### Inclusion Criteria

Liste des visites avec cette fiches :Randomisation

#### IC

|  |  |  |  |
| --- | --- | --- | --- |
| Label de la question | Check | Réponses possibles | Sas |
| IC01 |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | IC01 |
| IC02 |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | IC02 |
| IC03 |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | IC03 |
| IC04 |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | IC04 |
| IC05 |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | IC05 |
| IC06 |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | IC06 |
| IC07 |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | IC07 |
| IC08 |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | IC08 |
| IC09 |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | IC09 |
| IC10 |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | IC10 |
| IC11 |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | IC11 |
| IC12 |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | IC12 |
| IC13 |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | IC13 |
| IC14 |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | IC14 |
| IC15 |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | IC15 |

### Non inclusion Criteria

Liste des visites avec cette fiches :Randomisation

#### EC

|  |  |  |  |
| --- | --- | --- | --- |
| Label de la question | Check | Réponses possibles | Sas |
| EC01 |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | EC01 |
| EC02 |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | EC02 |
| EC03 |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | EC03 |
| EC04 |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | EC04 |
| EC05 |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | EC05 |
| EC06 |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | EC06 |
| EC07 |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | EC07 |
| EC08 |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | EC08 |
| EC09 |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | EC09 |
| EC10 |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | EC10 |
| EC11 |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | EC11 |
| EC12 |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | EC12 |
| EC13 |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | EC13 |
| EC14 |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | EC14 |
| EC15 |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | EC15 |

### Randomisation request

Liste des visites avec cette fiches :Randomisation

#### CT

|  |  |  |  |
| --- | --- | --- | --- |
| Label de la question | Check | Réponses possibles | Sas |
| Center |  |  | CENTER |
| CRA's name |  |  | CRA |
| Investigator's name |  |  | INV |

#### STRAT

|  |  |  |  |
| --- | --- | --- | --- |
| Label de la question | Check | Réponses possibles | Sas |
| Stratification factor 1 |  | 🔘 1 - <b>Response 1</b><br>🔘 2 - <b>Response 2</b>🔘 1 - <b>Response 1</b><br>🔘 2 - <b>Response 2</b> | STRAT1 |
| Stratification factor 2 |  | 🔘 1 - <b>Response 1</b><br>🔘 2 - <b>Response 2</b>🔘 1 - <b>Response 1</b><br>🔘 2 - <b>Response 2</b> | STRAT2 |

#### RDConsent

|  |  |  |  |
| --- | --- | --- | --- |
| Label de la question | Check | Réponses possibles | Sas |
| Informed consent signature date by the patient |  |  | PCONSDT |
| Informed consent signature date by the investigator |  |  | ICONSDT |
| Version of informed consent signed |  |  | CONSVERS |

#### OTHERQ

|  |  |  |  |
| --- | --- | --- | --- |
| Label de la question | Check | Réponses possibles | Sas |
| Additional question 1 |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | OPTN1 |
| Additional question 2 |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | OPTN11 |

#### TAS

|  |  |  |  |
| --- | --- | --- | --- |
| Label de la question | Check | Réponses possibles | Sas |
| Planned start date of treatment |  |  | PLSDT |

#### REQCC

|  |  |  |  |
| --- | --- | --- | --- |
| Label de la question | Check | Réponses possibles | Sas |
| <i><font color="#808080">Checks are ok for the form 1: inclusion criteria</font></i> |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | 🔒 CHECKIC |
| <i><font color="#808080">Checks are ok for the form 2: non inclusion criteria</font></i> |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | 🔒 CHECKEC |
| <i><font color="#808080">Checks are ok for the form 3: inclusion request</font></i> |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | 🔒 CHECKREQ |
| <i><font color="#808080">Final check: authorisation to include the patient (without procotol deviation)</font></i><font color="#808080"> |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | 🔒 FCHECK |
| <font color="#808080">Overrule all checks (only for Data Manager)</font> |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | DMOVER |

#### CRACONF

|  |  |  |  |
| --- | --- | --- | --- |
| Label de la question | Check | Réponses possibles | Sas |
| Status of the request |  | 🔘 1 - <b>Proceed with the inclusion (no protocol deviation)</b><br>🔘 2 - <b>Proceed with the inclusion in spite of protocol deviation(s)</b><br>🔘 0 - <b>Do not proceed with the inclusion (screen failure)</b>🔘 1 - <b>Proceed with the inclusion (no protocol deviation)</b><br>🔘 2 - <b>Proceed with the inclusion in spite of protocol deviation(s)</b><br>🔘 0 - <b>Do not proceed with the inclusion (screen failure)</b> | REQSTATU |
| Please verify: |  |  | DISCONF |
| I confirm that all information are exact |  |  | REQCONF |

#### WAIV

|  |  |  |  |
| --- | --- | --- | --- |
| Label de la question | Check | Réponses possibles | Sas |
| <i>The criteria entered are not consistent with the criteria required.</i> |  |  | WAIVCOM |
| The investigator confirms the registration/randomisation of this patient in spite of the non-respect of an eligibility criteria |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | WAIVYN |
| Description of the deviation |  |  | WAIV\_R |

#### SF

|  |  |  |  |
| --- | --- | --- | --- |
| Label de la question | Check | Réponses possibles | Sas |
| Reason for screen failure |  | 🔘 1 - <b>Reason 1</b><br>🔘 2 - <b>Reason 2</b><br>🔘 99 - <b>Other</b>🔘 1 - <b>Reason 1</b><br>🔘 2 - <b>Reason 2</b><br>🔘 99 - <b>Other</b> | SF\_R |
| If other, specify |  |  | SF\_S |

### Randomisation result

Liste des visites avec cette fiches :Randomisation

#### RRESG

|  |  |  |  |
| --- | --- | --- | --- |
| Label de la question | Check | Réponses possibles | Sas |
| Manual randomisation in case of absence of eCRF (DM only) |  |  | Mrand |
| Date of inclusion |  |  | 🔒 ENROLLDT |
| Number |  |  | 🔒 ENROLLID |
| FLAGNOTIF |  |  | 👻🔒 FLAGNOTI |
| Arm |  | 🔘 1 - <b>TRT 1</b><br>🔘 2 - <b>TRT2</b>🔘 1 - <b>TRT 1</b><br>🔘 2 - <b>TRT2</b> | 🔒 ARM |
| Remove read only |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | RREAD |
| Correction of inclusion data |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | COR\_YN |
| Resend notification |  | 🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b>🔘 1 - <b>Yes</b><br>🔘 0 - <b>No</b> | RESENDNO |

### Correction of randomisation criteria

Liste des visites avec cette fiches :Randomisation

#### COR\_G

|  |  |  |  |
| --- | --- | --- | --- |
| Label de la question | Check | Réponses possibles | Sas |
| What is the correction related to? |  | 🔘 1 - <b>Reason N°1</b><br>🔘 98 - <b>Stratification criteria AND Other</b><br>🔘 99 - <b>Other</b>🔘 1 - <b>Reason N°1</b><br>🔘 98 - <b>Stratification criteria AND Other</b><br>🔘 99 - <b>Other</b> | COR\_R |
| If other, specify |  |  | COR\_S |