EFC6546 / AVE0005

VENICE

Case Report Form

A Multicenter, Randomized, Double-blind Study Comparing the Efficacy and Safety of Aflibercept versus Placebo Administered every 3 weeks in Patients treated with Docetaxel / Prednisone for Metastatic Androgen-Independent Prostate Cancer

Country number: ___ ___ ___ Centre number: ___ ___ ___

Subject number: ___ ___ ___ Subject initials: ___ ___ ___

sanofi aventis
Because health matters

LABORATORY NORMAL RANGES *LABNR_1*

BIOCHEMISTRY

Investigator: _____ Country No: |__|__|__| Centre No: |__|__|__|

Laboratory Name: _____

Address: _____

_____

Effective date: |__|__| |__|__| |__|__|__|__| (day / month / year)

TESTS	UNIT	IF OTHER UNIT, SPECIFY	SEX (M = male, F = female, B = both)	AGE (Unit: Year ☒) Low	AGE (Unit: Year ☒) High	NORMAL RANGES Lower limit	NORMAL RANGES 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	µmol/L						
Glucose	mmol/L						
AST	IU/L						
ALT	IU/L						
Alkaline Phosphatase	IU/L						
Total Bilirubin	mg/dL						
Total Protein	g/dL						
Albumin	g/dL						
LDH	IU/L						
Haptoglobin	g/L						
Orosmucoïd	g/L						
Testosterone	ng/dL						

LABORATORY NORMAL RANGES *LABNR_1*

HEMATOLOGY

Investigator: _____	Country No: ⌊__⌋⌊__⌋⌊__⌋ Centre No: ⌊__⌋⌊__⌋⌊__⌋
Laboratory Name: _____ Address: _____ _____	Effective date: ⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋ day month year

TESTS	UNIT	IF OTHER UNIT, SPECIFY	SEX M = male F = female B = both	AGE (Unit: Year ☒)		NORMAL RANGES	
				Low	High	Lower limit	Upper limit
INR	Ratio						

LABORATORY NORMAL RANGES *LABNR_1*

URINALYSIS

Investigator: _____	Country No: ⌊__⌋⌊__⌋⌊__⌋ Centre No: ⌊__⌋⌊__⌋⌊__⌋
Laboratory Name: _____ Address: _____ _____	Effective date: ⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋ day month year

TESTS	UNIT	IF OTHER UNIT, SPECIFY	SEX M = male F = female B = both	AGE (Unit: Year ☒)		NORMAL RANGES	
				Low	High	Lower limit	Upper limit
Protein	g/L						
Creatinine	g/L						

LABORATORY NORMAL RANGES *LABNR_1*

ELECTROPHORESIS

Investigator: _____	Country No: ⌊__⌋⌊__⌋⌊__⌋ Centre No: ⌊__⌋⌊__⌋⌊__⌋
Laboratory Name: _____ Address: _____ _____	Effective date: ⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋ day month year

TESTS	UNIT	IF OTHER UNIT, SPECIFY	SEX M = male F = female B = both	AGE (Unit: Year ☒)		NORMAL RANGES	
				Low	High	Lower limit	Upper limit
Albumin	g/L						
Alpha 1 Globulin	g/L						
Alpha 2 Globulin	g/L						
Beta Globulin	g/L						
Gamma Globulin	g/L						

INFORMED CONSENT *INFCN_01*

Date consent obtained:

__ __ / __ __ __ / __ __ __ __

day month year

DEMOGRAPHY *DEMOG_01*

Date of birth: __ __ / __ __ __ / 1 9 __ __ (day / month / year)

Sex:
- Male ☑
- Female ☐

Race:
- Caucasian/White ☐
- Black ☐
- Asian/Oriental ☐
- Other ☐ *If Other, specify:* _____

CANCER DIAGNOSIS *CDIAG_01*

- Date of initial diagnosis: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ (Date of histological diagnosis)
  day month year

LOCATION *(tick one box only):*

- ❑ 18 Prostate
- ❑ 30 Other, ***specify*:** _____

HISTOLOGY TYPE *(tick one box only):*

- ❑ Adenocarcinoma
- ❑ Other, ***specify:*** _____

HISTOPATHOLOGY *(tick one box only):*

- ❑ Unknown
- ❑ Poorly differentiated
- ❑ Moderately differentiated
- ❑ Well differentiated

- **STAGING:** T ⌊_⌋ N ⌊_⌋ M ⌊_⌋
- **GLEASON SCORE** (2-10): ⌊_⌋⌊_⌋

SURGERY *SURG_01*

PRIOR SURGERY FOR PROSTATIC CARCINOMA EXCLUDING ANDROGEN ABLATION

NONE ❑

	SURGERY	SURGERY DATE OR NOT PERFORMED Day Month Year
1	Prostatectomy	❑ Not performed
2	Pelvic lymphadenectomy	❑ Not performed
3		
4		

SURGERY *SURG_01*

PRIOR SURGERY FOR ANDROGEN ABLATION

NONE ❑

	SURGERY	SURGERY DATE OR NOT PERFORMED Day Month Year
1	Bilateral Orchiectomy	❑ Not performed
2	Bilateral Adrenalectomy	❑ Not performed
3	Hypophysectomy	❑ Not performed
4		

*LOCATION:	
03	Bone
11.01	Regional Lymph Nodes
11.02	Distant Lymph Nodes
18	Prostate
99	Other

RADIATION THERAPY *RADTX_01*

PRIOR RADIATION THERAPY

PLEASE RECORD ALL THE PRIOR RADIATION THERAPY RELATED TO PROSTATE CANCER

NONE ❑

	SITE LOCATION*	START DATE day month year	STOP DATE day month year	TOTAL DOSE	UNITS	INTENT
1	␣␣.␣␣	␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
2	␣␣.␣␣	␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
3	␣␣.␣␣	␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
4	␣␣.␣␣	␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
5	␣␣.␣␣	␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
6	␣␣.␣␣	␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
7	␣␣.␣␣	␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
8	␣␣.␣␣	␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
9	␣␣.␣␣	␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
10	␣␣.␣␣	␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative

* **INTENT:**

1 - Neoadjuvant 2 - Adjuvant 3 - Advanced

** **THERAPY TYPE:**

HO - Hormonotherapy

OT - Other

CH - Chemotherapy

BI - Biologicals

ANTI-CANCER THERAPY *CANTX_02*

PRIOR TREATMENT

NONE ❑

PLEASE RECORD ALL THE PRIOR MEDICAL HORMONAL THERAPIES AND ALL ESTRAMUSTINE THERAPY AND CHEMOTHERAPY RELATED TO PROSTATE CANCER.

REGIMEN NO.	INTENT*	DRUG PER REGIMEN	THERAPY TYPE**	START DATE DAY MONTH YEAR	END DATE DAY MONTH YEAR	ONGOING
1.	⌊⌋	1	⌊⌋⌊⌋	⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋⌊⌋	⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋⌊⌋	❑
		2	⌊⌋⌊⌋	⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋⌊⌋	⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋⌊⌋	❑
		3	⌊⌋⌊⌋	⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋⌊⌋	⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋⌊⌋	❑
		4	⌊⌋⌊⌋	⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋⌊⌋	⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋⌊⌋	❑
2.	⌊⌋	1	⌊⌋⌊⌋	⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋⌊⌋	⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋⌊⌋	❑
		2	⌊⌋⌊⌋	⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋⌊⌋	⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋⌊⌋	❑
		3	⌊⌋⌊⌋	⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋⌊⌋	⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋⌊⌋	❑
		4	⌊⌋⌊⌋	⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋⌊⌋	⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋⌊⌋	❑
3.	⌊⌋	1	⌊⌋⌊⌋	⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋⌊⌋	⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋⌊⌋	❑
		2	⌊⌋⌊⌋	⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋⌊⌋	⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋⌊⌋	❑
		3	⌊⌋⌊⌋	⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋⌊⌋	⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋⌊⌋	❑
		4	⌊⌋⌊⌋	⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋⌊⌋	⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋⌊⌋	❑

MEDICAL HISTORY 1/2 *MHX_02*

❑ None

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

	MEDICAL / SURGICAL HISTORY	START DATE OR NOT OCCURRED Month Year	ONGOING
1	Angina Pectoris	❑ Not Occurred	❑ Yes ❑ No If yes, disease/symptoms controlled: ❑ Yes ❑ No
2	Unstable Angina	❑ Not Occurred	❑ Yes ❑ No If yes, disease/symptoms controlled: ❑ Yes ❑ No
3	Myocardial Infarction	❑ Not Occurred	❑ Yes ❑ No If yes, disease/symptoms controlled: ❑ Yes ❑ No
4	Atrial Fibrillation	❑ Not Occurred	❑ Yes ❑ No If yes, disease/symptoms controlled: ❑ Yes ❑ No
5	Transient Ischemic Attack	❑ Not Occurred	❑ Yes ❑ No If yes, disease/symptoms controlled: ❑ Yes ❑ No
6	Stroke	❑ Not Occurred	❑ Yes ❑ No If yes, disease/symptoms controlled: ❑ Yes ❑ No
7	Peripheral Arterial Thrombotic Disease	❑ Not Occurred	❑ Yes ❑ No If yes, disease/symptoms controlled: ❑ Yes ❑ No
8	Deep Venous Thrombosis	❑ Not Occurred	❑ Yes ❑ No If yes, disease/symptoms controlled: ❑ Yes ❑ No

MEDICAL HISTORY 2/2 *MHX_02*

❑ None

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

	MEDICAL / SURGICAL HISTORY	START DATE OR NOT OCCURRED Month Year	ONGOING
9	Pulmonary Embolism	❑ Not Occurred	❑ Yes ❑ No If yes, disease/symptoms controlled: ❑ Yes ❑ No
10	High Blood Pressure	❑ Not Occurred	❑ Yes ❑ No If yes, disease/symptoms controlled: ❑ Yes ❑ No
11	Hypercholesterolemia	❑ Not Occurred	❑ Yes ❑ No If yes, disease/symptoms controlled: ❑ Yes ❑ No
12	Diabetes mellitus	❑ Not Occurred	❑ Yes ❑ No If yes, disease/symptoms controlled: ❑ Yes ❑ No
13	Smoker	❑ Not Occurred	❑ Yes ❑ No If yes, disease/symptoms controlled: ❑ Yes ❑ No
14		❑ Not Occurred	❑ Yes ❑ No If yes, disease/symptoms controlled: ❑ Yes ❑ No
15		❑ Not Occurred	❑ Yes ❑ No If yes, disease/symptoms controlled: ❑ Yes ❑ No
16		❑ Not Occurred	❑ Yes ❑ No If yes, disease/symptoms controlled: ❑ Yes ❑ No

MEDICAL OR SURGICAL HISTORY *MHX_02*

None ❑

Record relevant Medical/Surgical History other than the disease studied and other thrombovascular events and cardiovascular risk factors.

	MEDICAL / SURGICAL HISTORY	START DATE Month Year	ONGOING
1		⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑ Yes ❑ No If yes, disease/symptoms controlled: ❑ Yes ❑ No
2		⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑ Yes ❑ No If yes, disease/symptoms controlled: ❑ Yes ❑ No
3		⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑ Yes ❑ No If yes, disease/symptoms controlled: ❑ Yes ❑ No
4		⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑ Yes ❑ No If yes, disease/symptoms controlled: ❑ Yes ❑ No
5		⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑ Yes ❑ No If yes, disease/symptoms controlled: ❑ Yes ❑ No
6		⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑ Yes ❑ No If yes, disease/symptoms controlled: ❑ Yes ❑ No
7		⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑ Yes ❑ No If yes, disease/symptoms controlled: ❑ Yes ❑ No
8		⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑ Yes ❑ No If yes, disease/symptoms controlled: ❑ Yes ❑ No

MEDICATION BIPHOSPHONATES *MED_02*

None ❑

Record all biphosphonates therapies that the subject has taken.

	DRUG / MEDICATION (Brand or Generic Name)	DOSAGE (TOTAL DAILY DOSE)	DOSE UNIT	ROUTE*	START DATE Day Month Year	END DATE OR TICK IF ONGOING Day Month Year
1					␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Ongoing
2					␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Ongoing
3					␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Ongoing
4					␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Ongoing
5					␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Ongoing
6					␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Ongoing
7					␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Ongoing
8					␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Ongoing
9					␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Ongoing
10					␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Ongoing

* **ROUTE:** 19 = Intravenous 23 = Oral 24 = Other

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

* **ROUTE:**

1	=	Cutaneous	19	=	Intravenous	27	=	Rectal
2	=	Buccal	23	=	Oral	28	=	Subcutaneous
6	=	Inhalation	24	=	Other	29	=	Sublingua
12	=	Intramuscular						

MEDICATION ANALGESIC *MED_02*

PLEASE RECORD ALL ANALGESIC MEDICATION EXCLUDING BIPHOSPHONATE.

None ❑

	DRUG / MEDICATION (Brand or Generic Name)	DOSAGE (TOTAL DAILY DOSE)	DOSE UNIT	ROUTE *	START DATE Day Month Year	END DATE OR TICK IF ONGOING Day Month Year
1					␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣ ❑ Ongoing
2					␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣ ❑ Ongoing
3					␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣ ❑ Ongoing
4					␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣ ❑ Ongoing
5					␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣ ❑ Ongoing
6					␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣ ❑ Ongoing
7					␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣ ❑ Ongoing
8					␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣ ❑ Ongoing
9					␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣ ❑ Ongoing
10					␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣ ❑ Ongoing

TO BE PERFORMED OVER 7 CONSECUTIVE DAYS PRIOR TO THE RANDOMIZATION, AND THE LAST DAILY EVALUATION SHOULD BE OBTAINED WITHIN 3 DAYS PRIOR TO RANDOMIZATION.

PAIN EVALUATION

NOT DONE ❑

	DATE OF ASSESSMENT Day Month Year	PRESENT PAIN INTENSITY SCORE
1st Day	__/__ __/__/__ __/__/__/__	____
2nd Day	__/__ __/__/__ __/__/__/__	____
3rd Day	__/__ __/__/__ __/__/__/__	____
4th Day	__/__ __/__/__ __/__/__/__	____
5th Day	__/__ __/__/__ __/__/__/__	____
6th Day	__/__ __/__/__ __/__/__/__	____
7th Day	__/__ __/__/__ __/__/__/__	____

SCREENING V 00

MEDICATION PRIOR *MED_02*

PLEASE RECORD ALL MEDICATIONS OTHER THAN ANTI-CANCER DRUG THERAPY AND OTHER THAN ANALGESIC AND BIPHOSPHONATE MEDICATION WITHIN 21 DAYS PRIOR TO RANDOMIZATION.

None ❑

	DRUG / MEDICATION (Brand or Generic Name)	START DATE Day Month Year	END DATE OR TICK IF ONGOING Day Month Year
1		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Ongoing
2		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Ongoing
3		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Ongoing
4		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Ongoing
5		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Ongoing
6		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Ongoing
7		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Ongoing
8		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Ongoing
9		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Ongoing

TUMOR MARKERS *TMARK_01*

PSA VALUE 1 /VALUE 2 / VALUE 3

RECORD THE THREE LAST VALUES OF PSA.
IN CASE OF RISING PSA AT STUDY ENTRY, RECORD AS MANY VALUES AS NEEDED TO EVIDENCE THE PROTOCOL-DEFINED RISING PSA.

TEST	DATE OF EVALUATION day month year	VALUE	UNIT	Normal range	
				Lower limit	Upper limit
1. PSA	__/__ __/__/__ 20__				
2. PSA	__/__ __/__/__ 20__				
3. PSA	__/__ __/__/__ 20__				

BIOCHEMISTRY *LABB_1*

TESTOSTERONE VALUE

TO BE PERFORMED WITHIN 21 DAYS PRIOR TO RANDOMIZATION.

Laboratory Name: _____

Address: _____

- Date of sampling: __/__ __/__/__ 20__ (day / month / year)

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Testosterone		NG/DL	

STATUS AT STUDY ENTRY

- Extent at study entry: ❑ Metastatic ❑ Loco regional

- Date of progression: ⌊_⌊_⌋ ⌊_⌊_⌊_⌋ ⌊_⌊_⌊_⌊_⌋
  day month year

- Criteria for progression: *(tick all that apply)*
  - ❑ Increase in measurable disease (RECIST)
  - ❑ Appearance of new lesions including those on bone scan
  - ❑ Rising PSA

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.

VITAL SIGNS *VITAL_1*

TO BE PERFORMED WITHIN 8 DAYS PRIOR TO RANDOMIZATION.

- Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊2⌋⌊0⌋⌊_⌋⌊_⌋
  day month year

Height: ⌊_⌋⌊_⌋⌊_⌋ cm

Weight: ⌊_⌋⌊_⌋⌊_⌋ . ⌊_⌋ kg

- Blood pressure: Systolic ⌊_⌋⌊_⌋⌊_⌋ mmHg / Diastolic ⌊_⌋⌊_⌋⌊_⌋ mmHg

ECOG Performance Status

0	1	2	3	4
❑	❑	❑	❑	❑

SKELETAL RELATED EVENT EVALUATION

- Occurence of SRE: **Yes** ❑ **No** ❑

In case of:

- pathological fractures and/or spinal cord compression, please fill in an AE/SAE Form at cycle 1.
- bone irradiation, including radioisotopes or bone surgery, please complete the radiation or surgery Form as appropriate.
- change of antineoplastic therapy (including introduction of biphosphonates in the face of increase in pain) to treat bone pain, please fill in either further anticancer therapy and / or Biphosphonate Medication Form.

TO BE PERFORMED WITHIN 8 DAYS PRIOR TO RANDOMIZATION.
THEN DURING TREATMENT PERIOD, IF CLINICALLY INDICATED. IN THIS CASE, PLEASE USE AN ADDITIONAL ECG FORM.

ELECTROCARDIOGRAM *ECG_01*

Date performed: __ __ (day) __ __ __ (month) 2 0 __ __ (year)

- ❑ Normal
- ❑ Abnormal

  If abnormal, clinically significant? ❑ Yes ❑ No

IF ABNORMAL, CLINICALLY SIGNIFICANT, RECORD ON THE MEDICAL HISTORY FORM .

HEMATOLOGY *LABH_1*

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

• Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊2⌋⌊0⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Hemoglobin		g/L	
Platelets count		10^9/L	
WBC		10^9/L	
Neutrophils		10^9/L	

HEMATOLOGY *LABH_1*

❑ Not Done

TO BE PERFORMED ONLY FOR PATIENT UNDER VITAMIN K ANTAGONIST.

• Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊2⌋⌊0⌋⌊_⌋⌊_⌋
day month year

Laboratory Name: _____

Address: _____

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
INR		Ratio	

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

BIOCHEMISTRY *LABB_1*

Laboratory Name: _____

Address: _____

- Date of sampling: __ __ day __ __ __ month 2 0 __ __ year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Sodium		mmol/L	
Calcium		mmol/L	
Potassium		mmol/L	
Phosphorus		mmol/L	
Blood Urea Nitrogen		mg/dL	
Urea**		mmol/L	
Magnesium		mg/dL	
Creatinine		µmol/L	
Calculated Creatinine clearance*		ml/min	
Glucose		mmol/L	
AST		IU/L	
ALT		IU/L	
Alkaline phosphatase		IU/L	
Total bilirubin		mg/dL	
Total protein		g/dL	
Albumin		g/dL	

* If creatinine > ULN, please report the calculated creatinine clearance.
** If BUN is not evaluated, UREA value must be documented.

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

DIPSTICK URINALYSIS *LABU_1*

• Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊2⌋⌊0⌋⌊_⌋⌊_⌋
day month year

WBC	❑ Absent	❑ +	❑ ++	❑ +++	❑ Not evaluable
RBC	❑ Absent	❑ +	❑ ++	❑ +++	❑ Not evaluable

MORNING SPOT URINALYSIS *LABU_2*

Not Done ❑

Laboratory name: _____

Address: _____

• Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊2⌋⌊0⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Protein		mg/dL	
Creatinine		mg/dL	

24-HOUR URINALYSIS *LABU_2*

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

❑ Not Done

Laboratory name: _____

Address: _____

- Start date of collection: ☐☐ (day) ☐☐☐ (month) 20☐☐ (year)
- Start time of collection: ☐☐:☐☐ (24-hour clock)
- End date of collection: ☐☐ (day) ☐☐☐ (month) 20☐☐ (year)
- End time of collection: ☐☐:☐☐ (24-hour clock)

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Urinary Volume		L	
Protein		g/L	
Creatinine		g/L	

IS THERE ANY HEMOGLOBIN OR RBC IN 24-HOUR URIN SAMPLE.

Hemoglobin	❑ Negative	❑ Positive
RBC	❑ Negative	❑ Positive

* LOCATION:	
03	Bone
06	Brain/CNS
11	Lymph Nodes
18	Prostate
24	Abdomen
26	Pelvis
29	Thorax
	Abdomino Pelvic
30	Other

**METHOD OF TUMOR MEASUREMENT:			
1	CT Scan	8	X-ray
2	Spiral CT Scan	9	Endoscopy
3	MRI	10	Physical Exam
4	PET	11	Multi-Slice CT
5	Scintigraphy	12	DCE MRI
6	SPECT	99	Other
7	Ultrasound		

TUMOR EVALUATION (AT BASELINE) *TUEVA_01*

TO BE PERFORMED WITHIN 21 DAYS PRIOR TO RANDOMIZATION.

	LOCATION*	METHOD OF TUMOR MEASUREMENT**	DATE day month year	NORMAL	IF ABNORMAL, SPECIFY:
1.	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	☐	☐ Tumor related ☐ Other: _____
2.	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	☐	☐ Tumor related ☐ Other: _____
3.	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	☐	☐ Tumor related ☐ Other: _____
4.	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	☐	☐ Tumor related ☐ Other: _____
5.	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	☐	☐ Tumor related ☐ Other: _____
6.	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	☐	☐ Tumor related ☐ Other: _____
7.	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	☐	☐ Tumor related ☐ Other: _____
8.	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	99 - Other, specify: _____	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	☐	☐ Tumor related ☐ Other: _____
9.	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	99 - Other, specify: _____	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	☐	☐ Tumor related ☐ Other: _____
10.	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	99 - Other, specify: _____	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	☐	☐ Tumor related ☐ Other: _____

***LOCATION:**

01	Skin	11.09	Supraclavicular
02	Muscle/Soft Tissue	12	Liver
03	Bone	13	Stomach
04	Bone Marrow	14	Pancreas
05	Peripheral Blood Stream	15	Kidneys
06	Brain/CNS	17	Bladder
07	Head/Neck	18	Prostate
08	Eosaphagus	20.10	Colon
10	Lungs	20.20	Rectum
11	Lymph Nodes	21	Adrenal
11.01	Regional Lymph Nodes	22	Mediastinum
11.02	Distant Lymph Nodes	24	Abdomen
11.03	Axillary	25	Gastrointestinal Tract
11.04	Cervical	26	Pelvis
11.05	Inguinal	27	Peritoneum
11.06	Intra Abdominal	28	Testis
11.07	Mediastinal	29	Thorax
11.08	Para Aortic	29.01	Pleura
		30	Other

****METHOD OF TUMOR MEASUREMENT:**

1	CT Scan	8	X-ray
2	Spiral CT Scan	9	Endoscopy
3	MRI	10	Physical Exam
4	PET	11	Multi-Slice CT
5	Scintigraphy	12	DCE MRI
6	SPECT	99	Other
7	Ultrasound		

TUMOR MEASUREMENT (AT BASELINE) *TUMEA_01*

LESION NUMBER	LESION LOCATION*	LESION DESCRIPTION (subsite)	DATE OF ASSESSMENT day month year	METHOD OF TUMOR MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	NON TARGET
1	☐☐.☐☐		☐☐ ☐☐☐ ☐☐☐☐	☐☐	☐☐☐ mm	☐
2	☐☐.☐☐		☐☐ ☐☐☐ ☐☐☐☐	☐☐	☐☐☐ mm	☐
3	☐☐.☐☐		☐☐ ☐☐☐ ☐☐☐☐	☐☐	☐☐☐ mm	☐
4	☐☐.☐☐		☐☐ ☐☐☐ ☐☐☐☐	☐☐	☐☐☐ mm	☐
5	☐☐.☐☐		☐☐ ☐☐☐ ☐☐☐☐	☐☐	☐☐☐ mm	☐
6	☐☐.☐☐		☐☐ ☐☐☐ ☐☐☐☐	☐☐	☐☐☐ mm	☐
7	☐☐.☐☐		☐☐ ☐☐☐ ☐☐☐☐	☐☐	☐☐☐ mm	☐
8	☐☐.☐☐		☐☐ ☐☐☐ ☐☐☐☐	☐☐	☐☐☐ mm	☐
9	☐☐.☐☐		☐☐ ☐☐☐ ☐☐☐☐	☐☐	☐☐☐ mm	☐
10	☐☐.☐☐		☐☐ ☐☐☐ ☐☐☐☐	☐☐	☐☐☐ mm	☐

FACT P

❑ Assessment not done

Specify the primary reason:

❑ Subject is unable due to toxicity/disease

❑ Administrative failure to distribute the questionnaire to the patient

❑ Patient refusal

❑ Death

❑ Patient did not wish to show up

❑ Translation not available

❑ Other, *specify:* _____

FACT P QUESTIONNAIRE

Below is a list of statements that other people with your illness have said are important
By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

Date of questionnaire completion : ☐☐ ☐☐☐ ☐☐☐☐

	PHYSICAL WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GP1	I have a lack of energy.....	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by side effects of treatment	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4

	SOCIAL/FAMILY WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family.....	0	1	2	3	4
GS3	I get support from my friends.....	0	1	2	3	4
GS4	My family has accepted my illness	0	1	2	3	4
GS5	I am satisfied with family communication about my illness.....	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support).....	0	1	2	3	4
Q1	*Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please check this box and go to the next section.*					
GS7	I am satisfied with my sex life.....	0	1	2	3	4

By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

	EMOTIONAL WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GE1	I feel sad	0	1	2	3	4
GE2	I am satisfied with how I am coping with my illness	0	1	2	3	4
GE3	I am losing hope in the fight against my illness	0	1	2	3	4
GE4	I feel nervous	0	1	2	3	4
GE5	I worry about dying	0	1	2	3	4
GE6	I worry that my condition will get worse	0	1	2	3	4

	FUNCTIONAL WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GF1	I am able to work (include work at home)	0	1	2	3	4
GF2	My work (include work at home) is fulfilling	0	1	2	3	4
GF3	I am able to enjoy life	0	1	2	3	4
GF4	I have accepted my illness	0	1	2	3	4
GF5	I am sleeping well	0	1	2	3	4
GF6	I am enjoying the things I usually do for fun	0	1	2	3	4
GF7	I am content with the quality of my life right now	0	1	2	3	4

By circling one (1) number per line, please indicate how true each statement has been for you <u>during the past 7 days</u>.

	ADDITIONAL CONCERNS	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
C2	I am losing weight	0	1	2	3	4
C6	I have a good appetite	0	1	2	3	4
P1	I have aches and pains that bother me	0	1	2	3	4
P2	I have certain parts of my body where I experience pain ...	0	1	2	3	4
P3	My pain keeps me from doing things I want to do	0	1	2	3	4
P4	I am satisfied with my present comfort level	0	1	2	3	4
P5	I am able to feel like a man	0	1	2	3	4
P6	I have trouble moving my bowels	0	1	2	3	4
P7	I have difficulty urinating	0	1	2	3	4
BL2	I urinate more frequently than usual	0	1	2	3	4
P8	My problems with urinating limit my activities	0	1	2	3	4
BL5	I am able to have and maintain an erection	0	1	2	3	4

ONLY SERIOUS ADVERSE EVENT OCCURING BETWEEN INFORMED CONSENT AND FIRST DOSE SHOULD BE REPORTED

ADVERSE EVENT FORM *AE_03*

NONE ❑

1. **ADVERSE EVENT (DIAGNOSIS)**	AE form no: ␣␣-␣␣ AE ref. no: ␣␣-␣␣
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ␣␣ ␣␣ ␣␣␣␣ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO INVESTIGATIONAL PRODUCTS*	Yes ❑ No ☑
5. ACTION TAKEN WITH INVESTIGATIONAL PRODUCTS**	0 ☑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ␣␣ ␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ␣␣ ␣␣ ␣␣␣␣ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE <<SAFETY COMPLEMENTARY FORM>>**	Yes ❑ No ❑ ➲ **IF YES** - Date event became serious: ␣␣ ␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
9. IS IT AN EVENT SUCH AS: **OVERDOSE OF THE IP?**	Yes ❑ No ☑
Investigator's name, date, and signature:	Monitoring representative's name, date of receipt:

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

** 0= None / 1= Permanently discontinued / 2= Delayed / 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted

ELIGIBILITY FOR RANDOMIZATION

ELIG_01

Will the subject continue in the randomization phase 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: I__ __ __ I__ __ __ I__ __ __

Exclusion criterion number: E__ __ __ E__ __ __ E__ __ __

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.**

VITAL SIGNS *O.VITAL_2*

☐ Not Applicable if already done within 8 days prior to randomization.

- Date performed : day month **2** **0** year
- Weight : ___ . ___ kg

- Blood pressure: Systolic ___ mmHg / Diastolic ___ mmHg

ECOG Performance Status

0	1	2	3	4
☐	☐	☐	☐	☐

PHYSICAL EXAMINATION

A PHYSICAL EXAMINATION SHOULD BE PERFORMED.

IF THERE ARE ANY CLINICALLY SIGNIFICANT CHANGES FROM THE PREVIOUS EXAMINATION, RECORD AS AN ADVERSE EVENT.

HEMATOLOGY *LABH_1*

☐ Not Applicable if already done within 8 days prior to randomization.

• Date of sampling: ☐☐ ☐☐☐ 2 0 ☐☐
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Hemoglobin		g/L	
Platelets count		10^9/L	
WBC		10^9/L	
Neutrophils		10^9/L	

HEMATOLOGY *LABH_1*

☐ Not Applicable if already done within 8 days prior to randomization.

TO BE PERFORMED ONLY FOR PATIENT UNDER VITAMIN K ANTAGONIST.

• Date of sampling: ☐☐ ☐☐☐ 2 0 ☐☐
day month year

Laboratory Name: _____

Address: _____

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
INR		Ratio	

BIOCHEMISTRY *LABB_1*

☐ Not Applicable if already done within 8 days prior to randomization.

Laboratory Name: _____

Address: _____

• Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊2⌋⌊0⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Sodium		mmol/L	
Calcium		mmol/L	
Potassium		mmol/L	
Phosphorus		mmol/L	
Blood Urea Nitrogen		mg/dL	
Urea**		mmol/L	
Magnesium		mg/dL	
Creatinine		µmol/L	
Calculated Creatinine clearance*		ml/min	
Glucose		mmol/L	
AST		IU/L	
ALT		IU/L	
Alkaline phosphatase		IU/L	
Total bilirubin		mg/dL	
Total protein		g/dL	
Albumin		g/dL	

* If creatinine > ULN, please report the calculated creatinine clearance.
** If BUN is not evaluated, UREA value must be documented.

DIPSTICK URINALYSIS *LABU_1*

❑ Not Applicable if already done within 8 days prior to randomization.

• Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊2⌋⌊0⌋⌊_⌋⌊_⌋
day month year

WBC	❑ Absent	❑ +	❑ ++	❑ +++	❑ Not evaluable
RBC	❑ Absent	❑ +	❑ ++	❑ +++	❑ Not evaluable

MORNING SPOT URINALYSIS *LABU_2*

❑ Not Applicable if already done within 8 days prior to randomization.

Laboratory name: _____

Address: _____

• Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊2⌋⌊0⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Protein		mg/dL	
Creatinine		mg/dL	

If UPCR is > 1 then 24 hour urine collection must be performed to assess the urine protein rate, as well as an urine protein electrophoresis. Please complete page 654.

If proteinuria is associated with hematuria then LDH, haptoglobin, schistocytes and orosomucoid will be measured in blood. Please complete page 655.

TO BE PERFORMED AT DAY 1 JUST BEFORE THE STUDY DRUG INFUSION.

TUMOR MARKERS *TMARK_01*

PSA

❑ Not Done

- Date of evaluation : ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊2⌋⌊0⌋⌊_⌋⌊_⌋
  day month year

	TEST	VALUE	UNIT	NORMAL RANGE	
				LOWER LIMIT	UPPER LIMIT
1.	**PSA**				

INVESTIGATIONAL PRODUCT ADMINISTRATION *IPA_05*

AFLIBERCEPT/PLACEBO

SCHEDULED DAY	TREATMENT NUMBER	TICK IF NOT ADMINISTERED/ TAKEN	DATE / TIME*	INTENDED DOSE mg/kg	ACTUAL DOSE mg
Day 1	⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑	START ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ day month year ⌊_⌋⌊_⌋:⌊_⌋⌊_⌋ 24-hour clock END ⌊_⌋⌊_⌋:⌊_⌋⌊_⌋ 24-hour clock		

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

SCHEDULED DAY	TREATMENT NUMBER	TICK IF NOT ADMINISTERED/ TAKEN	DATE / TIME*	INTENDED DOSE mg/kg	ACTUAL DOSE mg
Day ⌊_⌋	⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑	START ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ day month year ⌊_⌋⌊_⌋:⌊_⌋⌊_⌋ 24-hour clock END ⌊_⌋⌊_⌋:⌊_⌋⌊_⌋ 24-hour clock		

***Time to be given only for PK patients**

INVESTIGATIONAL PRODUCT ADMINISTRATION *IPA_04*

DOCETAXEL

SCHEDULED DAY	BATCH NUMBER	TICK IF NOT ADMINISTERED/ TAKEN	DATE	INTENDED DOSE mg/m²	ACTUAL DOSE mg
Day 1	⌊_⌊_⌊_⌊_⌊_⌊_⌊_⌋	❑	⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ day month year		

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

SCHEDULED DAY	BATCH NUMBER	TICK IF NOT ADMINISTERED/ TAKEN	DATE	INTENDED DOSE mg/m²	ACTUAL DOSE mg
Day ⌊_⌋	⌊_⌊_⌊_⌊_⌊_⌊_⌊_⌋	❑	⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ day month year		

INVESTIGATIONAL PRODUCT ADMINISTRATION *IPA_10*

PREDNISONE / PREDNISOLONE

SCHEDULED PERIOD	TICK IF NOT ADMINISTERED/ TAKEN	DATE (S)	INTENDED DAILY DOSE mg	DOSE MODIFIED	NUMBER OF DAYS WITH NO INTAKE
Cycle 1	❑	START ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ day month year END ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ day month year		❑ YES ❑ NO	⌊_⌋⌊_⌋⌊_⌋

SETTING

Outpatient clinic ❑ Inpatient clinic ❑

MEDICATION : PRE/POST DOCETAXEL CORTICOSTEROID *MED_03*

Record if docetaxel corticosteroïd premedication has been administered as per protocol.

None ❑

Record information for the following medications during the cycle.

	DRUG / MEDICATION (Drug Class / Brand or Generic Name)	TAKEN	NOT TAKEN
1	Corticosteroid	❑	❑

If any change compared to protocol ie "Not taken" or dose modified, please report the information on the Concomitant Medication Form.

VITAL SIGNS

VITAL_01

TO BE PERFORMED PREFERABLY DURING WEEK 2 EG BETWEEN D8 AND D15.

- Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊2⌋⌊0⌋⌊_⌋⌊_⌋
  day month year

Blood pressure: Systolic ⌊_⌋⌊_⌋⌊_⌋ mmHg / Diastolic ⌊_⌋⌊_⌋⌊_⌋ mmHg

CYCLE 1 V 01

MEDICATION BIPHOSPHONATES *MED_02*

None ❑

Record all biphosphonates therapies that the subject has taken within the cycle, and record any changes.

	DRUG / MEDICATION (Brand or Generic Name)	DOSAGE (TOTAL DAILY DOSE)	DOSE UNIT	ROUTE*	START DATE Day Month Year	END DATE OR TICK IF ONGOING Day Month Year
1					❑ Previously Reported	❑ Ongoing
2					❑ Previously Reported	❑ Ongoing
3					❑ Previously Reported	❑ Ongoing
4					❑ Previously Reported	❑ Ongoing
5					❑ Previously Reported	❑ Ongoing
6					❑ Previously Reported	❑ Ongoing
7					❑ Previously Reported	❑ Ongoing
8					❑ Previously Reported	❑ Ongoing
9					❑ Previously Reported	❑ Ongoing
10					❑ Previously Reported	❑ Ongoing

* **ROUTE:** 19 = Intravenous 23 = Oral 24 = Other

ANALGESIC MEDICATION SHOULD BE COLLECTED DAILY FOR SEVEN CONSECUTIVE DAYS PRIOR TO THE NEXT INFUSION

THE LAST RECORDS SHOULD BE OBTAINED WITHIN 3 DAYS PRIOR TO THE NEXT INFUSION

* **ROUTE:**

1	=	Cutaneous	19	=	Intravenous	27	=	Rectal
2	=	Buccal	23	=	Oral	28	=	Subcutaneous
6	=	Inhalation	24	=	Other	29	=	Sublingua
12	=	Intramuscular						

MEDICATION ANALGESIC *MED_02*

PLEASE RECORD ALL ANALGESIC MEDICATION EXCLUDING BIPHOSPHONATE.

None ❑

	DRUG / MEDICATION (Brand or Generic Name)	DOSAGE (TOTAL DAILY DOSE)	DOSE UNIT	ROUTE *	START DATE Day Month Year	END DATE OR TICK IF ONGOING Day Month Year
1					❑ Previously Reported	❑ Ongoing
2					❑ Previously Reported	❑ Ongoing
3					❑ Previously Reported	❑ Ongoing
4					❑ Previously Reported	❑ Ongoing
5					❑ Previously Reported	❑ Ongoing
6					❑ Previously Reported	❑ Ongoing
7					❑ Previously Reported	❑ Ongoing
8					❑ Previously Reported	❑ Ongoing
9					❑ Previously Reported	❑ Ongoing
10					❑ Previously Reported	❑ Ongoing

- **TO BE PERFORMED OVER 7 CONSECUTIVE DAYS PRIOR TO THE NEXT INFUSION.**
- **THE LAST RECORDS SHOULD BE OBTAINED WITHIN 3 DAYS PRIOR TO THE NEXT INFUSION.**

PAIN EVALUATION

NOT DONE ☐

	DATE OF ASSESSMENT Day Month Year	PRESENT PAIN INTENSITY SCORE
1st Day	__/__/____	____
2nd Day	__/__/____	____
3rd Day	__/__/____	____
4th Day	__/__/____	____
5th Day	__/__/____	____
6th Day	__/__/____	____
7th Day	__/__/____	____

SKELETAL RELATED EVENT EVALUATION

- Occurence of SRE: **Yes** ❑ **No** ❑

In case of:

- pathological fractures and/or spinal cord compression, please fill in an AE/SAE Form as appropriate.
- bone irradiation, including radioisotopes or bone surgery, please complete the concomitant radiation or surgery Form as appropriate.
- change of antineoplastic therapy (including introduction of biphosphonates in the face of increase in pain) to treat bone pain, please fill in either further anticancer therapy and / or Biphosphonate Medication Form.

SURGERY CONCOMITANT *SURG_01*

NONE ❑

Record relevant surgery information within the cycle.

	SURGERY	SURGERY DATE Day Month Year
1		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
2		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
3		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
4		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
5		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
6		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋

*LOCATION:	
03	Bone
11.01	Regional Lymph Nodes
11.02	Distant Lymph Nodes
18	Prostate
99	Other

RADIATION THERAPY *RADTX_01*

CONCOMITANT TREATMENT RADIATION THERAPY

NONE ❑

	SITE LOCATION*	START DATE day month year	STOP DATE day month year	TOTAL DOSE	UNITS	INTENT
1	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
2	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
3	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
4	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
5	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
6	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
7	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
8	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
9	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
10	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative

FACT P

❑ Assessment not done

Specify the primary reason:

❑ Subject is unable due to toxicity/disease

❑ Administrative failure to distribute the questionnaire to the patient

❑ Patient refusal

❑ Death

❑ Patient did not wish to show up

❑ Translation not available

❑ Other, *specify:* _____

FACT P QUESTIONNAIRE

Below is a list of statements that other people with your illness have said are important
By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

Date of questionnaire completion : ☐☐ ☐☐☐ ☐☐☐☐

	PHYSICAL WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GP1	I have a lack of energy.....	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by side effects of treatment	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4

	SOCIAL/FAMILY WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family.....	0	1	2	3	4
GS3	I get support from my friends.....	0	1	2	3	4
GS4	My family has accepted my illness	0	1	2	3	4
GS5	I am satisfied with family communication about my illness.....	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support).....	0	1	2	3	4
Q1	*Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please check this box and go to the next section.*					
GS7	I am satisfied with my sex life.....	0	1	2	3	4

By circling one (1) number per line, please indicate how true each statement has been for you <u>during the past 7 days</u>.

	EMOTIONAL WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GE1	I feel sad	0	1	2	3	4
GE2	I am satisfied with how I am coping with my illness	0	1	2	3	4
GE3	I am losing hope in the fight against my illness	0	1	2	3	4
GE4	I feel nervous	0	1	2	3	4
GE5	I worry about dying	0	1	2	3	4
GE6	I worry that my condition will get worse	0	1	2	3	4

	FUNCTIONAL WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GF1	I am able to work (include work at home)	0	1	2	3	4
GF2	My work (include work at home) is fulfilling	0	1	2	3	4
GF3	I am able to enjoy life	0	1	2	3	4
GF4	I have accepted my illness	0	1	2	3	4
GF5	I am sleeping well	0	1	2	3	4
GF6	I am enjoying the things I usually do for fun	0	1	2	3	4
GF7	I am content with the quality of my life right now	0	1	2	3	4

By circling one (1) number per line, please indicate how true each statement has been for you <u>during the past 7 days</u>.

	ADDITIONAL CONCERNS	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
C2	I am losing weight	0	1	2	3	4
C6	I have a good appetite	0	1	2	3	4
P1	I have aches and pains that bother me	0	1	2	3	4
P2	I have certain parts of my body where I experience pain ...	0	1	2	3	4
P3	My pain keeps me from doing things I want to do	0	1	2	3	4
P4	I am satisfied with my present comfort level	0	1	2	3	4
P5	I am able to feel like a man	0	1	2	3	4
P6	I have trouble moving my bowels	0	1	2	3	4
P7	I have difficulty urinating	0	1	2	3	4
BL2	I urinate more frequently than usual	0	1	2	3	4
P8	My problems with urinating limit my activities	0	1	2	3	4
BL5	I am able to have and maintain an erection	0	1	2	3	4

***LOCATION:**

01	Skin	11.09	Supraclavicular
02	Muscle/Soft Tissue	12	Liver
03	Bone	13	Stomach
04	Bone Marrow	14	Pancreas
05	Peripheral Blood Stream	15	Kidneys
06	Brain/CNS	17	Bladder
07	Head/Neck	18	Prostate
08	Eosaphagus	20.10	Colon
10	Lungs	20.20	Rectum
11	Lymph Nodes	21	Adrenal
11.01	Regional Lymph Nodes	22	Mediastinum
11.02	Distant Lymph Nodes	24	Abdomen
11.03	Axillary	25	Gastrointestinal Tract
11.04	Cervical	26	Pelvis
11.05	Inguinal	27	Peritoneum
11.06	Intra Abdominal	28	Testis
11.07	Mediastinal	29	Thorax
11.08	Para Aortic	29.01	Pleura
		30	Other

****METHOD OF TUMOR MEASUREMENT:**

1	CT Scan	8	X-ray
2	Spiral CT Scan	9	Endoscopy
3	MRI	10	Physical Exam
4	PET	11	Multi-Slice CT
5	Scintigraphy	12	DCE MRI
6	SPECT	99	Other
7	Ultrasound		

*** **RESPONSE OF NON-TARGET LESIONS:**

CR = Complete Response	UNK = Unknown
IR/SD = Incomplete Response / Stable Disease	NA = Not Applicable
PD = Progressive Disease	NL = New Lesion

TUMOR MEASUREMENTS *TUMEA_02*

NONE ❑

LESION NUMBER	LESION LOCATION*	DATE OF ASSESSMENT day month year	METHOD OF TUMOR MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1	⌊_⌊_.⌊_⌊_	⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ ❑ Not Done	⌊_⌊_	⌊_⌊_⌊_ mm	⌊_⌊_
2	⌊_⌊_.⌊_⌊_	⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ ❑ Not Done	⌊_⌊_	⌊_⌊_⌊_ mm	⌊_⌊_
3	⌊_⌊_.⌊_⌊_	⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ ❑ Not Done	⌊_⌊_	⌊_⌊_⌊_ mm	⌊_⌊_
4	⌊_⌊_.⌊_⌊_	⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ ❑ Not Done	⌊_⌊_	⌊_⌊_⌊_ mm	⌊_⌊_
5	⌊_⌊_.⌊_⌊_	⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ ❑ Not Done	⌊_⌊_	⌊_⌊_⌊_ mm	⌊_⌊_
6	⌊_⌊_.⌊_⌊_	⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ ❑ Not Done	⌊_⌊_	⌊_⌊_⌊_ mm	⌊_⌊_
7	⌊_⌊_.⌊_⌊_	⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ ❑ Not Done	⌊_⌊_	⌊_⌊_⌊_ mm	⌊_⌊_
8	⌊_⌊_.⌊_⌊_	⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ ❑ Not Done	⌊_⌊_	⌊_⌊_⌊_ mm	⌊_⌊_
9	⌊_⌊_.⌊_⌊_	⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ ❑ Not Done	⌊_⌊_	⌊_⌊_⌊_ mm	⌊_⌊_
10	⌊_⌊_.⌊_⌊_	⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ ❑ Not Done	⌊_⌊_	⌊_⌊_⌊_ mm	⌊_⌊_
11	⌊_⌊_.⌊_⌊_	⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ ❑ Not Done	⌊_⌊_	⌊_⌊_⌊_ mm	⌊_⌊_
12	⌊_⌊_.⌊_⌊_	⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ ❑ Not Done	⌊_⌊_	⌊_⌊_⌊_ mm	⌊_⌊_

SINCE LAST CYCLE, IF ANY OF THE FOLLOWING EVENTS OCCUR OR IF THERE IS A WORSENING INTENSITY OF ONGOING LISTED BELOW EVENTS, PLEASE TICK YES AND COMPLETE AN ADVERSE EVENT FORM.

CLINICAL EVENT "THROMBOVASCULAR" *CLINE_01*

❑ None

	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: _____

ADVERSE EVENT FORM *AE_03*

NONE ❑

1. **ADVERSE EVENT (DIAGNOSIS)**	AE form no: ␣␣-␣␣ AE ref. no: ␣␣-␣␣
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ␣␣ ␣␣ ␣␣␣␣ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO INVESTIGATIONAL PRODUCTS*	Yes ❑ No ❑
5. ACTION TAKEN WITH INVESTIGATIONAL PRODUCTS**	0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ␣␣ ␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ␣␣ ␣␣ ␣␣␣␣ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE <<SAFETY COMPLEMENTARY FORM>>**	Yes ❑ No ❑ ➲ **IF YES** - Date event became serious: ␣␣ ␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
9. IS IT AN EVENT SUCH AS: **OVERDOSE OF THE IP?**	Yes ❑ No ❑
Investigator's name, date, and signature:	Monitoring representative's name, date of receipt:

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

** 0= None / 1= Permanently discontinued / 2= Delayed / 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted

VITAL SIGNS *O.VITAL_2*

- Date performed : __ __ (day) __ __ __ (month) 2 0 __ __ (year)
- Weight : ___ . _ kg

- Blood pressure: Systolic ___ mmHg / Diastolic ___ mmHg

ECOG Performance Status

0	1	2	3	4
❑	❑	❑	❑	❑

PHYSICAL EXAMINATION

A PHYSICAL EXAMINATION SHOULD BE PERFORMED.

IF THERE ARE ANY CLINICALLY SIGNIFICANT CHANGES FROM THE PREVIOUS EXAMINATION, RECORD AS AN ADVERSE EVENT.

HEMATOLOGY *LABH_1*

• Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊2⌋⌊0⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Hemoglobin		g/L	
Platelets count		10^9/L	
WBC		10^9/L	
Neutrophils		10^9/L	

HEMATOLOGY *LABH_1*

❑ Not Done

TO BE PERFORMED ONLY FOR PATIENT UNDER VITAMIN K ANTAGONIST.

• Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊2⌋⌊0⌋⌊_⌋⌊_⌋
day month year

Laboratory Name: _____

Address: _____

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
INR		Ratio	

BIOCHEMISTRY *LABB_1*

Laboratory Name: _____

Address: _____

- Date of sampling: ⌊_⌊_⌋ ⌊_⌊_⌊_⌋ ⌊2⌊0⌋_⌊_⌋
  day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Sodium		mmol/L	
Calcium		mmol/L	
Potassium		mmol/L	
Phosphorus		mmol/L	
Blood Urea Nitrogen		mg/dL	
Urea**		mmol/L	
Magnesium		mg/dL	
Creatinine		µmol/L	
Calculated Creatinine clearance*		ml/min	
Glucose		mmol/L	
AST		IU/L	
ALT		IU/L	
Alkaline phosphatase		IU/L	
Total bilirubin		mg/dL	
Total protein		g/dL	
Albumin		g/dL	

* If creatinine > ULN, please report the calculated creatinine clearance.
** If BUN is not evaluated, UREA value must be documented.

DIPSTICK URINALYSIS *LABU_1*

• Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊2⌋⌊0⌋⌊_⌋⌊_⌋
day month year

WBC	❑ Absent	❑ +	❑ ++	❑ +++	❑ Not evaluable
RBC	❑ Absent	❑ +	❑ ++	❑ +++	❑ Not evaluable

MORNING SPOT URINALYSIS *LABU_2*

• Not Done: ❑

Laboratory name: _____

Address: _____

• Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊2⌋⌊0⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Protein		mg/dL	
Creatinine		mg/dL	

If UPCR is > 1 then 24 hour urine collection must be performed to assess the urine protein rate, as well as an urine protein electrophoresis. Please complete page 654.

If proteinuria is associated with hematuria then LDH, haptoglobin, schistocytes and orosomucoid will be measured in blood. Please complete page 655.

TO BE PERFORMED AT DAY 1 JUST BEFORE THE STUDY DRUG INFUSION.

TUMOR MARKERS *TMARK_01*

PSA

☐ Not done

- Date of evaluation : ␣␣ ␣␣␣␣ ␣␣␣␣
  day month year

	TEST	VALUE	UNIT	NORMAL RANGE	
				LOWER LIMIT	UPPER LIMIT
1.	**PSA**				

INVESTIGATIONAL PRODUCT ADMINISTRATION *IPA_05*

AFLIBERCEPT/PLACEBO

SCHEDULED DAY	TREATMENT NUMBER	TICK IF NOT ADMINISTERED/ TAKEN	DATE / TIME*	INTENDED DOSE mg/kg	ACTUAL DOSE mg
Day 1	⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑	START ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ day month year ⌊_⌋⌊_⌋:⌊_⌋⌊_⌋ 24-hour clock END ⌊_⌋⌊_⌋:⌊_⌋⌊_⌋ 24-hour clock		

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

SCHEDULED DAY	TREATMENT NUMBER	TICK IF NOT ADMINISTERED/ TAKEN	DATE / TIME*	INTENDED DOSE mg/kg	ACTUAL DOSE mg
Day ⌊_⌋	⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑	START ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ day month year ⌊_⌋⌊_⌋:⌊_⌋⌊_⌋ 24-hour clock END ⌊_⌋⌊_⌋:⌊_⌋⌊_⌋ 24-hour clock		

INVESTIGATIONAL PRODUCT ADMINISTRATION *IPA_04*

DOCETAXEL

SCHEDULED DAY	BATCH NUMBER	TICK IF NOT ADMINISTERED/ TAKEN	DATE	INTENDED DOSE mg/m²	ACTUAL DOSE mg
Day 1	⌊_⌊_⌊_⌊_⌊_⌊_⌊_⌊	❑	⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ day month year		

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

SCHEDULED DAY	BATCH NUMBER	TICK IF NOT ADMINISTERED/ TAKEN	DATE	INTENDED DOSE mg/m²	ACTUAL DOSE mg
Day ⌊_⌊	⌊_⌊_⌊_⌊_⌊_⌊_⌊_⌊	❑	⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ day month year		

INVESTIGATIONAL PRODUCT ADMINISTRATION *IPA_10*

PREDNISONE / PREDNISOLONE

SCHEDULED PERIOD	TREATMENT NAME	TICK IF NOT ADMINISTERED/ TAKEN	DATE (S)	INTENDED DAILY DOSE mg	DOSE MODIFIED	NUMBER OF DAYS WITH NO INTAKE
Cycle 1	PREDNISONE/PREDNISOLONE	❑	START __ __ day __ __ __ month __ __ __ __ year END __ __ day __ __ __ month __ __ __ __ year		❑ YES ❑ NO	__ __ __

SETTING

Outpatient clinic ❑ Inpatient clinic ❑

MEDICATION : PRE/POST DOCETAXEL CORTICOSTEROID *MED_03*

Record if docetaxel corticosteroïd premedication has been administered as per protocol.

None ❑

Record information for the following medications during the cycle.

	DRUG / MEDICATION (Drug Class / Brand or Generic Name)	TAKEN	NOT TAKEN
1	Corticosteroid	❑	❑

If any change compared to protocol ie "Not taken" or dose modified, please report the information on the Concomitant Medication Form.

VITAL SIGNS

VITAL_01

TO BE PERFORMED PREFERABLY DURING WEEK 2 BETWEEN D8 AND D15.

- Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊2⌋⌊0⌋⌊_⌋⌊_⌋
  day month year

Blood pressure: Systolic ⌊_⌋⌊_⌋⌊_⌋ mmHg / Diastolic ⌊_⌋⌊_⌋⌊_⌋ mmHg

MEDICATION BIPHOSPHONATES *MED_02*

None ❑

Record all biphosphonates therapies that the subject has taken within the cycle, and record any changes.

	DRUG / MEDICATION (Brand or Generic Name)	DOSAGE (TOTAL DAILY DOSE)	DOSE UNIT	ROUTE*	START DATE Day Month Year	END DATE OR TICK IF ONGOING Day Month Year
1					❑ Previously Reported	❑ Ongoing
2					❑ Previously Reported	❑ Ongoing
3					❑ Previously Reported	❑ Ongoing
4					❑ Previously Reported	❑ Ongoing
5					❑ Previously Reported	❑ Ongoing
6					❑ Previously Reported	❑ Ongoing
7					❑ Previously Reported	❑ Ongoing
8					❑ Previously Reported	❑ Ongoing
9					❑ Previously Reported	❑ Ongoing
10					❑ Previously Reported	❑ Ongoing

* **ROUTE:** 19 = Intravenous 23 = Oral 24 = Other

ANALGESIC MEDICATION SHOULD BE COLLECTED DAILY FOR SEVEN CONSECUTIVE DAYS PRIOR TO THE NEXT INFUSION

THE LAST RECORDS SHOULD BE OBTAINED WITHIN 3 DAYS PRIOR TO THE NEXT INFUSION

* **ROUTE:**

1	=	Cutaneous	19	=	Intravenous	27	=	Rectal
2	=	Buccal	23	=	Oral	28	=	Subcutaneous
6	=	Inhalation	24	=	Other	29	=	Sublingua
12	=	Intramuscular						

MEDICATION ANALGESIC *MED_02*

PLEASE RECORD ALL ANALGESIC MEDICATION EXCLUDING BIPHOSPHONATE.

None ❑

	DRUG / MEDICATION (Brand or Generic Name)	DOSAGE (TOTAL DAILY DOSE)	DOSE UNIT	ROUTE *	START DATE Day Month Year	END DATE OR TICK IF ONGOING Day Month Year
1					❑ Previously Reported	❑ Ongoing
2					❑ Previously Reported	❑ Ongoing
3					❑ Previously Reported	❑ Ongoing
4					❑ Previously Reported	❑ Ongoing
5					❑ Previously Reported	❑ Ongoing
6					❑ Previously Reported	❑ Ongoing
7					❑ Previously Reported	❑ Ongoing
8					❑ Previously Reported	❑ Ongoing
9					❑ Previously Reported	❑ Ongoing
10					❑ Previously Reported	❑ Ongoing

- **TO BE PERFORMED OVER 7 CONSECUTIVE DAYS PRIOR TO THE NEXT INFUSION.**

- **THE LAST RECORDS SHOULD BE OBTAINED WITHIN 3 DAYS PRIOR TO THE NEXT INFUSION.**

PAIN EVALUATION

NOT DONE ☐

	DATE OF ASSESSMENT Day Month Year	PRESENT PAIN INTENSITY SCORE
1st Day	__/__/____	____
2nd Day	__/__/____	____
3rd Day	__/__/____	____
4th Day	__/__/____	____
5th Day	__/__/____	____
6th Day	__/__/____	____
7th Day	__/__/____	____

SKELETAL RELATED EVENT EVALUATION

- Occurence of SRE: **Yes** ❑ **No** ❑

In case of:

- pathological fractures and/or spinal cord compression, please fill in an AE/SAE Form as appropriate.
- bone irradiation, including radioisotopes or bone surgery, please complete the concomitant radiation or surgery Form as appropriate.
- change of antineoplastic therapy (including introduction of biphosphonates in the face of increase in pain) to treat bone pain, please fill in either further anticancer therapy and / or Biphosphonate Medication Form.

SURGERY CONCOMITANT *SURG_01*

NONE ❑

Record relevant surgery information within the cycle.

	SURGERY	SURGERY DATE Day Month Year
1		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
2		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
3		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
4		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
5		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
6		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋

*LOCATION:	
03	Bone
11.01	Regional Lymph Nodes
11.02	Distant Lymph Nodes
18	Prostate
99	Other

RADIATION THERAPY *RADTX_01*

CONCOMITANT TREATMENT RADIATION THERAPY

NONE ❑

	SITE LOCATION*	START DATE day month year	STOP DATE day month year	TOTAL DOSE	UNITS	INTENT
1	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
2	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
3	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
4	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
5	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
6	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
7	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
8	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
9	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
10	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative

FACT P

❑ Assessment not done

Specify the primary reason:

❑ Subject is unable due to toxicity/disease

❑ Administrative failure to distribute the questionnaire to the patient

❑ Patient refusal

❑ Death

❑ Patient did not wish to show up

❑ Translation not available

❑ Other, *specify:* _____

FACT P QUESTIONNAIRE

Below is a list of statements that other people with your illness have said are important
By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

Date of questionnaire completion : ☐☐ ☐☐☐ ☐☐☐☐

	PHYSICAL WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GP1	I have a lack of energy.....	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by side effects of treatment	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4

	SOCIAL/FAMILY WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family.....	0	1	2	3	4
GS3	I get support from my friends.....	0	1	2	3	4
GS4	My family has accepted my illness	0	1	2	3	4
GS5	I am satisfied with family communication about my illness.....	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support).....	0	1	2	3	4
Q1	*Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please check this box and go to the next section.*					
GS7	I am satisfied with my sex life.....	0	1	2	3	4

By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

	EMOTIONAL WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GE1	I feel sad	0	1	2	3	4
GE2	I am satisfied with how I am coping with my illness	0	1	2	3	4
GE3	I am losing hope in the fight against my illness	0	1	2	3	4
GE4	I feel nervous	0	1	2	3	4
GE5	I worry about dying	0	1	2	3	4
GE6	I worry that my condition will get worse	0	1	2	3	4

	FUNCTIONAL WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GF1	I am able to work (include work at home)	0	1	2	3	4
GF2	My work (include work at home) is fulfilling	0	1	2	3	4
GF3	I am able to enjoy life	0	1	2	3	4
GF4	I have accepted my illness	0	1	2	3	4
GF5	I am sleeping well	0	1	2	3	4
GF6	I am enjoying the things I usually do for fun	0	1	2	3	4
GF7	I am content with the quality of my life right now	0	1	2	3	4

By circling one (1) number per line, please indicate how true each statement has been for you <u>during the past 7 days</u>.

	ADDITIONAL CONCERNS	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
C2	I am losing weight	0	1	2	3	4
C6	I have a good appetite	0	1	2	3	4
P1	I have aches and pains that bother me	0	1	2	3	4
P2	I have certain parts of my body where I experience pain ...	0	1	2	3	4
P3	My pain keeps me from doing things I want to do	0	1	2	3	4
P4	I am satisfied with my present comfort level	0	1	2	3	4
P5	I am able to feel like a man	0	1	2	3	4
P6	I have trouble moving my bowels	0	1	2	3	4
P7	I have difficulty urinating	0	1	2	3	4
BL2	I urinate more frequently than usual	0	1	2	3	4
P8	My problems with urinating limit my activities	0	1	2	3	4
BL5	I am able to have and maintain an erection	0	1	2	3	4

***LOCATION:**

01	Skin	11.09	Supraclavicular
02	Muscle/Soft Tissue	12	Liver
03	Bone	13	Stomach
04	Bone Marrow	14	Pancreas
05	Peripheral Blood Stream	15	Kidneys
06	Brain/CNS	17	Bladder
07	Head/Neck	18	Prostate
08	Eosaphagus	20.10	Colon
10	Lungs	20.20	Rectum
11	Lymph Nodes	21	Adrenal
11.01	Regional Lymph Nodes	22	Mediastinum
11.02	Distant Lymph Nodes	24	Abdomen
11.03	Axillary	25	Gastrointestinal Tract
11.04	Cervical	26	Pelvis
11.05	Inguinal	27	Peritoneum
11.06	Intra Abdominal	28	Testis
11.07	Mediastinal	29	Thorax
11.08	Para Aortic	29.01	Pleura
		30	Other

****METHOD OF TUMOR MEASUREMENT:**

1	CT Scan	8	X-ray
2	Spiral CT Scan	9	Endoscopy
3	MRI	10	Physical Exam
4	PET	11	Multi-Slice CT
5	Scintigraphy	12	DCE MRI
6	SPECT	99	Other
7	Ultrasound		

*** **RESPONSE OF NON-TARGET LESIONS:**

CR = Complete Response	UNK = Unknown
IR/SD = Incomplete Response / Stable Disease	NA = Not Applicable
PD = Progressive Disease	NL = New Lesion

TUMOR MEASUREMENTS *TUMEA_02*

NONE ❑

LESION NUMBER	LESION LOCATION*	DATE OF ASSESSMENT day month year	METHOD OF TUMOR MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
2	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
3	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
4	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
5	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
6	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
7	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
8	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
9	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
10	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
11	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
12	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣

SINCE LAST CYCLE, IF ANY OF THE FOLLOWING EVENTS OCCUR OR IF THERE IS A WORSENING INTENSITY OF ONGOING LISTED BELOW EVENTS, PLEASE TICK YES AND COMPLETE AN ADVERSE EVENT FORM.

CLINICAL EVENT "THROMBOVASCULAR" *CLINE_01*

❑ None

	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: _____

ADVERSE EVENT FORM *AE_03*

NONE ❑

1. **ADVERSE EVENT (DIAGNOSIS)**	AE form no: ␣␣-␣␣ AE ref. no: ␣␣-␣␣
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ␣␣ ␣␣ ␣␣␣␣ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO INVESTIGATIONAL PRODUCTS*	Yes ❑ No ❑
5. ACTION TAKEN WITH INVESTIGATIONAL PRODUCTS**	0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ␣␣ ␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ␣␣ ␣␣ ␣␣␣␣ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE <<SAFETY COMPLEMENTARY FORM>>**	Yes ❑ No ❑ ➲ **IF YES** - Date event became serious: ␣␣ ␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
9. IS IT AN EVENT SUCH AS: **OVERDOSE OF THE IP?**	Yes ❑ No ❑
Investigator's name, date, and signature:	Monitoring representative's name, date of receipt:

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

** 0= None / 1= Permanently discontinued / 2= Delayed / 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted

VITAL SIGNS *O.VITAL_2*

- Date performed : ☐☐ ☐☐☐ 20☐☐ (day / month / year)
- Weight : ☐☐☐ . ☐ kg

- Blood pressure: Systolic ☐☐☐ mmHg / Diastolic ☐☐☐ mmHg

ECOG Performance Status

0	1	2	3	4
❑	❑	❑	❑	❑

PHYSICAL EXAMINATION

A PHYSICAL EXAMINATION SHOULD BE PERFORMED.

IF THERE ARE ANY CLINICALLY SIGNIFICANT CHANGES FROM THE PREVIOUS EXAMINATION, RECORD AS AN ADVERSE EVENT.

HEMATOLOGY *LABH_1*

• Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊2⌋⌊0⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Hemoglobin		g/L	
Platelets count		10^9/L	
WBC		10^9/L	
Neutrophils		10^9/L	

HEMATOLOGY *LABH_1*

❑ Not Done

TO BE PERFORMED ONLY FOR PATIENT UNDER VITAMIN K ANTAGONIST.

• Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊2⌋⌊0⌋⌊_⌋⌊_⌋
day month year

Laboratory Name: _____

Address: _____

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
INR		Ratio	

BIOCHEMISTRY *LABB_1*

Laboratory Name: _____

Address: _____

- Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊2⌋⌊0⌋⌊_⌋⌊_⌋
  day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Sodium		mmol/L	
Calcium		mmol/L	
Potassium		mmol/L	
Phosphorus		mmol/L	
Blood Urea Nitrogen		mg/dL	
Urea**		mmol/L	
Magnesium		mg/dL	
Creatinine		µmol/L	
Calculated Creatinine clearance*		ml/min	
Glucose		mmol/L	
AST		IU/L	
ALT		IU/L	
Alkaline phosphatase		IU/L	
Total bilirubin		mg/dL	
Total protein		g/dL	
Albumin		g/dL	

* If creatinine > ULN, please report the calculated creatinine clearance.
** If BUN is not evaluated, UREA value must be documented.

DIPSTICK URINALYSIS *LABU_1*

• Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊2⌋⌊0⌋⌊_⌋⌊_⌋
day month year

WBC	❑ Absent	❑ +	❑ ++	❑ +++	❑ Not evaluable
RBC	❑ Absent	❑ +	❑ ++	❑ +++	❑ Not evaluable

MORNING SPOT URINALYSIS *LABU_2*

Laboratory name: _____

Address: _____

• Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊2⌋⌊0⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Protein		mg/dL	
Creatinine		mg/dL	

If UPCR is > 1 then 24 hour urine collection must be performed to assess the urine protein rate, as well as an urine protein electrophoresis. Please complete page 654.

If proteinuria is associated with hematuria then LDH, haptoglobin, schistocytes and orosomucoid will be measured in blood. Please complete page 655.

TO BE PERFORMED AT DAY 1 JUST BEFORE THE STUDY DRUG INFUSION.

TUMOR MARKERS *TMARK_01*

PSA

Not done ❑

- Date of evaluation : ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
  day month year

	TEST	VALUE	UNIT	NORMAL RANGE	
				LOWER LIMIT	UPPER LIMIT
1.	PSA				

INVESTIGATIONAL PRODUCT ADMINISTRATION *IPA_05*

AFLIBERCEPT/PLACEBO

SCHEDULED DAY	TREATMENT NUMBER	TICK IF NOT ADMINISTERED/ TAKEN	DATE / TIME*	INTENDED DOSE mg/kg	ACTUAL DOSE mg
Day 1	⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑	START ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ day month year ⌊_⌋⌊_⌋:⌊_⌋⌊_⌋ 24-hour clock END ⌊_⌋⌊_⌋:⌊_⌋⌊_⌋ 24-hour clock		

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

SCHEDULED DAY	TREATMENT NUMBER	TICK IF NOT ADMINISTERED/ TAKEN	DATE / TIME*	INTENDED DOSE mg/kg	ACTUAL DOSE mg
Day ⌊_⌋	⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑	START ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ day month year ⌊_⌋⌊_⌋:⌊_⌋⌊_⌋ 24-hour clock END ⌊_⌋⌊_⌋:⌊_⌋⌊_⌋ 24-hour clock		

INVESTIGATIONAL PRODUCT ADMINISTRATION *IPA_04*

DOCETAXEL

SCHEDULED DAY	BATCH NUMBER	TICK IF NOT ADMINISTERED/ TAKEN	DATE	INTENDED DOSE mg/m²	ACTUAL DOSE mg
Day 1	⌊⌋⌊⌋⌊⌋⌊⌋⌊⌋⌊⌋⌊⌋	❑	⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋⌊⌋ day month year		

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

SCHEDULED DAY	BATCH NUMBER	TICK IF NOT ADMINISTERED/ TAKEN	DATE	INTENDED DOSE mg/m²	ACTUAL DOSE mg
Day ⌊⌋	⌊⌋⌊⌋⌊⌋⌊⌋⌊⌋⌊⌋⌊⌋	❑	⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋⌊⌋ day month year		

INVESTIGATIONAL PRODUCT ADMINISTRATION *IPA_10*

PREDNISONE / PREDNISOLONE

SCHEDULED PERIOD	TREATMENT NAME	TICK IF NOT ADMINISTERED/ TAKEN	DATE (S)	INTENDED DAILY DOSE mg	DOSE MODIFIED	NUMBER OF DAYS WITH NO INTAKE
Cycle 1	PREDNISONE/PREDNISOLONE	❑	START __ __ day __ __ month __ __ __ __ year END __ __ day __ __ month __ __ __ __ year		❑ YES ❑ NO	__ __ __

SETTING

Outpatient clinic ❑ Inpatient clinic ❑

MEDICATION : PRE/POST DOCETAXEL CORTICOSTEROID *MED_03*

Record if docetaxel corticosteroïd premedication has been administered as per protocol.

None ❑

Record information for the following medications during the cycle.

	DRUG / MEDICATION (Drug Class / Brand or Generic Name)	TAKEN	NOT TAKEN
1	Corticosteroid	❑	❑

If any change compared to protocol ie "Not taken" or dose modified, please report the information on the Concomitant Medication Form.

VITAL SIGNS

VITAL_01

TO BE PERFORMED PREFERABLY DURING WEEK 2 BETWEEN D8 AND D15.

- Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊2⌋⌊0⌋⌊_⌋⌊_⌋
  day month year

Blood pressure: Systolic ⌊_⌋⌊_⌋⌊_⌋ mmHg / Diastolic ⌊_⌋⌊_⌋⌊_⌋ mmHg

MEDICATION BIPHOSPHONATES *MED_02*

None ❑

Record all biphosphonates therapies that the subject has taken within the cycle, and record any changes.

	DRUG / MEDICATION (Brand or Generic Name)	DOSAGE (TOTAL DAILY DOSE)	DOSE UNIT	ROUTE*	START DATE Day Month Year	END DATE OR TICK IF ONGOING Day Month Year
1					❑ Previously Reported	❑ Ongoing
2					❑ Previously Reported	❑ Ongoing
3					❑ Previously Reported	❑ Ongoing
4					❑ Previously Reported	❑ Ongoing
5					❑ Previously Reported	❑ Ongoing
6					❑ Previously Reported	❑ Ongoing
7					❑ Previously Reported	❑ Ongoing
8					❑ Previously Reported	❑ Ongoing
9					❑ Previously Reported	❑ Ongoing
10					❑ Previously Reported	❑ Ongoing

* **ROUTE:** 19 = Intravenous 23 = Oral 24 = Other

ANALGESIC MEDICATION SHOULD BE COLLECTED DAILY FOR SEVEN CONSECUTIVE DAYS PRIOR TO THE NEXT INFUSION

THE LAST RECORDS SHOULD BE OBTAINED WITHIN 3 DAYS PRIOR TO THE NEXT INFUSION

* **ROUTE:**

1	=	Cutaneous	19	=	Intravenous	27	=	Rectal
2	=	Buccal	23	=	Oral	28	=	Subcutaneous
6	=	Inhalation	24	=	Other	29	=	Sublingua
12	=	Intramuscular						

MEDICATION ANALGESIC *MED_02*

PLEASE RECORD ALL ANALGESIC MEDICATION EXCLUDING BIPHOSPHONATE.

None ❑

	DRUG / MEDICATION (Brand or Generic Name)	DOSAGE (TOTAL DAILY DOSE)	DOSE UNIT	ROUTE *	START DATE Day Month Year	END DATE OR TICK IF ONGOING Day Month Year
1					❑ Previously Reported	❑ Ongoing
2					❑ Previously Reported	❑ Ongoing
3					❑ Previously Reported	❑ Ongoing
4					❑ Previously Reported	❑ Ongoing
5					❑ Previously Reported	❑ Ongoing
6					❑ Previously Reported	❑ Ongoing
7					❑ Previously Reported	❑ Ongoing
8					❑ Previously Reported	❑ Ongoing
9					❑ Previously Reported	❑ Ongoing
10					❑ Previously Reported	❑ Ongoing

- **TO BE PERFORMED OVER 7 CONSECUTIVE DAYS PRIOR TO THE NEXT INFUSION.**
- **THE LAST RECORDS SHOULD BE OBTAINED WITHIN 3 DAYS PRIOR TO THE NEXT INFUSION.**

PAIN EVALUATION

NOT DONE ☐

	DATE OF ASSESSMENT Day Month Year	PRESENT PAIN INTENSITY SCORE
1st Day	__/__/____	____
2nd Day	__/__/____	____
3rd Day	__/__/____	____
4th Day	__/__/____	____
5th Day	__/__/____	____
6th Day	__/__/____	____
7th Day	__/__/____	____

SKELETAL RELATED EVENT EVALUATION

- Occurence of SRE: **Yes** ❑ **No** ❑

In case of:

- pathological fractures and/or spinal cord compression, please fill in an AE/SAE Form as appropriate.
- bone irradiation, including radioisotopes or bone surgery, please complete the concomitant radiation or surgery Form as appropriate.
- change of antineoplastic therapy (including introduction of biphosphonates in the face of increase in pain) to treat bone pain, please fill in either further anticancer therapy and / or Biphosphonate Medication Form.

SURGERY CONCOMITANT *SURG_01*

NONE ☐

Record relevant surgery information within the cycle.

	SURGERY	SURGERY DATE Day Month Year
1		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
2		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
3		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
4		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
5		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
6		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋

*LOCATION:	
03	Bone
11.01	Regional Lymph Nodes
11.02	Distant Lymph Nodes
18	Prostate
99	Other

RADIATION THERAPY *RADTX_01*

CONCOMITANT TREATMENT RADIATION THERAPY

NONE ❑

	SITE LOCATION*	START DATE day month year	STOP DATE day month year	TOTAL DOSE	UNITS	INTENT
1	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
2	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
3	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
4	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
5	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
6	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
7	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
8	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
9	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
10	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative

FACT P

❑ Assessment not done

Specify the primary reason:

❑ Subject is unable due to toxicity/disease

❑ Administrative failure to distribute the questionnaire to the patient

❑ Patient refusal

❑ Death

❑ Patient did not wish to show up

❑ Translation not available

❑ Other, *specify:* _____

FACT P QUESTIONNAIRE

Below is a list of statements that other people with your illness have said are important
By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

Date of questionnaire completion : ☐☐ ☐☐☐ ☐☐☐☐

	PHYSICAL WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GP1	I have a lack of energy.....	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by side effects of treatment	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4

	SOCIAL/FAMILY WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family.....	0	1	2	3	4
GS3	I get support from my friends.....	0	1	2	3	4
GS4	My family has accepted my illness	0	1	2	3	4
GS5	I am satisfied with family communication about my illness.....	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support).....	0	1	2	3	4
Q1	*Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please check this box and go to the next section.*					
GS7	I am satisfied with my sex life.....	0	1	2	3	4

By circling one (1) number per line, please indicate how true each statement has been for you <u>during the past 7 days</u>.

	EMOTIONAL WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GE1	I feel sad	0	1	2	3	4
GE2	I am satisfied with how I am coping with my illness	0	1	2	3	4
GE3	I am losing hope in the fight against my illness	0	1	2	3	4
GE4	I feel nervous	0	1	2	3	4
GE5	I worry about dying	0	1	2	3	4
GE6	I worry that my condition will get worse	0	1	2	3	4

	FUNCTIONAL WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GF1	I am able to work (include work at home)	0	1	2	3	4
GF2	My work (include work at home) is fulfilling	0	1	2	3	4
GF3	I am able to enjoy life	0	1	2	3	4
GF4	I have accepted my illness	0	1	2	3	4
GF5	I am sleeping well	0	1	2	3	4
GF6	I am enjoying the things I usually do for fun	0	1	2	3	4
GF7	I am content with the quality of my life right now	0	1	2	3	4

By circling one (1) number per line, please indicate how true each statement has been for you <u>during the past 7 days</u>.

	ADDITIONAL CONCERNS	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
C2	I am losing weight	0	1	2	3	4
C6	I have a good appetite	0	1	2	3	4
P1	I have aches and pains that bother me	0	1	2	3	4
P2	I have certain parts of my body where I experience pain ...	0	1	2	3	4
P3	My pain keeps me from doing things I want to do	0	1	2	3	4
P4	I am satisfied with my present comfort level	0	1	2	3	4
P5	I am able to feel like a man	0	1	2	3	4
P6	I have trouble moving my bowels	0	1	2	3	4
P7	I have difficulty urinating	0	1	2	3	4
BL2	I urinate more frequently than usual	0	1	2	3	4
P8	My problems with urinating limit my activities	0	1	2	3	4
BL5	I am able to have and maintain an erection	0	1	2	3	4

***LOCATION:**

01	Skin	11.09	Supraclavicular
02	Muscle/Soft Tissue	12	Liver
03	Bone	13	Stomach
04	Bone Marrow	14	Pancreas
05	Peripheral Blood Stream	15	Kidneys
06	Brain/CNS	17	Bladder
07	Head/Neck	18	Prostate
08	Eosaphagus	20.10	Colon
10	Lungs	20.20	Rectum
11	Lymph Nodes	21	Adrenal
11.01	Regional Lymph Nodes	22	Mediastinum
11.02	Distant Lymph Nodes	24	Abdomen
11.03	Axillary	25	Gastrointestinal Tract
11.04	Cervical	26	Pelvis
11.05	Inguinal	27	Peritoneum
11.06	Intra Abdominal	28	Testis
11.07	Mediastinal	29	Thorax
11.08	Para Aortic	29.01	Pleura
		30	Other

****METHOD OF TUMOR MEASUREMENT:**

1	CT Scan	8	X-ray
2	Spiral CT Scan	9	Endoscopy
3	MRI	10	Physical Exam
4	PET	11	Multi-Slice CT
5	Scintigraphy	12	DCE MRI
6	SPECT	99	Other
7	Ultrasound		

*** **RESPONSE OF NON-TARGET LESIONS:**

CR = Complete Response	UNK = Unknown
IR/SD = Incomplete Response / Stable Disease	NA = Not Applicable
PD = Progressive Disease	NL = New Lesion

TUMOR MEASUREMENTS *TUMEA_02*

NONE ❑

LESION NUMBER	LESION LOCATION*	DATE OF ASSESSMENT day month year	METHOD OF TUMOR MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
2	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
3	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
4	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
5	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
6	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
7	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
8	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
9	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
10	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
11	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
12	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋

SINCE LAST CYCLE, IF ANY OF THE FOLLOWING EVENTS OCCUR OR IF THERE IS A WORSENING INTENSITY OF ONGOING LISTED BELOW EVENTS, PLEASE TICK YES AND COMPLETE AN ADVERSE EVENT FORM.

CLINICAL EVENT "THROMBOVASCULAR" *CLINE_01*

❑ None

	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: _____

ADVERSE EVENT FORM *AE_03*

NONE ❑

1. **ADVERSE EVENT (DIAGNOSIS)**	AE form no: ␣␣-␣␣ AE ref. no: ␣␣-␣␣
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ␣␣ ␣␣ ␣␣␣␣ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO INVESTIGATIONAL PRODUCTS*	Yes ❑ No ❑
5. ACTION TAKEN WITH INVESTIGATIONAL PRODUCTS**	0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ␣␣ ␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ␣␣ ␣␣ ␣␣␣␣ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE <<SAFETY COMPLEMENTARY FORM>>**	Yes ❑ No ❑ ➲ **IF YES** - Date event became serious: ␣␣ ␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
9. IS IT AN EVENT SUCH AS: **OVERDOSE OF THE IP?**	Yes ❑ No ❑
Investigator's name, date, and signature:	Monitoring representative's name, date of receipt:

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

** 0= None / 1= Permanently discontinued / 2= Delayed / 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted

END OF TREATMENT

EOT_02

Main reason for stopping treatment (tick "✓" one box only):

- 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.**

END OF TREATMENT

EOT_03

In case of early, permanent discontinuation of one of the Study Treatments, 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*

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: ␣␣ ␣␣␣␣ ␣␣␣␣ (day / month / year) Time performed: ␣␣ : ␣␣ (24-hour clock)

Reason:

- ❑ AE
- ❑ 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.

VITAL SIGNS *O.VITAL_2*

- Date performed : __/__ __/__/__ 20__ (day / month / year)

- Weight : ___ . _ kg

- Blood pressure: Systolic ___ mmHg / Diastolic ___ mmHg

ECOG Performance Status

0	1	2	3	4
❑	❑	❑	❑	❑

PHYSICAL EXAMINATION

A PHYSICAL EXAMINATION SHOULD BE PERFORMED.

IF THERE ARE ANY CLINICALLY SIGNIFICANT CHANGES FROM THE PREVIOUS EXAMINATION, RECORD AS AN ADVERSE EVENT.

HEMATOLOGY *LABH_1*

❑ Not done

• Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊2⌋⌊0⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Hemoglobin		g/L	
Platelets count		10^9/L	
WBC		10^9/L	
Neutrophils		10^9/L	

HEMATOLOGY *LABH_1*

❑ Not Done

TO BE PERFORMED ONLY FOR PATIENT UNDER VITAMIN K ANTAGONIST.

• Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊2⌋⌊0⌋⌊_⌋⌊_⌋
day month year

Laboratory Name: _____

Address: _____

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
INR		Ratio	

BIOCHEMISTRY *LABB_1*

☐ Not done

Laboratory Name: _____

Address: _____

• Date of sampling: ⌊_⌊_⌋ ⌊_⌊_⌊_⌋ 2 0⌊_⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Sodium		mmol/L	
Calcium		mmol/L	
Potassium		mmol/L	
Phosphorus		mmol/L	
Blood Urea Nitrogen		mg/dL	
Urea**		mmol/L	
Magnesium		mg/dL	
Creatinine		µmol/L	
Calculated Creatinine clearance*		ml/min	
Glucose		mmol/L	
AST		IU/L	
ALT		IU/L	
Alkaline phosphatase		IU/L	
Total bilirubin		mg/dL	
Total protein		g/dL	
Albumin		g/dL	

* If creatinine > ULN, please report the calculated creatinine clearance.
** If BUN is not evaluated, UREA value must be documented.

DIPSTICK URINALYSIS *LABU_1*

❑ Not done

• Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊2⌋⌊0⌋⌊_⌋⌊_⌋
day month year

WBC	❑ Absent	❑ +	❑ ++	❑ +++	❑ Not evaluable
RBC	❑ Absent	❑ +	❑ ++	❑ +++	❑ Not evaluable

MORNING SPOT URINALYSIS *LABU_2*

❑ Not done

Laboratory name: _____

Address: _____

• Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊2⌋⌊0⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Protein		mg/dL	
Creatinine		mg/dL	

If UPCR is > 1 then 24 hour urine collection must be performed to assess the urine protein rate, as well as an urine protein electrophoresis. Please complete page 654.

If proteinuria is associated with hematuria then LDH, haptoglobin, schistocytes and orosomucoid will be measured in blood. Please complete page 655.

TUMOR MARKERS *TMARK_01*

PSA

Not done ❑

- Date of evaluation : ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
  day month year

	TEST	VALUE	UNIT	NORMAL RANGE	
				LOWER LIMIT	UPPER LIMIT
1.	**PSA**				

***LOCATION:**

01	Skin	11.09	Supraclavicular
02	Muscle/Soft Tissue	12	Liver
03	Bone	13	Stomach
04	Bone Marrow	14	Pancreas
05	Peripheral Blood Stream	15	Kidneys
06	Brain/CNS	17	Bladder
07	Head/Neck	18	Prostate
08	Eosaphagus	20.10	Colon
10	Lungs	20.20	Rectum
11	Lymph Nodes	21	Adrenal
11.01	Regional Lymph Nodes	22	Mediastinum
11.02	Distant Lymph Nodes	24	Abdomen
11.03	Axillary	25	Gastrointestinal Tract
11.04	Cervical	26	Pelvis
11.05	Inguinal	27	Peritoneum
11.06	Intra Abdominal	28	Testis
11.07	Mediastinal	29	Thorax
11.08	Para Aortic	29.01	Pleura
		30	Other

****METHOD OF TUMOR MEASUREMENT:**

1	CT Scan	8	X-ray
2	Spiral CT Scan	9	Endoscopy
3	MRI	10	Physical Exam
4	PET	11	Multi-Slice CT
5	Scintigraphy	12	DCE MRI
6	SPECT	99	Other
7	Ultrasound		

*** **RESPONSE OF NON-TARGET LESIONS:**

CR = Complete Response	UNK = Unknown
IR/SD = Incomplete Response / Stable Disease	NA = Not Applicable
PD = Progressive Disease	NL = New Lesion

TUMOR MEASUREMENTS *TUMEA_02*

NONE ❑

LESION NUMBER	LESION LOCATION*	DATE OF ASSESSMENT day month year	METHOD OF TUMOR MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
2	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
3	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
4	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
5	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
6	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
7	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
8	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
9	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
10	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
11	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
12	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋

OVERALL OBJECTIVE RESPONSE *RESP_01*

BEST OVERALL OBJECTIVE RESPONSE

Date of Assessment: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

SUMMARY OF LESIONS						
Best Overall Objective Response*	CR	PR	SD	PD	UNK	NA
	❑	❑	❑	❑	❑	❑

* Tick "✓" one box only

FACT P

❑ Assessment not done

Specify the primary reason:

- ❑ Subject is unable due to toxicity/disease
- ❑ Administrative failure to distribute the questionnaire to the patient
- ❑ Patient refusal
- ❑ Death
- ❑ Patient did not wish to show up
- ❑ Translation not available
- ❑ Other, *specify:* _____

FACT P QUESTIONNAIRE

Below is a list of statements that other people with your illness have said are important
By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

Date of questionnaire completion : ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋

	PHYSICAL WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GP1	I have a lack of energy.....	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by side effects of treatment	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4

	SOCIAL/FAMILY WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family.....	0	1	2	3	4
GS3	I get support from my friends.....	0	1	2	3	4
GS4	My family has accepted my illness	0	1	2	3	4
GS5	I am satisfied with family communication about my illness.....	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support).....	0	1	2	3	4
Q1	*Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please check this box and go to the next section.*					
GS7	I am satisfied with my sex life.....	0	1	2	3	4

By circling one (1) number per line, please indicate how true each statement has been for you <u>during the past 7 days</u>.

	EMOTIONAL WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GE1	I feel sad.....	0	1	2	3	4
GE2	I am satisfied with how I am coping with my illness	0	1	2	3	4
GE3	I am losing hope in the fight against my illness	0	1	2	3	4
GE4	I feel nervous	0	1	2	3	4
GE5	I worry about dying	0	1	2	3	4
GE6	I worry that my condition will get worse	0	1	2	3	4

	FUNCTIONAL WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GF1	I am able to work (include work at home)	0	1	2	3	4
GF2	My work (include work at home) is fulfilling.....	0	1	2	3	4
GF3	I am able to enjoy life.....	0	1	2	3	4
GF4	I have accepted my illness.....	0	1	2	3	4
GF5	I am sleeping well.....	0	1	2	3	4
GF6	I am enjoying the things I usually do for fun	0	1	2	3	4
GF7	I am content with the quality of my life right now.....	0	1	2	3	4

By circling one (1) number per line, please indicate how true each statement has been for you <u>during the past 7 days</u>.

	ADDITIONAL CONCERNS	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
C2	I am losing weight	0	1	2	3	4
C6	I have a good appetite	0	1	2	3	4
P1	I have aches and pains that bother me	0	1	2	3	4
P2	I have certain parts of my body where I experience pain ...	0	1	2	3	4
P3	My pain keeps me from doing things I want to do	0	1	2	3	4
P4	I am satisfied with my present comfort level	0	1	2	3	4
P5	I am able to feel like a man	0	1	2	3	4
P6	I have trouble moving my bowels	0	1	2	3	4
P7	I have difficulty urinating	0	1	2	3	4
BL2	I urinate more frequently than usual	0	1	2	3	4
P8	My problems with urinating limit my activities	0	1	2	3	4
BL5	I am able to have and maintain an erection	0	1	2	3	4

SUBJECT STATUS

SUBST_01

Date of last contact: __ __ __ __ __ __ __ __ (day / month / year)

Subject condition at the time of the scheduled visit (tick one condition only):

- ❑ Alive
- ❑ Lost to follow-up
- ❑ Dead*

Method of contact:

- ❑ Scheduled visit
- ❑ Phone
- ❑ 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 *O.VITAL_2*

- Date performed : ☐☐ ☐☐☐ 2 0 ☐☐
  day month year

- Blood pressure: Systolic ☐☐☐ mmHg / Diastolic ☐☐☐ mmHg

ECOG Performance Status

0	1	2	3	4
❑	❑	❑	❑	❑

PHYSICAL EXAMINATION

A PHYSICAL EXAMINATION SHOULD BE PERFORMED.

IF THERE ARE ANY CLINICALLY SIGNIFICANT CHANGES FROM THE PREVIOUS EXAMINATION, RECORD AS AN ADVERSE EVENT.

TUMOR MARKERS *TMARK_01*

PSA

Not done ❑

- Date of evaluation : ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
  day month year

	TEST	VALUE	UNIT	NORMAL RANGE	
				LOWER LIMIT	UPPER LIMIT
1.	**PSA**				

MEDICATION BIPHOSPHONATES *MED_02*

None ❑

Record all biphosphonates therapies that the subject has taken within the follow-up period, and record any changes.

	DRUG / MEDICATION (Brand or Generic Name)	DOSAGE (TOTAL DAILY DOSE)	DOSE UNIT	ROUTE*	START DATE Day Month Year	END DATE OR TICK IF ONGOING Day Month Year
1					❑ Previously Reported	❑ Ongoing
2					❑ Previously Reported	❑ Ongoing
3					❑ Previously Reported	❑ Ongoing
4					❑ Previously Reported	❑ Ongoing
5					❑ Previously Reported	❑ Ongoing
6					❑ Previously Reported	❑ Ongoing
7					❑ Previously Reported	❑ Ongoing
8					❑ Previously Reported	❑ Ongoing
9					❑ Previously Reported	❑ Ongoing
10					❑ Previously Reported	❑ Ongoing

* **ROUTE:** 19 = Intravenous 23 = Oral 24 = Other

ANALGESIC MEDICATION SHOULD BE COLLECTED DAILY FOR SEVEN CONSECUTIVE DAYS PRIOR TO THE NEXT FOLLOW-UP VISIT.

THE LAST RECORDS SHOULD BE OBTAINED WITHIN 3 DAYS PRIOR TO THE NEXT FOLLOW-UP VISIT.

* **ROUTE:**

1	=	Cutaneous	19	=	Intravenous	27	=	Rectal
2	=	Buccal	23	=	Oral	28	=	Subcutaneous
6	=	Inhalation	24	=	Other	29	=	Sublingua
12	=	Intramuscular						

MEDICATION ANALGESIC *MED_02*

PLEASE RECORD ALL ANALGESIC MEDICATION EXCLUDING BIPHOSPHONATE.

None ❑

	DRUG / MEDICATION (Brand or Generic Name)	DOSAGE (TOTAL DAILY DOSE)	DOSE UNIT	ROUTE *	START DATE Day Month Year	END DATE OR TICK IF ONGOING Day Month Year
1					❑ Previously Reported	❑ Ongoing
2					❑ Previously Reported	❑ Ongoing
3					❑ Previously Reported	❑ Ongoing
4					❑ Previously Reported	❑ Ongoing
5					❑ Previously Reported	❑ Ongoing
6					❑ Previously Reported	❑ Ongoing
7					❑ Previously Reported	❑ Ongoing
8					❑ Previously Reported	❑ Ongoing
9					❑ Previously Reported	❑ Ongoing
10					❑ Previously Reported	❑ Ongoing

- **TO BE PERFORMED OVER 7 CONSECUTIVE DAYS PRIOR TO THE NEXT FOLLOW-UP VISIT.**
- **THE LAST RECORDS SHOULD BE OBTAINED WITHIN 3 DAYS PRIOR TO THE NEXT FOLLOW-UP VISIT.**

PAIN EVALUATION

NOT DONE ☐

	DATE OF ASSESSMENT Day Month Year	PRESENT PAIN INTENSITY SCORE
1st Day	__/__/____	____
2nd Day	__/__/____	____
3rd Day	__/__/____	____
4th Day	__/__/____	____
5th Day	__/__/____	____
6th Day	__/__/____	____
7th Day	__/__/____	____

SKELETAL RELATED EVENT EVALUATION

- Occurence of SRE: **Yes** ❑ **No** ❑

In case of:

- pathological fractures and/or spinal cord compression, please fill in an AE/SAE Form as appropriate.
- bone irradiation, including radioisotopes or bone surgery, please complete the post radiation or surgery Form as appropriate.
- change of antineoplastic therapy (including introduction of biphosphonates in the face of increase in pain) to treat bone pain, please fill in either further anticancer therapy and / or Biphosphonate Medication Form.

SURGERY: POST TREATMENT ANTI-CANCER *SURG_01*

NONE ❑

	SURGERY	SURGERY DATE Day Month Year
1		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
2		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
3		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋

*LOCATION:	
03	Bone
11.01	Regional Lymph Nodes
11.02	Distant Lymph Nodes
18	Prostate
99	Other

RADIATION THERAPY *RADTX_01*

POST TREATMENT

NONE ❑

	SITE LOCATION	START DATE day month year	STOP DATE day month year	TOTAL DOSE	UNITS	INTENT
1	␣␣.␣␣	␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
2	␣␣.␣␣	␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
3	␣␣.␣␣	␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
4	␣␣.␣␣	␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
5	␣␣.␣␣	␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
6	␣␣.␣␣	␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
7	␣␣.␣␣	␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
8	␣␣.␣␣	␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative

ANTI-CANCER THERAPY *CANTX_02*

POST TREATMENT

NONE ❑

REGIMEN NO.	DRUG PER REGIMEN	THERAPY TYPE *	CUMULATIVE DOSE	DOSE UNIT	ROUTE	START DATE day month year	END DATE day month year	ONGOING
1	1	␣␣				␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
	2	␣␣				␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
	3	␣␣				␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
	4	␣␣				␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
2	1	␣␣				␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
	2	␣␣				␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
	3	␣␣				␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
	4	␣␣				␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑

* **THERAPY TYPE:**
CH - Chemotherapy
GE - Gene Therapy
BI - Biologicals
HO - Hormonotherapy
IM - Immunotherapy
OT - Other

** **ROUTE:**
1 = Cutaneous
2 = Buccal
7 = Intraarterial
12 = Intramuscular
19 = Intravenous
23 = Oral
24 = Other
27 = Rectal
28 = Subcutaneous

FACT P

❑ Assessment not done

Specify the primary reason:

- ❑ Subject is unable due to toxicity/disease
- ❑ Administrative failure to distribute the questionnaire to the patient
- ❑ Patient refusal
- ❑ Death
- ❑ Patient did not wish to show up
- ❑ Translation not available
- ❑ Other, *specify:* _____

FACT P QUESTIONNAIRE

Below is a list of statements that other people with your illness have said are important
By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

Date of questionnaire completion : ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋

	PHYSICAL WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GP1	I have a lack of energy.....	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by side effects of treatment	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4

	SOCIAL/FAMILY WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family.....	0	1	2	3	4
GS3	I get support from my friends.....	0	1	2	3	4
GS4	My family has accepted my illness	0	1	2	3	4
GS5	I am satisfied with family communication about my illness.....	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support).....	0	1	2	3	4
Q1	*Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please check this box and go to the next section.*					
GS7	I am satisfied with my sex life.....	0	1	2	3	4

By circling one (1) number per line, please indicate how true each statement has been for you <u>during the past 7 days</u>.

	EMOTIONAL WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GE1	I feel sad	0	1	2	3	4
GE2	I am satisfied with how I am coping with my illness	0	1	2	3	4
GE3	I am losing hope in the fight against my illness	0	1	2	3	4
GE4	I feel nervous	0	1	2	3	4
GE5	I worry about dying	0	1	2	3	4
GE6	I worry that my condition will get worse	0	1	2	3	4

	FUNCTIONAL WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GF1	I am able to work (include work at home)	0	1	2	3	4
GF2	My work (include work at home) is fulfilling	0	1	2	3	4
GF3	I am able to enjoy life	0	1	2	3	4
GF4	I have accepted my illness	0	1	2	3	4
GF5	I am sleeping well	0	1	2	3	4
GF6	I am enjoying the things I usually do for fun	0	1	2	3	4
GF7	I am content with the quality of my life right now	0	1	2	3	4

By circling one (1) number per line, please indicate how true each statement has been for you <u>during the past 7 days</u>.

	ADDITIONAL CONCERNS	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
C2	I am losing weight	0	1	2	3	4
C6	I have a good appetite	0	1	2	3	4
P1	I have aches and pains that bother me	0	1	2	3	4
P2	I have certain parts of my body where I experience pain ...	0	1	2	3	4
P3	My pain keeps me from doing things I want to do	0	1	2	3	4
P4	I am satisfied with my present comfort level	0	1	2	3	4
P5	I am able to feel like a man	0	1	2	3	4
P6	I have trouble moving my bowels	0	1	2	3	4
P7	I have difficulty urinating	0	1	2	3	4
BL2	I urinate more frequently than usual	0	1	2	3	4
P8	My problems with urinating limit my activities	0	1	2	3	4
BL5	I am able to have and maintain an erection	0	1	2	3	4

***LOCATION:**

01	Skin	11.09	Supraclavicular
02	Muscle/Soft Tissue	12	Liver
03	Bone	13	Stomach
04	Bone Marrow	14	Pancreas
05	Peripheral Blood Stream	15	Kidneys
06	Brain/CNS	17	Bladder
07	Head/Neck	18	Prostate
08	Eosaphagus	20.10	Colon
10	Lungs	20.20	Rectum
11	Lymph Nodes	21	Adrenal
11.01	Regional Lymph Nodes	22	Mediastinum
11.02	Distant Lymph Nodes	24	Abdomen
11.03	Axillary	25	Gastrointestinal Tract
11.04	Cervical	26	Pelvis
11.05	Inguinal	27	Peritoneum
11.06	Intra Abdominal	28	Testis
11.07	Mediastinal	29	Thorax
11.08	Para Aortic	29.01	Pleura
		30	Other

****METHOD OF TUMOR MEASUREMENT:**

1	CT Scan	8	X-ray
2	Spiral CT Scan	9	Endoscopy
3	MRI	10	Physical Exam
4	PET	11	Multi-Slice CT
5	Scintigraphy	12	DCE MRI
6	SPECT	99	Other
7	Ultrasound		

*** **RESPONSE OF NON-TARGET LESIONS:**

CR = Complete Response	UNK = Unknown
IR/SD = Incomplete Response / Stable Disease	NA = Not Applicable
PD = Progressive Disease	NL = New Lesion

TUMOR MEASUREMENTS *TUMEA_02*

NONE ❑

LESION NUMBER	LESION LOCATION*	DATE OF ASSESSMENT day month year	METHOD OF TUMOR MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1	⌊_⌊_.⌊_⌊_	⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ ❑ Not Done	⌊_⌊_	⌊_⌊_⌊_ mm	⌊_⌊_
2	⌊_⌊_.⌊_⌊_	⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ ❑ Not Done	⌊_⌊_	⌊_⌊_⌊_ mm	⌊_⌊_
3	⌊_⌊_.⌊_⌊_	⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ ❑ Not Done	⌊_⌊_	⌊_⌊_⌊_ mm	⌊_⌊_
4	⌊_⌊_.⌊_⌊_	⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ ❑ Not Done	⌊_⌊_	⌊_⌊_⌊_ mm	⌊_⌊_
5	⌊_⌊_.⌊_⌊_	⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ ❑ Not Done	⌊_⌊_	⌊_⌊_⌊_ mm	⌊_⌊_
6	⌊_⌊_.⌊_⌊_	⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ ❑ Not Done	⌊_⌊_	⌊_⌊_⌊_ mm	⌊_⌊_
7	⌊_⌊_.⌊_⌊_	⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ ❑ Not Done	⌊_⌊_	⌊_⌊_⌊_ mm	⌊_⌊_
8	⌊_⌊_.⌊_⌊_	⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ ❑ Not Done	⌊_⌊_	⌊_⌊_⌊_ mm	⌊_⌊_
9	⌊_⌊_.⌊_⌊_	⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ ❑ Not Done	⌊_⌊_	⌊_⌊_⌊_ mm	⌊_⌊_
10	⌊_⌊_.⌊_⌊_	⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ ❑ Not Done	⌊_⌊_	⌊_⌊_⌊_ mm	⌊_⌊_
11	⌊_⌊_.⌊_⌊_	⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ ❑ Not Done	⌊_⌊_	⌊_⌊_⌊_ mm	⌊_⌊_
12	⌊_⌊_.⌊_⌊_	⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ ❑ Not Done	⌊_⌊_	⌊_⌊_⌊_ mm	⌊_⌊_

SINCE LAST CYCLE, IF ANY OF THE FOLLOWING EVENTS OCCUR

OR IF THERE IS A WORSENING INTENSITY OF ONGOING LISTED BELOW EVENTS,

PLEASE TICK YES AND COMPLETE AN ADVERSE EVENT FORM.

CLINICAL EVENT "THROMBOVASCULAR" *CLINE_01*

❑ None

	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: _____

ADVERSE EVENT FORM *AE_03*

NONE ❑

1. **ADVERSE EVENT (DIAGNOSIS)**	AE form no: ⌊_⌊_-⌊_⌊_ AE ref. no: ⌊_⌊_-⌊_⌊_
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO INVESTIGATIONAL PRODUCTS*	Yes ❑ No ❑
5. ACTION TAKEN WITH INVESTIGATIONAL PRODUCTS**	0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE <<SAFETY COMPLEMENTARY FORM>>**	Yes ❑ No ❑ ➲ **IF YES** - Date event became serious: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
9. IS IT AN EVENT SUCH AS: **OVERDOSE OF THE IP?**	Yes ❑ No ❑
Investigator's name, date, and signature:	Monitoring representative's name, date of receipt:

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

** 0= None / 1= Permanently discontinued / 2= Delayed / 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted

SUBJECT STATUS

SUBST_01

Date of last contact: __/__ __/__/__ __/__/__/__ (day / month / year)

Subject condition at the time of the scheduled visit (tick one condition only):

- ❑ Alive
- ❑ Lost to follow-up
- ❑ Dead*

Method of contact:

- ❑ Scheduled visit
- ❑ Phone
- ❑ 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 *O.VITAL_2*

- Date performed : ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊2⌋⌊0⌋⌊_⌋⌊_⌋
  day month year

- Blood pressure: Systolic ⌊_⌋⌊_⌋⌊_⌋ mmHg / Diastolic ⌊_⌋⌊_⌋⌊_⌋ mmHg

ECOG Performance Status

0	1	2	3	4
❑	❑	❑	❑	❑

PHYSICAL EXAMINATION

A PHYSICAL EXAMINATION SHOULD BE PERFORMED.

IF THERE ARE ANY CLINICALLY SIGNIFICANT CHANGES FROM THE PREVIOUS EXAMINATION, RECORD AS AN ADVERSE EVENT.

TUMOR MARKERS *TMARK_01*

PSA

Not done ❑

- Date of evaluation : ⌊_⌊_⌋ ⌊_⌊_⌊_⌋ ⌊_⌊_⌊_⌊_⌋
  day month year

	TEST	VALUE	UNIT	NORMAL RANGE	
				LOWER LIMIT	UPPER LIMIT
1.	**PSA**				

MEDICATION BIPHOSPHONATES *MED_02*

None ❑

Record all biphosphonates therapies that the subject has taken within the follow-up period, and record any changes.

	DRUG / MEDICATION (Brand or Generic Name)	DOSAGE (TOTAL DAILY DOSE)	DOSE UNIT	ROUTE*	START DATE Day Month Year	END DATE OR TICK IF ONGOING Day Month Year
1					␣␣ ␣␣␣ ␣␣␣␣ ❑ Previously Reported	␣␣ ␣␣␣ ␣␣␣␣ ❑ Ongoing
2					␣␣ ␣␣␣ ␣␣␣␣ ❑ Previously Reported	␣␣ ␣␣␣ ␣␣␣␣ ❑ Ongoing
3					␣␣ ␣␣␣ ␣␣␣␣ ❑ Previously Reported	␣␣ ␣␣␣ ␣␣␣␣ ❑ Ongoing
4					␣␣ ␣␣␣ ␣␣␣␣ ❑ Previously Reported	␣␣ ␣␣␣ ␣␣␣␣ ❑ Ongoing
5					␣␣ ␣␣␣ ␣␣␣␣ ❑ Previously Reported	␣␣ ␣␣␣ ␣␣␣␣ ❑ Ongoing
6					␣␣ ␣␣␣ ␣␣␣␣ ❑ Previously Reported	␣␣ ␣␣␣ ␣␣␣␣ ❑ Ongoing
7					␣␣ ␣␣␣ ␣␣␣␣ ❑ Previously Reported	␣␣ ␣␣␣ ␣␣␣␣ ❑ Ongoing
8					␣␣ ␣␣␣ ␣␣␣␣ ❑ Previously Reported	␣␣ ␣␣␣ ␣␣␣␣ ❑ Ongoing
9					␣␣ ␣␣␣ ␣␣␣␣ ❑ Previously Reported	␣␣ ␣␣␣ ␣␣␣␣ ❑ Ongoing
10					␣␣ ␣␣␣ ␣␣␣␣ ❑ Previously Reported	␣␣ ␣␣␣ ␣␣␣␣ ❑ Ongoing

* **ROUTE:** 19 = Intravenous 23 = Oral 24 = Other

ANALGESIC MEDICATION SHOULD BE COLLECTED DAILY FOR SEVEN CONSECUTIVE DAYS PRIOR TO THE NEXT FOLLOW-UP VISIT.

THE LAST RECORDS SHOULD BE OBTAINED WITHIN 3 DAYS PRIOR TO THE NEXT FOLLOW-UP VISIT.

* **ROUTE:**

1	=	Cutaneous	19	=	Intravenous	27	=	Rectal
2	=	Buccal	23	=	Oral	28	=	Subcutaneous
6	=	Inhalation	24	=	Other	29	=	Sublingua
12	=	Intramuscular						

MEDICATION ANALGESIC *MED_02*

PLEASE RECORD ALL ANALGESIC MEDICATION EXCLUDING BIPHOSPHONATE.

None ❑

	DRUG / MEDICATION (Brand or Generic Name)	DOSAGE (TOTAL DAILY DOSE)	DOSE UNIT	ROUTE *	START DATE Day Month Year	END DATE OR TICK IF ONGOING Day Month Year
1					❑ Previously Reported	❑ Ongoing
2					❑ Previously Reported	❑ Ongoing
3					❑ Previously Reported	❑ Ongoing
4					❑ Previously Reported	❑ Ongoing
5					❑ Previously Reported	❑ Ongoing
6					❑ Previously Reported	❑ Ongoing
7					❑ Previously Reported	❑ Ongoing
8					❑ Previously Reported	❑ Ongoing
9					❑ Previously Reported	❑ Ongoing
10					❑ Previously Reported	❑ Ongoing

- **TO BE PERFORMED OVER 7 CONSECUTIVE DAYS PRIOR TO THE NEXT FOLLOW-UP VISIT.**
- **THE LAST RECORDS SHOULD BE OBTAINED WITHIN 3 DAYS PRIOR TO THE NEXT FOLLOW-UP VISIT.**

PAIN EVALUATION

NOT DONE ❑

	DATE OF ASSESSMENT Day Month Year	PRESENT PAIN INTENSITY SCORE
1st Day	⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋	⌊____⌋
2nd Day	⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋	⌊____⌋
3rd Day	⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋	⌊____⌋
4th Day	⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋	⌊____⌋
5th Day	⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋	⌊____⌋
6th Day	⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋	⌊____⌋
7th Day	⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋	⌊____⌋

SKELETAL RELATED EVENT EVALUATION

- Occurence of SRE: **Yes** ❑ **No** ❑

In case of:

- pathological fractures and/or spinal cord compression, please fill in an AE/SAE Form as appropriate.
- bone irradiation, including radioisotopes or bone surgery, please complete the post radiation or surgery Form as appropriate.
- change of antineoplastic therapy (including introduction of biphosphonates in the face of increase in pain) to treat bone pain, please fill in either further anticancer therapy and / or Biphosphonate Medication Form.

SURGERY: POST TREATMENT ANTI-CANCER *SURG_01*

NONE ❑

	SURGERY	SURGERY DATE OR NONE Day Month Year
1		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
2		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
3		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋

*LOCATION:	
03	Bone
11.01	Regional Lymph Nodes
11.02	Distant Lymph Nodes
18	Prostate
99	Other

RADIATION THERAPY *RADTX_01*

POST TREATMENT RADIATION THERAPY

NONE ❑

	SITE LOCATION	START DATE day month year	STOP DATE day month year	TOTAL DOSE	UNITS	INTENT
1	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
2	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
3	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
4	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
5	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
6	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
7	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative
8	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣		❑ Grays ❑ Rads	❑ Palliative ❑ Curative

ANTI-CANCER THERAPY

CANTX_02

POST TREATMENT

NONE ❑

REGIMEN NO.	DRUG PER REGIMEN	THERAPY TYPE *	CUMULATIVE DOSE	DOSE UNIT	ROUTE	START DATE (day month year)	END DATE (day month year)	ONGOING
1	1	␣␣				␣␣ ␣␣␣ ␣␣␣␣ ❑ Previously reported	␣␣ ␣␣␣ ␣␣␣␣	❑
	2	␣␣				␣␣ ␣␣␣ ␣␣␣␣ ❑ Previously reported	␣␣ ␣␣␣ ␣␣␣␣	❑
	3	␣␣				␣␣ ␣␣␣ ␣␣␣␣ ❑ Previously reported	␣␣ ␣␣␣ ␣␣␣␣	❑
	4	␣␣				␣␣ ␣␣␣ ␣␣␣␣ ❑ Previously reported	␣␣ ␣␣␣ ␣␣␣␣	❑
2	1	␣␣				␣␣ ␣␣␣ ␣␣␣␣ ❑ Previously reported	␣␣ ␣␣␣ ␣␣␣␣	❑
	2	␣␣				␣␣ ␣␣␣ ␣␣␣␣ ❑ Previously reported	␣␣ ␣␣␣ ␣␣␣␣	❑
	3	␣␣				␣␣ ␣␣␣ ␣␣␣␣ ❑ Previously reported	␣␣ ␣␣␣ ␣␣␣␣	❑
	4	␣␣				␣␣ ␣␣␣ ␣␣␣␣ ❑ Previously reported	␣␣ ␣␣␣ ␣␣␣␣	❑

*** THERAPY TYPE:**

CH - Chemotherapy
GE - Gene Therapy
BI - Biologicals
HO - Hormonotherapy
IM - Immunotherapy
OT - Other

**** ROUTE:**

1 = Cutaneous
2 = Buccal
7 = Intraarterial
12 = Intramuscular
19 = Intravenous
23 = Oral
24 = Other
27 = Rectal
28 = Subcutaneous

FACT P

❑ Assessment not done

Specify the primary reason:

- ❑ Subject is unable due to toxicity/disease
- ❑ Administrative failure to distribute the questionnaire to the patient
- ❑ Patient refusal
- ❑ Death
- ❑ Patient did not wish to show up
- ❑ Translation not available
- ❑ Other, *specify:* _____

FACT P QUESTIONNAIRE

Below is a list of statements that other people with your illness have said are important
By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

Date of questionnaire completion : ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋

	PHYSICAL WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GP1	I have a lack of energy.....	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by side effects of treatment	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4

	SOCIAL/FAMILY WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family.....	0	1	2	3	4
GS3	I get support from my friends.....	0	1	2	3	4
GS4	My family has accepted my illness	0	1	2	3	4
GS5	I am satisfied with family communication about my illness.....	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support).....	0	1	2	3	4
Q1	*Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please check this box and go to the next section.*					
GS7	I am satisfied with my sex life.....	0	1	2	3	4

By circling one (1) number per line, please indicate how true each statement has been for you <u>during the past 7 days</u>.

	EMOTIONAL WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GE1	I feel sad	0	1	2	3	4
GE2	I am satisfied with how I am coping with my illness	0	1	2	3	4
GE3	I am losing hope in the fight against my illness	0	1	2	3	4
GE4	I feel nervous	0	1	2	3	4
GE5	I worry about dying	0	1	2	3	4
GE6	I worry that my condition will get worse	0	1	2	3	4

	FUNCTIONAL WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GF1	I am able to work (include work at home)	0	1	2	3	4
GF2	My work (include work at home) is fulfilling	0	1	2	3	4
GF3	I am able to enjoy life	0	1	2	3	4
GF4	I have accepted my illness	0	1	2	3	4
GF5	I am sleeping well	0	1	2	3	4
GF6	I am enjoying the things I usually do for fun	0	1	2	3	4
GF7	I am content with the quality of my life right now	0	1	2	3	4

By circling one (1) number per line, please indicate how true each statement has been for you <u>during the past 7 days</u>.

	ADDITIONAL CONCERNS	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
C2	I am losing weight	0	1	2	3	4
C6	I have a good appetite	0	1	2	3	4
P1	I have aches and pains that bother me	0	1	2	3	4
P2	I have certain parts of my body where I experience pain	0	1	2	3	4
P3	My pain keeps me from doing things I want to do	0	1	2	3	4
P4	I am satisfied with my present comfort level	0	1	2	3	4
P5	I am able to feel like a man	0	1	2	3	4
P6	I have trouble moving my bowels	0	1	2	3	4
P7	I have difficulty urinating	0	1	2	3	4
BL2	I urinate more frequently than usual	0	1	2	3	4
P8	My problems with urinating limit my activities	0	1	2	3	4
BL5	I am able to have and maintain an erection	0	1	2	3	4

***LOCATION:**

01	Skin	11.09	Supraclavicular
02	Muscle/Soft Tissue	12	Liver
03	Bone	13	Stomach
04	Bone Marrow	14	Pancreas
05	Peripheral Blood Stream	15	Kidneys
06	Brain/CNS	17	Bladder
07	Head/Neck	18	Prostate
08	Eosaphagus	20.10	Colon
10	Lungs	20.20	Rectum
11	Lymph Nodes	21	Adrenal
11.01	Regional Lymph Nodes	22	Mediastinum
11.02	Distant Lymph Nodes	24	Abdomen
11.03	Axillary	25	Gastrointestinal Tract
11.04	Cervical	26	Pelvis
11.05	Inguinal	27	Peritoneum
11.06	Intra Abdominal	28	Testis
11.07	Mediastinal	29	Thorax
11.08	Para Aortic	29.01	Pleura
		30	Other

****METHOD OF TUMOR MEASUREMENT:**

1	CT Scan	8	X-ray
2	Spiral CT Scan	9	Endoscopy
3	MRI	10	Physical Exam
4	PET	11	Multi-Slice CT
5	Scintigraphy	12	DCE MRI
6	SPECT	99	Other
7	Ultrasound		

*** **RESPONSE OF NON-TARGET LESIONS:**

CR = Complete Response	UNK = Unknown
IR/SD = Incomplete Response / Stable Disease	NA = Not Applicable
PD = Progressive Disease	NL = New Lesion

TUMOR MEASUREMENTS *TUMEA_02*

NONE ❑

LESION NUMBER	LESION LOCATION*	DATE OF ASSESSMENT day month year	METHOD OF TUMOR MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
2	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
3	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
4	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
5	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
6	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
7	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
8	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
9	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
10	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
11	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
12	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋

SINCE LAST CYCLE, IF ANY OF THE FOLLOWING EVENTS OCCUR OR IF THERE IS A WORSENING INTENSITY OF ONGOING LISTED BELOW EVENTS, PLEASE TICK YES AND COMPLETE AN ADVERSE EVENT FORM.

CLINICAL EVENT "THROMBOVASCULAR" *CLINE_01*

❑ None

	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: _____

ADVERSE EVENT FORM *AE_03*

NONE ❑

1. **ADVERSE EVENT (DIAGNOSIS)**	AE form no: ⌊_⌋⌊_⌋-⌊_⌋⌊_⌋ AE ref. no: ⌊_⌋⌊_⌋-⌊_⌋⌊_⌋
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO INVESTIGATIONAL PRODUCTS*	Yes ❑ No ❑
5. ACTION TAKEN WITH INVESTIGATIONAL PRODUCTS**	0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE <<SAFETY COMPLEMENTARY FORM>>**	Yes ❑ No ❑ ➲ **IF YES** - Date event became serious: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
9. IS IT AN EVENT SUCH AS: **OVERDOSE OF THE IP?**	Yes ❑ No ❑
Investigator's name, date, and signature:	Monitoring representative's name, date of receipt:

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

** 0= None / 1= Permanently discontinued / 2= Delayed / 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted

MEDICATION *MED_01*

❑ None

Record all concomitant medications other than analgesic and biphosphonates that the subject has taken during the study period as defined in the protocol.

DRUG / MEDICATION (Brand or Generic Name)	START DATE Day Month Year	END DATE OR TICK IF ONGOING Day Month Year
	❑ Previously Reported	❑ Ongoing
	❑ Previously Reported	❑ Ongoing
	❑ Previously Reported	❑ Ongoing
	❑ Previously Reported	❑ Ongoing
	❑ Previously Reported	❑ Ongoing
	❑ Previously Reported	❑ Ongoing
	❑ Previously Reported	❑ Ongoing
	❑ Previously Reported	❑ Ongoing
	❑ Previously Reported	❑ Ongoing
	❑ Previously Reported	❑ Ongoing

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MEDICATION *MED_01*

Record all concomitant medications other than analgesic and biphosphonates that the subject has taken during the study period as defined in the protocol.

DRUG / MEDICATION (Brand or Generic Name)	START DATE Day Month Year	END DATE OR TICK IF ONGOING Day Month Year
	☐ Previously Reported	☐ Ongoing
	☐ Previously Reported	☐ Ongoing
	☐ Previously Reported	☐ Ongoing
	☐ Previously Reported	☐ Ongoing
	☐ Previously Reported	☐ Ongoing
	☐ Previously Reported	☐ Ongoing
	☐ Previously Reported	☐ Ongoing
	☐ Previously Reported	☐ Ongoing
	☐ Previously Reported	☐ Ongoing
	☐ Previously Reported	☐ Ongoing

ADDITIONAL HEMATOLOGY *LABH_1*

• Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊2⌋⌊0⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Hemoglobin		g/L	
Platelets count		10^9/L	
WBC		10^9/L	
Neutrophils		10^9/L	

HEMATOLOGY *LABH_1*

❑ Not Done

TO BE PERFORMED ONLY FOR PATIENT UNDER VITAMIN K ANTAGONIST.

• Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊2⌋⌊0⌋⌊_⌋⌊_⌋
day month year

Laboratory Name: _____

Address: _____

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
INR		Ratio	

ADDITIONAL BIOCHEMISTRY *LABB_1*

Laboratory Name: _____

Address: _____

- Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊2⌋⌊0⌋⌊_⌋⌊_⌋
  day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Sodium		mmol/L	
Calcium		mmol/L	
Potassium		mmol/L	
Phosphorus		mmol/L	
Blood Urea Nitrogen		mg/dL	
Urea**		mmol/L	
Magnesium		mg/dL	
Creatinine		µmol/L	
Calculated Creatinine clearance*		ml/min	
Glucose		mmol/L	
AST		IU/L	
ALT		IU/L	
Alkaline phosphatase		IU/L	
Total bilirubin		mg/dL	
Total protein		g/dL	
Albumin		g/dL	

* If creatinine > ULN, please report the calculated creatinine clearance.
** If BUN is not evaluated, UREA value must be documented.

TO BE COMPLETED IF UPCR > 1.

24-HOUR URINALYSIS *LABU_2*

Laboratory name: _____

Address: _____

- Start date of collection: ☐☐ ☐☐☐ 20☐☐ (day / month / year)
- Start time of collection: ☐☐:☐☐ (24-hour clock)
- End date of collection: ☐☐ ☐☐☐ 20☐☐ (day / month / year)
- End time of collection: ☐☐:☐☐ (24-hour clock)

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Urinary Volume		L	
Protein		g/L	
Creatinine		g/L	

ELECTROPHORESIS

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Albumin		g/L	
α1 Globulin		g/L	
α2 Globulin		g/L	
β Globulin		g/L	
γ Globulin		g/L	

IS THERE ANY HEMOGLOBIN OR RBC IN 24-HOUR URIN SAMPLE.

Hemoglobin	❑ Negative	❑ Positive
RBC	❑ Negative	❑ Positive

TO BE COMPLETED IF PROTEINURIA IS ASSOCIATED WITH HEMATURIA.

HEMATOLOGY *LABH_1*

- Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
  day month year

TEST	NEGATIVE (MD if not done)	POSITIVE (MD if not done)
Schistocytes	❑	❑

BIOCHEMISTRY *LABB_1*

Laboratory Name: _____

Address: _____

- Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
  day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
LDH	----------	IU/L	----------
Haptoglobin	----------	g/L	----------
Orosomucoïd	----------	g/L	----------

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UNSCHEDULED LABORATORY TESTS *UNSLAB_1*

Laboratory Name: _____

Address: _____

	TESTS	DATE OF SAMPLING (day month year)	VALUE	UNIT	NORMAL RANGES Lower limit	NORMAL RANGES Upper limit
1		__ __ __ __ __ __ __ __				
2		__ __ __ __ __ __ __ __				
3		__ __ __ __ __ __ __ __				
4		__ __ __ __ __ __ __ __				
5		__ __ __ __ __ __ __ __				
6		__ __ __ __ __ __ __ __				
7		__ __ __ __ __ __ __ __				
8		__ __ __ __ __ __ __ __				
9		__ __ __ __ __ __ __ __				
10		__ __ __ __ __ __ __ __				

OTHER PROCEDURES *OTHPR_03*

None ❑

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 (day/month/year)	OUTCOME
1		␣␣ ␣␣␣ ␣␣␣␣	❑ Not Applicable ❑ Normal ❑ Abnormal If abnormal, clinically significant? ❑ Yes* ❑ No
	* Specify: _____		
2		␣␣ ␣␣␣ ␣␣␣␣	❑ Not Applicable ❑ Normal ❑ Abnormal If abnormal, clinically significant? ❑ Yes* ❑ No
	* Specify: _____		
3		␣␣ ␣␣␣ ␣␣␣␣	❑ Not Applicable ❑ Normal ❑ Abnormal If abnormal, clinically significant? ❑ Yes* ❑ No
	* Specify: _____		
4		␣␣ ␣␣␣ ␣␣␣␣	❑ Not Applicable ❑ Normal ❑ Abnormal If abnormal, clinically significant? ❑ Yes* ❑ No
	* Specify: _____		

ELECTROCARDIOGRAM *ECG_01*

Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

❑ Normal
❑ Abnormal
If abnormal, clinically significant? ❑ Yes ❑ No

IF ABNORMAL, CLINICALLY SIGNIFICANT, RECORD ON THE ADVERSE EVENT FORM.

SYMPTOMATIC DETERIORATION *SYMDE_01*

Date: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

If symptomatic deterioration occurs during the study period as defined in the protocol, record on the Adverse Event form.

DEATH *DEATH_01*

Date of death: ☐☐ ☐☐☐ ☐☐☐☐
day month year

Reason for death (tick "✓" one box only):

- ☐ Disease progression
- ☐ Adverse event
- ☐ Other *Specify:* _____

ADDITIONAL VITAL SIGNS *O.VITAL_2*

- Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
  day month year

- Blood pressure: Systolic ⌊_⌋⌊_⌋⌊_⌋ mmHg / Diastolic ⌊_⌋⌊_⌋⌊_⌋ mmHg

ADVERSE EVENT FORM *AE_03*

NONE ❑

1. **ADVERSE EVENT (DIAGNOSIS)**	AE form no: ⌊_⌋⌊_⌋-⌊_⌋⌊_⌋ AE ref. no: ⌊_⌋⌊_⌋-⌊_⌋⌊_⌋
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO INVESTIGATIONAL PRODUCTS*	Yes ❑ No ❑
5. ACTION TAKEN WITH INVESTIGATIONAL PRODUCTS**	0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ / 2 ❑ Date: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ (day / month / year) Specify sequelae: _____ 3 ❑ 5 ❑ Date of death: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE <<SAFETY COMPLEMENTARY FORM>>**	Yes ❑ No ❑ ➲ **IF YES** - Date event became serious: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
9. IS IT AN EVENT SUCH AS: **OVERDOSE OF THE IP?**	Yes ❑ No ❑
Investigator's name, date, and signature:	Monitoring representative's name, date of receipt:

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

** 0= None / 1= Permanently discontinued / 2= Delayed / 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted

SAFETY COMPLEMENTARY FORM *SAEC_03*

AE / SPECIFIC EVENT FORM NUMBER: ⌊_⌋⌊_⌋ . ⌊_⌋⌊_⌋

1. DEMOGRAPHIC INFORMATION

Date of birth: ⌊_⌋⌊_⌋ (day) ⌊_⌋⌊_⌋⌊_⌋ (month) ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ (year)

or Age: ⌊_⌋⌊_⌋

Sex: ❑ male ❑ female

Race:
❑ Caucasian/White ❑ Black
❑ Asian, Oriental ❑ Other
*If other, specify:*_____

Height: ⌊_⌋⌊_⌋⌊_⌋ cm 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):

⌊_⌋⌊_⌋ (day) ⌊_⌋⌊_⌋⌊_⌋ (month) 20⌊_⌋⌊_⌋ (year)

4. INVESTIGATIONAL PRODUCTS

➲ **Date of the FIRST administration of study treatment:** ⌊_⌋⌊_⌋ (day) ⌊_⌋⌊_⌋⌊_⌋ (month) 20⌊_⌋⌊_⌋ (year)

Current Treatment number: ⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋ Current Cycle n° ⌊_⌋⌊_⌋

➲ **Date of the LAST administration before SAE:**		Last dosage before SAE	Action Taken*
Aflibercept/Placebo:	⌊_⌋⌊_⌋ (day) ⌊_⌋⌊_⌋⌊_⌋ (month) 20⌊_⌋⌊_⌋ (year)	⌊_⌋⌊_⌋⌊_⌋ mg/Kg	⌊_⌋
Docetaxel:	⌊_⌋⌊_⌋ (day) ⌊_⌋⌊_⌋⌊_⌋ (month) 20⌊_⌋⌊_⌋ (year)	⌊_⌋⌊_⌋⌊_⌋ mg/m²	⌊_⌋
Prednisone/Prednisolone:	⌊_⌋⌊_⌋ (day) ⌊_⌋⌊_⌋⌊_⌋ (month) 20⌊_⌋⌊_⌋ (year)	⌊_⌋⌊_⌋⌊_⌋ mg/day	⌊_⌋

** 0 = None; 1 = Permanently discontinued; 2 = Delayed; 3 = Dose Reduced; 4 = Delayed and reduced; 5 = Interrupted.*

5. IN CASE OF HOSPITALIZATION *(hospital report to be sent)*

Date of admission: ⌊_⌋⌊_⌋ (day) ⌊_⌋⌊_⌋⌊_⌋ (month) 20⌊_⌋⌊_⌋ (year)

6. IN CASE OF DEATH

Autopsy report: ❑ Yes *(copy to be sent)* ❑ No

7. CORRECTIVE TREATMENT/THERAPY

(Relevant CRF page can be faxed)

8. PREVIOUS AND CONCOMITANT MEDICATIONS:

(Relevant CRF page can be faxed)

9. RELEVANT MEDICAL HISTORY AND CONCOMITANT DISEASES:

(Relevant CRF page can be faxed)

SAFETY FOLLOW-UP FORM *SAEF_01*

PROVIDE THE SPONSOR BY FAX WITH ALL ADDITIONAL INFORMATION INCLUDING AE FORM IF UPDATED

AE / SPECIFIC EVENT FORM NUMBER: ⌊_⌋⌊_⌋ . ⌊_⌋⌊_⌋

1. ADVERSE EVENT (diagnosis):

2. DATE OF THE EVALUATION: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

3. NEW RELEVANT INFORMATION ADDED TO INITIAL REPORT(S):

Investigator's name, date and signature:	Monitoring representative's name, date of receipt: