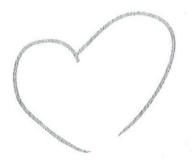
AVE0005 | EFC10547

CASE REPORT FORM



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

COUNTRY NUMBER:		CENTRE NUMBER:	
Subject number:			
Confidential ■ Final vers	ion ■ 21-Sep-2007	sanofi	aventis

sanofi aventis	EFC10547		X 4 Country Center Subject	1.1 Page No
L'essentiel c'est la santé.	Visit Name:	VISIT 0		
-				

Date of visit:

(DD-MMM-YYYY)

INFORMED CONSENT

Date consent obtained:
(DD-MMM-YYYY)

DEMOGRAPHY DEMOG_01

Date of I	Birth (dd-mmm-y	ууу)			
Sex	Male Female				
Race	Caucasian/White Black Asian/Oriental Other	e	If Other, specify		

Confidential Information

Repeat No.



EFC10547

Х	4							
Country		С	ent	er	Sι	ıbje	ect	

2.1	
Page No.	

0	
Repeat	No.

VISIT 0

CANCER DIAGNOSIS

CDIA	G 01

Date of initial diagnosis	DD-MM-YYYY			
Location				
Pancreas Pancreas head Pancreas tail Pancreas body Pan				
Other	Specify			
Histology type				
Adenocarcinoma				
Other	Specify			
Stage AT DIAGN	OSIS			
	0 🗆	ı 🗆	ΠП	
	шП	ı∨□	Unknown \square	



EFC10547	
EFC10547	

Х	4							
Сс	un	trv	С	Center		Sι	ıbie	ect

3.1	
Page	No.

0 Repeat No.

Visit Name:

VISIT 0

(dd-mmm-yyyy)

STATUS AT STUDY ENTRY

STENT_01

EXTENT AT STUDY ENTRY:	

Date of progression :

Metastatic ☐ Locally advanced ☐

Sanofi aventis L'essentiel d'est la santé.	EFC10547 Visit Name:	VISIT 0	X 4 Country	Center Subject	4.1 Page No.	0 Repeat No.	
SURGERY PRIOR							
RECORD RELEVANT SURGERY, RELATED TO PANCREATIC CANCER INFORMATION							
Data ☑ No Data ☐							

Surgery term	Surgery Date (DD-MMM-YYYY)	
DISTAL PANCREATECTOMY		
TOTAL PANCREATECTOMY		
PANCREATICODUODENECTOMY		
HEPATICOJEJUNOSTOMY		
CHOLEDOCHOJEJUNOSTOMY		
CHOLEDOCHODUODENOSTOMY		
CHOLECYSTOJEJUNOSTOMY		
GASTRIC BYPASS		



Х	4							
Country		С	ent	er	Sι	ıbje	ect	

4.2		
Page	No.	

0	
Repeat	No.

VISIT 0

Surgery term	Surgery Date (DD-MMM-YYYY	Not performed



Х	4							
Country			С	ent	er	Sı	ıbje	ect

5.1	
Page	No.

0	
Repeat	No.

VISIT 0

RADIATION THERAPY	PRIOR RADIA	RADTX_01				
Data ☑ No Data ☐						
Lesion location	Start Date (dd-mmm-yyyy)	End Date (dd-mmm-yyyy)	Total Dose	Unit	Intent	_
				Grays 🗌 Rads 🔲	Palliative Curative	
				Grays ☐ Rads ☐	Palliative Curative	
				Grays ☐ Rads ☐	Palliative Curative	
				Grays ☐ Rads ☐	Palliative Curative	
				Grays ☐ Rads ☐	Palliative Curative	
				Grays ☐ Rads ☐	Palliative Curative	
				Grays ☐ Rads ☐	Palliative Curative	
				Grays ☐ Rads ☐	Palliative Curative	
				Grays ☐ Rads ☐	Palliative Curative	

Confidential Information

AVE0005 - EFC10547 (VANILLA)



Х	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

!	5.2
_	Page No.

0	
Repeat	No.

/ISIT 0		

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

XXX						
sanofi aventis						
L'essentiel c'est la santé.						

Data ✓ No Data 🗌

EFC10547

Χ	4							
Country		С	ent	er	Sι	ıbje	ect	

6.1	
Page N	lo.

Repeat No.

Visit Name:

VISIT 0

ANTI-CANCER THERAPY

PRIOR TREATMENT

CANTX_01

ntent			
Reason for Disc	continuation		
If other, sp	ecify		
Regimen Number	Drug Per Regimen	Start Date DD-MM-YYYY	End Date DD-MM-YYYY
REGIMEN 1			



EFC10547

Χ	4							
Country		С	ent	er	Sι	ıbje	ect	

7.1	
Page No.	

0	
Repeat	No.

VISIT 0

MHX_03

MEDICAL HISTORY Data ✓ No Data ☐		MHX <u>.</u>
Record relevant medical history for thrombovascular events and cardio	ovascular risk factors.	
Medical/Surgical History	Start Date or Not Occurred MMM-YYYY	Ongoing
ANGINA PECTORIS	If yes, disea	res ☐ No ☐ ase/symptoms controlled: res ☐ No ☐
UNSTABLE ANGINA	If yes, disea	res ☐ No ☐ ase/symptoms controlled: res ☐ No ☐
MYOCARDIAL INFARCTION	If yes, disea	'es ☐ No ☐ ase/symptoms controlled: 'es ☐ No ☐
ATRIAL FIBRILLATION	If yes, disea	res ☐ No ☐ ase/symptoms controlled: res ☐ No ☐
TRANSIENT ISCHEMIC ATTACK	If yes, disea	res ☐ No ☐ ase/symptoms controlled: res ☐ No ☐



<u> </u>	un	tr.	_	ont	er	<u>ر</u>	hic	L_
Х	4							

7.2	l
Page No.	_

0	
Repeat	No.

VISIT 0		
---------	--	--

Medical/Surgical History	Start Date or Not Occurred MMM-YYYY	Ongoing
STROKE	☐ Not Occurred	Yes ☐ No ☐ If yes, disease/symptoms controlled: Yes ☐ No ☐
PERIPHERAL ARTERIAL THROMBOTIC DISEASE	☐ Not Occurred	Yes No No If yes, disease/symptoms controlled: Yes No □
DEEP VENOUS THROMBOSIS	☐ Not Occurred	Yes No No If yes, disease/symptoms controlled: Yes No □
PULMONARY EMBOLISM	Not Occurred	Yes ☐ No ☐ If yes, disease/symptoms controlled: Yes ☐ No ☐
HIGH BLOOD PRESSURE	☐ Not Occurred	Yes No No Street No



EFC10547

Χ	4							
Country			С	Center		Subject		

7.3	
Page No.	•

0	
Repeat	No.

VISIT 0	
---------	--

Medical/Surgical History	Start Date or Not Occurred Ongoing MMM-YYYYY
HYPERCHOLESTEROLEMIA	Yes No No No If yes, disease/symptoms controlled: Not Occurred Yes No
DIABETES MELLITUS	Yes No No If yes, disease/symptoms controlled: Not Occurred Yes No I
SMOKER	Yes No No If yes, disease/symptoms controlled: Not Occurred Yes No No
	Yes No No If yes, disease/symptoms controlled: Not Occurred Yes No
	Yes No No If yes, disease/symptoms controlled: Not Occurred Yes No

Confidential Information

AVE0005 - EFC10547 (VANILLA)



Coi		400.0	$\overline{}$	224	<u></u>	٣.	ıbje	L Not
Х	4							

7.4	
Page	No.

0	
Repeat	No.

ISIT 0		

Medical/Surgical History	Start Date or Not Occurred MMM-YYYY	Ongoing
	☐ Not Occurred	Yes No □ es, disease/symptoms controlled: Yes No □
	☐ Not Occurred	Yes No No es, disease/symptoms controlled:
	☐ Not Occurred	Yes No es, disease/symptoms controlled: Yes No
	☐ Not Occurred	Yes No No es, disease/symptoms controlled:
	☐ Not Occurred	Yes No es, disease/symptoms controlled:



EFC10547		X 4		8.1	0
		Country	Center Subject	Page No.	Repeat No.
Visit Name:	VISIT 0				

MEDICAL HISTORY Data ☑ No Data ☐		MHX_03
Record relevant medical/surgical history other than the disea	se studied and other than thrombovas	cular events and cardiovascular risk factors.
Medical/Surgical History	Start Date MMM-YYYY	Ongoing Yes No No I If yes, disease/symptoms controlled: Yes No No
		Yes ☐ No ☐ If yes, disease/symptoms controlled: Yes ☐ No ☐
		Yes ☐ No ☐ If yes, disease/symptoms controlled: Yes ☐ No ☐
		Yes ☐ No ☐ If yes, disease/symptoms controlled: Yes ☐ No ☐
		Yes ☐ No ☐ If yes, disease/symptoms controlled: Yes ☐ No ☐



Χ	4							
Country		С	ent	er	Sι	ıbje	ect	

8.2	
Page	No.

0	
Repeat	No.

VISIT 0	
V 1311 U	

Medical/Surgical History	Start Date MMM-YYYY	Ongoing
		Yes ☐ No ☐ If yes, disease/symptoms controlled: Yes ☐ No ☐
		Yes□ No□ If yes, disease/symptoms controlled: Yes□ No□
		Yes No ☐ If yes, disease/symptoms controlled: Yes ☐ No ☐
		Yes No No No No No No No No No N
		Yes□ No□ If yes, disease/symptoms controlled: Yes□ No□



EFC10547

Λ	บท	\coprod	$\overline{}$	ent	<u>د</u> .	L Ibie	با
Χ	4						

8.3	l
Page No.	

0	
Repeat	No.

ISIT 0		

Medical/Surgical History	Start Date MMM-YYYY	Ongoing
		Yes No I No I If yes, disease/symptoms controlled: Yes No I
		Yes No No See No No See No No See No
		Yes☐ No☐ If yes, disease/symptoms controlled: Yes☐ No☐
		Yes□ No□ If yes, disease/symptoms controlled: Yes□ No□
		Yes No No See No No See

Confidential Information

AVE0005 - EFC10547 (VANILLA)

Final Version: 24OCT2007



EFC10547	
----------	--

\triangle	un	Ш •».	_	ent	 <u>ر</u>	المار	L
Х	4						

8.4	
Page	No.

0	
Repeat	No.

ISIT 0		

Medical/Surgical History	Start Date MMM-YYYY	Ongoing
		Yes No No If yes, disease/symptoms controlled: Yes No No
		Yes No No Service No
		Yes ☐ No ☐ If yes, disease/symptoms controlled: Yes ☐ No ☐
		Yes No No Sees No
		Yes ☐ No ☐ If yes, disease/symptoms controlled: Yes ☐ No ☐

TOTAL
sanofi aventis
L'essentiel c'est la santé.

Χ	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

9.1	
Page	No.

0	
Repeat	Nο

VISIT 0

PAIN INTENSITY ASSESSED VIA VISUAL ANALOG SCALE

Data ✓ No Data 🗌

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

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

XXX
sanofi aventis
L'essentiel c'est la santé.

ANALGESIC

Х	4							
Сс	un	trv	Center		Sι	ıbie	ect	

10.1	
Page N	Ю.

0	
Repeat	No.

MEDICATION

VISIT 0

MED_02

		_	
Data	1	No Data	
Data		INO Data	

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

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



EFC10547	
----------	--

Х	4							
Сс	un	try	Center		Sι	ıbje	ect	

10.2	
Page	No.

0	
Repeat	No.

ISIT 0		

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



Х	4							
Country		С	Center		Sι	ıbje	ect	

10.3	
Page	No.

0	
Repeat	No.

VISIT 0

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

XXX				
sanofi aventis				
L'essentiel c'est la santé.				

MEDICATION

Х	4							
Co	un	try	С	ent	er	Sι	ıbje	ect

11.1	
Page	No.

0	
Repeat	No.

Visit Name:

PRIOR

VISIT 0

MED_01

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

Data ✓ No Data 🗌			
Drug/Medication (brand or generic name)	Start Date (dd-mmm-yyyy)	End Date (dd-mmm-yyyy)	Or tick if Ongoing

sanofi aventis Uessentiel C'est la santé.	EFC10547 Visit Name: VIS		Country Center Subject	Page No. Repeat No.
Drug/Medication	VISITIVATILE. VIS	Start Date	End Date	Or tick if Ongoing
(brand or generic name)	ſ	(dd-mmm-yyyy)	(dd-mmm-yyyy)	П
	l			
	[
	[
	[
	[
	[
	[
				_

XX	EFC10547]	X 4		11.3	0
Sanofi aventis L'essentiel c'est la santé.	Visit Name: VIS		Country Center S	ubject	Page No.	Repeat No.
Drug/Medication (brand or generic name)	VIO	Start Date (dd-mmm-yyyy)		End Date (dd-mmm-yyyy)	Or tick if Ongo	bing
	С					
	С					
	_				_	



EFC10547

	un	trv	\vdash	ent	احا	ıbic	L_
Х	4						

12.1	
Page	No.

0	
Repeat	No.

VISIT 0

VITAL SIGNS

VITAL_01

PHYSICAL EXAMINATION AND PRE-EXISTING SIGNS AND SYMPTOMS AT BASELINE

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

Data ☑ No Data ☐				
	TO BE PERFORMED WITHIN	8 DAYS PR	IOR TO RANDOMIZA	TION
Date performed: (DD-MMM-1)	YYYY)			
Height:	cm	Weight:		kg
Blood pressure: Systolic:	mmHg	/ Diastolic:		mmH
ECOG Performance Status 0	1 2 3 4			



EFC10547

Х	4					Ļ	L	
Country		С	ent	er	Sι	ıbie	ect	

13.1	
Page	No.

0 Repeat No.

Visit Name:

VISIT 0

ELECTROCARDIOGRAM

ECG_01

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

Data ✓ No Data 🗌
Date performed (DD-MMM-YYYY)
Normal

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

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



EFC10547		X 4			14.1	0	!
		Country	Center	Subject	Page No.	Repeat No.	
Visit Name:	VISIT 0						

LAB_01 **HEMATOLOGY** Data ✓ No Data TO BE PERFORMED WITHIN 8 DAYS PRIOR TO RANDOMIZATION. TO BE REPEATED IF MORE THAN 8 DAYS BEFORE FIRST INFUSION Date of sampling (dd-mmm-yyyy) Unit SI Ranges If other unit, specify **Upper Limit** Test Value SI Value SI Unit Lower Limit HEMOGLOBIN G/L 10E9/L PLATELET COUNT (THROMBO WBC 10E9/L NEUTROPHILS 10E9/L TO BE PERFORMED ONLY FOR PATIENT UNDER VITAMIN K ANTAGONIST RATIO INR



\triangle	un	Ш •».	_	ent	 <u>ر</u>	المار	L
Х	4						

15.1	l
Page No.	•

0	
Repeat	No.

VISIT 0

BIOCHEMISTRY

Data ☑ No Data ☐

LAB_01

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

Name Address		
City Country		
Name [For Technical use :	
Address		
City Country		



EFC10547	Х	4							
	Сс	un	try	С	ent	er	Sı	ıbje	ect

15.2	0
Page No.	Repeat No.

Visit Name:	VISIT 0
-------------	---------

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

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



EFC10547	
EFC10547	

Χ	4							
Country			С	ent	er	Sι	ıbje	ect

16.1	
Page	No.

0	
Repeat	No.

VISIT 0

DIPSTICK URINALYSIS	BHCG TEST H	AS TO BI	E PERFO	RMED WITH	HIN 8 DAYS BEFORE RANDOMIZATION	LABU_1		
Data ✓ No Data □	TO BE PERFORMED WITHIN 8 DAYS PRIOR TO RANDOMIZATION. TO BE REPEATED IF MORE THAN 8 DAYS BEFORE FIRST INFUSION.							
Date of sampling								
Test name								
WHITE BLOOD CELLS (QT	Absent	+	++	+++	☐ Not evaluable			
RED BLOOD CELLS (QUAI	☐ Absent	□ +	□ ++	_ +++	☐ Not evaluable			



Х	4							
Co	un	try	С	ent	er	Sι	ıbje	ect

17.1	
Page No.	

0	
Repeat	No.

VISIT 0

MORNING SPOT URINALYSIS

LAB_01

TO BE PERFORMED WITHIN 8 DAYS PRIOR TO RANDOMIZATION. TO BE REPEATED IF MORE THAN 8 DAYS BEFORE FIRST INFUSION. Data ☑ No Data ☐

Name Address						
City Country						
		For Technical	l use :			
Name Address						
City Country						
Date of sampling	(dd-mmm-yy)	уу)				
		Unit			SI Ra	nges
Test	Value	If other unit, specify	SI Value	SI Unit	Lower Limit	Upper Limit
PROTEIN (URINE)		MG/DL] [
CREATININE (URINE)		MG/DL] [



Х	_					Ļ	Ļ	
Co	un	try	С	ent	er	Sι	ıbje	ect

18.1	
Page	No.

0	
Repeat No.	

VISIT 0

24-HOUR URINALYSIS Data ☑ No Data □		HIN 8 DAYS PRIOR TO RAND RE THAN 8 DAYS BEFORE FI	
Name Address			
City Country			
Name Address	For Technical use :		
City Country			
Date (dd-mmm- Start date of collection: End date of collection:	Start Time of collection : End Time of collection :	(24-hour clock)	
Test Value	Unit	SI Value SI Unit	SI RANGES Lower limit Upper Limit
URINARY VOLUME	L		
PROTEIN (URINE)	G/L		
CREATININE (URIN	G/L		

ANA
sanofi aventis
L'essentiel c'est la santé.

Χ	4							
Country		С	Center		Sι	ıbje	ect	

18.2	
Page	No.

0 Repeat No.

Visit Name:

VISIT 0

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

LABU_1

Data ✓ No Data 🗌

RED BLOOD CELLS (QUAI



\triangle	un	Ш •».	_	ent	 <u>ر</u>	المار	L
Х	4						

19.1	
Page	No.

0 Repeat No.

Visit Name:

VISIT 0

TUMOR MARKERS
TMARK_01

TO BE PERFORMED WITHIN 21 DAYS PRIOR TO RANDOMIZATION

Data 🗹 No Data 🗌	
Date of evaluation	
	(dd-mmm-yyyy)

TEST	VALUE	UNIT	NORMAL RANGE		
			LOWER LIMIT	UPPER LIMIT	
CA19-9					1



EFC10547	
----------	--

Х	4							
Country		С	Center		Sι	ıbje	ect	

20.1	
Page	No.

0	
Repeat	No.

VISIT 0

TUMOR EVALUATION (AT BASELINE) TO BE PERFORMED WITHIN 21 DAYS PRIOR TO RANDOMIZATION. Data No Data						
Lesion location	Method of tumor measurement	Date (dd-mmm-yyyy)	Normal	If Abnormal, specify:		
	If Other, specify:			Tumor related :		
	If Other, specify:			Tumor related :		
	If Other, specify:			Tumor related		
	If Other, specify:			Tumor related :		
	If Other, specify:			Tumor related :		
	If Other, specify:			Tumor related :		
	If Other, specify:			Tumor related :		
	If Other, specify:			Tumor related :		
	If Other, specify:			Tumor related :		
	If Other, specify:			Tumor related		

Confidential Information

AVE0005 - EFC10547 (VANILLA)

Final Version: 24OCT2007

XXX				
sanofi aventis				
L'assantial c'ass la canté				

Х	4								
Сс	un	try	С	ent	er	Sι	ıbje	ect	

20.2	
Page	No.

0	
Repeat	No.

VISIT 0
VISIT 0

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



Х	4							
Со	un	try	Center		Sι	ıbje	ect	

21.1	
Page No.	

0	
Repeat	No.

VISIT 0

TUMOR MEASUREMENT (A	T BASELINE)			TUMEA_01
Data ☑ No Data ☐				
Lesion Lesion location Number	Lesion description (Subsite)	Date of Assessment (dd-mmm-yyyy)	Method of tumor measurement	Measurement of Non target lesion: Target longest diameter
				mm
				mm
		_		mm
		_] mm
				mm
	<u> </u>] mm
		_		mm
]			mm
	<u> </u>			mm
	٦] mm

Confidential Information



EFC10547	
----------	--

Χ	4							
Сс	un	try	Center		Sι	ıbje	ect	

21.2	
Page	No.

0	
Repeat	No.

ISIT 0		

Lesion Number	Lesion location	Lesion description (Subsite)	Date of Assessment (dd-mmm-yyyy)	Method of tumor measurement	Measurement of Non target lesion: Target longest diameter
]			mm
]			mm
]			mm
]			mm
]			mm
]			mm
]			mm
]			mm
]			mm
]			mm

Confidential Information

AVE0005 - EFC10547 (VANILLA)

Final Version: 24OCT2007

XXX
sanofi aventis
L'essentiel c'est la santé.

EFC10547

Χ	4							
Country		Center		Sι	ıbje	ect		

500.1 Page No.

Repeat No.

Visit Name:

VISIT 0

ELIGIBILITY FOR RANDOMIZATION

ELIG_01

_	
Data ✓ No Data ☐	
Will the subject continue in the randomization of the study ? Yes No	
Does the subject satisfy all inclusion/exclusion criteria ? Yes \[\] No \[\]	
If No, please specify the main criteria not met	
Inclusion criterion number	
Exclusion criterion number	
Are there other reasons why the subject cannot continue? Yes No	_
If Yes, (tick all that apply)	
Serious Adverse Event*	
Lost to Follow-up	
Subject did not wish to continue	
Other Reason If other reason, specify	

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



EFC10547	
----------	--

Χ	4							
Country		С	Center		Sι	ıbje	ect	

600.1 Page No.

Repeat No.

Visit Name:

VISIT 0 AE

ADVERSE EVENT Data No Data 1. Adverse Event (Diagnosis):		AE Form Number AE_03 AE Reference ID
2. Status of Adverse Event	New Date of Start	(dd-mmm-yyyy)
	Ongoing without change (do not complete the Ongoing with change	e remaining items)
3. Grade	1	
4. Relationship to investigational product *	Yes No No	
5. Action Taken with Investigat. Product	None Permanently discontinued Delayed Delayed	ose reduced Delayed and reduced Interrupted
6. Corrective treatment/therapy	Yes No No	
7. Outcome	Recovered Date of Recovery	
	Recovered with sequelae Specify:	(dd-mmm-yyyy)
	Recovering	
	Not recovered	
	Fatal Date of Death	(complete the death report form)
	Unknown	(dd-mmm-yyyy)
8. Seriousness Criteria	Yes No If Yes : -Date event became s	erious (dd-mmm-yyyy)
IF YES, COMPLETE THIS SECTION AND	-Tick below all criteria	
THE SAFETY COMPLEMENTARY FORM	Results in Death Life Threatening	Persistant/significant disability/incapacity Congenital anomaly or Birth Defect
9. Is it an event such as:	Requires or prolongs hospitalization	Other medically important event
Overdose of the IP	Yes No No	
Pregnancy	Yes No No	
*Is there a rea	sonable possibility that the AE was caused by Investigation	stigational Product?

Confidential Information



EFC10547

Х	4							
Country		С	ent	er	Sι	ıbje	ect	

600.2	
Page	No.

Visit Name:

VISIT 0 AE

AE / Specific Event Form Number	
1. Demographic Information Weight (kg)	
2. Detailed Description of the Adverse Event (including complementary investigations)	
3. Date of Start of Event (Initial date of onset of the considered event) (DD-MMM-YYYY)	
4. Investigational Products	
Date of the FIRST administration of study treatment : (DD-MMM-YYYY)	
Current Treatment number : Current Cycle :	
Date of the LAST administration before SAE: (dd-mmm-yyyy) Last Dosage before SAE: Action Ta	aken :
AFLIBERCEPT/PLACEBO MG/KG	
GEMCITABINE MG/M2	
5. In case of hospitalization Date of admission (DD-MMM-YYYY) (hospital report to be sent)	
6. In case of death Autopsy report Yes No (copy to be sent)	
7. Corrective Treatment / Therapy	

Confidential Information

sanofi aventis	EFC10547	X 4 Country Center Subject	22.1 0 Repeat No.
L'essentiel c'est la santé.	Visit Name: VISIT 1		
Date of visit :	(DD-MMM-YYYY)		

 VITAL SIGNS

 Data ☑ No Data ☐

 DAY 1

 Not Applicable if already done within 8 days prior to inclusion

 Date performed ☐

 (dd-mmm-yyyy)

 Weight: ☐
 kg

 Blood pressure: Systolic: ☐
 mmHg

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

A PHYSICAL EXAMINATION SHOULD BE PERFORMED.

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

Confidential Information

VISIT_01



EFC10547	
----------	--

Х	4							
Country			С	ent	er	Sι	ıbje	ect

23.1	
Page No.	

0	
Repeat	No.

VISIT 1

HEMATOLOGY							LAB_01
Data ☑ No Data ☐	Not applicable i	f already done within 8 day	s prior to infusi	on.			
DAY 1							
Date of sampling	(dd-mmm-yyyy)						
		Unit			SI Ran	ges	
Test	Value	If other unit, specify	SI Value	SI Unit	Lower Limit	Upper Limit	
HEMOGLOBIN		G/L					
PLATELET COUNT (THROMBO		10E9/L					
WBC		10E9/L					
NEUTROPHILS		10E9/L					
Т	O BE PERFO	RMED ONLY FOR PA	ATIENT UND	ER VITAM	IN K ANTAGO	ONIST	
INR		RATIO					



EFC10547	
----------	--

Х	4							
Country			С	ent	er	Sι	ıbje	ect

24.1	
Page	No.

Visit Name:

VISIT 1

LAB_01

BIOCHEMIS	STRY
Data 🗹 No Data	Not applicable if already done within 8 days prior to infusion.
DAY 1	
Please ir	ndicate if the laboratory is the : Same as baseline Same as previous
Name [
Address	
City	
Country [
	For Technical use :
Name [
Address	
City	
Country [



|--|

Х	4							
Country			С	ent	er	Sı	ıbje	ect

24.2	
Page	No.

0	
Repeat	No.

VISIT 1

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

^{*} If creatinine > 1 ULN please report the calculated creatinine clearance.
** If blood Urea Nitrogen is not evaluable, Urea value must be documented.



EFC10547

Х	4							
Country		С	ent	er	Sι	ıbje	ect	

25.1	
Page	No.

Visit Name:

VISIT 1

DIPSTICK URINALYSIS	DΙ	PS ₁	ΓICK	URI	NAL	YSIS
---------------------	----	-----------------	------	------------	-----	------

LABU_1

Data ✓ No Data 🗌	Not applicable if already done within 8 days prior to infusion.				
DAY 1					
Date of sampling					
Test name					
WHITE BLOOD CELLS (Q	Absent	_ +	-++	_ +++	■ Not evaluable
RED BLOOD CELLS (QUAI	☐ Absent	□ +	++	+++	☐ Not evaluable



EFC10547

Χ	4							
Country		С	Center			ıbje	ect	

26.1	
Page	No.

Visit Name:

VISIT 1

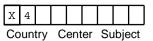
MG/DL

LAB_01 **MORNING SPOT URINALYSIS** Data ✓ No Data 🗌 Not applicable if already done within 8 days prior to infusion. DAY 1 Please indicate if the laboratory is the : Same as baseline Same as previous Name Address City Country For Technical use: Name Address City Country Date of sampling (dd-mmm-yyyy) Unit SI Ranges Test Value If other unit, specify SI Value SI Unit Lower Limit Upper Limit PROTEIN (URINE) MG/DL

CREATININE (URINE)



EFC10547	
EFC10547	



970.01.1 Page No.

Repeat No.

Visit Name:

VISIT 1

PHARMACOKINETIC BLOOD

PK_01

Data ☑ No Data ☐

TO BE COMPLETED FOR ALL PATIENTS

FREE AND BOUND AFLIBERCEPT

DAY 1

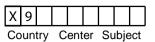
Sample ID P00

Theoretical Time TOH

Sample Date (dd-mmm-yyyy)

Sample Time 24-hour clock





1001.01.1 Page No.

0 Repeat No.

Visit Name:

VISIT 1

PHARMACOKINETIC BLOOD

PK_01

	AND BOUND AFI IBERCEPT	_
IFKFF	ANI) KOUNI) AFI IKEKEEPI	

DAY 1

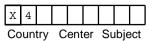
Data ✓ No Data 🗌

Sample ID P00 Theoretical Time Sample Date (dd-mmm-yyyy)

24-hour clock

Sample Time





970.02.1 Page No.

Repeat No.

Visit Name:

VISIT 1

PHARMACOKINETIC BLOOD

PK_01

TO BE COMPL	ETED FOR	AL L	PATIENTS

ANTI-AFLIBERCEPT ANTIBODIES

DAY 1

Data ✓ No Data 🗌

Sample ID

Theoretical
Time

Sample Date (dd-mmm-yyyy)

Sample Time (24-hour clock)

TOTAL
sanofi aventis
L'essentiel c'est la santé.

EFC10547	X 9						
	Country	y	Cent	er	Sı	ıbje	ect

1001.02.1 Page No.

0 Repeat No.

Visit Name:

VISIT 1

PHARMACOKINETIC BLOOD

PK_01

Data ✓ No Data	
ANTI-AFLIBERCEPT	ANTIBODIES
DAY 1	

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



EFC10547

Х	4					Ļ	L	
Country		С	ent	er	Sι	ıbie	ect	

971.01.1
Page No.

0	
Repeat	No.

VISIT 1

PHARMACOKINETIC BLOOD

PK_01

Data ✓ No Data 🗌	TO BE COMPLETED ONLY FOR PK PATIENTS
------------------	--------------------------------------

ENDOGENEOUS	VEGF
DAY 1	

Sample ID
L00

Theoretical	
Time	
тон	,

Date
(dd-mmm-yyyy)

Time	
24-hour clock	

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

Confidential Information

TOTA
sanofi aventis
L'essentiel c'est la santé.

EFC10547	X 9							
	Coun	try	С	ent	er	Sı	ıbje	ect

1001.03.1 Page No.

Repeat No.

Visit Name:

VISIT 1

PHARMACOKINETIC BLOOD

PK_01

Data No Data ENDOGENEOUS VEGF

DAY 1

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

TOTAL
sanofi aventis
L'essentiel c'est la santé.

\sim	un	L	$\overline{}$	004	 ٣.	ıbie	
Χ	4						

971.02.1 Page No.

0 Repeat No.

Visit Name:

VISIT 1

PHARMACOKINETIC BLOOD

PK_01

Data ✓	No Data	
--------	---------	--

TO BE COMPLETED ONLY FOR PK PATIENTS.

FREE AND BOUND AFLIBERCEPT

DAY 1

Sample ID

Theoretical Time

Sample Date (dd-mmm-yyyy)

Sample Time 24-hour clock

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

XXX
sanofi aventis
L'essentiel c'est la santé.

|--|

Χ	9							
Country		С	ent	er	Sι	ıbje	ect	

1001.04.1 Page No.

0 Repeat No.

Visit Name:

VISIT 1

PHARMACOKINETIC BLOOD

PK_01

Amendment 1: 05SEP2008

FREE AND BOUND AFLIBERCEPT

DAY 1

Data ✓ No Data 🗌

Sample ID P01 Theoretical Time

Sample Date (dd-mmm-yyyy)

Sample Time 24-hour clock

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



Х	4							
Co	un	trv	С	ent	er	Sι	ıbie	ect

27.1 Page No.

0 Repeat No.

Visit Name:

VISIT 1

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_05

Data ☑ No Data ☐					
AFLIBERCEPT/PLAG	CEBO				
Scheduled	Treatment Number	Not Administered/	Date / Time	Intended Dose	Actual Dose
Day		Taken	START	MG/KG	MG
DAY 1			(dd-mmm-yyyy)		
			(24-hour clock)		
			END		
			(24-hour clock)		

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

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

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



EF(C10)547	
EF(ر 10)547	

Х	5							
Country		С	Center			Subject		

28.1	l
Page No.	•

)		
Repeat	No.	

VISIT 1

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_04

Data ☑ No Data ☐					
GEMCITABINE					
Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose MG/M2	Actual Dose
DAY 1					
IF DOSE INTERRU	PTED AND READ	MINISTERED, PI	LEASE REPORT	THE INFORMATION	ON BELOW:
Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose MG/M2	Actual Dose
(*)				NOT APPLICABLE	

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

Confidential Information



EFC10547	
----------	--

Χ	4							
Country		С	ent	er	Sι	ıbje	ect	

29.1	
Page	No.

Visit Name:

VISIT 1

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☑ No Data ☐

DAY 1

Outpatient Clinic Inpatient Clinic



EF(C10)547	
EF(ر 10)547	

Χ	4							
Country		С	ent	er	Sι	ıbje	ect	

30.1	
Page	No.

Visit Name:

VISIT 1

VITAL SIGNS

Data ☑ No Data ☐

DAY 8

Date performed (dd-mmm-yyyy)

Blood pressure: Systolic: mmHg

/ Diastolic: mmHg

ECOG Performance Status 0 1 1 2 3 4 1



Χ	4					Ļ		
Country			С	ent	er	Sι	ıbie	ect

31.1	
Page	No.

0	
Repeat	No.

VISIT 1

10E9/L

LAB_01 **HEMATOLOGY** Data ✓ No Data 🗌 DAY 8 Date of sampling (dd-mmm-yyyy) SI Ranges Unit Test Value If other unit, specify SI Value SI Unit Lower Limit Upper Limit G/L HEMOGLOBIN PLATELET COUNT (THROMBO 10E9/L WBC 10E9/L

Confidential Information

NEUTROPHILS



EFC10547

Χ	5							
Country		С	ent	er	Sι	ıbje	ect	

32.1	
Page	No.

Visit Name:

VISIT 1

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_04

Data ✓ No Data ☐ GEMCITABINE					
Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose	Actual Dose
DAY 8					
IF DOSE INTERRU	JPTED AND REA	ADMINISTERED, PI	LEASE REPORT	THE INFORMATION	ON BELOW:
Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose MG/M2	Actual Dose
(*)				NOT APPLICABLE	v

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



Χ	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

33.1	
Page	No.

Visit Name:

VISIT 1

SETTI_01

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

Data ☑ No Data ☐

DAY 8

Outpatient Clinic Inpatient Clinic



X	4			Sı	
Х	4				

34.1	
Page	No.

Visit Name:

VISIT 1

VITAL SIGNS

DAY 15

Data ✓ No Data 🗌

Date performed (dd-mmm-yyyy)

Weight: kg

Blood pressure: Systolic: mmHg / Diastolic: mmHg

ECOG Performance Status 0 1 1 2 3 4



EFC10547	

Χ	4							
Cc	un	try	С	ent	er	Sι	ıbje	ect

35.1	ſ
Page No.	

0	
Repeat No.	

VISIT 1

10E9/L

LAB_01 **HEMATOLOGY** Data ✓ No Data 🗌 DAY 15 Date of sampling (dd-mmm-yyyy) SI Ranges Unit Test Value If other unit, specify SI Value SI Unit Lower Limit Upper Limit G/L HEMOGLOBIN PLATELET COUNT (THROMBO 10E9/L WBC 10E9/L

NEUTROPHILS



Χ	4							
Сс	un	trv	С	ent	er	Sι	ıbie	ect

36.1	
Page	No.

Visit Name:

VISIT 1

DIPSTICK URINALYSIS

LABU_1

Data ☑ No Data ☐

DAY 15

Date of sampling

Test name

WHITE BLOOD CELLS (QI

☐ Absent

RED BLOOD CELLS (QUAI

☐ Absent

_ ++

☐ Not evaluable



EFC10547

Х	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

37.1	
Page	No.

Visit Name:

VISIT 1

LAB_01

MORNING SP	OT URINALYSIS						LAB_01
Data ✓ No Data 🗆]						
DAY 15							
	Please indicate if the lab	oratory is the: Same as b					
		Same as p	revious				
Name							
Address							
City							
Country							
		For Technical	use .				
Name						_	
Address						=	
Addicss							
City						- 	
Country						- 	
Date of sampling	(dd-mmm-yyy	y)					
		Unit			SI Rar	nges	
Test	Value	If other unit, specify	SI Value	SI Unit	Lower Limit	Upper Limit	
PROTEIN (URIN	Ε)	MG/DL					
CREATININE (U	RINE)	MG/DL					



Χ	4							
Cc	un	try	С	ent	er	Sι	ıbje	ect

972.1 Page No.

Repeat No.

Visit Name: VISIT 1

PHARMACOKINETIC BLOOD

PK_01

TO BE	COMPL	ETED	ONLY	FOR	PK	PATIENTS.

FREE AND BOUND AFLIBERCEPT

DAY 15

Data ✓ No Data

Sample ID P02

Theoretical Time TOH

Sample Date (dd-mmm-yyyy)

Sample Time 24-hour clock



EFC10547

Χ	4							
Country			С	ent	er	Sι	ıbie	ect

38.1	
Page No.	•

0	
Repeat	No.

VISIT 1

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_05

Data ✓ No Data 🗌					
AFLIBERCEPT/PLACEBO)				
Scheduled	Treatment Number	Not Administered/	Date / Time*	Intended Dose	Actual Dose
Day		Taken	START	MG/KG	MG
DAY 15			(dd-mmm-yyyy)		
			(24-hour clock)		
			END		
	*Time to be	given only for PK patients	(24-hour clock)		

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

Treatment Number	Not Administered/	Date / Time*	Intended Dose	Actual Dose
	raken	START	MG/KG	MG
			NOT APPLICABLE	
		(dd-mmm-yyyy)		
		(24-hour clock)		
		END		
*Time to be	given only for PK patients	(24-hour clock)		
		Treatment Number Not Administered/ Taken	Taken START (dd-mmm-yyyy) (24-hour clock) END *Time to be given only for PK patients	Taken START MG/KG NOT APPLICABLE (dd-mmm-yyyy) (24-hour clock) END *Time to be given only for PK patients

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



EFC10547

Co		450.1	_	ont	Sι	hic	<u></u>
Х	5						

39.1		
Page	No.	

Visit Name:

VISIT 1

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_04

Data ☑ No Data ☐					
GEMCITABINE					
Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose	Actual Dose
DAY 15					
IF DOSE INTERR	UPTED AND RE	ADMINISTERED, PL	LEASE REPORT	THE INFORMATION	ON BELOW:
Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose	Actual Dose
(*)				NOT APPLICABLE	

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



EF(C10)547	
EF(ر 10)547	

Χ	4							
Cc	un	try	С	ent	er	Sι	ıbje	ect

40.1	
Page	No.

Visit Name:

VISIT 1

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☑ No Data ☐

DAY 15

Outpatient Clinic Inpatient Clinic



EEC10547	
EFC10547	

X 4	ㅗ	<u>_</u>	Ĺ	Ļ	L_I
Country	$C_{\Delta i}$	nter	Si	ıhic	∆C†

41.1	
Page No.	

Visit Name:

VISIT 1

VITAL_02 **VITAL SIGNS**

Data ✓ No Data 🗌

DAY 22

Date performed (dd-mmm-yyyy)

Blood pressure: Systolic:

mmHg

/ Diastolic:

mmHg

ECOG Performance Status 0 1 2 3 4 1



Х	4							
Country		Center			Subject			

42.1	
Page	No.

0	
Repeat No).

VISIT 1

10E9/L

HEMATOLOGY							LAB_01
Data ☑ No Data ☐							
DAY 22							
Date of sampling	(dd-mmm-	уууу)					
		Unit	SI Ranges				
Test	Value	If other unit, specify	SI Value	SI Unit	Lower Limit	Upper Limit	
HEMOGLOBIN		G/L					
PLATELET COUNT (TH	ROMB(10E9/L					
WBC		10E9/L					

NEUTROPHILS



EFC10547

Χ	5							
Country			С	ent	er	Sι	ıbje	ect

43.1	
Page	No.

0	
Repeat	No.

VISIT 1

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_04

Data ☑ No Data ☐					
GEMCITABINE					
Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose	Actual Dose
DAY 22					
IF DOSE INTERR	UPTED AND RE	EADMINISTERED, PL	EASE REPORT	THE INFORMATION	ON BELOW:
Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose	Actual Dose
(*)				NOT APPLICABLE	

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



EFC10547

X 4	ㅗ	<u>_</u>	Ĺ	Ļ	L_
Country	$C_{\Delta i}$	nter	Si	ıhic	∆C†

44.1	
Page	No.

0	
Repeat	No.

VISIT 1

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☑ No Data ☐

DAY 22

Outpatient Clinic Inpatient Clinic

ACT
sanofi aventis
L'essentiel c'est la santé.

EFC10547	

Χ	4					Ļ		
Country			С	ent	er	Sι	ıbje	ect

45.1	
Page	No.

0	
Repeat	No.

VISIT 1

PAIN INTENSITY

ASSESSED VIA VISUAL ANALOG SCALE

Data ✓ No Data 🗌

Data corresponding to current cycle

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

Confidential Information

AVE0005 - EFC10547 (VANILLA)

TOTAL
sanofi aventis
L'essentiel c'est la santé.

Χ	4							
Country		С	ent	er	Sι	ıbje	ect	

45.2	
Page	No.

Visit Name:

VISIT 1

Period	Date	Measure
DAY 22		
DAY 23		
DAY 24		
DAY 25		
DAY 26		
DAY 27		
DAY 28		
DAY 29		
DAY 30		
DAY 31		
DAY 32		
DAY 33		
DAY 34		
DAY 35		
DAY 36		
DAY 37		
DAY 38		
DAY 39		
DAY 40		
DAY 41		
DVA 43		\vdash

XXX
sanofi aventis
L'essentiel c'est la santé.

Χ	4							
Country		С	Center		Subject			

46.1	l
Page No.	

0	
Repeat	No.

MEDICATION	ANALGESIC	MED_02

Data ☑ No Data ☐

ANALGESIC MEDICATION SHOULD BE COLLECTED DAILY PRIOR TO THE NEXT INFUSION

VISIT 1

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

XXX
sanofi aventis
L'essentiel c'est la santé.

EFC10547

VISIT 1

Х	4							
Cc	un	try	С	ent	er	Sι	ıbje	ect

46.2	ı
Page No.	_

0	
Repeat	No.

Visit Name:

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

XXX
sanofi aventis
L'essentiel c'est la santé.

EFC10547

Χ	4							
Co	un	try	С	ent	er	Sι	ıbje	ect

46.3	
Page	No.

0	
Repeat	No.

VISIT 1

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



Χ	4							
Country		С	ent	er	Sι	ıbje	ect	

47.1	
Page	No.

0	
Repeat	No.

VISIT 1

TUMOR	RMEASUREMENTS					TUMEA_02
Data ✓ N	lo Data 🗌					
Lesion Number	Lesion Location	Date of Assessment (dd-mmm-yyyy)	Method of Tumor Measurement	Measurement of Target Lesion longest diameter	Response of Non target Lesions	
] mm		
		Not Done		mm		
		☐ Not Done		mm		
		☐ Not Done		mm		
		Not Done		mm		
		☐ Not Done] mm		
		☐ Not Done		mm		
		Not Done] mm		
		Not Done				
		Not Done]		
		☐ Not Done		ı		



EFC10547

Χ	4							
Country		С	ent	er	Sι	ıbje	ect	

47.2 Page No.

0 Repeat No.

Visit Name:

VISIT 1

Lesion Number	Lesion Location	Date of Assessment (dd-mmm-yyyy)	Method of Tumor Measurement	Measurement of Target Lesion longest diameter	Response of Non target Lesions
		Not Done		mr	m 🔲
				mr	m
		Not Done		mr	m
		☐ Not Done		mr	m
		☐ Not Done		mr	m
		☐ Not Done		mr	m
		☐ Not Done		mr	n
		☐ Not Done		mr	m [
		☐ Not Done			
		Not Done		"""	"
		Not Done		mr	m



Χ	4							
Co	un	try	С	ent	er	Sι	ıbje	ect

48.1	
Page	No.

Visit Name:

VISIT 1

TUMOR MARKERS

TMARK_01

Data	✓	No Data	
------	---	---------	--

Date of evaluation

(dd-mmm-yyyy)

TEST VALUE UNIT NORMAL RANGE
LOWER LIMIT UPPER LIMIT

CA19-9



X	_		_			Ļ		Ļ
Country			Center			Subject		

49.1	
Page	No.

Visit Name:

VISIT 1

CLINICAL EVENT THROMBOVASCULAR

Data ✓ No Data ☐	Yes	No
ANGINA PECTORIS / UNSTABLE ANGINA / MYOCARDIAL INFARCTION		
STROKE / TRANSIENT ISCHEMIC ATTACK		
PERIPHERAL ARTERIAL THROMBOSIS		
DEEP VENOUS THROMBOSIS		
PULMONARY EMBOLISM		
INTRAABDOMINAL ARTERIAL THROMBOSIS		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		



EFC10547

Χ	4							
Country		С	Center			ıbje	ect	

601.1 Page No.

0 Repeat No.

Visit Name:

VISIT 1 AE

ADVERSE EVENT Data No Data 1. Adverse Event (Diagnosis):	AE Form Number AE_03 AE Reference ID
2. Status of Adverse Event	New Date of Start (dd-mmm-yyyy) Ongoing without change (do not complete the remaining items) Ongoing with change
3. Grade4. Relationship to investigational product *	1
5. Action Taken with Investigat. Product	None Permanently discontinued Delayed Dose reduced Delayed and reduced Interrupted
6. Corrective treatment/therapy	Yes
7. Outcome	Recovered Date of Recovery
	Recovered with sequelae Specify :
	Recovering
	Not recovered
	Fatal Date of Death (complete the death report form) Unknown
8. Seriousness Criteria	Yes No If Yes : -Date event became serious
IF YES, COMPLETE THIS SECTION AND	-Tick below all criteria that apply :
THE SAFETY COMPLEMENTARY FORM	Results in Death Persistant/significant disability/incapacity Congenital anomaly or Birth Defect Other medically important event
9. Is it an event such as:	
Overdose of the IP	Yes No No
Pregnancy	Yes No No
*Is there a rea	sonable possibility that the AE was caused by Investigational Product?



Χ	4							
Country			С	Center			ıbje	ect

601.2 Page No.

0 Repeat No.

Visit Name:

VISIT 1 AE

AE / Specific Event Form Number	
1. Demographic Information Weight (kg)	
2. Detailed Description of the Adverse Event (including complementary investigations)	
3. Date of Start of Event (Initial date of onset of the considered event) (DD-MMM-YYYY)	
4. Investigational Products	
Date of the FIRST administration of study treatment : (DD-MMM-YYYY)	
Current Treatment number : Current Cycle :	
Date of the LAST administration before SAE: (dd-mmm-yyyy) Last Dosage before SAE: Action Ta	aken :
AFLIBERCEPT/PLACEBO MG/KG	
GEMCITABINE MG/M2	
5. In case of hospitalization Date of admission (DD-MMM-YYYY) (hospital report to be sent)	
6. In case of death Autopsy report Yes No (copy to be sent)	
7. Corrective Treatment / Therapy	



INR

EFC10547	
----------	--

Χ	4							
Co	un	try	С	ent	er	Sι	ıbje	ect

701.01.1	
Page No.	

0		l
Repeat	No.	

Visit Name:

VISIT 1 LAB

RATIO

ADDITIONAL HEMATO	LOGY						LAB_01
Data ☑ No Data ☐							
Date of sampling	(dd-mmm-yyyy)					
		Unit			SI Rar	nges	
Test	Value	If other unit, specify	SI Value	SI Unit	Lower Limit	Upper Limit	
HEMOGLOBIN		G/L					
PLATELET COUNT (THROMBO		10E9/L					
WBC		10E9/L					
NEUTROPHILS		10E9/L					
Т	O BE PERF	ORMED ONLY FOR P	ATIENT UND	ER VITAN	IIN K ANTAG	ONIST	



EFC10547	
----------	--

Х	4							
Co	un	try	С	ent	er	Sι	ıbje	ect

701.02.1
Page No.

Visit Name:

VISIT 1 LAB

ADDITIONAL BIOCHEMISTRY

LAB_01

Data ✓ No Data	a 🗌	
Please ir	ndicate if the laboratory is the : Same as baseline Same as previous	
Name [Address		
City Country		
	For Technical use :	
Name Address		
City Country		



EF(C10)547	
EF(ر 10)547	

Х	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

701.02.2
Page No.

0	
Repeat	No.

VISIT 1 LAB

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

^{*} If creatinine > 1 ULN please report the calculated creatinine clearance.
** If blood Urea Nitrogen is not evaluable, Urea value must be documented.



EFC10547

Χ	4							
Country		С	ent	er	Sι	ıbje	ect	

701.03.1
Page No.

Visit Name:

VISIT 1 LAB

ADDITIONAL DIPSTICK URINALYSIS

LABU_1

Data ✓ No Data 🗌					
Date of sampling					
Test name					
WHITE BLOOD CELLS (QI	Absent	+		+++	□ Not evaluable
RED BLOOD CELLS (QUAI	☐ Absent	□ +	□ ++	□ +++	☐ Not evaluable



EFC10547	
----------	--

Х	4							
Country		Center			Sι	ıbje	ect	

701.04.1
Page No.

Visit Name:

VISIT 1 LAB

ADDITIONAL MORNING SPOT URINALYSIS

LAB_01

Data ✓ No Data							
	Please indi	cate if the lab	oratory is the : Same as	baseline previous			
Name Address							
City Country							
			For Technic	al use :			
Name Address							
City Country							
Date of sampling		(dd-mmm-yyy	y)				
			Unit			SI Rai	nges
Test		Value	If other unit, specify	SI Value	SI Unit	Lower Limit	Upper Limit
PROTEIN (UR	INE)		MG/DL				
CREATININE	(URINE)		MG/DL			1	



EFC10547	
----------	--

Χ	4							
Country			С	Center			ıbje	ect

701.05.1 Page No.

0 Repeat No.

Visit Name:

VISIT 1 LAB

24-HOUR URIN Data ✓ No Data ☐	LYSIS		TO BE COMPL	ETED IF UP	CR > 1				LAB_04
Please indicate if the la	aboratory is th	eSame as baselir Same as previou							
Name Address									
City Country									
		For T	echnical use :						
Name Address									
City Country									
	Date (dd-mmn			(24-hour clock	r)				
Start date of collection:			e of collection :				0.5		
End date of collection:			of collection :					ANGES	
Test	Value	Unit			SI Value	SI Unit	Lower lin	nit Upper Limit	1
URINARY VOLUME		L L					_	_	
PROTEIN (URINE)		G/L				┩┝──		_	
CREATININE (URIN		G/L							j
	ELE	CTROPHORES	SIS						
ALBUMIN		G/L					1]
ALPHA 1 GLOBULIN		G/L				1 T	1		1
ALPHA 2 GLOBULIN		G/L							
BETA GLOBULIN		G/L							<u> </u>
GAMMA GLOBULIN		G/L							

TOTA
sanofi aventis
L'essentiel c'est la santé.

EFC10547	
EFC10547	

Х	4					Ļ	L	
Country			С	ent	er	Sι	ıbie	ect

701.05.2
Page No.

Visit Name:

VISIT 1 LAB

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

LABU_1

Data ✓ No Data 🗌

Test name Negative Positive

RED BLOOD CELLS (QUAI

HEMOGLOBIN (QUALITAT:



EFC10547	
EFC10547	

Χ	4							
Country			С	Center			ıbje	ect

701.06.1 Page No.

Repeat No.

Visit Name:

VISIT 1 LAB

TO BE COMPLETED IF PROTEINURIA IS ASSOCIATED WITH HEMATURIA.

ADDITIONAL H	IEMATOLOGY				LAE
Data ☑ No Data ☐					
Date of sampling					
Test name	Unit	Negative	Positive		
SCHISTOCYTES (QU	ALITA NONE				



EFC10547

Х	4							
Country			С	ent	er	Sι	ıbie	ect

701.06.2 Page No.

Repeat No.

Visit Name:

VISIT 1 LAB

ADDITION Data No Da	AL BIOCHE	EMISTRY					LAB_01
Please indicate	e if the laboratory	is the : Same a Same a	s baseline s previous				
Name Addre							
City Coun	try						
			For Tech	nical use :			
Name Addre							
City Coun	try						
Date of sampling	ng	(dd-mmm-yyyy)	Unit			SI Ra	nges
Test		Value	If other unit, specify	SI Value	SI Unit	Lower Limit	Upper Limit
LDH			IU/L				
HAPTOGLOB	IN		G/L				
OROSOMUCO	ID		G/L				

Confidential Information

TOTAL	EFC10547		X 4	50.1
sanofi aventis			Country Center Subject	Page I
L'essentiel c'est la santé.	Visit Name:	VISIT 2		

Repeat No. VISIT_01 Date of visit: (DD-MMM-YYYY) VITAL_02 **VITAL SIGNS** Data ✓ No Data 🗌 DAY 1 Date performed (dd-mmm-yyyy) Weight: kg Blood pressure: Systolic: mmHg / Diastolic: mmHg ECOG Performance Status 0 1 2 3 4

A PHYSICAL EXAM SHOULD BE PERFORMED.

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

RECORD AS AN ADVERSE EVENT



Х	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

51.1	
Page	No.

0	
Repeat	No.

VISIT 2

HEMATOLOGY							LAB_01
Data ✓ No Data 🗌							
DAY 1							
Date of sampling	(dd-mmm-yyyy)						
		Unit			SI Ran	ges	
Test	Value	If other unit, specify	SI Value	SI Unit	Lower Limit	Upper Limit	
HEMOGLOBIN		G/L					
PLATELET COUNT (THROMB		10E9/L					
WBC		10E9/L					
NEUTROPHILS		10E9/L					
7	O BE PERFO	DRMED ONLY FOR PA	ATIENT UND	ER VITAN	IIN K ANTAG	ONIST	
INR		RATIO					



City Country

EFC10547

Х	4							
Co	un	trv	С	ent	er	Sι	ıbie	ect

l	52.1	l
	Page No.	

0 Repeat No.

Visit Name:

VISIT 2

BIOCHEMISTRY

Data No Data

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

Name
Address

	For Technical use :
Name	
Address	
City Country	
Country	



EFC10547		X	4							
	(Co	un	try	С	ent	er	Sı	ıbje	ect

52.2	0
Page No.	Repeat No.

Visit Name:	VISIT 2

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

^{*} If creatinine > 1 ULN please report the calculated creatinine clearance.
** If blood Urea Nitrogen is not evaluable, Urea value must be documented.



\sim	un	tr.	_	ont	er	٥.	ıbic	L Vot
Χ	4							

53.1	
Page	No.

Visit Name:

VISIT 2

DIPSTICK URINALYSIS

LABU_1

Data No Data Day 1

Date of sampling

Test name

WHITE BLOOD CELLS (QI

Absent

_+ _-

__++ ___+++

☐ Not evaluable

RED BLOOD CELLS (QUAI

☐ Absent

· 🗆+

☐ Not evaluable



EFC10547	
----------	--

Х	4							
Country			С	ent	er	Sι	ıbje	ect

54.1	
Page	No.

0	
Repeat	No.

VISIT 2

MG/DL

LAB_01 **MORNING SPOT URINALYSIS** Data ✓ No Data 🗌 DAY 1 Please indicate if the laboratory is the : Same as baseline Same as previous Name Address City Country For Technical use: Name Address City Country Date of sampling (dd-mmm-yyyy) Unit SI Ranges If other unit, specify Test Value SI Value SI Unit Lower Limit Upper Limit PROTEIN (URINE) MG/DL

Confidential Information

CREATININE (URINE)

ATA					
sanofi aventis					
L'essentiel c'est la santé.					

Χ	9							
Country		С	ent	er	Sι	ıbje	ect	

1002.01.1 Page No.

Repeat No.

Visit Name:

VISIT 2

PK_01

PHARMACOKINETIC BLOOD

Data ✓ No Data 🗌

FREE AND BOUND AFLIBERCEPT

DAY 1

Theoretical Time Sample Date (dd-mmm-yyyy)

Sample Time 24-hour clock

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

XXX						
sanofi aventis						
L'essentiel c'est la santé.						

EFC10547

X	9							
Country			С	ent	er	Sι	ıbie	ect

1002.02.1 Page No.

Repeat No.

Visit Name:

VISIT 2

PHARMACOKINETIC BLOOD

PK_01

Data No Data ANTI-AFLIBERCEPT ANTIBODIES

DAY 1

Theoretical
Time
TOH *

Sample Date (dd-mmm-yyyy)

Sample Time (24-hour clock)

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



EFC10547

Х	4							
Country			С	ent	er	Sι	ıbie	ect

55.1	
Page No.	•

0	
Repeat	No.

VISIT 2

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_05

Data ✓ No Data 🗌					
AFLIBERCEPT/PLACE	30				
Scheduled Day DAY 1	Treatment Number	Not Administered/ Taken	Date / Time* START (dd-mmm-yyyy) (24-hour clock) END	Intended Dose MG/KG	Actual Dose
	*Time to be	given only for PK patients	(24-hour clock)		

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

Treatment Number	Not Administered/	Date / Time*	Intended Dose	Actual Dose
	laken	START	MG/KG	MG
			NOT APPLICABLE	
		(dd-mmm-yyyy)		
		(24-hour clock)		
		END		
*Time to be (given only for PK patients	(24-hour clock)		
		Treatment Number Not Administered/ Taken	Taken START (dd-mmm-yyyy) (24-hour clock) END *Time to be given only for PK patients	Taken START MG/KG NOT APPLICABLE (dd-mmm-yyyy) (24-hour clock) END *Time to be given only for PK patients

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



0547
0547

Х	4							
Country			Center			Sι	ıbie	ect

5	6.1	
T	² age	No.

)	
Repeat	No.

VISIT 2

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_04

Data ✓ No Data 🗌					
GEMCITABINE					
Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose	Actual Dose
DAY 1					
IF DOSE INTERR	UPTED AND RE	ADMINISTERED, P	LEASE REPORT	THE INFORMATION	ON BELOW:
Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose	Actual Dose
(*)				NOT APPLICABLE	

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



EFC10547

Χ	4							
Co	un	try	С	ent	er	Sι	ıbje	ect

57.1	
Page	No.

0	
Repeat	No.

VISIT 2

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☑ No Data ☐

DAY 1

Outpatient Clinic Inpatient Clinic



Cc	บท	<u>ا</u>	$\overline{}$	ent	 <u>د</u> ،	لــــا منط،	ect
Х	4						

58.1	
Page	No.

Visit Name:

VISIT 2

VITAL SIGNS

Data ✓ No Data 🗌

DAY 8

Date performed (dd-mmm-yyyy)

Blood pressure: Systolic: mmHg

/ Diastolic: mmHg

ECOG Performance Status 0 1 1 2 3 4 1



Χ	4							
Country		С	ent	er	Sι	ıbje	ect	

59.1	
Page No.	•

Visit Name:

VISIT 2

10E9/L

HEMATOLOGY							LAB_01
Data ☑ No Data ☐							
DAY 8							
Date of sampling	(dd-mmm-	yyyy)					
		Unit			SI Ra	nges	
Test	Value	If other unit, specify	SI Value	SI Unit	Lower Limit	Upper Limit	
HEMOGLOBIN		G/L					
PLATELET COUNT (THRO	MB(10E9/L					
WBC		10E9/L					

NEUTROPHILS



Х	4							
Country		Center			Sι	ıbje	ect	

60.1	
Page	No.

)	
Repeat	No.

VISIT 2

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_04

Data ☑ No Data ☐								
GEMCITABINE								
Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose	Actual Dose			
DAY 8								
IF DOSE INTERRUPTED AND READMINISTERED, PLEASE REPORT THE INFORMATION BELOW:								
Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose	Actual Dose			
(*)				NOT APPLICABLE				

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



EF(C10)547	
EF(ر 10)547	

X 4	ㅗ	<u>_</u>	Ĺ	Ļ	L_I
Country	$C_{\Delta i}$	nter	Si	ıhic	∆C†

61.1	
Page	No.

0	
Repeat	No.

VISIT 2

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☑ No Data ☐

DAY 8

Outpatient Clinic Inpatient Clinic



EEC10547	
EFC10547	

Х	4							
Co	un	try	С	ent	er	Sι	ıbje	ect

62.1	
Page	No.

Visit Name:

VISIT 2

VITAL SIGNS

Data ✓ No Data 🗌

DAY 15

Date performed (dd-mmm-yyyy)

Weight: kg

Blood pressure: Systolic: mmHg / Diastolic: mmHg

ECOG Performance Status 0 1 2 3 4 1



Х	4							
Co	un	try	С	ent	er	Sι	ıbie	ect

63.1	
Page	No.

Visit Name:

VISIT 2

LAB_01 **HEMATOLOGY** Data ✓ No Data 🗌 DAY 15 Date of sampling (dd-mmm-yyyy) SI Ranges Unit Test Value If other unit, specify SI Value SI Unit Lower Limit Upper Limit G/L HEMOGLOBIN PLATELET COUNT (THROMBO 10E9/L WBC 10E9/L NEUTROPHILS 10E9/L



EF(C10)547	
EF(ر 10)547	

\sim	un	tr.	_	ont	er	٥.	ıbic	L Vot
Χ	4							

64.1	
Page	No.

Visit Name:

VISIT 2

DIPSTICK URINALYSIS

LABU_1

Data ☑ No Data ☐

DAY 15

Date of sampling

Test name

WHITE BLOOD CELLS (QI

☐ Absent

_ + _

_ ++ _ +++

■ Not evaluable

RED BLOOD CELLS (QUAI

☐ Absent

+ 🗆 +-

☐ Not evaluable



EFC10547

Χ	4							
Country		С	Center			ıbje	ect	

65.1	
Page	No.

Visit Name:

VISIT 2

MORNING	SPOT	URINAI	LYSIS
----------------	-------------	---------------	--------------

LAB_01

Data ✓ No Data ☐						
DAY 15 Please in	ndicate if the la	boratory is the: Same as b Same as p				
Name Address						
City Country						
		For Technical	l use :			
Name Address						
City Country						
Pate of sampling	(dd-mmm-y	yyy)				
		Unit			SI Ra	nges
Test	Value	If other unit, specify	SI Value	SI Unit	Lower Limit	Upper Limit
PROTEIN (URINE)		MG/DL				
CREATININE (URINE)		MG/DL				



Х	4							
Co	un	try	С	ent	er	Subje		ect

66.1	l
Page No.	•

0	
Repeat	No.

VISIT 2

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_05

Data ✓ No Data 🗌					
AFLIBERCEPT/PLACEB	0				
Scheduled Day	Treatment Number	Not Administered/ Taken	Date / Time*	Intended Dose	Actual Dose
DAY 15			START (dd-mmm-yyyy)	MG/KG	MG
	*Time to be	given only for PK patients	(24-hour clock) END (24-hour clock)		

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

Treatment Number	Not Administered/	Date / Time*	Intended Dose	Actual Dose
	raken	START	MG/KG	MG
			NOT APPLICABLE	
		(dd-mmm-yyyy)		
		(24-hour clock)		
		END		
*Time to be	given only for PK patients	(24-hour clock)		
		Treatment Number Not Administered/ Taken	Taken START (dd-mmm-yyyy) (24-hour clock) END *Time to be given only for PK patients	Taken START MG/KG NOT APPLICABLE (dd-mmm-yyyy) (24-hour clock) END *Time to be given only for PK patients

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



EFC10547	
----------	--

Х	4							
Co	un	try	С	ent	er	Sι	ıbje	ect

ı	67.1	
	Page No.	

)	
Repeat	No.

VISIT 2

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_04

Data No Data					
GEMCITABINE					
Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose	Actual Dose
DAY 15					
IF DOSE INTERF	RUPTED AND REA	ADMINISTERED, PI	LEASE REPORT	THE INFORMATION	ON BELOW:
Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose	Actual Dose
(*)				NOT APPLICABLE	

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



EFC10547	
----------	--

Χ	4							
Country		С	ent	er	Sι	ıbje	ect	

68.1	
Page	No.

Visit Name:

VISIT 2

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☑ No Data ☐

DAY 15

Outpatient Clinic Inpatient Clinic

TOTAL
sanofi aventis
L'essentiel c'est la santé.

Х	4							
Со	un	try	С	ent	er	Sι	ıbje	ect

69.1	
Page	No.

0	
Repeat	No.

rtiel c'est la santé. Visit Name:

VISIT 2

PAIN INTENSITY

ASSESSED VIA VISUAL ANALOG SCALE

Data ✓ No Data 🗌

Data corresponding to current cycle

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

Confidential Information

AVE0005 - EFC10547 (VANILLA)

TOTA
sanofi aventis
L'essentiel c'est la santé.

EEC10547	
EFC10547	

Х	4					Ļ	L	
Country		С	ent	er	Sι	ıbie	ect	

69.2	
Page	Nο

0	
Repeat	No.

VISIT 2

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

ANA
sanofi aventis
L'essentiel c'est la santé.

Х	4							
Со	Country			ent	er	Sι	ıbje	ect

70.1	
Page No.	ļ.

0	
Repeat	No.

MEDICATION

ANALGESIC	
-----------	--

MED_02

Data ✓ No Data

ANALGESIC MEDICATION SHOULD BE COLLECTED DAILY PRIOR TO THE NEXT INFUSION

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

ANA
sanofi aventis
L'essentiel c'est la santé.

EFC10547

Х	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

70.2	
Page N	<u>o.</u>

0	
Repeat	No.

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

ANA
sanofi aventis
L'essentiel c'est la santé.

Х	4							
Country		С	ent	er	Sι	ıbie	ect	

70.3	
Page No	

0	
Repeat	No.

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



EFC10547

Χ	4							
Сс	un	try	С	Center		Sι	ıbje	ect

71.1 Page No.

0 Repeat No.

Visit Name:

VISIT 2

TUMOR	MEASUREMENTS					TUMEA_02
Data ✓ No	o Data 🗌					
Lesion Number	Lesion Location	Date of Assessment (dd-mmm-yyyy)	Method of Tumor Measurement	Measurement of Target Lesion longest diameter	Response of Non target Lesions	
				mm		
		Not Done		mm		
		Not Done		mm		
		Not Done		mm		
		Not Done		mm		
		☐ Not Done ☐ Not Done ☐ Not Done		mm		
		Not Done		mm		
		Not Done		mm		
		Not Done		mm		
				mm		
		☐ Not Done				



EFC10547

Χ	4							
Сс	un	try	С	Center		Sι	ıbje	ect

71.2	
Page	No.

Visit Name:

Lesion Number	Lesion Location	Date of Assessment (dd-mmm-yyyy)	Method of Tumor Measurement	Measurement of Target Lesion longest diameter	Response of Non target Lesions
		Not Done		mı	m
		Not Done		mı	m
		Not Done		mı	m
		Not Done		mı	m
		Not Done		mı	m
		Not Done		mı	m
		Not Done		mı	m
		Not Done		mı	m
		Not Done		mı	m
		□ Not Done		mr	m



Χ	4							
Co	un	try	С	ent	er	Sι	ıbje	ect

72.1	
Page	No.

TMARK_01

Visit Name:

VISIT 2

TUMOR MARKERS

Data ✓ No Data ✓	
Date of evaluation	
	(dd-mmm-yyyy)

TEST VALUE UNIT NORMAL RANGE
LOWER LIMIT UPPER LIMIT

CA19-9



Χ	4							
Country		Center			Sι	ıbje	ect	

73.1	
Page	No.

Visit Name:

VISIT 2

CLINICAL EVENT THROMBOVASCULAR

Data ✓ No Data ☐	Yes	No
ANGINA PECTORIS / UNSTABLE ANGINA / MYOCARDIAL INFARCTION		
STROKE / TRANSIENT ISCHEMIC ATTACK		
PERIPHERAL ARTERIAL THROMBOSIS		
DEEP VENOUS THROMBOSIS		
PULMONARY EMBOLISM		
INTRAABDOMINAL ARTERIAL THROMBOSIS		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		



EFC10547	
----------	--

Χ	4							
Cc	un	try	С	ent	er	Sι	ıbje	ect

602.1 Page No.

0 Repeat No.

Visit Name: VISIT 2 AE

ADVERSE EVENT Data No Data 1. Adverse Event (Diagnosis):	AE Form Number AE_03 AE Reference ID
2. Status of Adverse Event	New Date of Start (dd-mmm-yyyy) Ongoing without change (do not complete the remaining items) Ongoing with change
3. Grade4. Relationship to investigational product *	1
5. Action Taken with Investigat. Product	None Permanently discontinued Delayed Dose reduced Delayed and reduced Interrupted
6. Corrective treatment/therapy	Yes
7. Outcome	Recovered Date of Recovery
	Recovered with sequelae Specify :
	Recovering
	Not recovered
	Fatal Date of Death (complete the death report form) Unknown
8. Seriousness Criteria	Yes No If Yes : -Date event became serious
IF YES, COMPLETE THIS SECTION AND	-Tick below all criteria that apply :
THE SAFETY COMPLEMENTARY FORM	Results in Death Persistant/significant disability/incapacity Congenital anomaly or Birth Defect Other medically important event
9. Is it an event such as:	
Overdose of the IP	Yes No No
Pregnancy	Yes No No
*Is there a rea	sonable possibility that the AE was caused by Investigational Product?



Χ	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

602.2	
Page	No.

Visit Name:

VISIT 2 AE

AE / Specific Event Form Number	
1. Demographic Information Weight (kg)	
2. Detailed Description of the Adverse Event (including complementary investigations)	
3. Date of Start of Event (Initial date of onset of the considered event) (DD-MMM-YYYY)	
4. Investigational Products	
Date of the FIRST administration of study treatment : (DD-MMM-YYYY)	
Current Treatment number : Current Cycle :	
Date of the LAST administration before SAE: (dd-mmm-yyyy) Last Dosage before SAE: Action Ta	aken :
AFLIBERCEPT/PLACEBO MG/KG	
GEMCITABINE MG/M2	
5. In case of hospitalization Date of admission (DD-MMM-YYYY) (hospital report to be sent)	
6. In case of death Autopsy report Yes No (copy to be sent)	
7. Corrective Treatment / Therapy	



EFC10547	
----------	--

Х	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

702.01.1
Page No.

)	
Repeat	No.

VISIT 2 LAB

ADDITIONAL HEMATO	DLOGY						LAB_01
Data ☑ No Data ☐							
Date of sampling	(dd-mmm-yyyy))					
		Unit			SI Ra	nges	
Test	Value	If other unit, specify	SI Value	SI Unit	Lower Limit	Upper Limit	
HEMOGLOBIN		G/L					
PLATELET COUNT (THROMB	(10E9/L					
WBC		10E9/L					
NEUTROPHILS		10E9/L					
٦	TO BE PERF	ORMED ONLY FOR	PATIENT UN	IDER VITA	MIN K ANTAG	SONIST	
INR		RATIO			1		



Χ	4							
Cc	un	try	С	ent	er	Sι	ıbje	ect

702.02.1
Page No.

Visit Name:

VISIT 2 LAB

ADDITIONAL BIOCHEMISTRY

LAB_01

Data ✓ No Dat	a 🗌	
Please i	indicate if the laboratory is the : Same as baseline Same as previous	
Name		
Address		
City		
Country		
	For Technical use :	
Name		
Address		
City		
Country		
1		



Χ	4							
Country		Center			Sι	ıbje	ect	

702.02.2 Page No.

Repeat No.

Visit Name:

VISIT 2 LAB

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

^{*} If creatinine > 1 ULN please report the calculated creatinine clearance.
** If blood Urea Nitrogen is not evaluable, Urea value must be documented.



Χ	4							
Country			С	ent	er	Sι	ıbje	ect

702.03.1	
Page No.	

Visit Name:

VISIT 2 LAB

ADDITIONAL DIPSTICK URINALYSIS

LABU_1

Data ✓ No Data 🗌					
Date of sampling					
Test name					
WHITE BLOOD CELLS (Q	☐ Absent	+		_ +++	□ Not evaluable
RED BLOOD CELLS (OUA)	☐ Absent	□+	□++	□+++	☐ Not evaluable



Χ	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

702.04.1
Page No.

Visit Name:

VISIT 2 LAB

ADDITIONAL MORNING SPOT URINALYSIS

Data ☑ No Data ☐						
Please in	dicate if the la	boratory is the : Same as b				
Name		Same as p	revious			_
Name Address						
City						
Country						
		For Technical	use:			
Name						
Address						
City						₫
Country						
Date of sampling	(dd-mmm-yy	vyy)				
		Unit			SI Ran	ges
Test	Value	If other unit, specify	SI Value	SI Unit	Lower Limit	Upper Limit
PROTEIN (URINE)		MG/DL				
CREATININE (URINE)		MG/DL				



10547
10547

Χ	4							
Country			С	Center			ıbje	ect

702.05.1 Page No.

0 Repeat No.

Visit Name:

VISIT 2 LAB

24-HOUR URINA Data ☑ No Data ☐			TO BE COMPL	ETED IF UPO	CR > 1				LAB_04
Please indicate if the	aboratory is th	ne Same as base Same as previ							
Name Address									
City Country									
		For	Technical use :						
Name Address									
City Country									
	Date (dd-mm		, u .:	(24-hour clock	·)				
Start date of collection End date of collection			me of collection :				SLR	ANGES	
Test	· L Value	Unit	ic or concention.		SI Value	SI Unit		nit Upper Limit	ł
URINARY VOLUME		L				7	1		1
PROTEIN (URINE)		G/L							1
CREATININE (URIN		G/L]
	ELE	CTROPHORE	ESIS						
ALBUMIN		G/L					1		1
ALPHA 1 GLOBULIN		G/L							1
ALPHA 2 GLOBULIN		G/L]
BETA GLOBULIN		G/L]
GAMMA GLOBULTN		G/L							1



EFC10547	
----------	--

Χ	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

702.05.2
Page No.

0	
Repeat	No.

VISIT 2 LAB

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

LABU_1

Data ✓ No Data 🗌

HEMOGLOBIN (QUALITAT:

Test name Negative Positive

RED BLOOD CELLS (QUAI



EFC10547	
EFC10547	

Χ	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

702.06.1
Page No.

Visit Name:

NONE

VISIT 2 LAB

TO BE COMPLETED IF PROTEINURIA IS ASSOCIATED WITH HEMATURIA.

ADDITIONAL HEMA	TOLOGY				LABU_1
Data ☑ No Data ☐					
Date of sampling					
Test name	Unit	Negative	Positive		

SCHISTOCYTES (QUALITA



EFC10)547	
	J341	

Х	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

702.06.2 Page No.

Repeat No.

Visit Name:

VISIT 2 LAB

ADDITIONA Data No Data		MISTRY						LAE	B_01
Please indicate i	the laboratory		s baseline s previous						
Name Addres	6								
City Countr	,								
				For Technic	cal use :				
Name Addres	S .								
City Countr	,								
Date of sampling		(dd-mmm-yyyy)	Unit				SI Rar	ges	
Test		Value	If other uni	t, specify	SI Value	SI Unit	Lower Limit	Upper Limit	
LDH			IU/L						
HAPTOGLOBIN			G/L						
OROSOMUCOII			G/L						

Confidential Information

sanofi aventis	EFC10547		X 4 Country Center Subject	74.1 Page I
L'essentiel c'est la santé.	Visit Name:	VISIT 3		

VITAL SIGNS
Data V No Data

DAY 1

Repeat No.

Final Version: 24OCT2007

Weight: kg

Blood pressure: Systolic: mmHg / Diastolic: mmHg

ECOG Performance Status 0 1 2 3 4

A PHYSICAL EXAM SHOULD BE PERFORMED.

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

RECORD AS AN ADVERSE EVENT

Confidential Information

Date performed

(dd-mmm-yyyy)



Х	4							
Country		Center		Sι	ıbje	ect		

75.1	
Page	No.

Visit Name:

HEMATOLOGY							LAB_01
Data ✓ No Data 🗌							
DAY 1							
Date of sampling	(dd-mmm-yyyy)						
		Unit			SI Ran	ges	
Test	Value	If other unit, specify	SI Value	SI Unit	Lower Limit	Upper Limit	
HEMOGLOBIN		G/L					
PLATELET COUNT (THROMB		10E9/L					
WBC		10E9/L					
NEUTROPHILS		10E9/L					
7	O BE PERFO	DRMED ONLY FOR PA	ATIENT UND	ER VITAN	IIN K ANTAG	ONIST	
INR		RATIO					



City Country

Х	4							
Country			С	ent	er	Sι	ıbie	ect

76.1	
Page	No.

0 Repeat No.

Visit Name:

VISIT 3

BIOCHEMISTRY

Data No Data

DAY 1

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

Name
Address

	For Technical use :
Name Address	
City	
City Country	



EFC10547	X	4						
	Co	oui	ntry	С	ent	er	Su	ıbje

76.2	0
Page No.	Repeat No.

Visit Name:	VISIT 3	

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

^{*} If creatinine > 1 ULN please report the calculated creatinine clearance.
** If blood Urea Nitrogen is not evaluable, Urea value must be documented.



EF(C10)547	
EF(ر 10)547	

Х	4			Sı	
Х	4				

77.1	
Page	No.

LABU_1

Visit Name:

VISIT 3

DIPSTICK URINALYSIS

Data ✓ No Data 🗌

DAY 1

Date of sampling

Test name

WHITE BLOOD CELLS (QUAIRED BLOOD CELLS (QUAI

☐ Absent

++ Not evaluable

☐ Absent

-++

☐ Not evaluable



Х	4							
Country			С	ent	er	Sι	ıbje	ect

78.1	
Page	No.

Visit Name:

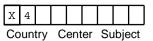
VISIT 3

MG/DL

LAB_01 **MORNING SPOT URINALYSIS** Data ✓ No Data 🗌 DAY 1 Please indicate if the laboratory is the : Same as baseline Same as previous Name Address City Country For Technical use: Name Address City Country Date of sampling (dd-mmm-yyyy) Unit SI Ranges Test Value If other unit, specify SI Value SI Unit Lower Limit Upper Limit PROTEIN (URINE) MG/DL

CREATININE (URINE)

XXX
sanofi aventis
L'essentiel c'est la santé.



973.1 Page No.

Repeat No.

Visit Name:

P03

VISIT 3

PHARMACOKINETIC BLOOD

PK_01

Data ☑ No Data ☐		TO BE COMPLET	TO BE COMPLETED ONLY FOR PK PATIENTS.			
FREE AND BOUND A	AFLIBERCEPT					
DAY 1	Sample	Theoretical	Sample Date	Sample Time		
	ID	Time	(dd-mmm-yyyy)	24-hour clock		

TOH

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

ANA
sanofi aventis
L'essentiel c'est la santé.

Data ✓ No Data 🗌

DAY 1

|--|--|

Χ	9							
Country		С	ent	er	Sι	ıbje	ect	

1003.01.1 Page No.

0 Repeat No.

Visit Name:

VISIT 3

PHARMACOKINETIC BLOOD

PK_01

FREE AND BOUND AFLIBERCEPT

Theoretical	
Time	
T0H	*

Sample Date (dd-mmm-yyyy)

Sample Time 24-hour clock

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

XXX					
sanofi aventis					
L'essentiel c'est la santé.					

Χ	9							
Country		С	ent	er	Sι	ıbje	ect	

1003.02.1 Page No.

Repeat No.

Visit Name:

VISIT 3

PHARMACOKINETIC BLOOD

PK_01

Data No Data ANTI-AFLIBERCEPT ANTIBODIES

DAY 1

Theoretical				
Time				
TOH *				

Sample Date (dd-mmm-yyyy)

Sample Time (24-hour clock)

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



Х	4							
Co	un	trv	С	ent	er	Sι	ıbie	ect

79.1 Page No.

0 Repeat No.

Visit Name:

VISIT 3

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_05

Data ✓ No Data					
AFLIBERCEPT/PLACEB Scheduled Day DAY 1	Treatment Number	Not Administered/ Taken	Date / Time* START (dd-mmm-yyyy) (24-hour clock)	Intended Dose MG/KG	Actual Dose
IF DOSE INTER		given only for PK patients ADMINISTERED, PLEA	END (24-hour clock)	IFORMATION BELOV	v :
Scheduled Day	Treatment Number	Not Administered/ Taken	Date / Time* START	Intended Dose MG/KG NOT APPLICABLE	Actual Dose

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

*Time to be given only for PK patients

Confidential Information

(dd-mmm-yyyy)

(24-hour clock)

(24-hour clock)

END



EFC10547	
----------	--

Х	4							
Co	un	try	С	ent	er	Sι	ıbje	ect

80.1	l
Page No.	•

)	
Repeat	No.

VISIT 3

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_04

Data No Data					
GEMCITABINE					
Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose MG/M2	Actual Dose
DAY 1					
IF DOSE INTERF	RUPTED AND REA	ADMINISTERED, P	LEASE REPORT	THE INFORMATION	ON BELOW:
Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose	Actual Dose
(*)				NOT APPLICABLE	v

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



EFC10547

Χ	4							
Country		С	ent	er	Sι	ıbie	ect	

81.1	ı
Page No.	_

0	
Repeat	No.

VISIT 3

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☑ No Data ☐

DAY 1

Outpatient Clinic Inpatient Clinic



EEC10547	
EFC10547	

Χ	4							
Country			С	ent	er	Sι	ıbje	ect

82.1	
Page	No.

Visit Name:

VISIT 3

VITAL SIGNS

Data ✓ No Data 🗌

DAY 8

Date performed (dd-mmm-yyyy)

Blood pressure: Systolic: mmHg

/ Diastolic: mmHg

ECOG Performance Status 0 1 2 3 4 1



EFC10547	

Х	4							
Country			С	ent	er	Sι	ıbje	ect

83.1	
Page	No.

0	
Repeat	No.

VISIT 3

10E9/L

LAB_01 **HEMATOLOGY** Data ✓ No Data 🗌 DAY 8 Date of sampling (dd-mmm-yyyy) SI Ranges Unit Test Value If other unit, specify SI Value SI Unit Lower Limit Upper Limit G/L HEMOGLOBIN PLATELET COUNT (THROMBO 10E9/L WBC 10E9/L

Confidential Information

NEUTROPHILS



<u>^</u>	un	Ш • п/	_		Sι	L Ibid	L
Х	4						

8	34.1		
	Page	No.	

)		
Repeat	No.	

VISIT 3

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_04

Data ☑ No Data ☐					
GEMCITABINE					
Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose MG/M2	Actual Dose
DAY 8					
IF DOSE INTERRU	JPTED AND RE	EADMINISTERED, PL	EASE REPORT	THE INFORMATION	ON BELOW:
Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose	Actual Dose
(*)				NOT APPLICABLE	

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



EFC10547

Χ	4							
Country		С	ent	er	Sι	ıbje	ect	

85.1	
Page	No.

0	
Repeat	No.

VISIT 3

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☑ No Data ☐

DAY 8

Outpatient Clinic Inpatient Clinic



EFC10547	
EFC10547	

\sim	un	tr.	_	ont	er	٥.	ıbic	L Vot
Χ	4							

86.1	
Page	No.

Visit Name:

VISIT 3

VITAL SIGNS

Data ✓ No Data 🗌

DAY 15

Date performed (dd-mmm-yyyy)

Weight: kg

Blood pressure: Systolic: mmHg / Diastolic: mmHg

ECOG Performance Status 0 1 2 3 4



Χ	4					Ļ		
Country			С	ent	er	Sι	ıbie	ect

87.1		
Page	No.	

Final Version: 24OCT2007

Visit Name:

VISIT 3

10E9/L

HEMATOLOGY							LAB_01
Data ☑ No Data ☐							
DAY 15							
Date of sampling	(dd-mmm-	yyyy)					
		Unit			SI Ra	nges	
Test	Value	If other unit, specify	SI Value	SI Unit	Lower Limit	Upper Limit	
HEMOGLOBIN		G/L					
PLATELET COUNT (THRON	ИВ(10E9/L					
WBC		10E9/L					

NEUTROPHILS



Cc	บท	<u>ا</u>	$\overline{}$	ent	 <u>د</u> ،	لــــا منط،	ect
Х	4						

88.1	
Page	No.

Visit Name:

VISIT 3

DIPSTICK URINALYSIS

LABU_1

Data ✓ No Data

DAY 15

Date of sampling

Test name

WHITE BLOOD CELLS (QT

☐ Absent

_ + _ ++

___++ ____+++

☐ Not evaluable

RED BLOOD CELLS (QUAI

Absent

+ 🗆 ++

☐ Not evaluable



10547
10547

Х	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

89.1	
Page	No.

Visit Name:

VISIT 3

MG/DL

LAB_01 **MORNING SPOT URINALYSIS** Data ✓ No Data 🗌 DAY 15 Please indicate if the laboratory is the : Same as baseline Same as previous Name Address City Country For Technical use: Name Address City Country Date of sampling (dd-mmm-yyyy) Unit SI Ranges Test Value If other unit, specify SI Value SI Unit Lower Limit Upper Limit PROTEIN (URINE) MG/DL

CREATININE (URINE)



Х	4							
Co	un	trv	С	ent	er	Sι	ıbie	ect

90.1	
Page No.	•

0	
Repeat	No.

VISIT 3

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_05

Data ✓ No Data 🗌					
AFLIBERCEPT/PLACEBO	l.				
Scheduled	Treatment Number	Not Administered/	Date / Time*	Intended Dose	Actual Dose
Day		Taken	START	MG/KG	MG
DAY 15			(dd-mmm-yyyy)		
			(24-hour clock)		
			END		
	*Time to be	given only for PK patients	(24-hour clock)		

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

Treatment Number	Not Administered/	Date / Time*	Intended Dose	Actual Dose
	raken	START	MG/KG	MG
			NOT APPLICABLE	
		(dd-mmm-yyyy)		
		(24-hour clock)		
		END		
*Time to be	given only for PK patients	(24-hour clock)		
		Treatment Number Not Administered/ Taken	Taken START (dd-mmm-yyyy) (24-hour clock) END *Time to be given only for PK patients	Taken START MG/KG NOT APPLICABLE (dd-mmm-yyyy) (24-hour clock) END *Time to be given only for PK patients

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



EF(C10)547	
EF(ر 10)547	

<u>^</u>	un	Ш • п/	_		Sι	L Ibid	L
Х	4						

91.1	
Page No.	•

NOT APPLICABLE

)	
Repeat	No.

Visit Name:

VISIT 3

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_04

Data ✓ No Data 🗆					
GEMCITABINE					
Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose	Actual Dose
DAY 15					
IF DOSE INTE	RRUPTED AND REA	ADMINISTERED, PL	LEASE REPORT	THE INFORMAT	TION BELOW:
Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose	Actual Dose

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

Confidential Information

(*)



EF(C10)547	
EF(ر 10)547	

Χ	4							
Сс	un	try	С	Center		Sι	ıbje	ect

92.1	
Page	No.

Visit Name:

VISIT 3

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☑ No Data ☐

DAY 15

Outpatient Clinic Inpatient Clinic

XXX
sanofi aventis
L'essentiel c'est la santé.

Х	4							
Co	un	try	С	ent	er	Sι	ıbje	ect

93.1	
Page	No.

0	
Repeat	No.

VISIT 3

PAIN INTENSITY

ASSESSED VIA VISUAL ANALOG SCALE

Data ✓ No Data 🗌

Data corresponding to current cycle

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

Confidential Information

AVE0005 - EFC10547 (VANILLA)

MA
sanofi aventis
L'essentiel c'est la santé.

EFC10547

X 4 Country Center Subject

93.2 Page No.

Repeat No.

Visit Name:

VISIT 3

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

XXX
sanofi aventis
L'essentiel c'est la santé.

EFC10547

	Х	4							
Country		С	ent	er	Sι	ıbie	ect		

94.1	
Page No.	ļ.

0	
Repeat	No.

MEDICATION

ANALGESIC	

MED_02

Data ✓ No Data 🗌

ANALGESIC MEDICATION SHOULD BE COLLECTED DAILY PRIOR TO THE NEXT INFUSION

VISIT 3

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

ANA
sanofi aventis
L'essentiel c'est la santé.

EFC10547	
----------	--

Х	4							
Co	un	trv	С	ent	er	Sι	ıbie	ect

94.2	
Page N	<u>vo.</u>

0	
Repeat	No.

VISIT 3

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

ANA
sanofi aventis
L'essentiel c'est la santé.

VISIT 3

Χ	4							
Country		С	ent	er	Sι	ıbje	ect	

94.3	
Page	No.

0	
Repeat	No.

Visit Name:

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



Χ	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

95.1	
Page I	Vo.

0	
Repeat	No.

VISIT 3

TUMOR	MEASUREMENTS					TUMEA_02
Data ✓ N	o Data 🗌					
Lesion Number	Lesion Location	Date of Assessment (dd-mmm-yyyy)	Method of Tumor Measurement	Measurement of Target Lesion longest diameter	Response of Non target Lesions	
				mm		
		Not Done		mm		
		☐ Not Done				
		Not Done		mm		
				mm		
		Not Done		mm		
		☐ Not Done				
				mm		
		☐ Not Done		mm		
		Not Done				
		Not Done		mm		
		☐ Not Done		mm		
				mm		
		☐ Not Done				



Х	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

95.2	
Page	No.

0	
Repeat	No.

VISIT 3

Lesion Number	Lesion Location	Date of Assessment (dd-mmm-yyyy)	Method of Tumor Measurement	Measurement of Target Lesion longest diameter	Response of Non target Lesions
		Not Done		mr	n
		□ Not Done		mr	n
		□ Not Done		mr	n
		☐ Not Done		mr	n
		☐ Not Done		mr	n
		Not Done		mr	n
		☐ Not Done		mr	n
		Not Done		mr	n
		☐ Not Done		mr	n
		☐ Not Done		mr	n



<u>^</u>	un	Ш • п/	_		Sι	L Ibid	L
Х	4						

96.1	
Page	No.

)		
Repeat	No.	

VISIT 3

TUMOR MARKERS

TMARK_01

Data ✓ No Data ✓	
Date of evaluation	
	(dd-mmm-yyyy)

TEST	VALUE	UNIT	NORMAL RANGE		
			LOWER LIMIT	UPPER LIMIT	
'A 1 9 - 9					1



	C10547	
ıĿĿ	C10547	

Χ	4							
Co	un	try	С	Center			ıbje	ect

97.1	
Page	No.

0	
Repeat	No.

VISIT 3

CLINICAL EVENT THROMBOVASCULAR

Data No Data	Yes	No
ANGINA PECTORIS / UNSTABLE ANGINA / MYOCARDIAL INFARCTION		
STROKE / TRANSIENT ISCHEMIC ATTACK		
PERIPHERAL ARTERIAL THROMBOSIS		
DEEP VENOUS THROMBOSIS		
PULMONARY EMBOLISM		
INTRAABDOMINAL ARTERIAL THROMBOSIS		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		



EFC10547

Χ	4							
Country		С	Center		Sι	ıbje	ect	

603.1 Page No.

Repeat No.

risit Name:	VISIT 3 AE

ADVERSE EVENT Data No Data 1. Adverse Event (Diagnosis):	AE Form Number AE_03 AE Reference ID
2. Status of Adverse Event	New Date of Start (dd-mmm-yyyy) Ongoing without change (do not complete the remaining items) Ongoing with change
3. Grade4. Relationship to investigational product *	1
5. Action Taken with Investigat. Product	None Permanently discontinued Delayed Dose reduced Delayed and reduced Interrupted
6. Corrective treatment/therapy	Yes
7. Outcome	Recovered Date of Recovery
	Recovered with sequelae Specify :
	Recovering
	Not recovered
	Fatal Date of Death (complete the death report form)
	Unknown
8. Seriousness Criteria	Yes No If Yes : -Date event became serious (dd-mmm-yyyy)
IF YES, COMPLETE THIS SECTION AND	-Tick below all criteria that apply :
THE SAFETY COMPLEMENTARY FORM	Results in Death Persistant/significant disability/incapacity Life Threatening Congenital anomaly or Birth Defect Requires or prolongs hospitalization Other medically important event
9. Is it an event such as:	
Overdose of the IP	Yes No
Pregnancy	Yes No No
*Is there a rea	asonable possibility that the AE was caused by Investigational Product?



Χ	4							
Country		С	Center			ıbje	ect	

603.2 Page No.

0 Repeat No.

Visit Name:

VISIT 3 AE

AE / Specific Event Form Number	
1. Demographic Information	
Weight (kg)	
2. Detailed Description of the Adverse Event (including complementary investigations)	
3. Date of Start of Event (Initial date of onset of the considered event) (DD-MMM-YYYY)	
4. Investigational Products	
Date of the FIRST administration of study treatment : (DD-MMM-YYYY)	
Current Treatment number : Current Cycle : Cur	
Date of the LAST administration before SAE: (dd-mmm-yyyy) Last Dosage before SAE:	Action Taken :
AFLIBERCEPT/PLACEBO MG/KG	
GEMCITABINE MG/M2	
5. In case of hospitalization Date of admission (DD-MMM-YYYY) (hospital report to be	sent)
5. In case of death Autopsy report Yes No (copy to be sent)	



EFC10547	
----------	--

Χ	4							
Country			С	ent	er	Sι	ıbje	ect

703.01.1	
Page No.	•

0	
Repeat	No.

VISIT 3 LAB

ADDITIONAL HEM	ATOLOGY						LAB_01
Data ☑ No Data ☐							
Date of sampling	(dd-mmm-y	/yyy)					
		Unit			SI Ra	inges	
Test	Value	If other unit, specify	SI Value	SI Unit	Lower Limit	Upper Limit	
HEMOGLOBIN		G/L					
PLATELET COUNT (TH	ROMB(10E9/L					
WBC		10E9/L					
NEUTROPHILS		10E9/L					
	TO BE PER	RFORMED ONLY FOR	PATIENT UN	IDER VITA	MIN K ANTAG	ONIST	
INR		RATIO					



EFC10547

Χ	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

703.02.1
Page No.

Visit Name:

VISIT 3 LAB

ADDITIONAL BIOCHEMISTRY

LAB_01

Data ✓ No Data	a□	
Please ii	ndicate if the laboratory is the : Same as baseline Same as previous	
Name Address		
City [Country [
	For Technical use :	
Name Address		
City [Country [



EF(C10)547	
EF(ر 10)547	

Х	4							
Country		С	Center		Sι	ıbje	ect	

703.02.2 Page No.

Repeat No.

Visit Name:

VISIT 3 LAB

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

^{*} If creatinine > 1 ULN please report the calculated creatinine clearance.
** If blood Urea Nitrogen is not evaluable, Urea value must be documented.



EF(C10)547	
EF(ر 10)547	

Χ	4							
Country		С	Center		Sι	ıbje	ect	

703.03.1	
Page No.	

)		
Repeat	No.	

VISIT 3 LAB

ADDITIONAL DIPSTICK URINALYSIS

LABU_1

Data ✓ No Data 🗌					
Date of sampling					
Test name					
WHITE BLOOD CELLS (QI	Absent	+		+++	☐ Not evaluable
RED BLOOD CELLS (QUAI	☐ Absent	□ +	□ ++	□ +++	☐ Not evaluable



(dd-mmm-yyyy)

Х	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

703.04.1 Page No.

0 Repeat No.

Visit Name:

VISIT 3 LAB

ADDITIONA Data No Data	AL MORNING SPOT URINALYSIS	LAB_01
	Please indicate if the laboratory is the : Same as baseline Same as previous	
Name		
Address		
City		
Country		
	For Technical use :	
Name		
Address		
City		
Country		

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

Confidential Information

Date of sampling



Χ	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

703.05.1 Page No.

0 Repeat No.

Visit Name:

VISIT 3 LAB

24-HOUR URINA Data ☑ No Data ☐			TO BE COMPL	ETED IF UPO	CR > 1				LAB_04
Please indicate if the	aboratory is th	ne Same as base Same as previ							
Name Address									
City Country									
		For	Technical use :						
Name Address									
City Country									
	Date (dd-mm		, u .:	(24-hour clock	·)				
Start date of collection End date of collection			me of collection :				SLR	ANGES	
Test	· L Value	Unit	ic or concention.		SI Value	SI Unit		nit Upper Limit	ł
URINARY VOLUME		L				7	1		1
PROTEIN (URINE)		G/L							1
CREATININE (URIN		G/L]
	ELE	CTROPHORE	ESIS						
ALBUMIN		G/L					7		1
ALPHA 1 GLOBULIN		G/L							1
ALPHA 2 GLOBULIN		G/L]
BETA GLOBULIN		G/L]
GAMMA GLOBULTN		G/L							1

TOTA
sanofi aventis
L'essentiel c'est la santé.

EFC10547	
EFC10547	

Х	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

703.05.2
Page No.

Visit Name:

VISIT 3 LAB

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

LABU_1

Data ✓ No Data 🗌

Test name Negative Positive

RED BLOOD CELLS (QUAI



EFC10547	
----------	--

Χ	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

703.06.1
Page No.

Visit Name:

VISIT 3 LAB

TO BE COMPLETED IF PROTEINURIA IS ASSOCIATED WITH HEMATURIA.

ADDITIONAL HEMATOLOGY							
Data ✓ No Data ☐							
Date of sampling							
Test name	Unit	Negative	Positive				
SCHISTOCYTES (QU	ALITA NONE						



Х	4							
Country		Center			Subject			

703.06.2 Page No.

0 Repeat No.

Visit Name:

VISIT 3 LAB

G/L

LAB 01 **ADDITIONAL BIOCHEMISTRY** Data ✓ No Data 🗌 Please indicate if the laboratory is the : Same as baseline \Box Same as previous Name Address City Country For Technical use: Name Address City Country Date of sampling (dd-mmm-yyyy) Unit SI Ranges Value If other unit, specify Lower Limit Upper Limit Test SI Value SI Unit IU/L LDH HAPTOGLOBIN G/L

Confidential Information

OROSOMUCOID

sanofi aventis	EFC10547		X 4 Country Center Subject	98.1 Page I
L'essentiel c'est la santé.	Visit Name:	VISIT 4		

A PHYSICAL EXAM SHOULD BE PERFORMED.

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

RECORD AS AN ADVERSE EVENT

Confidential Information

ECOG Performance Status 0 1 2 3 4

Repeat No.



Χ	4							
Country			С	ent	er	Sι	ıbie	ect

99.1	
Page	No.

Visit Name:

HEMATOLOGY							LAB_01
Data ✓ No Data 🗌							
DAY 1							
Date of sampling	(dd-mmm-yyyy)						
		Unit			SI Ran	ges	
Test	Value	If other unit, specify	SI Value	SI Unit	Lower Limit	Upper Limit	
HEMOGLOBIN		G/L					
PLATELET COUNT (THROMBO		10E9/L					
WBC		10E9/L					
NEUTROPHILS		10E9/L					
Т	O BE PERFO	DRMED ONLY FOR P	ATIENT UND	ER VITAM	IIN K ANTAG	ONIST	
INR		RATIO					



EFC10547

X 4								
Country			С	Center			ıbie	ect

100.1	
Page	No.

Visit Name:

VISIT 4

LAB_01

BIOCHEMIS	STRY	
Data ✓ No Data	a 🗌	
DAY 1		
Please i	ndicate if the laboratory is the : Same as baseline Same as previous	
Name		
Address		
City		
Country		
	For Technical use :	
Name		
Address		
City		
Country		



|--|

Х	4							
Country			С	ent	er	Sι	ıbje	ect

100.2	
Page	No.

0	
Repeat	No.

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

^{*} If creatinine > 1 ULN please report the calculated creatinine clearance.
** If blood Urea Nitrogen is not evaluable, Urea value must be documented.



EF(C10)547	
EF(ر 10)547	

Χ	4							
Country		С	Center			ıbje	ect	

101.1	
Page	No.

0	
Repeat	No.

VISIT 4

DIPSTICK URINALYSIS

LABU_1

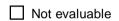
Data 🗸	No Data	

DAY 1

Date of sampling

Test name

WHITE BLOOD CELLS (ζ
---------------------	---





EFC10547

Χ	4							
Country		С	Center			ıbje	ect	

102.1	
Page	No.

Visit Name:

VISIT 4

LAB_01

MORNING SPO	T URINALYSIS						LAB_01
Data ☑ No Data ☐							
DAY 1							
Ple	ease indicate if the lat	poratory is the: Same as b	aseline 🗌				
		Same as p	revious				
Name							
Address							
City							
Country							
		For Technical	luca:				
No.		1 Of Technica					
Name Address						 	
Address							
City						- 	
Country							
Country							
Date of sampling	(dd-mmm-yy	yy)					
Date of camping	,	Unit			CI Do	200	
Test	Value		SI Value	SI Unit	SI Ra	=	
1 691	value	If other unit, specify	Si value		Lower Limit	Upper Limit	
PROTEIN (URINE)		MG/DL					
CREATININE (URIN	E)	MG/DL					



Χ	9							
Country		С	ent	er	Sı	ıbie	ect	

1004.01.1 Page No.

Repeat No.

Visit Name:

VISIT 4

PHARMACOKINETIC BLOOD

PK_01

Data ✓ No Data 🗌

FREE AND BOUND AFLIBERCEPT

DAY 1

Theoretical Time Sample Date (dd-mmm-yyyy)

Sample Time 24-hour clock

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

TOTAL
sanofi aventis
L'essentiel c'est la santé.

EFC10547	
----------	--

Χ	9							
Country		С	ent	er	Sι	ıbie	ect	

1004.02.1 Page No.

Repeat No.

Visit Name:

VISIT 4

PHARMACOKINETIC BLOOD

PK_01

Data ☑ No Data	
ANTI-AFLIBERCEPT	ANTIBODIES
DAY 1	

Theoretical Time Sample Date (dd-mmm-yyyy)

Sample Time (24-hour clock)

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



EFC10547

Х	4							
Country		С	ent	er	Sι	ıbie	ect	

103.1	
Page	No.

Visit Name:

VISIT 4

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_05

Data ✓ No Data 🗌					
AFLIBERCEPT/PLAC	EBO				
Scheduled	Treatment Number	Not Administered/	Date / Time*	Intended Dose	Actual Dose
Day		Taken	START	MG/KG	MG
DAY 1			(dd-mmm-yyyy)		
			(24-hour clock)		
			END		
	*Time to be	given only for PK patients	(24-hour clock)		
IF DOSE INTE	ERRUPTED AND RE	ADMINISTERED, PLEA	ASE REPORT THE II	NFORMATION BELOV	N :
Scheduled	Treatment Number	Not Administered/	Date / Time*	Intended Dose	Actual Dose
Day		Taken	START	MG/KG	MG
				NOT APPLICABLE	

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

*Time to be given only for PK patients

Confidential Information

(dd-mmm-yyyy)

(24-hour clock)

(24-hour clock)

END



EFC10547	
----------	--

Х	4							
Country		С	ent	er	Sι	ıbje	ect	

104.1	
Page	No.

Repeat	No.

VISIT 4

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_04

Data ☑ No Data ☐					
GEMCITABINE					
Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose	Actual Dose
DAY 1					
IF DOSE INTER	RUPTED AND REA	ADMINISTERED, PI	LEASE REPORT	THE INFORMATI	ON BELOW:
Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose	Actual Dose
(*)				NOT APPLICABLE	

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

Confidential Information



EFC10547

Х	4					Ļ	L	
Country		С	ent	er	Sι	ıbie	ect	

105.1	
Page	No.

Visit Name:

VISIT 4

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☑ No Data ☐

DAY 1

Outpatient Clinic Inpatient Clinic



EEC10547	
EFC10547	

Χ	4							
Country		С	ent	er	Sι	ıbje	ect	

106.1	
Page	No.

Visit Name:

VISIT 4

VITAL SIGNS

Data ✓ No Data 🗌

DAY 8

Date performed (dd-mmm-yyyy)

Blood pressure: Systolic: mmHg

/ Diastolic: mmHg

ECOG Performance Status 0 1 2 3 4 1



EFC10547	
----------	--

Х	4							
Country		С	ent	er	Sι	ıbie	ect	

107.1	
Page	No.

Visit Name:

VISIT 4

10E9/L

LAB_01 **HEMATOLOGY** Data ✓ No Data 🗌 DAY 8 Date of sampling (dd-mmm-yyyy) SI Ranges Unit Test Value If other unit, specify SI Value SI Unit Lower Limit Upper Limit G/L HEMOGLOBIN PLATELET COUNT (THROMBO 10E9/L WBC 10E9/L

Confidential Information

NEUTROPHILS



Χ	4							
Cc	un	try	С	ent	er	Sι	ıbje	ect

108.1	
Page	No.

Visit Name:

VISIT 4

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_04

Data ✓ No Data 🗌					
GEMCITABINE					
Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose	Actual Dose
DAY 8					
IF DOSE INTER	RUPTED AND REA	ADMINISTERED, PL	EASE REPORT	THE INFORMATION	ON BELOW:
Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose	Actual Dose
(*)				NOT APPLICABLE	

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

Confidential Information



EF(C10)547	
EF(ر 10)547	

Χ	4							
Country		С	ent	er	Sι	ıbje	ect	

109.1	
Page	No.

Visit Name:

VISIT 4

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☑ No Data ☐

DAY 8

Outpatient Clinic Inpatient Clinic



Χ	4							
Country		С	ent	er	Sı	ıbje	ect	

110.1	
Page	No.

Visit Name:

VISIT 4

VITAL SIGNS

Data ☑ No Data ☐

DAY 15

Date performed (dd-mmm-yyyy)

Weight: kg

Blood pressure: Systolic: mmHg / Diastolic: mmHg

ECOG Performance Status 0 1 2 3 4 1



Χ	4							
Cc	un	try	С	ent	er	Sι	ıbje	ect

111.1	
Page No.	•

0	l
Repeat No.	•

VISIT 4

10E9/L

LAB_01 **HEMATOLOGY** Data ✓ No Data 🗌 DAY 15 Date of sampling (dd-mmm-yyyy) SI Ranges Unit Test Value If other unit, specify SI Value SI Unit Lower Limit Upper Limit G/L HEMOGLOBIN PLATELET COUNT (THROMBO 10E9/L WBC 10E9/L

Confidential Information

NEUTROPHILS



\sim	un	tr.	_	ont	er	٥.	ıbic	L Vot
Χ	4							

112.1	
Page	No.

Visit Name:

VISIT 4

DIPSTICK URINALYSIS

LABU_1

Data ☑ No Data ☐

DAY 15

Date of sampling

Test name

WHITE BLOOD CELLS (QI

Absent

_ + _ _ ++

__++ ___+++

■ Not evaluable

RED BLOOD CELLS (QUAI

☐ Absent

☐ +++ ☐ Not evaluable

Confidential Information



EFC10547	
----------	--

Х	4							
Country		С	Center		Sı	ıbje	ect	

113.1	
Page	No.

0	
Repeat	No.

VISIT 4

MG/DL

LAB_01 **MORNING SPOT URINALYSIS** Data ✓ No Data 🗌 DAY 15 Please indicate if the laboratory is the : Same as baseline Same as previous Name Address City Country For Technical use: Name Address City Country Date of sampling (dd-mmm-yyyy) Unit SI Ranges If other unit, specify Test Value SI Value SI Unit Lower Limit Upper Limit PROTEIN (URINE) MG/DL

CREATININE (URINE)



EFC10547

Χ	4							
Country		С	Center			ıbje	ect	

114.1 Page No.

0 Repeat No.

Visit Name:

VISIT 4

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_05

Data ✓ No Data 🗌					
AFLIBERCEPT/PLACEBO)				
Scheduled	Treatment Number	Not Administered/	Date / Time*	Intended Dose	Actual Dose
Day		Taken	START	MG/KG	MG
DAY 15			(dd-mmm-yyyy)		
			(24-hour clock)		
			END		
	*Time to be	given only for PK patients	(24-hour clock)		

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

Treatment Number	Not Administered/	Date / Time*	Intended Dose	Actual Dose
Taken	raken	START	MG/KG	MG
			NOT APPLICABLE	
		(dd-mmm-yyyy)		
		(24-hour clock)		
	END			
*Time to be	given only for PK patients	(24-hour clock)		
		Treatment Number Not Administered/ Taken	Taken START (dd-mmm-yyyy) (24-hour clock) END *Time to be given only for PK patients	Taken START MG/KG NOT APPLICABLE (dd-mmm-yyyy) (24-hour clock) END *Time to be given only for PK patients

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



EFC10547	
----------	--

Х	4							
Co	un	try	С	ent	er	Sι	ıbje	ect

115.1	
Page	No.

Visit Name:

VISIT 4

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_04

Data ✓ No Data 🗌					
GEMCITABINE					
Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose	Actual Dose
DAY 15					
IF DOSE INTERF	RUPTED AND REA	ADMINISTERED, PI	LEASE REPORT	THE INFORMATION	ON BELOW:
Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose	Actual Dose
(*)				NOT APPLICABLE	

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



EF(C10)547	
EF(ر 10)547	

Χ	4							
Country		С	ent	er	Sι	ıbie	ect	

116.1	
Page	No.

Visit Name:

VISIT 4

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☑ No Data ☐

DAY 15

Outpatient Clinic Inpatient Clinic

TOTAL
sanofi aventis
L'essentiel c'est la santé.

Х	4					Ļ		
Cc	un	try	С	ent	er	Sι	ıbje	ect

117.1 Page No.

Repeat No.

ressentiel c'est la santé. Visit Name:

VISIT 4

PAIN INTENSITY

ASSESSED VIA VISUAL ANALOG SCALE

Data ✓ No Data 🗌

Data corresponding to current cycle

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

Confidential Information

AVE0005 - EFC10547 (VANILLA)

TOTA
sanofi aventis
L'essentiel c'est la santé.

EFC10547	

X 4 Country Center Subject

117.2 Page No.

Repeat No.

Visit Name:

VISIT 4

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

ANA
sanofi aventis
L'essentiel c'est la santé.

EFC10547

Χ	4							
Country		С	ent	er	Sι	ıbje	ect	

118.1	
Page No	<u>. </u>

0	
Repeat	No.

MEDICATION

ANALGESIC		

MED_02

Data ✓ No Data 🗌

ANALGESIC MEDICATION SHOULD BE COLLECTED DAILY PRIOR TO THE NEXT INFUSION

Drug/Medication (Brand or generic name)	Dosage Units (Total daily dose)	Route	Start Date Previously reported (dd-mmm-yyyy)	End Date Ongo (dd-mmm-yyyy)

ANA
sanofi aventis
L'essentiel c'est la santé.

EFC10547	
----------	--

Х	4							
Сс	un	trv	С	ent	er	Sι	ıbie	ect

118.2	
Page	No.

0	
Repeat	No.

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

ANA				
sanofi aventis				
L'essentiel c'est la santé.				

Х	4							
Co	un	try	С	ent	er	Sι	ıbie	ect

118.3	
Page	No.

0	
Repeat	No.

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



Coi		400.0	$\overline{}$	224	<u></u>	٣.	ıbje	L Not
Х	4							

119.1 Page No.

0 Repeat No.

Visit Name:

VISIT 4

TUMOR N	IEASUREMENT	S				TUMEA_02
Data ☑ No D	ata 🗌					
Lesion Number	Lesion Location	Date of Assessment (dd-mmm-yyyy)	Method of Tumor Measurement	Measurement of Target Lesion longest diameter	Response of Non target Lesions	
				mm		
		Not Done		mm		
		Not Done		mm		
		Not Done		mm		
		Not Done		mm		
		Not Done		mm		
		Not Done		mm		
		Not Done		mm		
		Not Done		mm		
		☐ Not Done ☐ Not Done		mm		

Confidential Information



Х	4							
Country		С	ent	er	Sι	ıbje	ect	

119.2	
Page	No.

Visit Name:

Lesion Number	Lesion Location	Date of Assessment (dd-mmm-yyyy)	Method of Tumor Measurement	Measurement of Target Lesion longest diameter	Response of Non target Lesions
		Not Done		mı	m
		Not Done		mı	m
		Not Done		mı	m
		Not Done		mı	m
		Not Done		mı	m
		Not Done		mı	m
		Not Done		mı	m
		Not Done		mı	m
		Not Done		mı	m
		□ Not Done		mr	m



Χ	4							
Country		С	ent	er	Sι	ıbje	ect	

120.1	
Page	No.

Visit Name:

VISIT 4

TUMOR MARKERS
TMARK_01

Data ✓ No Data 🗌	
Date of evaluation	
	(dd-mmm-yyyy)

TEST	VALUE	UNIT	NORMAL RANGE		
			LOWER LIMIT	UPPER LIMIT	
CA19-9					1



EEC4	0E 47
EFC1	U54 <i>1</i>

Χ	4							
Country		С	Center		Sι	ıbje	ect	

121.1	
Page	No.

Visit Name:

VISIT 4

CLINICAL EVENT THROMBOVASCULAR

Data No Data	Yes	No
ANGINA PECTORIS / UNSTABLE ANGINA / MYOCARDIAL INFARCTION		
STROKE / TRANSIENT ISCHEMIC ATTACK		
PERIPHERAL ARTERIAL THROMBOSIS		
DEEP VENOUS THROMBOSIS		
PULMONARY EMBOLISM		
INTRAABDOMINAL ARTERIAL THROMBOSIS		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		



EFC10547

Χ	4							
Country		С	Center			ıbje	ect	

604.1 Page No.

Repeat No.

Visit Name: VISIT 4 AE

ADVERSE EVENT Data No Data 1. Adverse Event (Diagnosis):	AE Form Number AE_03 AE Reference ID
Status of Adverse Event	New Date of Start (dd-mmm-yyyy) Ongoing without change (do not complete the remaining items) Ongoing with change
3. Grade4. Relationship to investigational product *	1
5. Action Taken with Investigat. Product	None Permanently discontinued Delayed Dose reduced Delayed and reduced Interrupted
6. Corrective treatment/therapy	Yes
7. Outcome	Recovered Date of Recovery (dd-mmm-yyyy)
	Recovered with sequelae Specify :
	Recovering
	Not recovered (accordance to a control of the death report forms)
	Fatal Date of Death (complete the death report form) Unknown
8. Seriousness Criteria	Yes No If Yes : -Date event became serious (dd-mmm-yyyy)
IF YES, COMPLETE THIS SECTION AND	-Tick below all criteria that apply :
THE SAFETY COMPLEMENTARY FORM	Results in Death Life Threatening Requires or prolongs hospitalization Persistant/significant disability/incapacity Congenital anomaly or Birth Defect Other medically important event
Is it an event such as: Overdose of the IP	Yes ☐ No ☐
Pregnancy	Yes No
*Is there a rea	asonable possibility that the AE was caused by Investigational Product?



Χ	4							
Country		С	Center			ıbje	ect	

604.2		
Page	No.	

Visit Name:

VISIT 4 AE

AE / Specific Event Form Number	
1. Demographic Information	
Weight (kg)	
2. Detailed Description of the Adverse Event (including complementary investigations)	
3. Date of Start of Event (Initial date of onset of the considered event) (DD-MMM-YYYY)	
4. Investigational Products	
Date of the FIRST administration of study treatment : (DD-MMM-YYYY)	
Current Treatment number : Current Cycle : Cur	
Date of the LAST administration before SAE: (dd-mmm-yyyy) Last Dosage before SAE:	Action Taken :
AFLIBERCEPT/PLACEBO MG/KG	
GEMCITABINE MG/M2	
5. In case of hospitalization Date of admission (DD-MMM-YYYY) (hospital report to be	sent)
5. In case of death Autopsy report Yes No (copy to be sent)	

Confidential Information



EFC10547	
EFC10547	

Χ	4							
Country			С	Center			ıbje	ect

704.01.1	
Page No.	•

0	
Repeat	No.

VISIT 4 LAB

ADDITIONAL HEMATO	LOGY						LAB_01
Data ☑ No Data ☐							
Date of sampling	(dd-mmm-yyyy)						
		Unit			SI Ran	iges	
Test	Value	If other unit, specify	SI Value	SI Unit	Lower Limit	Upper Limit	
HEMOGLOBIN		G/L					
PLATELET COUNT (THROMBO		10E9/L					
WBC		10E9/L					
NEUTROPHILS		10E9/L					
т	O RE DEDEC	DEMEDIONI VIEODID	ATIENT LIND	ED VITAM	IN K ANTAG	ONIST	

INR	RATIO			

Confidential Information



EFC10547	
----------	--

Х	4							
Country		Center			Sı	ıbje	ect	

704.02.1 Page No.

0 Repeat No.

Visit Name:

VISIT 4 LAB

ADDITIONAL BIOCHEMISTRY

LAB_01

Data 🗸 No Data		
Please ir	ndicate if the laboratory is the : Same as baseline Same as previous	
Name Address		
City [Country [
	For Technical use :	
Name Address		
City Country		



Х	4							
Country		С	Center			ıbje	ect	

704.02.2 Page No.

Repeat No.

Visit Name:

VISIT 4 LAB

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

^{*} If creatinine > 1 ULN please report the calculated creatinine clearance.
** If blood Urea Nitrogen is not evaluable, Urea value must be documented.



Χ	4							
Country			С	Center			ıbje	ect

704.03.1	
Page No.	

)	
Repeat No.	

VISIT 4 LAB

ADDITIONAL DIPSTICK URINALYSIS

LABU_1

Data ✓ No Data 🗌					
Date of sampling					
Test name					
WHITE BLOOD CELLS (QI	☐ Absent	<u> </u>	++	+++	□ Not evaluable
RED BLOOD CELLS (QUAI	☐ Absent	□ +	□ ++	+++	☐ Not evaluable



EFC10547

Χ	4							
Country			С	ent	er	Sι	ıbje	ect

704.04.1 Page No.

0 Repeat No.

Visit Name:

VISIT 4 LAB

ADDITIONAL MORNING SPOT URINALYSIS

LAB_01

Data 🔽 No Data							
	Please indi	cate if the lat	oratory is the : Same as	baseline previous			
Name Address							
City Country							
			For Technica	al use :			
Name Address							
City Country							
Date of sampling		(dd-mmm-yy	уу)				
			Unit			SI Ra	nges
Test		Value	If other unit, specify	SI Value	SI Unit	Lower Limit	Upper Limit
PROTEIN (URI	NE)		MG/DL				
CREATININE (URINE)		MG/DL				



10547
10547

X	4			Sı	
Х	4				

704.05.1 Page No.

0 Repeat No.

Visit Name:

VISIT 4 LAB

24-HOUR URINA Data ☑ No Data ☐	LYSIS	TO BE COMPLI	ETED IF UPC	R > 1			LAB_04
_	boratory is the Same as base Same as previ						
Name Address							
City Country							
	For	Technical use :					
Name Address							
City Country							
	Date (dd-mmm-yyyy)		(24-hour clock)				
Start date of collection:		ne of collection :				CLDAN	NOTO
End date of collection:		e of collection:		01.17	0111.7	SIRAN	
	Value Unit			SI Value	SI Unit	Lower limit	Upper Limit
URINARY VOLUME	L						
PROTEIN (URINE) CREATININE (URINI	G/L G/L				-		
CREATININE (ORIN	<u> </u>] [, L
	ELECTROPHORE	SIS					
ALBUMIN	G/L						
ALPHA 1 GLOBULIN	G/L						
ALPHA 2 GLOBULIN	G/L						
BETA GLOBULIN	G/L						
GAMMA GLOBULIN	G/L			1	1 1	1 1	1 I

TOTAL
sanofi aventis
L'essentiel c'est la santé.

EFC10547	
EFC10547	

Χ	4		_			Ļ		
Country			С	ent	er	Sι	ıbje	ect

704.05.2 Page No.

0 Repeat No.

Visit Name:

VISIT 4 LAB

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

LABU_1

Data ✓ No Data 🗌

HEMOGLOBIN (QUALITAT:

Test name Negative Positive

RED BLOOD CELLS (QUAI



EFC10547	
EFC10547	

Χ	4							
Country			С	ent	er	Sι	ıbje	ect

704.06.1 Page No.

0 Repeat No.

Visit Name:

VISIT 4 LAB

TO BE COMPLETED IF PROTEINURIA IS ASSOCIATED WITH HEMATURIA.

ADDITIONAL HEMATOLOGY								
Data ☑ No Data ☐								
Date of sampling								
Test name	Unit	Negative	Positive					
SCHISTOCYTES (QU.	ALITA NONE							



EFC10547

Χ	4							
Country		С	ent	er	Sι	ıbje	ect	

704.06.2 Page No.

0 Repeat No.

Visit Name:

VISIT 4 LAB

ADDITION Data No Da	AL BIOCHE	EMISTRY					LAB_01
Please indicate	e if the laboratory	is the : Same a Same a	s baseline s previous				
Name Addre							
City Coun	try						
			For Techr	nical use :			
Name Addre							
City Coun	try						
Date of sampli	ng	(dd-mmm-yyyy)	Unit			SI Rai	nges
Test		Value	If other unit, specify	SI Value	SI Unit	Lower Limit	Upper Limit
LDH			IU/L				
HAPTOGLOB:	IN		G/L				
OROSOMUCO:	[D		G/L][

ATA.	EFC10547		X 4 Country Center Subject	122.1 Page I
L'essentiel d'est la santé.	Visit Name:	VISIT 5	Country Control Cubject	

Repeat No. VISIT_01 Date of visit: (DD-MMM-YYYY) VITAL_02 **VITAL SIGNS** Data ✓ No Data 🗌 DAY 1 Date performed (dd-mmm-yyyy) Weight: kg Blood pressure: Systolic: mmHg / Diastolic: mmHg ECOG Performance Status 0 1 2 3 4

A PHYSICAL EXAM SHOULD BE PERFORMED.

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

RECORD AS AN ADVERSE EVENT



Х	4							
Country		Center			Sι	ıbje	ect	

123.1	
Page	No.

Visit Name:

VISIT 5

HEMATOLOGY							LAB_01
Data ☑ No Data ☐							
DAY 1							
Date of sampling	(dd-mmm-yyyy)						
		Unit			SI Ran	ges	
Test	Value	If other unit, specify	SI Value	SI Unit	Lower Limit	Upper Limit	
HEMOGLOBIN		G/L					
PLATELET COUNT (THROMBO		10E9/L					
WBC		10E9/L					
NEUTROPHILS		10E9/L					
T	O BE PERFO	DRMED ONLY FOR P	ATIENT UND	ER VITAN	IIN K ANTAG	ONIST	
INR		RATIO					



City

EFC10547

Х	4							
Country		С	ent	er	Sι	ıbie	ect	

124.1	
Page	No.

0 Repeat No.

Visit Name:

VISIT 5

BIOCHEMISTRY

Data No Data

DAY 1

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

Name
Address

Country	
	For Technical use :
Name Address	
Address	
City Country	
Country	



EFC10547	[Χ
	_	C

VISIT 5

Х	4							
Country		С	Center			ıbje	ect	

124.2	
Page No.	

0	l
Repeat No.	

Visit	Name:
Visit	Name:

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

G/DL

ALBUMIN

^{*} If creatinine > 1 ULN please report the calculated creatinine clearance.
** If blood Urea Nitrogen is not evaluable, Urea value must be documented.



EFC10547	
EFC10547	

Cc	บท	<u>ا</u>	$\overline{}$	ent	 <u>د</u> ،	لــــا منط،	ect
Х	4						

125.1	
Page	No.

Visit Name:

VISIT 5

DIPSTICK URINALYSIS

LABU_1

Data ☑ No Data ☐

DAY 1

Date of sampling

Test name

WHITE BLOOD CELLS (QI

Absent

□ +

_ ++ _ +++

■ Not evaluable

RED BLOOD CELLS (QUAI

☐ Absent

_ ++

☐ Not evaluable



Χ	4							
Country		С	Center			ıbje	ect	

126.1	
Page	No.

Visit Name:

VISIT 5

LAB_01

MORNING SPO	T URINALYSIS						LAB_01
Data ☑ No Data ☐							
DAY 1							
Ple	ease indicate if the lat	poratory is the: Same as b	aseline 🗌				
		Same as p	revious				
Name							
Address							
City							
Country							
		For Technical	luca:				
No.		1 Of Technica					
Name Address						 	
Address							
City						- 	
Country							
Country							
Date of sampling	(dd-mmm-yy	yy)					
Date of camping	,	Unit			CI Do	200	
Test	Value		SI Value	SI Unit	SI Ra	=	
1 691	value	If other unit, specify	Si value		Lower Limit	Upper Limit	
PROTEIN (URINE)		MG/DL					
CREATININE (URIN	E)	MG/DL					

XXX
sanofi aventis
L'essentiel c'est la santé.

EFC10547	
----------	--

Х	4							
Country			С	Center			ıbje	ect

974.1 Page No.

Repeat No.

Visit Name:

VISIT 5

PHARMACOKINETIC BLOOD

PK_01

TO BE COMPLETED ONLY FOR PK PATIENTS.

FREE AND BOUND AFLIBERCEPT
DAY 1

Sample
P04

Theoretical Time

Sample Date (dd-mmm-yyyy)

Sample Time 24-hour clock

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

ANA
sanofi aventis
L'essentiel c'est la santé.

Data ✓ No Data 🗌

DAY 1

EFC10547

Χ	9							
Country			С	ent	er	Sι	ıbie	

1005.01.1 Page No.

Repeat No.

Visit Name:

VISIT 5

PHARMACOKINETIC BLOOD

PK_01

FREE AND BOUND AFLIBERCEPT

Theoretical Time *

Sample Date (dd-mmm-yyyy)

Sample Time 24-hour clock

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



EFC10547

Χ	9							
Country			С	ent	er	Sι	ıbie	

1005.02.1
Page No.

Visit Name:

VISIT 5

PHARMACOKINETIC BLOOD

PK_01

Data ✓ No Data	
ANTI-AFLIBERCEPT	ANTIBODIES
DAY 1	

Theoretical	
Time	
ТОН	*

Sample Date
(dd-mmm-yyyy)



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



Х	4							
Co	un	try	С	ent	er	Sι	ıbie	ect

127.1	
Page No).

0	
Repeat	No.

VISIT 5

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_05

Data ✓ No Data 🗌					
AFLIBERCEPT/PLACEBO	O				
Scheduled	Treatment Number	Not Administered/	Date / Time*	Intended Dose	Actual Dose
Day		Taken	START	MG/KG	MG
DAY 1			(dd-mmm-yyyy)		
			(24-hour clock)		
			END		
	*Time to be (given only for PK patients	(24-hour clock)		
IF DOSE INTER	RUPTED AND REA	ADMINISTERED, PLEAS	SE REPORT THE IN	IFORMATION BELOV	V :
Scheduled	Treatment Number	Not Administered/	Date / Time*	Intended Dose	Actual Dose
Day		Taken	START	MG/KG	MG
(*)				NOT APPLICABLE	
(/			(dd-mmm-yyyy)		

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

*Time to be given only for PK patients

Confidential Information

(24-hour clock)

(24-hour clock)

END



EFC10547	
----------	--

Χ	4							
Cc	un	try	С	ent	er	Sι	ıbje	ect

128.1	
Page	No.

0	
Repeat	No.

VISIT 5

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_04

Data ☑ No Data ☐					
GEMCITABINE					
Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose	Actual Dose
DAY 1					
IF DOSE INTER	RUPTED AND REA	ADMINISTERED, PI	LEASE REPORT	THE INFORMATION	ON BELOW:
Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose	Actual Dose
(*)				NOT APPLICABLE	

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



EFC10547	
----------	--

Χ	4							
Country		С	ent	er	Sι	ıbje	ect	

129.1	
Page	No.

Visit Name:

VISIT 5

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☑ No Data ☐

DAY 1

Outpatient Clinic Inpatient Clinic



Χ	4							
Country		С	ent	er	Sι	ıbie	ect	

130.1	
Page	No.

Visit Name:

VISIT 5

VITAL_02 **VITAL SIGNS**

DAY 8

Data ✓ No Data 🗌

Date performed (dd-mmm-yyyy)

Blood pressure: Systolic:

mmHg

/ Diastolic:

mmHg

ECOG Performance Status 0 1 1 2 3 4 1



X		Ш	Ų	Щ		Ļ	Ļ	Ļ
Country			С	ent	er	Sι	ıbie	ect

131.1	
Page No.	

Visit Name:

VISIT 5

10E9/L

LAB_01 **HEMATOLOGY** Data ✓ No Data 🗌 DAY 8 Date of sampling (dd-mmm-yyyy) SI Ranges Unit Test Value If other unit, specify SI Value SI Unit Lower Limit Upper Limit G/L HEMOGLOBIN PLATELET COUNT (THROMBO 10E9/L WBC 10E9/L

NEUTROPHILS



Χ	4							
Country			С	ent	er	Sι	ıbje	ect

132.1	
Page	No.

Visit Name:

VISIT 5

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_04

Data ✓ No Data 🗌					
GEMCITABINE					
Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose	Actual Dose
DAY 8					
IF DOSE INTERI	RUPTED AND REA	ADMINISTERED, PI	LEASE REPORT	THE INFORMATION	ON BELOW:
Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose	Actual Dose
(*)				NOT APPLICABLE	

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



EFC10547

Χ	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

133.1	
Page	No.

Visit Name:

VISIT 5

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

Data ☑ No Data ☐

DAY 8

Outpatient Clinic Inpatient Clinic



EFC10547	
LI C10347	

Χ	4							
Co	un	try	С	ent	er	Sι	ıbje	ect

134.1	
Page	No.

Visit Name:

VISIT 5

VITAL SIGNS

DAY 15

Data ✓ No Data 🗌

Date performed (dd-mmm-yyyy)

Weight: kg

Blood pressure: Systolic: mmHg / Diastolic: mmHg

ECOG Performance Status 0 1 2 3 4



WBC

NEUTROPHILS

EFC10547

Х	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

135.1	
Page No.	

0 Repeat No.

Visit Name:

VISIT 5

10E9/L

10E9/L

LAB_01 **HEMATOLOGY** Data ✓ No Data 🗌 DAY 15 Date of sampling (dd-mmm-yyyy) SI Ranges Unit Test Value If other unit, specify SI Value SI Unit Lower Limit Upper Limit G/L HEMOGLOBIN PLATELET COUNT (THROMBO 10E9/L



\sim	un	tr.	_	ont	er	٥.	ıbic	L Vot
Χ	4							

136.1	
Page	No.

Visit Name:

VISIT 5

DIPSTICK URINALYSIS

Data ✓ No Data ☐
DAY 15
Date of sampling

Test name

WHITE BLOOD CELLS	JQ)	Absent	□ +	++	+++	■ Not evaluable
-------------------	-----	--------	-----	----	-----	-----------------



EFC10547

Χ	4							
Сс	Country Cen		ent	er	Sι	ıbje	ect	

137.1	
Page	No.

Visit Name:

VISIT 5

LAB_01

MORNING SPOT	URINALYSIS	3				LAE
Data ☑ No Data ☐						
DAY 15						
Pleas	se indicate if the la	boratory is the: Same as b	aseline 🗌			
		Same as p	revious			
Name						
Address						
City						
Country						
		For Technical	 l use :			
Name						-
Address						=
City						=
Country						=
Date of sampling	(dd-mmm-y	ууу)				
· ·		Unit			SI Ra	anges
Test	Value	If other unit, specify	SI Value	SI Unit	Lower Limit	Upper Limit
PROTEIN (URINE)		MG/DL				1
CREATININE (URINE		MG/DL		7 -		<u>-</u>
CKEAIININE (UKINE	<u>/</u>	חת / חדו				



X 4	ㅗ	<u>_</u>	Ĺ	Ļ	L_I
Country	Center		Subject		∆C†

138.1	
Page	No.

Visit Name:

VISIT 5

INVESTIGATIONAL PRODUCT ADMINISTRATION

IPA_05

Data ✓ No Data 🗌					
AFLIBERCEPT/PLACE	30				
Scheduled	Treatment Number	Not Administered/	Date / Time*	Intended Dose	Actual Dose
Day		Taken	START	MG/KG	MG
DAY 15			(dd-mmm-yyyy)		
			(24-hour clock)		
			END		
	*Time to be	given only for PK patients	(24-hour clock)		

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

Treatment Number	Not Administered/	Date / Time*	Intended Dose	Actual Dose
	raken	START	MG/KG	MG
			NOT APPLICABLE	
		(dd-mmm-yyyy)		
		(24-hour clock)		
		END		
*Time to be o	given only for PK patients	(24-hour clock)		
		Treatment Number Not Administered/ Taken	Taken START (dd-mmm-yyyy) (24-hour clock) END *Time to be given only for PK patients	Taken START MG/KG NOT APPLICABLE (dd-mmm-yyyy) (24-hour clock) END *Time to be given only for PK patients

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



DAY 15

EFC	C10547	7
EFC	10547ر	,

Х	4							
Country		С	ent	er	Sι	ıbie	ect	

139.1	
Page	No.

Repeat No.

IPA_04

Visit Name:

VISIT 5

INVESTIGATIONAL PRODUCT ADMINISTRATION								
Data ☑ No Data ☐								
GEMCITABINE								
Scheduled Day	Batch Number	Not Administred/ Taken	Date	Intended Dose MG/M2	Actual Dose			

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

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

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



EFC10547	
----------	--

Χ	4							
Сс	un	try	С	Center		Sι	ıbje	ect

140.1	
Page	No.

Visit Name:

VISIT 5

INVESTIGATIONAL PRODUCT ADMINISTRATION SETTING

SETTI_01

DAY 15

Data ☑ No Data ☐

Outpatient Clinic Inpatient Clinic

XXX
sanofi aventis
L'essentiel c'est la santé.

Х	4							
Co	un	try	С	ent	er	Sι	ıbje	ect

141.1	
Page	No.

ı	0	
•	Repeat	No.

VISIT 5

PAIN INTENSITY ASSESSED VIA VISUAL ANALOG SCALE

Data ✓ No Data 🗌

Data corresponding to current cycle

Period	Date	Measure
		MM
DAY 1		
DAY 2		
DAY 3		
DAY 4		
DAY 5		
DAY 6		
DAY 7		
DAY 8		
DAY 9		
DAY 10		
DAY 11		
DAY 12		
DAY 13		
DAY 14		
DAY 15		
DAY 16		
DAY 17		
DAY 18		$\exists \Box$
DAY 19		
DAY 20		ラ
DAY 21		

Confidential Information

AVE0005 - EFC10547 (VANILLA)

Final Version: 24OCT2007

TOTAL
sanofi aventis
L'essentiel c'est la santé.

\triangle	un	Ш •».	_	ent	 <u>ر</u>	المار	L
Х	4						

141.2
Page No.

Visit Name:

VISIT 5

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

ANA
sanofi aventis
L'essentiel c'est la santé.

EFC10547

Х	4							
Country			С	ent	er	Sι	ıbie	ect

142.1		
Page	No.	

0	
Repeat	No.

MEDICATION

MED_02

Data ✓ No Data 🗌

ANALGESIC MEDICATION SHOULD BE COLLECTED DAILY PRIOR TO THE NEXT INFUSION

VISIT 5

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

XXX
sanofi aventis
L'essentiel c'est la santé.

EFC10547

	Х	4							
Country		С	ent	er	Sı	ıbje	ect		

142.2	
Page No.	

0	
Repeat	No.

VISIT 5	

Drug/Medication (Brand or generic name)	Dosage Units (Total daily dose)	Route	Start Date Previously reported (dd-mmm-yyyy)	End Date Ongoin (dd-mmm-yyyy)

XXX
sanofi aventis
L'essentiel c'est la santé.

EFC10547

Х	4							
Country		С	ent	er	Sι	ıbje	ect	

142.3	
Page	No.

0	
Repeat	No.

VISIT 5

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



Χ	4							
Country		С	Center			ıbje	ect	

143.1	
Page	No.

Visit Name:

VISIT 5

TUMOR	R MEASUREMENTS					TUMEA_02
Data ✓ N	o Data 🗌					
Lesion Number	Lesion Location	Date of Assessment (dd-mmm-yyyy)	Method of Tumor Measurement	Measurement of Target Lesion longest diameter	Response of Non target Lesions	
				mm		
		☐ Not Done		mm		
		Not Done		mm		
		Not Done				
		☐ Not Done		mm		
		□ □ Not Dance		mm		
		☐ Not Done		mm		
		Not Done				
		L ☐ Not Done		mm		
		☐ Not Done		mm		
		☐ Not Done		mm		
		☐ Not Done		mm		



Χ	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

143.2	
Page	No.

0	
Repeat	No.

ISIT 5		

Lesion Number	Lesion Location	Date of Assessment (dd-mmm-yyyy)	Method of Tumor Measurement	Measurement of Target Lesion longest diameter	Response of Non target Lesions
		Not Done		mr	m
		☐ Not Done		mr	m
		Not Done		mr	m
		Not Done		mr	m
		Not Done		mr	m
		Not Done		mr	m
		Not Done		mr	m
		Not Done		mr	m
		☐ Not Done		mr	m
		□ Not Done		mr	m



Χ	4							
Country			Center			Subject		

144.1	
Page	No.

Visit Name:

VISIT 5

TUMOR MARKERS

TMARK_01

Data	✓	No Data 🗌
------	---	-----------

Date of evaluation

(dd-mmm-yyyy)

TEST VALUE UNIT NORMAL RANGE
LOWER LIMIT UPPER LIMIT

CA19-9



EFC10547	

Χ	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

145.1	
Page	No.

Visit Name:

VISIT 5

CLINICAL EVENT THROMBOVASCULAR

Data ☑ No Data ☐	Yes	No
ANGINA PECTORIS / UNSTABLE ANGINA / MYOCARDIAL INFARCTION		
STROKE / TRANSIENT ISCHEMIC ATTACK		
PERIPHERAL ARTERIAL THROMBOSIS		
DEEP VENOUS THROMBOSIS		
PULMONARY EMBOLISM		
INTRAABDOMINAL ARTERIAL THROMBOSIS		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		



EFC10547	
----------	--

Χ	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

605.1 Page No.

Repeat No.

Visit Name:	VISIT 5 AE

ADVERSE EVENT Data No Data 1. Adverse Event (Diagnosis):	AE Form Number AE_03 AE Reference ID
2. Status of Adverse Event	New Date of Start (dd-mmm-yyyy) Ongoing without change (do not complete the remaining items) Ongoing with change
3. Grade4. Relationship to investigational product *	1
5. Action Taken with Investigat. Product	None Permanently discontinued Delayed Dose reduced Delayed and reduced Interrupted
6. Corrective treatment/therapy	Yes
7. Outcome	Recovered Date of Recovery (dd-mmm-yyyy)
	Recovered with sequelae Specify :
	Recovering
	Not recovered Fatal Date of Death (complete the death report form) Unknown
8. Seriousness Criteria	Yes No If Yes : -Date event became serious (dd-mmm-yyyy)
IF YES, COMPLETE THIS SECTION AND	-Tick below all criteria that apply :
9. Is it an event such as: Overdose of the IP	Results in Death Life Threatening Requires or prolongs hospitalization Yes No
Pregnancy	Yes No No
*Is there a rea	asonable possibility that the AE was caused by Investigational Product?



Χ	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

605.2		
Page	No.	

Visit Name:

VISIT 5 AE

AE / Specific Event Form Number	
1. Demographic Information Weight (kg)	
2. Detailed Description of the Adverse Event (including complementary investigations)	
3. Date of Start of Event (Initial date of onset of the considered event) (DD-MMM-YYYY)	
4. Investigational Products	
Date of the FIRST administration of study treatment : (DD-MMM-YYYY)	
Current Treatment number : Current Cycle : Cur	
Date of the LAST administration before SAE: (dd-mmm-yyyy) Last Dosage before SAE: Action Ta	aken :
AFLIBERCEPT/PLACEBO MG/KG	
GEMCITABINE MG/M2	
5. In case of hospitalization Date of admission (DD-MMM-YYYY) (hospital report to be sent)	
6. In case of death Autopsy report Yes No (copy to be sent)	
7. Corrective Treatment / Therapy	



INR

EF(C10)547	
EF(ر 10)547	

Χ	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

705.01.1	
Page No.	

0	
Repeat	No.

Visit Name:

VISIT 5 LAB

RATIO

ADDITIONAL HEMATO	LOGY						LAB_01
Data ☑ No Data ☐							
Date of sampling	(dd-mmm-yyyy	<i>(</i>)					
		Unit			SI Rai	nges	
Test	Value	If other unit, specify	SI Value	SI Unit	Lower Limit	Upper Limit	
HEMOGLOBIN		G/L					
PLATELET COUNT (THROMBO		10E9/L					
WBC		10E9/L					
NEUTROPHILS		10E9/L					
T	O BE PERF	ORMED ONLY FOR F	PATIENT UND	ER VITAN	IIN K ANTAG	ONIST	



EFC10547	
----------	--

Х	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

705.02.1
Page No.

Visit Name:

VISIT 5 LAB

ADDITIONAL BIOCHEMISTRY

LAB_01

Data ☑ No Dat	a 🗌	
Please i	indicate if the laboratory is the : Same as baseline Same as previous	
Name		
Address		
City		
Country		
	For Technical use :	
Name		
Address		
City		
Country		



EF(C10)547	
EF(ر 10)547	

Χ	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

705.02.2
Page No.

0	
Repeat	No.

Visit Name:

VISIT 5 LAB

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

^{*} If creatinine > 1 ULN please report the calculated creatinine clearance.
** If blood Urea Nitrogen is not evaluable, Urea value must be documented.



Х	4					Ļ	L	
Country			С	ent	er	Sι	ıbie	ect

705.03.1
Page No.

Visit Name:

VISIT 5 LAB

ADDITIONAL DIPSTICK URINALYSIS

LABU_1

Data ✓ No Data ☐					
Date of sampling					
Test name					
WHITE BLOOD CELLS (QT	Absent	+		+++	□ Not evaluable
RED BLOOD CELLS (QUAI	☐ Absent	□ +		□ +++	☐ Not evaluable



EFC10547	
----------	--

Х	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

705.04.1
Page No.

Visit Name:

VISIT 5 LAB

ADDITIONAL MORNING SPOT URINALYSIS

LAB_01

Data No Data									
	Please indi	cate if the lab	oratory is the: Same	e as basel e as previ					
Name Address								\exists	
Address									
City Country									
			For Tec	hnical use):				
Name Address								\exists	
City Country									
Date of sampling		(dd-mmm-yyy	y)						
			Unit				SI Rar	nges	
Test		Value	If other unit, spec	ify S	SI Value	SI Unit	Lower Limit	Upper Limit	
PROTEIN (UR	INE)		MG/DL	[
CREATININE	(URINE)		MG/DL	Γ		1] [7



Χ	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

705.05.1 Page No.

0 Repeat No.

Visit Name:

VISIT 5 LAB

24-HOUR URIN Data ✓ No Data	LYSIS		TO BE COMPL	ETED IF UPO	CR > 1				LAB_04
Please indicate if the la	aboratory is th	eSame as baselir Same as previo	_						
Name Address									
City Country									
		For T	echnical use :						
Name Address									
City Country									
	Date (dd-mmn			(24-hour clock	r)				
Start date of collection:			e of collection :				01.5	411050	
End date of collection:			e of collection :					ANGES	
Test	Value	Unit			SI Value	SI Unit	Lower lim	nit Upper Limit	1
URINARY VOLUME		L L				_		⊣	
PROTEIN (URINE)		G/L				┩┝──		⊣	
CREATININE (URIN		G/L							j
	ELE	CTROPHORES	SIS						
ALBUMIN		G/L					1		1
ALPHA 1 GLOBULIN		G/L				1	1		1
ALPHA 2 GLOBULIN		G/L]
BETA GLOBULIN		G/L]
GAMMA GLOBULIN		G/L							

TOTAL
sanofi aventis
L'essentiel c'est la santé.

EFC10547	
EFC10547	

Χ	4							
Country			С	Center			ıbje	ect

705.05.2
Page No.

Visit Name:

VISIT 5 LAB

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

LABU_1

Data ✓ No Data 🗌

HEMOGLOBIN (QUALITAT:

Test name Positive Negative

RED BLOOD CELLS (QUAI



EFC10547	
EFC10547	

Χ	4							
Country		С	Center			ıbje	ect	

705.06.1
Page No.

0	
Repeat	No.

Visit Name:

VISIT 5 LAB

TO BE COMPLETED IF PROTEINURIA IS ASSOCIATED WITH HEMATURIA.

ADDITIONAL H	IEMATOLOGY			
Data ☑ No Data ☐				
Date of sampling				
Test name	Unit	Negative	Positive	
SCHISTOCYTES (QU	ALITA NONE			



X		Ш	Ų	Щ		Ļ	Ļ	Ļ
Country			С	ent	er	Sι	ıbie	ect

705.06.2 Page No.

0 Repeat No.

Visit Name:

VISIT 5 LAB

ADDITION		MISTRY					LAB_01	
Please indicate	f the laboratory	is the : Same a Same a	s baseline s previous					
Name Addre	SS							
City Count	у							
			For Tech	nical use :				
Name Addres	ss							
City Count	у							
Date of samplin	9	(dd-mmm-yyyy)	Unit			SI Rai	nges	
Test		Value	If other unit, specify	SI Value	SI Unit	Lower Limit	Upper Limit	
LDH			IU/L					
HAPTOGLOBI	I		G/L					
OROSOMUCOI)		G/L					



Х	4							
Country			С	ent	er	Sι	ıbie	ect

501.1	
Page	No.

0	
Repeat	No.

Visit Name:

VISIT 80

END OF TREATMENT

EOT_01

atment
. H
otocol
H
Ш

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

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

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



Data ✓ No Data 🗌

Х	4							
Сс	Country			Center			ıbje	ect

502.1	
Page	No.

0 Repeat No.

Visit Name:

VISIT 80

END OF TREATMENT

EOT_03

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

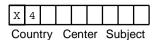
Adverse event *
Other reason

If other reason, specify

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

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





503.1 Page No.

Repeat No.

Visit Name:

VISIT 80

CODE BREAKING (ON SITE)

CODEB 01

Data ☐ No Data ✓

The code has been broken by

Investigator Pharmacist Study nurse Other (site staff)

If other, specify

Name

Performed by:

lvrs Code breaking material

Date performed: (DD-MMM-YYYY)

Time performed (24-hour clock)

Reason: Adverse event

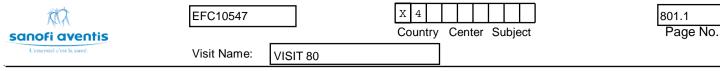
Other

==> AE Form Number

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.



| Visit Name: Name

A PHYSICAL EXAM SHOULD BE PERFORMED.

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

RECORD AS AN ADVERSE EVENT

Confidential Information

Repeat No.



Х	4							
Country			Center			Sı	ıbje	ect

802.1	
Page	No.

0	
Repeat	No.

Visit Name:

VISIT 80

HEMATOLOGY Data ☑ No Data ☐							LAB_01
Date of sampling	(dd-mmm-yyyy)						
		Unit			SI Ran	ges	
Test	Value	If other unit, specify	SI Value	SI Unit	Lower Limit	Upper Limit	
HEMOGLOBIN		G/L					
PLATELET COUNT (THROMB	(10E9/L					
WBC		10E9/L					
NEUTROPHILS		10E9/L					
1	O BE PERFO	ORMED ONLY FOR P	ATIENT UND	ER VITAM	IN K ANTAG	ONIST	
INR		RATIO					



EFC10547

Х	4							
Country		Center			Sι	ıbje	ect	

803.1	
Page	No.

Visit Name:

VISIT 80

BIOCHEMISTRY LAB_01

ata ☑ No Data		
Please in	dicate if the laboratory is the : Same as baseline Same as previous	
Name _	<u> </u>	
Address		
City		
Country		
	For Technical use :	
Name		
Address		
City		
Country		



	EFC10547	
--	----------	--

Х	4							
Country			С	ent	er	Sι	ıbje	ect

803.2
Page No.

0	
Repeat	No.

Visit Name:

VISIT 80

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

^{*} If creatinine > 1 ULN please report the calculated creatinine clearance.
** If blood Urea Nitrogen is not evaluable, Urea value must be documented.



Data ✓ No Data 🗌

Χ	4							
Country			С	ent	er	Sι	ıbje	ect

804.1	
Page	No.

0 Repeat No.

Visit Name:

VISIT 80

DIPSTICK URINALYSIS

LABU_1

Date of sampling	
Test name	
WHITE BLOOD CELLS (QT	

☐ Absent	□ +	++	+++	■ Not evaluable



Х	4							
C	Country		Center			Sι	ıbje	ect

805.1	
Page	No.

Visit Name:

VISIT 80

MORNING SPOT URINALYSIS Data No Data

LAB.	_01

ata 🛂 No Data 🔼						
	Please indicate if the lab	ooratory is the : Same as b Same as p				
Name						
Address						
City						\dashv
Country						
		For Technical	use :			
Name						
Address						
City Country						_
ate of sampling	(dd-mmm-yy	уу)				
		Unit			SI Ra	nges
est	Value	If other unit, specify	SI Value	SI Unit	Lower Limit	Upper Limit
PROTEIN (URINE	Ξ)	MG/DL] [
CDEATINING (III	OTNE)	MG/DI.			1]

XXX
sanofi aventis
L'essentiel c'est la santé.

Χ	4							
Country			Center			Subject		

975.01.1 Page No.

Repeat No.

Visit Name:

VISIT 80

PHARMACOKINETIC BLOOD

PK_01

Data ☑ No Data ☐

FREE AND BOUND AFLIBERCEPT

Sample ID

Theoretical Time Sample Date (dd-mmm-yyyy)

Sample Time 24-hour clock

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



Χ	9							
Country		Center			Subject			

975.01.1 Page No.

Repeat No.

Visit Name:

VISIT 80

PHARMACOKINETIC BLOOD

PK_01

Data ✓ No Data 🗌

FREE AND BOUND AFLIBERCEPT

Theoretical Time Sample Date (dd-mmm-yyyy)

Sample Time 24-hour clock

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

XXX						
sanofi aventis						
L'essentiel c'est la santé.						

Х	4							
Co	un	trv	С	ent	er	Sι	ıbie	ect

975.02.1 Page No.

Repeat No.

Visit Name:

VISIT 80

PHARMACOKINETIC BLOOD

PK_01

Data <u></u> ✓	No Data L	J

ANTI-AFLIBERCEPT ANTIBODIES

Sample ID Theoretical
Time

Sample Date (dd-mmm-yyyy)

Sample Time (24-hour clock)

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



Χ	9							
Country			Center			Subject		

975.02.1 Page No.

Repeat No.

Visit Name:

VISIT 80

PHARMACOKINETIC BLOOD

PK_01

Data ✓ No Data 🗌

ANTI-AFLIBERCEPT ANTIBODIES

Theoretical Time Sample Date (dd-mmm-yyyy)

Sample Time (24-hour clock)

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



EFC10547

Χ	4								
Country			С	Center			Subject		

806.1 Page No.

0 Repeat No.

Visit Name:

VISIT 80

TUMOR	MEASUREMENTS					TUMEA_02
Data ☑ No	Data 🗌					
Lesion Number	Lesion Location	Date of Assessment (dd-mmm-yyyy)	Method of Tumor Measurement	Measurement of Target Lesion longest diameter	Response of Non target Lesions	
				mm		
		Not Done		mm		
		Not Done		mm		
		☐ Not Done ☐ Not Done		mm		
		Not Done		mm		
		Not Done		mm		
		☐ Not Done		mm		
		Not Done		mm		
		☐ Not Done		mm		
		□ Net Dans		mm		
		☐ Not Done				



EFC10547

Х	4							
Country		С	ent	er	Sι	ıbje	ect	

806.2	
Page	No.

Visit Name:

VISIT 80

Lesion Number	Lesion Location	Date of Assessment (dd-mmm-yyyy)	Method of Tumor Measurement	Measurement of Target Lesion longest diameter	Response of Non target Lesions
		Not Done		mr	n
		Not Done		mr	n
		Not Done] mr	n
		☐ Not Done		mr	n
		Not Done		mr	<u> </u>
		Not Done] [mr	
		Not Done] [mr	
		Not Done]	n []
		☐ Not Done] mr	n
		☐ Not Done		mr	n



EFC1	0547	

Χ	4							
Country		С	ent	er	Sι	ıbje	ect	

807.1	
Page	No.

Visit Name:

VISIT 80

TUMOR MARKERS

TMARK_01

Data ☑ No Data ☐	
Date of evaluation	

(dd-mmm-yyyy)

TEST VALUE UNIT NORMAL RANGE
LOWER LIMIT UPPER LIMIT

CA19-9



INR

EFC10547	
----------	--

Χ	4							
Country			С	ent	er	Sι	ıbje	ect

780.01.1	
Page No.	

0		l
Repeat	No.	

Visit Name:

VISIT 80 LAB

RATIO

ADDITIONAL HEMATOLOGY								
Data ☑ No Data ☐								
Date of sampling	(dd-mmm-yyyy)							
		Unit			SI Ran	ges		
Test	Value	If other unit, specify	SI Value	SI Unit	Lower Limit	Upper Limit		
HEMOGLOBIN		G/L						
PLATELET COUNT (THROMBO		10E9/L						
WBC		10E9/L						
NEUTROPHILS		10E9/L						
Т	O BE PERFO	DRMED ONLY FOR P	ATIENT UND	ER VITAM	IN K ANTAG	ONIST		



Χ	4							
Co	oun	try	С	ent	er	Sι	ıbje	ect

780.02.1
Page No.

Visit Name:

VISIT 80 LAB

ADDITIONAL BIOCHEMISTRY

LAB_01

Data ✓ No Dat	ea 🗌	
Please i	indicate if the laboratory is the : Same as baseline Same as previous	
Name		
Address		
City		
Country		
	For Technical use :	
Name		
Address		
City		
Country		



Х	4							
Country		С	Center			ıbje	ect	

780.02.2 Page No.

Repeat No.

Visit Name:

VISIT 80 LAB

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

^{*} If creatinine > 1 ULN please report the calculated creatinine clearance.
** If blood Urea Nitrogen is not evaluable, Urea value must be documented.



Χ	4							
Country			Center			Subject		

780.03.1	
Page No.	

Visit Name:

VISIT 80 LAB

ADDITIONAL DIPSTICK URINALYSIS

LABU_1

Data ✓ No Data 🗌					
Date of sampling					
Test name					
WHITE BLOOD CELLS (Q	☐ Absent	<u> </u>	<u></u> ++	+++	□ Not evaluable
RED BLOOD CELLS (QUAI	☐ Absent	□ +	□ ++	+++	☐ Not evaluable



EFC10547	
----------	--

Х	4							
Co	Country		Center			Sι	ıbje	ect

780.04.1
Page No.

Visit Name:

VISIT 80 LAB

ADDITIONAL MORNING SPOT URINALYSIS

LAB_01

Data 🔽 No Data	a 🗌						
	Please indi	cate if the labo	ratory is the : Same as b Same as p	oaseline orevious			
Name							
Address							
City							
Country							
			For Technica	l use :			
Name							
Address							
City							=
Country							
Date of sampling	ı	(dd-mmm-yyyy))				
		_	Unit			SI Raı	nges
Test		Value	If other unit, specify	SI Value	SI Unit	Lower Limit	Upper Limit
PROTEIN (UR	INE)		MG/DL				
CREATININE	(URINE)		MG/DL		7] [



EFC10547	
EFC10547	

Χ	4							
Country			Center			Sι	ıbje	ect

780.05.1 Page No.

0 Repeat No.

Visit Name:

VISIT 80 LAB

24-HOUR URIN Data ✓ No Data ✓	LYSIS		TO BE COMPL	ETED IF UPO	CR > 1				LAB_04
Please indicate if the la	aboratory is th	eSame as base Same as previ							
Name Address									
City Country									
		For	Technical use :						
Name Address									
City Country									
	Date (dd-mmn			(24-hour clock	r)			I	
Start date of collection: End date of collection:			me of collection :				SI	RANGES	
Test	Value	Unit	io or component.		SI Value	SI Unit		imit Upper Limi	it
URINARY VOLUME		L							7
PROTEIN (URINE)		G/L]
CREATININE (URIN		G/L]
	ELE(CTROPHORE	SIS						
ALBUMIN		G/L					1		٦
ALPHA 1 GLOBULIN		G/L							Ī
ALPHA 2 GLOBULIN		G/L							_
BETA GLOBULIN		G/L				┥┝──		⊣	4
CAMMA CLOBIILIN	1	II(∴/I. I			1	1 1	1 1	1.1	



EFC	C10547	7
EFC	10547ر	,

Χ	4							
Country			Center			Sι	ıbje	ect

780.05.2
Page No.

Visit Name:

VISIT 80 LAB

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

LABU_1

Data ☑ No Data ☐

Test name Negative Positive HEMOGLOBIN (QUALITAT:

RED BLOOD CELLS (QUAI



EFC10547

Χ	4							
Country			Center			Sι	ıbje	ect

780.06.1
Page No.

Visit Name:

NONE

VISIT 80 LAB

TO BE COMPLETED IF PROTEINURIA IS ASSOCIATED WITH HEMATURIA.

ADDITIONAL HEMA	TOLOGY				LABU_1
Data☑ No Data☐					
Date of sampling					
Test name	Unit	Negative	Positive		

SCHISTOCYTES (QUALITA



EFC10547

Х	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

780.06.2 Page No.

0 Repeat No.

Visit Name:

VISIT 80 LAB

G/L

LAB 01 **ADDITIONAL BIOCHEMISTRY** Data ✓ No Data 🗌 Please indicate if the laboratory is the : Same as baseline \Box Same as previous Name Address City Country For Technical use: Name Address City Country Date of sampling (dd-mmm-yyyy) Unit SI Ranges Value If other unit, specify Lower Limit Upper Limit Test SI Value SI Unit IU/L LDH HAPTOGLOBIN G/L

Confidential Information

OROSOMUCOID

sanofi aventis	EFC10547	X 4	808.1 0 Repeat No.
L'essentiel c'est la santé.	Visit Name: VISIT 81		
Date of visit :	(DD-MMM-YYYY)		VISIT_01
SUBJECT STAT	TUS		SUBST_01
Data ☑ No Data ☐			
AT 90 DAYS AFTER L	AST STUDY DRUG ADMINISTRA	TION	
Date of last contact:	(DD-MMM-YYYY)		

Subject condition at the time of the scheduled visit :

If other, specify _____

Alive

Dead *

Phone

Other

Lost to follow-up

Method of contact:

Scheduled Visit

Final Version: 24OCT2007

^{*} 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.



Х	4							
Co	un	try	С	ent	er	Sι	ıbje	ect

809.1	
Page	No.

Visit Name:

VISIT 81

VITAL SIGNS

Data ☑ No Data □	
Date performed (dd-mmm-yyyy)	
Weight: kg	
Blood pressure: Systolic: mmHg	/ Diastolic: mmHg
ECOG Performance Status 0 1 2 3 4	

A PHYSICAL EXAM SHOULD BE PERFORMED.

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

RECORD AS AN ADVERSE EVENT



\sim	un	tr.	_	ont	er	٥.	ıbic	L Vot
Χ	4							

976.01.1 Page No.

Repeat No.

Visit Name:

VISIT 81

PHARMACOKINETIC BLOOD

PK_01

Data ☑ No Data ☐

FREE AND BOUND AFLIBERCEPT

Sample ID

Theoretical Time

Sample Date (dd-mmm-yyyy)

Sample Time 24-hour clock

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



Χ	9							
Country		С	ent	er	Sι	ıbie	ect	

976.01.1	l
Page No.	

Visit Name:

VISIT 81

PHARMACOKINETIC BLOOD

PK_01

Data ✓ No Data 🗌

FREE AND BOUND AFLIBERCEPT

Theoretical	
Time	
TOH	*

Sample Date
(dd-mmm-yyyy)

5	Sample 24-hour o	

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



EFC10547	
----------	--

Χ	4							
Сс	un	try	С	Center		Sι	ıbje	ect

976.02.1 Page No.

Repeat No.

Visit Name:

VISIT 81

PHARMACOKINETIC BLOOD

PK_01

Data ☑ No Data ☐

ANTI-AFLIBERCEPT ANTIBODIES

Sample ID

Theoretical
Time

Sample Date (dd-mmm-yyyy)

Sample Time (24-hour clock)

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



Χ	9							
Сс	un	trv	Center		Sι	ıbie	ect	

976.02.1	l
Page No.	

0	
Repeat	No.

VISIT 81

PHARMACOKINETIC BLOOD

PK_01

Data ✓ No Data 🗌
ANTI-AFLIBERCEPT ANTIBODIES

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

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

TOTA
sanofi aventis
L'assantial c'ast la canté

SURGERY

10547
10547

Х	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

810.1	
Page	No.

)	
Repeat	No.

Visit Name:

POST TREATMENT ANTI CANCER

VISIT 81

SURG_01

Data ✓ No Data □	
Surgery	Surgery Date (DD-MMM-YYYY)



VISIT 81

Visit Name:

Χ	4							
Country		С	Center			ıbje	ect	

811.1	
Page No.	_

0 Repeat No.

ANTI-CANCER THERAPY							
POST TREATMENT							
Data ✓ No Data 🗌							
Regimen Number Drug/Medication REGIMEN 1	Therapy Type Type	Cumulative Dose	Dose Units	Route	Start Date	End Date	Ongoing
ANTI-CANCER THERAPY POST TREATMENT Data No Data							
Regimen Number Drug/Medication	Therapy Type	Cumulative Dose	Dose Units	Route	Start Date	End Date	Ongoing
REGIMEN 2							
REGIFIEN Z							



Χ	4							
Country			С	ent	er	Sι	ıbje	ect

812.1	
Page No.	

0	
Repeat	No.

RADIATION THERAPY

POST TREATMENT

VISIT 81

	TΧ	01

Data ☑ No Data ☐ Lesion location	Start Date (dd-mmm-yyyy)	End Date (dd-mmm-yyyy)	Total Dose	Unit	Intent
				Grays ☐ Rads ☐	Palliative Curative
				Grays ☐ Rads ☐	Palliative Curative
				Grays ☐ Rads ☐	Palliative Curative
				Grays ☐ Rads ☐	Palliative Curative
				Grays ☐ Rads ☐	Palliative Curative
				Grays ☐ Rads ☐	Palliative Curative
				Grays ☐ Rads ☐	Palliative Curative
				Grays ☐ Rads ☐	Palliative Curative
				Grays ☐ Rads ☐	Palliative Curative



EFC10547	
----------	--

Х	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

812.2	
Page	No.

0	
Repeat	No.

Visit Name: VISIT 81

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

ANA
sanofi aventis
L'essentiel c'est la santé.

Co		trv		 or	ر ا	ıbje	L_
Х	4						

813.1	
Page	No.

Visit Name:

VISIT 81

PAIN INTENSITY

Data ✓ No Data □

ASSESSED VIA VISUAL ANALOG SCALE

SINCE LAST VISIT

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

Period	Date	Measure
		MM
DAY 1		
DAY 2		
DAY 3		
DAY 4		
DAY 5		
DAY 6		
DAY 7		
DAY 8		
DAY 9		
DAY 10		
DAY 11		Ш
DAY 12		
DAY 13		
DAY 14		
DAY 15		І Ш
DAY 16		_
DAY 17		
DAY 18		ΙШ
DAY 19		_
DAY 20		
DAY 21		
DAY 22		l
DAY 23		l
DAY 24		\sqcup
DAY 25		ΙШ
DAY 26		



Χ	4							
Country			С	ent	er	Sι	ıbie	ect

813.2 Page No.

Repeat No.

Visit Name:

VISIT 81

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



Χ	4							
Co	บท	trv	C	ent	er	Su	ıbie	ect

813.3	
Page	No.

0	
Repeat	No.

VISIT 81

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

ANA
sanofi aventis
L'essentiel c'est la santé.

EFC10547

Х	4							
Со	un	try	С	ent	er	Sι	ıbje	ect

814.1	
Page No.	_

0	
Repeat	No.

MEDICATION

ANALGESIC	

VISIT 81

MED_02

Data ☑ No Data ☐

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

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

XXX
sanofi aventis
L'essentiel c'est la santé.

EFC10547	
----------	--

Х	4							
Country		С	ent	er	Sι	ıbje	ect	

814.2	
Page	No.

0	
Repeat	No.

VISIT 81

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

ANA		
sanofi aventis		
L'essentiel c'est la santé.		

EFC10547	

Х	4							
Country		Center			Sι	ıbje	ect	

814.3	
Page	No.

0	
Repeat	No.

VISIT 81

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



EFC10547

Χ	4							
Country		С	Center			ıbje	ect	

815.1	l
Page No.	

0	
Repeat	No.

VISIT 81

TUMOR N	IEASUREMENT	S				I UMEA_02
Data ✓ No D	oata 🗌	TO BE COMPLET	ED UNTIL DIS	EASE PROGRESS	ION	
Lesion Number	Lesion Location	Date of Assessment (dd-mmm-yyyy)	Method of Tumor Measurement	Measurement of Target Lesion longest diameter	Response of Non target Lesions	
		☐ Not Done] mm		
		Not Done		mm		
				mm		
		☐ Not Done] mm		
		☐ Not Done] mm		
		☐ Not Done] mm		
		☐ Not Done] mm		
		☐ Not Done] mm		
		Not Done] [mm		
		Not Done] mm		
		L L L Not Done] [] """		



EFC10547

Х	4								
Country		С	Center			ıbje	ect		

815.2 Page No.

0 Repeat No.

Visit Name:

VISIT 81

Lesion Number	Lesion Location	Date of Assessment (dd-mmm-yyyy)	Method of Tumor Measurement	Measurement of Response of Target Lesion Non target longest diameter Lesions
		Not Done		mm
		Not Done		mm
		□ Not Done		mm
		Not Done		mm
		Not Done		mm
		Not Done		mm
		Not Done		mm
		Not Done		mm
		☐ Not Done		mm
		☐ Not Done		mm



Х	4							
Country			С	ent	er	Sι	ıbje	ect

816.1	
Page	No.

Visit Name:

VISIT 81

TUMOR MARKERS

TMARK_01

Data	✓ No Data	
------	-----------	--

Date of evaluation

(dd-mmm-yyyy)

TEST VALUE

UNIT

NORMAL RANGE

LOWER LIMIT **UPPER LIMIT**

CA19-9



EFC10547	

Χ	4							
Country			С	Center			ıbje	ect

817.1	
Page	No.

Visit Name:

VISIT 81

CLINICAL EVENT THROMBOVASCULAR

Data ☑ No Data ☐	Yes	No
ANGINA PECTORIS / UNSTABLE ANGINA / MYOCARDIAL INFARCTION		
STROKE / TRANSIENT ISCHEMIC ATTACK		
PERIPHERAL ARTERIAL THROMBOSIS		
DEEP VENOUS THROMBOSIS		
PULMONARY EMBOLISM		
INTRAABDOMINAL ARTERIAL THROMBOSIS		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		



EFC10547

Χ	4							
Country			С	ent	er	Sι	ıbje	ect

681.1 Page No.

0 Repeat No.

Visit Name: VISIT 81 AE

ADVERSE EVENT Data ✓ No Data ☐	AE Form Number AE_03 AE Reference ID
 Adverse Event (Diagnosis) : Status of Adverse Event 	New Date of Start (dd-mmm-yyyy) Ongoing without change (do not complete the remaining items) Ongoing with change
3. Grade4. Relationship to investigational product *	1
5. Action Taken with Investigat. Product	None Permanently discontinued Delayed Dose reduced Delayed and reduced Interrupted
6. Corrective treatment/therapy	Yes
7. Outcome	Recovered Date of Recovery (dd-mmm-yyyy)
	Recovered with sequelae
	Not recovered
	Fatal Date of Death (complete the death report form) Unknown
8. Seriousness Criteria	Yes No If Yes : -Date event became serious (dd-mmm-yyyy)
IF YES, COMPLETE THIS SECTION AND	-Tick below all criteria that apply :
THE SAFETY COMPLEMENTARY FORM	Results in Death Persistant/significant disability/incapacity Life Threatening Congenital anomaly or Birth Defect Requires or prolongs hospitalization Other medically important event
9. Is it an event such as:	
Overdose of the IP	Yes No No
Pregnancy	Yes No No
*Is there a rea	asonable possibility that the AE was caused by Investigational Product?



Χ	4							
Country			С	ent	er	Sı	ıbje	ect

681.2	
Page	No.

Visit Name:

VISIT 81 AE

AE / Specific Event Form Number	
1. Demographic Information	
Weight (kg)	
2. Detailed Description of the Adverse Event (including complementary investigations)	
3. Date of Start of Event (Initial date of onset of the considered event) (DD-MMM-YYYY)	
Investigational Products	
Date of the FIRST administration of study treatment : (DD-MMM-YYYY)	
Current Treatment number : Current Cycle : Cur	
Date of the LAST administration before SAE: (dd-mmm-yyyy) Last Dosage before SAE: Action Taken:	
AFLIBERCEPT/PLACEBO MG/KG	
GEMCITABINE MG/M2	\equiv
5. In case of hospitalization Date of admission (DD-MMM-YYYY) (hospital report to be sent)	
6. In case of death Autopsy report Yes No (copy to be sent)	
7. Corrective Treatment / Therapy	



INR

EFC10547	
----------	--

Χ	4							
Country			С	ent	er	Sι	ıbje	ect

781.01.1	
Page No.	

0	
Repeat	No.

Visit Name:

VISIT 81 LAB

RATIO

DDITIONAL HEMATOLOGY									
Data ☑ No Data ☐									
Date of sampling	(dd-mmm-yy	vyy)							
		Unit			SI Ra	anges			
Test	Value	If other unit, specify	SI Value	SI Unit	Lower Limit	Upper Limit			
HEMOGLOBIN		G/L							
PLATELET COUNT (THROMB		10E9/L							
WBC		10E9/L							
NEUTROPHILS		10E9/L							
7	O BE PER	FORMED ONLY FOR	PATIENT UN	IDER VITA	MIN K ANTAG	ONIST			



Χ	4							
Country			С	ent	er	Sι	ıbje	ect

781.02.1
Page No.

Visit Name:

VISIT 81 LAB

ADDITIONAL BIOCHEMISTRY

LAB_01

Data ☑ No Dat	a 🗌	
Please i	indicate if the laboratory is the : Same as baseline Same as previous	
Name		
Address		
City		
Country		
	For Technical use :	
Name		
Address		
City		
Country		



Х	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

781.02.2 Page No.

Repeat No.

Visit Name:

VISIT 81 LAB

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

^{*} If creatinine > 1 ULN please report the calculated creatinine clearance.
** If blood Urea Nitrogen is not evaluable, Urea value must be documented.



EFC10547

Χ	4							
Country			С	ent	er	Sι	ıbje	ect

781.03.1
Page No.

Visit Name:

VISIT 81 LAB

ADDITIONAL DIPSTICK URINALYSIS

LABU_1

Data ✓ No Data 🗌					
Date of sampling					
Test name					
WHITE BLOOD CELLS (Q	☐ Absent	<u> </u>	<u></u> ++	+++	□ Not evaluable
RED BLOOD CELLS (QUAI	☐ Absent	□ +	□ ++	+++	☐ Not evaluable



EFC10547

Х	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

781.04.1
Page No.

)	
Repeat	No.

VISIT 81 LAB

ADDITIONAL MORNING SPOT URINALYSIS

LAB_01

Data ✓ No Data							
	Please indic	cate if the labora	tory is the: Same as ba Same as pr				
Name Address							
City Country							
			For Technical	use :			
Name Address							
City Country							
Date of sampling		(dd-mmm-yyyy)					
			Unit			SI Ran	
Test		Value	If other unit, specify	SI Value	SI Unit	Lower Limit	Upper Limit
PROTEIN (URI	NE)		MG/DL				
CREATININE	(URINE)		MG/DL		1		



EFC10547	
----------	--

Χ	4							
Co	oun	try	С	ent	er	Sι	ıbje	ect

781.05.1 Page No. 0 Repeat No.

Visit Name:

VISIT 81 LAB

ADDITIONAL 24 Data V No Data	-HOUR UF	RINALYS	IS				LAB_04
Please indicate if the	aboratory is the	Same as ba	aseline \square				
	·	Same as pr					
Name Address							
City Country							
		i	For Technical use :				
Name Address							
City Country							
	Date (dd-mmm		Time of collection .	(24-hour clock)			
Start date of collection End date of collection			Time of collection :				SI RANGES
Test	Value	Unit	Time or composition :		SI Value	SI Unit	Lower limit Upper Limit
URINARY VOLUME		L					
PROTEIN (URINE)		G/L					
CREATININE (URINI		G/L					
	ELEC	TROPHO	RESIS				
ALBUMIN		G/L]				
ALPHA 1 GLOBULIN		G/L					
ALPHA 2 GLOBULIN		G/L				4	+
BETA GLOBULIN GAMMA GLOBULIN		G/L G/L]			 	

TOTAL
sanofi aventis
L'essentiel c'est la santé.

Χ	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

781.05.2 Page No.

0 Repeat No.

Visit Name:

VISIT 81 LAB

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

LABU_1

Data ✓ No Data 🗌

Test name Negative Positive

HEMOGLOBIN (QUALITAT:

RED BLOOD CELLS (QUAI



EFC10547

X	4			Sı	
Х	4				

781.06.1
Page No.

Visit Name:

VISIT 81 LAB

ADDITIONAL HEMATOLOGY

LABU_1

Data ✓ No Data 🗌			
Date of sampling			
Test name	Unit		
		Negative	Positive
SCHISTOCYTES (QU	JALITA NONE		



EFC10547	
----------	--

Х	4							
Co	un	trv	С	ent	er	Sι	ıbie	ect

781.06.2 Page No.

0 Repeat No.

Visit Name:

VISIT 81 LAB

G/L

G/L

ADDITIONAL BIO	CHEMISTRY					LAB	_01
Data ✓ No Data 🗌							
Diagon indicate if the lab		a bassiina 🖂					
Please indicate if the lab		s previous					
		- Provided					
Name							
Address							
City							
Country							
		For Tech	nical use :				
Name		10110011					
Address							
City Country							
Country							
Date of sampling	(dd-mmm-yyyy)	Unit			SI Ra	nges	
Test	Value	If other unit, specify	SI Value	SI Unit	Lower Limit	Upper Limit	
LDH		IU/L					

Confidential Information

HAPTOGLOBIN

OROSOMUCOID

sanofi aventis
L'essentiel c'est la santé.

EFC10547

VISIT 82

Visit Name:

Х	4							
Co	un	try	С	ent	er	Sι	ıbje	ect

818.1	
Page	No.

0 Repeat No.

Date of visit : (DD-MMM-YYYY)

VISIT_01

SUBJECT STATUS

SUBST_01

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

Subject condition at the time of the scheduled visit :

Data ✓ No Data 🗌

Dead *

Method of contact:

Scheduled Visit

Other

If other, specify

^{*} If the subject died, please complete a Death report form.

^{*} If the subject died/has had a sudden non-treatment related death please complete an Adverse Event form.



\sim	un	tr.	_	ont	er	٥.	ıbic	L Vot
Χ	4							

819.1	
Page	No.

Visit Name:

VISIT 82

VITAL SIGNS

Data ✓ No Data ☐	
Date performed (dd-mmm-yyyy)	
Weight: kg	
Blood pressure: Systolic: mmHg	/ Diastolic: mmHg
ECOG Performance Status 0 1 2 3 4	

TOTA
sanofi aventis
L'assantial c'ass la canté

SURGERY

EFC10547

Х	4							
Country		Center			Sι	ıbje	ect	

820.1	
Page	No.

0	
Repeat	No.

Visit Name:

POST TREATMENT ANTI CANCER

VISIT 82

SURG_01

Data ✓ No Data □	
Surgery	Surgery Date (DD-MMM-YYYY)



EFC10547	
----------	--

VISIT 82

Visit Name:

Χ	5							
Country		С	Center			ıbje	ect	

821.1	
Page No.	

0	
Repeat	No.

A 1 1 7	- ^	NOF	·	
ANI	I-CA	NGEF	(IHE	ERAPY

POST TREATMENT						
Data ☑ No Data ☐						
Regimen Number Therapy Drug/Medication Type	Cumulative Dose Dose Units	Route Sta	art Date	Previously reported	End Date	Ongoing
REGIMEN 1						
ANTI-CANCER THERAPY POST TREATMENT						
Data No Data						
Regimen Number Therapy Drug/Medication Type	Cumulative Dose Dose Units	Route	Start Date	Previously reported	End Date	Ongoing
REGIMEN 2						

Confidential Information

AVE0005 - EFC10547 (VANILLA)



EFC10547

Х	5							
Сс	un	try	С	Center		Sι	ıbje	ect

822.1	
Page	No.

0	
Repeat N	0.

VISIT 82

RADIATION THERAPY	POST TREATI	POST TREATMENT						
Data ☑ No Data ☐								
Lesion location	Start Date (dd-mmm-yyyy)	End Date (dd-mmm-yyyy)	Total Dose	Unit	Intent			
				Grays 🗌 Rads 🔲	Palliative Curative			
				Grays ☐ Rads ☐	Palliative Curative			
				Grays ☐ Rads ☐	Palliative Curative			
				Grays ☐ Rads ☐	Palliative Curative			
				Grays ☐ Rads ☐	Palliative Curative			
				Grays ☐ Rads ☐	Palliative Curative			
				Grays ☐ Rads ☐	Palliative Curative			
				Grays ☐ Rads ☐	Palliative Curative			
				Grays ☐ Rads ☐	Palliative Curative			

Confidential Information

AVE0005 - EFC10547 (VANILLA)



EFC10547	
----------	--

Х	5							
Сс	un	try	С	Center		Sι	ıbje	ect

822.2	
Page	No.

0	
Repeat	No.

Visit Name: VISIT 82

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

TOTAL
sanofi aventis
L'essentiel c'est la santé.

Х	5							
Country			С	ent	er	Sι	ıbje	ect

823.1	
Page	No.

Repeat No.

Visit Name:

VISIT 82

PAIN INTENSITY

Data ✓ No Data □

ASSESSED VIA VISUAL ANALOG SCALE

011105 | 407 \ // 017

SINCE LAST VISIT

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

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

Confidential Information

AVE0005 - EFC10547 (VANILLA)



<u> </u>	un	tr.	_	ent	<u>د</u> ،	ıbie	L_
Х	٦						

823.2	
Page	Nο

0 Repeat No.

Visit Name:

VISIT 82

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



EFC1054	1 7
EFC 1032	+1

Χ	5							
Country		С	ent	er	Sι	ıbie	ect	

823.3	
Page	No.

0	
Repeat	No.

VISIT 82

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

XXX
sanofi aventis
L'essentiel c'est la santé.

X 5		
Country	Center	Subject

824.1	
Page No.	_

0	
Repeat	No.

MEDICATION

ANALGESIC	
ANALGESIC	

VISIT 82

MED_02

Data ☑ No Data ☐

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

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

XXX
sanofi aventis
L'essentiel c'est la santé.

EFC10547

Х	5							
Сс	un	try	С	Center		Sι	ıbje	ect

824.2	
Page	No.

0	
Repeat No	

VISIT 82

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

XXX
sanofi aventis
L'essentiel c'est la santé.

EFC10547	
----------	--

Χ	5							
Country			С	ent	er	Sι	ıbje	ect

824.3	
Page	No.

0	
Repeat	No.

VISIT 82

Drug/Medication (Brand or generic name)	Dosage Units (Total daily dose)	Route	Start Date Previously reported (dd-mmm-yyyy)	End Date Ongo	ing



_	oun	Ш	_	1	er	<u>_</u>	ر د : دا.	Ш
Χ	5							

825.1	
Page	No.

0	
Repeat	No.

VISIT 82

TUMOR MEASUREMENTS					TUMEA_02
Data ☑ No Data ☐	TO BE COMPLET	TED UNTIL DISE	EASE PROGRESS	ION	
Lesion Lesion Number Location	Date of Assessment (dd-mmm-yyyy)	Method of Tumor Measurement	Measurement of Target Lesion longest diameter	Response of Non target Lesions	
	☐ Not Done		mm		
	Not Done		mm		
	☐ Not Done		mm		
	☐ Not Done		mm		
	☐ Not Done		mm		
	Not Done		mm		
	Not Done		mm		
	Not Done		mm		
	Not Done		mm		
	☐ Not Done		mm		

Confidential Information



EFC10547	
----------	--

Χ	5							
Country		С	Center		Sι	ıbje	ect	

825.2 Page No.

Repeat No.

Visit Name:

VISIT 82

Lesion Number	Lesion Location	Date of Assessment (dd-mmm-yyyy)	Method of Tumor Measurement	Measurement of Target Lesion longest diameter	Response of Non target Lesions
		Not Done		mr	m
		Not Done		mr	m
		Not Done		mr	m
				mr	m
		Not Done Not Done Not Done		mr	m
		Not Done		mr	m
		Not Done		mr	m
		Not Done		mr	m
		Not Done		mr	m
		Not Done		mr	m



EF(C10)547	
EF(ر 10)547	

_	5		_			Ļ	Ļ	Ļ
Country			Center			Subject		

826.1	
Page	No.

0 Repeat No.

Visit Name:

VISIT 82

TUMOR MARKERS

TMARK_01

Final Version: 24OCT2007

Data 🗹 No Data 🗌						
Date of evaluation	(dd-mmm-yyyy)					
TEST		VALUE	UNIT	NORM LOWER LIMIT	MAL RANGE UPPER LIMIT	
CA19-9						



_	
EFC1	10547
	100-1

Χ	5							
Country		С	Center			ıbje	ect	

Page No.

Repeat No.

Visit Name:

VISIT 82

CLINICAL EVENT THROMBOVASCULAR

Data ☑ No Data ☐	Yes	No
ANGINA PECTORIS / UNSTABLE ANGINA / MYOCARDIAL INFARCTION		
STROKE / TRANSIENT ISCHEMIC ATTACK		
PERIPHERAL ARTERIAL THROMBOSIS		
DEEP VENOUS THROMBOSIS		
PULMONARY EMBOLISM		
INTRAABDOMINAL ARTERIAL THROMBOSIS		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		
OTHER THROMBOVASCULAR EVENT , SPECIFY :		



EFC10547

Χ	5							
Country		С	Center			ıbje	ect	

Page No.

Repeat No.

Visit Name: VISIT 82 AE

AE 03 **ADVERSE EVENT** AE Form Number AE Reference ID Data ✓ No Data 🗆 1. Adverse Event (Diagnosis): Date of Start 2. Status of Adverse Event New (dd-mmm-yyyy) Ongoing without change (do not complete the remaining items) Ongoing with change 3. Grade 4 1 🔲 2 \square 3 □ No \square 4. Relationship to investigational product * Yes \square None Permanently discontinued Delayed Dose reduced Delayed and reduced Interrupted 5. Action Taken with Investigat. Product 6. Corrective treatment/therapy Yes \square No□ 7. Outcome Recovered Date of Recovery Recovered with sequelae Specify: Recovering Not recovered Date of Death (complete the death report form) Fatal (dd-mmm-yyyy) Unknown 8. Seriousness Criteria Yes \square No□ If Yes: -Date event became serious (dd-mmm-yyyy) IF YES, COMPLETE THIS SECTION AND -Tick below all criteria that apply: THE SAFETY COMPLEMENTARY FORM Persistant/significant disability/incapacity Results in Death Congenital anomaly or Birth Defect Life Threatening Requires or prolongs hospitalization Other medically important event 9. Is it an event such as: No 🗌 Overdose of the IP Yes Yes 🗌 No 🗌 Pregnancy *Is there a reasonable possibility that the AE was caused by Investigational Product?



Χ	5								
Country			С	Center			Subject		

882.2	
Page	No.

0 Repeat No.

Visit Name:

VISIT 82 AE

^ _	/ On a sittle Format Format Normalism	
	/ Specific Event Form Number	
	Demographic Information	
	Veight (kg)	_
2. D	etailed Description of the Adverse Event (including complementary investigations)	
 3. D	ate of Start of Event (Initial date of onset of the considered event) (DD-MMM-YYYY)	
4. Ir	nvestigational Products	
D	ate of the FIRST administration of study treatment : (DD-MMM-YYYY)	
	Current Treatment number : Current Cycle :	
D	ate of the LAST administration before SAE: (dd-mmm-yyyy) Last Dosage before SAE: Action Taken:	
	AFLIBERCEPT/PLACEBO MG/KG]
	GEMCITABINE MG/M2]
		-
 5. Ir	n case of hospitalization Date of admission (DD-MMM-YYYY) (hospital report to be sent)	
6. Ir	n case of death Autopsy report Yes No (copy to be sent)	
	Corrective Treatment / Therapy	
1. U		

Confidential Information



EFC10547	
----------	--

Χ	4							
Со	un	try	С	ent	er	Sι	ıbje	ect

782.01.1 Page No. 0 Repeat No.

Visit Name:

VISIT 82 LAB

ADDITIONAL HEMATOLOGY

LAB_01

Data ☑ No Data ☐							
Date of sampling	(dd-mmm-yyyy)						
		Unit				SI Ran	ges
Test	Value	If other uni	t, specify	SI Value	SI Unit	Lower Limit	Upper Limit
HEMOGLOBIN		G/L					
PLATELET COUNT (THROMBO		10E9/L					
WBC		10E9/L					
NEUTROPHILS		10E9/L					
T	O BE PERFO	ORMED O	NLY FOR PA	ATIENT UNDI	ER VITAN	IIN K ANTAG	ONIST
INR		RATIO					



ΙF	FC10547	
	FC10341	

-	5							
Cc	un	try	С	ent	er	Sι	ıbje	ect

782.02.1 Page No. 0 Repeat No.

Visit Name:

VISIT 82 LAB

LAB_01

ADDITIONAL BIOCHEMISTRY

Data ☑ No Dat	ta 🔲
Please	indicate if the laboratory is the : Same as baseline Same as previous
Name Address	
City Country	
	For Technical use :
Name	
Address	
City	
Country	



EFC10547

Х	5							
Сс	un	try	С	ent	er	Sı	ıbje	ect

782.02.2 Page No. Repeat No.

Visit Name:

VISIT 82 LAB

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

^{*} If creatinine > 1 ULN please report the calculated creatinine clearance.
** If blood Urea Nitrogen is not evaluable, Urea value must be documented.



IEFC10547)547	lefC1
-----------	--	--	------	-------

Χ	4							
Co	un	try	С	ent	er	Sι	ıbje	ect

782.03.1 Page No. 0 Repeat No.

Visit Name:

VISIT 82 LAB

ADDITIONAL DIPSTICK URINALYSIS

LABU_1

Data ☑ No Data ☐					
Date of sampling					
Test name					
WHITE BLOOD CELLS (Q	Absent	+	-++	_ +++	☐ Not evaluable
RED BLOOD CELLS (OUA)	☐ Absent	\Box +	□++	□+++	☐ Not evaluable



EFC10547

Χ	4								
Сс	Country		С	ent	er	Subject			

782.04.1 Page No. 0 Repeat No.

Visit Name:

VISIT 82 LAB

ADDITIONAL MORNING SPOT URINALYSIS

LAB_01

Data ☑ No Data							
	Please indic	cate if the labora	atory is the: Same as ba Same as pre				
Name							
Address							
City							4
Country							
			For Technical (use :			
Name							
Address							
City							Ⅎ 丨
Country							
Date of sampling		(dd-mmm-yyyy)					
			Unit			SI Ran	ges
Test		Value	If other unit, specify	SI Value	SI Unit	Lower Limit	Upper Limit
PROTEIN (URI	NE)		MG/DL				
CREATININE (URINE)		MG/DL				



IEFC10547	
-----------	--

^	4	L try	ent	 <u>د</u> ،	hic	
Х	4					

782.05.1 Page No. 0 Repeat No.

Visit Name:

VISIT 82 LAB

ADDITION.		HOUR UR	INALYS	SIS				LAB_04
Data No Delicate		-	Same as ba Same as pr					
Name Address								
City Country								
Name Address			I	For Technical use :				
City Country		_						
Start date of co		Date (dd-mmm-	Start	t Time of collection :	(24-hour clock)			SI RANGES
Test URINARY VOL PROTEIN (UR	UME	Value	Unit L G/L G/L			SI Value	SI Unit	Lower limit Upper Limit
		ELEC	TROPHO	RESIS				
ALBUMIN (UR ALPHA 1 GLO ALPHA 2 GLO BETA GLOBUL GAMMA GLOBU	BULIN BULIN IN		G/L G/L G/L G/L					



EFC10547

X	4							
\mathbb{C}^{C}	un	try	С	ent	er	Su	ıbje	ect

782.05.2 Page No. 0 Repeat No.

Visit Name:

VISIT 82 LAB

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

LABU_1

Data ✓ No Data 🗌

Test name Negative Positive

HEMOGLOBIN (QUALITAT)

RED BLOOD CELLS (QUAI

Confidential Information AVE0005 - EFC10547 (VANILLA) Final Version: 24OCT2007



EFC10547

Χ	4							
Со	un	trv	С	ent	er	Sı	ıbie	ect

782.06.1 Page No. 0 Repeat No.

Visit Name:

VISIT 82 LAB

ADDITIONAL HEMATOLOGY

LABU_1

Data ✓ No Data 🗌			
Date of sampling			
Test name	Unit	Negative	Positive
SCHISTOCYTES (QUALITA	NONE		



EFC10547

^	4	L try	ent	 <u>د</u> ،	hic	
Х	4					

782.06.2 Page No. 0 Repeat No.

LAB_01

Visit Name:

ADDITIONAL BIOCHEMISTRY

Country

VISIT 82 LAB

Data ✓ No Data		
Please indicate if th	e laboratory is the : Same as baseline Same as previous	
Name		
Address		
City		
Country		
	For Technical use :	
Name		
Address		
City		

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



*Specify: _

EFC10547		X 4	560.1
		Country Center Subject	Page No.
Visit Name:	VISIT 99		

Page No. Repeat No.

OTHPR_01 **OTHER PROCEDURES** Data ✓ No Data 🗆 Only additional procedures related or performed as a result of an ADVERSE EVENT or additional procedures not planned in the protocol but of interest to support safety analysis as defined in the protocol Procedure Date Outcome Procedure Description (DD-MMM-YYYY) Not applicable Normal Abnormal If abnormal, clinically significant? □Yes* □No *Specify: Not applicable Normal Abnormal If abnormal, clinically significant? ☐Yes* □No *Specify: Not applicable Normal Abnormal If abnormal, clinically significant? □Yes* □No *Specify: _____ Not applicable Normal Abnormal If abnormal, clinically significant? ☐Yes* □No

Confidential Information AVE0005 - EFC10547 (VANILLA) Final Version: 24OCT2007



EFC10547

Х	4							
Country		С	ent	er	Sι	ıbje	ect	

560.2	
Page	No.

0	
Repeat	No.

/ISIT	99		

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



Procedure Description

EFC10547

Х	4							
Сс	un	try	С	Center		Sι	ıbje	ect

560.3	
Page	No.

0	
Reneat	Nο

Visit Name:

VISIT 99

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

*Specify: _____



EFC10547	
----------	--

Х	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

560.4	
Page No.	

0	
Repeat	Nο

VISI	T 99	

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



EFC10547

Х	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

560.5	
Page	No.

0	
Repeat	Nο

VISIT 99

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



Date :

	_		4	_	`ente	_
EFC10547	Х	4				

561.1 Page No.

0 Repeat No.

Visit Name:

(dd-mmm-yyyy)

VISIT 99

SYMPTOMATIC DETERIORATION

SYMDE_01

Data ✓ No Data 🗌

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



EFC10547		X 4 Country Center	Subject	976.1 Page No.	0 Repeat No.	
Visit Name:	VISIT 99					

PHARMACOKINETIC	BLOOD	PK_01
Data ☑ No Data ☐		

SERUM SAMPLING FOR DETECTION OF FREE AND BOUND AFLIBERCEPT

If sampling performed, report the information below in the sample ID

	Sample ID	Sample Date (dd-mmm-yyyy)	Sample Time (24-hour clock)
FREE AND BOUND AFLIBERCEF	P07		
FREE AND BOUND AFLIBERCER	P08		
FREE AND BOUND AFLIBERCER	P09		
FREE AND BOUND AFLIBERCER	P10		
FREE AND BOUND AFLIBERCEE	P11		
FREE AND BOUND AFLIBERCEE	P12		
FREE AND BOUND AFLIBERCER	P13		
FREE AND BOUND AFLIBERCEE	P14		
FREE AND BOUND AFLIBERCER	P15		
FREE AND BOUND AFLIBERCEE	P16		

Confidential Information AVE0005 - EFC10547 (VANILLA) Final Version: 24OCT2007

TOTAL
sanofi aventis
L'essentiel c'est la santé.

EFC10547	
----------	--

Χ	9							
Co	un	trv	С	ent	er	Sι	ıbie	ect

976.1	l
Page No.	

0	
Repeat	No.

VISIT 99

PHARMACOKINETIC BLOOD			PK_01
Data 🗸 No Data 🗌			
FREE AND BOUND AFLIBERCEPT			
	Sample Date (dd-mmm-yyyy)	Sample Time (24-hour clock)	
FREE AND BOUND AFLIBERCEPT			
FREE AND BOUND AFLIBERCEPT			
FREE AND BOUND AFLIBERCEPT			
FREE AND BOUND AFLIBERCEPT			
FREE AND BOUND AFLIBERCEPT			
FREE AND BOUND AFLIBERCEPT			
FREE AND BOUND AFLIBERCEPT			
FREE AND BOUND AFLIBERCEPT			
FREE AND BOUND AFLIBERCEPT			

FREE AND BOUND AFLIBERCEPT



IEFC10547	
-----------	--

Χ	4							
Сс	un	try	С	ent	er	Sι	ıbje	ect

976.2 Page No. 0 Repeat No.

Visit Name:

VISIT 99

. ago . to

If sampling performed, report the information below in the sample ID

	Sample ID	Sample Date (dd-mmm-yyyy)	Sample Time (24-hour clock)
FREE AND BOUND AFLIBERCEE	P17		
FREE AND BOUND AFLIBERCEE	P18		
FREE AND BOUND AFLIBERCEE	P19		
FREE AND BOUND AFLIBERCEE	P20		
FREE AND BOUND AFLIBERCEE	P21		
FREE AND BOUND AFLIBERCEF	P22		
FREE AND BOUND AFLIBERCEF	P23		
FREE AND BOUND AFLIBERCEF	P24		
FREE AND BOUND AFLIBERCEF	P25		
FREE AND BOUND AFLIBERCES	P26		



Χ	9							
Country		С	ent	er	Sι	ıbje	ect	

976.2	
Page	No.

Repeat No.

Visit Name:

VISIT 99

	Sample Date (dd-mmm-yyyy)	Sample Time (24-hour clock)
FREE AND BOUND AFLIBERCEPT		



EFC10547	X 4	977.1 0	
	Country Center Subject	Page No. R	epeat No.
Visit Name: VISIT 99			

PHARMACOKINETIC	BLOOD	PK	_01
Data ✓ No Data 🗌			

SERUM SAMPLING FOR DETECTION OF ANTI-AFLIBERCEPT ANTIBODIES

If sampling performed, report the information below in the sample ID

	Sample ID	Sample Date (dd-mmm-yyyy)	Sample Time (24-hour clock)
ANTI-AFLIBERCEPT ANTIBODI	A03		
ANTI-AFLIBERCEPT ANTIBODI	A04		
ANTI-AFLIBERCEPT ANTIBODI	A05		
ANTI-AFLIBERCEPT ANTIBODI	A06		
ANTI-AFLIBERCEPT ANTIBODI	A07		
ANTI-AFLIBERCEPT ANTIBODI	A08		
ANTI-AFLIBERCEPT ANTIBODI	A09		
ANTI-AFLIBERCEPT ANTIBODI	A10		
ANTI-AFLIBERCEPT ANTIBODI	A11		
ANTI-AFLIBERCEPT ANTIBODI	A12		

Confidential Information AVE0005 - EFC10547 (VANILLA) Final Version: 24OCT2007

XXX
sanofi aventis
L'essentiel c'est la santé.

EFC10547	
----------	--

Χ	9							
Сс	un	try	Center		Sι	ıbje	ect	

977.1	l
Page No.	

0	
Repeat	No.

VISIT 99

PK_01

PHARMACOKINETIC BLOOD			PK_01
Data ✓ No Data ☐			
ANTI-AFLIBERCEPT ANTIBODIES			
	Sample Date (dd-mmm-yyyy)	Sample Time (24-hour clock)	
ANTI-AFLIBERCEPT ANTIBODIES			



TEEC/10547		EFC10547
------------	--	----------

Χ	4							
Со	un	try	Center		Sı	ıbje	ect	

977.2	
Page	Nο

)	
Repeat	No.

VISIT 99

Page No.

If sampling performed, report the information below in the sample ID

	Sample ID	Sample Date (dd-mmm-yyyy)	Sample Time (24-hour clock)
ANTI-AFLIBERCEPT ANTIBODI	A13		
ANTI-AFLIBERCEPT ANTIBODI	A14		
ANTI-AFLIBERCEPT ANTIBODI	A15		
ANTI-AFLIBERCEPT ANTIBODI	A16		
ANTI-AFLIBERCEPT ANTIBODI	A17		
ANTI-AFLIBERCEPT ANTIBODI	A18		
ANTI-AFLIBERCEPT ANTIBODI	A19		
ANTI-AFLIBERCEPT ANTIBODI	A20		
ANTI-AFLIBERCEPT ANTIBODI	A21		
ANTI-AFLIBERCEPT ANTIBODI	A22		



EFC10547	

Χ	9							
Country		С	ent	er	Sι	ıbje	ect	

977.2	
Page	No.

Repeat No.

Visit Name:

VISIT 99

	Sample Date (dd-mmm-yyyy)	Sample Time (24-hour clock)
ANTI-AFLIBERCEPT ANTIBODIES		



EFC10547		X	4							
	_	Сс	un	try	С	ent	er	Sı	ıbje	ect

999.1 Page No. 0 Repeat No.

Visit Name:

VISIT 99

DEATH 01

DEATH		· · · · · _ · · ·
Data ✓ No Data 🗌		
Date of Death :	(dd-mmm-yyyy)	
Reason for death :		
Adverse event		
Disease progression		
Other reason	Specify:	



EFC10547	X 5	562.1
	Country Center Subject	Page No

Visit Name: VISIT 99 MED

MEDICATION				MED_01
Data ✓ No Data 🗌				
RECORD CONCOMITANT ME DEFINED IN THE PROTOCOL		N ANALGESICS T	HE SUBJECT HAS TAKE	EN DURING THE STUDY PERIOD AS
Drug/Medication (brand or generic name)	Start Date (dd-mmm-yyyy)	Previously Reported	End Date (dd-mmm-yyyy)	Or tick if Ongoing

Confidential Information AVE0005 - EFC10547 (VANILLA) Final Version: 24OCT2007

TOTAL
sanofi aventis

EFC10547

Cou		ᄂᢩ	Щ.	ᄂ	ıbje	ب
Χ	5					

562.2 Page No. 0 Repeat No.

Visit Name:

VISIT 99 MED

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

TOTAL	
sanofi aventis	

EFC10547

x 5	1

562.3	
Page	No.

)	
Reneat	Nο

VISIT 99 MED

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



EFC10547	
----------	--

	un	tr.	_	L ont	 ٥.	ıbje	L Vot
Х	4						

563.1 Page No. 0 Repeat No.

Visit Name:

VISIT 99 LAB

LAB_06

UNSCHEDULED LABORATORY TESTS

Data 🗸 No Da	ta 🗌							
Start Date	(dd-mn	п-уууу)						
			Ra	nges				
Test	Value	Unit		Upper Limit	SI Value	SI Unit	Lower Limit	Upper Limit
						1		
						1		
						1		



EFC10547	
----------	--

Χ	4							
Country Cente				er	Sι	ıbje	ect	

564.1	
Page	No.

0 Repeat No.

Visit Name:

VISIT 99 ECG

ECG_01

ADDITIONAL ELECTROCARDIOGRAM

Data 🗹 No Data [
Date performed (DD-MMM-YYYY)		
☐ Normal ☐ Abnormal	If abnormal, clinically significant?	Yes No No
IF ABNORMAL CL	INICALLY SIGNIFICANT, PLEASE F	RECORD AN ADVERSE EVENT



EFC10547	
----------	--

Χ	4							
Country			С	ent	er	Sι	ıbje	ect

565.1	
Page	No.

0 Repeat No.

Visit Name:

VISIT 99 VITAL

VITAL_02

ADDITIONAL VITAL SIGNS

Data ✓ No Data	Ш					
Date performed:	(DD-MMM	I-YYYY)				
Blood pressure:	Systolic:		mmHg	/ Diastol	c:	mmHg