason for change and the implemented modifications) | |  | | |
|  | Name | | Date of approval | Signature |
| ORTA Lead DM |  | |  |  |

(\*) indicate the number of each study step affected by the change. If all study steps are affected, list “All”.

**To be completed for each new major version of the ORTA program:**

|  |  |  |
| --- | --- | --- |
| Program version number  ORTA Designer  Study step(s) to approve (\*) | **All** | |
| Summary of changes  (indicate reason for change and the implemented modifications) |  | |
| Is the study randomized:  YES  NO  If yes, (repeat for each randomization step)   * Institution is a stratification factor YES  NO * Stratification factors:  |  |  | | --- | --- | | Factor | Levels | |  |  | |  |  |  * Study arms and ratio:  |  |  | | --- | --- | | Arm | Ratio | |  |  | |  |  |   Is the study blinded:  YES  NO  If yes, Blinded step: Unblind step | | **To be completed by the ORTA Designer if modified** |
| Minimization:   * Threshold value:   : equal to the number of stratification factors.  : specify threshold value =   * Random element: YES  NO   if yes, specify random element (<0.5) =  Blocks  Block length is set to       (specify with relative frequencies) | | **To be completed by the ORTA Statistician if modified** |

|  |  |  |  |
| --- | --- | --- | --- |
|  | Name | Date of approval | Signature |

|  |  |  |  |
| --- | --- | --- | --- |
| ORTA Lead DM |  |  |  |
| ORTA Statistician  *(if randomized step)* |  |  |  |

(\*) indicate the number of each study step affected by the change. If all study steps are affected, list “All”.

**Note:**