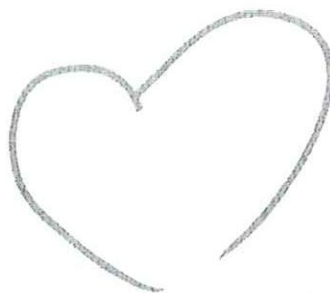


AVE0005 / EFC10547

CASE REPORT FORM



**A MULTINATIONAL, RANDOMIZED, DOUBLE BLIND STUDY, COMPARING THE
EFFICACY OF AFLIBERCEPT ONCE EVERY 2 WEEKS VERSUS PLACEBO IN PATIENTS
TREATED WITH GEMCITABINE FOR METASTATIC PANCREATIC CANCER**

COUNTRY NUMBER:

CENTRE NUMBER:

SUBJECT NUMBER:

Confidential ■ Final version ■ 21-Sep-2007

sanofi aventis

sanofi-sintelabo - sanofi

EFC10547

| | | | | | | | | |
|---------|--------|---------|--|--|--|--|--|--|
| X | 4 | | | | | | | |
| Country | Center | Subject | | | | | | |

1.1

Page No.

0

Repeat No.

Visit Name: VISIT 0

Date of visit :

(DD-MMM-YYYY)

VISIT_01

INFORMED CONSENT

INFCN_01

Date consent obtained:

(DD-MMM-YYYY)

DEMOGRAPHY

DEMOG_01

Date of Birth

(dd-mmm-yyyy)

Sex Male ☐
 Female ☐

Race Caucasian/White ☐
 Black ☐
 Asian/Oriental ☐
 Other ☐

If Other, specify

Visit Name: VISIT 0

CANCER DIAGNOSIS

CDIAG_01

Date of initial diagnosis
DD-MM-YYYY

Location

Pancreas ☐

Pancreas head ☐

Pancreas tail ☐

Pancreas body ☐

Other ☐

Specify

Histology type

Adenocarcinoma ☐

Other ☐

Specify

Stage

0 ☐

I ☐

II ☐

III ☐

IV ☐

Unknown ☐

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

3.1

Page No.

0

Repeat No.

Visit Name:

VISIT 0

STATUS AT STUDY ENTRY

STENT_01

Date of progression : (dd-mm-yyyy)

EXTENT AT STUDY ENTRY :

Metastatic ☐ Locally advanced ☐

SURGERY PRIOR

RECORD RELEVANT SURGERY, RELATED TO PANCREATIC CANCER INFORMATION

Data ☒ No Data ☐

| Surgery term | Surgery Date (DD-MMM-YYYY) | Not performed |
|-------------------------|-------------------------------|--------------------------|
| DISTAL PANCREATECTOMY | | <input type="checkbox"/> |
| TOTAL PANCREATECTOMY | | <input type="checkbox"/> |
| PANCREATICODUODENECTOMY | | <input type="checkbox"/> |
| HEPATICOJEJUNOSTOMY | | <input type="checkbox"/> |
| CHOLEDOCHOJEJUNOSTOMY | | <input type="checkbox"/> |
| CHOLEDOCHODUODENOSTOMY | | <input type="checkbox"/> |
| CHOLECYSTOJEJUNOSTOMY | | <input type="checkbox"/> |
| GASTRIC BYPASS | | <input type="checkbox"/> |
| | | <input type="checkbox"/> |
| | | <input type="checkbox"/> |
| | | <input type="checkbox"/> |
| | | <input type="checkbox"/> |

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

4.2

Page No.

0

Repeat No.

Visit Name:

VISIT 0

Surgery term

Surgery Date
(DD-MMM-YYYY)

Not performed

| | | |
|--|--|--------------------------|
| | | <input type="checkbox"/> |
| | | <input type="checkbox"/> |
| | | <input type="checkbox"/> |
| | | <input type="checkbox"/> |
| | | <input type="checkbox"/> |
| | | <input type="checkbox"/> |
| | | <input type="checkbox"/> |
| | | <input type="checkbox"/> |

EFC10547

X 4 Country Center Subject

5.1

Page No.

0

Repeat No.

Visit Name: VISIT 0

RADIATION THERAPY

PRIOR RADIATION THERAPY

RADTX_01

Data ☒ No Data ☐

| Lesion location | Start Date (dd-mmm-yyyy) | End Date (dd-mmm-yyyy) | Total Dose | Unit | Intent |
|-----------------|-----------------------------|---------------------------|------------|---|--|
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |

EFC10547

X 4

Country Center Subject

5.2

Page No.

0

Repeat No.

Visit Name: VISIT 0

| Lesion location | Start Date (dd-mmm-yyyy) | End Date (dd-mmm-yyyy) | Total Dose | Unit | Intent |
|-----------------|-----------------------------|---------------------------|------------|---|--|
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |

EFC10547

| | | | | | | | |
|---------|--------|---------|--|--|--|--|--|
| X | 4 | | | | | | |
| Country | Center | Subject | | | | | |

6.1

Page No.

0

Repeat No.

Visit Name: VISIT 0

ANTI-CANCER THERAPY

PRIOR TREATMENT

CANTX_01

Data ☒ No Data ☐

Intent

Reason for Discontinuation

If other, specify

Regimen Number

Drug Per Regimen

Start Date
DD-MM-YYYY

End Date
DD-MM-YYYY

REGIMEN 1

MEDICAL HISTORY

MHX_03

Data ☒ No Data ☐

Record relevant medical history for thrombovascular events and cardiovascular risk factors.

Medical/Surgical History

Start Date or Not Occurred
MMM-YYYY

Ongoing

Yes ☐ No ☐

If yes, disease/symptoms controlled:

Yes ☐ No ☐
ANGINA PECTORIS

☐ Not Occurred

Yes ☐ No ☐

If yes, disease/symptoms controlled:

Yes ☐ No ☐
UNSTABLE ANGINA

☐ Not Occurred

Yes ☐ No ☐

If yes, disease/symptoms controlled:

Yes ☐ No ☐
MYOCARDIAL INFARCTION

☐ Not Occurred

Yes ☐ No ☐

If yes, disease/symptoms controlled:

Yes ☐ No ☐
ATRIAL FIBRILLATION

☐ Not Occurred

Yes ☐ No ☐

If yes, disease/symptoms controlled:

Yes ☐ No ☐
TRANSIENT ISCHEMIC ATTACK

☐ Not Occurred

EFC10547

X 4 Country Center Subject

7.2

Page No.

0

Repeat No.

Visit Name: VISIT 0

Medical/Surgical History

Start Date or Not Occurred
MMM-YYYY

Ongoing

STROKE

☐ Not Occurred

Yes ☐ No ☐

If yes, disease/symptoms controlled:

Yes ☐ No ☐

PERIPHERAL ARTERIAL THROMBOTIC DISEASE

☐ Not Occurred

Yes ☐ No ☐

If yes, disease/symptoms controlled:

Yes ☐ No ☐

DEEP VENOUS THROMBOSIS

☐ Not Occurred

Yes ☐ No ☐

If yes, disease/symptoms controlled:

Yes ☐ No ☐

PULMONARY EMBOLISM

☐ Not Occurred

Yes ☐ No ☐

If yes, disease/symptoms controlled:

Yes ☐ No ☐

HIGH BLOOD PRESSURE

☐ Not Occurred

Yes ☐ No ☐

If yes, disease/symptoms controlled:

Yes ☐ No ☐

EFC10547

X 4 Country Center Subject

7.3

Page No.

0

Repeat No.

Visit Name: VISIT 0

Medical/Surgical History

Start Date or Not Occurred
MMM-YYYY

Ongoing

HYPERCHOLESTEROLEMIA

☐ Not Occurred

Yes ☐ No ☐

If yes, disease/symptoms controlled:

Yes ☐ No ☐

DIABETES MELLITUS

☐ Not Occurred

Yes ☐ No ☐

If yes, disease/symptoms controlled:

Yes ☐ No ☐

SMOKER

☐ Not Occurred

Yes ☐ No ☐

If yes, disease/symptoms controlled:

Yes ☐ No ☐

☐ Not Occurred

Yes ☐ No ☐

If yes, disease/symptoms controlled:

Yes ☐ No ☐

☐ Not Occurred

Yes ☐ No ☐

If yes, disease/symptoms controlled:

Yes ☐ No ☐

EFC10547

X 4

Country Center Subject

7.4

Page No.

0

Repeat No.

Visit Name:

VISIT 0

Medical/Surgical History

Start Date or Not Occurred

MMM-YYYY

Ongoing

☐ Not Occurred

Yes ☐ No ☐

If yes, disease/symptoms controlled:

Yes ☐ No ☐

☐ Not Occurred

Yes ☐ No ☐

If yes, disease/symptoms controlled:

Yes ☐ No ☐

☐ Not Occurred

Yes ☐ No ☐

If yes, disease/symptoms controlled:

Yes ☐ No ☐

☐ Not Occurred

Yes ☐ No ☐

If yes, disease/symptoms controlled:

Yes ☐ No ☐

☐ Not Occurred

Yes ☐ No ☐

If yes, disease/symptoms controlled:

Yes ☐ No ☐

MEDICAL HISTORY

MHX_03

Data ☒ No Data ☐

Record relevant medical/surgical history other than the disease studied and other than thrombovascular events and cardiovascular risk factors.

Medical/Surgical History

Start Date
MMM-YYYY

Ongoing

Yes ☐ No ☐

If yes, disease/symptoms controlled:

Yes ☐ No ☐

Yes ☐ No ☐

If yes, disease/symptoms controlled:

Yes ☐ No ☐

Yes ☐ No ☐

If yes, disease/symptoms controlled:

Yes ☐ No ☐

Yes ☐ No ☐

If yes, disease/symptoms controlled:

Yes ☐ No ☐

Yes ☐ No ☐

If yes, disease/symptoms controlled:

Yes ☐ No ☐

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

8.2

Page No.

0

Repeat No.

Visit Name: VISIT 0

Medical/Surgical History

Start Date
MMM-YYYY

Ongoing

Yes ☐ No ☐
If yes, disease/symptoms controlled:
Yes ☐ No ☐

Yes ☐ No ☐
If yes, disease/symptoms controlled:
Yes ☐ No ☐

Yes ☐ No ☐
If yes, disease/symptoms controlled:
Yes ☐ No ☐

Yes ☐ No ☐
If yes, disease/symptoms controlled:
Yes ☐ No ☐

Yes ☐ No ☐
If yes, disease/symptoms controlled:
Yes ☐ No ☐

EFC10547

X 4

Country Center Subject

8.3

Page No.

0

Repeat No.

Visit Name:

VISIT 0

Medical/Surgical History

Start Date

MMM-YYYY

Ongoing

Yes ☐ No ☐

If yes, disease/symptoms controlled:

Yes ☐ No ☐

Yes ☐ No ☐

If yes, disease/symptoms controlled:

Yes ☐ No ☐

Yes ☐ No ☐

If yes, disease/symptoms controlled:

Yes ☐ No ☐

Yes ☐ No ☐

If yes, disease/symptoms controlled:

Yes ☐ No ☐

Yes ☐ No ☐

If yes, disease/symptoms controlled:

Yes ☐ No ☐

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

8.4

Page No.

0

Repeat No.

Visit Name:

VISIT 0

Medical/Surgical History

Start Date

MMM-YYYY

Ongoing

Yes ☐ No ☐

If yes, disease/symptoms controlled:

Yes ☐ No ☐

Yes ☐ No ☐

If yes, disease/symptoms controlled:

Yes ☐ No ☐

Yes ☐ No ☐

If yes, disease/symptoms controlled:

Yes ☐ No ☐

Yes ☐ No ☐

If yes, disease/symptoms controlled:

Yes ☐ No ☐

Yes ☐ No ☐

If yes, disease/symptoms controlled:

Yes ☐ No ☐

Visit Name: VISIT 0

PAIN INTENSITY ASSESSED VIA VISUAL ANALOG SCALE

Data ☒ No Data ☐

Data corresponding to Baseline Visit (7 days prior to first dose)

| | Date (dd-mmm-yyyy) | Measure (MM) |
|-------|-----------------------|-------------------|
| DAY 1 | | |
| DAY 2 | | |
| DAY 3 | | |
| DAY 4 | | |
| DAY 5 | | |
| DAY 6 | | |
| DAY 7 | | |

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

10.1

Page No.

0

Repeat No.

Visit Name:

VISIT 0

MEDICATION

ANALGESIC

MED_02

Data ☒ No Data ☐

ANALGESIC MEDICATION SHOULD BE COLLECTED DAILY FOR SEVEN CONSECUTIVE
DAYS PRIOR TO THE FIRST STUDY DRUG ADMINISTRATION

| Drug/Medication (Brand or generic name) | Dosage (Total daily dose) | Units | Route | Start Date (dd-mmm-yyyy) | End Date (dd-mmm-yyyy) | Ongoing |
|--|------------------------------|-------|-------|-----------------------------|---------------------------|--------------------------|
| | | | | | | <input type="checkbox"/> |
| | | | | | | <input type="checkbox"/> |
| | | | | | | <input type="checkbox"/> |
| | | | | | | <input type="checkbox"/> |
| | | | | | | <input type="checkbox"/> |
| | | | | | | <input type="checkbox"/> |

EFC10547

X 4

Country Center Subject

10.2

Page No.

0

Repeat No.

Visit Name:

VISIT 0

| Drug/Medication (Brand or generic name) | Dosage (Total daily dose) | Units | Route | Start Date (dd-mmm-yyyy) | End Date (dd-mmm-yyyy) | Ongoing |
|--|------------------------------|-------|-------|-----------------------------|---------------------------|--------------------------|
| | | | | | | <input type="checkbox"/> |
| | | | | | | <input type="checkbox"/> |
| | | | | | | <input type="checkbox"/> |
| | | | | | | <input type="checkbox"/> |
| | | | | | | <input type="checkbox"/> |
| | | | | | | <input type="checkbox"/> |
| | | | | | | <input type="checkbox"/> |
| | | | | | | <input type="checkbox"/> |

EFC10547

X 4

Country Center Subject

10.3

Page No.

0

Repeat No.

Visit Name:

VISIT 0

| Drug/Medication (Brand or generic name) | Dosage (Total daily dose) | Units | Route | Start Date (dd-mmm-yyyy) | End Date (dd-mmm-yyyy) | Ongoing |
|--|------------------------------|-------|-------|-----------------------------|---------------------------|--------------------------|
| | | | | | | <input type="checkbox"/> |
| | | | | | | <input type="checkbox"/> |
| | | | | | | <input type="checkbox"/> |
| | | | | | | <input type="checkbox"/> |
| | | | | | | <input type="checkbox"/> |
| | | | | | | <input type="checkbox"/> |
| | | | | | | <input type="checkbox"/> |
| | | | | | | <input type="checkbox"/> |

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

11.1

Page No.

0

Repeat No.

Visit Name:

VISIT 0

MEDICATION

PRIOR

MED_01

RECORD ALL MEDICATIONS OTHER THAN ANTI-CANCER DRUG THERAPY AND ANALGESICS
THAT THE SUBJECT HAS TAKEN WITHIN 21 DAYS PRIOR TO RANDOMIZATION.

Data ☒ No Data ☐

| Drug/Medication (brand or generic name) | Start Date (dd-mmm-yyyy) | End Date (dd-mmm-yyyy) | Or tick if Ongoing |
|--|-----------------------------|---------------------------|--------------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> |

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

11.2

Page No.

0

Repeat No.

Visit Name:

VISIT 0

Drug/Medication
(brand or generic name)

Start Date
(dd-mmm-yyyy)

End Date
(dd-mmm-yyyy)

Or tick if Ongoing

☐

☐

☐

☐

☐

☐

☐

☐

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

11.3

Page No.

0

Repeat No.

Visit Name:

VISIT 0

Drug/Medication
(brand or generic name)

Start Date
(dd-mmm-yyyy)

End Date
(dd-mmm-yyyy)

Or tick if Ongoing

☐

☐

☐

☐

☐

☐

☐

☐

Visit Name: VISIT 0

VITAL SIGNS

VITAL_01

PHYSICAL EXAMINATION AND PRE-EXISTING SIGNS AND SYMPTOMS AT BASELINE

**TO BE PERFORMED WITHIN 8 DAYS PRIOR TO RANDOMIZATION.
ANY EXISTING EVENT SHOULD BE REPORTED ON MEDICAL OR SURGICAL HISTORY PAGE, AND ANY
EXISTING EVENT THAT BECAME SERIOUS SHOULD BE REPORTED ON AN ADDITIONAL AE PAGE AT V0.**

Data ☒ No Data ☐

TO BE PERFORMED WITHIN 8 DAYS PRIOR TO RANDOMIZATION

Date performed:
(DD-MMM-YYYY)

Height: cm

Weight: kg

Blood pressure: Systolic: mmHg / Diastolic: mmHg

ECOG Performance Status 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐

ELECTROCARDIOGRAM

ECG_01

To be performed within 8 days prior to randomization then during the treatment period, if clinically indicated, in this case, please use an additional ECG form

Data ☒ No Data ☐Date performed
(DD-MMM-YYYY)☐ Normal☐ AbnormalIf abnormal, clinically significant ? Yes ☐ No ☐

If abnormal, clinically significant, record on the Medical History form.

EFC10547

X 4

Country Center Subject

14.1

Page No.

0

Repeat No.

Visit Name:

VISIT 0

HEMATOLOGY

LAB_01

Data ☒ No Data ☐

TO BE PERFORMED WITHIN 8 DAYS PRIOR TO RANDOMIZATION.
TO BE REPEATED IF MORE THAN 8 DAYS BEFORE FIRST INFUSION

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit | SI Value | SI Unit | SI Ranges | |
|---------------------------|----------------------|------------------------|----------------------|----------------------|----------------------|----------------------|
| | | If other unit, specify | | | Lower Limit | Upper Limit |
| HEMOGLOBIN | <input type="text"/> | G/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| PLATELET COUNT (THROMBOC) | <input type="text"/> | 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| WBC | <input type="text"/> | 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| NEUTROPHILS | <input type="text"/> | 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

TO BE PERFORMED ONLY FOR PATIENT UNDER VITAMIN K ANTAGONIST

| | | | | | | |
|-----|----------------------|-------|----------------------|----------------------|----------------------|----------------------|
| INR | <input type="text"/> | RATIO | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
|-----|----------------------|-------|----------------------|----------------------|----------------------|----------------------|

EFC10547

| | | | | | | | | |
|---------|--------|---------|--|--|--|--|--|--|
| X | 4 | | | | | | | |
| Country | Center | Subject | | | | | | |

15.1

Page No.

0

Repeat No.

Visit Name: VISIT 0

BIOCHEMISTRY

LAB_01

Data ☒ No Data ☐

TO BE PERFORMED WITHIN 8 DAYS PRIOR TO RANDOMIZATION.
TO BE REPEATED IF MORE THAN 8 DAYS BEFORE FIRST INFUSION

Name

Address

City

Country

For Technical use :

Name

Address

City

Country

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

16.1

Page No.

0

Repeat No.

Visit Name: VISIT 0

DIPSTICK URINALYSIS

BHCG TEST HAS TO BE PERFORMED WITHIN 8 DAYS BEFORE RANDOMIZATION

LABU_1

Data ☒ No Data ☐

TO BE PERFORMED WITHIN 8 DAYS PRIOR TO RANDOMIZATION.
TO BE REPEATED IF MORE THAN 8 DAYS BEFORE FIRST INFUSION.

Date of sampling

Test name

WHITE BLOOD CELLS (QU)

☐ Absent ☐ + ☐ ++ ☐ +++ ☐ Not evaluable

RED BLOOD CELLS (QUA)

☐ Absent ☐ + ☐ ++ ☐ +++ ☐ Not evaluable

EFC10547

X 4

Country Center Subject

17.1

Page No.

0

Repeat No.

Visit Name: VISIT 0

MORNING SPOT URINALYSIS

TO BE PERFORMED WITHIN 8 DAYS PRIOR TO RANDOMIZATION.
TO BE REPEATED IF MORE THAN 8 DAYS BEFORE FIRST INFUSION.

LAB_01

Data ☒ No Data ☐

Name
Address
City
Country

For Technical use :

Name
Address
City
Country

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit If other unit, specify | SI Value | SI Unit | SI Ranges | |
|--------------------|-------|--------------------------------|----------|---------|-------------|-------------|
| | | | | | Lower Limit | Upper Limit |
| PROTEIN (URINE) | | MG/DL | | | | |
| CREATININE (URINE) | | MG/DL | | | | |

EFC10547

X 4 Country Center Subject

18.1

Page No.

0

Repeat No.

Visit Name: VISIT 0

24-HOUR URINALYSIS

TO BE PERFORMED WITHIN 8 DAYS PRIOR TO RANDOMIZATION.
TO BE REPEATED IF MORE THAN 8 DAYS BEFORE FIRST INFUSION.

LAB_04

Data ☒ No Data ☐

| | |
|---------|--|
| Name | |
| Address | |
| City | |
| Country | |

| For Technical use : | |
|---------------------|--|
| Name | |
| Address | |
| City | |
| Country | |

| | | | |
|---------------------------|--------------------|----------------------------|-----------------|
| | Date (dd-mmm-yyyy) | | (24-hour clock) |
| Start date of collection: | | Start Time of collection : | |
| End date of collection: | | End Time of collection : | |

| Test | Value | Unit | SI RANGES | |
|------------------|-------|------|-----------|---------|
| | | | SI Value | SI Unit |
| URINARY VOLUME | | L | | |
| PROTEIN (URINE) | | G/L | | |
| CREATININE (URIN | | G/L | | |

EFC10547

| | | | | | | | | |
|---|---|--|--|--|--|--|--|--|
| X | 4 | | | | | | | |
|---|---|--|--|--|--|--|--|--|

Country Center Subject

18.2

Page No.

0

Repeat No.

Visit Name:

VISIT 0

Is there any Hemoglobin or RBC in 24 Hour urine sample ?

LABU_1

Data ☒ No Data ☐

Test name

Negative

Positive

HEMOGLOBIN (QUALITAT

☐☐

RED BLOOD CELLS (QUA

☐☐

EFC10547

X 4

Country Center Subject

19.1

Page No.

0

Repeat No.

Visit Name:

VISIT 0

TUMOR MARKERS

TMARK_01

TO BE PERFORMED WITHIN 21 DAYS PRIOR TO RANDOMIZATION

Data ☒ No Data ☐

Date of evaluation

(dd-mmm-yyyy)

| TEST | VALUE | UNIT | NORMAL RANGE | |
|--------|-------|------|--------------|-------------|
| | | | LOWER LIMIT | UPPER LIMIT |
| CA19-9 | | | | |

EFC10547

X 4 Country Center Subject

20.1

Page No.

0

Repeat No.

Visit Name: VISIT 0

TUMOR EVALUATION (AT BASELINE) TO BE PERFORMED WITHIN 21 DAYS PRIOR TO RANDOMIZATION.

TUEVA_01

Data ☒ No Data ☐

| Lesion location | Method of tumor measurement | Date (dd-mmm-yyyy) | Normal | If Abnormal, specify: |
|----------------------|---|----------------------|--------------------------|---|
| <input type="text"/> | <input type="text"/> If Other, specify : <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | Tumor related <input type="checkbox"/> Other <input type="checkbox"/> : <input type="text"/> |
| <input type="text"/> | <input type="text"/> If Other, specify : <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | Tumor related <input type="checkbox"/> Other <input type="checkbox"/> : <input type="text"/> |
| <input type="text"/> | <input type="text"/> If Other, specify : <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | Tumor related <input type="checkbox"/> Other <input type="checkbox"/> : <input type="text"/> |
| <input type="text"/> | <input type="text"/> If Other, specify : <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | Tumor related <input type="checkbox"/> Other <input type="checkbox"/> : <input type="text"/> |
| <input type="text"/> | <input type="text"/> If Other, specify : <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | Tumor related <input type="checkbox"/> Other <input type="checkbox"/> : <input type="text"/> |
| <input type="text"/> | <input type="text"/> If Other, specify : <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | Tumor related <input type="checkbox"/> Other <input type="checkbox"/> : <input type="text"/> |
| <input type="text"/> | <input type="text"/> If Other, specify : <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | Tumor related <input type="checkbox"/> Other <input type="checkbox"/> : <input type="text"/> |
| <input type="text"/> | <input type="text"/> If Other, specify : <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | Tumor related <input type="checkbox"/> Other <input type="checkbox"/> : <input type="text"/> |
| <input type="text"/> | <input type="text"/> If Other, specify : <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | Tumor related <input type="checkbox"/> Other <input type="checkbox"/> : <input type="text"/> |
| <input type="text"/> | <input type="text"/> If Other, specify : <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | Tumor related <input type="checkbox"/> Other <input type="checkbox"/> : <input type="text"/> |

EFC10547

X 4

Country Center Subject

20.2

Page No.

0

Repeat No.

Visit Name: VISIT 0

| Lesion location | Method of tumor measurement | Date (dd-mmm-yyyy) | Normal | If Abnormal, specify: |
|-----------------|---|----------------------|--------------------------|---|
| | <input type="text"/> If Other, specify : <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | Tumor related <input type="checkbox"/> Other <input type="checkbox"/> : <input type="text"/> |
| | <input type="text"/> If Other, specify : <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | Tumor related <input type="checkbox"/> Other <input type="checkbox"/> : <input type="text"/> |
| | <input type="text"/> If Other, specify : <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | Tumor related <input type="checkbox"/> Other <input type="checkbox"/> : <input type="text"/> |
| | <input type="text"/> If Other, specify : <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | Tumor related <input type="checkbox"/> Other <input type="checkbox"/> : <input type="text"/> |
| | <input type="text"/> If Other, specify : <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | Tumor related <input type="checkbox"/> Other <input type="checkbox"/> : <input type="text"/> |
| | <input type="text"/> If Other, specify : <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | Tumor related <input type="checkbox"/> Other <input type="checkbox"/> : <input type="text"/> |
| | <input type="text"/> If Other, specify : <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | Tumor related <input type="checkbox"/> Other <input type="checkbox"/> : <input type="text"/> |
| | <input type="text"/> If Other, specify : <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | Tumor related <input type="checkbox"/> Other <input type="checkbox"/> : <input type="text"/> |
| | <input type="text"/> If Other, specify : <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | Tumor related <input type="checkbox"/> Other <input type="checkbox"/> : <input type="text"/> |
| | <input type="text"/> If Other, specify : <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | Tumor related <input type="checkbox"/> Other <input type="checkbox"/> : <input type="text"/> |

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

21.1

Page No.

0

Repeat No.

Visit Name: VISIT 0

TUMOR MEASUREMENT (AT BASELINE)

TUMEA_01

Data ☒ No Data ☐

| Lesion Number | Lesion location | Lesion description (Subsite) | Date of Assessment (dd-mmm-yyyy) | Method of tumor measurement | Measurement of target lesion: longest diameter | Non Target |
|----------------------|----------------------|------------------------------|----------------------------------|-----------------------------|--|--------------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> mm | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> mm | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> mm | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> mm | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> mm | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> mm | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> mm | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> mm | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> mm | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> mm | <input type="checkbox"/> |

EFC10547

X 4

Country Center Subject

21.2

Page No.

0

Repeat No.

Visit Name: VISIT 0

| Lesion Number | Lesion location | Lesion description (Subsite) | Date of Assessment (dd-mmm-yyyy) | Method of tumor measurement | Measurement of target lesion: longest diameter | Non Target |
|----------------------|----------------------|------------------------------|----------------------------------|-----------------------------|--|--------------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> mm | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> mm | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> mm | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> mm | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> mm | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> mm | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> mm | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> mm | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> mm | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> mm | <input type="checkbox"/> |

EFC10547

| | | | | | | | |
|---------|--------|---------|--|--|--|--|--|
| X | 4 | | | | | | |
| Country | Center | Subject | | | | | |

500.1

Page No.

0

Repeat No.

Visit Name: VISIT 0

ELIGIBILITY FOR RANDOMIZATION

ELIG_01

Data ☒ No Data ☐

Will the subject continue in the randomization of the study ? Yes ☐ No ☐

Does the subject satisfy all inclusion/exclusion criteria ? Yes ☐ No ☐

If No, please specify the main criteria not met

Inclusion criterion number

Exclusion criterion number

Are there other reasons why the subject cannot continue ? Yes ☐ No ☐

If Yes, (tick all that apply)

Serious Adverse Event * ☐

Lost to Follow-up ☐

Subject did not wish to continue ☐

Other Reason ☐

If other reason, specify

*** In case of an adverse event complete the Adverse Event form.**

EFC10547

X 4 Country Center Subject

600.1

Page No.

0

Repeat No.

Visit Name: VISIT 0 AE

ADVERSE EVENT

AE Form Number

AE_03

Data ☒ No Data ☐

AE Reference ID

1. Adverse Event (Diagnosis) :

2. Status of Adverse Event

New ☐ Date of Start
(dd-mmm-yyyy)

Ongoing without change ☐ (do not complete the remaining items)

Ongoing with change ☐

3. Grade

1 ☐ 2 ☐ 3 ☐ 4 ☐

4. Relationship to investigational product *

Yes ☐ No ☐

5. Action Taken with Investigat. Product

None ☐ Permanently discontinued ☐ Delayed ☐ Dose reduced ☐ Delayed and reduced ☐ Interrupted ☐

6. Corrective treatment/therapy

Yes ☐ No ☐

7. Outcome

Recovered ☐ Date of Recovery
(dd-mmm-yyyy)

Recovered with sequelae ☐ Specify : _____

Recovering ☐

Not recovered ☐

Fatal ☐ Date of Death (complete the death report form)
(dd-mmm-yyyy)

Unknown ☐

8. Seriousness Criteria

Yes ☐ No ☐ If Yes : -Date event became serious
(dd-mmm-yyyy)

IF YES, COMPLETE THIS SECTION AND THE SAFETY COMPLEMENTARY FORM

-Tick below all criteria that apply :

| | | | |
|--------------------------------------|--------------------------|--|--------------------------|
| Results in Death | <input type="checkbox"/> | Persistent/significant disability/incapacity | <input type="checkbox"/> |
| Life Threatening | <input type="checkbox"/> | Congenital anomaly or Birth Defect | <input type="checkbox"/> |
| Requires or prolongs hospitalization | <input type="checkbox"/> | Other medically important event | <input type="checkbox"/> |

9. Is it an event such as :

Overdose of the IP Yes ☐ No ☐

Pregnancy Yes ☐ No ☐

*Is there a reasonable possibility that the AE was caused by Investigational Product?

EFC10547

| | | | | | | | |
|---------|--------|---------|--|--|--|--|--|
| X | 4 | | | | | | |
| Country | Center | Subject | | | | | |

600.2

Page No.

0

Repeat No.

Visit Name: VISIT 0 AE

SAFETY COMPLEMENTARY FORM

SAEC_03

AE / Specific Event Form Number

1. Demographic Information

Weight (kg)

2. Detailed Description of the Adverse Event *(including complementary investigations)*

3. Date of Start of Event (Initial date of onset of the considered event) (DD-MMM-YYYY)

4. Investigational Products

Date of the FIRST administration of study treatment : (DD-MMM-YYYY)

Current Treatment number :

Current Cycle :

Date of the LAST administration before SAE : (dd-mmm-yyyy)

Last Dosage before SAE :

Action Taken :

AFLIBERCEPT/PLACEBO

GEMCITABINE

MG/KG

MG/M2

5. In case of hospitalization Date of admission (DD-MMM-YYYY) *(hospital report to be sent)*

6. In case of death Autopsy report Yes ☐ No ☐ *(copy to be sent)*

7. Corrective Treatment / Therapy

EFC10547

| | | | | | | | |
|---------|--------|---------|--|--|--|--|--|
| X | 4 | | | | | | |
| Country | Center | Subject | | | | | |

22.1

Page No.

0

Repeat No.

Visit Name: VISIT 1

Date of visit :

(DD-MMM-YYYY)

VISIT_01

VITAL SIGNS

VITAL_02

Data ☒ No Data ☐

DAY 1

*Not Applicable if already done within 8 days prior to inclusion*Date performed
(dd-mmm-yyyy)Weight: kgBlood pressure: Systolic: mmHg / Diastolic: mmHgECOG Performance Status 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐

**A PHYSICAL EXAMINATION SHOULD BE PERFORMED.
IF THERE ARE ANY CLINICALLY SIGNIFICANT CHANGES FROM THE PREVIOUS EXAMINATION,
RECORD AS AN ADVERSE EVENT.**

EFC10547

X 4

Country Center Subject

23.1

Page No.

0

Repeat No.

Visit Name: VISIT 1

HEMATOLOGY

LAB_01

Data ☒ No Data ☐

Not applicable if already done within 8 days prior to infusion.

DAY 1

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit | SI Value | SI Unit | SI Ranges | |
|---------------------------|-------|------------------------|----------|---------|-------------|-------------|
| | | If other unit, specify | | | Lower Limit | Upper Limit |
| HEMOGLOBIN | | G/L | | | | |
| PLATELET COUNT (THROMBOC) | | 10E9/L | | | | |
| WBC | | 10E9/L | | | | |
| NEUTROPHILS | | 10E9/L | | | | |

TO BE PERFORMED ONLY FOR PATIENT UNDER VITAMIN K ANTAGONIST

| | | | | | | |
|-----|--|-------|--|--|--|--|
| INR | | RATIO | | | | |
|-----|--|-------|--|--|--|--|

EFC10547

X 4

Country Center Subject

24.1

Page No.

0

Repeat No.

Visit Name: VISIT 1

BIOCHEMISTRY

LAB_01

Data ☒ No Data ☐

Not applicable if already done within 8 days prior to infusion.

DAY 1

Please indicate if the laboratory is the : Same as baseline ☐

Same as previous ☐

Name
Address
City
Country

For Technical use :

Name
Address
City
Country

EFC10547

X 4 Country Center Subject

24.2

Page No.

0

Repeat No.

Visit Name: VISIT 1

| Date of sampling | (dd-mmm-yyyy) | Unit | SI Ranges | | | |
|-------------------------|---------------|------------------------|-----------|---------|-------------|-------------|
| Test | Value | If other unit, specify | SI Value | SI Unit | Lower Limit | Upper Limit |
| SODIUM | | MMOL/L | | | | |
| CALCIUM | | MMOL/L | | | | |
| POTASSIUM | | MMOL/L | | | | |
| PHOSPHORUS | | MMOL/L | | | | |
| ** BLOOD UREA NITROGEN | | MG/DL | | | | |
| ** UREA | | MMOL/L | | | | |
| MAGNESIUM | | MG/DL | | | | |
| * CREATININE | | UMOL/L | | | | |
| CREATININE CLEARANCE CA | | ML/MIN | | | | |
| GLUCOSE | | MMOL/L | | | | |
| AST | | IU/L | | | | |
| ALT | | IU/L | | | | |
| ALKALINE PHOSPHATASE | | IU/L | | | | |
| TOTAL BILIRUBIN | | MG/DL | | | | |
| TOTAL PROTEINS | | G/DL | | | | |
| ALBUMIN | | G/DL | | | | |

* If creatinine > 1 ULN please report the calculated creatinine clearance.

** If blood Urea Nitrogen is not evaluable, Urea value must be documented.

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

25.1

Page No.

0

Repeat No.

Visit Name: VISIT 1

DIPSTICK URINALYSIS

LABU_1

Data ☒ No Data ☐

Not applicable if already done within 8 days prior to infusion.

DAY 1

Date of sampling

Test name

WHITE BLOOD CELLS (QU)

☐ Absent ☐ + ☐ ++ ☐ +++ ☐ Not evaluable

RED BLOOD CELLS (QUA)

☐ Absent ☐ + ☐ ++ ☐ +++ ☐ Not evaluable

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

26.1

Page No.

0

Repeat No.

Visit Name: VISIT 1

MORNING SPOT URINALYSIS

LAB_01

Data ☒ No Data ☐

Not applicable if already done within 8 days prior to infusion.

DAY 1

Please indicate if the laboratory is the : Same as baseline ☐

Same as previous ☐

Name

Address

City

Country

For Technical use :

Name

Address

City

Country

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit If other unit, specify | SI Value | SI Unit | SI Ranges | |
|--------------------|----------------------|--------------------------------|----------------------|----------------------|----------------------|----------------------|
| | | | | | Lower Limit | Upper Limit |
| PROTEIN (URINE) | <input type="text"/> | MG/DL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| CREATININE (URINE) | <input type="text"/> | MG/DL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

EFC10547

| | | | | | | | |
|---------|--------|---------|--|--|--|--|--|
| X | 4 | | | | | | |
| Country | Center | Subject | | | | | |

970.01.1

Page No.

0

Repeat No.

Visit Name:

VISIT 1

PHARMACOKINETIC BLOOD

PK_01

Data ☒ No Data ☐

TO BE COMPLETED FOR ALL PATIENTS

FREE AND BOUND AFLIBERCEPT

DAY 1

Sample
ID

P00

Theoretical
Time

T0H

*

Sample Date
(dd-mm-yyyy)

Sample Time
24-hour clock

T0h* = Pre-dose - just before the start of Aflibercept/Placebo infusion

EFC10547

X 9

Country Center Subject

1001.01.1

Page No.

0

Repeat No.

Visit Name:

VISIT 1

PHARMACOKINETIC BLOOD

PK_01

Data ☒ No Data ☐

FREE AND BOUND AFLIBERCEPT

DAY 1

Sample
ID

P00

Theoretical
Time

T0H

*

Sample Date
(dd-mm-yyyy)

Sample Time
24-hour clock

T0h* = Pre-dose - just before the start of Aflibercept/Placebo infusion

EFC10547

X 4

Country Center Subject

970.02.1

Page No.

0

Repeat No.

Visit Name: VISIT 1

PHARMACOKINETIC BLOOD

PK_01

Data ☒ No Data ☐

TO BE COMPLETED FOR ALL PATIENTS

ANTI-AFLIBERCEPT ANTIBODIES

DAY 1

Sample
ID

A00

Theoretical
Time

T0H *

Sample Date
(dd-mmm-yyyy)

Sample Time
(24-hour clock)

T0h* = Pre-dose - just before the start of Aflibercept/Placebo infusion

EFC10547

X 9

Country Center Subject

1001.02.1

Page No.

0

Repeat No.

Visit Name:

VISIT 1

PHARMACOKINETIC BLOOD

PK_01

Data ☒ No Data ☐

ANTI-AFLIBERCEPT ANTIBODIES

DAY 1

Theoretical
Time

T0H *

Sample Date
(dd-mmm-yyyy)

Sample Time
(24-hour clock)

T0h* = Pre-dose - just before the start of Aflibercept/Placebo infusion

EFC10547

| | | | | | | | |
|---------|--------|---------|--|--|--|--|--|
| X | 4 | | | | | | |
| Country | Center | Subject | | | | | |

971.01.1

Page No.

0

Repeat No.

Visit Name:

VISIT 1

PHARMACOKINETIC ^{BLOOD}

PK_01

Data ☒ No Data ☐

TO BE COMPLETED ONLY FOR PK PATIENTS

ENDOGENEOUS VEGF

DAY 1

Sample
ID

L00

Theoretical
Time

T0H

*

Date
(dd-mmm-yyyy)

Time
24-hour clock

T0h* = Pre-dose - just before the start of Aflibercept/Placebo infusion

EFC10547

X 9

Country Center Subject

1001.03.1

Page No.

0

Repeat No.

Visit Name:

VISIT 1

PHARMACOKINETIC BLOOD

PK_01

Data ☒ No Data ☐

ENDOGENEOUS VEGF

DAY 1

Theoretical
Time

T0H *

Date
(dd-mmm-yyyy)

Time
24-hour clock

T0h* = Pre-dose - just before the start of Aflibercept/Placebo infusion

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

971.02.1

Page No.

0

Repeat No.

Visit Name:

VISIT 1

PHARMACOKINETIC BLOOD

PK_01

Data ☒ No Data ☐

TO BE COMPLETED ONLY FOR PK PATIENTS.

FREE AND BOUND AFLIBERCEPT

DAY 1

Sample
ID

P01

Theoretical
Time

T1H

*

Sample Date
(dd-mmm-yyyy)

Sample Time
24-hour clock

T1h* = Post-Dose - at the end of the infusion of Aflibercept/Placebo

EFC10547

X 9

Country Center Subject

1001.04.1

Page No.

0

Repeat No.

Visit Name:

VISIT 1

PHARMACOKINETIC BLOOD

PK_01

Data ☒ No Data ☐

FREE AND BOUND AFLIBERCEPT

DAY 1

Sample
ID

P01

Theoretical
Time

T1H

*

Sample Date
(dd-mmm-yyyy)

Sample Time
24-hour clock

T1h* = Post-Dose - at the end of the infusion of Aflibercept/Placebo

EFC10547

X 4 Country Center Subject

27.1

Page No.

0

Repeat No.

Visit Name: VISIT 1

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_05

Data ☒ No Data ☐

AFLIBERCEPT / PLACEBO

| Scheduled Day | Treatment Number | Not Administered/ Taken | Date / Time START | Intended Dose | Actual Dose |
|---------------|------------------|----------------------------|----------------------|---------------|-------------|
| DAY 1 | | <input type="checkbox"/> | (dd-mmm-yyyy) | MG / KG | MG |
| | | | (24-hour clock) | | |
| | | | END | | |
| | | | (24-hour clock) | | |

IF DOSE INTERRUPTED AND READMINISTERED, PLEASE REPORT THE INFORMATION BELOW :

| Scheduled Day | Treatment Number | Not Administered/ Taken | Date / Time START | Intended Dose | Actual Dose |
|---------------|------------------|----------------------------|----------------------|----------------|-------------|
| (*) | | <input type="checkbox"/> | (dd-mmm-yyyy) | MG / KG | MG |
| | | | (24-hour clock) | NOT APPLICABLE | |
| | | | END | | |
| | | | (24-hour clock) | | |

(*) In case of additionnal information, enter "DAY 1" in Scheduled Day

EFC10547

| | | | | | | | |
|---------|--------|---------|--|--|--|--|--|
| X | 5 | | | | | | |
| Country | Center | Subject | | | | | |

28.1

Page No.

0

Repeat No.

Visit Name: VISIT 1

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_04

Data ☒ No Data ☐

GEMCITABINE

| Scheduled Day | Batch Number | Not Administred/ Taken | Date | Intended Dose MG/M2 | Actual Dose MG |
|---------------|--------------|---------------------------|------|------------------------|-------------------|
| DAY 1 | | <input type="checkbox"/> | | | |
| | | | | | |
| | | | | | |

IF DOSE INTERRUPTED AND READMINISTERED, PLEASE REPORT THE INFORMATION BELOW :

| Scheduled Day | Batch Number | Not Administred/ Taken | Date | Intended Dose MG/M2 | Actual Dose MG |
|---------------|--------------|---------------------------|------|------------------------|-------------------|
| | | <input type="checkbox"/> | | NOT APPLICABLE | |
| | | | | | |
| | | | | | |

(*) In case of additionnal information, enter "DAY 1" in Scheduled Day

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

29.1

Page No.

0

Repeat No.

Visit Name:

VISIT 1

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☒ No Data ☐

DAY 1

Outpatient Clinic ☐ Inpatient Clinic ☐

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

30.1

Page No.

0

Repeat No.

Visit Name:

VISIT 1

VITAL SIGNS

VITAL_02

Data ☒ No Data ☐

DAY 8

Date performed
(dd-mmm-yyyy)

Blood pressure: Systolic: mmHg

/ Diastolic: mmHg

ECOG Performance Status 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐

EFC10547

X 4

Country Center Subject

31.1

Page No.

0

Repeat No.

Visit Name: VISIT 1

HEMATOLOGY

LAB_01

Data ☒ No Data ☐

DAY 8

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit If other unit, specify | SI Ranges | | | |
|---------------------------|-------|--------------------------------|-----------|---------|-------------|-------------|
| | | | SI Value | SI Unit | Lower Limit | Upper Limit |
| HEMOGLOBIN | | G/L | | | | |
| PLATELET COUNT (THROMBOC) | | 10E9/L | | | | |
| WBC | | 10E9/L | | | | |
| NEUTROPHILS | | 10E9/L | | | | |

EFC10547

X 5 Country Center Subject

32.1

Page No.

0

Repeat No.

Visit Name: VISIT 1

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_04

Data ☒ No Data ☐

GEMCITABINE

| Scheduled Day | Batch Number | Not Administred/ Taken | Date | Intended Dose MG/M2 | Actual Dose MG |
|---------------|--------------|---------------------------|------|------------------------|-------------------|
| DAY 8 | | <input type="checkbox"/> | | | |

IF DOSE INTERRUPTED AND READMINISTERED, PLEASE REPORT THE INFORMATION BELOW :

| Scheduled Day | Batch Number | Not Administred/ Taken | Date | Intended Dose MG/M2 | Actual Dose MG |
|---------------|--------------|---------------------------|------|------------------------|-------------------|
| | | <input type="checkbox"/> | | NOT APPLICABLE | |

(*) In case of additionnal information, enter "DAY 8" in Scheduled Day

EFC10547

| | | | | | | | | |
|---|---|--|--|--|--|--|--|--|
| X | 4 | | | | | | | |
|---|---|--|--|--|--|--|--|--|

Country Center Subject

33.1

Page No.

0

Repeat No.

Visit Name:

VISIT 1

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☒ No Data ☐

DAY 8

Outpatient Clinic ☐ Inpatient Clinic ☐

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

34.1

Page No.

0

Repeat No.

Visit Name:

VISIT 1

VITAL SIGNS

VITAL_02

Data ☒ No Data ☐

DAY 15

Date performed
(dd-mmm-yyyy)

Weight: kg

Blood pressure: Systolic: mmHg / Diastolic: mmHg

ECOG Performance Status 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐

EFC10547

X 4

Country Center Subject

35.1

Page No.

0

Repeat No.

Visit Name: VISIT 1

HEMATOLOGY

LAB_01

Data ☒ No Data ☐

DAY 15

Date of sampling (dd-mm-yyyy)

| Test | Value | Unit If other unit, specify | SI Ranges | | | |
|---------------------------|----------------------|--------------------------------|----------------------|----------------------|----------------------|----------------------|
| | | | SI Value | SI Unit | Lower Limit | Upper Limit |
| HEMOGLOBIN | <input type="text"/> | G/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| PLATELET COUNT (THROMBOC) | <input type="text"/> | 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| WBC | <input type="text"/> | 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| NEUTROPHILS | <input type="text"/> | 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

EFC10547

| | | | | | | | | |
|---|---|--|--|--|--|--|--|--|
| X | 4 | | | | | | | |
|---|---|--|--|--|--|--|--|--|

Country Center Subject

36.1

Page No.

0

Repeat No.

Visit Name:

VISIT 1

DIPSTICK URINALYSIS

LABU_1

Data ☒ No Data ☐

DAY 15

Date of sampling

Test name

WHITE BLOOD CELLS (QU)

☐ Absent ☐ + ☐ ++ ☐ +++ ☐ Not evaluable

RED BLOOD CELLS (QUA)

☐ Absent ☐ + ☐ ++ ☐ +++ ☐ Not evaluable

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

37.1

Page No.

0

Repeat No.

Visit Name: VISIT 1

MORNING SPOT URINALYSIS

LAB_01

Data ☒ No Data ☐

DAY 15

Please indicate if the laboratory is the : Same as baseline ☐

Same as previous ☐

Name

Address

City

Country

For Technical use :

Name

Address

City

Country

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit If other unit, specify | SI Ranges | | | |
|--------------------|----------------------|--------------------------------|----------------------|----------------------|----------------------|----------------------|
| | | | SI Value | SI Unit | Lower Limit | Upper Limit |
| PROTEIN (URINE) | <input type="text"/> | MG/DL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| CREATININE (URINE) | <input type="text"/> | MG/DL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

EFC10547

X 4

Country Center Subject

972.1

Page No.

0

Repeat No.

Visit Name: VISIT 1

PHARMACOKINETIC BLOOD

PK_01

Data ☒ No Data ☐

TO BE COMPLETED ONLY FOR PK PATIENTS.

FREE AND BOUND AFLIBERCEPT

DAY 15

Sample
ID

P02

Theoretical
Time

T0H *

Sample Date
(dd-mmm-yyyy)

Sample Time
24-hour clock

T0h* = Pre-dose - just before the start of Aflibercept/Placebo infusion

EFC10547

X 4 Country Center Subject

38.1

Page No.

0

Repeat No.

Visit Name: VISIT 1

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_05

Data ☒ No Data ☐

AFLIBERCEPT / PLACEBO

| Scheduled Day | Treatment Number | Not Administered/ Taken | Date / Time* START | Intended Dose MG / KG | Actual Dose MG |
|---------------|------------------|----------------------------|-----------------------|--------------------------|-------------------|
| DAY 15 | | <input type="checkbox"/> | | | |
| | | | (dd-mmm-yyyy) | | |
| | | | (24-hour clock) | | |
| | | | END | | |
| | | | (24-hour clock) | | |

*Time to be given only for PK patients

IF DOSE INTERRUPTED AND READMINISTERED, PLEASE REPORT THE INFORMATION BELOW :

| Scheduled Day | Treatment Number | Not Administered/ Taken | Date / Time* START | Intended Dose MG / KG | Actual Dose MG |
|---------------|------------------|----------------------------|-----------------------|--------------------------|-------------------|
| (*) | | <input type="checkbox"/> | | NOT APPLICABLE | |
| | | | (dd-mmm-yyyy) | | |
| | | | (24-hour clock) | | |
| | | | END | | |
| | | | (24-hour clock) | | |

*Time to be given only for PK patients

(*) In case of additionnal information, enter "DAY 15" in Scheduled Day

EFC10547

X 5 Country Center Subject

39.1

Page No.

0

Repeat No.

Visit Name: VISIT 1

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_04

Data ☒ No Data ☐

GEMCITABINE

| Scheduled Day | Batch Number | Not Administred/ Taken | Date | Intended Dose MG/M2 | Actual Dose MG |
|---------------|--------------|---------------------------|------|------------------------|-------------------|
| DAY 15 | | <input type="checkbox"/> | | | |

IF DOSE INTERRUPTED AND READMINISTERED, PLEASE REPORT THE INFORMATION BELOW :

| Scheduled Day | Batch Number | Not Administred/ Taken | Date | Intended Dose MG/M2 | Actual Dose MG |
|---------------|--------------|---------------------------|------|------------------------|-------------------|
| | | <input type="checkbox"/> | | NOT APPLICABLE | |

(*) In case of additionnal information, enter "DAY 15" in Scheduled Day

EFC10547

| | | | | | | | | |
|---|---|--|--|--|--|--|--|--|
| X | 4 | | | | | | | |
|---|---|--|--|--|--|--|--|--|

Country Center Subject

40.1

Page No.

0

Repeat No.

Visit Name:

VISIT 1

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☒ No Data ☐

DAY 15

Outpatient Clinic ☐ Inpatient Clinic ☐

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

41.1

Page No.

0

Repeat No.

Visit Name:

VISIT 1

VITAL SIGNS

VITAL_02

Data ☒ No Data ☐

DAY 22

Date performed
(dd-mmm-yyyy)

Blood pressure: Systolic: mmHg

/ Diastolic: mmHg

ECOG Performance Status 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐

EFC10547

X 4

Country Center Subject

42.1

Page No.

0

Repeat No.

Visit Name: VISIT 1

HEMATOLOGY

LAB_01

Data ☒ No Data ☐

DAY 22

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit If other unit, specify | SI Ranges | | | |
|---------------------------|-------|--------------------------------|-----------|---------|-------------|-------------|
| | | | SI Value | SI Unit | Lower Limit | Upper Limit |
| HEMOGLOBIN | | G/L | | | | |
| PLATELET COUNT (THROMBOC) | | 10E9/L | | | | |
| WBC | | 10E9/L | | | | |
| NEUTROPHILS | | 10E9/L | | | | |

EFC10547

X 5 Country Center Subject

43.1

Page No.

0

Repeat No.

Visit Name: VISIT 1

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_04

Data ☒ No Data ☐

GEMCITABINE

| Scheduled Day | Batch Number | Not Administred/ Taken | Date | Intended Dose MG/M2 | Actual Dose MG |
|---------------|--------------|---------------------------|------|------------------------|-------------------|
| DAY 22 | | <input type="checkbox"/> | | | |

IF DOSE INTERRUPTED AND READMINISTERED, PLEASE REPORT THE INFORMATION BELOW :

| Scheduled Day | Batch Number | Not Administred/ Taken | Date | Intended Dose MG/M2 | Actual Dose MG |
|---------------|--------------|---------------------------|------|------------------------|-------------------|
| | | <input type="checkbox"/> | | NOT APPLICABLE | |

(*) In case of additionnal information, enter "DAY 22" in Scheduled Day

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

44.1

Page No.

0

Repeat No.

Visit Name:

VISIT 1

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☒ No Data ☐

DAY 22

Outpatient Clinic ☐ Inpatient Clinic ☐

Visit Name: VISIT 1

PAIN INTENSITY

ASSESSED VIA VISUAL ANALOG SCALE

Data ☒ No Data ☐

Data corresponding to current cycle

| Period | Date | Measure |
|--------|------|---------|
| | | MM |
| DAY 1 | | |
| DAY 2 | | |
| DAY 3 | | |
| DAY 4 | | |
| DAY 5 | | |
| DAY 6 | | |
| DAY 7 | | |
| DAY 8 | | |
| DAY 9 | | |
| DAY 10 | | |
| DAY 11 | | |
| DAY 12 | | |
| DAY 13 | | |
| DAY 14 | | |
| DAY 15 | | |
| DAY 16 | | |
| DAY 17 | | |
| DAY 18 | | |
| DAY 19 | | |
| DAY 20 | | |
| DAY 21 | | |

Period Date Measure

| | | |
|--------|--|--|
| DAY 22 | | |
| DAY 23 | | |
| DAY 24 | | |
| DAY 25 | | |
| DAY 26 | | |
| DAY 27 | | |
| DAY 28 | | |
| DAY 29 | | |
| DAY 30 | | |
| DAY 31 | | |
| DAY 32 | | |
| DAY 33 | | |
| DAY 34 | | |
| DAY 35 | | |
| DAY 36 | | |
| DAY 37 | | |
| DAY 38 | | |
| DAY 39 | | |
| DAY 40 | | |
| DAY 41 | | |
| DAY 42 | | |

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

46.1

Page No.

0

Repeat No.

Visit Name: VISIT 1

MEDICATION

ANALGESIC

MED_02

Data ☒ No Data ☐

ANALGESIC MEDICATION SHOULD BE COLLECTED DAILY PRIOR TO THE NEXT INFUSION

| Drug/Medication (Brand or generic name) | Dosage (Total daily dose) | Units | Route | Start Date (dd-mmm-yyyy) | Previously reported | End Date (dd-mmm-yyyy) | Ongoing |
|--|------------------------------|-------|-------|-----------------------------|--------------------------|---------------------------|--------------------------|
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |

EFC10547

X 4

Country Center Subject

46.2

Page No.

0

Repeat No.

Visit Name: VISIT 1

| Drug/Medication (Brand or generic name) | Dosage (Total daily dose) | Units | Route | Start Date (dd-mmm-yyyy) | Previously reported | End Date (dd-mmm-yyyy) | Ongoing |
|--|------------------------------|-------|-------|-----------------------------|--------------------------|---------------------------|--------------------------|
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |

EFC10547

X 4

Country Center Subject

46.3

Page No.

0

Repeat No.

Visit Name: VISIT 1

| Drug/Medication (Brand or generic name) | Dosage (Total daily dose) | Units | Route | Start Date (dd-mmm-yyyy) | Previously reported | End Date (dd-mmm-yyyy) | Ongoing |
|--|------------------------------|-------|-------|-----------------------------|--------------------------|---------------------------|--------------------------|
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |

TUMOR MEASUREMENTS

TUMEA_02

Data ☒ No Data ☐

| Lesion Number | Lesion Location | Date of Assessment (dd-mmm-yyyy) | Method of Tumor Measurement | Measurement of Target Lesion longest diameter | Response of Non target Lesions |
|----------------------|----------------------|---|-----------------------------|--|--------------------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |

EFC10547

X 4

Country Center Subject

47.2

Page No.

0

Repeat No.

Visit Name: VISIT 1

| Lesion Number | Lesion Location | Date of Assessment (dd-mm-yyyy) | Method of Tumor Measurement | Measurement of Target Lesion longest diameter | Response of Non target Lesions |
|----------------------|----------------------|---|-----------------------------|---|--------------------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |

EFC10547

X 4

Country Center Subject

48.1

Page No.

0

Repeat No.

Visit Name:

VISIT 1

TUMOR MARKERS

TMARK_01

Data ☒ No Data ☐

Date of evaluation

(dd-mmm-yyyy)

| TEST | VALUE | UNIT | NORMAL RANGE | |
|--------|-------|------|--------------|-------------|
| | | | LOWER LIMIT | UPPER LIMIT |
| CA19-9 | | | | |

CLINICAL EVENT THROMBOVASCULAR

Data ☒ No Data ☐

ANGINA PECTORIS / UNSTABLE ANGINA / MYOCARDIAL INFARCTION

Yes No

☐
☐

STROKE / TRANSIENT ISCHEMIC ATTACK

☐
☐

PERIPHERAL ARTERIAL THROMBOSIS

☐
☐

DEEP VENOUS THROMBOSIS

☐
☐

PULMONARY EMBOLISM

☐
☐

INTRAABDOMINAL ARTERIAL THROMBOSIS

☐
☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐
☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐
☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐
☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐
☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐
☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐
☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐
☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐
☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐
☐

Visit Name: VISIT 1 AE

ADVERSE EVENT

AE Form Number

AE_03

Data ☒ No Data ☐

AE Reference ID

1. Adverse Event (Diagnosis) :

2. Status of Adverse Event

New ☐ Date of Start
(dd-mmm-yyyy)

Ongoing without change ☐ (do not complete the remaining items)

Ongoing with change ☐

3. Grade

1 ☐ 2 ☐ 3 ☐ 4 ☐

4. Relationship to investigational product *

Yes ☐ No ☐

5. Action Taken with Investigat. Product

None ☐ Permanently discontinued ☐ Delayed ☐ Dose reduced ☐ Delayed and reduced ☐ Interrupted ☐

6. Corrective treatment/therapy

Yes ☐ No ☐

7. Outcome

Recovered ☐ Date of Recovery
(dd-mmm-yyyy)

Recovered with sequelae ☐ Specify : _____

Recovering ☐

Not recovered ☐

Fatal ☐ Date of Death (complete the death report form)
(dd-mmm-yyyy)

Unknown ☐

8. Seriousness Criteria

Yes ☐ No ☐ If Yes : -Date event became serious
(dd-mmm-yyyy)

IF YES, COMPLETE THIS SECTION AND THE SAFETY COMPLEMENTARY FORM

-Tick below all criteria that apply :

| | | | |
|--------------------------------------|--------------------------|--|--------------------------|
| Results in Death | <input type="checkbox"/> | Persistent/significant disability/incapacity | <input type="checkbox"/> |
| Life Threatening | <input type="checkbox"/> | Congenital anomaly or Birth Defect | <input type="checkbox"/> |
| Requires or prolongs hospitalization | <input type="checkbox"/> | Other medically important event | <input type="checkbox"/> |

9. Is it an event such as :

Overdose of the IP

Yes ☐ No ☐

Pregnancy

Yes ☐ No ☐

*Is there a reasonable possibility that the AE was caused by Investigational Product?

EFC10547

| | | | | | | | |
|---------|--------|---------|--|--|--|--|--|
| X | 4 | | | | | | |
| Country | Center | Subject | | | | | |

601.2

Page No.

0

Repeat No.

Visit Name: VISIT 1 AE

SAFETY COMPLEMENTARY FORM

SAEC_03

AE / Specific Event Form Number

1. Demographic Information

Weight (kg)

2. Detailed Description of the Adverse Event *(including complementary investigations)*

3. Date of Start of Event (Initial date of onset of the considered event) (DD-MMM-YYYY)

4. Investigational Products

Date of the FIRST administration of study treatment : (DD-MMM-YYYY)

Current Treatment number :

Current Cycle :

Date of the LAST administration before SAE : (dd-mmm-yyyy)

Last Dosage before SAE :

Action Taken :

AFLIBERCEPT/PLACEBO

GEMCITABINE

MG/KG

MG/M2

5. In case of hospitalization Date of admission (DD-MMM-YYYY) *(hospital report to be sent)*

6. In case of death Autopsy report Yes ☐ No ☐ *(copy to be sent)*

7. Corrective Treatment / Therapy

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

701.01.1

Page No.

0

Repeat No.

Visit Name: VISIT 1 LAB

ADDITIONAL HEMATOLOGY

LAB_01

Data ☒ No Data ☐

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit | SI Value | SI Unit | SI Ranges | |
|---------------------------|----------------------|-----------------------------|----------------------|----------------------|----------------------|----------------------|
| | | If other unit, specify | | | Lower Limit | Upper Limit |
| HEMOGLOBIN | <input type="text"/> | <input type="text"/> G/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| PLATELET COUNT (THROMBOC) | <input type="text"/> | <input type="text"/> 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| WBC | <input type="text"/> | <input type="text"/> 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| NEUTROPHILS | <input type="text"/> | <input type="text"/> 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

TO BE PERFORMED ONLY FOR PATIENT UNDER VITAMIN K ANTAGONIST

| | | | | | | |
|-----|----------------------|----------------------------|----------------------|----------------------|----------------------|----------------------|
| INR | <input type="text"/> | <input type="text"/> RATIO | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
|-----|----------------------|----------------------------|----------------------|----------------------|----------------------|----------------------|

Visit Name: VISIT 1 LAB

ADDITIONAL BIOCHEMISTRY

LAB_01

Data ☒ No Data ☐

Please indicate if the laboratory is the : Same as baseline ☐

Same as previous ☐

Name

Address

City

Country

For Technical use :

Name

Address

City

Country

EFC10547

X 4 Country Center Subject

701.02.2

Page No.

0

Repeat No.

Visit Name: VISIT 1 LAB

| Date of sampling | (dd-mm-yyyy) | Unit | SI Ranges | | | |
|-------------------------|--------------|------------------------|-----------|---------|-------------|-------------|
| Test | Value | If other unit, specify | SI Value | SI Unit | Lower Limit | Upper Limit |
| SODIUM | | MMOL/L | | | | |
| CALCIUM | | MMOL/L | | | | |
| POTASSIUM | | MMOL/L | | | | |
| PHOSPHORUS | | MMOL/L | | | | |
| ** BLOOD UREA NITROGEN | | MG/DL | | | | |
| ** UREA | | MMOL/L | | | | |
| MAGNESIUM | | MG/DL | | | | |
| * CREATININE | | UMOL/L | | | | |
| CREATININE CLEARANCE CA | | ML/MIN | | | | |
| GLUCOSE | | MMOL/L | | | | |
| AST | | IU/L | | | | |
| ALT | | IU/L | | | | |
| ALKALINE PHOSPHATASE | | IU/L | | | | |
| TOTAL BILIRUBIN | | MG/DL | | | | |
| TOTAL PROTEINS | | G/DL | | | | |
| ALBUMIN | | G/DL | | | | |

* If creatinine > 1 ULN please report the calculated creatinine clearance.

** If blood Urea Nitrogen is not evaluable, Urea value must be documented.

EFC10547

| | | | | | | | |
|---------|--------|---------|--|--|--|--|--|
| X | 4 | | | | | | |
| Country | Center | Subject | | | | | |

701.03.1

Page No.

0

Repeat No.

Visit Name: VISIT 1 LAB

ADDITIONAL DIPSTICK URINALYSIS

LABU_1

Data ☒ No Data ☐

Date of sampling

Test name

WHITE BLOOD CELLS (QU)

☐ Absent ☐ + ☐ ++ ☐ +++ ☐ Not evaluable

RED BLOOD CELLS (QUAL)

☐ Absent ☐ + ☐ ++ ☐ +++ ☐ Not evaluable

ADDITIONAL MORNING SPOT URINALYSIS

LAB_01

Data ☒ No Data ☐

Please indicate if the laboratory is the : Same as baseline ☐
Same as previous ☐

| | |
|---------|----------------------|
| Name | <input type="text"/> |
| Address | <input type="text"/> |
| City | <input type="text"/> |
| Country | <input type="text"/> |

| For Technical use : | |
|---------------------|----------------------|
| Name | <input type="text"/> |
| Address | <input type="text"/> |
| City | <input type="text"/> |
| Country | <input type="text"/> |

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit If other unit, specify | SI Value | SI Unit | SI Ranges | |
|--------------------|----------------------|--------------------------------|----------------------|----------------------|----------------------|----------------------|
| | | | | | Lower Limit | Upper Limit |
| PROTEIN (URINE) | <input type="text"/> | MG/DL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| CREATININE (URINE) | <input type="text"/> | MG/DL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

24-HOUR URINALYSIS

TO BE COMPLETED IF UPCR > 1

LAB_04

Data ☒ No Data ☐

Please indicate if the laboratory is the Same as baseline ☐
Same as previous ☐

| | |
|---------|--|
| Name | |
| Address | |
| City | |
| Country | |

| | |
|---------------------|--|
| For Technical use : | |
| Name | |
| Address | |
| City | |
| Country | |

Date (dd-mmm-yyyy) (24-hour clock)

Start date of collection: Start Time of collection :

End date of collection: End Time of collection :

| Test | Value | Unit |
|------------------|----------------------|------|
| URINARY VOLUME | <input type="text"/> | L |
| PROTEIN (URINE) | <input type="text"/> | G/L |
| CREATININE (URIN | <input type="text"/> | G/L |

| SI RANGES | | | |
|----------------------|----------------------|----------------------|----------------------|
| SI Value | SI Unit | Lower limit | Upper Limit |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

ELECTROPHORESIS

| | | |
|------------------|----------------------|-----|
| ALBUMIN | <input type="text"/> | G/L |
| ALPHA 1 GLOBULIN | <input type="text"/> | G/L |
| ALPHA 2 GLOBULIN | <input type="text"/> | G/L |
| BETA GLOBULIN | <input type="text"/> | G/L |
| GAMMA GLOBULIN | <input type="text"/> | G/L |

| | | | |
|----------------------|----------------------|----------------------|----------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

EFC10547

| | | | | | | | | |
|---|---|--|--|--|--|--|--|--|
| X | 4 | | | | | | | |
|---|---|--|--|--|--|--|--|--|

Country Center Subject

701.05.2

Page No.

0

Repeat No.

Visit Name: VISIT 1 LAB

Is there any Hemoglobin or RBC in 24 Hour urine sample ?

LABU_1

Data ☒ No Data ☐

Test name

Negative

Positive

HEMOGLOBIN (QUALITAT

☐☐

RED BLOOD CELLS (QUA

☐☐

Visit Name: VISIT 1 LAB

TO BE COMPLETED IF PROTEINURIA IS ASSOCIATED WITH HEMATURIA.**ADDITIONAL HEMATOLOGY**

LABU_1

Data ☒ No Data ☐Date of sampling

Test name

Unit

Negative

Positive

SCHISTOCYTES (QUALITA

NONE

☐☐

EFC10547

| | | | | | | | |
|---------|--------|---------|--|--|--|--|--|
| X | 4 | | | | | | |
| Country | Center | Subject | | | | | |

701.06.2

Page No.

0

Repeat No.

Visit Name: VISIT 1 LAB

ADDITIONAL BIOCHEMISTRY

LAB_01

Data ☒ No Data ☐

Please indicate if the laboratory is the : Same as baseline ☐
Same as previous ☐

| | |
|---------|--|
| Name | |
| Address | |
| City | |
| Country | |

| For Technical use : | |
|---------------------|--|
| Name | |
| Address | |
| City | |
| Country | |

| Date of sampling | (dd-mmm-yyyy) | Unit | SI Ranges | | | |
|------------------|---------------|------------------------|-----------|---------|-------------|-------------|
| Test | Value | If other unit, specify | SI Value | SI Unit | Lower Limit | Upper Limit |
| LDH | | IU/L | | | | |
| HAPTOGLOBIN | | G/L | | | | |
| OROSOMUCOID | | G/L | | | | |

EFC10547

| | | | | | | | |
|---------|--------|---------|--|--|--|--|--|
| X | 4 | | | | | | |
| Country | Center | Subject | | | | | |

50.1

Page No.

0

Repeat No.

Visit Name: VISIT 2

Date of visit :

(DD-MMM-YYYY)

VISIT_01

VITAL SIGNS

VITAL_02

Data ☒ No Data ☐

DAY 1

Date performed
(dd-mmm-yyyy)

Weight: kg

Blood pressure: Systolic: mmHg / Diastolic: mmHg

ECOG Performance Status 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐

A PHYSICAL EXAM SHOULD BE PERFORMED.

IF THERE ARE ANY CLINICALLY SIGNIFICANT CHANGES FROM THE PREVIOUS EXAM,

RECORD AS AN ADVERSE EVENT

EFC10547

X 4

Country Center Subject

51.1

Page No.

0

Repeat No.

Visit Name: VISIT 2

HEMATOLOGY

LAB_01

Data ☒ No Data ☐

DAY 1

Date of sampling (dd-mm-yyyy)

| Test | Value | Unit | SI Ranges | | | |
|---------------------------|-------|------------------------|-----------|---------|-------------|-------------|
| | | If other unit, specify | SI Value | SI Unit | Lower Limit | Upper Limit |
| HEMOGLOBIN | | G/L | | | | |
| PLATELET COUNT (THROMBOC) | | 10E9/L | | | | |
| WBC | | 10E9/L | | | | |
| NEUTROPHILS | | 10E9/L | | | | |

TO BE PERFORMED ONLY FOR PATIENT UNDER VITAMIN K ANTAGONIST

| | | | | | | |
|-----|--|-------|--|--|--|--|
| INR | | RATIO | | | | |
|-----|--|-------|--|--|--|--|

EFC10547

| | | | | | | | | |
|---------|--------|---------|--|--|--|--|--|--|
| X | 4 | | | | | | | |
| Country | Center | Subject | | | | | | |

52.1

Page No.

0

Repeat No.

Visit Name: VISIT 2

BIOCHEMISTRY

LAB_01

Data ☒ No Data ☐

DAY 1

Please indicate if the laboratory is the : Same as baseline ☐
Same as previous ☐

| | |
|---------|--|
| Name | |
| Address | |
| City | |
| Country | |

For Technical use :

| | |
|---------|--|
| Name | |
| Address | |
| City | |
| Country | |

EFC10547

X 4

Country Center Subject

52.2

Page No.

0

Repeat No.

Visit Name: VISIT 2

| Date of sampling | (dd-mmm-yyyy) | Unit | SI Ranges | | | |
|-------------------------|---------------|------------------------|-----------|---------|-------------|-------------|
| Test | Value | If other unit, specify | SI Value | SI Unit | Lower Limit | Upper Limit |
| SODIUM | | MMOL/L | | | | |
| CALCIUM | | MMOL/L | | | | |
| POTASSIUM | | MMOL/L | | | | |
| PHOSPHORUS | | MMOL/L | | | | |
| ** BLOOD UREA NITROGEN | | MG/DL | | | | |
| ** UREA | | MMOL/L | | | | |
| MAGNESIUM | | MG/DL | | | | |
| * CREATININE | | UMOL/L | | | | |
| CREATININE CLEARANCE CA | | ML/MIN | | | | |
| GLUCOSE | | MMOL/L | | | | |
| AST | | IU/L | | | | |
| ALT | | IU/L | | | | |
| ALKALINE PHOSPHATASE | | IU/L | | | | |
| TOTAL BILIRUBIN | | MG/DL | | | | |
| TOTAL PROTEINS | | G/DL | | | | |
| ALBUMIN | | G/DL | | | | |

* If creatinine > 1 ULN please report the calculated creatinine clearance.

** If blood Urea Nitrogen is not evaluable, Urea value must be documented.

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

53.1

Page No.

0

Repeat No.

Visit Name:

VISIT 2

DIPSTICK URINALYSIS

LABU_1

Data ☒ No Data ☐

DAY 1

Date of sampling

Test name

WHITE BLOOD CELLS (QU)

☐ Absent ☐ + ☐ ++ ☐ +++ ☐ Not evaluable

RED BLOOD CELLS (QUA)

☐ Absent ☐ + ☐ ++ ☐ +++ ☐ Not evaluable

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

54.1

Page No.

0

Repeat No.

Visit Name: VISIT 2

MORNING SPOT URINALYSIS

LAB_01

Data ☒ No Data ☐

DAY 1

Please indicate if the laboratory is the : Same as baseline ☐

Same as previous ☐

Name

Address

City

Country

For Technical use :

Name

Address

City

Country

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit If other unit, specify | SI Ranges | | | |
|--------------------|----------------------|--------------------------------|----------------------|----------------------|----------------------|----------------------|
| | | | SI Value | SI Unit | Lower Limit | Upper Limit |
| PROTEIN (URINE) | <input type="text"/> | MG/DL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| CREATININE (URINE) | <input type="text"/> | MG/DL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

EFC10547

X 9

Country Center Subject

1002.01.1

Page No.

0

Repeat No.

Visit Name:

VISIT 2

PHARMACOKINETIC BLOOD

PK_01

Data ☒ No Data ☐

FREE AND BOUND AFLIBERCEPT

DAY 1

Theoretical
Time

T0H *

Sample Date
(dd-mmm-yyyy)

Sample Time
24-hour clock

T0h* = Pre-dose - just before the start of Aflibercept/Placebo infusion

EFC10547

X 9

Country Center Subject

1002.02.1

Page No.

0

Repeat No.

Visit Name:

VISIT 2

PHARMACOKINETIC BLOOD

PK_01

Data ☒ No Data ☐

ANTI-AFLIBERCEPT ANTIBODIES

DAY 1

Theoretical
Time

T0H *

Sample Date
(dd-mm-yyyy)

Sample Time
(24-hour clock)

T0h* = Pre-dose - just before the start of Aflibercept/Placebo infusion

EFC10547

X 4 Country Center Subject

55.1

Page No.

0

Repeat No.

Visit Name: VISIT 2

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_05

Data ☒ No Data ☐

AFLIBERCEPT / PLACEBO

| Scheduled Day | Treatment Number | Not Administered/ Taken | Date / Time* START | Intended Dose MG / KG | Actual Dose MG |
|---------------|------------------|----------------------------|-----------------------|--------------------------|-------------------|
| DAY 1 | | <input type="checkbox"/> | (dd-mmm-yyyy) | | |
| | | | (24-hour clock) | | |
| | | | END | | |
| | | | (24-hour clock) | | |

*Time to be given only for PK patients

IF DOSE INTERRUPTED AND READMINISTERED, PLEASE REPORT THE INFORMATION BELOW :

| Scheduled Day | Treatment Number | Not Administered/ Taken | Date / Time* START | Intended Dose MG / KG | Actual Dose MG |
|---------------|------------------|----------------------------|-----------------------|--------------------------|-------------------|
| (*) | | <input type="checkbox"/> | (dd-mmm-yyyy) | NOT APPLICABLE | |
| | | | (24-hour clock) | | |
| | | | END | | |
| | | | (24-hour clock) | | |

*Time to be given only for PK patients

(*) In case of additionnal information, enter "DAY 1" in Scheduled Day

EFC10547

X 4
Country Center Subject

56.1

Page No.

0

Repeat No.

Visit Name: VISIT 2

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_04

Data ☒ No Data ☐

GEMCITABINE

| Scheduled Day | Batch Number | Not Administred/ Taken | Date | Intended Dose MG/M2 | Actual Dose MG |
|---------------|----------------------|---------------------------|----------------------|------------------------|----------------------|
| DAY 1 | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| | <input type="text"/> | | | | |
| | <input type="text"/> | | | | |

IF DOSE INTERRUPTED AND READMINISTERED, PLEASE REPORT THE INFORMATION BELOW :

| Scheduled Day | Batch Number | Not Administred/ Taken | Date | Intended Dose MG/M2 | Actual Dose MG |
|--------------------------|----------------------|---------------------------|----------------------|------------------------|----------------------|
| <input type="text"/> (*) | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | NOT APPLICABLE | <input type="text"/> |
| | <input type="text"/> | | | | |
| | <input type="text"/> | | | | |

(*) In case of additionnal information, enter "DAY 1" in Scheduled Day

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

57.1

Page No.

0

Repeat No.

Visit Name:

VISIT 2

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☒ No Data ☐

DAY 1

Outpatient Clinic ☐ Inpatient Clinic ☐

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

58.1

Page No.

0

Repeat No.

Visit Name:

VISIT 2

VITAL SIGNS

VITAL_02

Data ☒ No Data ☐

DAY 8

Date performed
(dd-mmm-yyyy)

Blood pressure: Systolic: mmHg

/ Diastolic: mmHg

ECOG Performance Status 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐

EFC10547

X 4

Country Center Subject

59.1

Page No.

0

Repeat No.

Visit Name: VISIT 2

HEMATOLOGY

LAB_01

Data ☒ No Data ☐

DAY 8

Date of sampling (dd-mm-yyyy)

| Test | Value | Unit If other unit, specify | SI Ranges | | | |
|---------------------------|-------|--------------------------------|-----------|---------|-------------|-------------|
| | | | SI Value | SI Unit | Lower Limit | Upper Limit |
| HEMOGLOBIN | | G/L | | | | |
| PLATELET COUNT (THROMBOC) | | 10E9/L | | | | |
| WBC | | 10E9/L | | | | |
| NEUTROPHILS | | 10E9/L | | | | |

EFC10547

X 4
Country Center Subject

60.1

Page No.

0

Repeat No.

Visit Name: VISIT 2

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_04

Data ☒ No Data ☐

GEMCITABINE

| Scheduled Day | Batch Number | Not Administred/ Taken | Date | Intended Dose MG/M2 | Actual Dose MG |
|---------------|--------------|---------------------------|------|------------------------|-------------------|
| DAY 8 | | <input type="checkbox"/> | | | |

IF DOSE INTERRUPTED AND READMINISTERED, PLEASE REPORT THE INFORMATION BELOW :

| Scheduled Day | Batch Number | Not Administred/ Taken | Date | Intended Dose MG/M2 | Actual Dose MG |
|---------------|--------------|---------------------------|------|------------------------|-------------------|
| | | <input type="checkbox"/> | | NOT APPLICABLE | |

(*) In case of additionnal information, enter "DAY 8" in Scheduled Day

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

61.1

Page No.

0

Repeat No.

Visit Name:

VISIT 2

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☒ No Data ☐

DAY 8

Outpatient Clinic ☐ Inpatient Clinic ☐

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

62.1

Page No.

0

Repeat No.

Visit Name:

VISIT 2

VITAL SIGNS

VITAL_02

Data ☒ No Data ☐

DAY 15

Date performed
(dd-mmm-yyyy)

Weight: kg

Blood pressure: Systolic: mmHg / Diastolic: mmHg

ECOG Performance Status 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐

EFC10547

X 4

Country Center Subject

63.1

Page No.

0

Repeat No.

Visit Name: VISIT 2

HEMATOLOGY

LAB_01

Data ☒ No Data ☐

DAY 15

Date of sampling (dd-mm-yyyy)

| Test | Value | Unit If other unit, specify | SI Ranges | | | |
|---------------------------|-------|--------------------------------|-----------|---------|-------------|-------------|
| | | | SI Value | SI Unit | Lower Limit | Upper Limit |
| HEMOGLOBIN | | G/L | | | | |
| PLATELET COUNT (THROMBOC) | | 10E9/L | | | | |
| WBC | | 10E9/L | | | | |
| NEUTROPHILS | | 10E9/L | | | | |

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

64.1

Page No.

0

Repeat No.

Visit Name:

VISIT 2

DIPSTICK URINALYSIS

LABU_1

Data ☒ No Data ☐

DAY 15

Date of sampling

Test name

WHITE BLOOD CELLS (QU)

☐ Absent ☐ + ☐ ++ ☐ +++ ☐ Not evaluable

RED BLOOD CELLS (QUA)

☐ Absent ☐ + ☐ ++ ☐ +++ ☐ Not evaluable

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

65.1

Page No.

0

Repeat No.

Visit Name: VISIT 2

MORNING SPOT URINALYSIS

LAB_01

Data ☒ No Data ☐

DAY 15

Please indicate if the laboratory is the : Same as baseline ☐

Same as previous ☐

Name

Address

City

Country

For Technical use :

Name

Address

City

Country

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit If other unit, specify | SI Ranges | | | |
|--------------------|----------------------|--------------------------------|----------------------|----------------------|----------------------|----------------------|
| | | | SI Value | SI Unit | Lower Limit | Upper Limit |
| PROTEIN (URINE) | <input type="text"/> | MG/DL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| CREATININE (URINE) | <input type="text"/> | MG/DL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

EFC10547

X 4 Country Center Subject

66.1

Page No.

0

Repeat No.

Visit Name: VISIT 2

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_05

Data ☒ No Data ☐

AFLIBERCEPT / PLACEBO

| Scheduled Day | Treatment Number | Not Administered/ Taken | Date / Time* START | Intended Dose | Actual Dose |
|---------------|------------------|----------------------------|-----------------------|---------------|-------------|
| DAY 15 | | <input type="checkbox"/> | (dd-mmm-yyyy) | MG / KG | MG |
| | | | (24-hour clock) | | |
| | | | END | | |
| | | | (24-hour clock) | | |

*Time to be given only for PK patients

IF DOSE INTERRUPTED AND READMINISTERED, PLEASE REPORT THE INFORMATION BELOW :

| Scheduled Day | Treatment Number | Not Administered/ Taken | Date / Time* START | Intended Dose | Actual Dose |
|---------------|------------------|----------------------------|-----------------------|----------------|-------------|
| (*) | | <input type="checkbox"/> | (dd-mmm-yyyy) | MG / KG | MG |
| | | | (24-hour clock) | NOT APPLICABLE | |
| | | | END | | |
| | | | (24-hour clock) | | |

*Time to be given only for PK patients

(*) In case of additionnal information, enter "DAY 15" in Scheduled Day

EFC10547

X 4
Country Center Subject

67.1

Page No.

0

Repeat No.

Visit Name: VISIT 2

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_04

Data ☒ No Data ☐

GEMCITABINE

| Scheduled Day | Batch Number | Not Administred/ Taken | Date | Intended Dose MG/M2 | Actual Dose MG |
|---------------|----------------------|---------------------------|----------------------|------------------------|----------------------|
| DAY 15 | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| | <input type="text"/> | | | | |
| | <input type="text"/> | | | | |

IF DOSE INTERRUPTED AND READMINISTERED, PLEASE REPORT THE INFORMATION BELOW :

| Scheduled Day | Batch Number | Not Administred/ Taken | Date | Intended Dose MG/M2 | Actual Dose MG |
|--------------------------|----------------------|---------------------------|----------------------|------------------------|----------------------|
| <input type="text"/> (*) | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | NOT APPLICABLE | <input type="text"/> |
| | <input type="text"/> | | | | |
| | <input type="text"/> | | | | |

(*) In case of additionnal information, enter "DAY 15" in Scheduled Day

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

68.1

Page No.

0

Repeat No.

Visit Name:

VISIT 2

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☒ No Data ☐

DAY 15

Outpatient Clinic ☐ Inpatient Clinic ☐

Visit Name: VISIT 2

PAIN INTENSITY

ASSESSED VIA VISUAL ANALOG SCALE

Data ☒ No Data ☐

Data corresponding to current cycle

| Period | Date | Measure |
|--------|------|---------|
| | | MM |
| DAY 1 | | |
| DAY 2 | | |
| DAY 3 | | |
| DAY 4 | | |
| DAY 5 | | |
| DAY 6 | | |
| DAY 7 | | |
| DAY 8 | | |
| DAY 9 | | |
| DAY 10 | | |
| DAY 11 | | |
| DAY 12 | | |
| DAY 13 | | |
| DAY 14 | | |
| DAY 15 | | |
| DAY 16 | | |
| DAY 17 | | |
| DAY 18 | | |
| DAY 19 | | |
| DAY 20 | | |
| DAY 21 | | |

Period Date Measure

| | | |
|--------|--|--|
| DAY 22 | | |
| DAY 23 | | |
| DAY 24 | | |
| DAY 25 | | |
| DAY 26 | | |
| DAY 27 | | |
| DAY 28 | | |
| DAY 29 | | |
| DAY 30 | | |
| DAY 31 | | |
| DAY 32 | | |
| DAY 33 | | |
| DAY 34 | | |
| DAY 35 | | |
| DAY 36 | | |
| DAY 37 | | |
| DAY 38 | | |
| DAY 39 | | |
| DAY 40 | | |
| DAY 41 | | |
| DAY 42 | | |

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

70.1

Page No.

0

Repeat No.

Visit Name: VISIT 2

MEDICATION

ANALGESIC

MED_02

Data ☒ No Data ☐

ANALGESIC MEDICATION SHOULD BE COLLECTED DAILY PRIOR TO THE NEXT INFUSION

| Drug/Medication (Brand or generic name) | Dosage (Total daily dose) | Units | Route | Start Date (dd-mmm-yyyy) | Previously reported | End Date (dd-mmm-yyyy) | Ongoing |
|--|------------------------------|-------|-------|-----------------------------|--------------------------|---------------------------|--------------------------|
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |

EFC10547

X 4

Country Center Subject

70.2

Page No.

0

Repeat No.

Visit Name: VISIT 2

| Drug/Medication (Brand or generic name) | Dosage (Total daily dose) | Units | Route | Start Date (dd-mmm-yyyy) | Previously reported | End Date (dd-mmm-yyyy) | Ongoing |
|--|------------------------------|-------|-------|-----------------------------|--------------------------|---------------------------|--------------------------|
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |

EFC10547

X 4

Country Center Subject

70.3

Page No.

0

Repeat No.

Visit Name: VISIT 2

| Drug/Medication (Brand or generic name) | Dosage (Total daily dose) | Units | Route | Start Date (dd-mmm-yyyy) | Previously reported | End Date (dd-mmm-yyyy) | Ongoing |
|--|------------------------------|-------|-------|-----------------------------|--------------------------|---------------------------|--------------------------|
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |

TUMOR MEASUREMENTS

TUMEA_02

Data ☒ No Data ☐

| Lesion Number | Lesion Location | Date of Assessment (dd-mmm-yyyy) | Method of Tumor Measurement | Measurement of Target Lesion longest diameter | Response of Non target Lesions |
|----------------------|----------------------|---|-----------------------------|--|--------------------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |

| Lesion Number | Lesion Location | Date of Assessment (dd-mmm-yyyy) | Method of Tumor Measurement | Measurement of Target Lesion longest diameter | Response of Non target Lesions |
|----------------------|----------------------|---|-----------------------------------|---|--------------------------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

72.1

Page No.

0

Repeat No.

Visit Name:

VISIT 2

TUMOR MARKERS

TMARK_01

Data ☒ No Data ☐

Date of evaluation

(dd-mmm-yyyy)

| TEST | VALUE | UNIT | NORMAL RANGE | |
|--------|-------|------|--------------|-------------|
| | | | LOWER LIMIT | UPPER LIMIT |
| CA19-9 | | | | |

CLINICAL EVENT THROMBOVASCULAR

Data ☒ No Data ☐

ANGINA PECTORIS / UNSTABLE ANGINA / MYOCARDIAL INFARCTION

Yes No

☐
☐

STROKE / TRANSIENT ISCHEMIC ATTACK

☐
☐

PERIPHERAL ARTERIAL THROMBOSIS

☐
☐

DEEP VENOUS THROMBOSIS

☐
☐

PULMONARY EMBOLISM

☐
☐

INTRAABDOMINAL ARTERIAL THROMBOSIS

☐
☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐
☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐
☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐
☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐
☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐
☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐
☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐
☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐
☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐
☐

Visit Name: VISIT 2 AE

ADVERSE EVENT

AE Form Number

AE_03

Data ☒ No Data ☐

AE Reference ID

1. Adverse Event (Diagnosis) :

2. Status of Adverse Event

New ☐ Date of Start
(dd-mmm-yyyy)

Ongoing without change ☐ (do not complete the remaining items)

Ongoing with change ☐

3. Grade

1 ☐ 2 ☐ 3 ☐ 4 ☐

4. Relationship to investigational product *

Yes ☐ No ☐

5. Action Taken with Investigat. Product

None ☐ Permanently discontinued ☐ Delayed ☐ Dose reduced ☐ Delayed and reduced ☐ Interrupted ☐

6. Corrective treatment/therapy

Yes ☐ No ☐

7. Outcome

Recovered ☐ Date of Recovery
(dd-mmm-yyyy)

Recovered with sequelae ☐ Specify : _____

Recovering ☐

Not recovered ☐

Fatal ☐ Date of Death (complete the death report form)
(dd-mmm-yyyy)

Unknown ☐

8. Seriousness Criteria

Yes ☐ No ☐ If Yes : -Date event became serious
(dd-mmm-yyyy)

IF YES, COMPLETE THIS SECTION AND THE SAFETY COMPLEMENTARY FORM

-Tick below all criteria that apply :

| | | | |
|--------------------------------------|--------------------------|--|--------------------------|
| Results in Death | <input type="checkbox"/> | Persistent/significant disability/incapacity | <input type="checkbox"/> |
| Life Threatening | <input type="checkbox"/> | Congenital anomaly or Birth Defect | <input type="checkbox"/> |
| Requires or prolongs hospitalization | <input type="checkbox"/> | Other medically important event | <input type="checkbox"/> |

9. Is it an event such as :

Overdose of the IP

Yes ☐ No ☐

Pregnancy

Yes ☐ No ☐

*Is there a reasonable possibility that the AE was caused by Investigational Product?

EFC10547

X 4
Country Center Subject

602.2

Page No.

0

Repeat No.

Visit Name: VISIT 2 AE

SAFETY COMPLEMENTARY FORM

SAEC_03

AE / Specific Event Form Number

1. Demographic Information

Weight (kg)

2. Detailed Description of the Adverse Event *(including complementary investigations)*

3. Date of Start of Event (Initial date of onset of the considered event) (DD-MMM-YYYY)

4. Investigational Products

Date of the FIRST administration of study treatment : (DD-MMM-YYYY)

Current Treatment number :

Current Cycle :

Date of the LAST administration before SAE : (dd-mmm-yyyy)

Last Dosage before SAE :

Action Taken :

AFLIBERCEPT/PLACEBO

MG/KG

GEMCITABINE

MG/M2

5. In case of hospitalization Date of admission (DD-MMM-YYYY) *(hospital report to be sent)*

6. In case of death Autopsy report Yes ☐ No ☐ *(copy to be sent)*

7. Corrective Treatment / Therapy

EFC10547

| | | | | | | | |
|---------|--------|---------|--|--|--|--|--|
| X | 4 | | | | | | |
| Country | Center | Subject | | | | | |

702.01.1
Page No.

0
Repeat No.

Visit Name: VISIT 2 LAB

ADDITIONAL HEMATOLOGY

LAB_01

Data ☒ No Data ☐

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit | SI Value | SI Unit | SI Ranges | |
|---------------------------|----------------------|------------------------|----------------------|----------------------|----------------------|----------------------|
| | | If other unit, specify | | | Lower Limit | Upper Limit |
| HEMOGLOBIN | <input type="text"/> | G/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| PLATELET COUNT (THROMBOC) | <input type="text"/> | 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| WBC | <input type="text"/> | 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| NEUTROPHILS | <input type="text"/> | 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

TO BE PERFORMED ONLY FOR PATIENT UNDER VITAMIN K ANTAGONIST

| | | | | | | |
|-----|----------------------|-------|----------------------|----------------------|----------------------|----------------------|
| INR | <input type="text"/> | RATIO | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
|-----|----------------------|-------|----------------------|----------------------|----------------------|----------------------|

EFC10547

| | | | | | | | |
|---------|--------|---------|--|--|--|--|--|
| X | 4 | | | | | | |
| Country | Center | Subject | | | | | |

702.02.1

Page No.

0

Repeat No.

Visit Name: VISIT 2 LAB

ADDITIONAL BIOCHEMISTRY

LAB_01

Data ☒ No Data ☐

Please indicate if the laboratory is the : Same as baseline ☐

Same as previous ☐

Name

Address

City

Country

For Technical use :

Name

Address

City

Country

| Date of sampling | (dd-mmm-yyyy) | Unit | SI Ranges | | | |
|-------------------------|---------------|------------------------|-----------|---------|-------------|-------------|
| Test | Value | If other unit, specify | SI Value | SI Unit | Lower Limit | Upper Limit |
| SODIUM | | MMOL/L | | | | |
| CALCIUM | | MMOL/L | | | | |
| POTASSIUM | | MMOL/L | | | | |
| PHOSPHORUS | | MMOL/L | | | | |
| ** BLOOD UREA NITROGEN | | MG/DL | | | | |
| ** UREA | | MMOL/L | | | | |
| MAGNESIUM | | MG/DL | | | | |
| * CREATININE | | UMOL/L | | | | |
| CREATININE CLEARANCE CA | | ML/MIN | | | | |
| GLUCOSE | | MMOL/L | | | | |
| AST | | IU/L | | | | |
| ALT | | IU/L | | | | |
| ALKALINE PHOSPHATASE | | IU/L | | | | |
| TOTAL BILIRUBIN | | MG/DL | | | | |
| TOTAL PROTEINS | | G/DL | | | | |
| ALBUMIN | | G/DL | | | | |

* If creatinine > 1 ULN please report the calculated creatinine clearance.

** If blood Urea Nitrogen is not evaluable, Urea value must be documented.

EFC10547

| | | | | | | | | |
|---------|--------|---------|--|--|--|--|--|--|
| X | 4 | | | | | | | |
| Country | Center | Subject | | | | | | |

702.03.1
Page No.

0
Repeat No.

Visit Name: VISIT 2 LAB

ADDITIONAL DIPSTICK URINALYSIS

LABU_1

Data ☒ No Data ☐

Date of sampling

Test name

WHITE BLOOD CELLS (QU)

☐ Absent ☐ + ☐ ++ ☐ +++ ☐ Not evaluable

RED BLOOD CELLS (QUA)

☐ Absent ☐ + ☐ ++ ☐ +++ ☐ Not evaluable

Visit Name: VISIT 2 LAB

ADDITIONAL MORNING SPOT URINALYSIS

LAB_01

Data ☒ No Data ☐

Please indicate if the laboratory is the : Same as baseline ☐

Same as previous ☐

| | |
|---------|----------------------|
| Name | <input type="text"/> |
| Address | <input type="text"/> |
| City | <input type="text"/> |
| Country | <input type="text"/> |

For Technical use :

| | |
|---------|----------------------|
| Name | <input type="text"/> |
| Address | <input type="text"/> |
| City | <input type="text"/> |
| Country | <input type="text"/> |

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit If other unit, specify | SI Value | SI Unit | SI Ranges | |
|--------------------|----------------------|--------------------------------|----------------------|----------------------|----------------------|----------------------|
| | | | | | Lower Limit | Upper Limit |
| PROTEIN (URINE) | <input type="text"/> | MG/DL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| CREATININE (URINE) | <input type="text"/> | MG/DL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

Visit Name: VISIT 2 LAB

24-HOUR URINALYSIS

TO BE COMPLETED IF UPCR > 1

LAB_04

Data ☒ No Data ☐

Please indicate if the laboratory is the Same as baseline ☐

Same as previous ☐

| | |
|---------|--|
| Name | |
| Address | |
| City | |
| Country | |

| | |
|---------------------|--|
| For Technical use : | |
| Name | |
| Address | |
| City | |
| Country | |

Date (dd-mmm-yyyy) (24-hour clock)

Start date of collection: Start Time of collection :

End date of collection: End Time of collection :

| Test | Value | Unit |
|------------------|-------|------|
| URINARY VOLUME | | L |
| PROTEIN (URINE) | | G/L |
| CREATININE (URIN | | G/L |

| SI RANGES | | | |
|-----------|---------|-------------|-------------|
| SI Value | SI Unit | Lower limit | Upper Limit |
| | | | |
| | | | |
| | | | |

ELECTROPHORESIS

| | | |
|------------------|--|-----|
| ALBUMIN | | G/L |
| ALPHA 1 GLOBULIN | | G/L |
| ALPHA 2 GLOBULIN | | G/L |
| BETA GLOBULIN | | G/L |
| GAMMA GLOBULIN | | G/L |

| | | | |
|--|--|--|--|
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

702.05.2

Page No.

0

Repeat No.

Visit Name: VISIT 2 LAB

Is there any Hemoglobin or RBC in 24 Hour urine sample ?

LABU_1

Data ☒ No Data ☐

Test name

Negative

Positive

HEMOGLOBIN (QUALITAT

☐☐

RED BLOOD CELLS (QUA

☐☐

Visit Name: VISIT 2 LAB

TO BE COMPLETED IF PROTEINURIA IS ASSOCIATED WITH HEMATURIA.

ADDITIONAL HEMATOLOGY

LABU_1

Data ☒ No Data ☐

Date of sampling

Test name

Unit

Negative

Positive

SCHISTOCYTES (QUALITA

NONE

☐☐

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

702.06.2

Page No.

0

Repeat No.

Visit Name: VISIT 2 LAB

ADDITIONAL BIOCHEMISTRY

LAB_01

Data ☒ No Data ☐

Please indicate if the laboratory is the : Same as baseline ☐
Same as previous ☐

| | |
|---------|--|
| Name | |
| Address | |
| City | |
| Country | |

| For Technical use : | |
|---------------------|--|
| Name | |
| Address | |
| City | |
| Country | |

| Date of sampling | (dd-mmm-yyyy) | Unit | SI Ranges | | | |
|------------------|---------------|------------------------|-----------|---------|-------------|-------------|
| Test | Value | If other unit, specify | SI Value | SI Unit | Lower Limit | Upper Limit |
| LDH | | IU/L | | | | |
| HAPTOGLOBIN | | G/L | | | | |
| OROSOMUCOID | | G/L | | | | |

EFC10547

| | | | | | | | |
|---------|--------|---------|--|--|--|--|--|
| X | 4 | | | | | | |
| Country | Center | Subject | | | | | |

74.1

Page No.

0

Repeat No.

Visit Name: VISIT 3

Date of visit :

(DD-MMM-YYYY)

VISIT_01

VITAL SIGNS

VITAL_02

Data ☒ No Data ☐

DAY 1

Date performed
(dd-mmm-yyyy)

Weight: kg

Blood pressure: Systolic: mmHg / Diastolic: mmHg

ECOG Performance Status 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐

A PHYSICAL EXAM SHOULD BE PERFORMED.

IF THERE ARE ANY CLINICALLY SIGNIFICANT CHANGES FROM THE PREVIOUS EXAM,

RECORD AS AN ADVERSE EVENT

EFC10547

X 4

Country Center Subject

75.1

Page No.

0

Repeat No.

Visit Name: VISIT 3

HEMATOLOGY

LAB_01

Data ☒ No Data ☐

DAY 1

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit | SI Ranges | | | |
|---------------------------|-------|------------------------|-----------|---------|-------------|-------------|
| | | If other unit, specify | SI Value | SI Unit | Lower Limit | Upper Limit |
| HEMOGLOBIN | | G/L | | | | |
| PLATELET COUNT (THROMBOC) | | 10E9/L | | | | |
| WBC | | 10E9/L | | | | |
| NEUTROPHILS | | 10E9/L | | | | |

TO BE PERFORMED ONLY FOR PATIENT UNDER VITAMIN K ANTAGONIST

| | | | | | | |
|-----|--|-------|--|--|--|--|
| INR | | RATIO | | | | |
|-----|--|-------|--|--|--|--|

EFC10547

| | | | | | | | | |
|---------|--------|---------|--|--|--|--|--|--|
| X | 4 | | | | | | | |
| Country | Center | Subject | | | | | | |

76.1

Page No.

0

Repeat No.

Visit Name: VISIT 3

BIOCHEMISTRY

LAB_01

Data ☒ No Data ☐

DAY 1

Please indicate if the laboratory is the : Same as baseline ☐
Same as previous ☐

| | |
|---------|--|
| Name | |
| Address | |
| City | |
| Country | |

For Technical use :

| | |
|---------|--|
| Name | |
| Address | |
| City | |
| Country | |

EFC10547

X 4

Country Center Subject

76.2

Page No.

0

Repeat No.

Visit Name: VISIT 3

| Date of sampling | (dd-mmm-yyyy) | Unit | Test | Value | If other unit, specify | SI Value | SI Unit | Lower Limit | Upper Limit |
|------------------|---------------|------|-------------------------|-------|------------------------|----------|---------|-------------|-------------|
| | | | SODIUM | | MMOL/L | | | | |
| | | | CALCIUM | | MMOL/L | | | | |
| | | | POTASSIUM | | MMOL/L | | | | |
| | | | PHOSPHORUS | | MMOL/L | | | | |
| | | | ** BLOOD UREA NITROGEN | | MG/DL | | | | |
| | | | ** UREA | | MMOL/L | | | | |
| | | | MAGNESIUM | | MG/DL | | | | |
| | | | * CREATININE | | UMOL/L | | | | |
| | | | CREATININE CLEARANCE CA | | ML/MIN | | | | |
| | | | GLUCOSE | | MMOL/L | | | | |
| | | | AST | | IU/L | | | | |
| | | | ALT | | IU/L | | | | |
| | | | ALKALINE PHOSPHATASE | | IU/L | | | | |
| | | | TOTAL BILIRUBIN | | MG/DL | | | | |
| | | | TOTAL PROTEINS | | G/DL | | | | |
| | | | ALBUMIN | | G/DL | | | | |

* If creatinine > 1 ULN please report the calculated creatinine clearance.

** If blood Urea Nitrogen is not evaluable, Urea value must be documented.

EFC10547

X 4

Country Center Subject

77.1

Page No.

0

Repeat No.

Visit Name:

VISIT 3

DIPSTICK URINALYSIS

LABU_1

Data ☒ No Data ☐

DAY 1

Date of sampling

Test name

WHITE BLOOD CELLS (QU)

☐ Absent ☐ + ☐ ++ ☐ +++ ☐ Not evaluable

RED BLOOD CELLS (QUA)

☐ Absent ☐ + ☐ ++ ☐ +++ ☐ Not evaluable

EFC10547

X 4

Country Center Subject

78.1

Page No.

0

Repeat No.

Visit Name: VISIT 3

MORNING SPOT URINALYSIS

LAB_01

Data ☒ No Data ☐

DAY 1

Please indicate if the laboratory is the : Same as baseline ☐

Same as previous ☐

Name

Address

City

Country

For Technical use :

Name

Address

City

Country

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit If other unit, specify | SI Value | SI Unit | SI Ranges | |
|--------------------|----------------------|--------------------------------|----------------------|----------------------|----------------------|----------------------|
| | | | | | Lower Limit | Upper Limit |
| PROTEIN (URINE) | <input type="text"/> | MG/DL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| CREATININE (URINE) | <input type="text"/> | MG/DL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

EFC10547

X 4

Country Center Subject

973.1

Page No.

0

Repeat No.

Visit Name: VISIT 3

PHARMACOKINETIC BLOOD

PK_01

Data ☒ No Data ☐

TO BE COMPLETED ONLY FOR PK PATIENTS.

FREE AND BOUND AFLIBERCEPT

DAY 1

Sample
ID

P03

Theoretical
Time

T0H

*

Sample Date
(dd-mmm-yyyy)

Sample Time
24-hour clock

T0h* = Pre-dose - just before the start of Aflibercept/Placebo infusion

EFC10547

X 9

Country Center Subject

1003.01.1

Page No.

0

Repeat No.

Visit Name:

VISIT 3

PHARMACOKINETIC BLOOD

PK_01

Data ☒ No Data ☐

FREE AND BOUND AFLIBERCEPT

DAY 1

Theoretical
Time

T0H *

Sample Date
(dd-mmm-yyyy)

Sample Time
24-hour clock

T0h* = Pre-dose - just before the start of Aflibercept/Placebo infusion

EFC10547

X 9

Country Center Subject

1003.02.1

Page No.

0

Repeat No.

Visit Name:

VISIT 3

PHARMACOKINETIC BLOOD

PK_01

Data ☒ No Data ☐

ANTI-AFLIBERCEPT ANTIBODIES

DAY 1

Theoretical
Time

T0H *

Sample Date
(dd-mm-yyyy)

Sample Time
(24-hour clock)

T0h* = Pre-dose - just before the start of Aflibercept/Placebo infusion

EFC10547

X 4 Country Center Subject

79.1

Page No.

0

Repeat No.

Visit Name: VISIT 3

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_05

Data ☒ No Data ☐

AFLIBERCEPT / PLACEBO

| Scheduled Day | Treatment Number | Not Administered/ Taken | Date / Time* START | Intended Dose MG / KG | Actual Dose MG |
|---------------|------------------|----------------------------|-----------------------|--------------------------|-------------------|
| DAY 1 | | <input type="checkbox"/> | (dd-mmm-yyyy) | | |
| | | | (24-hour clock) | | |
| | | | END | | |
| | | | (24-hour clock) | | |

*Time to be given only for PK patients

IF DOSE INTERRUPTED AND READMINISTERED, PLEASE REPORT THE INFORMATION BELOW :

| Scheduled Day | Treatment Number | Not Administered/ Taken | Date / Time* START | Intended Dose MG / KG | Actual Dose MG |
|---------------|------------------|----------------------------|-----------------------|--------------------------|-------------------|
| (*) | | <input type="checkbox"/> | (dd-mmm-yyyy) | NOT APPLICABLE | |
| | | | (24-hour clock) | | |
| | | | END | | |
| | | | (24-hour clock) | | |

*Time to be given only for PK patients

(*) In case of additionnal information, enter "DAY 1" in Scheduled Day

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

80.1

Page No.

0

Repeat No.

Visit Name:

VISIT 3

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_04

Data ☒ No Data ☐

GEMCITABINE

| Scheduled Day | Batch Number | Not Administred/ Taken | Date | Intended Dose MG/M2 | Actual Dose MG |
|---------------|--------------|---------------------------|------|------------------------|-------------------|
| DAY 1 | | <input type="checkbox"/> | | | |
| | | | | | |
| | | | | | |

IF DOSE INTERRUPTED AND READMINISTERED, PLEASE REPORT THE INFORMATION BELOW :

| Scheduled Day | Batch Number | Not Administred/ Taken | Date | Intended Dose MG/M2 | Actual Dose MG |
|---------------|--------------|---------------------------|------|------------------------|-------------------|
| | | <input type="checkbox"/> | | NOT APPLICABLE | |
| | | | | | |
| | | | | | |

(*) In case of additionnal information, enter "DAY 1" in Scheduled Day

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

81.1

Page No.

0

Repeat No.

Visit Name:

VISIT 3

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☒ No Data ☐

DAY 1

Outpatient Clinic ☐ Inpatient Clinic ☐

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

82.1

Page No.

0

Repeat No.

Visit Name:

VISIT 3

VITAL SIGNS

VITAL_02

Data ☒ No Data ☐

DAY 8

Date performed
(dd-mmm-yyyy)

Blood pressure: Systolic: mmHg

/ Diastolic: mmHg

ECOG Performance Status 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐

EFC10547

X 4

Country Center Subject

83.1

Page No.

0

Repeat No.

Visit Name: VISIT 3

HEMATOLOGY

LAB_01

Data ☒ No Data ☐

DAY 8

Date of sampling (dd-mm-yyyy)

| Test | Value | Unit If other unit, specify | SI Ranges | | | |
|---------------------------|-------|--------------------------------|-----------|---------|-------------|-------------|
| | | | SI Value | SI Unit | Lower Limit | Upper Limit |
| HEMOGLOBIN | | G/L | | | | |
| PLATELET COUNT (THROMBOC) | | 10E9/L | | | | |
| WBC | | 10E9/L | | | | |
| NEUTROPHILS | | 10E9/L | | | | |

EFC10547

| | | | | | | | |
|---------|--------|---------|--|--|--|--|--|
| X | 4 | | | | | | |
| Country | Center | Subject | | | | | |

84.1

Page No.

0

Repeat No.

Visit Name:

VISIT 3

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_04

Data ☒ No Data ☐

GEMCITABINE

| Scheduled Day | Batch Number | Not Administred/ Taken | Date | Intended Dose MG/M2 | Actual Dose MG |
|---------------|--------------|---------------------------|------|------------------------|-------------------|
| DAY 8 | | <input type="checkbox"/> | | | |

IF DOSE INTERRUPTED AND READMINISTERED, PLEASE REPORT THE INFORMATION BELOW :

| Scheduled Day | Batch Number | Not Administred/ Taken | Date | Intended Dose MG/M2 | Actual Dose MG |
|---------------|--------------|---------------------------|------|------------------------|-------------------|
| | | <input type="checkbox"/> | | NOT APPLICABLE | |

(*) In case of additionnal information, enter "DAY 8" in Scheduled Day

EFC10547

| | | | | | | | | |
|---|---|--|--|--|--|--|--|--|
| X | 4 | | | | | | | |
|---|---|--|--|--|--|--|--|--|

Country Center Subject

85.1

Page No.

0

Repeat No.

Visit Name:

VISIT 3

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☒ No Data ☐

DAY 8

Outpatient Clinic ☐ Inpatient Clinic ☐

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

86.1

Page No.

0

Repeat No.

Visit Name:

VISIT 3

VITAL SIGNS

VITAL_02

Data ☒ No Data ☐

DAY 15

Date performed
(dd-mmm-yyyy)

Weight: kg

Blood pressure: Systolic: mmHg / Diastolic: mmHg

ECOG Performance Status 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐

EFC10547

X 4

Country Center Subject

87.1

Page No.

0

Repeat No.

Visit Name: VISIT 3

HEMATOLOGY

LAB_01

Data ☒ No Data ☐

DAY 15

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit If other unit, specify | SI Ranges | | | |
|---------------------------|----------------------|--------------------------------|----------------------|----------------------|----------------------|----------------------|
| | | | SI Value | SI Unit | Lower Limit | Upper Limit |
| HEMOGLOBIN | <input type="text"/> | G/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| PLATELET COUNT (THROMBOC) | <input type="text"/> | 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| WBC | <input type="text"/> | 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| NEUTROPHILS | <input type="text"/> | 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

EFC10547

| | | | | | | | | |
|---|---|--|--|--|--|--|--|--|
| X | 4 | | | | | | | |
|---|---|--|--|--|--|--|--|--|

Country Center Subject

88.1

Page No.

0

Repeat No.

Visit Name:

VISIT 3

DIPSTICK URINALYSIS

LABU_1

Data ☒ No Data ☐

DAY 15

Date of sampling

Test name

WHITE BLOOD CELLS (QU)

☐ Absent ☐ + ☐ ++ ☐ +++ ☐ Not evaluable

RED BLOOD CELLS (QUA)

☐ Absent ☐ + ☐ ++ ☐ +++ ☐ Not evaluable

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

89.1

Page No.

0

Repeat No.

Visit Name: VISIT 3

MORNING SPOT URINALYSIS

LAB_01

Data ☒ No Data ☐

DAY 15

Please indicate if the laboratory is the : Same as baseline ☐
Same as previous ☐

Name
Address
City
Country

For Technical use :

Name
Address
City
Country

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit If other unit, specify | SI Value | SI Unit | SI Ranges | |
|--------------------|----------------------|--------------------------------|----------------------|----------------------|----------------------|----------------------|
| | | | | | Lower Limit | Upper Limit |
| PROTEIN (URINE) | <input type="text"/> | MG/DL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| CREATININE (URINE) | <input type="text"/> | MG/DL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

EFC10547

X 4 Country Center Subject

90.1

Page No.

0

Repeat No.

Visit Name: VISIT 3

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_05

Data ☒ No Data ☐

AFLIBERCEPT / PLACEBO

| Scheduled Day | Treatment Number | Not Administered/ Taken | Date / Time* START | Intended Dose MG / KG | Actual Dose MG |
|---------------|------------------|----------------------------|-----------------------|--------------------------|-------------------|
| DAY 15 | | <input type="checkbox"/> | (dd-mmm-yyyy) | | |
| | | | (24-hour clock) | | |
| | | | END | | |
| | | | (24-hour clock) | | |

*Time to be given only for PK patients

IF DOSE INTERRUPTED AND READMINISTERED, PLEASE REPORT THE INFORMATION BELOW :

| Scheduled Day | Treatment Number | Not Administered/ Taken | Date / Time* START | Intended Dose MG / KG | Actual Dose MG |
|---------------|------------------|----------------------------|-----------------------|--------------------------|-------------------|
| (*) | | <input type="checkbox"/> | (dd-mmm-yyyy) | NOT APPLICABLE | |
| | | | (24-hour clock) | | |
| | | | END | | |
| | | | (24-hour clock) | | |

*Time to be given only for PK patients

(*) In case of additionnal information, enter "DAY 15" in Scheduled Day

EFC10547

X 4
Country Center Subject

91.1

Page No.

0

Repeat No.

Visit Name:

VISIT 3

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_04

Data ☒ No Data ☐

GEMCITABINE

| Scheduled Day | Batch Number | Not Administred/ Taken | Date | Intended Dose MG/M2 | Actual Dose MG |
|---------------|----------------------|---------------------------|----------------------|------------------------|----------------------|
| DAY 15 | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| | <input type="text"/> | | | | |
| | <input type="text"/> | | | | |

IF DOSE INTERRUPTED AND READMINISTERED, PLEASE REPORT THE INFORMATION BELOW :

| Scheduled Day | Batch Number | Not Administred/ Taken | Date | Intended Dose MG/M2 | Actual Dose MG |
|--------------------------|----------------------|---------------------------|----------------------|------------------------|----------------------|
| <input type="text"/> (*) | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | NOT APPLICABLE | <input type="text"/> |
| | <input type="text"/> | | | | |
| | <input type="text"/> | | | | |

(*) In case of additionnal information, enter "DAY 15" in Scheduled Day

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

92.1

Page No.

0

Repeat No.

Visit Name:

VISIT 3

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☒ No Data ☐

DAY 15

Outpatient Clinic ☐ Inpatient Clinic ☐

Visit Name: VISIT 3

PAIN INTENSITY

ASSESSED VIA VISUAL ANALOG SCALE

Data ☒ No Data ☐

Data corresponding to current cycle

| Period | Date | Measure |
|--------|------|---------|
| | | MM |
| DAY 1 | | |
| DAY 2 | | |
| DAY 3 | | |
| DAY 4 | | |
| DAY 5 | | |
| DAY 6 | | |
| DAY 7 | | |
| DAY 8 | | |
| DAY 9 | | |
| DAY 10 | | |
| DAY 11 | | |
| DAY 12 | | |
| DAY 13 | | |
| DAY 14 | | |
| DAY 15 | | |
| DAY 16 | | |
| DAY 17 | | |
| DAY 18 | | |
| DAY 19 | | |
| DAY 20 | | |
| DAY 21 | | |

Period Date Measure

| | | |
|--------|--|--|
| DAY 22 | | |
| DAY 23 | | |
| DAY 24 | | |
| DAY 25 | | |
| DAY 26 | | |
| DAY 27 | | |
| DAY 28 | | |
| DAY 29 | | |
| DAY 30 | | |
| DAY 31 | | |
| DAY 32 | | |
| DAY 33 | | |
| DAY 34 | | |
| DAY 35 | | |
| DAY 36 | | |
| DAY 37 | | |
| DAY 38 | | |
| DAY 39 | | |
| DAY 40 | | |
| DAY 41 | | |
| DAY 42 | | |

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

94.1

Page No.

0

Repeat No.

Visit Name: VISIT 3

MEDICATION

ANALGESIC

MED_02

Data ☒ No Data ☐

ANALGESIC MEDICATION SHOULD BE COLLECTED DAILY PRIOR TO THE NEXT INFUSION

| Drug/Medication (Brand or generic name) | Dosage (Total daily dose) | Units | Route | Start Date (dd-mmm-yyyy) | Previously reported | End Date (dd-mmm-yyyy) | Ongoing |
|--|------------------------------|-------|-------|-----------------------------|--------------------------|---------------------------|--------------------------|
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |

EFC10547

X 4

Country Center Subject

94.2

Page No.

0

Repeat No.

Visit Name: VISIT 3

| Drug/Medication (Brand or generic name) | Dosage (Total daily dose) | Units | Route | Start Date (dd-mmm-yyyy) | Previously reported | End Date (dd-mmm-yyyy) | Ongoing |
|--|------------------------------|-------|-------|-----------------------------|--------------------------|---------------------------|--------------------------|
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |

EFC10547

X 4

Country Center Subject

94.3

Page No.

0

Repeat No.

Visit Name: VISIT 3

| Drug/Medication (Brand or generic name) | Dosage (Total daily dose) | Units | Route | Start Date (dd-mmm-yyyy) | Previously reported | End Date (dd-mmm-yyyy) | Ongoing |
|--|------------------------------|-------|-------|-----------------------------|--------------------------|---------------------------|--------------------------|
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |

TUMOR MEASUREMENTS

TUMEA_02

Data ☒ No Data ☐

| Lesion Number | Lesion Location | Date of Assessment (dd-mmm-yyyy) | Method of Tumor Measurement | Measurement of Target Lesion longest diameter | Response of Non target Lesions |
|----------------------|----------------------|---|-----------------------------|--|--------------------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |

| Lesion Number | Lesion Location | Date of Assessment (dd-mm-yyyy) | Method of Tumor Measurement | Measurement of Target Lesion longest diameter | Response of Non target Lesions |
|----------------------|----------------------|---|-----------------------------|---|--------------------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

96.1

Page No.

0

Repeat No.

Visit Name:

VISIT 3

TUMOR MARKERS

TMARK_01

Data ☒ No Data ☐

Date of evaluation

(dd-mmm-yyyy)

| TEST | VALUE | UNIT | NORMAL RANGE | |
|--------|-------|------|--------------|-------------|
| | | | LOWER LIMIT | UPPER LIMIT |
| CA19-9 | | | | |

CLINICAL EVENT THROMBOVASCULAR

Data ☒ No Data ☐

ANGINA PECTORIS / UNSTABLE ANGINA / MYOCARDIAL INFARCTION

Yes No

☐
☐

STROKE / TRANSIENT ISCHEMIC ATTACK

☐
☐

PERIPHERAL ARTERIAL THROMBOSIS

☐
☐

DEEP VENOUS THROMBOSIS

☐
☐

PULMONARY EMBOLISM

☐
☐

INTRAABDOMINAL ARTERIAL THROMBOSIS

☐
☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐
☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐
☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐
☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐
☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐
☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐
☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐
☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐
☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐
☐

Visit Name: VISIT 3 AE

ADVERSE EVENT

AE Form Number

AE_03

Data ☒ No Data ☐

AE Reference ID

1. Adverse Event (Diagnosis) :

2. Status of Adverse Event

New ☐ Date of Start
(dd-mmm-yyyy)

Ongoing without change ☐ (do not complete the remaining items)

Ongoing with change ☐

3. Grade

1 ☐ 2 ☐ 3 ☐ 4 ☐

4. Relationship to investigational product *

Yes ☐ No ☐

5. Action Taken with Investigat. Product

None ☐ Permanently discontinued ☐ Delayed ☐ Dose reduced ☐ Delayed and reduced ☐ Interrupted ☐

6. Corrective treatment/therapy

Yes ☐ No ☐

7. Outcome

Recovered ☐ Date of Recovery
(dd-mmm-yyyy)

Recovered with sequelae ☐ Specify :

Recovering ☐

Not recovered ☐

Fatal ☐ Date of Death (complete the death report form)
(dd-mmm-yyyy)

Unknown ☐

8. Seriousness Criteria

Yes ☐ No ☐ If Yes : -Date event became serious
(dd-mmm-yyyy)

IF YES, COMPLETE THIS SECTION AND THE SAFETY COMPLEMENTARY FORM

-Tick below all criteria that apply :

| | | | |
|--------------------------------------|--------------------------|--|--------------------------|
| Results in Death | <input type="checkbox"/> | Persistent/significant disability/incapacity | <input type="checkbox"/> |
| Life Threatening | <input type="checkbox"/> | Congenital anomaly or Birth Defect | <input type="checkbox"/> |
| Requires or prolongs hospitalization | <input type="checkbox"/> | Other medically important event | <input type="checkbox"/> |

9. Is it an event such as :

Overdose of the IP Yes ☐ No ☐

Pregnancy Yes ☐ No ☐

*Is there a reasonable possibility that the AE was caused by Investigational Product?

EFC10547

| | | | | | | | |
|---------|--------|---------|--|--|--|--|--|
| X | 4 | | | | | | |
| Country | Center | Subject | | | | | |

603.2

Page No.

0

Repeat No.

Visit Name: VISIT 3 AE

SAFETY COMPLEMENTARY FORM

SAEC_03

AE / Specific Event Form Number

1. Demographic Information

Weight (kg) 2. Detailed Description of the Adverse Event *(including complementary investigations)*3. Date of Start of Event (Initial date of onset of the considered event) (DD-MMM-YYYY)

4. Investigational Products

Date of the **FIRST** administration of study treatment : (DD-MMM-YYYY)Current Treatment number : Current Cycle : Date of the **LAST** administration before SAE : (dd-mmm-yyyy)

Last Dosage before SAE :

Action Taken :

AFLIBERCEPT/PLACEBO

MG/KG

GEMCITABINE

MG/M2

5. In case of hospitalization Date of admission (DD-MMM-YYYY) *(hospital report to be sent)*6. In case of death Autopsy report Yes ☐ No ☐ *(copy to be sent)*

7. Corrective Treatment / Therapy

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

703.01.1
Page No.

0
Repeat No.

Visit Name: VISIT 3 LAB

ADDITIONAL HEMATOLOGY

LAB_01

Data ☒ No Data ☐

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit | SI Value | SI Unit | SI Ranges | |
|---------------------------|----------------------|-----------------------------|----------------------|----------------------|----------------------|----------------------|
| | | If other unit, specify | | | Lower Limit | Upper Limit |
| HEMOGLOBIN | <input type="text"/> | <input type="text"/> G/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| PLATELET COUNT (THROMBOC) | <input type="text"/> | <input type="text"/> 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| WBC | <input type="text"/> | <input type="text"/> 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| NEUTROPHILS | <input type="text"/> | <input type="text"/> 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

TO BE PERFORMED ONLY FOR PATIENT UNDER VITAMIN K ANTAGONIST

| | | | | | | |
|-----|----------------------|----------------------------|----------------------|----------------------|----------------------|----------------------|
| INR | <input type="text"/> | <input type="text"/> RATIO | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
|-----|----------------------|----------------------------|----------------------|----------------------|----------------------|----------------------|

ADDITIONAL BIOCHEMISTRY

LAB_01

Data ☒ No Data ☐

Please indicate if the laboratory is the : Same as baseline ☐

Same as previous ☐

| | |
|---------|----------------------|
| Name | <input type="text"/> |
| Address | <input type="text"/> |
| City | <input type="text"/> |
| Country | <input type="text"/> |

| | |
|---------------------|----------------------|
| For Technical use : | |
| Name | <input type="text"/> |
| Address | <input type="text"/> |
| City | <input type="text"/> |
| Country | <input type="text"/> |

EFC10547

X 4 Country Center Subject

703.02.2

Page No.

0

Repeat No.

Visit Name: VISIT 3 LAB

| Date of sampling | (dd-mmm-yyyy) | Unit | SI Ranges | | | |
|-------------------------|---------------|------------------------|-----------|---------|-------------|-------------|
| Test | Value | If other unit, specify | SI Value | SI Unit | Lower Limit | Upper Limit |
| SODIUM | | MMOL/L | | | | |
| CALCIUM | | MMOL/L | | | | |
| POTASSIUM | | MMOL/L | | | | |
| PHOSPHORUS | | MMOL/L | | | | |
| ** BLOOD UREA NITROGEN | | MG/DL | | | | |
| ** UREA | | MMOL/L | | | | |
| MAGNESIUM | | MG/DL | | | | |
| * CREATININE | | UMOL/L | | | | |
| CREATININE CLEARANCE CA | | ML/MIN | | | | |
| GLUCOSE | | MMOL/L | | | | |
| AST | | IU/L | | | | |
| ALT | | IU/L | | | | |
| ALKALINE PHOSPHATASE | | IU/L | | | | |
| TOTAL BILIRUBIN | | MG/DL | | | | |
| TOTAL PROTEINS | | G/DL | | | | |
| ALBUMIN | | G/DL | | | | |

* If creatinine > 1 ULN please report the calculated creatinine clearance.

** If blood Urea Nitrogen is not evaluable, Urea value must be documented.

ADDITIONAL DIPSTICK URINALYSIS

LABU_1

Data ☒ No Data ☐

Date of sampling

Test name

WHITE BLOOD CELLS (QU)

☐ Absent ☐ + ☐ ++ ☐ +++ ☐ Not evaluable

RED BLOOD CELLS (QUAL)

☐ Absent ☐ + ☐ ++ ☐ +++ ☐ Not evaluable

Visit Name: VISIT 3 LAB

ADDITIONAL MORNING SPOT URINALYSIS

LAB_01

Data ☒ No Data ☐

Please indicate if the laboratory is the : Same as baseline ☐

Same as previous ☐

| | |
|---------|----------------------|
| Name | <input type="text"/> |
| Address | <input type="text"/> |
| City | <input type="text"/> |
| Country | <input type="text"/> |

For Technical use :

| | |
|---------|----------------------|
| Name | <input type="text"/> |
| Address | <input type="text"/> |
| City | <input type="text"/> |
| Country | <input type="text"/> |

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit If other unit, specify | SI Value | SI Unit | SI Ranges | |
|--------------------|----------------------|--------------------------------|----------------------|----------------------|----------------------|----------------------|
| | | | | | Lower Limit | Upper Limit |
| PROTEIN (URINE) | <input type="text"/> | MG/DL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| CREATININE (URINE) | <input type="text"/> | MG/DL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

Visit Name: VISIT 3 LAB

24-HOUR URINALYSIS

TO BE COMPLETED IF UPCR > 1

LAB_04

Data ☒ No Data ☐

Please indicate if the laboratory is the Same as baseline ☐
Same as previous ☐

| | |
|---------|--|
| Name | |
| Address | |
| City | |
| Country | |

| | |
|---------------------|--|
| For Technical use : | |
| Name | |
| Address | |
| City | |
| Country | |

Date (dd-mmm-yyyy) (24-hour clock)

Start date of collection: Start Time of collection :

End date of collection: End Time of collection :

| Test | Value | Unit | SI Value | SI Unit | Lower limit | Upper Limit |
|-------------------|----------------------|------|----------------------|----------------------|----------------------|----------------------|
| URINARY VOLUME | <input type="text"/> | L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| PROTEIN (URINE) | <input type="text"/> | G/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| CREATININE (URIN) | <input type="text"/> | G/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

ELECTROPHORESIS

| | | | | | | |
|------------------|----------------------|-----|----------------------|----------------------|----------------------|----------------------|
| ALBUMIN | <input type="text"/> | G/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| ALPHA 1 GLOBULIN | <input type="text"/> | G/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| ALPHA 2 GLOBULIN | <input type="text"/> | G/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| BETA GLOBULIN | <input type="text"/> | G/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| GAMMA GLOBULIN | <input type="text"/> | G/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

703.05.2

Page No.

0

Repeat No.

Visit Name: VISIT 3 LAB

Is there any Hemoglobin or RBC in 24 Hour urine sample ?

LABU_1

Data ☒ No Data ☐

Test name

Negative

Positive

HEMOGLOBIN (QUALITAT

☐☐

RED BLOOD CELLS (QUA

☐☐

TO BE COMPLETED IF PROTEINURIA IS ASSOCIATED WITH HEMATURIA.

ADDITIONAL HEMATOLOGY

LABU_1

Data ☒ No Data ☐

Date of sampling

Test name

Unit

Negative

Positive

SCHISTOCYTES (QUALITA NONE

☐☐

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

703.06.2

Page No.

0

Repeat No.

Visit Name: VISIT 3 LAB

ADDITIONAL BIOCHEMISTRY

LAB_01

Data ☒ No Data ☐

Please indicate if the laboratory is the : Same as baseline ☐
Same as previous ☐

Name
Address
City
Country

For Technical use :

Name
Address
City
Country

Date of sampling (dd-mm-yyyy)

| Test | Value | Unit | If other unit, specify | SI Ranges | | | |
|-------------|----------------------|------|------------------------|----------------------|----------------------|----------------------|----------------------|
| | | | | SI Value | SI Unit | Lower Limit | Upper Limit |
| LDH | <input type="text"/> | IU/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| HAPTOGLOBIN | <input type="text"/> | G/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| OROSOMUCOID | <input type="text"/> | G/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

EFC10547

| | | | | | | | | |
|---------|--------|---------|--|--|--|--|--|--|
| X | 4 | | | | | | | |
| Country | Center | Subject | | | | | | |

98.1

Page No.

0

Repeat No.

Visit Name: VISIT 4

Date of visit :

(DD-MMM-YYYY)

VISIT_01

VITAL SIGNS

VITAL_02

Data ☒ No Data ☐

DAY 1

Date performed
(dd-mmm-yyyy)

Weight: kg

Blood pressure: Systolic: mmHg / Diastolic: mmHg

ECOG Performance Status 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐

A PHYSICAL EXAM SHOULD BE PERFORMED.

IF THERE ARE ANY CLINICALLY SIGNIFICANT CHANGES FROM THE PREVIOUS EXAM,

RECORD AS AN ADVERSE EVENT

EFC10547

X 4 Country Center Subject

99.1

Page No.

0

Repeat No.

Visit Name: VISIT 4

HEMATOLOGY

LAB_01

Data ☒ No Data ☐

DAY 1

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit | SI Value | SI Unit | SI Ranges | |
|---------------------------|-------|------------------------|----------|---------|-------------|-------------|
| | | If other unit, specify | | | Lower Limit | Upper Limit |
| HEMOGLOBIN | | G/L | | | | |
| PLATELET COUNT (THROMBOC) | | 10E9/L | | | | |
| WBC | | 10E9/L | | | | |
| NEUTROPHILS | | 10E9/L | | | | |

TO BE PERFORMED ONLY FOR PATIENT UNDER VITAMIN K ANTAGONIST

| | | | | | | |
|-----|--|-------|--|--|--|--|
| INR | | RATIO | | | | |
|-----|--|-------|--|--|--|--|

EFC10547

| | | | | | | | | |
|---|---|--|--|--|--|--|--|--|
| X | 4 | | | | | | | |
|---|---|--|--|--|--|--|--|--|

Country Center Subject

100.1

Page No.

0

Repeat No.

Visit Name: VISIT 4

BIOCHEMISTRY

LAB_01

Data ☒ No Data ☐

DAY 1

Please indicate if the laboratory is the : Same as baseline ☐
Same as previous ☐

Name
Address
City
Country

For Technical use :

Name
Address
City
Country

EFC10547

| | | | | | | | | |
|---|---|--|--|--|--|--|--|--|
| X | 4 | | | | | | | |
|---|---|--|--|--|--|--|--|--|

Country Center Subject

101.1

Page No.

0

Repeat No.

Visit Name:

VISIT 4

DIPSTICK URINALYSIS

LABU_1

Data ☒ No Data ☐

DAY 1

Date of sampling

Test name

WHITE BLOOD CELLS (QU)

☐ Absent ☐ + ☐ ++ ☐ +++ ☐ Not evaluable

RED BLOOD CELLS (QUA)

☐ Absent ☐ + ☐ ++ ☐ +++ ☐ Not evaluable

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

102.1

Page No.

0

Repeat No.

Visit Name: VISIT 4

MORNING SPOT URINALYSIS

LAB_01

Data ☒ No Data ☐

DAY 1

Please indicate if the laboratory is the : Same as baseline ☐

Same as previous ☐

Name

Address

City

Country

For Technical use :

Name

Address

City

Country

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit If other unit, specify | SI Ranges | | | |
|--------------------|----------------------|--------------------------------|----------------------|----------------------|----------------------|----------------------|
| | | | SI Value | SI Unit | Lower Limit | Upper Limit |
| PROTEIN (URINE) | <input type="text"/> | MG/DL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| CREATININE (URINE) | <input type="text"/> | MG/DL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

EFC10547

X 9

Country Center Subject

1004.01.1

Page No.

0

Repeat No.

Visit Name:

VISIT 4

PHARMACOKINETIC BLOOD

PK_01

Data ☒ No Data ☐

FREE AND BOUND AFLIBERCEPT

DAY 1

Theoretical
Time

T0H

*

Sample Date
(dd-mmm-yyyy)

Sample Time
24-hour clock

T0h* = Pre-dose - just before the start of Aflibercept/Placebo infusion

EFC10547

| | | | | | | | |
|---------|--------|---------|--|--|--|--|--|
| X | 9 | | | | | | |
| Country | Center | Subject | | | | | |

1004.02.1

Page No.

0

Repeat No.

Visit Name:

VISIT 4

PHARMACOKINETIC BLOOD

PK_01

Data ☒ No Data ☐

ANTI-AFLIBERCEPT ANTIBODIES

DAY 1

Theoretical
Time

T0H *

Sample Date
(dd-mmm-yyyy)

Sample Time
(24-hour clock)

T0h* = Pre-dose - just before the start of Aflibercept/Placebo infusion

EFC10547

X 4 Country Center Subject

103.1

Page No.

0

Repeat No.

Visit Name: VISIT 4

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_05

Data ☒ No Data ☐

AFLIBERCEPT / PLACEBO

| Scheduled Day | Treatment Number | Not Administered/ Taken | Date / Time* START | Intended Dose MG / KG | Actual Dose MG |
|---------------|------------------|----------------------------|-----------------------|--------------------------|-------------------|
| DAY 1 | | <input type="checkbox"/> | (dd-mmm-yyyy) | | |
| | | | (24-hour clock) | | |
| | | | END | | |
| | | | (24-hour clock) | | |

*Time to be given only for PK patients

IF DOSE INTERRUPTED AND READMINISTERED, PLEASE REPORT THE INFORMATION BELOW :

| Scheduled Day | Treatment Number | Not Administered/ Taken | Date / Time* START | Intended Dose MG / KG | Actual Dose MG |
|---------------|------------------|----------------------------|-----------------------|--------------------------|-------------------|
| (*) | | <input type="checkbox"/> | (dd-mmm-yyyy) | NOT APPLICABLE | |
| | | | (24-hour clock) | | |
| | | | END | | |
| | | | (24-hour clock) | | |

*Time to be given only for PK patients

(*) In case of additionnal information, enter "DAY 1" in Scheduled Day

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

104.1
Page No.

0
Repeat No.

Visit Name: VISIT 4

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_04

Data ☒ No Data ☐

GEMCITABINE

| Scheduled Day | Batch Number | Not Administred/ Taken | Date | Intended Dose MG/M2 | Actual Dose MG |
|---------------|--------------|---------------------------|------|------------------------|-------------------|
| DAY 1 | | <input type="checkbox"/> | | | |
| | | | | | |
| | | | | | |

IF DOSE INTERRUPTED AND READMINISTERED, PLEASE REPORT THE INFORMATION BELOW :

| Scheduled Day | Batch Number | Not Administred/ Taken | Date | Intended Dose MG/M2 | Actual Dose MG |
|---------------|--------------|---------------------------|------|------------------------|-------------------|
| | | <input type="checkbox"/> | | NOT APPLICABLE | |
| | | | | | |
| | | | | | |

(*) In case of additionnal information, enter "DAY 1" in Scheduled Day

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

105.1

Page No.

0

Repeat No.

Visit Name:

VISIT 4

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☒ No Data ☐

DAY 1

Outpatient Clinic ☐ Inpatient Clinic ☐

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

106.1

Page No.

0

Repeat No.

Visit Name:

VISIT 4

VITAL SIGNS

VITAL_02

Data ☒ No Data ☐

DAY 8

Date performed
(dd-mmm-yyyy)

Blood pressure: Systolic: mmHg

/ Diastolic: mmHg

ECOG Performance Status 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐

EFC10547

X 4

Country Center Subject

107.1

Page No.

0

Repeat No.

Visit Name: VISIT 4

HEMATOLOGY

LAB_01

Data ☒ No Data ☐

DAY 8

Date of sampling (dd-mm-yyyy)

| Test | Value | Unit If other unit, specify | SI Ranges | | | |
|---------------------------|-------|--------------------------------|-----------|---------|-------------|-------------|
| | | | SI Value | SI Unit | Lower Limit | Upper Limit |
| HEMOGLOBIN | | G/L | | | | |
| PLATELET COUNT (THROMBOC) | | 10E9/L | | | | |
| WBC | | 10E9/L | | | | |
| NEUTROPHILS | | 10E9/L | | | | |

EFC10547

| | | | | | | | |
|---------|--------|---------|--|--|--|--|--|
| X | 4 | | | | | | |
| Country | Center | Subject | | | | | |

108.1
Page No.

0
Repeat No.

Visit Name: VISIT 4

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_04

Data ☒ No Data ☐

GEMCITABINE

| Scheduled Day | Batch Number | Not Administred/ Taken | Date | Intended Dose MG/M2 | Actual Dose MG |
|---------------|--------------|---------------------------|------|------------------------|-------------------|
| DAY 8 | | <input type="checkbox"/> | | | |

IF DOSE INTERRUPTED AND READMINISTERED, PLEASE REPORT THE INFORMATION BELOW :

| Scheduled Day | Batch Number | Not Administred/ Taken | Date | Intended Dose MG/M2 | Actual Dose MG |
|---------------|--------------|---------------------------|------|------------------------|-------------------|
| | | <input type="checkbox"/> | | NOT APPLICABLE | |

(*) In case of additionnal information, enter "DAY 8" in Scheduled Day

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

109.1

Page No.

0

Repeat No.

Visit Name:

VISIT 4

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☒ No Data ☐

DAY 8

Outpatient Clinic ☐ Inpatient Clinic ☐

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

110.1

Page No.

0

Repeat No.

Visit Name:

VISIT 4

VITAL SIGNS

VITAL_02

Data ☒ No Data ☐

DAY 15

Date performed
(dd-mmm-yyyy)

Weight: kg

Blood pressure: Systolic: mmHg / Diastolic: mmHg

ECOG Performance Status 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐

EFC10547

X 4

Country Center Subject

111.1

Page No.

0

Repeat No.

Visit Name: VISIT 4

HEMATOLOGY

LAB_01

Data ☒ No Data ☐

DAY 15

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit If other unit, specify | SI Ranges | | | |
|---------------------------|-------|--------------------------------|-----------|---------|-------------|-------------|
| | | | SI Value | SI Unit | Lower Limit | Upper Limit |
| HEMOGLOBIN | | G/L | | | | |
| PLATELET COUNT (THROMBOC) | | 10E9/L | | | | |
| WBC | | 10E9/L | | | | |
| NEUTROPHILS | | 10E9/L | | | | |

EFC10547

| | | | | | | | | |
|---|---|--|--|--|--|--|--|--|
| X | 4 | | | | | | | |
|---|---|--|--|--|--|--|--|--|

Country Center Subject

112.1

Page No.

0

Repeat No.

Visit Name:

VISIT 4

DIPSTICK URINALYSIS

LABU_1

Data ☒ No Data ☐

DAY 15

Date of sampling

Test name

WHITE BLOOD CELLS (QU)

☐ Absent

☐ +

☐ ++

☐ +++

☐ Not evaluable

RED BLOOD CELLS (QUA)

☐ Absent

☐ +

☐ ++

☐ +++

☐ Not evaluable

EFC10547

X 4

Country Center Subject

113.1

Page No.

0

Repeat No.

Visit Name: VISIT 4

MORNING SPOT URINALYSIS

LAB_01

Data ☒ No Data ☐

DAY 15

Please indicate if the laboratory is the : Same as baseline ☐

Same as previous ☐

Name

Address

City

Country

For Technical use :

Name

Address

City

Country

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit If other unit, specify | SI Value | SI Unit | SI Ranges | |
|--------------------|----------------------|--------------------------------|----------------------|----------------------|----------------------|----------------------|
| | | | | | Lower Limit | Upper Limit |
| PROTEIN (URINE) | <input type="text"/> | MG/DL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| CREATININE (URINE) | <input type="text"/> | MG/DL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

EFC10547

X 4 Country Center Subject

114.1

Page No.

0

Repeat No.

Visit Name: VISIT 4

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_05

Data ☒ No Data ☐

AFLIBERCEPT / PLACEBO

| Scheduled Day | Treatment Number | Not Administered/ Taken | Date / Time* START | Intended Dose MG / KG | Actual Dose MG |
|---------------|------------------|----------------------------|-----------------------|--------------------------|-------------------|
| DAY 15 | | <input type="checkbox"/> | (dd-mmm-yyyy) | | |
| | | | (24-hour clock) | | |
| | | | END | | |
| | | | (24-hour clock) | | |

*Time to be given only for PK patients

IF DOSE INTERRUPTED AND READMINISTERED, PLEASE REPORT THE INFORMATION BELOW :

| Scheduled Day | Treatment Number | Not Administered/ Taken | Date / Time* START | Intended Dose MG / KG | Actual Dose MG |
|---------------|------------------|----------------------------|-----------------------|--------------------------|-------------------|
| (*) | | <input type="checkbox"/> | (dd-mmm-yyyy) | NOT APPLICABLE | |
| | | | (24-hour clock) | | |
| | | | END | | |
| | | | (24-hour clock) | | |

*Time to be given only for PK patients

(*) In case of additionnal information, enter "DAY 15" in Scheduled Day

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

115.1
Page No.

0
Repeat No.

Visit Name: VISIT 4

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_04

Data ☒ No Data ☐

GEMCITABINE

| Scheduled Day | Batch Number | Not Administred/ Taken | Date | Intended Dose MG/M2 | Actual Dose MG |
|---------------|--------------|---------------------------|------|------------------------|-------------------|
| DAY 15 | | <input type="checkbox"/> | | | |

IF DOSE INTERRUPTED AND READMINISTERED, PLEASE REPORT THE INFORMATION BELOW :

| Scheduled Day | Batch Number | Not Administred/ Taken | Date | Intended Dose MG/M2 | Actual Dose MG |
|---------------|--------------|---------------------------|------|------------------------|-------------------|
| | | <input type="checkbox"/> | | NOT APPLICABLE | |

(*) In case of additionnal information, enter "DAY 15" in Scheduled Day

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

116.1

Page No.

0

Repeat No.

Visit Name:

VISIT 4

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☒ No Data ☐

DAY 15

Outpatient Clinic ☐ Inpatient Clinic ☐

Visit Name: VISIT 4

PAIN INTENSITY

ASSESSED VIA VISUAL ANALOG SCALE

Data ☒ No Data ☐

Data corresponding to current cycle

| Period | Date | Measure |
|--------|------|---------|
| | | MM |
| DAY 1 | | |
| DAY 2 | | |
| DAY 3 | | |
| DAY 4 | | |
| DAY 5 | | |
| DAY 6 | | |
| DAY 7 | | |
| DAY 8 | | |
| DAY 9 | | |
| DAY 10 | | |
| DAY 11 | | |
| DAY 12 | | |
| DAY 13 | | |
| DAY 14 | | |
| DAY 15 | | |
| DAY 16 | | |
| DAY 17 | | |
| DAY 18 | | |
| DAY 19 | | |
| DAY 20 | | |
| DAY 21 | | |

Period Date Measure

| | | |
|--------|--|--|
| DAY 22 | | |
| DAY 23 | | |
| DAY 24 | | |
| DAY 25 | | |
| DAY 26 | | |
| DAY 27 | | |
| DAY 28 | | |
| DAY 29 | | |
| DAY 30 | | |
| DAY 31 | | |
| DAY 32 | | |
| DAY 33 | | |
| DAY 34 | | |
| DAY 35 | | |
| DAY 36 | | |
| DAY 37 | | |
| DAY 38 | | |
| DAY 39 | | |
| DAY 40 | | |
| DAY 41 | | |
| DAY 42 | | |

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

118.1

Page No.

0

Repeat No.

Visit Name: VISIT 4

MEDICATION

ANALGESIC

MED_02

Data ☒ No Data ☐

ANALGESIC MEDICATION SHOULD BE COLLECTED DAILY PRIOR TO THE NEXT INFUSION

| Drug/Medication (Brand or generic name) | Dosage (Total daily dose) | Units | Route | Start Date (dd-mmm-yyyy) | Previously reported | End Date (dd-mmm-yyyy) | Ongoing |
|--|------------------------------|-------|-------|-----------------------------|--------------------------|---------------------------|--------------------------|
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |

EFC10547

X 4

Country Center Subject

118.2

Page No.

0

Repeat No.

Visit Name: VISIT 4

| Drug/Medication (Brand or generic name) | Dosage (Total daily dose) | Units | Route | Start Date (dd-mmm-yyyy) | Previously reported | End Date (dd-mmm-yyyy) | Ongoing |
|--|------------------------------|-------|-------|-----------------------------|--------------------------|---------------------------|--------------------------|
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |

EFC10547

X 4

Country Center Subject

118.3

Page No.

0

Repeat No.

Visit Name: VISIT 4

| Drug/Medication (Brand or generic name) | Dosage (Total daily dose) | Units | Route | Start Date (dd-mmm-yyyy) | Previously reported | End Date (dd-mmm-yyyy) | Ongoing |
|--|------------------------------|-------|-------|-----------------------------|--------------------------|---------------------------|--------------------------|
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |

TUMOR MEASUREMENTS

TUMEA_02

Data ☒ No Data ☐

| Lesion Number | Lesion Location | Date of Assessment (dd-mmm-yyyy) | Method of Tumor Measurement | Measurement of Target Lesion longest diameter | Response of Non target Lesions |
|----------------------|----------------------|---|-----------------------------|--|--------------------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |

| Lesion Number | Lesion Location | Date of Assessment (dd-mm-yyyy) | Method of Tumor Measurement | Measurement of Target Lesion longest diameter | Response of Non target Lesions |
|----------------------|----------------------|---|-----------------------------|---|--------------------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

120.1

Page No.

0

Repeat No.

Visit Name:

VISIT 4

TUMOR MARKERS

TMARK_01

Data ☒ No Data ☐

Date of evaluation

(dd-mmm-yyyy)

| TEST | VALUE | UNIT | NORMAL RANGE | |
|--------|-------|------|--------------|-------------|
| | | | LOWER LIMIT | UPPER LIMIT |
| CA19-9 | | | | |

CLINICAL EVENT THROMBOVASCULAR

Data ☒ No Data ☐

ANGINA PECTORIS / UNSTABLE ANGINA / MYOCARDIAL INFARCTION

Yes No

☐ ☐

STROKE / TRANSIENT ISCHEMIC ATTACK

☐ ☐

PERIPHERAL ARTERIAL THROMBOSIS

☐ ☐

DEEP VENOUS THROMBOSIS

☐ ☐

PULMONARY EMBOLISM

☐ ☐

INTRAABDOMINAL ARTERIAL THROMBOSIS

☐ ☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐ ☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐ ☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐ ☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐ ☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐ ☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐ ☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐ ☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐ ☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐ ☐

Visit Name: VISIT 4 AE

ADVERSE EVENT

AE Form Number

AE_03

Data ☒ No Data ☐

AE Reference ID

1. Adverse Event (Diagnosis) :

2. Status of Adverse Event

New ☐ Date of Start
(dd-mmm-yyyy)

Ongoing without change ☐ (do not complete the remaining items)

Ongoing with change ☐

3. Grade

1 ☐ 2 ☐ 3 ☐ 4 ☐

4. Relationship to investigational product *

Yes ☐ No ☐

5. Action Taken with Investigat. Product

None ☐ Permanently discontinued ☐ Delayed ☐ Dose reduced ☐ Delayed and reduced ☐ Interrupted ☐

6. Corrective treatment/therapy

Yes ☐ No ☐

7. Outcome

Recovered ☐ Date of Recovery
(dd-mmm-yyyy)

Recovered with sequelae ☐ Specify :

Recovering ☐

Not recovered ☐

Fatal ☐ Date of Death (complete the death report form)
(dd-mmm-yyyy)

Unknown ☐

8. Seriousness Criteria

Yes ☐ No ☐ If Yes : -Date event became serious
(dd-mmm-yyyy)

IF YES, COMPLETE THIS SECTION AND THE SAFETY COMPLEMENTARY FORM

-Tick below all criteria that apply :

| | | | |
|--------------------------------------|--------------------------|--|--------------------------|
| Results in Death | <input type="checkbox"/> | Persistent/significant disability/incapacity | <input type="checkbox"/> |
| Life Threatening | <input type="checkbox"/> | Congenital anomaly or Birth Defect | <input type="checkbox"/> |
| Requires or prolongs hospitalization | <input type="checkbox"/> | Other medically important event | <input type="checkbox"/> |

9. Is it an event such as :

Overdose of the IP

Yes ☐ No ☐

Pregnancy

Yes ☐ No ☐

*Is there a reasonable possibility that the AE was caused by Investigational Product?

EFC10547

X 4

Country Center Subject

604.2

Page No.

0

Repeat No.

Visit Name:

VISIT 4 AE

SAFETY COMPLEMENTARY FORM

SAEC_03

AE / Specific Event Form Number

1. Demographic Information

Weight (kg)

2. Detailed Description of the Adverse Event *(including complementary investigations)*

3. Date of Start of Event (Initial date of onset of the considered event) (DD-MMM-YYYY)

4. Investigational Products

Date of the FIRST administration of study treatment : (DD-MMM-YYYY)

Current Treatment number :

Current Cycle :

Date of the LAST administration before SAE : (dd-mmm-yyyy)

Last Dosage before SAE :

Action Taken :

AFLIBERCEPT/PLACEBO

MG/KG

GEMCITABINE

MG/M2

5. In case of hospitalization Date of admission (DD-MMM-YYYY) *(hospital report to be sent)*

6. In case of death Autopsy report Yes ☐ No ☐ *(copy to be sent)*

7. Corrective Treatment / Therapy

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

704.01.1

Page No.

0

Repeat No.

Visit Name: VISIT 4 LAB

ADDITIONAL HEMATOLOGY

LAB_01

Data ☒ No Data ☐

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit | SI Value | SI Unit | SI Ranges | |
|---------------------------|----------------------|-----------------------------|----------------------|----------------------|----------------------|----------------------|
| | | If other unit, specify | | | Lower Limit | Upper Limit |
| HEMOGLOBIN | <input type="text"/> | <input type="text"/> G/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| PLATELET COUNT (THROMBOC) | <input type="text"/> | <input type="text"/> 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| WBC | <input type="text"/> | <input type="text"/> 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| NEUTROPHILS | <input type="text"/> | <input type="text"/> 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

TO BE PERFORMED ONLY FOR PATIENT UNDER VITAMIN K ANTAGONIST

| | | | | | | |
|-----|----------------------|----------------------------|----------------------|----------------------|----------------------|----------------------|
| INR | <input type="text"/> | <input type="text"/> RATIO | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
|-----|----------------------|----------------------------|----------------------|----------------------|----------------------|----------------------|

Visit Name: VISIT 4 LAB

ADDITIONAL BIOCHEMISTRY

LAB_01

Data ☒ No Data ☐

Please indicate if the laboratory is the : Same as baseline ☐

Same as previous ☐

Name

Address

City

Country

For Technical use :

Name

Address

City

Country

| Date of sampling | (dd-mmm-yyyy) | Unit | SI Ranges | | | |
|-------------------------|---------------|------------------------|-----------|---------|-------------|-------------|
| Test | Value | If other unit, specify | SI Value | SI Unit | Lower Limit | Upper Limit |
| SODIUM | | MMOL/L | | | | |
| CALCIUM | | MMOL/L | | | | |
| POTASSIUM | | MMOL/L | | | | |
| PHOSPHORUS | | MMOL/L | | | | |
| ** BLOOD UREA NITROGEN | | MG/DL | | | | |
| ** UREA | | MMOL/L | | | | |
| MAGNESIUM | | MG/DL | | | | |
| * CREATININE | | UMOL/L | | | | |
| CREATININE CLEARANCE CA | | ML/MIN | | | | |
| GLUCOSE | | MMOL/L | | | | |
| AST | | IU/L | | | | |
| ALT | | IU/L | | | | |
| ALKALINE PHOSPHATASE | | IU/L | | | | |
| TOTAL BILIRUBIN | | MG/DL | | | | |
| TOTAL PROTEINS | | G/DL | | | | |
| ALBUMIN | | G/DL | | | | |

* If creatinine > 1 ULN please report the calculated creatinine clearance.

** If blood Urea Nitrogen is not evaluable, Urea value must be documented.

EFC10547

| | | | | | | | |
|---------|--------|---------|--|--|--|--|--|
| X | 4 | | | | | | |
| Country | Center | Subject | | | | | |

704.03.1
Page No.

0
Repeat No.

Visit Name: VISIT 4 LAB

ADDITIONAL DIPSTICK URINALYSIS

LABU_1

Data ☒ No Data ☐

Date of sampling

Test name

WHITE BLOOD CELLS (QU)

☐ Absent ☐ + ☐ ++ ☐ +++ ☐ Not evaluable

RED BLOOD CELLS (QUA)

☐ Absent ☐ + ☐ ++ ☐ +++ ☐ Not evaluable

ADDITIONAL MORNING SPOT URINALYSIS

LAB_01

Data ☒ No Data ☐

Please indicate if the laboratory is the : Same as baseline ☐
Same as previous ☐

| | |
|---------|----------------------|
| Name | <input type="text"/> |
| Address | <input type="text"/> |
| City | <input type="text"/> |
| Country | <input type="text"/> |

| For Technical use : | |
|---------------------|----------------------|
| Name | <input type="text"/> |
| Address | <input type="text"/> |
| City | <input type="text"/> |
| Country | <input type="text"/> |

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit If other unit, specify | SI Value | SI Unit | SI Ranges | |
|--------------------|----------------------|--------------------------------|----------------------|----------------------|----------------------|----------------------|
| | | | | | Lower Limit | Upper Limit |
| PROTEIN (URINE) | <input type="text"/> | MG/DL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| CREATININE (URINE) | <input type="text"/> | MG/DL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

Visit Name: VISIT 4 LAB

24-HOUR URINALYSIS

TO BE COMPLETED IF UPCR > 1

LAB_04

Data ☒ No Data ☐

Please indicate if the laboratory is the Same as baseline ☐

Same as previous ☐

| | |
|---------|--|
| Name | |
| Address | |
| City | |
| Country | |

| | |
|---------------------|--|
| For Technical use : | |
| Name | |
| Address | |
| City | |
| Country | |

Date (dd-mmm-yyyy) (24-hour clock)

Start date of collection: Start Time of collection :

End date of collection: End Time of collection :

| Test | Value | Unit |
|------------------|-------|------|
| URINARY VOLUME | | L |
| PROTEIN (URINE) | | G/L |
| CREATININE (URIN | | G/L |

| SI RANGES | | | |
|-----------|---------|-------------|-------------|
| SI Value | SI Unit | Lower limit | Upper Limit |
| | | | |
| | | | |
| | | | |

ELECTROPHORESIS

| | | |
|------------------|--|-----|
| ALBUMIN | | G/L |
| ALPHA 1 GLOBULIN | | G/L |
| ALPHA 2 GLOBULIN | | G/L |
| BETA GLOBULIN | | G/L |
| GAMMA GLOBULIN | | G/L |

| | | | |
|--|--|--|--|
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

EFC10547

X 4

Country Center Subject

704.05.2

Page No.

0

Repeat No.

Visit Name: VISIT 4 LAB

Is there any Hemoglobin or RBC in 24 Hour urine sample ?

LABU_1

Data ☒ No Data ☐

Test name

Negative

Positive

HEMOGLOBIN (QUALITAT

☐☐

RED BLOOD CELLS (QUA

☐☐

Visit Name: VISIT 4 LAB

TO BE COMPLETED IF PROTEINURIA IS ASSOCIATED WITH HEMATURIA.

ADDITIONAL HEMATOLOGY

LABU_1

Data ☒ No Data ☐

Date of sampling

Test name

Unit

Negative

Positive

SCHISTOCYTES (QUALITA

NONE

☐☐

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

704.06.2

Page No.

0

Repeat No.

Visit Name: VISIT 4 LAB

ADDITIONAL BIOCHEMISTRY

LAB_01

Data ☒ No Data ☐

Please indicate if the laboratory is the : Same as baseline ☐
Same as previous ☐

Name
Address
City
Country

For Technical use :

Name
Address
City
Country

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit | If other unit, specify | SI Ranges | | |
|-------------|----------------------|------|------------------------|----------------------|----------------------|-------------------------|
| | | | | SI Value | SI Unit | Lower Limit Upper Limit |
| LDH | <input type="text"/> | IU/L | | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| HAPTOGLOBIN | <input type="text"/> | G/L | | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| OROSOMUCOID | <input type="text"/> | G/L | | <input type="text"/> | <input type="text"/> | <input type="text"/> |

EFC10547

| | | | | | | | |
|---------|--------|---------|--|--|--|--|--|
| X | 4 | | | | | | |
| Country | Center | Subject | | | | | |

122.1

Page No.

0

Repeat No.

Visit Name: VISIT 5

Date of visit :

(DD-MMM-YYYY)

VISIT_01

VITAL SIGNS

VITAL_02

Data ☒ No Data ☐

DAY 1

Date performed

(dd-mmm-yyyy)

Weight:

kg

Blood pressure: Systolic: mmHg

/ Diastolic: mmHg

ECOG Performance Status 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐

A PHYSICAL EXAM SHOULD BE PERFORMED.

IF THERE ARE ANY CLINICALLY SIGNIFICANT CHANGES FROM THE PREVIOUS EXAM,

RECORD AS AN ADVERSE EVENT

EFC10547

X 4

Country Center Subject

123.1

Page No.

0

Repeat No.

Visit Name: VISIT 5

HEMATOLOGY

LAB_01

Data ☒ No Data ☐

DAY 1

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit | SI Value | SI Unit | SI Ranges | |
|---------------------------|-------|------------------------|----------|---------|-------------|-------------|
| | | If other unit, specify | | | Lower Limit | Upper Limit |
| HEMOGLOBIN | | G/L | | | | |
| PLATELET COUNT (THROMBOC) | | 10E9/L | | | | |
| WBC | | 10E9/L | | | | |
| NEUTROPHILS | | 10E9/L | | | | |

TO BE PERFORMED ONLY FOR PATIENT UNDER VITAMIN K ANTAGONIST

| | | | | | | |
|-----|--|-------|--|--|--|--|
| INR | | RATIO | | | | |
|-----|--|-------|--|--|--|--|

EFC10547

| | | | | | | | | |
|---------|--------|---------|--|--|--|--|--|--|
| X | 4 | | | | | | | |
| Country | Center | Subject | | | | | | |

124.1

Page No.

0

Repeat No.

Visit Name: VISIT 5

BIOCHEMISTRY

LAB_01

Data ☒ No Data ☐

DAY 1

Please indicate if the laboratory is the : Same as baseline ☐
Same as previous ☐

| | |
|---------|--|
| Name | |
| Address | |
| City | |
| Country | |

For Technical use :

| | |
|---------|--|
| Name | |
| Address | |
| City | |
| Country | |

EFC10547

| | | | | | | | | |
|---|---|--|--|--|--|--|--|--|
| X | 4 | | | | | | | |
|---|---|--|--|--|--|--|--|--|

Country Center Subject

125.1

Page No.

0

Repeat No.

Visit Name:

VISIT 5

DIPSTICK URINALYSIS

LABU_1

Data ☒ No Data ☐

DAY 1

Date of sampling

Test name

WHITE BLOOD CELLS (QU)

☐ Absent ☐ + ☐ ++ ☐ +++ ☐ Not evaluable

RED BLOOD CELLS (QUA)

☐ Absent ☐ + ☐ ++ ☐ +++ ☐ Not evaluable

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

126.1

Page No.

0

Repeat No.

Visit Name: VISIT 5

MORNING SPOT URINALYSIS

LAB_01

Data ☒ No Data ☐

DAY 1

Please indicate if the laboratory is the : Same as baseline ☐

Same as previous ☐

Name

Address

City

Country

For Technical use :

Name

Address

City

Country

Date of sampling (dd-mm-yyyy)

| Test | Value | Unit If other unit, specify | SI Value | SI Unit | SI Ranges | |
|--------------------|----------------------|--------------------------------|----------------------|----------------------|----------------------|----------------------|
| | | | | | Lower Limit | Upper Limit |
| PROTEIN (URINE) | <input type="text"/> | MG/DL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| CREATININE (URINE) | <input type="text"/> | MG/DL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

974.1

Page No.

0

Repeat No.

Visit Name:

VISIT 5

PHARMACOKINETIC BLOOD

PK_01

Data ☒ No Data ☐

TO BE COMPLETED ONLY FOR PK PATIENTS.

FREE AND BOUND AFLIBERCEPT

DAY 1

Sample
ID

P04

Theoretical
Time

T0H

*

Sample Date
(dd-mmm-yyyy)

Sample Time
24-hour clock

T0h* = Pre-dose - just before the start of Aflibercept/Placebo infusion

EFC10547

X 9

Country Center Subject

1005.01.1

Page No.

0

Repeat No.

Visit Name:

VISIT 5

PHARMACOKINETIC BLOOD

PK_01

Data ☒ No Data ☐

FREE AND BOUND AFLIBERCEPT

DAY 1

Theoretical
Time

T0H *

Sample Date
(dd-mmm-yyyy)

Sample Time
24-hour clock

T0h* = Pre-dose - just before the start of Aflibercept/Placebo infusion

EFC10547

X 9

Country Center Subject

1005.02.1

Page No.

0

Repeat No.

Visit Name:

VISIT 5

PHARMACOKINETIC BLOOD

PK_01

Data ☒ No Data ☐

ANTI-AFLIBERCEPT ANTIBODIES

DAY 1

Theoretical
Time

T0H *

Sample Date
(dd-mmm-yyyy)

Sample Time
(24-hour clock)

T0h* = Pre-dose - just before the start of Aflibercept/Placebo infusion

EFC10547

X 4 Country Center Subject

127.1
Page No.

0
Repeat No.

Visit Name: VISIT 5

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_05

Data ☒ No Data ☐

AFLIBERCEPT / PLACEBO

| Scheduled Day | Treatment Number | Not Administered/ Taken | Date / Time* START | Intended Dose MG / KG | Actual Dose MG |
|---------------|------------------|----------------------------|-----------------------|--------------------------|-------------------|
| DAY 1 | | <input type="checkbox"/> | (dd-mmm-yyyy) | | |
| | | | (24-hour clock) | | |
| | | | END | | |
| | | | (24-hour clock) | | |

*Time to be given only for PK patients

IF DOSE INTERRUPTED AND READMINISTERED, PLEASE REPORT THE INFORMATION BELOW :

| Scheduled Day | Treatment Number | Not Administered/ Taken | Date / Time* START | Intended Dose MG / KG | Actual Dose MG |
|---------------|------------------|----------------------------|-----------------------|--------------------------|-------------------|
| (*) | | <input type="checkbox"/> | (dd-mmm-yyyy) | NOT APPLICABLE | |
| | | | (24-hour clock) | | |
| | | | END | | |
| | | | (24-hour clock) | | |

*Time to be given only for PK patients

(*) In case of additionnal information, enter "DAY 1" in Scheduled Day

EFC10547

| | | | | | | | |
|---------|--------|---------|--|--|--|--|--|
| X | 4 | | | | | | |
| Country | Center | Subject | | | | | |

128.1
Page No.

0
Repeat No.

Visit Name: VISIT 5

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_04

Data ☒ No Data ☐

GEMCITABINE

| Scheduled Day | Batch Number | Not Administred/ Taken | Date | Intended Dose MG/M2 | Actual Dose MG |
|---------------|--------------|---------------------------|------|------------------------|-------------------|
| DAY 1 | | <input type="checkbox"/> | | | |
| | | | | | |
| | | | | | |

IF DOSE INTERRUPTED AND READMINISTERED, PLEASE REPORT THE INFORMATION BELOW :

| Scheduled Day | Batch Number | Not Administred/ Taken | Date | Intended Dose MG/M2 | Actual Dose MG |
|---------------|--------------|---------------------------|------|------------------------|-------------------|
| | | <input type="checkbox"/> | | NOT APPLICABLE | |
| | | | | | |
| | | | | | |

(*) In case of additionnal information, enter "DAY 1" in Scheduled Day

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

129.1

Page No.

0

Repeat No.

Visit Name:

VISIT 5

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☒ No Data ☐

DAY 1

Outpatient Clinic ☐ Inpatient Clinic ☐

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

130.1

Page No.

0

Repeat No.

Visit Name:

VISIT 5

VITAL SIGNS

VITAL_02

Data ☒ No Data ☐

DAY 8

Date performed
(dd-mmm-yyyy)

Blood pressure: Systolic: mmHg

/ Diastolic: mmHg

ECOG Performance Status 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐

EFC10547

X 4

Country Center Subject

131.1

Page No.

0

Repeat No.

Visit Name:

VISIT 5

HEMATOLOGY

LAB_01

Data ☒ No Data ☐

DAY 8

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit If other unit, specify | SI Ranges | | | |
|---------------------------|----------------------|--------------------------------|----------------------|----------------------|----------------------|----------------------|
| | | | SI Value | SI Unit | Lower Limit | Upper Limit |
| HEMOGLOBIN | <input type="text"/> | G/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| PLATELET COUNT (THROMBOC) | <input type="text"/> | 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| WBC | <input type="text"/> | 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| NEUTROPHILS | <input type="text"/> | 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

EFC10547

X 4

Country Center Subject

132.1

Page No.

0

Repeat No.

Visit Name: VISIT 5

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_04

Data ☒ No Data ☐

GEMCITABINE

| Scheduled Day | Batch Number | Not Administred/ Taken | Date | Intended Dose MG/M2 | Actual Dose MG |
|---------------|--------------|---------------------------|------|------------------------|-------------------|
| DAY 8 | | <input type="checkbox"/> | | | |

IF DOSE INTERRUPTED AND READMINISTERED, PLEASE REPORT THE INFORMATION BELOW :

| Scheduled Day | Batch Number | Not Administred/ Taken | Date | Intended Dose MG/M2 | Actual Dose MG |
|---------------|--------------|---------------------------|------|------------------------|-------------------|
| (*) | | <input type="checkbox"/> | | NOT APPLICABLE | |

(*) In case of additionnal information, enter "DAY 8" in Scheduled Day



EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

133.1

Page No.

0

Repeat No.

Visit Name: VISIT 5

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☒ No Data ☐

DAY 8

Outpatient Clinic ☐ Inpatient Clinic ☐

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

134.1

Page No.

0

Repeat No.

Visit Name:

VISIT 5

VITAL SIGNS

VITAL_02

Data ☒ No Data ☐

DAY 15

Date performed
(dd-mmm-yyyy)

Weight: kg

Blood pressure: Systolic: mmHg / Diastolic: mmHg

ECOG Performance Status 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐

EFC10547

X 4

Country Center Subject

135.1

Page No.

0

Repeat No.

Visit Name:

VISIT 5

HEMATOLOGY

LAB_01

Data ☒ No Data ☐

DAY 15

Date of sampling (dd-mm-yyyy)

| Test | Value | Unit If other unit, specify | SI Ranges | | | |
|---------------------------|----------------------|--------------------------------|----------------------|----------------------|----------------------|----------------------|
| | | | SI Value | SI Unit | Lower Limit | Upper Limit |
| HEMOGLOBIN | <input type="text"/> | G/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| PLATELET COUNT (THROMBOC) | <input type="text"/> | 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| WBC | <input type="text"/> | 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| NEUTROPHILS | <input type="text"/> | 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

EFC10547

| | | | | | | | |
|---------|--------|---------|--|--|--|--|--|
| X | 4 | | | | | | |
| Country | Center | Subject | | | | | |

136.1
Page No.

0
Repeat No.

Visit Name: VISIT 5

DIPSTICK URINALYSIS

LABU_1

Data ☒ No Data ☐

DAY 15

Date of sampling

Test name

WHITE BLOOD CELLS (QU)

☐ Absent ☐ + ☐ ++ ☐ +++ ☐ Not evaluable

RED BLOOD CELLS (QUA)

☐ Absent ☐ + ☐ ++ ☐ +++ ☐ Not evaluable

EFC10547

X 4

Country Center Subject

137.1

Page No.

0

Repeat No.

Visit Name: VISIT 5

MORNING SPOT URINALYSIS

LAB_01

Data ☒ No Data ☐

DAY 15

Please indicate if the laboratory is the : Same as baseline ☐

Same as previous ☐

Name

Address

City

Country

For Technical use :

Name

Address

City

Country

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit If other unit, specify | SI Value | SI Unit | SI Ranges | |
|--------------------|----------------------|--------------------------------|----------------------|----------------------|----------------------|----------------------|
| | | | | | Lower Limit | Upper Limit |
| PROTEIN (URINE) | <input type="text"/> | MG/DL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| CREATININE (URINE) | <input type="text"/> | MG/DL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

EFC10547

X 4 Country Center Subject

138.1

Page No.

0

Repeat No.

Visit Name: VISIT 5

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_05

Data ☒ No Data ☐

AFLIBERCEPT / PLACEBO

| Scheduled Day | Treatment Number | Not Administered/ Taken | Date / Time* START | Intended Dose MG / KG | Actual Dose MG |
|---------------|------------------|----------------------------|-----------------------|--------------------------|-------------------|
| DAY 15 | | <input type="checkbox"/> | (dd-mmm-yyyy) | | |
| | | | (24-hour clock) | | |
| | | | END | | |
| | | | (24-hour clock) | | |

*Time to be given only for PK patients

IF DOSE INTERRUPTED AND READMINISTERED, PLEASE REPORT THE INFORMATION BELOW :

| Scheduled Day | Treatment Number | Not Administered/ Taken | Date / Time* START | Intended Dose MG / KG | Actual Dose MG |
|---------------|------------------|----------------------------|-----------------------|--------------------------|-------------------|
| (*) | | <input type="checkbox"/> | (dd-mmm-yyyy) | NOT APPLICABLE | |
| | | | (24-hour clock) | | |
| | | | END | | |
| | | | (24-hour clock) | | |

*Time to be given only for PK patients

(*) In case of additionnal information, enter "DAY 15" in Scheduled Day

EFC10547

X 4 Country Center Subject

139.1
Page No.

0
Repeat No.

Visit Name: VISIT 5

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_04

Data ☒ No Data ☐

GEMCITABINE

| Scheduled Day | Batch Number | Not Administred/ Taken | Date | Intended Dose MG/M2 | Actual Dose MG |
|---------------|--------------|---------------------------|------|------------------------|-------------------|
| DAY 15 | | <input type="checkbox"/> | | | |

IF DOSE INTERRUPTED AND READMINISTERED, PLEASE REPORT THE INFORMATION BELOW :

| Scheduled Day | Batch Number | Not Administred/ Taken | Date | Intended Dose MG/M2 | Actual Dose MG |
|---------------|--------------|---------------------------|------|------------------------|-------------------|
| | | <input type="checkbox"/> | | NOT APPLICABLE | |

(*) In case of additionnal information, enter "DAY 15" in Scheduled Day

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

140.1

Page No.

0

Repeat No.

Visit Name:

VISIT 5

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☒ No Data ☐

DAY 15

Outpatient Clinic ☐ Inpatient Clinic ☐

Visit Name: VISIT 5

PAIN INTENSITY

ASSESSED VIA VISUAL ANALOG SCALE

Data ☒ No Data ☐

Data corresponding to current cycle

| Period | Date | Measure |
|--------|------|---------|
| | | MM |
| DAY 1 | | |
| DAY 2 | | |
| DAY 3 | | |
| DAY 4 | | |
| DAY 5 | | |
| DAY 6 | | |
| DAY 7 | | |
| DAY 8 | | |
| DAY 9 | | |
| DAY 10 | | |
| DAY 11 | | |
| DAY 12 | | |
| DAY 13 | | |
| DAY 14 | | |
| DAY 15 | | |
| DAY 16 | | |
| DAY 17 | | |
| DAY 18 | | |
| DAY 19 | | |
| DAY 20 | | |
| DAY 21 | | |

Period Date Measure

| | | |
|--------|--|--|
| DAY 22 | | |
| DAY 23 | | |
| DAY 24 | | |
| DAY 25 | | |
| DAY 26 | | |
| DAY 27 | | |
| DAY 28 | | |
| DAY 29 | | |
| DAY 30 | | |
| DAY 31 | | |
| DAY 32 | | |
| DAY 33 | | |
| DAY 34 | | |
| DAY 35 | | |
| DAY 36 | | |
| DAY 37 | | |
| DAY 38 | | |
| DAY 39 | | |
| DAY 40 | | |
| DAY 41 | | |
| DAY 42 | | |

EFC10547

X 4

Country Center Subject

142.1

Page No.

0

Repeat No.

Visit Name: VISIT 5

MEDICATION

ANALGESIC

MED_02

Data ☒ No Data ☐

ANALGESIC MEDICATION SHOULD BE COLLECTED DAILY PRIOR TO THE NEXT INFUSION

| Drug/Medication (Brand or generic name) | Dosage (Total daily dose) | Units | Route | Start Date (dd-mmm-yyyy) | Previously reported | End Date (dd-mmm-yyyy) | Ongoing |
|--|------------------------------|-------|-------|-----------------------------|--------------------------|---------------------------|--------------------------|
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |

EFC10547

X 4

Country Center Subject

142.2

Page No.

0

Repeat No.

Visit Name: VISIT 5

| Drug/Medication (Brand or generic name) | Dosage (Total daily dose) | Units | Route | Start Date (dd-mmm-yyyy) | Previously reported | End Date (dd-mmm-yyyy) | Ongoing |
|--|------------------------------|-------|-------|-----------------------------|--------------------------|---------------------------|--------------------------|
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |

EFC10547

X 4

Country Center Subject

142.3

Page No.

0

Repeat No.

Visit Name: VISIT 5

| Drug/Medication (Brand or generic name) | Dosage (Total daily dose) | Units | Route | Start Date (dd-mmm-yyyy) | Previously reported | End Date (dd-mmm-yyyy) | Ongoing |
|--|------------------------------|-------|-------|-----------------------------|--------------------------|---------------------------|--------------------------|
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |

TUMOR MEASUREMENTS

TUMEA_02

Data ☒ No Data ☐

| Lesion Number | Lesion Location | Date of Assessment (dd-mmm-yyyy) | Method of Tumor Measurement | Measurement of Target Lesion longest diameter | Response of Non target Lesions |
|----------------------|----------------------|---|-----------------------------|--|--------------------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |

| Lesion Number | Lesion Location | Date of Assessment (dd-mm-yyyy) | Method of Tumor Measurement | Measurement of Target Lesion longest diameter | Response of Non target Lesions |
|----------------------|----------------------|---|-----------------------------|---|--------------------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

144.1

Page No.

0

Repeat No.

Visit Name:

VISIT 5

TUMOR MARKERS

TMARK_01

Data ☒ No Data ☐

Date of evaluation

(dd-mmm-yyyy)

| TEST | VALUE | UNIT | NORMAL RANGE | |
|--------|-------|------|--------------|-------------|
| | | | LOWER LIMIT | UPPER LIMIT |
| CA19-9 | | | | |

CLINICAL EVENT THROMBOVASCULAR

Data ☒ No Data ☐

ANGINA PECTORIS / UNSTABLE ANGINA / MYOCARDIAL INFARCTION

Yes No

☐
☐

STROKE / TRANSIENT ISCHEMIC ATTACK

☐
☐

PERIPHERAL ARTERIAL THROMBOSIS

☐
☐

DEEP VENOUS THROMBOSIS

☐
☐

PULMONARY EMBOLISM

☐
☐

INTRAABDOMINAL ARTERIAL THROMBOSIS

☐
☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐
☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐
☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐
☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐
☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐
☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐
☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐
☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐
☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐
☐

Visit Name: VISIT 5 AE

ADVERSE EVENT

AE Form Number

AE_03

Data ☒ No Data ☐

AE Reference ID

1. Adverse Event (Diagnosis) :

2. Status of Adverse Event

New ☐ Date of Start
(dd-mmm-yyyy)

Ongoing without change ☐ (do not complete the remaining items)

Ongoing with change ☐

3. Grade

1 ☐ 2 ☐ 3 ☐ 4 ☐

4. Relationship to investigational product *

Yes ☐ No ☐

5. Action Taken with Investigat. Product

None ☐ Permanently discontinued ☐ Delayed ☐ Dose reduced ☐ Delayed and reduced ☐ Interrupted ☐

6. Corrective treatment/therapy

Yes ☐ No ☐

7. Outcome

Recovered ☐ Date of Recovery
(dd-mmm-yyyy)

Recovered with sequelae ☐ Specify : _____

Recovering ☐

Not recovered ☐

Fatal ☐ Date of Death (complete the death report form)
(dd-mmm-yyyy)

Unknown ☐

8. Seriousness Criteria

Yes ☐ No ☐ If Yes : -Date event became serious
(dd-mmm-yyyy)

IF YES, COMPLETE THIS SECTION AND THE SAFETY COMPLEMENTARY FORM

-Tick below all criteria that apply :

| | | | |
|--------------------------------------|--------------------------|--|--------------------------|
| Results in Death | <input type="checkbox"/> | Persistent/significant disability/incapacity | <input type="checkbox"/> |
| Life Threatening | <input type="checkbox"/> | Congenital anomaly or Birth Defect | <input type="checkbox"/> |
| Requires or prolongs hospitalization | <input type="checkbox"/> | Other medically important event | <input type="checkbox"/> |

9. Is it an event such as :

Overdose of the IP

Yes ☐ No ☐

Pregnancy

Yes ☐ No ☐

*Is there a reasonable possibility that the AE was caused by Investigational Product?

EFC10547

| | | | | | | | |
|---------|--------|---------|--|--|--|--|--|
| X | 4 | | | | | | |
| Country | Center | Subject | | | | | |

605.2

Page No.

0

Repeat No.

Visit Name: VISIT 5 AE

SAFETY COMPLEMENTARY FORM

SAEC_03

AE / Specific Event Form Number

1. Demographic Information

Weight (kg)

2. Detailed Description of the Adverse Event *(including complementary investigations)*

3. Date of Start of Event (Initial date of onset of the considered event) (DD-MMM-YYYY)

4. Investigational Products

Date of the FIRST administration of study treatment : (DD-MMM-YYYY)

Current Treatment number :

Current Cycle :

Date of the LAST administration before SAE : *(dd-mmm-yyyy)*

Last Dosage before SAE :

Action Taken :

AFLIBERCEPT/PLACEBO

MG/KG

GEMCITABINE

MG/M2

5. In case of hospitalization Date of admission (DD-MMM-YYYY) *(hospital report to be sent)*

6. In case of death Autopsy report Yes ☐ No ☐ *(copy to be sent)*

7. Corrective Treatment / Therapy

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

705.01.1
Page No.

0
Repeat No.

Visit Name: VISIT 5 LAB

ADDITIONAL HEMATOLOGY

LAB_01

Data ☒ No Data ☐

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit | SI Value | SI Unit | SI Ranges | |
|---------------------------|----------------------|------------------------|----------------------|----------------------|----------------------|----------------------|
| | | If other unit, specify | | | Lower Limit | Upper Limit |
| HEMOGLOBIN | <input type="text"/> | G/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| PLATELET COUNT (THROMBOC) | <input type="text"/> | 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| WBC | <input type="text"/> | 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| NEUTROPHILS | <input type="text"/> | 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

TO BE PERFORMED ONLY FOR PATIENT UNDER VITAMIN K ANTAGONIST

| | | | | | | |
|-----|----------------------|-------|----------------------|----------------------|----------------------|----------------------|
| INR | <input type="text"/> | RATIO | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
|-----|----------------------|-------|----------------------|----------------------|----------------------|----------------------|

EFC10547

| | | | | | | | |
|---------|--------|---------|--|--|--|--|--|
| X | 4 | | | | | | |
| Country | Center | Subject | | | | | |

705.02.1

Page No.

0

Repeat No.

Visit Name: VISIT 5 LAB

ADDITIONAL BIOCHEMISTRY

LAB_01

Data ☒ No Data ☐

Please indicate if the laboratory is the : Same as baseline ☐

Same as previous ☐

Name

Address

City

Country

For Technical use :

Name

Address

City

Country

EFC10547

X 4

Country Center Subject

705.02.2

Page No.

0

Repeat No.

Visit Name: VISIT 5 LAB

| Date of sampling | (dd-mmm-yyyy) | Unit | SI Ranges | | | |
|-------------------------|---------------|------------------------|-----------|---------|-------------|-------------|
| Test | Value | If other unit, specify | SI Value | SI Unit | Lower Limit | Upper Limit |
| SODIUM | | MMOL/L | | | | |
| CALCIUM | | MMOL/L | | | | |
| POTASSIUM | | MMOL/L | | | | |
| PHOSPHORUS | | MMOL/L | | | | |
| ** BLOOD UREA NITROGEN | | MG/DL | | | | |
| ** UREA | | MMOL/L | | | | |
| MAGNESIUM | | MG/DL | | | | |
| * CREATININE | | UMOL/L | | | | |
| CREATININE CLEARANCE CA | | ML/MIN | | | | |
| GLUCOSE | | MMOL/L | | | | |
| AST | | IU/L | | | | |
| ALT | | IU/L | | | | |
| ALKALINE PHOSPHATASE | | IU/L | | | | |
| TOTAL BILIRUBIN | | MG/DL | | | | |
| TOTAL PROTEINS | | G/DL | | | | |
| ALBUMIN | | G/DL | | | | |

* If creatinine > 1 ULN please report the calculated creatinine clearance.

** If blood Urea Nitrogen is not evaluable, Urea value must be documented.

EFC10547

| | | | | | | | |
|---------|--------|---------|--|--|--|--|--|
| X | 4 | | | | | | |
| Country | Center | Subject | | | | | |

705.03.1

Page No.

0

Repeat No.

Visit Name: VISIT 5 LAB

ADDITIONAL DIPSTICK URINALYSIS

LABU_1

Data ☒ No Data ☐

Date of sampling

Test name

WHITE BLOOD CELLS (QU)

☐ Absent ☐ + ☐ ++ ☐ +++ ☐ Not evaluable

RED BLOOD CELLS (QUAL)

☐ Absent ☐ + ☐ ++ ☐ +++ ☐ Not evaluable

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

705.04.1

Page No.

0

Repeat No.

Visit Name: VISIT 5 LAB

ADDITIONAL MORNING SPOT URINALYSIS

LAB_01

Data ☒ No Data ☐

Please indicate if the laboratory is the : Same as baseline ☐

Same as previous ☐

Name

Address

City

Country

For Technical use :

Name

Address

City

Country

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit If other unit, specify | SI Value | SI Unit | SI Ranges | |
|--------------------|----------------------|--------------------------------|----------------------|----------------------|----------------------|----------------------|
| | | | | | Lower Limit | Upper Limit |
| PROTEIN (URINE) | <input type="text"/> | MG/DL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| CREATININE (URINE) | <input type="text"/> | MG/DL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

Visit Name: VISIT 5 LAB

24-HOUR URINALYSIS

TO BE COMPLETED IF UPCR > 1

LAB_04

Data ☒ No Data ☐

Please indicate if the laboratory is the Same as baseline ☐

Same as previous ☐

| | |
|---------|--|
| Name | |
| Address | |
| City | |
| Country | |

| | |
|---------------------|--|
| For Technical use : | |
| Name | |
| Address | |
| City | |
| Country | |

Date (dd-mmm-yyyy) (24-hour clock)

Start date of collection: Start Time of collection :

End date of collection: End Time of collection :

| Test | Value | Unit | SI Value | SI Unit | Lower limit | Upper Limit |
|-------------------|----------------------|------|----------------------|----------------------|----------------------|----------------------|
| URINARY VOLUME | <input type="text"/> | L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| PROTEIN (URINE) | <input type="text"/> | G/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| CREATININE (URIN) | <input type="text"/> | G/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

ELECTROPHORESIS

| | | | | | | |
|------------------|----------------------|-----|----------------------|----------------------|----------------------|----------------------|
| ALBUMIN | <input type="text"/> | G/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| ALPHA 1 GLOBULIN | <input type="text"/> | G/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| ALPHA 2 GLOBULIN | <input type="text"/> | G/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| BETA GLOBULIN | <input type="text"/> | G/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| GAMMA GLOBULIN | <input type="text"/> | G/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

705.05.2

Page No.

0

Repeat No.

Visit Name: VISIT 5 LAB

Is there any Hemoglobin or RBC in 24 Hour urine sample ?

LABU_1

Data ☒ No Data ☐

Test name

Negative

Positive

HEMOGLOBIN (QUALITAT

☐☐

RED BLOOD CELLS (QUA

☐☐

Visit Name: VISIT 5 LAB

TO BE COMPLETED IF PROTEINURIA IS ASSOCIATED WITH HEMATURIA.

ADDITIONAL HEMATOLOGY

LABU_1

Data ☒ No Data ☐

Date of sampling

Test name

Unit

Negative

Positive

SCHISTOCYTES (QUALITA

NONE

☐☐

Visit Name: VISIT 5 LAB

ADDITIONAL BIOCHEMISTRY

LAB_01

Data ☒ No Data ☐

Please indicate if the laboratory is the : Same as baseline ☐
Same as previous ☐

| | |
|---------|--|
| Name | |
| Address | |
| City | |
| Country | |

| | |
|---------------------|--|
| For Technical use : | |
| Name | |
| Address | |
| City | |
| Country | |

| Date of sampling | (dd-mmm-yyyy) | Unit | SI Ranges | | | |
|------------------|---------------|------------------------|-----------|---------|-------------|-------------|
| Test | Value | If other unit, specify | SI Value | SI Unit | Lower Limit | Upper Limit |
| LDH | | IU/L | | | | |
| HAPTOGLOBIN | | G/L | | | | |
| OROSOMUCOID | | G/L | | | | |

END OF TREATMENT

EOT_01

Main reason for stopping treatment

- Adverse event * ☐
- Disease progression ☐
- Poor compliance to protocol ☐
- Lost to follow-up ☐
- Other reason ☐

If other reason, specify

In case of code-breaking, complete the Code Breaking CRF page.

*** In case of an adverse event complete the Adverse Event form.**

PLEASE CALL IVRS TO INFORM END OF TREATMENT FOR THIS PATIENT.

EFC10547

| | | | | | | | |
|---------|--------|---------|--|--|--|--|--|
| X | 4 | | | | | | |
| Country | Center | Subject | | | | | |

502.1

Page No.

0

Repeat No.

Visit Name:

VISIT 80

END OF TREATMENT

EOT_03

Data ☒ No Data ☐

In case of early, permanent discontinuation of one of the Investigational Products, specify the reason:

Adverse event * ☐

Other reason ☐

If other reason, specify

In case of code-breaking, complete the Code Breaking CRF page.

*** In case of an adverse event complete the Adverse Event form.**

EFC10547

| | | | | | | | |
|---------|--------|---------|--|--|--|--|--|
| X | 4 | | | | | | |
| Country | Center | Subject | | | | | |

503.1

Page No.

0

Repeat No.

Visit Name: VISIT 80

CODE BREAKING (ON SITE)

CODEB_01

Data ☐ No Data ☒

The code has been broken by

Investigator ☐

Pharmacist ☐

Study nurse ☐

Other (site staff) ☐

If other, specify

Name

Performed by : Ivrs

Code breaking material ☐

Date performed : (DD-MMM-YYYY)

Time performed (24-hour clock)

Reason : Adverse event ☐

==> AE Form Number

Other ☐

If other, specify

Treatment Number :

The code must be broken only in exceptional circumstances when knowledge of the study medication is essential for treating the subject. If possible contact the Monitoring Team before breaking the code.

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

801.1

Page No.

0

Repeat No.

Visit Name:

VISIT 80

Date of visit :

(DD-MMM-YYYY)

VISIT_01

VITAL SIGNS

VITAL_02

Data ☒ No Data ☐

Date performed

(dd-mmm-yyyy)

Weight:

kg

Blood pressure: Systolic: mmHg

/ Diastolic: mmHg

ECOG Performance Status 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐

**A PHYSICAL EXAM SHOULD BE PERFORMED.
IF THERE ARE ANY CLINICALLY SIGNIFICANT CHANGES FROM THE PREVIOUS EXAM,
RECORD AS AN ADVERSE EVENT**

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

802.1

Page No.

0

Repeat No.

Visit Name:

VISIT 80

HEMATOLOGY

LAB_01

Data ☒ No Data ☐

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit | SI Value | SI Unit | SI Ranges | |
|---------------------------|----------------------|-----------------------------|----------------------|----------------------|----------------------|----------------------|
| | | If other unit, specify | | | Lower Limit | Upper Limit |
| HEMOGLOBIN | <input type="text"/> | <input type="text"/> G/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| PLATELET COUNT (THROMBOC) | <input type="text"/> | <input type="text"/> 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| WBC | <input type="text"/> | <input type="text"/> 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| NEUTROPHILS | <input type="text"/> | <input type="text"/> 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

TO BE PERFORMED ONLY FOR PATIENT UNDER VITAMIN K ANTAGONIST

| | | | | | | |
|-----|----------------------|----------------------------|----------------------|----------------------|----------------------|----------------------|
| INR | <input type="text"/> | <input type="text"/> RATIO | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
|-----|----------------------|----------------------------|----------------------|----------------------|----------------------|----------------------|

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

803.1

Page No.

0

Repeat No.

Visit Name:

VISIT 80

BIOCHEMISTRY

LAB_01

Data ☒ No Data ☐

Please indicate if the laboratory is the : Same as baseline ☐

Same as previous ☐

Name

Address

City

Country

For Technical use :

Name

Address

City

Country

EFC10547

| | | | | | | | | |
|---------|--------|---------|--|--|--|--|--|--|
| X | 4 | | | | | | | |
| Country | Center | Subject | | | | | | |

804.1

Page No.

0

Repeat No.

Visit Name:

VISIT 80

DIPSTICK URINALYSIS

LABU_1

Data ☒ No Data ☐

Date of sampling

Test name

WHITE BLOOD CELLS (QU)

☐ Absent ☐ + ☐ ++ ☐ +++ ☐ Not evaluable

RED BLOOD CELLS (QUA)

☐ Absent ☐ + ☐ ++ ☐ +++ ☐ Not evaluable

EFC10547

| | | | | | | | |
|---------|--------|---------|--|--|--|--|--|
| X | 4 | | | | | | |
| Country | Center | Subject | | | | | |

805.1

Page No.

0

Repeat No.

Visit Name: VISIT 80

MORNING SPOT URINALYSIS

LAB_01

Data ☒ No Data ☐

Please indicate if the laboratory is the : Same as baseline ☐

Same as previous ☐

Name

Address

City

Country

For Technical use :

Name

Address

City

Country

Date of sampling (dd-mm-yyyy)

| Test | Value | Unit If other unit, specify | SI Value | SI Unit | SI Ranges | |
|--------------------|----------------------|--------------------------------|----------------------|----------------------|----------------------|----------------------|
| | | | | | Lower Limit | Upper Limit |
| PROTEIN (URINE) | <input type="text"/> | MG/DL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| CREATININE (URINE) | <input type="text"/> | MG/DL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

EFC10547

| | | | | | | | |
|---------|--------|---------|--|--|--|--|--|
| X | 4 | | | | | | |
| Country | Center | Subject | | | | | |

975.01.1

Page No.

0

Repeat No.

Visit Name:

VISIT 80

PHARMACOKINETIC BLOOD

PK_01

Data ☒ No Data ☐

FREE AND BOUND AFLIBERCEPT

Sample
ID

P05

Theoretical
Time

T0H *

Sample Date
(dd-mmm-yyyy)

Sample Time
24-hour clock

T0h* = Post-dose - 30 Days after last Aflibercept/Placebo infusion

EFC10547

X 9

Country Center Subject

975.01.1

Page No.

0

Repeat No.

Visit Name:

VISIT 80

PHARMACOKINETIC BLOOD

PK_01

Data ☒ No Data ☐

FREE AND BOUND AFLIBERCEPT

Theoretical
Time

T0H *

Sample Date
(dd-mmm-yyyy)

Sample Time
24-hour clock

T0h* = Post-dose - 30 Days after last Aflibercept/Placebo infusion

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

975.02.1

Page No.

0

Repeat No.

Visit Name:

VISIT 80

PHARMACOKINETIC BLOOD

PK_01

Data ☒ No Data ☐

ANTI-AFLIBERCEPT ANTIBODIES

Sample
ID

A01

Theoretical
Time

T0H

*

Sample Date
(dd-mm-yyyy)

Sample Time
(24-hour clock)

T0h* = Post-dose - 30 Days after last Aflibercept/Placebo infusion

EFC10547

X 9

Country Center Subject

975.02.1

Page No.

0

Repeat No.

Visit Name:

VISIT 80

PHARMACOKINETIC BLOOD

PK_01

Data ☒ No Data ☐

ANTI-AFLIBERCEPT ANTIBODIES

Theoretical
Time

T0H *

Sample Date
(dd-mmm-yyyy)

Sample Time
(24-hour clock)

T0h* = Post-dose - 30 Days after last Aflibercept/Placebo infusion

TUMOR MEASUREMENTS

TUMEA_02

Data ☒ No Data ☐

| Lesion Number | Lesion Location | Date of Assessment (dd-mmm-yyyy) | Method of Tumor Measurement | Measurement of Target Lesion longest diameter | Response of Non target Lesions |
|----------------------|----------------------|---|-----------------------------|--|--------------------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |

| Lesion Number | Lesion Location | Date of Assessment (dd-mm-yyyy) | Method of Tumor Measurement | Measurement of Target Lesion longest diameter | Response of Non target Lesions |
|----------------------|----------------------|---|-----------------------------|---|--------------------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

807.1

Page No.

0

Repeat No.

Visit Name:

VISIT 80

TUMOR MARKERS

TMARK_01

Data ☒ No Data ☐

Date of evaluation

(dd-mmm-yyyy)

| TEST | VALUE | UNIT | NORMAL RANGE | |
|--------|-------|------|--------------|-------------|
| | | | LOWER LIMIT | UPPER LIMIT |
| CA19-9 | | | | |

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

780.01.1
Page No.

0
Repeat No.

Visit Name: VISIT 80 LAB

ADDITIONAL HEMATOLOGY

LAB_01

Data ☒ No Data ☐

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit | SI Value | SI Unit | SI Ranges | |
|---------------------------|----------------------|-----------------------------|----------------------|----------------------|----------------------|----------------------|
| | | If other unit, specify | | | Lower Limit | Upper Limit |
| HEMOGLOBIN | <input type="text"/> | <input type="text"/> G/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| PLATELET COUNT (THROMBOC) | <input type="text"/> | <input type="text"/> 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| WBC | <input type="text"/> | <input type="text"/> 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| NEUTROPHILS | <input type="text"/> | <input type="text"/> 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

TO BE PERFORMED ONLY FOR PATIENT UNDER VITAMIN K ANTAGONIST

| | | | | | | |
|-----|----------------------|----------------------------|----------------------|----------------------|----------------------|----------------------|
| INR | <input type="text"/> | <input type="text"/> RATIO | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
|-----|----------------------|----------------------------|----------------------|----------------------|----------------------|----------------------|

EFC10547

| | | | | | | | |
|---------|--------|---------|--|--|--|--|--|
| X | 4 | | | | | | |
| Country | Center | Subject | | | | | |

780.02.1

Page No.

0

Repeat No.

Visit Name: VISIT 80 LAB

ADDITIONAL BIOCHEMISTRY

LAB_01

Data ☒ No Data ☐

Please indicate if the laboratory is the : Same as baseline ☐

Same as previous ☐

Name

Address

City

Country

For Technical use :

Name

Address

City

Country

EFC10547

X 4 Country Center Subject

780.02.2

Page No.

0

Repeat No.

Visit Name: VISIT 80 LAB

| Date of sampling | (dd-mmm-yyyy) | Unit | SI Ranges | | | |
|-------------------------|---------------|------------------------|-----------|---------|-------------|-------------|
| Test | Value | If other unit, specify | SI Value | SI Unit | Lower Limit | Upper Limit |
| SODIUM | | MMOL/L | | | | |
| CALCIUM | | MMOL/L | | | | |
| POTASSIUM | | MMOL/L | | | | |
| PHOSPHORUS | | MMOL/L | | | | |
| ** BLOOD UREA NITROGEN | | MG/DL | | | | |
| ** UREA | | MMOL/L | | | | |
| MAGNESIUM | | MG/DL | | | | |
| * CREATININE | | UMOL/L | | | | |
| CREATININE CLEARANCE CA | | ML/MIN | | | | |
| GLUCOSE | | MMOL/L | | | | |
| AST | | IU/L | | | | |
| ALT | | IU/L | | | | |
| ALKALINE PHOSPHATASE | | IU/L | | | | |
| TOTAL BILIRUBIN | | MG/DL | | | | |
| TOTAL PROTEINS | | G/DL | | | | |
| ALBUMIN | | G/DL | | | | |

* If creatinine > 1 ULN please report the calculated creatinine clearance.

** If blood Urea Nitrogen is not evaluable, Urea value must be documented.

EFC10547

| | | | | | | | |
|---------|--------|---------|--|--|--|--|--|
| X | 4 | | | | | | |
| Country | Center | Subject | | | | | |

780.03.1

Page No.

0

Repeat No.

Visit Name: VISIT 80 LAB

ADDITIONAL DIPSTICK URINALYSIS

LABU_1

Data ☒ No Data ☐

Date of sampling

Test name

WHITE BLOOD CELLS (QU)

☐ Absent ☐ + ☐ ++ ☐ +++ ☐ Not evaluable

RED BLOOD CELLS (QUAL)

☐ Absent ☐ + ☐ ++ ☐ +++ ☐ Not evaluable

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

780.04.1
Page No.

0
Repeat No.

Visit Name: VISIT 80 LAB

ADDITIONAL MORNING SPOT URINALYSIS

LAB_01

Data ☒ No Data ☐

Please indicate if the laboratory is the : Same as baseline ☐
Same as previous ☐

Name
Address
City
Country

For Technical use :

Name
Address
City
Country

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit If other unit, specify | SI Value | SI Unit | SI Ranges | |
|--------------------|----------------------|--------------------------------|----------------------|----------------------|----------------------|----------------------|
| | | | | | Lower Limit | Upper Limit |
| PROTEIN (URINE) | <input type="text"/> | MG/DL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| CREATININE (URINE) | <input type="text"/> | MG/DL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

EFC10547

X 4

Country Center Subject

780.05.2

Page No.

0

Repeat No.

Visit Name: VISIT 80 LAB

Is there any Hemoglobin or RBC in 24 Hour urine sample ?

LABU_1

Data ☒ No Data ☐

Test name

Negative

Positive

HEMOGLOBIN (QUALITAT

☐☐

RED BLOOD CELLS (QUA

☐☐

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

780.06.1

Page No.

0

Repeat No.

Visit Name: VISIT 80 LAB

TO BE COMPLETED IF PROTEINURIA IS ASSOCIATED WITH HEMATURIA.

ADDITIONAL HEMATOLOGY

LABU_1

Data ☒ No Data ☐

Date of sampling

Test name

Unit

Negative

Positive

SCHISTOCYTES (QUALITA NONE

☐☐

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

780.06.2

Page No.

0

Repeat No.

Visit Name: VISIT 80 LAB

ADDITIONAL BIOCHEMISTRY

LAB_01

Data ☒ No Data ☐

Please indicate if the laboratory is the : Same as baseline ☐
Same as previous ☐

Name
Address
City
Country

For Technical use :

Name
Address
City
Country

Date of sampling (dd-mm-yyyy)

| Test | Value | Unit | If other unit, specify | SI Ranges | | |
|-------------|----------------------|------|------------------------|----------------------|----------------------|-------------------------|
| | | | | SI Value | SI Unit | Lower Limit Upper Limit |
| LDH | <input type="text"/> | IU/L | | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| HAPTOGLOBIN | <input type="text"/> | G/L | | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| OROSOMUCOID | <input type="text"/> | G/L | | <input type="text"/> | <input type="text"/> | <input type="text"/> |

EFC10547

X 4

Country Center Subject

808.1

Page No.

0

Repeat No.

Visit Name: VISIT 81

Date of visit :

(DD-MMM-YYYY)

VISIT_01

SUBJECT STATUS

SUBST_01

Data ☒ No Data ☐

AT 90 DAYS AFTER LAST STUDY DRUG ADMINISTRATION

Date of last contact: (DD-MMM-YYYY)

Subject condition at the time of the scheduled visit :

Alive ☐Lost to follow-up ☐Dead * ☐

Method of contact:

Scheduled Visit ☐Phone ☐Other ☐ If other, specify _____** If the subject died, please complete a Death report form.*** If the subject died/has had a sudden non-treatment related death please complete an Adverse Event form.*

Visit Name: VISIT 81

VITAL SIGNS

VITAL_02

Data ☒ No Data ☐

Date performed
(dd-mmm-yyyy)

Weight: kg

Blood pressure: Systolic: mmHg / Diastolic: mmHg

ECOG Performance Status 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐

**A PHYSICAL EXAM SHOULD BE PERFORMED.
IF THERE ARE ANY CLINICALLY SIGNIFICANT CHANGES FROM THE PREVIOUS EXAM,
RECORD AS AN ADVERSE EVENT**

EFC10547

| | | | | | | | |
|---------|--------|---------|--|--|--|--|--|
| X | 4 | | | | | | |
| Country | Center | Subject | | | | | |

976.01.1

Page No.

0

Repeat No.

Visit Name:

VISIT 81

PHARMACOKINETIC BLOOD

PK_01

Data ☒ No Data ☐

FREE AND BOUND AFLIBERCEPT

Sample
ID

P06

Theoretical
Time

T0H

*

Sample Date
(dd-mmm-yyyy)

Sample Time
24-hour clock

T0h* = Post-dose - 90 days after last Aflibercept/Placebo infusion.

EFC10547

| | | | | | | | |
|---------|--------|---------|--|--|--|--|--|
| X | 9 | | | | | | |
| Country | Center | Subject | | | | | |

976.01.1

Page No.

0

Repeat No.

Visit Name:

VISIT 81

PHARMACOKINETIC BLOOD

PK_01

Data ☒ No Data ☐

FREE AND BOUND AFLIBERCEPT

Theoretical
Time

T0H *

Sample Date
(dd-mmm-yyyy)

Sample Time
24-hour clock

T0h* = Post-dose - 90 days after last Aflibercept/Placebo infusion.

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

976.02.1

Page No.

0

Repeat No.

Visit Name:

VISIT 81

PHARMACOKINETIC BLOOD

PK_01

Data ☒ No Data ☐

ANTI-AFLIBERCEPT ANTIBODIES

Sample
ID

A02

Theoretical
Time

T0H *

Sample Date
(dd-mm-yyyy)

Sample Time
(24-hour clock)

T0h* = Post-dose - 90 days after last Aflibercept/Placebo infusion.

EFC10547

X 9

Country Center Subject

976.02.1

Page No.

0

Repeat No.

Visit Name:

VISIT 81

PHARMACOKINETIC BLOOD

PK_01

Data ☒ No Data ☐

ANTI-AFLIBERCEPT ANTIBODIES

Theoretical
Time

T0H *

Sample Date
(dd-mmm-yyyy)

Sample Time
(24-hour clock)

T0h* = Post-dose - 90 days after last Aflibercept/Placebo infusion.



EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

810.1

Page No.

0

Repeat No.

Visit Name: VISIT 81

SURGERY

POST TREATMENT ANTI CANCER

SURG_01

Data ☒ No Data ☐

Surgery

Surgery Date
(DD-MMM-YYYY)

ANTI-CANCER THERAPY

POST TREATMENT

Data ☒ No Data ☐

| Regimen Number | Drug/Medication | Therapy Type | Cumulative Dose | Dose Units | Route | Start Date | End Date | Ongoing |
|----------------|-----------------|--------------|-----------------|------------|-------|------------|----------|--------------------------|
| REGIMEN 1 | | | | | | | | <input type="checkbox"/> |
| | | | | | | | | <input type="checkbox"/> |
| | | | | | | | | <input type="checkbox"/> |
| | | | | | | | | <input type="checkbox"/> |

ANTI-CANCER THERAPY

POST TREATMENT

Data ☒ No Data ☐

| Regimen Number | Drug/Medication | Therapy Type | Cumulative Dose | Dose Units | Route | Start Date | End Date | Ongoing |
|----------------|-----------------|--------------|-----------------|------------|-------|------------|----------|--------------------------|
| REGIMEN 2 | | | | | | | | <input type="checkbox"/> |
| | | | | | | | | <input type="checkbox"/> |
| | | | | | | | | <input type="checkbox"/> |
| | | | | | | | | <input type="checkbox"/> |

EFC10547

X 4

Country Center Subject

812.1

Page No.

0

Repeat No.

Visit Name: VISIT 81

RADIATION THERAPY

POST TREATMENT

RADTX_01

Data ☒ No Data ☐

| Lesion location | Start Date (dd-mmm-yyyy) | End Date (dd-mmm-yyyy) | Total Dose | Unit | Intent |
|-----------------|-----------------------------|---------------------------|------------|---|--|
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |

EFC10547

X 4

Country Center Subject

812.2

Page No.

0

Repeat No.

Visit Name: VISIT 81

| Lesion location | Start Date (dd-mmm-yyyy) | End Date (dd-mmm-yyyy) | Total Dose | Unit | Intent |
|-----------------|-----------------------------|---------------------------|------------|---|--|
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |

PAIN INTENSITY ASSESSED VIA VISUAL ANALOG SCALE

Data ☒ No Data ☐

SINCE LAST VISIT

TO BE COMPLETED UNTIL DISEASE PROGRESSION OR START OF FURTHER ANTI-CANCER THERAPIES.

Period Date Measure

MM

| | | |
|--------|--|--|
| DAY 1 | | |
| DAY 2 | | |
| DAY 3 | | |
| DAY 4 | | |
| DAY 5 | | |
| DAY 6 | | |
| DAY 7 | | |
| DAY 8 | | |
| DAY 9 | | |
| DAY 10 | | |
| DAY 11 | | |
| DAY 12 | | |
| DAY 13 | | |
| DAY 14 | | |
| DAY 15 | | |
| DAY 16 | | |
| DAY 17 | | |
| DAY 18 | | |
| DAY 19 | | |
| DAY 20 | | |
| DAY 21 | | |
| DAY 22 | | |
| DAY 23 | | |
| DAY 24 | | |
| DAY 25 | | |
| DAY 26 | | |

| Period | Date | Measure |
|--------|------|---------|
| DAY 27 | | |
| DAY 28 | | |
| DAY 29 | | |
| DAY 30 | | |
| DAY 31 | | |
| DAY 32 | | |
| DAY 33 | | |
| DAY 34 | | |
| DAY 35 | | |
| DAY 36 | | |
| DAY 37 | | |
| DAY 38 | | |
| DAY 39 | | |
| DAY 40 | | |
| DAY 41 | | |
| DAY 42 | | |
| DAY 43 | | |
| DAY 44 | | |
| DAY 45 | | |
| DAY 46 | | |
| DAY 47 | | |
| DAY 48 | | |
| DAY 49 | | |
| DAY 50 | | |
| DAY 51 | | |
| DAY 52 | | |
| DAY 53 | | |
| DAY 54 | | |
| DAY 55 | | |

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

813.3

Page No.

0

Repeat No.

Visit Name:

VISIT 81

| Period | Date | Measure |
|--------|------|---------|
| DAY 56 | | |
| DAY 57 | | |
| DAY 58 | | |
| DAY 59 | | |
| DAY 60 | | |
| DAY 61 | | |
| DAY 62 | | |
| DAY 63 | | |
| DAY 64 | | |
| DAY 65 | | |
| DAY 66 | | |
| DAY 67 | | |
| DAY 68 | | |
| DAY 69 | | |
| DAY 70 | | |
| DAY 71 | | |
| DAY 72 | | |
| DAY 73 | | |
| DAY 74 | | |
| DAY 75 | | |

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

814.1

Page No.

0

Repeat No.

Visit Name:

VISIT 81

MEDICATION

ANALGESIC

MED_02

Data ☒ No Data ☐

TO BE COMPLETED UNTIL DISEASE PROGRESSION OR START OF FURTHER ANTI-CANCER THERAPIES.

| Drug/Medication (Brand or generic name) | Dosage (Total daily dose) | Units | Route | Start Date (dd-mmm-yyyy) | Previously reported | End Date (dd-mmm-yyyy) | Ongoing |
|--|------------------------------|----------------------|----------------------|-----------------------------|--------------------------|---------------------------|--------------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |

EFC10547

X 4

Country Center Subject

814.2

Page No.

0

Repeat No.

Visit Name: VISIT 81

| Drug/Medication (Brand or generic name) | Dosage (Total daily dose) | Units | Route | Start Date (dd-mmm-yyyy) | Previously reported | End Date (dd-mmm-yyyy) | Ongoing |
|--|------------------------------|-------|-------|-----------------------------|--------------------------|---------------------------|--------------------------|
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |

EFC10547

X 4

Country Center Subject

814.3

Page No.

0

Repeat No.

Visit Name: VISIT 81

| Drug/Medication (Brand or generic name) | Dosage (Total daily dose) | Units | Route | Start Date (dd-mmm-yyyy) | Previously reported | End Date (dd-mmm-yyyy) | Ongoing |
|--|------------------------------|-------|-------|-----------------------------|--------------------------|---------------------------|--------------------------|
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |

TUMOR MEASUREMENTS

TUMEA_02

Data ☒ No Data ☐

TO BE COMPLETED UNTIL DISEASE PROGRESSION

| Lesion Number | Lesion Location | Date of Assessment (dd-mmm-yyyy) | Method of Tumor Measurement | Measurement of Target Lesion longest diameter | Response of Non target Lesions |
|----------------------|----------------------|---|-----------------------------|--|--------------------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |

EFC10547

X 4

Country Center Subject

815.2

Page No.

0

Repeat No.

Visit Name: VISIT 81

| Lesion Number | Lesion Location | Date of Assessment (dd-mm-yyyy) | Method of Tumor Measurement | Measurement of Target Lesion longest diameter | Response of Non target Lesions |
|----------------------|----------------------|---|-----------------------------|---|--------------------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

816.1

Page No.

0

Repeat No.

Visit Name:

VISIT 81

TUMOR MARKERS

TMARK_01

Data ☒ No Data ☐

Date of evaluation

(dd-mmm-yyyy)

| TEST | VALUE | UNIT | NORMAL RANGE | |
|--------|-------|------|--------------|-------------|
| | | | LOWER LIMIT | UPPER LIMIT |
| CA19-9 | | | | |

CLINICAL EVENT THROMBOVASCULAR

Data ☒ No Data ☐

ANGINA PECTORIS / UNSTABLE ANGINA / MYOCARDIAL INFARCTION

Yes No

☐ ☐

STROKE / TRANSIENT ISCHEMIC ATTACK

☐ ☐

PERIPHERAL ARTERIAL THROMBOSIS

☐ ☐

DEEP VENOUS THROMBOSIS

☐ ☐

PULMONARY EMBOLISM

☐ ☐

INTRAABDOMINAL ARTERIAL THROMBOSIS

☐ ☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐ ☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐ ☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐ ☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐ ☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐ ☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐ ☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐ ☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐ ☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐ ☐

EFC10547

X 4 Country Center Subject

681.1

Page No.

0

Repeat No.

Visit Name: VISIT 81 AE

ADVERSE EVENT

AE Form Number

AE_03

Data ☒ No Data ☐

AE Reference ID

1. Adverse Event (Diagnosis) :

2. Status of Adverse Event

New ☐ Date of Start
(dd-mmm-yyyy)

Ongoing without change ☐ (do not complete the remaining items)

Ongoing with change ☐

3. Grade

1 ☐ 2 ☐ 3 ☐ 4 ☐

4. Relationship to investigational product *

Yes ☐ No ☐

5. Action Taken with Investigat. Product

None ☐ Permanently discontinued ☐ Delayed ☐ Dose reduced ☐ Delayed and reduced ☐ Interrupted ☐

6. Corrective treatment/therapy

Yes ☐ No ☐

7. Outcome

Recovered ☐ Date of Recovery
(dd-mmm-yyyy)

Recovered with sequelae ☐ Specify : _____

Recovering ☐

Not recovered ☐

Fatal ☐ Date of Death (complete the death report form)
(dd-mmm-yyyy)

Unknown ☐

8. Seriousness Criteria

Yes ☐ No ☐ If Yes : -Date event became serious
(dd-mmm-yyyy)

IF YES, COMPLETE THIS SECTION AND THE SAFETY COMPLEMENTARY FORM

-Tick below all criteria that apply :

| | | | |
|--------------------------------------|--------------------------|--|--------------------------|
| Results in Death | <input type="checkbox"/> | Persistent/significant disability/incapacity | <input type="checkbox"/> |
| Life Threatening | <input type="checkbox"/> | Congenital anomaly or Birth Defect | <input type="checkbox"/> |
| Requires or prolongs hospitalization | <input type="checkbox"/> | Other medically important event | <input type="checkbox"/> |

9. Is it an event such as :

Overdose of the IP

Yes ☐ No ☐

Pregnancy

Yes ☐ No ☐

*Is there a reasonable possibility that the AE was caused by Investigational Product?

EFC10547

| | | | | | | | |
|---------|--------|---------|--|--|--|--|--|
| X | 4 | | | | | | |
| Country | Center | Subject | | | | | |

681.2

Page No.

0

Repeat No.

Visit Name: VISIT 81 AE

SAFETY COMPLEMENTARY FORM

SAEC_03

AE / Specific Event Form Number

1. Demographic Information

Weight (kg)

2. Detailed Description of the Adverse Event *(including complementary investigations)*

3. Date of Start of Event (Initial date of onset of the considered event) (DD-MMM-YYYY)

4. Investigational Products

Date of the FIRST administration of study treatment : (DD-MMM-YYYY)

Current Treatment number :

Current Cycle :

Date of the LAST administration before SAE : (dd-mmm-yyyy)

Last Dosage before SAE :

Action Taken :

AFLIBERCEPT/PLACEBO

GEMCITABINE

MG/KG

MG/M2

5. In case of hospitalization Date of admission (DD-MMM-YYYY) *(hospital report to be sent)*

6. In case of death Autopsy report Yes ☐ No ☐ *(copy to be sent)*

7. Corrective Treatment / Therapy

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

781.01.1

Page No.

0

Repeat No.

Visit Name: VISIT 81 LAB

ADDITIONAL HEMATOLOGY

LAB_01

Data ☒ No Data ☐

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit | SI Value | SI Unit | SI Ranges | |
|---------------------------|----------------------|-----------------------------|----------------------|----------------------|----------------------|----------------------|
| | | If other unit, specify | | | Lower Limit | Upper Limit |
| HEMOGLOBIN | <input type="text"/> | <input type="text"/> G/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| PLATELET COUNT (THROMBOC) | <input type="text"/> | <input type="text"/> 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| WBC | <input type="text"/> | <input type="text"/> 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| NEUTROPHILS | <input type="text"/> | <input type="text"/> 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

TO BE PERFORMED ONLY FOR PATIENT UNDER VITAMIN K ANTAGONIST

| | | | | | | |
|-----|----------------------|----------------------------|----------------------|----------------------|----------------------|----------------------|
| INR | <input type="text"/> | <input type="text"/> RATIO | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
|-----|----------------------|----------------------------|----------------------|----------------------|----------------------|----------------------|

Visit Name: VISIT 81 LAB

ADDITIONAL BIOCHEMISTRY

LAB_01

Data ☒ No Data ☐Please indicate if the laboratory is the : Same as baseline ☐Same as previous ☐

| | |
|---------|--|
| Name | |
| Address | |
| City | |
| Country | |

For Technical use :

| | |
|---------|--|
| Name | |
| Address | |
| City | |
| Country | |

EFC10547

X 4 Country Center Subject

781.02.2

Page No.

0

Repeat No.

Visit Name: VISIT 81 LAB

| Date of sampling | (dd-mm-yyyy) | Unit | SI Ranges | | | |
|-------------------------|--------------|------------------------|-----------|---------|-------------|-------------|
| Test | Value | If other unit, specify | SI Value | SI Unit | Lower Limit | Upper Limit |
| SODIUM | | MMOL/L | | | | |
| CALCIUM | | MMOL/L | | | | |
| POTASSIUM | | MMOL/L | | | | |
| PHOSPHORUS | | MMOL/L | | | | |
| ** BLOOD UREA NITROGEN | | MG/DL | | | | |
| ** UREA | | MMOL/L | | | | |
| MAGNESIUM | | MG/DL | | | | |
| * CREATININE | | UMOL/L | | | | |
| CREATININE CLEARANCE CA | | ML/MIN | | | | |
| GLUCOSE | | MMOL/L | | | | |
| AST | | IU/L | | | | |
| ALT | | IU/L | | | | |
| ALKALINE PHOSPHATASE | | IU/L | | | | |
| TOTAL BILIRUBIN | | MG/DL | | | | |
| TOTAL PROTEINS | | G/DL | | | | |
| ALBUMIN | | G/DL | | | | |

* If creatinine > 1 ULN please report the calculated creatinine clearance.

** If blood Urea Nitrogen is not evaluable, Urea value must be documented.

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

781.03.1

Page No.

0

Repeat No.

Visit Name: VISIT 81 LAB

ADDITIONAL DIPSTICK URINALYSIS

LABU_1

Data ☒ No Data ☐

Date of sampling

Test name

WHITE BLOOD CELLS (QU)

☐ Absent ☐ + ☐ ++ ☐ +++ ☐ Not evaluable

RED BLOOD CELLS (QUA)

☐ Absent ☐ + ☐ ++ ☐ +++ ☐ Not evaluable

EFC10547

X 4

Country Center Subject

781.04.1

Page No.

0

Repeat No.

Visit Name: VISIT 81 LAB

ADDITIONAL MORNING SPOT URINALYSIS

LAB_01

Data ☒ No Data ☐

Please indicate if the laboratory is the : Same as baseline ☐

Same as previous ☐

| | |
|---------|--|
| Name | |
| Address | |
| City | |
| Country | |

For Technical use :

| | |
|---------|--|
| Name | |
| Address | |
| City | |
| Country | |

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit If other unit, specify | SI Ranges | | | |
|--------------------|----------------------|--------------------------------|----------------------|----------------------|----------------------|----------------------|
| | | | SI Value | SI Unit | Lower Limit | Upper Limit |
| PROTEIN (URINE) | <input type="text"/> | MG/DL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| CREATININE (URINE) | <input type="text"/> | MG/DL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

EFC10547

X 4 Country Center Subject

781.05.1

Page No.

0

Repeat No.

Visit Name: VISIT 81 LAB

ADDITIONAL 24-HOUR URINALYSIS

LAB_04

Data ☒ No Data ☐

Please indicate if the laboratory is the Same as baseline ☐
Same as previous ☐

| | |
|---------|--|
| Name | |
| Address | |
| City | |
| Country | |

| For Technical use : | |
|---------------------|--|
| Name | |
| Address | |
| City | |
| Country | |

Date (dd-mmm-yyyy) (24-hour clock)

Start date of collection: End date of collection:

Start Time of collection : End Time of collection :

| Test | Value | Unit |
|------------------|-------|------|
| URINARY VOLUME | | L |
| PROTEIN (URINE) | | G/L |
| CREATININE (URIN | | G/L |

| SI Value | SI Unit | SI RANGES | |
|-------------|-------------|-----------|--|
| Lower limit | Upper Limit | | |
| | | | |
| | | | |
| | | | |

ELECTROPHORESIS

| | | |
|------------------|--|-----|
| ALBUMIN | | G/L |
| ALPHA 1 GLOBULIN | | G/L |
| ALPHA 2 GLOBULIN | | G/L |
| BETA GLOBULIN | | G/L |
| GAMMA GLOBULIN | | G/L |

| | | | |
|--|--|--|--|
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

EFC10547

| | | | | | | | | |
|---|---|--|--|--|--|--|--|--|
| X | 4 | | | | | | | |
|---|---|--|--|--|--|--|--|--|

Country Center Subject

781.05.2

Page No.

0

Repeat No.

Visit Name: VISIT 81 LAB

Is there any Hemoglobin or RBC in 24 Hour urine sample ?

LABU_1

Data ☒ No Data ☐

Test name

Negative

Positive

HEMOGLOBIN (QUALITAT

☐☐

RED BLOOD CELLS (QUA

☐☐

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

781.06.1

Page No.

0

Repeat No.

Visit Name: VISIT 81 LAB

ADDITIONAL HEMATOLOGY

LABU_1

Data ☒ No Data ☐

Date of sampling

Test name

Unit

Negative

Positive

| | |
|------------------------|------|
| SCHISTOCYTES (QUALITY) | NONE |
|------------------------|------|

☐☐

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

781.06.2

Page No.

0

Repeat No.

Visit Name: VISIT 81 LAB

ADDITIONAL BIOCHEMISTRY

LAB_01

Data ☒ No Data ☐

Please indicate if the laboratory is the : Same as baseline ☐
Same as previous ☐

Name
Address
City
Country

For Technical use :

Name
Address
City
Country

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit | If other unit, specify | SI Ranges | | |
|-------------|----------------------|------|------------------------|----------------------|----------------------|-------------------------|
| | | | | SI Value | SI Unit | Lower Limit Upper Limit |
| LDH | <input type="text"/> | IU/L | | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| HAPTOGLOBIN | <input type="text"/> | G/L | | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| OROSOMUCOID | <input type="text"/> | G/L | | <input type="text"/> | <input type="text"/> | <input type="text"/> |

EFC10547

| | | | | | | | |
|---------|--------|---------|--|--|--|--|--|
| X | 4 | | | | | | |
| Country | Center | Subject | | | | | |

818.1

Page No.

0

Repeat No.

Visit Name:

VISIT 82

Date of visit :

(DD-MMM-YYYY)

VISIT_01

SUBJECT STATUS

SUBST_01

Data ☒ No Data ☐Date of last contact:

(DD-MMM-YYYY)

Subject condition at the time of the scheduled visit :

Alive ☐Lost to follow-up ☐Dead * ☐

Method of contact:

Scheduled Visit ☐Phone ☐Other ☐ If other, specify _____** If the subject died, please complete a Death report form.*** If the subject died/has had a sudden non-treatment related death please complete an Adverse Event form.*

EFC10547

| | | | | | | | |
|---------|--------|---------|--|--|--|--|--|
| X | 4 | | | | | | |
| Country | Center | Subject | | | | | |

819.1

Page No.

0

Repeat No.

Visit Name:

VISIT 82

VITAL SIGNS

VITAL_02

Data ☒ No Data ☐

Date performed
(dd-mmm-yyyy)

Weight: kg

Blood pressure: Systolic: mmHg / Diastolic: mmHg

ECOG Performance Status 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐

SURGERY

POST TREATMENT ANTI CANCER

SURG_01

Data ☒ No Data ☐

Surgery

Surgery Date
(DD-MMM-YYYY)

ANTI-CANCER THERAPY

POST TREATMENT

Data ☒ No Data ☐

| Regimen Number | Drug/Medication | Therapy Type | Cumulative Dose | Dose Units | Route | Start Date | Previously reported | End Date | Ongoing |
|----------------|-----------------|--------------|-----------------|------------|-------|------------|--------------------------|----------|--------------------------|
| REGIMEN 1 | | | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |

ANTI-CANCER THERAPY

POST TREATMENT

Data ☒ No Data ☐

| Regimen Number | Drug/Medication | Therapy Type | Cumulative Dose | Dose Units | Route | Start Date | Previously reported | End Date | Ongoing |
|----------------|-----------------|--------------|-----------------|------------|-------|------------|--------------------------|----------|--------------------------|
| REGIMEN 2 | | | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | | | | | | <input type="checkbox"/> | | <input type="checkbox"/> |

EFC10547

X 5

Country Center Subject

822.1

Page No.

0

Repeat No.

Visit Name: VISIT 82

RADIATION THERAPY

POST TREATMENT

RADTX_01

Data ☒ No Data ☐

| Lesion location | Start Date (dd-mmm-yyyy) | End Date (dd-mmm-yyyy) | Total Dose | Unit | Intent |
|-----------------|-----------------------------|---------------------------|------------|---|--|
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |

EFC10547

X 5

Country Center Subject

822.2

Page No.

0

Repeat No.

Visit Name: VISIT 82

| Lesion location | Start Date (dd-mmm-yyyy) | End Date (dd-mmm-yyyy) | Total Dose | Unit | Intent |
|-----------------|-----------------------------|---------------------------|------------|---|--|
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |
| | | | | Grays <input type="checkbox"/> Rads <input type="checkbox"/> | Palliative <input type="checkbox"/> Curative <input type="checkbox"/> |

PAIN INTENSITY ASSESSED VIA VISUAL ANALOG SCALE

Data ☒ No Data ☐

SINCE LAST VISIT

TO BE COMPLETED UNTIL DISEASE PROGRESSION OR START OF FURTHER ANTI-CANCER THERAPIES.

Period Date Measure

MM

| | | |
|--------|--|--|
| DAY 1 | | |
| DAY 2 | | |
| DAY 3 | | |
| DAY 4 | | |
| DAY 5 | | |
| DAY 6 | | |
| DAY 7 | | |
| DAY 8 | | |
| DAY 9 | | |
| DAY 10 | | |
| DAY 11 | | |
| DAY 12 | | |
| DAY 13 | | |
| DAY 14 | | |
| DAY 15 | | |
| DAY 16 | | |
| DAY 17 | | |
| DAY 18 | | |
| DAY 19 | | |
| DAY 20 | | |
| DAY 21 | | |
| DAY 22 | | |
| DAY 23 | | |
| DAY 24 | | |
| DAY 25 | | |
| DAY 26 | | |

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 5 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

823.2

Page No.

0

Repeat No.

Visit Name: VISIT 82

| Period | Date | Measure |
|--------|------|---------|
| DAY 27 | | |
| DAY 28 | | |
| DAY 29 | | |
| DAY 30 | | |
| DAY 31 | | |
| DAY 32 | | |
| DAY 33 | | |
| DAY 34 | | |
| DAY 35 | | |
| DAY 36 | | |
| DAY 37 | | |
| DAY 38 | | |
| DAY 39 | | |
| DAY 40 | | |
| DAY 41 | | |
| DAY 42 | | |
| DAY 43 | | |
| DAY 44 | | |
| DAY 45 | | |
| DAY 46 | | |
| DAY 47 | | |
| DAY 48 | | |
| DAY 49 | | |
| DAY 50 | | |
| DAY 51 | | |
| DAY 52 | | |
| DAY 53 | | |
| DAY 54 | | |
| DAY 55 | | |

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 5 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

823.3

Page No.

0

Repeat No.

Visit Name:

VISIT 82

| Period | Date | Measure |
|--------|------|---------|
| DAY 56 | | |
| DAY 57 | | |
| DAY 58 | | |
| DAY 59 | | |
| DAY 60 | | |
| DAY 61 | | |
| DAY 62 | | |
| DAY 63 | | |
| DAY 64 | | |
| DAY 65 | | |
| DAY 66 | | |
| DAY 67 | | |
| DAY 68 | | |
| DAY 69 | | |
| DAY 70 | | |
| DAY 71 | | |
| DAY 72 | | |
| DAY 73 | | |
| DAY 74 | | |
| DAY 75 | | |

EFC10547

X 5
Country Center Subject

824.1

Page No.

0

Repeat No.

Visit Name:

VISIT 82

MEDICATION

ANALGESIC

MED_02

Data ☒ No Data ☐

TO BE COMPLETED UNTIL DISEASE PROGRESSION OR START OF FURTHER ANTI-CANCER THERAPIES.

| Drug/Medication (Brand or generic name) | Dosage (Total daily dose) | Units | Route | Start Date (dd-mmm-yyyy) | Previously reported | End Date (dd-mmm-yyyy) | Ongoing |
|--|------------------------------|----------------------|----------------------|-----------------------------|--------------------------|---------------------------|--------------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |

EFC10547

X 5
Country Center Subject

824.2

Page No.

0

Repeat No.

Visit Name: VISIT 82

| Drug/Medication (Brand or generic name) | Dosage (Total daily dose) | Units | Route | Start Date (dd-mmm-yyyy) | Previously reported | End Date (dd-mmm-yyyy) | Ongoing |
|--|------------------------------|----------------------|----------------------|-----------------------------|--------------------------|---------------------------|--------------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |

EFC10547

X 5
Country Center Subject

824.3

Page No.

0

Repeat No.

Visit Name: VISIT 82

| Drug/Medication (Brand or generic name) | Dosage (Total daily dose) | Units | Route | Start Date (dd-mmm-yyyy) | Previously reported | End Date (dd-mmm-yyyy) | Ongoing |
|--|------------------------------|----------------------|----------------------|-----------------------------|--------------------------|---------------------------|--------------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |

TUMOR MEASUREMENTS

TUMEA_02

Data ☒ No Data ☐

TO BE COMPLETED UNTIL DISEASE PROGRESSION

| Lesion Number | Lesion Location | Date of Assessment (dd-mmm-yyyy) | Method of Tumor Measurement | Measurement of Target Lesion longest diameter | Response of Non target Lesions |
|----------------------|----------------------|---|-----------------------------|--|--------------------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |

EFC10547

X 5

Country Center Subject

825.2

Page No.

0

Repeat No.

Visit Name: VISIT 82

| Lesion Number | Lesion Location | Date of Assessment (dd-mm-yyyy) | Method of Tumor Measurement | Measurement of Target Lesion longest diameter | Response of Non target Lesions |
|----------------------|----------------------|---|-----------------------------|---|--------------------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="checkbox"/> Not Done | <input type="text"/> | <input type="text"/> mm | <input type="text"/> |

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 5 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

826.1

Page No.

0

Repeat No.

Visit Name:

VISIT 82

TUMOR MARKERS

TMARK_01

Data ☒ No Data ☐

Date of evaluation

(dd-mmm-yyyy)

| TEST | VALUE | UNIT | NORMAL RANGE | |
|--------|-------|------|--------------|-------------|
| | | | LOWER LIMIT | UPPER LIMIT |
| CA19-9 | | | | |

CLINICAL EVENT THROMBOVASCULAR

Data ☒ No Data ☐

ANGINA PECTORIS / UNSTABLE ANGINA / MYOCARDIAL INFARCTION

Yes No

☐ ☐

STROKE / TRANSIENT ISCHEMIC ATTACK

☐ ☐

PERIPHERAL ARTERIAL THROMBOSIS

☐ ☐

DEEP VENOUS THROMBOSIS

☐ ☐

PULMONARY EMBOLISM

☐ ☐

INTRAABDOMINAL ARTERIAL THROMBOSIS

☐ ☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐ ☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐ ☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐ ☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐ ☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐ ☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐ ☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐ ☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐ ☐

OTHER THROMBOVASCULAR EVENT , SPECIFY :

☐ ☐

EFC10547

X 5 Country Center Subject

882.1

Page No.

0

Repeat No.

Visit Name: VISIT 82 AE

ADVERSE EVENT

AE Form Number

AE_03

Data ☒ No Data ☐

AE Reference ID

1. Adverse Event (Diagnosis) :

2. Status of Adverse Event

New ☐ Date of Start
(dd-mmm-yyyy)

Ongoing without change ☐ (do not complete the remaining items)

Ongoing with change ☐

3. Grade

1 ☐ 2 ☐ 3 ☐ 4 ☐

4. Relationship to investigational product *

Yes ☐ No ☐

5. Action Taken with Investigat. Product

None ☐ Permanently discontinued ☐ Delayed ☐ Dose reduced ☐ Delayed and reduced ☐ Interrupted ☐

6. Corrective treatment/therapy

Yes ☐ No ☐

7. Outcome

Recovered ☐ Date of Recovery
(dd-mmm-yyyy)

Recovered with sequelae ☐ Specify : _____

Recovering ☐

Not recovered ☐

Fatal ☐ Date of Death (complete the death report form)
(dd-mmm-yyyy)

Unknown ☐

8. Seriousness Criteria

Yes ☐ No ☐ If Yes : -Date event became serious
(dd-mmm-yyyy)

IF YES, COMPLETE THIS SECTION AND THE SAFETY COMPLEMENTARY FORM

-Tick below all criteria that apply :

| | | | |
|--------------------------------------|--------------------------|--|--------------------------|
| Results in Death | <input type="checkbox"/> | Persistent/significant disability/incapacity | <input type="checkbox"/> |
| Life Threatening | <input type="checkbox"/> | Congenital anomaly or Birth Defect | <input type="checkbox"/> |
| Requires or prolongs hospitalization | <input type="checkbox"/> | Other medically important event | <input type="checkbox"/> |

9. Is it an event such as :

Overdose of the IP

Yes ☐ No ☐

Pregnancy

Yes ☐ No ☐

*Is there a reasonable possibility that the AE was caused by Investigational Product?

EFC10547

| | | | | | | | |
|---------|--------|---------|--|--|--|--|--|
| X | 5 | | | | | | |
| Country | Center | Subject | | | | | |

882.2

Page No.

0

Repeat No.

Visit Name: VISIT 82 AE

SAFETY COMPLEMENTARY FORM

SAEC_03

AE / Specific Event Form Number

1. Demographic Information

Weight (kg)

2. Detailed Description of the Adverse Event *(including complementary investigations)*

3. Date of Start of Event (Initial date of onset of the considered event) (DD-MMM-YYYY)

4. Investigational Products

Date of the FIRST administration of study treatment : (DD-MMM-YYYY)

Current Treatment number :

Current Cycle :

Date of the LAST administration before SAE : (dd-mmm-yyyy)

Last Dosage before SAE :

Action Taken :

AFLIBERCEPT/PLACEBO

GEMCITABINE

MG/KG

MG/M2

5. In case of hospitalization Date of admission (DD-MMM-YYYY) *(hospital report to be sent)*

6. In case of death Autopsy report Yes ☐ No ☐ *(copy to be sent)*

7. Corrective Treatment / Therapy

EFC10547

X 4

Country Center Subject

782.01.1

Page No.

0

Repeat No.

Visit Name: VISIT 82 LAB

ADDITIONAL HEMATOLOGY

LAB_01

Data ☒ No Data ☐

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit If other unit, specify | SI Value | SI Unit | SI Ranges Lower Limit Upper Limit | |
|---------------------------|----------------------|--------------------------------|----------------------|----------------------|--------------------------------------|----------------------|
| HEMOGLOBIN | <input type="text"/> | G/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| PLATELET COUNT (THROMBOC) | <input type="text"/> | 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| WBC | <input type="text"/> | 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| NEUTROPHILS | <input type="text"/> | 10E9/L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

TO BE PERFORMED ONLY FOR PATIENT UNDER VITAMIN K ANTAGONIST

| | | | | | | |
|-----|----------------------|-------|----------------------|----------------------|----------------------|----------------------|
| INR | <input type="text"/> | RATIO | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
|-----|----------------------|-------|----------------------|----------------------|----------------------|----------------------|

ADDITIONAL BIOCHEMISTRY

LAB_01

Data ☒ No Data ☐

Please indicate if the laboratory is the : Same as baseline ☐
Same as previous ☐

Name
Address
City
Country

For Technical use :

Name
Address
City
Country

EFC10547

X 5 Country Center Subject

782.02.2
Page No.

0
Repeat No.

Visit Name: VISIT 82 LAB

| Date of sampling | (dd-mmm-yyyy) | Unit | SI Ranges | | | |
|-------------------------|---------------|------------------------|-----------|---------|-------------|-------------|
| Test | Value | If other unit, specify | SI Value | SI Unit | Lower Limit | Upper Limit |
| SODIUM | | MMOL/L | | | | |
| CALCIUM | | MMOL/L | | | | |
| POTASSIUM | | MMOL/L | | | | |
| PHOSPHORUS | | MMOL/L | | | | |
| ** BLOOD UREA NITROGEN | | MG/DL | | | | |
| ** UREA | | MMOL/L | | | | |
| MAGNESIUM | | MG/DL | | | | |
| * CREATININE | | UMOL/L | | | | |
| CREATININE CLEARANCE CA | | ML/MIN | | | | |
| GLUCOSE | | MMOL/L | | | | |
| AST | | IU/L | | | | |
| ALT | | IU/L | | | | |
| ALKALINE PHOSPHATASE | | IU/L | | | | |
| TOTAL BILIRUBIN | | MG/DL | | | | |
| TOTAL PROTEINS | | G/DL | | | | |
| ALBUMIN | | G/DL | | | | |

* If creatinine > 1 ULN please report the calculated creatinine clearance.

** If blood Urea Nitrogen is not evaluable, Urea value must be documented.

EFC10547

X 4

Country Center Subject

782.03.1

Page No.

0

Repeat No.

Visit Name: VISIT 82 LAB

ADDITIONAL DIPSTICK URINALYSIS

LABU_1

Data ☒ No Data ☐

Date of sampling

Test name

WHITE BLOOD CELLS (QUA)

☐ Absent ☐ + ☐ ++ ☐ +++ ☐ Not evaluable

RED BLOOD CELLS (QUAL)

☐ Absent ☐ + ☐ ++ ☐ +++ ☐ Not evaluable

EFC10547

X 4

Country Center Subject

782.04.1

Page No.

0

Repeat No.

Visit Name: VISIT 82 LAB

ADDITIONAL MORNING SPOT URINALYSIS

LAB_01

Data ☒ No Data ☐

Please indicate if the laboratory is the : Same as baseline ☐
Same as previous ☐

Name

Address

City

Country

For Technical use :

Name

Address

City

Country

Date of sampling (dd-mmm-yyyy)

| Test | Value | Unit If other unit, specify | SI Value | SI Unit | SI Ranges Lower Limit Upper Limit | |
|--------------------|----------------------|--------------------------------|----------------------|----------------------|--------------------------------------|----------------------|
| PROTEIN (URINE) | <input type="text"/> | MG/DL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| CREATININE (URINE) | <input type="text"/> | MG/DL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

EFC10547

X 4

Country Center Subject

782.05.1

Page No.

0

Repeat No.

Visit Name: VISIT 82 LAB

ADDITIONAL 24-HOUR URINALYSIS

LAB_04

Data ☒ No Data ☐

Please indicate if the laboratory is the Same as baseline ☐
Same as previous ☐

| | |
|---------|--|
| Name | |
| Address | |
| City | |
| Country | |

| For Technical use : | |
|---------------------|--|
| Name | |
| Address | |
| City | |
| Country | |

Date (dd-mmm-yyyy) (24-hour clock)

Start date of collection: Start Time of collection :
End date of collection: End Time of collection :

| Test | Value | Unit |
|--------------------|-------|------|
| URINARY VOLUME | | L |
| PROTEIN (URINE) | | G/L |
| CREATININE (URINE) | | G/L |

| SI RANGES | | | |
|-----------|---------|-------------|-------------|
| SI Value | SI Unit | Lower limit | Upper Limit |
| | | | |
| | | | |
| | | | |

ELECTROPHORESIS

| | | |
|------------------|--|-----|
| ALBUMIN (URINE) | | G/L |
| ALPHA 1 GLOBULIN | | G/L |
| ALPHA 2 GLOBULIN | | G/L |
| BETA GLOBULIN | | G/L |
| GAMMA GLOBULIN | | G/L |

| | | | |
|--|--|--|--|
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

EFC10547

X 4

Country Center Subject

782.05.2

Page No.

0

Repeat No.

Visit Name: VISIT 82 LAB

Is there any Hemoglobin or RBC in 24 Hour urine sample ?

LABU_1

Data ☒ No Data ☐

Test name

Negative

Positive

HEMOGLOBIN (QUALITAT

☐☐

RED BLOOD CELLS (QUA

☐☐

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

782.06.1

Page No.

0

Repeat No.

Visit Name: VISIT 82 LAB

ADDITIONAL HEMATOLOGY

LABU_1

Data ☒ No Data ☐

Date of sampling

Test name

Unit

Negative

Positive

| | |
|-----------------------|------|
| SCHISTOCYTES (QUALITA | NONE |
|-----------------------|------|

☐☐

EFC10547

X 4

Country Center Subject

782.06.2

Page No.

0

Repeat No.

Visit Name: VISIT 82 LAB

ADDITIONAL BIOCHEMISTRY

LAB_01

Data ☒ No Data ☐

Please indicate if the laboratory is the : Same as baseline ☐
Same as previous ☐

| | |
|---------|--|
| Name | |
| Address | |
| City | |
| Country | |

| For Technical use : | |
|---------------------|--|
| Name | |
| Address | |
| City | |
| Country | |

Date of sampling (dd-mm-yyyy)

| Test | Value | Unit | SI Value | SI Unit | Lower Limit | Upper Limit |
|-------------|-------|------|----------|---------|-------------|-------------|
| LDH | | IU/L | | | | |
| HAPTOGLOBIN | | G/L | | | | |
| OROSOMUCOID | | G/L | | | | |

OTHER PROCEDURES

OTHPR_01

Data ☒ No Data ☐

Only additional procedures related or performed as a result of an ADVERSE EVENT or additional procedures not planned in the protocol but of interest to support safety analysis as defined in the protocol

Procedure Description

Procedure Date
(DD-MMM-YYYY)

Outcome

☐ Not applicable
☐ Normal
☐ Abnormal
If abnormal, clinically significant?
☐ Yes* ☐ No

*Specify:

☐ Not applicable
☐ Normal
☐ Abnormal
If abnormal, clinically significant?
☐ Yes* ☐ No

*Specify:

☐ Not applicable
☐ Normal
☐ Abnormal
If abnormal, clinically significant?
☐ Yes* ☐ No

*Specify:

☐ Not applicable
☐ Normal
☐ Abnormal
If abnormal, clinically significant?
☐ Yes* ☐ No

*Specify:

EFC10547

X 4

Country Center Subject

560.2

Page No.

0

Repeat No.

Visit Name:

VISIT 99

Procedure Description

Procedure Date
(DD-MMM-YYYY)

Outcome

- ☐ Not applicable
☐ Normal
☐ Abnormal
 If abnormal, clinically significant?
☐ Yes* ☐ No

*Specify: _____

- ☐ Not applicable
☐ Normal
☐ Abnormal
 If abnormal, clinically significant?
☐ Yes* ☐ No

*Specify: _____

- ☐ Not applicable
☐ Normal
☐ Abnormal
 If abnormal, clinically significant?
☐ Yes* ☐ No

*Specify: _____

- ☐ Not applicable
☐ Normal
☐ Abnormal
 If abnormal, clinically significant?
☐ Yes* ☐ No

*Specify: _____

EFC10547

X

4

Country Center Subject

560.3

Page No.

0

Repeat No.

Visit Name: VISIT 99

Procedure Description

Procedure Date
(DD-MMM-YYYY)

Outcome

- ☐ Not applicable
☐ Normal
☐ Abnormal
 If abnormal, clinically significant?
☐ Yes* ☐ No

*Specify: _____

- ☐ Not applicable
☐ Normal
☐ Abnormal
 If abnormal, clinically significant?
☐ Yes* ☐ No

*Specify: _____

- ☐ Not applicable
☐ Normal
☐ Abnormal
 If abnormal, clinically significant?
☐ Yes* ☐ No

*Specify: _____

- ☐ Not applicable
☐ Normal
☐ Abnormal
 If abnormal, clinically significant?
☐ Yes* ☐ No

*Specify: _____

EFC10547

X 4
Country Center Subject

560.4

Page No.

0

Repeat No.

Visit Name: VISIT 99

Procedure Description

Procedure Date
(DD-MMM-YYYY)

Outcome

- ☐ Not applicable
☐ Normal
☐ Abnormal
 If abnormal, clinically significant?
☐ Yes* ☐ No

*Specify: _____

- ☐ Not applicable
☐ Normal
☐ Abnormal
 If abnormal, clinically significant?
☐ Yes* ☐ No

*Specify: _____

- ☐ Not applicable
☐ Normal
☐ Abnormal
 If abnormal, clinically significant?
☐ Yes* ☐ No

*Specify: _____

- ☐ Not applicable
☐ Normal
☐ Abnormal
 If abnormal, clinically significant?
☐ Yes* ☐ No

*Specify: _____

EFC10547

X 4

Country Center Subject

560.5

Page No.

0

Repeat No.

Visit Name:

VISIT 99

Procedure Description

Procedure Date
(DD-MMM-YYYY)

Outcome

- ☐ Not applicable
☐ Normal
☐ Abnormal
 If abnormal, clinically significant?
☐ Yes* ☐ No

*Specify:

- ☐ Not applicable
☐ Normal
☐ Abnormal
 If abnormal, clinically significant?
☐ Yes* ☐ No

*Specify:

- ☐ Not applicable
☐ Normal
☐ Abnormal
 If abnormal, clinically significant?
☐ Yes* ☐ No

*Specify:

- ☐ Not applicable
☐ Normal
☐ Abnormal
 If abnormal, clinically significant?
☐ Yes* ☐ No

*Specify:

EFC10547

| | | | | | | | | |
|---|---|--|--|--|--|--|--|--|
| X | 4 | | | | | | | |
|---|---|--|--|--|--|--|--|--|

Country Center Subject

561.1

Page No.

0

Repeat No.

Visit Name:

VISIT 99

SYMPTOMATIC DETERIORATION

SYMDE_01

Data ☒ No Data ☐Date : (dd-mmm-yyyy)

If symptomatic deterioration occurs during the study period as defined in the protocol, record on the Adverse Event form.

EFC10547

X 4

Country Center Subject

976.1

Page No.

0

Repeat No.

Visit Name:

VISIT 99

PHARMACOKINETIC

BLOOD

PK_01

Data ☒ No Data ☐

SERUM SAMPLING FOR DETECTION OF FREE AND BOUND AFLIBERCEPT

If sampling performed, report the information below in the sample ID

| | Sample ID | Sample Date (dd-mmm-yyyy) | Sample Time (24-hour clock) |
|----------------------------|-----------|------------------------------|--------------------------------|
| FREE AND BOUND AFLIBERCEPT | P07 | | |
| FREE AND BOUND AFLIBERCEPT | P08 | | |
| FREE AND BOUND AFLIBERCEPT | P09 | | |
| FREE AND BOUND AFLIBERCEPT | P10 | | |
| FREE AND BOUND AFLIBERCEPT | P11 | | |
| FREE AND BOUND AFLIBERCEPT | P12 | | |
| FREE AND BOUND AFLIBERCEPT | P13 | | |
| FREE AND BOUND AFLIBERCEPT | P14 | | |
| FREE AND BOUND AFLIBERCEPT | P15 | | |
| FREE AND BOUND AFLIBERCEPT | P16 | | |

EFC10547

X 9

Country Center Subject

976.1

Page No.

0

Repeat No.

Visit Name: VISIT 99

PHARMACOKINETIC BLOOD

PK_01

Data ☒ No Data ☐

FREE AND BOUND AFLIBERCEPT

| | Sample Date (dd-mmm-yyyy) | Sample Time (24-hour clock) |
|----------------------------|------------------------------|--------------------------------|
| FREE AND BOUND AFLIBERCEPT | | |
| FREE AND BOUND AFLIBERCEPT | | |
| FREE AND BOUND AFLIBERCEPT | | |
| FREE AND BOUND AFLIBERCEPT | | |
| FREE AND BOUND AFLIBERCEPT | | |
| FREE AND BOUND AFLIBERCEPT | | |
| FREE AND BOUND AFLIBERCEPT | | |
| FREE AND BOUND AFLIBERCEPT | | |
| FREE AND BOUND AFLIBERCEPT | | |
| FREE AND BOUND AFLIBERCEPT | | |

EFC10547

X 4

Country Center Subject

976.2

Page No.

0

Repeat No.

Visit Name: VISIT 99

If sampling performed, report the information below in the sample ID

| | Sample ID | Sample Date (dd-mmm-yyyy) | Sample Time (24-hour clock) |
|---------------------------|-----------|------------------------------|--------------------------------|
| FREE AND BOUND AFLIBERCEE | P17 | | |
| FREE AND BOUND AFLIBERCEE | P18 | | |
| FREE AND BOUND AFLIBERCEE | P19 | | |
| FREE AND BOUND AFLIBERCEE | P20 | | |
| FREE AND BOUND AFLIBERCEE | P21 | | |
| FREE AND BOUND AFLIBERCEE | P22 | | |
| FREE AND BOUND AFLIBERCEE | P23 | | |
| FREE AND BOUND AFLIBERCEE | P24 | | |
| FREE AND BOUND AFLIBERCEE | P25 | | |
| FREE AND BOUND AFLIBERCEE | P26 | | |

EFC10547

X 9

Country Center Subject

976.2

Page No.

0

Repeat No.

Visit Name:

VISIT 99

| | Sample Date (dd-mmm-yyyy) | Sample Time (24-hour clock) |
|----------------------------|------------------------------|--------------------------------|
| FREE AND BOUND AFLIBERCEPT | | |
| FREE AND BOUND AFLIBERCEPT | | |
| FREE AND BOUND AFLIBERCEPT | | |
| FREE AND BOUND AFLIBERCEPT | | |
| FREE AND BOUND AFLIBERCEPT | | |
| FREE AND BOUND AFLIBERCEPT | | |
| FREE AND BOUND AFLIBERCEPT | | |
| FREE AND BOUND AFLIBERCEPT | | |
| FREE AND BOUND AFLIBERCEPT | | |
| FREE AND BOUND AFLIBERCEPT | | |

EFC10547

X 4 Country Center Subject

977.1

Page No.

0

Repeat No.

Visit Name: VISIT 99

PHARMACOKINETIC

BLOOD

PK_01

Data ☒ No Data ☐

SERUM SAMPLING FOR DETECTION OF ANTI-AFLIBERCEPT ANTIBODIES

If sampling performed, report the information below in the sample ID

| | Sample ID | Sample Date (dd-mmm-yyyy) | Sample Time (24-hour clock) |
|---------------------------|-----------|------------------------------|--------------------------------|
| ANTI-AFLIBERCEPT ANTIBODI | A03 | | |
| ANTI-AFLIBERCEPT ANTIBODI | A04 | | |
| ANTI-AFLIBERCEPT ANTIBODI | A05 | | |
| ANTI-AFLIBERCEPT ANTIBODI | A06 | | |
| ANTI-AFLIBERCEPT ANTIBODI | A07 | | |
| ANTI-AFLIBERCEPT ANTIBODI | A08 | | |
| ANTI-AFLIBERCEPT ANTIBODI | A09 | | |
| ANTI-AFLIBERCEPT ANTIBODI | A10 | | |
| ANTI-AFLIBERCEPT ANTIBODI | A11 | | |
| ANTI-AFLIBERCEPT ANTIBODI | A12 | | |



EFC10547

X 9

Country Center Subject

977.1

Page No.

0

Repeat No.

Visit Name: VISIT 99

PHARMACOKINETIC BLOOD

PK_01

Data ☒ No Data ☐

ANTI-AFLIBERCEPT ANTIBODIES

| | Sample Date (dd-mmm-yyyy) | Sample Time (24-hour clock) |
|-----------------------------|------------------------------|--------------------------------|
| ANTI-AFLIBERCEPT ANTIBODIES | | |
| ANTI-AFLIBERCEPT ANTIBODIES | | |
| ANTI-AFLIBERCEPT ANTIBODIES | | |
| ANTI-AFLIBERCEPT ANTIBODIES | | |
| ANTI-AFLIBERCEPT ANTIBODIES | | |
| ANTI-AFLIBERCEPT ANTIBODIES | | |
| ANTI-AFLIBERCEPT ANTIBODIES | | |
| ANTI-AFLIBERCEPT ANTIBODIES | | |
| ANTI-AFLIBERCEPT ANTIBODIES | | |
| ANTI-AFLIBERCEPT ANTIBODIES | | |

EFC10547

X 4

Country Center Subject

977.2

Page No.

0

Repeat No.

Visit Name:

VISIT 99

If sampling performed, report the information below in the sample ID

| | Sample ID | Sample Date (dd-mmm-yyyy) | Sample Time (24-hour clock) |
|---------------------------|-----------|------------------------------|--------------------------------|
| ANTI-AFLIBERCEPT ANTIBODI | A13 | | |
| ANTI-AFLIBERCEPT ANTIBODI | A14 | | |
| ANTI-AFLIBERCEPT ANTIBODI | A15 | | |
| ANTI-AFLIBERCEPT ANTIBODI | A16 | | |
| ANTI-AFLIBERCEPT ANTIBODI | A17 | | |
| ANTI-AFLIBERCEPT ANTIBODI | A18 | | |
| ANTI-AFLIBERCEPT ANTIBODI | A19 | | |
| ANTI-AFLIBERCEPT ANTIBODI | A20 | | |
| ANTI-AFLIBERCEPT ANTIBODI | A21 | | |
| ANTI-AFLIBERCEPT ANTIBODI | A22 | | |

EFC10547

X 9

Country Center Subject

977.2

Page No.

0

Repeat No.

Visit Name: VISIT 99

| | Sample Date (dd-mmm-yyyy) | Sample Time (24-hour clock) |
|-----------------------------|------------------------------|--------------------------------|
| ANTI-AFLIBERCEPT ANTIBODIES | | |
| ANTI-AFLIBERCEPT ANTIBODIES | | |
| ANTI-AFLIBERCEPT ANTIBODIES | | |
| ANTI-AFLIBERCEPT ANTIBODIES | | |
| ANTI-AFLIBERCEPT ANTIBODIES | | |
| ANTI-AFLIBERCEPT ANTIBODIES | | |
| ANTI-AFLIBERCEPT ANTIBODIES | | |
| ANTI-AFLIBERCEPT ANTIBODIES | | |
| ANTI-AFLIBERCEPT ANTIBODIES | | |
| ANTI-AFLIBERCEPT ANTIBODIES | | |

EFC10547

| | | | | | | | | |
|---|---|--|--|--|--|--|--|--|
| X | 4 | | | | | | | |
|---|---|--|--|--|--|--|--|--|

Country Center Subject

999.1

Page No.

0

Repeat No.

Visit Name:

VISIT 99

DEATH

DEATH_01

Data ☒ No Data ☐

Date of Death : (dd-mmm-yyyy)

Reason for death :

Adverse event ☐

Disease progression ☐

Other reason ☐

Specify :

EFC10547

X 5

Country Center Subject

562.1

Page No.

0

Repeat No.

Visit Name: VISIT 99 MED

MEDICATION

MED_01

Data ☒ No Data ☐

RECORD CONCOMITANT MEDICATIONS OTHER THAN ANALGESICS THE SUBJECT HAS TAKEN DURING THE STUDY PERIOD AS DEFINED IN THE PROTOCOL

| Drug/Medication (brand or generic name) | Start Date (dd-mmm-yyyy) | Previously Reported | End Date (dd-mmm-yyyy) | Or tick if Ongoing |
|--|-----------------------------|--------------------------|---------------------------|--------------------------|
| <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |

EFC10547

X 5
Country Center Subject

562.2

Page No.

0

Repeat No.

Visit Name: VISIT 99 MED

| Drug/Medication (brand or generic name) | Start Date (dd-mmm-yyyy) | Previously Reported | End Date (dd-mmm-yyyy) | Or tick if Ongoing |
|--|-----------------------------|--------------------------|---------------------------|--------------------------|
| <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |

EFC10547

X 5
Country Center Subject

562.3

Page No.

0

Repeat No.

Visit Name: VISIT 99 MED

| Drug/Medication (brand or generic name) | Start Date (dd-mmm-yyyy) | Previously Reported | End Date (dd-mmm-yyyy) | Or tick if Ongoing |
|--|-----------------------------|--------------------------|---------------------------|--------------------------|
| <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |
| <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="checkbox"/> |

UNSCHEDULED LABORATORY TESTS

LAB_06

Data ☒ No Data ☐

Start Date (dd-mm-yyyy)[illegible]

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

564.1

Page No.

0

Repeat No.

Visit Name: VISIT 99 ECG

ADDITIONAL ELECTROCARDIOGRAM

ECG_01

Data ☒ No Data ☐

Date performed
(DD-MMM-YYYY)

☐ Normal

☐ Abnormal If abnormal, clinically significant ? Yes ☐ No ☐

IF ABNORMAL CLINICALLY SIGNIFICANT, PLEASE RECORD AN ADVERSE EVENT.

EFC10547

| | | | | | | | |
|---|---|--|--|--|--|--|--|
| X | 4 | | | | | | |
|---|---|--|--|--|--|--|--|

Country Center Subject

565.1

Page No.

0

Repeat No.

Visit Name: VISIT 99 VITAL

ADDITIONAL VITAL SIGNS

VITAL_02

Data ☒ No Data ☐

Date performed:
(DD-MMM-YYYY)

Blood pressure: Systolic: mmHg / Diastolic: mmHg