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| --- | --- | --- |
| Patient Information [PAT] | | |
| You can’t enroll patient now *[REFUSLABEL]* | | |
| Message from promotor *[REFUSLABEL]* | |  |
| Hard check to prevent save *[HCHECK]* | |  |
| Patient Information *[PATIENT\_INFORMATION]* | | |
| First name Initial *[FNAME]* | | |\_\_| |
| Last name initial *[LNAME]* | | |\_\_| |
| Patient Number *[PTNO]* | | |\_\_|\_\_|\_\_| |
| Birthdate *[DNAIS]* | | |\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_|  MM/YYYY |
| Sex *[SEX]* | | 🌕 Male 🌕 Female |
| Patient Caption *[PATIEN]* | | |\_\_|\_\_|\_\_|-|\_\_|-|\_\_| |
| Active *[PTACTV]* | | 🌕 No 🌕 Yes |
| Dropped *[PTDROP]* | | 🌕 No 🌕 Yes |
| Enrolled *[PTENRL]* | | 🌕 No 🌕 Yes |
| Randomization Number *[PTRNNO]* | | |\_\_|\_\_|\_\_| |
| Randomization Date *[PTRNDT]* | | |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_|  DD/MM/YYYY |
| Check of duplicate patient *[CHECKDUP]* | |  |
| Overrule the duplicate check (DM only) *[OVERDUP]* | | 🌕 No 🌕 Yes |
| Informed consent *[CONSENT]* | | |
| Informed consent signature date by the patient | |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_| *[PCONSDT]*  DD/MM/YYYY | |
| Informed consent signature date by the investigator | |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_| *[ICONSDT]*  DD/MM/YYYY | |
| *Age of the patient* | |\_\_|\_\_| *[AGE]* | |
| Version of informed consent signed | |\_\_|\_\_| *[CONSVERS]* | |

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| Inclusion Criteria [IC] | |
| Inclusion Criteria *[IC]* | |
| IC01 | 🌕 No 🌕 Yes *[IC01]* |
| IC02 | 🌕 No 🌕 Yes *[IC02]* |
| IC03 | 🌕 No 🌕 Yes *[IC03]* |
| IC04 | 🌕 No 🌕 Yes *[IC04]* |
| IC05 | 🌕 No 🌕 Yes *[IC05]* |
| IC06 | 🌕 No 🌕 Yes *[IC06]* |
| IC07 | 🌕 No 🌕 Yes *[IC07]* |
| IC08 | 🌕 No 🌕 Yes *[IC08]* |
| IC09 | 🌕 No 🌕 Yes *[IC09]* |
| IC10 | 🌕 No 🌕 Yes *[IC10]* |
| IC11 | 🌕 No 🌕 Yes *[IC11]* |
| IC12 | 🌕 No 🌕 Yes *[IC12]* |
| IC13 | 🌕 No 🌕 Yes *[IC13]* |
| IC14 | 🌕 No 🌕 Yes *[IC14]* |
| IC15 | 🌕 No 🌕 Yes *[IC15]* |

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| Exclusion Criteria [EC] | |
| Exclusion Criteria *[EC]* | |
| EC01 | 🌕 No 🌕 Yes *[EC01]* |
| EC02 | 🌕 No 🌕 Yes *[EC02]* |
| EC03 | 🌕 No 🌕 Yes *[EC03]* |
| EC04 | 🌕 No 🌕 Yes *[EC04]* |
| EC05 | 🌕 No 🌕 Yes *[EC05]* |
| EC06 | 🌕 No 🌕 Yes *[EC06]* |
| EC07 | 🌕 No 🌕 Yes *[EC07]* |
| EC08 | 🌕 No 🌕 Yes *[EC08]* |
| EC09 | 🌕 No 🌕 Yes *[EC09]* |
| EC10 | 🌕 No 🌕 Yes *[EC10]* |
| EC11 | 🌕 No 🌕 Yes *[EC11]* |
| EC12 | 🌕 No 🌕 Yes *[EC12]* |
| EC13 | 🌕 No 🌕 Yes *[EC13]* |
| EC14 | 🌕 No 🌕 Yes *[EC14]* |
| EC15 | 🌕 No 🌕 Yes *[EC15]* |

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| Registration request [EC] | |
| Center *[CT]* | |
| CRA's name | *[CRA]* |
| Investigator's name | *[INV]* |
| Other questions about patient *[OTHERQ]* | |
| Additional question 1 | 🌕 No 🌕 Yes *[OPTN1]* |
| Additional question 2 | 🌕 No 🌕 Yes *[OPTN2]* |
| Date of treatment *[TAS]* | |
| Planned start date of treatment | |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_| *[PLSDT]*  DD/MM/YYYY |
| Derived calculation for inclusion *[REQCC]* | |
| Inclusion request date | |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_| *[ENRREQDT]*  DD/MM/YYYY |
| *Checks are ok for the form 1: inclusion criteria* | 🌕 No 🌕 Yes *[CHECKIC]* |
| *Checks are ok for the form 2: exclusion criteria* | 🌕 No 🌕 Yes *[CHECKEC]* |
| *Checks are ok for the form 3: inclusion request* | 🌕 No 🌕 Yes *[CHECKREQ]* |
| *Hard Checks are ok for the inclusion* | 🌕 No 🌕 Yes *[HARDCHECK]* |
| *Final check: authorisation to include the patient (without procotol deviation)* | 🌕 No 🌕 Yes *[FCHECK]* |
| Overrule all checks (only for Data Manager) | 🌕 No 🌕 Yes *[DMOVER]* |
| Confirmation of inclusion *[CRACONF]* | |
| Status of the request | 🌕 Proceed with the inclusion (no protocol deviation)  🌕 Proceed with the inclusion in spite of protocol deviation(s) |
| Please verify : | *[DISCONF]* |
| I confirm that all information are exact | □ *[REQCONF]* |
| Non respect of an eligibility criteria *[WAIV]* | |
| *The criteria entered are not consistent with the criteria required. [WAIVCOM]* | |
| The investigator confirms the registration/randomisation of this patient in spite of the non-respect of an eligibility criteria | 🌕 No 🌕 Yes *[WAIVYN]* |
| Description of the deviation | *[WAIV\_R]* |

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| Registration result [RES] | |
| Save to get the patient number *[RRESG]* | |
| Date of inclusion | |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_| *[ENROLLDT]*  DD/MM/YYYY |
| Number | |\_\_|\_\_|\_\_| *[ENROLLID]* |
| FLAGNOTIF | *[FLAGNOTI]* |
| Arm | |\_\_| *[ARM]* |
| Remove read only | 🌕 No 🌕 Yes *[RREAD]* |
| Resend notification | 🌕 No 🌕 Yes *[RNOTIF]* |

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| Correction of registration criteria [COR] | |
| Inclusion correction *[COR\_G]* | |
| What is the correction related to? | 🌕 Reason n°1  🌕 Stratification criteria AND Other  🌕 Other *[COR\_R]* |
| If other, specify | *[COR\_S]* |

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| Screen failure [SFF] | |
| Screen failure *[SF]* | |
| Screen failure | 🌕 No 🌕 Yes *[RREAD]* |
| Reason for screen failure | 🌕 Reason 1 🌕 Reason 2 🌕 Other *[SF\_R]* |
| If other, specify | *[SF\_S]* |