test fiche # ERREUR DANS LES DOSSIERS DU FICHIER groupe/F00\_PAT est vide TBNodeId:62021 Inclusion Criteria

Liste des visites avec cette fiches :Randomisation IC

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| 1:Histologically proven advanced synchronous oligometastatic stage IV NSCLC. Note: this include newly metastatic disease or initially diagnosed and treated for stage I-III NSCLC (counting those who receive prior local/systemic treatments for this disease) who ultimately develop metastases. | 🔘 1 - **Yes**🔘 0 - **No** | **IC01** |
| 2:NSCLC patients eligible first line immunotherapy-based SoC according to the European Marketing Authorization | 🔘 1 - **Yes**🔘 0 - **No** | **IC02** |
| 3:PDL1 status available | 🔘 1 - **Yes**🔘 0 - **No** | **IC03** |
| 4:Metastases eligible to RLT according to the local MTB: ≤5 cm each in computed tomography (CT) scan, excluding primary tumour | 🔘 1 - **Yes**🔘 0 - **No** | **IC04** |
| 5:Maximum 5 metastases in 3 organs (EORTC criteria), according to brain MRI and FDG-PET | 🔘 1 - **Yes**🔘 0 - **No** | **IC05** |
| IC06 - info | Char - 1 | **IC06** |
| IC07 -info | Char - 1 | **IC07** |
| 8:Acceptable organ function for radical treatment | 🔘 1 - **Yes**🔘 0 - **No** | **IC08** |
| 9:ECOG performance status (PS) 0-1 | 🔘 1 - **Yes**🔘 0 - **No** | **IC09** |
| 10:Patient aged 18 or more | 🔘 1 - **Yes**🔘 0 - **No** | **IC10** |
| 11:Patient must have signed a written informed consent form prior to any study specific procedures | 🔘 1 - **Yes**🔘 0 - **No** | **IC11** |
| 12:Woman of childbearing potential and male patients must agree to use adequate contraception for the duration of study participation and up to 6 months after completing treatment/therapy | 🔘 1 - **Yes**🔘 0 - **No** | **IC12** |
| 13:Patients affiliated to the social security system | 🔘 1 - **Yes**🔘 0 - **No** | **IC13** |
| 14:Patient is willing and able to comply with the protocol for the duration of the study including undergoing treatment and scheduled visits, and examinations including follow-up. | 🔘 1 - **Yes**🔘 0 - **No** | **IC14** |

## Non inclusion Criteria

Liste des visites avec cette fiches :Randomisation EC

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| 1:Non-squamous NSCLC with targetable tumour mutations and approved first line targeted therapy (such as EGFR, ALK and ROS1). | 🔘 1 - **Yes**🔘 0 - **No** | **EC01** |
| 2:Metastases not eligible to RLT : e.g. brainstem or diffuse serosal metastases (meningeal, pericardial, pleural, peritoneal, mesenteric) or that invades the gastrointestinal tract | 🔘 1 - **Yes**🔘 0 - **No** | **EC02** |
| 3:Brain metastases only, without extra-cerebral metastases | 🔘 1 - **Yes**🔘 0 - **No** | **EC03** |
| 4:Uncontrolled severe comorbidity, symptomatic interstitial lung disease or active infection | 🔘 1 - **Yes**🔘 0 - **No** | **EC04** |
| 5:Prior therapy with T-cell costimulation or immune checkpoint-targeted agents within 1 year | 🔘 1 - **Yes**🔘 0 - **No** | **EC05** |
| 6:Uncontrolled concomitant (<1-year) malignancy except adequately treated basal or squamous cell carcinoma of the skin, or in-situ carcinoma of any organ or in-situ melanoma of the skin | 🔘 1 - **Yes**🔘 0 - **No** | **EC06** |
| 7 : Symptomatic lesions requiring urgent palliative radiation, is permitted prior to randomization. These treated lesions should be counted towards the total number of metastases at the time of enrolment. | 🔘 1 - **Yes**🔘 0 - **No** | **EC07** |

## Randomisation request

Liste des visites avec cette fiches :Randomisation CT

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Center | Char - 50 | **CENTER** |
| CRA's name | Char - 50 | **CRA** |
| Investigator's name | Char - 50 | **INV** |

### CONSENT

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Informed consent signature date by the patient | 📅 DD/MM/YYYY | **PCONSDT** |
| Informed consent signature date by the investigator | 📅 DD/MM/YYYY | **ICONSDT** |
| *Age of the patient* | Num - 3 | **🔒AGE** |
| Version of informed consent signed | Char - 5 | **CONSVERS** |

### OTHERQ

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Number of metastasis *(including Symptomatic lesions treated by urgent radiation or ablation)* | Num - 1 | **NBMETA** |
| date of computed tomography (CT) scan | 📅 DD/MM/YYYY | **SCAN\_DT** |
| Symptomatic lesion(s) requiring urgent radiation (*crit 6)* | 🔘 1 - **Yes**🔘 0 - **No** | **OPTN11** |
| Clinically required brain metastase(s) ablation *(crit 7)* | 🔘 1 - **Yes**🔘 0 - **No** | **🔒BR\_YN** |

### STRAT

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| PDL1 status | 🔘 1 - **<50%**🔘 2 - **≥ 50%** | **STRAT1** |
| number of metastases (stratification) | 🔘 1 - **1**🔘 2 - **≥ 2** | **STRAT2** |

### List of metastatic sites

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Site Number | Num - 2 | **SITE\_N** |
| Anatomical sites | 🔘 Radio bouton trop long | **ANASITE** |
| Other site, please specify | Char - 200 | **ANASITE\_** |
| date of discovery | 📅 DD/MM/YYYY | **DISCO\_DT** |
| Symptomatic lesions requiring urgent radiation | 🔘 1 - **Yes**🔘 0 - **No** | **RADLES** |
| Clinically required brain metastases ablation (crit 7) | 🔘 1 - **Yes**🔘 0 - **No** | **ABLARES** |
| Comment | Char - 500 | **SITECMT** |

### TAS

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Planned start date of treatment | 📅 DD/MM/YYYY | **PLSDT** |

### REQCC

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Inclusion request date | 📅 DD/MM/YYYY | **🔒ENRREQDT** |
| *Checks are ok for the form 1: inclusion criteria* | 🔘 1 - **Yes**🔘 0 - **No** | **🔒CHECKIC** |
| *Checks are ok for the form 2: non inclusion criteria* | 🔘 1 - **Yes**🔘 0 - **No** | **🔒CHECKEC** |
| *Checks are ok for the form 3: inclusion request* | 🔘 1 - **Yes**🔘 0 - **No** | **🔒CHECKREQ** |
| *Hard Checks are ok for the inclusion* | 🔘 1 - **Yes**🔘 0 - **No** | **🔒HARDCHEC** |
| *Final check: authorisation to include the patient (without procotol deviation)* | 🔘 1 - **Yes**🔘 0 - **No** | **🔒FCHECK** |
| Overrule all checks (only for Data Manager) | 🔘 1 - **Yes**🔘 0 - **No** | **DMOVER** |
| Calculated enrollment number | Num - 3 | **👻GETNUM** |

### CRACONF

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Status of the request | 🔘 1 - **Proceed with the inclusion (no protocol deviation)**🔘 2 - **Proceed with the inclusion in spite of protocol deviation(s)**🔘 0 - **Do not proceed with the inclusion (screen failure)** | **REQSTATU** |
| Please verify: | Char - 1 | **DISCONF** |
| I confirm that all information are exact | Num - 50 | **REQCONF** |

### WAIV

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| *The criteria entered are not consistent with the criteria required.* | Char - 1 | **WAIVCOM** |
| The investigator confirms the registration/randomisation of this patient in spite of the non-respect of an eligibility criteria | 🔘 1 - **Yes**🔘 0 - **No** | **WAIVYN** |
| Description of the deviation | Char - 50 | **WAIV\_R** |

### SF

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Reason for screen failure | 🔘 1 - **Reason 1**🔘 2 - **Reason 2**🔘 99 - **Other** | **SF\_R** |
| If other, specify | Char - 50 | **SF\_S** |

## Randomisation result

Liste des visites avec cette fiches :Randomisation RRESG

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Date of inclusion | 📅 DD/MM/YYYY | **🔒ENROLLDT** |
| Number | Char - 3 | **🔒ENROLLID** |
| FLAGNOTIF | Char - 50 | **👻🔒FLAGNOTI** |
| Arm | 🔘 1 - **RLT & Immunothérapie-based SoC**🔘 2 - **Immunothérapie-based SoC** | **🔒ARM** |
| Remove read only | 🔘 1 - **Yes**🔘 0 - **No** | **RREAD** |

## Correction of randomisation criteria

Liste des visites avec cette fiches :Randomisation COR\_G

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| What is the correction related to? | 🔘 1 - **Reason N°1**🔘 98 - **Stratification criteria AND Other**🔘 99 - **Other** | **COR\_R** |
| If other, specify | Char - 200 | **COR\_S** |

## F05-Protocol deviation and comments

Liste des visites avec cette fiches :Protocol deviation and comments 1-LIST OF DEVIATION AND COMMENTS\_MAX(99)\_

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Number | Char - 50 | **NB** |
| FROM | 🔘 1 - **Site**🔘 2 - **Monitor**🔘 3 - **Data manager** | **FROM** |
| Category | 🔘 1 - **Deviation**🔘 2 - **Comments about patient**🔘 3 - **Other** | **CAT** |
| DETAIL | Char - 50 | **DETAIL** |
| Status | 🔘 1 - **Na**🔘 2 - **Ongoing**🔘 3 - **on hold** | **STATUS** |
| About | 🔘 1 - **Database(ecrf)**🔘 2 - **Eligibility criteria**🔘 3 - **Randomisation**🔘 4 - **Treatment**🔘 5 - **Flowchart**🔘 6 - **Followup**🔘 7 - **Other** | **ABOUT** |
| Date of awareness | 📅 DD/MM/YYYY | **DEVDAT** |
| Action needed | 🔘 0 - **No**🔘 1 - **Yes** | **AC\_YN** |

## F06-Alcohol and Tobbaco

Liste des visites avec cette fiches :Baseline 1-TOBBACO

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Smoking history | 🔘 0 - **No**🔘 1 - **Yes** | **SMOK\_YN** |
| Smoking status | 🔘 1 - **Current**🔘 2 - **Former** | **SMOKING** |
| Pack years to get help, see exemple of calculation here : https://www.mdcalc.com/calc/10187/pack-years-calculator | Num - 3 | **PACK\_YEA** |

### 2-ALCOHOL

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Alcohol drinking 1 verre > 10 grammes d'alcool | 🔘 0 - **Zero**🔘 1 - **Low : 110 g/day (male) or 120 g/day (female)**🔘 2 - **Moderate : 4160 g/day (male) or 2140 g/day (female)**🔘 3 - **High : sup.60 g/day (male) or sup.40 d/day (female)** | **MHALCOHO** |

## F07-Medical History

Liste des visites avec cette fiches :Baseline 1-MEDICAL HISTORY\_MAX15\_

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Any significant medical history (previous or ongoing) | 🔘 0 - **No**🔘 1 - **Yes** | **MHYN** |

### 2-IF YES PLEASE COMPLETE BELOW\_MAX

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Organ or System (where abnormalities have been noted) | 🔘 1 - **HEENT : Head, Eye, Ear, Nose and Throat**🔘 2 - **Pulmonary, respiratory**🔘 3 - **Cardiovascular**🔘 4 - **Endocrinology**🔘 5 - **Gastrointestinal**🔘 6 - **Hepatic**🔘 7 - **Genitorurinary**🔘 8 - **Musculoskeletal**🔘 9 - **Neurological**🔘 10 - **Psychiatric**🔘 11 - **Allergies**🔘 12 - **Dermatological**🔘 13 - **Immunological**🔘 99 - **Other** | **MHSYST** |
| Medical history Details | Char - 300 | **MHDET** |
| ONGOING | 🔘 0 - **No**🔘 1 - **Yes** | **MHONGO** |
| Year of occurrence (use,ND or NK if needed) | 📅 DD/MM/YYYY | **MHYR** |

### 3-PREVIOUS CANCER

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Previous cancer | 🔘 0 - **No**🔘 1 - **Yes** | **PRCANC** |

### 4-PREVIOUS CANCER DETAILS \_MAX(15)\_

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Organ | Char - 200 | **MHORGAN** |
| Histology | Char - 200 | **MHHISTO** |
| Previous cancer details | Char - 1000 | **PCANCD** |
| Type of treatment | Char - 50 | **PCTPTREA** |
| Ongoing | 🔘 0 - **No**🔘 1 - **Yes** | **ICDONGO** |
| Year of occurrence (use,ND or NK if needed) | 📅 DD/MM/YYYY | **MHCANC\_Y** |

## F08-Lung Cancer Description

Liste des visites avec cette fiches :Baseline 1-CANCER AT DIAGNOSIS

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Date of tumor diagnosis | 📅 DD/MM/YYYY | **DIAGDT** |

### 2-CANCER AT INCLUSION

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| T at inclusion | 🔘 0 - **T0: absence of tumor**🔘 1 - **T1**🔘 2 - **T2**🔘 3 - **T3**🔘 4 - **T4**🔘 5 - **Tx** | **TNMT\_I** |
| N at inclusion | 🔘 0 - **N0: absence of metastasis nodes**🔘 1 - **N1**🔘 2 - **N2**🔘 3 - **N3** | **TNMT\_N** |
| M at inclusion | 🔘 0 - **M0: absence of distant metastasis nodes**🔘 1 - **M1a**🔘 2 - **M1b**🔘 3 - **M1c** | **TNMT\_M** |
| specify the type | 🔘 1 - **Adenocarcinoma**🔘 2 - **Squamous carcinoma**🔘 3 - **Large cell neuroendocrine carcinoma**🔘 4 - **Small cell neuroendocrine carcinoma**🔘 5 - **Adenosquamous**🔘 6 - **Undifferentiated**🔘 7 - **Sarcomatoid carcinoma**🔘 8 - **Adenocarcinoma + neuroendocrine component**🔘 9 - **Other** | **TYPNSCLC** |
| other : | Char - 50 | **TYPNSCLS** |

### 3-OTHER INFORMATION

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Kras mutation | 🔘 0 - **Negative**🔘 1 - **Positive**🔘 2 - **Unknown** | **KRAS** |
| PD-L1 status | 🔘 0 - **Negative**🔘 1 - **Positive**🔘 2 - **Unknown** | **PDL1STAT** |
| If positive, percentage of tumor cells: (%) | Char - 50 | **PDL1\_P** |
| Metastatic | 🔘 0 - **No**🔘 1 - **Yes** | **META\_YN** |
| Date of metastasis first diagnosis | 📅 DD/MM/YYYY | **META\_DT** |

## F09-prior inclusion locoregional treatment for metastatic sites

Liste des visites avec cette fiches :Baseline 1-PRIOR SURGERY

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Anatomical sites | Char - 50 | **PRSITE** |
| Locoregional treatment | 🔘 0 - **No**🔘 1 - **Yes** | **PRITR** |
| Surgery | 🔘 0 - **No**🔘 1 - **Yes** | **PRISR** |
| Surgery date | 📅 DD/MM/YYYY | **PRIDT** |

### 2-PRIOR RADIOTHERAPY

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Anatomical sites | Char - 50 | **PRSITE** |
| Radiotherapy | 🔘 0 - **No**🔘 1 - **Yes** | **PRIRT** |
| Stereotaxic | 🔘 0 - **No**🔘 1 - **Yes** | **PRSTER** |
| Following surgery | 🔘 0 - **No**🔘 1 - **Yes** | **PRSURG** |
| Radiotherapy start date | 📅 DD/MM/YYYY | **PRIRTST** |
| Radiotherapy end date | 📅 DD/MM/YYYY | **PRIRTND** |
| dose | Char - 50 | **PRDOS** |
| Number of Fraction | 🔘 1 - **Yes**🔘 0 - **No** | **PRFRAC** |

## Vital sign and Clinical Examination

Liste des visites avec cette fiches :Cycle 1-4 [Max:8]Maintenance[Max:99]End of Treatment VisitBaseline VS1

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Clinical Examination done ? | 🔘 0 - **Not done**🔘 1 - **Done** | **VSYN** |
| Date of clinical assessment | 📅 DD/MM/YYYY | **VSDT** |

### VS2

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Height (cm) | Num - 50 | **👻HEIGHT** |
| WEIGHT (kg) | Num - 50 | **WEIGHT** |
| PS (performance status measured using the ECOG Scale ) | Num - 50 | **VSPS** |

### Other form to fill

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Tumor evaluation done during this cycle ? | 🔘 1 - **Yes**🔘 0 - **No** | **TE** |
| Presence of adverse events of interest | 🔘 1 - **Yes**🔘 0 - **No** | **AE\_INT** |
| Concomitant treatment since last visit | 🔘 1 - **Yes**🔘 0 - **No** | **CM\_YN** |

## F11-Translational biopsy (optional)

Liste des visites avec cette fiches :Baseline 2-AT C2D1

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Blood samples for ctDNA | 🔘 0 - **Not done**🔘 1 - **Done** | **TB7** |
| Sampling date | 📅 DD/MM/YYYY | **TB7\_D** |

### 3-AT C5D1

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Digital pathology done ? | 🔘 0 - **Not done**🔘 1 - **Done** | **TB8** |
| Sampling date | 📅 DD/MM/YYYY | **TB8\_D** |
| Blood immunoprofiling | 🔘 0 - **Not done**🔘 1 - **Done** | **TB9** |
| Sampling date | 📅 DD/MM/YYYY | **TB9\_D** |
| Sampling date | 📅 DD/MM/YYYY | **TB10\_D** |
| Stool samples | 🔘 0 - **Not done**🔘 1 - **Done** | **TB10** |
| Blood samples for ctDNA | 🔘 0 - **Not done**🔘 1 - **Done** | **TB11** |
| Sampling date | 📅 DD/MM/YYYY | **TB11\_D** |
| CT images collection for radiomics | 🔘 0 - **Not done**🔘 1 - **Done** | **TB12** |
| Sampling date | 📅 DD/MM/YYYY | **TB12\_D** |

### 1-AT BASELINE

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Tumour paraffin embedded block | 🔘 0 - **Not done**🔘 1 - **Done** | **TB1** |
| Sampling date | 📅 DD/MM/YYYY | **TB1\_D** |
| Digital pathology done ? | 🔘 0 - **Not done**🔘 1 - **Done** | **TB2** |
| Sampling date | 📅 DD/MM/YYYY | **TB2\_D** |
| Blood immunoprofiling | 🔘 0 - **Not done**🔘 1 - **Done** | **TB3** |
| Sampling date | 📅 DD/MM/YYYY | **TB3\_D** |
| Stool samples | 🔘 0 - **Not done**🔘 1 - **Done** | **TB4** |
| Sampling date | 📅 DD/MM/YYYY | **TB4\_D** |
| Blood samples for ctDNA | 🔘 0 - **Not done**🔘 1 - **Done** | **TB5** |
| Sampling date | 📅 DD/MM/YYYY | **TB5\_D** |
| CT images collection for radiomics | 🔘 0 - **Not done**🔘 1 - **Done** | **TB6** |
| Sampling date | 📅 DD/MM/YYYY | **TB6\_D** |

## F13-Tumor Evaluation

Liste des visites avec cette fiches :Follow-Up [Max:9]Cycle 1-4 [Max:8]Maintenance[Max:99]End of Treatment VisitBaseline 3-GLOBAL RESPONSE

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Global response | 🔘 1 - **Complete response**🔘 2 - **Partial response**🔘 3 - **Stable disease**🔘 4 - **Progressive response**🔘 5 - **Peudo progressive response**🔘 6 - **Not evaluable** | **RCRESP** |

### 2-SUB RESPONSE

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Response of target lesions | 🔘 1 - **Complete response**🔘 2 - **Partial response**🔘 3 - **Stable disease**🔘 4 - **Progressive response**🔘 5 - **Not evaluable** | **RCTLRESP** |
| Response of non-target lesions | 🔘 1 - **Complete response**🔘 2 - **Noncr / nonpd**🔘 3 - **Progressive response**🔘 1 - **Not evaluable** | **RCNTLRES** |
| Appearance of new lesions | 🔘 0 - **No**🔘 1 - **Yes** | **RCNEW** |

### 1-TUMOR EVALUATION

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Tumor assessment period | Char - 50 | **LABEL\_RE** |
| Date of radiological evaluation by CT-scan | Char - 50 | **RCDT** |
| Date of radiological evaluation for brain disease (if applicable) | Char - 50 | **RAD\_BRAI** |
| Type of evaluation for brain disease | 🔘 1 - **Ct scan**🔘 2 - **Mri** | **EVALBR** |

## F15-QLQ-C30

Liste des visites avec cette fiches :Follow-Up [Max:9]Cycle 1-4 [Max:8]Maintenance[Max:99]End of Treatment VisitBaseline QLQEHEAD

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Questionnaire rempli par le patient | 🔘 1 - **Yes**🔘 0 - **No** | **QLQEYN** |
| Date de remplissage du questionnaire par le patient | 📅 DD/MM/YYYY | **QLQEDT** |
| Raison de non remplissage du questionnaire | Char - 200 | **QLQENO\_R** |
| Date à laquelle le questionnaire aurait dû être rempli | 📅 DD/MM/YYYY | **QLQEEXPD** |
| MISSING\_VAR | Num - 50 | **MISSING\_** |

### QLQC30G1

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| 1. Avez-vous des difficultés à faire certains efforts physiques prénibles comme porter un sac à provision chargé ou une valise ? | 🔘 1 - **Pas du tout**🔘 2 - **Un peu**🔘 3 - **Assez**🔘 4 - **Beaucoup** | **Q01** |
| 2. Avez-vous des difficultés à faire une LONGUE promenade ? | 🔘 1 - **Pas du tout**🔘 2 - **Un peu**🔘 3 - **Assez**🔘 4 - **Beaucoup** | **Q02** |
| 3. Avez-vous des difficultés à faire un PETIT tour dehors ? | 🔘 1 - **Pas du tout**🔘 2 - **Un peu**🔘 3 - **Assez**🔘 4 - **Beaucoup** | **Q03** |
| 4. Etes-vous obligé(e) de rester au lit ou dans un fauteuil pendant la journée ? | 🔘 1 - **Pas du tout**🔘 2 - **Un peu**🔘 3 - **Assez**🔘 4 - **Beaucoup** | **Q04** |
| 5. Avez-vous besoin d'aide pour manger, vous habiller, faire votre toilette ou aller aux WC ? | 🔘 1 - **Pas du tout**🔘 2 - **Un peu**🔘 3 - **Assez**🔘 4 - **Beaucoup** | **Q05** |

### QLQC30G2

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| 6. Avez-vous été gêné(e) pour faire votre travail ou vos activités de tous les jours ? | 🔘 1 - **Pas du tout**🔘 2 - **Un peu**🔘 3 - **Assez**🔘 4 - **Beaucoup** | **Q06** |
| 7. Avez-vous été gêné(e) dans vos activités de loisirs ? | 🔘 1 - **Pas du tout**🔘 2 - **Un peu**🔘 3 - **Assez**🔘 4 - **Beaucoup** | **Q07** |
| 8. Avez-vous eu le souffle court ? | 🔘 1 - **Pas du tout**🔘 2 - **Un peu**🔘 3 - **Assez**🔘 4 - **Beaucoup** | **Q08** |
| 9. Avez-vous ressenti de la douleur ? | 🔘 1 - **Pas du tout**🔘 2 - **Un peu**🔘 3 - **Assez**🔘 4 - **Beaucoup** | **Q09** |
| 10. Avez-vous eu besoin de repos ? | 🔘 1 - **Pas du tout**🔘 2 - **Un peu**🔘 3 - **Assez**🔘 4 - **Beaucoup** | **Q10** |
| 11. Avez-vous eu des difficultés à dormir ? | 🔘 1 - **Pas du tout**🔘 2 - **Un peu**🔘 3 - **Assez**🔘 4 - **Beaucoup** | **Q11** |
| 12. Vous êtes-vous senti(e) faible ? | 🔘 1 - **Pas du tout**🔘 2 - **Un peu**🔘 3 - **Assez**🔘 4 - **Beaucoup** | **Q12** |
| 13. Avez-vous manqué d'appétit ? | 🔘 1 - **Pas du tout**🔘 2 - **Un peu**🔘 3 - **Assez**🔘 4 - **Beaucoup** | **Q13** |
| 14. Avez-vous eu des nausées (mal au coeur) ? | 🔘 1 - **Pas du tout**🔘 2 - **Un peu**🔘 3 - **Assez**🔘 4 - **Beaucoup** | **Q14** |
| 15. Avez-vous vomi ? | 🔘 1 - **Pas du tout**🔘 2 - **Un peu**🔘 3 - **Assez**🔘 4 - **Beaucoup** | **Q15** |
| 16. Avez-vous été constipé(e) ? | 🔘 1 - **Pas du tout**🔘 2 - **Un peu**🔘 3 - **Assez**🔘 4 - **Beaucoup** | **Q16** |
| 17. Avez-vous eu de la diarrhée ? | 🔘 1 - **Pas du tout**🔘 2 - **Un peu**🔘 3 - **Assez**🔘 4 - **Beaucoup** | **Q17** |
| 18. Etiez-vous fatigué(e) ? | 🔘 1 - **Pas du tout**🔘 2 - **Un peu**🔘 3 - **Assez**🔘 4 - **Beaucoup** | **Q18** |
| 19. Des douleurs ont-elles perturbé vos activités quotidiennes ? | 🔘 1 - **Pas du tout**🔘 2 - **Un peu**🔘 3 - **Assez**🔘 4 - **Beaucoup** | **Q19** |
| 20. Avez-vous eu des difficultés à vous concentrer sur certaines choses, par exemple, pour lire le journal ou regarder la télévision ? | 🔘 1 - **Pas du tout**🔘 2 - **Un peu**🔘 3 - **Assez**🔘 4 - **Beaucoup** | **Q20** |
| 21. Vous êtes-vous senti(e) tendu(e) ? | 🔘 1 - **Pas du tout**🔘 2 - **Un peu**🔘 3 - **Assez**🔘 4 - **Beaucoup** | **Q21** |
| 22. Vous êtes-vous fait du souci ? | 🔘 1 - **Pas du tout**🔘 2 - **Un peu**🔘 3 - **Assez**🔘 4 - **Beaucoup** | **Q22** |
| 23. Vous êtes-vous senti(e) irritable ? | 🔘 1 - **Pas du tout**🔘 2 - **Un peu**🔘 3 - **Assez**🔘 4 - **Beaucoup** | **Q23** |
| 24. Vous êtes-vous senti(e) déprimé(e) ? | 🔘 1 - **Pas du tout**🔘 2 - **Un peu**🔘 3 - **Assez**🔘 4 - **Beaucoup** | **Q24** |
| 25. Avez-vous eu des difficultés à vous souvenir de certaines choses ? | 🔘 1 - **Pas du tout**🔘 2 - **Un peu**🔘 3 - **Assez**🔘 4 - **Beaucoup** | **Q25** |
| 26. Votre état physique ou votre traitement médical vous ont-ils gêné(e) dans votre vie FAMILIALE ? | 🔘 1 - **Pas du tout**🔘 2 - **Un peu**🔘 3 - **Assez**🔘 4 - **Beaucoup** | **Q26** |
| 27. Votre état physique ou votre traitement médical vous ont-ils gêné(e) dans vos activités SOCIALES (par exemple, sortir avec des amis, aller au cinéma, ...) ? | 🔘 1 - **Pas du tout**🔘 2 - **Un peu**🔘 3 - **Assez**🔘 4 - **Beaucoup** | **Q27** |
| 28. Votre état physique ou votre traitement médical vous ont-ils causé des problèmes financiers ? | 🔘 1 - **Pas du tout**🔘 2 - **Un peu**🔘 3 - **Assez**🔘 4 - **Beaucoup** | **Q28** |

### QLQC30G3

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| 29. Comment évalueriez-vous votre ETAT DE SANTE au cours de la semaine passée ? | Num - 1 | **Q29** |
| 30. Comment évalueriez-vous l'ensemble de votre QUALITE DE VIE au cours de la semaine passée ? | Num - 1 | **Q30** |

## F16-QLQ-LC-13

Liste des visites avec cette fiches :Follow-Up [Max:9]Cycle 1-4 [Max:8]Maintenance[Max:99]End of Treatment VisitBaseline

## F17-EQ-5D-5L

Liste des visites avec cette fiches :Follow-Up [Max:9]Cycle 1-4 [Max:8]Maintenance[Max:99]End of Treatment VisitBaseline

## F14-Adverse Event

Liste des visites avec cette fiches :Cycle 1-4 [Max:8]Maintenance[Max:99]End of Treatment Visit AE1

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Verbatim | Char - 70 | **AETERM** |

### AE2

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| CTCAE SOC | 🔘 Radio bouton trop long | **AESOC** |
| CTCAE Term | 🔘 Radio bouton trop long | **AEPT** |

### AE3

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Ongoing at the  beginning of treatment | Num - 100 | **AESGO** |
| Start date | 📅 DD/MM/YYYY | **AESDT** |
| Ongoing at  the end of treatment and/or  at the end of short-time follow up | Num - 100 | **AEEGO** |
| End date | 📅 DD/MM/YYYY | **AEEDT** |
| Cycle at which the event started | Num - 2 | **AECYCLE** |

### AE4

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Grade | Num - 1 | **AEGR** |
| DLT | 🔘 1 - **Yes**🔘 0 - **No** | **AEDLT** |
| **SAE** | 🔘 1 - **Yes**🔘 0 - **No** | **AESER** |
| FLAG | Char - 50 | **👻FLAG** |
| MISSING\_VAR | Num - 50 | **MISSING\_** |

### AE5

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Date of SAE reporting to PV | 📅 DD/MM/YYYY | **AESERDT** |
| CIOMS Number | Char - 9 | **AECIOMS** |

### AE6

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Related to | 🔘 1 - **Drug 1**🔘 2 - **Drug 2**🔘 3 - **Drug 3**🔘 4 - **Cancer**🔘 99 - **Other** | **AEREL** |
| If other, specify | Char - 50 | **AEREL\_S** |
| Action | 🔘 0 - **No action**🔘 1 - **Action 1**🔘 2 - **Action 2**🔘 99 - **Other** | **AEACN** |
| If other, specify | Char - 50 | **AEACN\_S** |
| Treatment required | 🔘 1 - **Yes**🔘 0 - **No** | **AETRTYN** |

## F18-RLT modality

Liste des visites avec cette fiches :Primary tumour managementMaintenance[Max:99] 1-GERENAL

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| RLT FAIT | 🔘 0 - **No**🔘 1 - **Yes** | **RLT\_YN** |
| Reason why RLT was not given | Char - 50 | **RLT\_REAS** |
| Chir | 🔘 0 - **No**🔘 1 - **Yes** | **RLT\_CHIR** |
| Radiothérapie | 🔘 0 - **No**🔘 1 - **Yes** | **RLT\_RAD** |
| Radiologie interventionelle | 🔘 0 - **No**🔘 1 - **Yes** | **RLT\_INT** |

### 4-INTERVENTIONAL RADIOLOGY \_MAX(5)\_

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Anatomical site | Char - 50 | **RADI\_SIT** |
| Surg date | 📅 DD/MM/YYYY | **RADI\_DT** |
| Technique | 🔘 1 - **Radiofrequence**🔘 2 - **Cryotherapie**🔘 3 - **Other** | **DADITEC** |
| Other, specify | Char - 50 | **DADITEC\_** |

### 2-RADIOTHERAPIE \_MAX(5)\_

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Anatomical site | Char - 50 | **RAD\_SITE** |
| Type | 🔘 1 - **Radiotherapie stereotaxique**🔘 2 - **Palliative** | **RAD\_TYPE** |
| Cumulative dose | Char - 50 | **RAD\_DOS** |
| Number of fractions | Char - 50 | **RAD\_FR** |
| date debut | 📅 DD/MM/YYYY | **RAD\_DB** |
| Date de fin | 📅 DD/MM/YYYY | **RAD\_FN** |

### 3-SURGERY \_MAX(5)\_

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Anatomical site | Char - 50 | **CHIR\_SIT** |
| Surg date | 📅 DD/MM/YYYY | **CHR\_DT** |
| Technique | 🔘 1 - **Videothoracoscopie**🔘 2 - **Celioscopie**🔘 3 - **Ouverte** | **CHR\_TEC** |

## F12-Immunotherapy based SoC

Liste des visites avec cette fiches :Maintenance[Max:99]End of Treatment Visit 1-IMMUNOTHERAPY BASED SOC

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Type of treatment | 🔘 1 - **platinumbased chemotherapy combined with an anti pd1 immunotherapy (pembrolizumab or cemiplimab)**🔘 2 - **pemetrexedplatinum combinations**🔘 3 - **paclitaxelplatinum combination**🔘 4 - **anti pd1 monotherapy: pembrolizumab**🔘 5 - **anti pd1 monotherapy: cemiplimab**🔘 6 - **nivolumabipilimumabchemotherapy**🔘 7 - **durvalumabtremelimumabchemotherapy association**🔘 8 - **Maintenance/immunotherapy**🔘 99 - **other : protocol deviation** | **TRT\_TP** |
| Other treatment, please specify | Char - 50 | **TRT\_S** |
| D1 of cycle | 📅 DD/MM/YYYY | **TRTDT** |
| Main SoC regimens respected | 🔘 0 - **No**🔘 1 - **Yes** | **TRTRES** |
| Si not Main SoC regimens respected, please specify | Char - 50 | **TRTRES\_S** |
| Dose modification | 🔘 0 - **No**🔘 1 - **Yes** | **TRTDOSMO** |
| Reason of Dose modification | Char - 50 | **TRTREAS** |
| Detail of Dose modification | Char - 50 | **TRTREAS\_** |

## F19-End of treatment summary of care

Liste des visites avec cette fiches :End of Treatment Visit 1-END OF SYSTEMIC TREATMENT

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Treatment | 🔘 1 - **platinumbased chemotherapy combined with an anti pd1 immunotherapy (pembrolizumab or cemiplimab)**🔘 2 - **pemetrexedplatinum combinations**🔘 3 - **paclitaxelplatinum combination**🔘 4 - **anti pd1 monotherapy: pembrolizumab**🔘 5 - **anti pd1 monotherapy: cemiplimab**🔘 6 - **nivolumabipilimumabchemotherapy**🔘 7 - **durvalumabtremelimumabchemotherapy association**🔘 8 - **Maintenance/immunotherapy**🔘 99 - **other : protocol deviation** | **SYSTREAT** |
| number of total injection | Char - 50 | **NBINJ** |
| First date injection | 📅 DD/MM/YYYY | **C1DT** |
| Last date of administration | 📅 DD/MM/YYYY | **LDDT** |
| Reason for stopping | 🔘 1 - **Toxicity**🔘 2 - **Progression**🔘 3 - **Enf of protocole**🔘 4 - **Other** | **OETREAS** |
| Other reason, specify | Char - 50 | **OETREAS\_** |
| Total dose administered | Char - 50 | **TTDOS** |
| if toxicity is the reason for stopping, please describe | Char - 50 | **TOX\_S** |

### 2-MAINTENANCE

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| if toxicity is the reason for stopping, please describe | Char - 50 | **TOX\_S** |
| Treatment | 🔘 1 - **platinumbased chemotherapy combined with an anti pd1 immunotherapy (pembrolizumab or cemiplimab)**🔘 2 - **pemetrexedplatinum combinations**🔘 3 - **paclitaxelplatinum combination**🔘 4 - **anti pd1 monotherapy: pembrolizumab**🔘 5 - **anti pd1 monotherapy: cemiplimab**🔘 6 - **nivolumabipilimumabchemotherapy**🔘 7 - **durvalumabtremelimumabchemotherapy association**🔘 8 - **Maintenance/immunotherapy**🔘 99 - **other : protocol deviation** | **MA\_TR** |
| number of total injection | Char - 50 | **MAINJ** |
| First date injection | 📅 DD/MM/YYYY | **MA\_SDT** |
| Last date of administration | 📅 DD/MM/YYYY | **MA\_EDT** |
| Reason for stopping | 🔘 1 - **Toxicity**🔘 2 - **Progression**🔘 3 - **Enf of protocole**🔘 4 - **Other** | **MATREAS** |
| Other reason, specify | Char - 50 | **MATREAS\_** |
| Total dose administered | Char - 50 | **MADO** |

## F20-Concomitant Treatment[Max:50]

Liste des visites avec cette fiches :Concomitant Treatments 2-DETAILS \_MAX(99)\_

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Family of concomitant treatment | Char - 50 | **CM\_C** |
| INN (International Non-proprietary Name) | Char - 50 | **CMINN** |
| Reason of administration | Char - 50 | **CM\_REAS** |
| dosage(qte, & unit) | Char - 50 | **CM\_DOSAG** |
| frequency of administration (once, by day, week, ETC.) | Char - 50 | **CM\_FREQ** |
| Ongoing before randomisation | Char - 50 | **CMSGO** |
| Start date | 📅 DD/MM/YYYY | **CMSDT** |
| Ongoing at the end of treatment | Char - 50 | **CMEGO** |
| End date | 📅 DD/MM/YYYY | **CMEDT** |

### 1-GENERAL

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Has concomitant medication been administered? | 🔘 0 - **No**🔘 1 - **Yes** | **CMYN** |

## F21-FU (every 12 weeks)[Max:99]

Liste des visites avec cette fiches :Follow-Up [Max:9] 1-FOLLOW-UP

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| During this follow-up visit, did you have any information on the patient? | Char - 50 | **FUYN** |
| If no, reason | 🔘 1 - **Consent withdrawn**🔘 2 - **Lost to followup**🔘 99 - **Other** | **FUNO\_R** |
| If other, specify | Char - 50 | **FUNO\_S** |
| Date of last news | 📅 DD/MM/YYYY | **FUDT** |
| Status of the patient | 🔘 0 - **Alive**🔘 1 - **Dead** | **FUCS** |
| If alive, Disease state? | 🔘 1 - **Complete response**🔘 2 - **Partial response**🔘 3 - **Stable disease**🔘 4 - **Progressive disease**🔘 5 - **Not evaluable**🔘 6 - **Unknown** | **FUDISCS** |
| Occurrence of a second cancer? | 🔘 0 - **No**🔘 1 - **Yes** | **FU2NDK** |
| New anticancer treatment ongoing? | 🔘 0 - **No**🔘 1 - **Yes** | **FUTRTGO** |
| If yes, treatment name | Char - 50 | **FUTRT\_S** |
| SAE since the last visit? | 🔘 0 - **No**🔘 1 - **Yes** | **FUSAEYN** |
| If yes, term(s) | Char - 50 | **FUSAE\_S** |

## F22-Subsequent treatment

Liste des visites avec cette fiches :Follow-Up [Max:9]

## F23-Progression

Liste des visites avec cette fiches :Events PD

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Did the patient progressed/relapsed? | 🔘 1 - **Yes**🔘 0 - **No** | **PDYN** |
| Date of cancer progression or relapse | 📅 DD/MM/YYYY | **PDDT** |
| Progression or relapse? | 🔘 1 - **Progression**🔘 2 - **Relapse** | **PDTYP** |
| Diagnostic of progression or relapse based on: | Char - 1 | **PDDIAGC** |
| Imaging | 🔘 1 - **Yes**🔘 0 - **No** | **PDIMGYN** |
| Clinical exam | 🔘 1 - **Yes**🔘 0 - **No** | **PDCLINYN** |
| Tumor markers | 🔘 1 - **Yes**🔘 0 - **No** | **PDBIOYN** |
| Local progression or relapse | 🔘 1 - **Yes**🔘 0 - **No** | **PDLOCYN** |
| Regional progression or relapse | 🔘 1 - **Yes**🔘 0 - **No** | **PDREGYN** |
| Metastasis progression or relapse | 🔘 1 - **Yes**🔘 0 - **No** | **PDMETAYN** |
| If yes, specify location | Char - 1 | **PDMTLOC** |
| Brain | 🔘 1 - **Yes**🔘 0 - **No** | **PDMTBR** |
| Lungs | 🔘 1 - **Yes**🔘 0 - **No** | **PDMTLG** |
| Bones | 🔘 1 - **Yes**🔘 0 - **No** | **PDMTBN** |
| Liver | 🔘 1 - **Yes**🔘 0 - **No** | **PDMTLV** |
| Other | 🔘 1 - **Yes**🔘 0 - **No** | **PDMTOTH** |
| If other, specify | Char - 50 | **PDMTOT\_S** |
| MISSING\_VAR | Num - 50 | **MISSING\_** |

## F24-Late Toxicity

Liste des visites avec cette fiches :Events 1-LATE TOXICITY

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Late toxicity | 🔘 0 - **No**🔘 1 - **Yes** | **LAT\_YN** |

## F25-Death

Liste des visites avec cette fiches :Events 1-DEATH

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Date of death | 📅 DD/MM/YYYY | **DTHDT** |
| Primary cause of death | 🔘 1 - **Cancer**🔘 2 - **Toxicity due to study treatment**🔘 3 - **Second cancer**🔘 4 - **Intercurrent illness**🔘 5 - **Unknown**🔘 99 - **Other** | **DTH\_R** |
| Specify | Char - 50 | **DTH\_S** |

## F26-End of Study

Liste des visites avec cette fiches :End of Study EOS

|  |  |  |
| --- | --- | --- |
| **Label de la question** | **Réponses possibles** | **Sas** |
|  |  |  |
| Date of end of study | 📅 DD/MM/YYYY | **EOSDT** |
| Reason for end of study | 🔘 1 - **End of study as defined by the protocol**🔘 2 - **Death**🔘 3 - **Consent withdrawal**🔘 4 - **Lost to Follow-Up**🔘 99 - **Other** | **EOS\_R** |
| If other, specify | Char - 60 | **EOS\_S** |