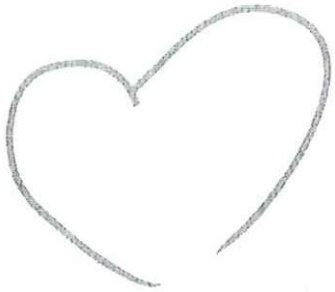
AVE0005 / EFC10547

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: ⌊_⌋⌊_⌋⌊_⌋

sanofi aventis

Date of visit :

VISIT_01

(DD-MMM-YYYY)

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* _____

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 AT DIAGNOSIS

0 ☐ I ☐ II ☐
III ☐ IV ☐ Unknown ☐

STATUS AT STUDY ENTRY

STENT_01

Date of progression : *(dd-mmm-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		☐
TOTAL PANCREATECTOMY		☐
PANCREATICODUODENECTOMY		☐
HEPATICOJEJUNOSTOMY		☐
CHOLEDOCHOJEJUNOSTOMY		☐
CHOLEDOCHODUODENOSTOMY		☐
CHOLECYSTOJEJUNOSTOMY		☐
GASTRIC BYPASS		☐
		☐
		☐
		☐
		☐

Surgery term	Surgery Date *(DD-MMM-YYYY)*	Not performed
		☐
		☐
		☐
		☐
		☐
		☐
		☐
		☐

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 ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐

Lesion location	Start Date *(dd-mmm-yyyy)*	End Date *(dd-mmm-yyyy)*	Total Dose	Unit	Intent
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐

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

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 ☐

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☐

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 ☐

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 ☐

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☐

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 ☐

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		

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
						☐
						☐
						☐
						☐
						☐
						☐

Drug/Medication (Brand or generic name)	Dosage (Total daily dose)	Units	Route	Start Date *(dd-mmm-yyyy)*	End Date *(dd-mmm-yyyy)*	Ongoing
						☐
						☐
						☐
						☐
						☐
						☐
						☐
						☐

Drug/Medication (Brand or generic name)	Dosage (Total daily dose)	Units	Route	Start Date *(dd-mmm-yyyy)*	End Date *(dd-mmm-yyyy)*	Ongoing
						☐
						☐
						☐
						☐
						☐
						☐
						☐
						☐

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
			☐
			☐
			☐
			☐
			☐
			☐

Drug/Medication (brand or generic name)	Start Date *(dd-mmm-yyyy)*	End Date *(dd-mmm-yyyy)*	Or tick if Ongoing
			☐
			☐
			☐
			☐
			☐
			☐
			☐
			☐

Drug/Medication (brand or generic name)	Start Date *(dd-mmm-yyyy)*	End Date *(dd-mmm-yyyy)*	Or tick if Ongoing
			☐
			☐
			☐
			☐
			☐
			☐
			☐
			☐
			☐

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
☐ Abnormal If abnormal, clinically significant ? Yes ☐ No ☐

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

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)*

		Unit			SI Ranges	
Test	Value	If other unit, specify	SI Value	SI Unit	Lower Limit	Upper Limit
HEMOGLOBIN		G/L				
PLATELET COUNT (THROMBO		10E9/L				
WBC		10E9/L				
NEUTROPHILS		10E9/L				
TO BE PERFORMED ONLY FOR PATIENT UNDER VITAMIN K ANTAGONIST						
INR		RATIO				

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

Date of sampling _____ *(dd-mmm-yyyy)*

Test	Value	Unit If other unit, specify	SI Ranges 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				

* In case of serum creatinine > 1 ULN please report the calculated creatinine clearance.
** If BUN is not evaluated, Urea value must be documented.

DIPSTICK URINALYSIS

LABU_1

BHCG TEST HAS TO BE PERFORMED WITHIN 8 DAYS BEFORE RANDOMIZATION

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

Data ☑ No Data ☐

Date of sampling

Test name

WHITE BLOOD CELLS (QU	☐ Absent	☐ +	☐ ++	☐ +++	☐ Not evaluable
RED BLOOD CELLS (QUAI	☐ Absent	☐ +	☐ ++	☐ +++	☐ Not evaluable

MORNING SPOT URINALYSIS

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

Date of sampling _____ *(dd-mmm-yyyy)*

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

24-HOUR URINALYSIS

LAB_04

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

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	SI RANGES Lower limit	SI RANGES Upper Limit
URINARY VOLUME		L				
PROTEIN (URINE)		G/L				
CREATININE (URINE)		G/L				

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 (QUAI	☐	☐

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				

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:
☐	☐ If Other, specify : ______	☐	☐	Tumor related ☐ Other ☐ : ______
☐	☐ If Other, specify : ______	☐	☐	Tumor related ☐ Other ☐ : ______
☐	☐ If Other, specify : ______	☐	☐	Tumor related ☐ Other ☐ : ______
☐	☐ If Other, specify : ______	☐	☐	Tumor related ☐ Other ☐ : ______
☐	☐ If Other, specify : ______	☐	☐	Tumor related ☐ Other ☐ : ______
☐	☐ If Other, specify : ______	☐	☐	Tumor related ☐ Other ☐ : ______
☐	☐ If Other, specify : ______	☐	☐	Tumor related ☐ Other ☐ : ______
☐	☐ If Other, specify : ______	☐	☐	Tumor related ☐ Other ☐ : ______
☐	☐ If Other, specify : ______	☐	☐	Tumor related ☐ Other ☐ : ______
☐	☐ If Other, specify : ______	☐	☐	Tumor related ☐ Other ☐ : ______

Lesion location	Method of tumor measurement		Date *(dd-mmm-yyyy)*	Normal	If Abnormal, specify:
☐	☐	If Other, specify : ______	☐	☐	Tumor related ☐ Other ☐: ______
☐	☐	If Other, specify : ______	☐	☐	Tumor related ☐ Other ☐: ______
☐	☐	If Other, specify : ______	☐	☐	Tumor related ☐ Other ☐: ______
☐	☐	If Other, specify : ______	☐	☐	Tumor related ☐ Other ☐: ______
☐	☐	If Other, specify : ______	☐	☐	Tumor related ☐ Other ☐: ______
☐	☐	If Other, specify : ______	☐	☐	Tumor related ☐ Other ☐: ______
☐	☐	If Other, specify : ______	☐	☐	Tumor related ☐ Other ☐: ______
☐	☐	If Other, specify : ______	☐	☐	Tumor related ☐ Other ☐: ______
☐	☐	If Other, specify : ______	☐	☐	Tumor related ☐ Other ☐: ______
☐	☐	If Other, specify : ______	☐	☐	Tumor related ☐ Other ☐: ______

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
☐					mm	☐
☐					mm	☐
☐					mm	☐
☐					mm	☐
☐					mm	☐
☐					mm	☐
☐					mm	☐
☐					mm	☐
☐					mm	☐
☐					mm	☐

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
					mm	
					mm	
					mm	
					mm	
					mm	
					mm	
					mm	
					mm	
					mm	
					mm	

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.**

ADVERSE EVENT

AE_03

AE Form Number

AE Reference ID

Data ☑ No Data ☐

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 ☐☐-☐☐☐-☐☐☐☐ *(dd-mmm-yyyy)* (complete the death report form)

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	☐	Persistant/significant disability/incapacity	☐
Life Threatening	☐	Congenital anomaly or Birth Defect	☐
Requires or prolongs hospitalization	☐	Other medically important event	☐

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?

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

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: _____ kg

Blood pressure: Systolic: _____ mmHg / Diastolic: _____ mmHg

ECOG 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.

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 If other unit, specify	SI Value	SI Unit	SI Ranges Lower Limit	SI Ranges Upper Limit
HEMOGLOBIN		G/L				
PLATELET COUNT (THROMBO		10E9/L				
WBC		10E9/L				
NEUTROPHILS		10E9/L				

TO BE PERFORMED ONLY FOR PATIENT UNDER VITAMIN K ANTAGONIST

INR		RATIO				

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

Date of sampling _____ *(dd-mmm-yyyy)*

Test	Value	Unit: If other unit, specify	SI Ranges: 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.

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 (QUAI	☐ Absent	☐ +	☐ ++	☐ +++	☐ Not evaluable

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	SI Ranges Upper Limit
PROTEIN (URINE)		MG/DL				
CREATININE (URINE)		MG/DL				

PHARMACOKINETIC BLOOD

PK_01

Data ☑ No Data ☐

TO BE COMPLETED FOR ALL PATIENTS

FREE AND BOUND AFLIBERCEPT

DAY 1

Sample ID	Theoretical Time		Sample Date *(dd-mmm-yyyy)*	Sample Time *24-hour clock*
P00	T0H	*		

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

PHARMACOKINETIC BLOOD

PK_01

Data ☑ No Data ☐

FREE AND BOUND AFLIBERCEPT

DAY 1

Sample ID	Theoretical Time		Sample Date *(dd-mmm-yyyy)*	Sample Time *24-hour clock*
P00	T0H	*		

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

PHARMACOKINETIC BLOOD

PK_01

Data ☑ No Data ☐

TO BE COMPLETED FOR ALL PATIENTS

ANTI-AFLIBERCEPT ANTIBODIES

DAY 1

Sample ID	Theoretical Time	Sample Date *(dd-mmm-yyyy)*	Sample Time *(24-hour clock)*
A00	T0H *		

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

PHARMACOKINETIC BLOOD

PK_01

Data ☑ No Data ☐

ANTI-AFLIBERCEPT ANTIBODIES

DAY 1

Theoretical Time	Sample Date *(dd-mmm-yyyy)*	Sample Time *(24-hour clock)*
T0H *		

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

PHARMACOKINETIC BLOOD

PK_01

Data ☑ No Data ☐

TO BE COMPLETED ONLY FOR PK PATIENTS

ENDOGENEOUS VEGF

DAY 1

Sample ID	Theoretical Time	Date *(dd-mmm-yyyy)*	Time *24-hour clock*
L00	T0H *		

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

PHARMACOKINETIC BLOOD

PK_01

Data ☑ No Data ☐

ENDOGENEOUS VEGF

DAY 1

Theoretical Time	Date *(dd-mmm-yyyy)*	Time *24-hour clock*
T0H *		

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

PHARMACOKINETIC BLOOD

PK_01

Data ☑ No Data ☐

TO BE COMPLETED ONLY FOR PK PATIENTS.

FREE AND BOUND AFLIBERCEPT

DAY 1

Sample ID	Theoretical Time		Sample Date *(dd-mmm-yyyy)*	Sample Time *24-hour clock*
P01	T1H	*		

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

PHARMACOKINETIC BLOOD

PK_01

Data ☑ No Data ☐

FREE AND BOUND AFLIBERCEPT

DAY 1

Sample ID	Theoretical Time	Sample Date *(dd-mmm-yyyy)*	Sample Time *24-hour clock*
P01	T1H *		

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

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_05

Data ☑ No Data ☐

AFLIBERCEPT/PLACEBO

Scheduled Day	Treatment Number	Not Administered/ Taken	Date / Time	Intended Dose	Actual Dose
DAY 1		☐	START (dd-mmm-yyyy) (24-hour clock) END (24-hour clock)	MG/KG	MG

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

Scheduled Day	Treatment Number	Not Administered/ Taken	Date / Time	Intended Dose	Actual Dose
(*)		☐	START (dd-mmm-yyyy) (24-hour clock) END (24-hour clock)	MG/KG NOT APPLICABLE	MG

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

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		☐			

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
(*)		☐		NOT APPLICABLE	

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

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☑ No Data ☐

DAY 1

Outpatient Clinic ☐ Inpatient Clinic ☐

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 ☐

HEMATOLOGY

LAB_01

Data ☑ No Data ☐

DAY 8

Date of sampling ____ *(dd-mmm-yyyy)*

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

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		☐			

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
(*)		☐		NOT APPLICABLE	

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

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☑ No Data ☐

DAY 8

Outpatient Clinic ☐ Inpatient Clinic ☐

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 ☐

HEMATOLOGY

LAB_01

Data ☑ No Data ☐

DAY 15

Date of sampling ____ *(dd-mmm-yyyy)*

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

DIPSTICK URINALYSIS

LABU_1

Data ☑ No Data ☐

DAY 15

Date of sampling

Test name

WHITE BLOOD CELLS (QU	☐ Absent	☐ +	☐ ++	☐ +++	☐ Not evaluable
RED BLOOD CELLS (QUAI	☐ Absent	☐ +	☐ ++	☐ +++	☐ Not evaluable

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	SI Ranges Upper Limit
PROTEIN (URINE)		MG/DL				
CREATININE (URINE)		MG/DL				

PHARMACOKINETIC BLOOD

PK_01

Data ☑ No Data ☐

TO BE COMPLETED ONLY FOR PK PATIENTS.

FREE AND BOUND AFLIBERCEPT

DAY 15

Sample ID	Theoretical Time		Sample Date *(dd-mmm-yyyy)*	Sample Time *24-hour clock*
P02	T0H	*		

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

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_05

Data ☑ No Data ☐

AFLIBERCEPT/PLACEBO

Scheduled Day	Treatment Number	Not Administered/ Taken	Date / Time*	Intended Dose	Actual Dose
DAY 15		☐	START (dd-mmm-yyyy) (24-hour clock)	MG/KG	MG
			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*	Intended Dose	Actual Dose
(*)		☐	START (dd-mmm-yyyy) (24-hour clock)	MG/KG NOT APPLICABLE	MG
			END (24-hour clock)		

*Time to be given only for PK patients

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

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		☐			

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
(*)		☐		NOT APPLICABLE	

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

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☑ No Data ☐

DAY 15

Outpatient Clinic ☐ Inpatient Clinic ☐

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 ☐

HEMATOLOGY

LAB_01

Data ☑ No Data ☐

DAY 22

Date of sampling ____ *(dd-mmm-yyyy)*

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

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_04

Data ☑ No Data ☐

GEMCITABINE

Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose	Actual Dose
				MG/M2	MG
DAY 22		☐			

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

Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose	Actual Dose
				MG/M2	MG
(*)		☐		NOT APPLICABLE	

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

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☑ No Data ☐

DAY 22

Outpatient Clinic ☐ Inpatient Clinic ☐

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		

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
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐

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
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐

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
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐

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
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	

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
		☐ Not Done			mm	
		☐ Not Done			mm	
		☐ Not Done			mm	
		☐ Not Done			mm	
		☐ Not Done			mm	
		☐ Not Done			mm	
		☐ Not Done			mm	
		☐ Not Done			mm	
		☐ Not Done			mm	
		☐ Not Done			mm	

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 ☐

		Yes	No
ANGINA PECTORIS / UNSTABLE ANGINA / MYOCARDIAL INFARCTION		☐	☐
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 :		☐	☐

ADVERSE EVENT

AE_03

AE Form Number

AE Reference ID

Data ☑ No Data ☐

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 ☐ *(dd-mmm-yyyy)* (complete the death report form)

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	☐	Persistant/significant disability/incapacity	☐
Life Threatening	☐	Congenital anomaly or Birth Defect	☐
Requires or prolongs hospitalization	☐	Other medically important event	☐

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?

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

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	SI Ranges Upper Limit
HEMOGLOBIN		G/L				
PLATELET COUNT (THROMBO		10E9/L				
WBC		10E9/L				
NEUTROPHILS		10E9/L				

TO BE PERFORMED ONLY FOR PATIENT UNDER VITAMIN K ANTAGONIST

INR		RATIO				

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
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 (QUAI	☐ 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
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	SI Ranges Upper Limit
PROTEIN (URINE)		MG/DL				
CREATININE (URINE)		MG/DL				

LAB_04

24-HOUR URINALYSIS

TO BE COMPLETED IF UPCR > 1

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 RANGES SI Value	SI Unit	Lower limit	Upper Limit
URINARY VOLUME		L				
PROTEIN (URINE)		G/L				
CREATININE (URIN		G/L				

ELECTROPHORESIS

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

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 (QUAI	☐	☐

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	☐	☐

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 Value	SI Unit	SI Ranges Lower Limit	SI Ranges Upper Limit
LDH		IU/L				
HAPTOGLOBIN		G/L				
OROSOMUCOID		G/L				

VISIT_01

Date of visit :

(DD-MMM-YYYY)

VITAL_02

VITAL SIGNS

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

HEMATOLOGY

LAB_01

Data ☑ No Data ☐

DAY 1

Date of sampling ____ *(dd-mmm-yyyy)*

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

TO BE PERFORMED ONLY FOR PATIENT UNDER VITAMIN K ANTAGONIST

INR		RATIO				

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	

Date of sampling (dd-mmm-yyyy)

Test	Value	Unit If other unit, specify	SI Ranges 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.

DIPSTICK URINALYSIS

LABU_1

Data ☑ No Data ☐

DAY 1

Date of sampling

Test name

WHITE BLOOD CELLS (QU	☐ Absent	☐ +	☐ ++	☐ +++	☐ Not evaluable
RED BLOOD CELLS (QUAI	☐ Absent	☐ +	☐ ++	☐ +++	☐ Not evaluable

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	SI Ranges Upper Limit
PROTEIN (URINE)		MG/DL				
CREATININE (URINE)		MG/DL				

PHARMACOKINETIC BLOOD

PK_01

Data ☑ No Data ☐

FREE AND BOUND AFLIBERCEPT

DAY 1

Theoretical Time		Sample Date *(dd-mmm-yyyy)*	Sample Time *24-hour clock*
T0H	*		

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

PHARMACOKINETIC BLOOD

PK_01

Data ☑ No Data ☐

ANTI-AFLIBERCEPT ANTIBODIES

DAY 1

Theoretical Time	Sample Date *(dd-mmm-yyyy)*	Sample Time *(24-hour clock)*
T0H *		

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

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_05

Data ☑ No Data ☐

AFLIBERCEPT/PLACEBO

Scheduled Day	Treatment Number	Not Administered/ Taken	Date / Time*	Intended Dose	Actual Dose
DAY 1		☐	START (dd-mmm-yyyy) (24-hour clock) END (24-hour clock)	MG/KG	MG

*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*	Intended Dose	Actual Dose
(*)		☐	START (dd-mmm-yyyy) (24-hour clock) END (24-hour clock)	MG/KG NOT APPLICABLE	MG

*Time to be given only for PK patients

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

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		☐			

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
(*)		☐		NOT APPLICABLE	

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

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☑ No Data ☐

DAY 1

Outpatient Clinic ☐ Inpatient Clinic ☐

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 ☐

HEMATOLOGY

LAB_01

Data ☑ No Data ☐

DAY 8

Date of sampling ____ *(dd-mmm-yyyy)*

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

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_04

Data ☑ No Data ☐

GEMCITABINE

Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose	Actual Dose
				MG/M2	MG
DAY 8		☐			

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

Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose	Actual Dose
				MG/M2	MG
(*)		☐		NOT APPLICABLE	

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

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☑ No Data ☐

DAY 8

Outpatient Clinic ☐ Inpatient Clinic ☐

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 ☐

HEMATOLOGY

LAB_01

Data ☑ No Data ☐

DAY 15

Date of sampling ____ *(dd-mmm-yyyy)*

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

DIPSTICK URINALYSIS

LABU_1

Data ☑ No Data ☐

DAY 15

Date of sampling

Test name

WHITE BLOOD CELLS (QU	☐ Absent	☐ +	☐ ++	☐ +++	☐ Not evaluable
RED BLOOD CELLS (QUAI	☐ Absent	☐ +	☐ ++	☐ +++	☐ Not evaluable

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	SI Ranges Upper Limit
PROTEIN (URINE)		MG/DL				
CREATININE (URINE)		MG/DL				

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_05

Data ☑ No Data ☐

AFLIBERCEPT/PLACEBO

Scheduled Day	Treatment Number	Not Administered/ Taken	Date / Time*	Intended Dose	Actual Dose
DAY 15		☐	START (dd-mmm-yyyy) (24-hour clock)	MG/KG	MG
			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*	Intended Dose	Actual Dose
(*)		☐	START (dd-mmm-yyyy) (24-hour clock)	MG/KG NOT APPLICABLE	MG
			END (24-hour clock)		

*Time to be given only for PK patients

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

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		☐			

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
(*)		☐		NOT APPLICABLE	

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

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☑ No Data ☐

DAY 15

Outpatient Clinic ☐ Inpatient Clinic ☐

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		

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
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐

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
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐

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
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐

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
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	

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
		☐ Not Done			mm	
		☐ Not Done			mm	
		☐ Not Done			mm	
		☐ Not Done			mm	
		☐ Not Done			mm	
		☐ Not Done			mm	
		☐ Not Done			mm	
		☐ Not Done			mm	
		☐ Not Done			mm	
		☐ Not Done			mm	

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 ☐

	Yes	No
ANGINA PECTORIS / UNSTABLE ANGINA / MYOCARDIAL INFARCTION	☐	☐
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 :	☐	☐

ADVERSE EVENT

AE_03

AE Form Number

AE Reference ID

Data ☑ No Data ☐

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 ☐ *(dd-mmm-yyyy)* (complete the death report form)

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	☐	Persistant/significant disability/incapacity	☐
Life Threatening	☐	Congenital anomaly or Birth Defect	☐
Requires or prolongs hospitalization	☐	Other medically important event	☐

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?

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

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	SI Ranges Upper Limit
HEMOGLOBIN		G/L				
PLATELET COUNT (THROMBO		10E9/L				
WBC		10E9/L				
NEUTROPHILS		10E9/L				

TO BE PERFORMED ONLY FOR PATIENT UNDER VITAMIN K ANTAGONIST

INR		RATIO				

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
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 (QUAI	☐ 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
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	SI Ranges Upper Limit
PROTEIN (URINE)		MG/DL				
CREATININE (URINE)		MG/DL				

LAB_04

24-HOUR URINALYSIS

TO BE COMPLETED IF UPCR > 1

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 RANGES SI Value	SI Unit	Lower limit	Upper Limit
URINARY VOLUME		L				
PROTEIN (URINE)		G/L				
CREATININE (URIN		G/L				

ELECTROPHORESIS

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

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 (QUAI	☐	☐

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	☐	☐

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 Value	SI Unit	SI Ranges Lower Limit	SI Ranges Upper Limit
LDH		IU/L				
HAPTOGLOBIN		G/L				
OROSOMUCOID		G/L				

VISIT_01

Date of visit :

(DD-MMM-YYYY)

VITAL_02

VITAL SIGNS

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

HEMATOLOGY

LAB_01

Data ☑ No Data ☐

DAY 1

Date of sampling ____ *(dd-mmm-yyyy)*

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

TO BE PERFORMED ONLY FOR PATIENT UNDER VITAMIN K ANTAGONIST

INR		RATIO				

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	

Date of sampling _____ *(dd-mmm-yyyy)*

Test	Value	Unit If other unit, specify	SI Ranges 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.

DIPSTICK URINALYSIS

LABU_1

Data ☑ No Data ☐

DAY 1

Date of sampling

Test name

WHITE BLOOD CELLS (QU	☐ Absent	☐ +	☐ ++	☐ +++	☐ Not evaluable
RED BLOOD CELLS (QUAI	☐ Absent	☐ +	☐ ++	☐ +++	☐ Not evaluable

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	SI Ranges Upper Limit
PROTEIN (URINE)		MG/DL				
CREATININE (URINE)		MG/DL				

PHARMACOKINETIC BLOOD

PK_01

Data ☑ No Data ☐

TO BE COMPLETED ONLY FOR PK PATIENTS.

FREE AND BOUND AFLIBERCEPT

DAY 1

Sample ID	Theoretical Time	Sample Date *(dd-mmm-yyyy)*	Sample Time *24-hour clock*
P03	T0H *		

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

PHARMACOKINETIC BLOOD

PK_01

Data ☑ No Data ☐

FREE AND BOUND AFLIBERCEPT

DAY 1

Theoretical Time	Sample Date *(dd-mmm-yyyy)*	Sample Time *24-hour clock*
T0H *		

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

PHARMACOKINETIC BLOOD

PK_01

Data ☑ No Data ☐

ANTI-AFLIBERCEPT ANTIBODIES

DAY 1

Theoretical Time	Sample Date *(dd-mmm-yyyy)*	Sample Time *(24-hour clock)*
T0H *		

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

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_05

Data ☑ No Data ☐

AFLIBERCEPT/PLACEBO

Scheduled Day	Treatment Number	Not Administered/ Taken	Date / Time*	Intended Dose	Actual Dose
DAY 1		☐	START (dd-mmm-yyyy) (24-hour clock)	MG/KG	MG
			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*	Intended Dose	Actual Dose
(*)		☐	START (dd-mmm-yyyy) (24-hour clock)	MG/KG NOT APPLICABLE	MG
			END (24-hour clock)		

*Time to be given only for PK patients

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

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		☐			

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
(*)		☐		NOT APPLICABLE	

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

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☑ No Data ☐

DAY 1

Outpatient Clinic ☐ Inpatient Clinic ☐

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 ☐

HEMATOLOGY

LAB_01

Data ☑ No Data ☐

DAY 8

Date of sampling ____ *(dd-mmm-yyyy)*

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

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_04

Data ☑ No Data ☐

GEMCITABINE

Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose	Actual Dose
				MG/M2	MG
DAY 8		☐			

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

Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose	Actual Dose
				MG/M2	MG
(*)		☐		NOT APPLICABLE	

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

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☑ No Data ☐

DAY 8

Outpatient Clinic ☐ Inpatient Clinic ☐

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 ☐

HEMATOLOGY

LAB_01

Data ☑ No Data ☐

DAY 15

Date of sampling ____ *(dd-mmm-yyyy)*

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

DIPSTICK URINALYSIS

LABU_1

Data ☑ No Data ☐

DAY 15

Date of sampling

Test name

WHITE BLOOD CELLS (QU	☐ Absent	☐ +	☐ ++	☐ +++	☐ Not evaluable
RED BLOOD CELLS (QUAI	☐ Absent	☐ +	☐ ++	☐ +++	☐ Not evaluable

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	SI Ranges Upper Limit
PROTEIN (URINE)		MG/DL				
CREATININE (URINE)		MG/DL				

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_05

Data ☑ No Data ☐

AFLIBERCEPT/PLACEBO

Scheduled Day	Treatment Number	Not Administered/ Taken	Date / Time*	Intended Dose	Actual Dose
DAY 15		☐	START (dd-mmm-yyyy) (24-hour clock)	MG/KG	MG
			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*	Intended Dose	Actual Dose
(*)		☐	START (dd-mmm-yyyy) (24-hour clock)	MG/KG NOT APPLICABLE	MG
			END (24-hour clock)		

*Time to be given only for PK patients

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

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		☐			

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
(*)		☐		NOT APPLICABLE	

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

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☑ No Data ☐

DAY 15

Outpatient Clinic ☐ Inpatient Clinic ☐

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		

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
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐

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
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐

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
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐

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
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	

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
☐		☐ Not Done			mm	
☐		☐ Not Done			mm	
☐		☐ Not Done			mm	
☐		☐ Not Done			mm	
☐		☐ Not Done			mm	
☐		☐ Not Done			mm	
☐		☐ Not Done			mm	
☐		☐ Not Done			mm	
☐		☐ Not Done			mm	
☐		☐ Not Done			mm	

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 ☐

		Yes	No
ANGINA PECTORIS / UNSTABLE ANGINA / MYOCARDIAL INFARCTION		☐	☐
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 :		☐	☐

ADVERSE EVENT

AE_03

AE Form Number

AE Reference ID

Data ☑ No Data ☐

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 ☐ *(dd-mmm-yyyy)* (complete the death report form)

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	☐	Persistant/significant disability/incapacity	☐
Life Threatening	☐	Congenital anomaly or Birth Defect	☐
Requires or prolongs hospitalization	☐	Other medically important event	☐

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?

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

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	SI Ranges Upper Limit
HEMOGLOBIN		G/L				
PLATELET COUNT (THROMBO		10E9/L				
WBC		10E9/L				
NEUTROPHILS		10E9/L				

TO BE PERFORMED ONLY FOR PATIENT UNDER VITAMIN K ANTAGONIST

INR		RATIO				

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
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 (QUAI	☐ 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
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	SI Ranges Upper Limit
PROTEIN (URINE)		MG/DL				
CREATININE (URINE)		MG/DL				

LAB_04

24-HOUR URINALYSIS

TO BE COMPLETED IF UPCR > 1

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	SI RANGES Lower limit	SI RANGES Upper Limit
URINARY VOLUME		L				
PROTEIN (URINE)		G/L				
CREATININE (URIN		G/L				

ELECTROPHORESIS

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

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 (QUAI	☐	☐

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	☐	☐

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 Value	SI Unit	SI Ranges Lower Limit	SI Ranges Upper Limit
LDH		IU/L				
HAPTOGLOBIN		G/L				
OROSOMUCOID		G/L				

VISIT_01

Date of visit :

(DD-MMM-YYYY)

VITAL_02

VITAL SIGNS

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

HEMATOLOGY

LAB_01

Data ☑ No Data ☐

DAY 1

Date of sampling ____ *(dd-mmm-yyyy)*

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

TO BE PERFORMED ONLY FOR PATIENT UNDER VITAMIN K ANTAGONIST

INR		RATIO				

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	

Date of sampling _____ *(dd-mmm-yyyy)*

Test	Value	Unit If other unit, specify	SI Ranges 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.

DIPSTICK URINALYSIS

LABU_1

Data ☑ No Data ☐

DAY 1

Date of sampling

Test name

WHITE BLOOD CELLS (QU	☐ Absent	☐ +	☐ ++	☐ +++	☐ Not evaluable
RED BLOOD CELLS (QUAI	☐ Absent	☐ +	☐ ++	☐ +++	☐ Not evaluable

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	SI Ranges Upper Limit
PROTEIN (URINE)		MG/DL				
CREATININE (URINE)		MG/DL				

PHARMACOKINETIC BLOOD

PK_01

Data ☑ No Data ☐

FREE AND BOUND AFLIBERCEPT

DAY 1

Theoretical Time		Sample Date *(dd-mmm-yyyy)*	Sample Time *24-hour clock*
T0H	*		

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

PHARMACOKINETIC BLOOD

PK_01

Data ☑ No Data ☐

ANTI-AFLIBERCEPT ANTIBODIES

DAY 1

Theoretical Time	Sample Date *(dd-mmm-yyyy)*	Sample Time *(24-hour clock)*
T0H *		

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

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_05

Data ☑ No Data ☐

AFLIBERCEPT/PLACEBO

Scheduled Day	Treatment Number	Not Administered/ Taken	Date / Time*	Intended Dose	Actual Dose
DAY 1		☐	START	MG/KG	MG
			(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*	Intended Dose	Actual Dose
(*)		☐	START	MG/KG	MG
			(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

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		☐			

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
(*)		☐		NOT APPLICABLE	

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

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☑ No Data ☐

DAY 1

Outpatient Clinic ☐ Inpatient Clinic ☐

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 ☐

HEMATOLOGY

LAB_01

Data ☑ No Data ☐

DAY 8

Date of sampling ____ *(dd-mmm-yyyy)*

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

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		☐			

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
(*)		☐		NOT APPLICABLE	

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

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☑ No Data ☐

DAY 8

Outpatient Clinic ☐ Inpatient Clinic ☐

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 ☐

HEMATOLOGY

LAB_01

Data ☑ No Data ☐

DAY 15

Date of sampling ____ *(dd-mmm-yyyy)*

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

DIPSTICK URINALYSIS

LABU_1

Data ☑ No Data ☐

DAY 15

Date of sampling

Test name

WHITE BLOOD CELLS (QU	☐ Absent	☐ +	☐ ++	☐ +++	☐ Not evaluable
RED BLOOD CELLS (QUAI	☐ Absent	☐ +	☐ ++	☐ +++	☐ Not evaluable

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	SI Ranges Upper Limit
PROTEIN (URINE)		MG/DL				
CREATININE (URINE)		MG/DL				

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_05

Data ☑ No Data ☐

AFLIBERCEPT/PLACEBO

Scheduled Day	Treatment Number	Not Administered/ Taken	Date / Time*	Intended Dose	Actual Dose
DAY 15		☐	START	MG/KG	MG
			(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*	Intended Dose	Actual Dose
(*)		☐	START	MG/KG	MG
			(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

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_04

Data ☑ No Data ☐

GEMCITABINE

Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose	Actual Dose
				MG/M2	MG
DAY 15		☐			

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

Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose	Actual Dose
				MG/M2	MG
(*)		☐		NOT APPLICABLE	

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

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☑ No Data ☐

DAY 15

Outpatient Clinic ☐ Inpatient Clinic ☐

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		

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
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐

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
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐

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
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐

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
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	

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
☐		☐ Not Done			mm	
☐		☐ Not Done			mm	
☐		☐ Not Done			mm	
☐		☐ Not Done			mm	
☐		☐ Not Done			mm	
☐		☐ Not Done			mm	
☐		☐ Not Done			mm	
☐		☐ Not Done			mm	
☐		☐ Not Done			mm	
☐		☐ Not Done			mm	

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 ☐

	Yes	No
ANGINA PECTORIS / UNSTABLE ANGINA / MYOCARDIAL INFARCTION	☐	☐
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 :	☐	☐

ADVERSE EVENT

AE_03

AE Form Number

AE Reference ID

Data ☑ No Data ☐

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 ☐☐-☐☐☐-☐☐☐☐ *(dd-mmm-yyyy)* (complete the death report form)

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	☐	Persistant/significant disability/incapacity	☐
Life Threatening	☐	Congenital anomaly or Birth Defect	☐
Requires or prolongs hospitalization	☐	Other medically important event	☐

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?

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

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	SI Ranges Upper Limit
HEMOGLOBIN		G/L				
PLATELET COUNT (THROMBO		10E9/L				
WBC		10E9/L				
NEUTROPHILS		10E9/L				
TO BE PERFORMED ONLY FOR PATIENT UNDER VITAMIN K ANTAGONIST						
INR		RATIO				

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
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 (QUAI	☐ 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
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	SI Ranges Upper Limit
PROTEIN (URINE)		MG/DL				
CREATININE (URINE)		MG/DL				

LAB_04

24-HOUR URINALYSIS

TO BE COMPLETED IF UPCR > 1

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	SI RANGES Lower limit	SI RANGES Upper Limit
URINARY VOLUME		L				
PROTEIN (URINE)		G/L				
CREATININE (URIN		G/L				

ELECTROPHORESIS

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

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 (QUAI	☐	☐

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	☐	☐

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 Value	SI Unit	SI Ranges Lower Limit	SI Ranges Upper Limit
LDH		IU/L				
HAPTOGLOBIN		G/L				
OROSOMUCOID		G/L				

VISIT_01

Date of visit :

(DD-MMM-YYYY)

VITAL_02

VITAL SIGNS

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

HEMATOLOGY

LAB_01

Data ☑ No Data ☐

DAY 1

Date of sampling ____ *(dd-mmm-yyyy)*

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

TO BE PERFORMED ONLY FOR PATIENT UNDER VITAMIN K ANTAGONIST

INR		RATIO				

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	

Date of sampling _____ *(dd-mmm-yyyy)*

Test	Value	Unit If other unit, specify	SI Ranges 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.

DIPSTICK URINALYSIS

LABU_1

Data ☑ No Data ☐

DAY 1

Date of sampling

Test name

WHITE BLOOD CELLS (QU	☐ Absent	☐ +	☐ ++	☐ +++	☐ Not evaluable
RED BLOOD CELLS (QUAI	☐ Absent	☐ +	☐ ++	☐ +++	☐ Not evaluable

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	SI Ranges Upper Limit
PROTEIN (URINE)		MG/DL				
CREATININE (URINE)		MG/DL				

PHARMACOKINETIC BLOOD

PK_01

Data ☑ No Data ☐

TO BE COMPLETED ONLY FOR PK PATIENTS.

FREE AND BOUND AFLIBERCEPT

DAY 1

Sample ID	Theoretical Time	Sample Date *(dd-mmm-yyyy)*	Sample Time *24-hour clock*
P04	T0H *		

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

PHARMACOKINETIC BLOOD

PK_01

Data ☑ No Data ☐

FREE AND BOUND AFLIBERCEPT

DAY 1

Theoretical Time	Sample Date *(dd-mmm-yyyy)*	Sample Time *24-hour clock*
T0H *		

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

PHARMACOKINETIC BLOOD

PK_01

Data ☑ No Data ☐

ANTI-AFLIBERCEPT ANTIBODIES

DAY 1

	Theoretical Time	Sample Date *(dd-mmm-yyyy)*	Sample Time *(24-hour clock)*
	T0H *		

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

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_05

Data ☑ No Data ☐

AFLIBERCEPT/PLACEBO

Scheduled Day	Treatment Number	Not Administered/ Taken	Date / Time*	Intended Dose	Actual Dose
DAY 1		☐	START (dd-mmm-yyyy) (24-hour clock) END (24-hour clock)	MG/KG	MG

*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*	Intended Dose	Actual Dose
(*)		☐	START (dd-mmm-yyyy) (24-hour clock) END (24-hour clock)	MG/KG NOT APPLICABLE	MG

*Time to be given only for PK patients

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

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		☐			

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
(*)		☐		NOT APPLICABLE	

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

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☑ No Data ☐

DAY 1

Outpatient Clinic ☐ Inpatient Clinic ☐

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 ☐

HEMATOLOGY

LAB_01

Data ☑ No Data ☐

DAY 8

Date of sampling ____ *(dd-mmm-yyyy)*

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

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		☐			

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
(*)		☐		NOT APPLICABLE	

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

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☑ No Data ☐

DAY 8

Outpatient Clinic ☐ Inpatient Clinic ☐

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 ☐

HEMATOLOGY

LAB_01

Data ☑ No Data ☐

DAY 15

Date of sampling ____ *(dd-mmm-yyyy)*

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

DIPSTICK URINALYSIS

LABU_1

Data ☑ No Data ☐

DAY 15

Date of sampling

Test name

WHITE BLOOD CELLS (QU	☐ Absent	☐ +	☐ ++	☐ +++	☐ Not evaluable
RED BLOOD CELLS (QUAI	☐ Absent	☐ +	☐ ++	☐ +++	☐ Not evaluable

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	SI Ranges Upper Limit
PROTEIN (URINE)		MG/DL				
CREATININE (URINE)		MG/DL				

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_05

Data ☑ No Data ☐

AFLIBERCEPT/PLACEBO

Scheduled Day	Treatment Number	Not Administered/ Taken	Date / Time*	Intended Dose	Actual Dose
DAY 15		☐	START (dd-mmm-yyyy) (24-hour clock)	MG/KG	MG
			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*	Intended Dose	Actual Dose
(*)		☐	START (dd-mmm-yyyy) (24-hour clock)	MG/KG NOT APPLICABLE	MG
			END (24-hour clock)		

*Time to be given only for PK patients

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

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_04

Data ☑ No Data ☐

GEMCITABINE

Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose	Actual Dose
				MG/M2	MG
DAY 15		☐			

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

Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose	Actual Dose
				MG/M2	MG
(*)		☐		NOT APPLICABLE	

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

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☑ No Data ☐

DAY 15

Outpatient Clinic ☐ Inpatient Clinic ☐

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		

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
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐

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
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐

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
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐

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
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	

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
		☐ Not Done			mm	
		☐ Not Done			mm	
		☐ Not Done			mm	
		☐ Not Done			mm	
		☐ Not Done			mm	
		☐ Not Done			mm	
		☐ Not Done			mm	
		☐ Not Done			mm	
		☐ Not Done			mm	
		☐ Not Done			mm	

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 ☐

	Yes	No
ANGINA PECTORIS / UNSTABLE ANGINA / MYOCARDIAL INFARCTION	☐	☐
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 :	☐	☐

ADVERSE EVENT

AE_03

AE Form Number
AE Reference ID

Data ☑ No Data ☐

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 ☐ *(dd-mmm-yyyy)* (complete the death report form)
   - 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	☐	Persistant/significant disability/incapacity	☐
Life Threatening	☐	Congenital anomaly or Birth Defect	☐
Requires or prolongs hospitalization	☐	Other medically important event	☐

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?

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

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	SI Ranges Upper Limit
HEMOGLOBIN		G/L				
PLATELET COUNT (THROMBO		10E9/L				
WBC		10E9/L				
NEUTROPHILS		10E9/L				
TO BE PERFORMED ONLY FOR PATIENT UNDER VITAMIN K ANTAGONIST						
INR		RATIO				

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
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 (QUAI	☐ 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
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	SI Ranges Upper Limit
PROTEIN (URINE)		MG/DL				
CREATININE (URINE)		MG/DL				

LAB_04

24-HOUR URINALYSIS

TO BE COMPLETED IF UPCR > 1

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	SI RANGES Lower limit	SI RANGES Upper Limit
URINARY VOLUME		L				
PROTEIN (URINE)		G/L				
CREATININE (URIN		G/L				

ELECTROPHORESIS

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

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 (QUAI	☐	☐

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	☐	☐

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 Value	SI Unit	SI Ranges Lower Limit	SI Ranges 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.

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.**

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.

Date of visit : _____ VISIT_01
(DD-MMM-YYYY)

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

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	SI Ranges Upper Limit
HEMOGLOBIN		G/L				
PLATELET COUNT (THROMBO		10E9/L				
WBC		10E9/L				
NEUTROPHILS		10E9/L				

TO BE PERFORMED ONLY FOR PATIENT UNDER VITAMIN K ANTAGONIST

INR		RATIO				

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
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.

DIPSTICK URINALYSIS

LABU_1

Data ☑ No Data ☐

Date of sampling

Test name

WHITE BLOOD CELLS (QU	☐ Absent	☐ +	☐ ++	☐ +++	☐ Not evaluable
RED BLOOD CELLS (QUAI	☐ Absent	☐ +	☐ ++	☐ +++	☐ Not evaluable

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	SI Ranges Upper Limit
PROTEIN (URINE)		MG/DL				
CREATININE (URINE)		MG/DL				

PHARMACOKINETIC BLOOD

PK_01

Data ☑ No Data ☐

FREE AND BOUND AFLIBERCEPT

Sample ID	Theoretical Time	Sample Date *(dd-mmm-yyyy)*	Sample Time *24-hour clock*
P05	T0H *		

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

PHARMACOKINETIC BLOOD

PK_01

Data ☑ No Data ☐

FREE AND BOUND AFLIBERCEPT

Theoretical Time	Sample Date *(dd-mmm-yyyy)*	Sample Time *24-hour clock*
T0H *		

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

PHARMACOKINETIC BLOOD

PK_01

Data ☑ No Data ☐

ANTI-AFLIBERCEPT ANTIBODIES

Sample ID	Theoretical Time		Sample Date *(dd-mmm-yyyy)*	Sample Time *(24-hour clock)*
A01	T0H	*		

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

PHARMACOKINETIC BLOOD

PK_01

Data ☑ No Data ☐

ANTI-AFLIBERCEPT ANTIBODIES

Theoretical Time	Sample Date *(dd-mmm-yyyy)*	Sample Time *(24-hour clock)*
T0H *		

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
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	

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
		☐ Not Done			mm	
		☐ Not Done			mm	
		☐ Not Done			mm	
		☐ Not Done			mm	
		☐ Not Done			mm	
		☐ Not Done			mm	
		☐ Not Done			mm	
		☐ Not Done			mm	
		☐ Not Done			mm	
		☐ Not Done			mm	

TUMOR MARKERS

TMARK_01

Data ☑ No Data ☐

Date of evaluation

(dd-mmm-yyyy)

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

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	SI Ranges Upper Limit
HEMOGLOBIN		G/L				
PLATELET COUNT (THROMBO		10E9/L				
WBC		10E9/L				
NEUTROPHILS		10E9/L				
TO BE PERFORMED ONLY FOR PATIENT UNDER VITAMIN K ANTAGONIST						
INR		RATIO				

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
	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 (QUAI	☐ 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
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	SI Ranges Upper Limit
PROTEIN (URINE)		MG/DL				
CREATININE (URINE)		MG/DL				

LAB_04

24-HOUR URINALYSIS

TO BE COMPLETED IF UPCR > 1

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	SI RANGES Lower limit	SI RANGES Upper Limit
URINARY VOLUME		L				
PROTEIN (URINE)		G/L				
CREATININE (URIN		G/L				

ELECTROPHORESIS

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

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 (QUAI	☐	☐

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	☐	☐

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 Value	SI Unit	SI Ranges Lower Limit	SI Ranges Upper Limit
LDH		IU/L				
HAPTOGLOBIN		G/L				
OROSOMUCOID		G/L				

VISIT_01

Date of visit : _____
(DD-MMM-YYYY)

SUBST_01

SUBJECT STATUS

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.*

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

PHARMACOKINETIC BLOOD

PK_01

Data ☑ No Data ☐

FREE AND BOUND AFLIBERCEPT

Sample ID	Theoretical Time	Sample Date *(dd-mmm-yyyy)*	Sample Time *24-hour clock*
P06	T0H *		

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

PHARMACOKINETIC BLOOD

PK_01

Data ☑ No Data ☐

FREE AND BOUND AFLIBERCEPT

Theoretical Time	Sample Date *(dd-mmm-yyyy)*	Sample Time *24-hour clock*
T0H *		

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

PHARMACOKINETIC BLOOD

PK_01

Data ☑ No Data ☐

ANTI-AFLIBERCEPT ANTIBODIES

Sample ID	Theoretical Time	Sample Date *(dd-mmm-yyyy)*	Sample Time *(24-hour clock)*
A02	T0H *		

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

PHARMACOKINETIC BLOOD

PK_01

Data ☑ No Data ☐

ANTI-AFLIBERCEPT ANTIBODIES

Theoretical Time	Sample Date *(dd-mmm-yyyy)*	Sample Time *(24-hour clock)*
T0H *		

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

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								

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								

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 ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐

Lesion location	Start Date (dd-mmm-yyyy)	End Date (dd-mmm-yyyy)	Total Dose	Unit	Intent
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐

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		

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		

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
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐

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
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐

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
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐

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
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	

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
☐		☐ Not Done			mm	☐
☐		☐ Not Done			mm	☐
☐		☐ Not Done			mm	☐
☐		☐ Not Done			mm	☐
☐		☐ Not Done			mm	☐
☐		☐ Not Done			mm	☐
☐		☐ Not Done			mm	☐
☐		☐ Not Done			mm	☐
☐		☐ Not Done			mm	☐
☐		☐ Not Done			mm	☐

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 ☐

		Yes	No
ANGINA PECTORIS / UNSTABLE ANGINA / MYOCARDIAL INFARCTION		☐	☐
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 :		☐	☐

ADVERSE EVENT

AE_03

AE Form Number

AE Reference ID

Data ☑ No Data ☐

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 ☐☐-☐☐☐-☐☐☐☐ *(dd-mmm-yyyy)* (complete the death report form)

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	☐	Persistant/significant disability/incapacity	☐
Life Threatening	☐	Congenital anomaly or Birth Defect	☐
Requires or prolongs hospitalization	☐	Other medically important event	☐

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?

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

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	SI Ranges Upper Limit
HEMOGLOBIN		G/L				
PLATELET COUNT (THROMBO		10E9/L				
WBC		10E9/L				
NEUTROPHILS		10E9/L				

TO BE PERFORMED ONLY FOR PATIENT UNDER VITAMIN K ANTAGONIST

INR		RATIO				

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
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 (QUAI	☐ 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
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	SI Ranges Upper Limit
PROTEIN (URINE)		MG/DL				
CREATININE (URINE)		MG/DL				

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	SI Value	SI Unit	SI RANGES Lower limit	SI RANGES Upper Limit
URINARY VOLUME		L				
PROTEIN (URINE)		G/L				
CREATININE (URINI		G/L				

ELECTROPHORESIS

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

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 (QUAI	☐	☐

ADDITIONAL HEMATOLOGY

LABU_1

Data ☑ No Data ☐

Date of sampling

Test name	Unit	Negative	Positive
SCHISTOCYTES (QUALITA	NONE	☐	☐

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 Value	SI Unit	SI Ranges Lower Limit	SI Ranges Upper Limit
LDH		IU/L				
HAPTOGLOBIN		G/L				
OROSOMUCOID		G/L				

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.*

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							☐		☐
							☐		☐
							☐		☐
							☐		☐

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							☐		☐
							☐		☐
							☐		☐
							☐		☐

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 ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐

Lesion location	Start Date (dd-mmm-yyyy)	End Date (dd-mmm-yyyy)	Total Dose	Unit	Intent
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐
				Grays ☐ Rads ☐	Palliative ☐ Curative ☐

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		

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		

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
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐

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
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐

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
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐
					☐		☐

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
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	
		☐ Not Done		mm	

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
☐		☐ Not Done			mm	
☐		☐ Not Done			mm	
☐		☐ Not Done			mm	
☐		☐ Not Done			mm	
☐		☐ Not Done			mm	
☐		☐ Not Done			mm	
☐		☐ Not Done			mm	
☐		☐ Not Done			mm	
☐		☐ Not Done			mm	
☐		☐ Not Done			mm	

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 ☐

	Yes	No
ANGINA PECTORIS / UNSTABLE ANGINA / MYOCARDIAL INFARCTION	☐	☐
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 :	☐	☐

ADVERSE EVENT

AE_03

AE Form Number

AE Reference ID

Data ☑ No Data ☐

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 ☐ *(dd-mmm-yyyy)* (complete the death report form)

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	☐	Persistant/significant disability/incapacity	☐
Life Threatening	☐	Congenital anomaly or Birth Defect	☐
Requires or prolongs hospitalization	☐	Other medically important event	☐

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?

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

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	SI Ranges Upper Limit
HEMOGLOBIN		G/L				
PLATELET COUNT (THROMB(		10E9/L				
WBC		10E9/L				
NEUTROPHILS		10E9/L				
TO BE PERFORMED ONLY FOR PATIENT UNDER VITAMIN K ANTAGONIST						
INR		RATIO				

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
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 (QUAI	☐ 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
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	SI Ranges Upper Limit
PROTEIN (URINE)		MG/DL				
CREATININE (URINE)		MG/DL				

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	SI Value	SI Unit	SI RANGES Lower limit	SI RANGES Upper Limit
URINARY VOLUME		L				
PROTEIN (URINE)		G/L				
CREATININE (URIN		G/L				

ELECTROPHORESIS

ALBUMIN (URINE)		G/L				
ALPHA 1 GLOBULIN		G/L				
ALPHA 2 GLOBULIN		G/L				
BETA GLOBULIN		G/L				
GAMMA GLOBULIN		G/L				

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 (QUAI	☐	☐

ADDITIONAL HEMATOLOGY

LABU_1

Data ☑ No Data ☐

Date of sampling

Test name	Unit	Negative	Positive
SCHISTOCYTES (QUALITA	NONE	☐	☐

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 Value	SI Unit	SI Ranges Lower Limit	SI Ranges 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:		

Procedure Description	Procedure Date *(DD-MMM-YYYY)*	Outcome
☐	☐	☐ Not applicable ☐ Normal ☐ Abnormal If abnormal, clinically significant? ☐ Yes* ☐ No

*Specify: ____________________

Procedure Description	Procedure Date *(DD-MMM-YYYY)*	Outcome
☐	☐	☐ Not applicable ☐ Normal ☐ Abnormal If abnormal, clinically significant? ☐ Yes* ☐ No

*Specify: ____________________

Procedure Description	Procedure Date *(DD-MMM-YYYY)*	Outcome
☐	☐	☐ Not applicable ☐ Normal ☐ Abnormal If abnormal, clinically significant? ☐ Yes* ☐ No

*Specify: ____________________

Procedure Description	Procedure Date *(DD-MMM-YYYY)*	Outcome
☐	☐	☐ Not applicable ☐ Normal ☐ Abnormal If abnormal, clinically significant? ☐ Yes* ☐ No

*Specify: ____________________

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: _____

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: _____

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: ______________________

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.

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 AFLIBERCEP	P07			
FREE AND BOUND AFLIBERCEP	P08			
FREE AND BOUND AFLIBERCEP	P09			
FREE AND BOUND AFLIBERCEP	P10			
FREE AND BOUND AFLIBERCEP	P11			
FREE AND BOUND AFLIBERCEP	P12			
FREE AND BOUND AFLIBERCEP	P13			
FREE AND BOUND AFLIBERCEP	P14			
FREE AND BOUND AFLIBERCEP	P15			
FREE AND BOUND AFLIBERCEP	P16			

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		

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 AFLIBERCEP	P17			
FREE AND BOUND AFLIBERCEP	P18			
FREE AND BOUND AFLIBERCEP	P19			
FREE AND BOUND AFLIBERCEP	P20			
FREE AND BOUND AFLIBERCEP	P21			
FREE AND BOUND AFLIBERCEP	P22			
FREE AND BOUND AFLIBERCEP	P23			
FREE AND BOUND AFLIBERCEP	P24			
FREE AND BOUND AFLIBERCEP	P25			
FREE AND BOUND AFLIBERCEP	P26			

	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		

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			

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		

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			

	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		

DEATH

DEATH_01

Data ☑ No Data ☐

Date of Death : ☐ *(dd-mmm-yyyy)*

Reason for death :

Adverse event ☐

Disease progression ☐

Other reason ☐ *Specify :* _____

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
		☐		☐
		☐		☐
		☐		☐
		☐		☐
		☐		☐
		☐		☐

Drug/Medication (brand or generic name)	Start Date *(dd-mmm-yyyy)*	Previously Reported	End Date *(dd-mmm-yyyy)*	Or tick if Ongoing
		☐		☐
		☐		☐
		☐		☐
		☐		☐
		☐		☐
		☐		☐
		☐		☐
		☐		☐

Drug/Medication (brand or generic name)	Start Date *(dd-mmm-yyyy)*	Previously Reported	End Date *(dd-mmm-yyyy)*	Or tick if Ongoing
		☐		☐
		☐		☐
		☐		☐
		☐		☐
		☐		☐
		☐		☐
		☐		☐
		☐		☐

UNSCHEDULED LABORATORY TESTS

LAB_06

Data ☑ No Data ☐

Start Date ☐ *(dd-mm-yyyy)*

			Ranges					
Test	Value	Unit	Lower Limit	Upper Limit	SI Value	SI Unit	Lower Limit	Upper Limit

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.

ADDITIONAL VITAL SIGNS

VITAL_02

Data ☑ No Data ☐

Date performed: _____
(DD-MMM-YYYY)

Blood pressure: Systolic: _____ mmHg / Diastolic: _____ mmHg