

VISIT INFORMATION

Visit not done

Date of Visit .
DD-MMM-YYYY

INFORMED CONSENT

Date consent obtained .
DD-MMM-YYYY

DEMOGRAPHY

Date of Birth .
DD-MMM-YYYY OR Age years

Sex Male
 Female

Race Caucasian/White
 Black
 Asian/Oriental
 Other

If Other - Specify _____

Ethnicity Hispanic
 Not hispanic

Confidential Information

VITAL SIGNS

Data No Data

Blood pressure

Systolic mmHg Diastolic mmHg

Heart rate (beats/min) beats/min

Respiratory rate (breaths/min)

Weight kg Height cm

Performance status ECOG 0 1 2 3 4



AVE5026EFC6521

X500

3

0

Country Center Subject

Page No.

Repeat No.

Visit Name SCREENING

MEDICAL HISTORY: RISK FACTORS FOR VTE

Record information for the following Medical History

Medical History

Date of Start

MM-YYYY

OR Not Occurred

HISTORY OF DVT (LAST EPISODE)

.

HISTORY OF PE (LAST EPISODE)

.

USE OF ORAL HORMONOTHERAPY (ANTIANDROGEN OR ESTROGEN)

.

CHRONIC HEART FAILURE

.

CHRONIC RESPIRATORY FAILURE

.

VENOUS INSUFFICIENCY / VARICOSE VEINS

.

Confidential Information



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Country Center Subject

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MEDICAL HISTORY: OTHER MEDICAL CONDITIONS

Record information for the following Medical History

Medical History

Date of Start

MM-YYYY

OR Not Occurred

CORONARY ARTERY DISEASE (EXCEPT MI)
MYOCARDIAL INFARCTION (LAST EPISODE)
ARTERIAL HYPERTENSION
PERIPHERAL ARTERIAL DISEASE
STROKE (LAST EPISODE)
DIABETES MELLITUS

.

<input type="checkbox"/>

Confidential Information



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Country Center Subject

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CANCER DIAGNOSIS

Data No Data Date of initial diagnosis
DD-MMM-YYYYLocation of primary tumor Histology type

STAGING AT DIAGNOSIS

T Stage

N Stage

M Stage

STAGING AT STUDY ENTRY

T Stage

N Stage

M Stage

Confidential Information



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p

Country Center Subject

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RADIATION THERAPY

PRIOR

Data



No Data



Lesion location

Stop date

DD-MMM-YYYY

Confidential Information

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7.1

0

Country Center Subject

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SCREENING

ANTI-CANCER THERAPY (PRIOR SYSTEMIC TREATMENT)

Data No Data

Regimen No. Intent

Drug per Regimen

.

Therapy Type

End Date

Confidential Information



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Country Center Subject

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Visit Name SCREENING

Regimen No. Intent

Drug per Regimen

-

Therapy Type End Date

Confidential Information



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Country Center Subject

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Visit Name SCREENING

Regimen No. Intent

Drug per Regimen

.

Therapy Type End Date

Confidential Information



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Country Center Subject

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Regimen No. Intent

Drug per Regimen

-

Therapy Type End Date

Confidential Information



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Country Center Subject

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Regimen No. Intent

Drug per Regimen

.

Therapy Type End Date

Confidential Information



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b

Country Center Subject

Page No.

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Visit Name **SCREENING**

SURGERY

PRIOR CANCER SURGERY

Data No Data

Surgery date Organ / Anatomical region Degree of resection

DD-MMM-YYYY

Confidential Information



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0

Country Center Subject

Page No.

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Visit Name SCREENING

CENTRAL VENOUS CATHETER

Data No Data

Central venous catheter? Yes No

IF YES:

Date of insertion
DD-MMM-YYYY

Side of insertion Left Right

Type of catheter

Confidential Information



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10

0

Country Center Subject

Page No.

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Visit Name SCREENING

LABORATORY TESTS HEMATOLOGY

Data No Data Date

DD-MMM-YYYY

Test	Value	Unit
HEMOGLOBIN		G/DL
WBC		10E9/L
NEUTROPHILS		10E9/L
PLATELET COUNT (THROMBOCYTE COUNT)		10E9/L

Confidential Information



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0

Country Center Subject

Page No.

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Visit Name SCREENING

LABORATORY TESTS BIOCHEMISTRY

Data No Data

DO NOT COMPLETE CROSSED OUT FIELDS

Date
DD-MMM-YYYY

Test	Value	Unit	NORMAL RANGES Upper limit
AST		IU/L	
ALT		IU/L	
ALKALINE PHOSPHATASE		IU/L	
TOTAL BILIRUBIN		UMOL/L	
CONJUGATED BILIRUBIN (DIRECT)		UMOL/L	
CREATININE		UMOL/L	X
ALBUMIN		G/L	X

Confidential Information



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0

Country Center Subject

Page No.

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Visit Name SCREENING

LABORATORY TESTS COAGULATION

Data No Data

DO NOT COMPLETE CROSSED OUT FIELDS

Date
DD-MMM-YYYY

NORMAL RANGES

Test	Value	Unit	Lower limit	Upper limit
INR	.	RATIO	X	X
APTT	.	S		
APTTc	.	S	X	X
APTR	.	RATIO	X	X

Confidential Information

VISIT INFORMATION

Visit not done

Date of Visit .
DD-MMM-YYYY

ELIGIBILITY FOR RANDOMIZATION

**THE SUBJECT HAS FULFILLED ALL INCLUSION CRITERIA.
PLEASE SCREEN THE SUBJECT FOR EXCLUSION CRITERIA.**

Does the subject have one or more exclusion criteria? Yes No

If Yes, please specify the exclusion criteria number(s):

Exclusion Criterion
Exclusion Criterion

Will the subject continue into the randomization phase? Yes No



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Country Center Subject

Page No.

Repeat No.

Visit Name RANDOMIZATION

INVESTIGATIONAL PRODUCT ADMINISTRATION

Scheduled Day/ Period	Treatment/Batch Number	Tick if not administered/taken	Start Date <i>DD-MMM-YYYY</i>	Start Time <i>24-hour clock</i>	Intended Daily Dose	Dose Units
DAY 1	.	<input type="checkbox"/>			1	SYRINGE

Confidential Information

Visit Name RANDOMIZATION

VITAL SIGNSData No Data

Blood pressure

Systolic mmHg Diastolic mmHgHeart rate beats/minRespiratory rate breaths/minWeight kg**Performance status ECOG** 0 1 2 3 4

CENTRALIZED DATA PK SAMPLE

Data No Data

Date performed

DD-MMM-YYYY

Number of samples



AVE5026EFC6521

X500

17

0

Country Center Subject

Page No.

Repeat No.

Visit Name RANDOMIZATION

LABORATORY TESTS HEMATOLOGY

Data No Data Date
DD-MMM-YYYYTime
24-hour clock

Test	Value	Unit
HEMOGLOBIN		G/DL
WBC		10E9/L
NEUTROPHILS		10E9/L
PLATELET COUNT (THROMBOCYTE COUNT)		10E9/L

Confidential Information



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X500

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0

Country Center Subject

Page No.

Repeat No.

Visit Name RANDOMIZATION

LABORATORY TESTS BIOCHEMISTRY

Data No Data Date DD-MMM-YYYY Time 24-hour clock

Test	Value	Unit	NORMAL RANGES Upper limit
AST		IU/L	
ALT		IU/L	
ALKALINE PHOSPHATASE		IU/L	
TOTAL BILIRUBIN		UMOL/L	
CONJUGATED BILIRUBIN (DIRECT)		UMOL/L	

Confidential Information



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X500

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0

Country Center Subject

Page No.

Repeat No.

Visit Name RANDOMIZATION

GENOMIC SUBSTUDY

Data No Data

Did the patient participate in the genomic sub-study? Yes No

INFORMED CONSENT FOR GENOMIC SUBSTUDY

Date consent obtained

DD-MMM-YYYY

Confidential Information



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20.1

0

Country Center Subject

Page No.

Repeat No.

Visit Name TREATMENT M1

VISIT INFORMATION

Visit not done Date of Visit
DD-MMM-YYYY



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20.2

0

Country Center Subject

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Visit Name TREATMENT M1

INVESTIGATIONAL PRODUCT ADMINISTRATION

Scheduled day/period

MONTH 1

Treatment/Batch Number

.

Treatment/Batch Number

Treatment/Batch Number

--

Dosing

Start Date
DD-MMM-YYYYEnd Date
DD-MMM-YYYY

Intended

Units

Actual

Units

Reason of Temporary
Discontinuation

.

1

SYRINGE

SYRINGE

Confidential Information

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sanofi aventis

L'essentiel c'est la santé.

AVE5026EFC6521

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20.3

9

Country Center Subject

Page No. Repeat No.

Visit Name

Dosing

Start Date

Start Date
DD-MMM-YYYY

End Date

End Date

Intended

Units

Actual

Units

Reason of Tempory Discontinuation

ANSWER

Confidential Information

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21

0

Country Center Subject

Page No.

Repeat No.

Visit Name TREATMENT M1

INVESTIGATIONAL PRODUCT ADMINISTRATION

TO BE COMPLETED ONLY FOR PATIENTS WITH PK SAMPLING

PLEASE REPORT THE DATE/TIME OF THE LAST 4 IP ADMINISTRATION (INCLUDING DAY/TIME OF THE ADMINISTRATION DONE ON SITE IF APPLICABLE)

Treatment/Batch Number	Start Date <i>DD-MMM-YYYY</i>	Start Time <i>24-hour clock</i>	Intended Daily Dose	Dose Units
.			1	SYRINGE

Confidential Information

AVE5026EFC6521

X500

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0

Country Center Subject

Page No.

Repeat No.

Visit Name TREATMENT M1

CLINICAL STATUS

Data No Data

Since the last visit, did the subject experience any of the following events (1-3) or performed any lung tumor evaluation imaging test (4)?

If Yes, complete the specified form

- 1. Suspected VTE (DVT and/or PE)** Yes No Diagnostic tests for suspected VTE, p. 754
- 2. Bleeding** Yes No Bleeding event form, Bleeding specific form/Safety complementary form (if serious), p. 611, p. 612, p. 631
- 3. Death** Yes No AE/Safety complementary form, p. 601, p. 631, Death form, p. 999
- 4. Scheduled lung tumor evaluation imaging test** Yes No Tumor evaluation (scheduled lung imaging test), p. 755

Confidential Information



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0

Country Center Subject

Page No.

Repeat No.

Visit Name TREATMENT M1

CENTRAL VENOUS CATHETER

Data No Data

Since the last visit, was there any change in the CVC status? Yes No

IF YES,

Was CVC removed? Yes No

IF YES: Date of removal
DD-MMM-YYYY

Was CVC inserted? Yes No

IF YES: Date of insertion
DD-MMM-YYYY

Side of insertion Left Right

Type of catheter

Confidential Information

VITAL SIGNS

Data No Data

Blood pressure

Systolic mmHg Diastolic mmHg

Heart rate beats/min

Respiratory rate breaths/min

Weight kg

Performance status ECOG 0 1 2 3 4

CENTRALIZED DATA PK SAMPLE

Data No Data

Date performed

DD-MMM-YYYY

Number of samples



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X500

26

0

Country Center Subject

Page No.

Repeat No.

Visit Name TREATMENT M1

LABORATORY TESTS HEMATOLOGY

WEEK 1

Data No Data

Date Time
DD-MMM-YYYY 24-hour clock

Test	Value	Unit
PLATELET COUNT (THROMBOCYTE COUNT)	<input type="text"/>	10E9/L

Confidential Information



AVE5026EFC6521

X500

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0

Country Center Subject

Page No.

Repeat No.

Visit Name TREATMENT M1

LABORATORY TESTS HEMATOLOGY

WEEK 2

Data No Data

Date
DD-MMM-YYYY

Time
24-hour clock

Test	Value	Unit
PLATELET COUNT (THROMBOCYTE COUNT)	<input type="text"/>	10E9/L

Confidential Information



AVE5026EFC6521

X500

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0

Country Center Subject

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Visit Name TREATMENT M1

LABORATORY TESTS HEMATOLOGY

WEEK 3

Data No Data

Date
DD-MMM-YYYY

Time
24-hour clock

Test	Value	Unit
PLATELET COUNT (THROMBOCYTE COUNT)	<input type="text"/>	10E9/L

Confidential Information



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X500

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Country Center Subject

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Visit Name TREATMENT M1

LABORATORY TESTS HEMATOLOGY

Data No Data Date
DD-MMM-YYYY Time
24-hour clock

Test	Value	Unit
HEMOGLOBIN		G/DL
WBC		10E9/L
NEUTROPHILS		10E9/L
PLATELET COUNT (THROMBOCYTE COUNT)		10E9/L

Confidential Information



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X500

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0

Country Center Subject

Page No.

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Visit Name TREATMENT M1

LABORATORY TESTS BIOCHEMISTRY

Data No Data

DO NOT COMPLETE CROSSED OUT FIELDS

Date Time

DD-MMM-YYYY

24-hour clock

Test	Value	Unit	NORMAL RANGES Upper limit
AST		IU/L	
ALT		IU/L	
ALKALINE PHOSPHATASE		IU/L	
TOTAL BILIRUBIN		UMOL/L	
CONJUGATED BILIRUBIN (DIRECT)		UMOL/L	
CREATININE		UMOL/L	X

Confidential Information



AVE5026EFC6521

X500

30.1

0

Country Center Subject

Page No.

Repeat No.

Visit Name TREATMENT M1

LABORATORY TESTS COAGULATION

Data No Data Date Time

Test	Value	Unit
INR	<input type="text"/>	RATIO

Confidential Information



AVE5026EFC6521

X500

M2 31.1

0

Country Center Subject

Page No.

Repeat No.

Visit Name TREATMENT M2

VISIT INFORMATION

Visit not done Date of Visit
DD-MMM-YYYY

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X500

M2 31.2

5

Country Center Subject

Page No. Repeat No.

Visit Name **TREATMENT M2**

INVESTIGATIONAL PRODUCT ADMINISTRATION

Scheduled day/period MONTH 2

Treatment/Batch Number

Treatment/Batch Number

Treatment/Batch Number

Dosing

Daily Dose

Start Date

DD-MMM-YYYY

End Date

DD-MMM-YYYY

Intended Units

Actual

Units

Reason of Tempory

Discontinuation

1

SYRINGE

ANSWER

SYRINGE

Confidential Information

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AVE5026EFC6521

X500

M2 31.3

5

Country Center Subject

Page No. Repeat No.

Visit Name TREATMENT M2

Dosing

Start Date

DD-MMM-YYYY

End Date

DD-MMM-YYYY

Daily Dose

Intended Units

Actual

Units

Reason of Temporary

Discontinuation

ANSWER

ANSWER

Confidential Information

AVE5026 - EFC6521 (Save-Onco)

Final Version: 14MAY2008

VITAL SIGNS

Data No Data

Blood pressure

Systolic mmHg Diastolic mmHg

Heart rate beats/min

Respiratory rate breaths/min

Weight kg

Performance status ECOG 0 1 2 3 4

Confidential Information



AVE5026EFC6521

X500

M2 33

0

Country Center Subject

Page No.

Repeat No.

Visit Name TREATMENT M2

CLINICAL STATUS

Data No Data

Since the last visit, did the subject experience any of the following events (1-3) or performed any lung tumor evaluation imaging test (4)?

If Yes, complete the specified form

1. Suspected VTE (DVT and/or PE) Yes No Diagnostic tests for suspected VTE, p. 754
2. Bleeding Yes No Bleeding event form, Bleeding specific form/Safety complementary form (if serious), p. 611, p. 612, p. 631
3. Death Yes No AE/Safety complementary form, p. 601, p. 631, Death form, p. 999
4. Scheduled lung tumor evaluation imaging test Yes No Tumor evaluation (scheduled lung imaging test), p. 755

Confidential Information



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X500

M2 34

0

Country Center Subject

Page No.

Repeat No.

Visit Name TREATMENT M2

CENTRAL VENOUS CATHETER

Data No Data

Since the last visit, was there any change in the CVC status? Yes No

IF YES,

Was CVC removed? Yes No

IF YES: Date of removal
DD-MMM-YYYY

Was CVC inserted? Yes No

IF YES: Date of insertion
DD-MMM-YYYY

Side of insertion Left Right

Type of catheter

Confidential Information



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X500

M2 35

0

Country Center Subject

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Visit Name TREATMENT M2

LABORATORY TESTS HEMATOLOGY

Data No Data Date
DD-MMM-YYYYTime
24-hour clock

Test	Value	Unit
HEMOGLOBIN		G/DL
WBC		10E9/L
NEUTROPHILS		10E9/L
PLATELET COUNT (THROMBOCYTE COUNT)		10E9/L

Confidential Information



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M2 36

0

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Visit Name TREATMENT M2

LABORATORY TESTS BIOCHEMISTRY

Data No Data

DO NOT COMPLETE CROSSED OUT FIELDS

Date

DD-MMM-YYYY

Time

24-hour clock

Test	Value	Unit	NORMAL RANGES Upper limit
AST		IU/L	
ALT		IU/L	
ALKALINE PHOSPHATASE		IU/L	
TOTAL BILIRUBIN		UMOL/L	
CONJUGATED BILIRUBIN (DIRECT)		UMOL/L	
CREATININE		UMOL/L	X

Confidential Information



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X500

M2 36.1

0

Country Center Subject

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Visit Name TREATMENT M2

LABORATORY TESTS COAGULATION

Data No Data Date Time

Test Value Unit

INR		RATIO
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Confidential Information



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37.1

0

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VISIT INFORMATION

Visit not done Date of Visit
.
DD-MMM-YYYY

Confidential Information



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37.2

0

Country Center Subject

Page No.

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Visit Name END OF TREATMENT

CLINICAL STATUS

Data No Data

Since the last visit, did the subject experience any of the following events (1-3) or performed any lung tumor evaluation imaging test (4)?

If Yes, complete the specified form

- | | |
|--|---|
| 1. Suspected VTE (DVT and/or PE) | Yes <input type="checkbox"/> No <input type="checkbox"/> Diagnostic tests for suspected VTE, p. 754 |
| 2. Bleeding | Yes <input type="checkbox"/> No <input type="checkbox"/> Bleeding event form, Bleeding specific form/Safety complementary form (if serious), p. 611, p. 612, p. 631 |
| 3. Death | Yes <input type="checkbox"/> No <input type="checkbox"/> AE/Safety complementary form, p. 601, p. 631, Death form, p. 999 |
| 4. Scheduled lung tumor evaluation imaging test | Yes <input type="checkbox"/> No <input type="checkbox"/> Tumor evaluation (scheduled lung imaging test), p. 755 |

Confidential Information

Visit Name **END OF TREATMENT**

VITAL SIGNS

Data No Data

Blood pressure

Systolic mmHg Diastolic mmHgHeart rate beats/minRespiratory rate breaths/minWeight kg**Performance status ECOG** 0 1 2 3 4



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X500

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Country Center Subject

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Visit Name END OF TREATMENT

LABORATORY TESTS HEMATOLOGY

Data No Data Date
DD-MMM-YYYYTime
24-hour clock

Test	Value	Unit
HEMOGLOBIN		G/DL
WBC		10E9/L
NEUTROPHILS		10E9/L
PLATELET COUNT (THROMBOCYTE COUNT)		10E9/L

Confidential Information



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X500

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0

Country Center Subject

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Visit Name END OF TREATMENT

LABORATORY TESTS BIOCHEMISTRY

Data No Data

DO NOT COMPLETE CROSSED OUT FIELDS

Date
DD-MMM-YYYY

Time
24-hour clock

Test	Value	Unit	NORMAL RANGES Upper limit
AST		IU/L	
ALT		IU/L	
ALKALINE PHOSPHATASE		IU/L	
TOTAL BILIRUBIN		UMOL/L	
CONJUGATED BILIRUBIN (DIRECT)		UMOL/L	
CREATININE		UMOL/L	X

Confidential Information



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X500

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0

Country Center Subject

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LABORATORY TESTS PREGNANCY TEST

Data No Data

Date

DD-MMM-YYYY

Test type

Serology
Urinalysis

Result

Negative
Positive

Confidential Information



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X500

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0

Country Center Subject

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Visit Name END OF TREATMENT

CENTRAL VENOUS CATHETER

Data No Data

Since the last visit, was there any change in the CVC status? Yes No

IF YES,

Was CVC removed? Yes No

IF YES: Date of removal
DD-MMM-YYYY

Was CVC inserted? Yes No

IF YES: Date of insertion
DD-MMM-YYYY

Side of insertion Left Right

Type of catheter

Confidential Information



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X500

42.1.1

0

Country Center Subject

Page No.

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Visit Name END OF TREATMENT

INVESTIGATIONAL PRODUCT ADMINISTRATION

Scheduled day/period V80 / END OF¹

Treatment/Batch Number

.

Treatment/Batch Number

Treatment/Batch Number

Dosing

Daily Dose

Start Date

DD-MMM-YYYY

End Date

DD-MMM-YYYY

Intended Units

Actual Units

Reason of Temporary

Discontinuation

-

1

SYRINGE

SYRINGE

Confidential Information



AVE5026EFC6521

X500

42.1.2

0

Country Center Subject

Page No.

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Visit Name END OF TREATMENT

Dosing**Daily Dose**

Start Date

DD-MMM-YYYY

End Date

DD-MMM-YYYY

Intended Units

Actual Units

Reason of Tempory
Discontinuation

Confidential Information

Overflow / Investigator Comments / Discrepancy Detail / Audit History for CRF IPA - V80/EOT

Numbers below correspond to superscript(s) appearing with fields in the previous CRF.

1

Overflow: V80/END OF TREATMENT VISIT



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X500

501

0

Country Center Subject

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Visit Name END OF TREATMENT

END OF TREATMENT - INVESTIGATIONAL PRODUCT

Data No Data

Did the subject complete treatment period per protocol? Yes No

IF NO,

Main reason for stopping treatment

If other reason, specify

Was it the subjects decision to permanently discontinue the treatment? Yes No

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

In case of an adverse event, complete the Adverse Event form

Confidential Information

VISIT INFORMATION

Visit not done

Date of Visit .
DD-MMM-YYYY

VITAL SIGNS

Data No Data

Blood pressure

Systolic mmHg Diastolic mmHg

Heart rate beats/min

Respiratory rate breaths/min

Weight kg

Performance status ECOG 0 1 2 3 4



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X500

44

0

Country Center Subject

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Visit Name FOLLOW UP

LABORATORY TESTS HEMATOLOGY

TO BE FILLED IN ONLY FOR UNRESOLVED ABNORMAL PARAMETERS AT END OF TREATMENT VISIT

Data No Data

Date
DD-MMM-YYYY

Time
24-hour clock

Test	Value	Unit
HEMOGLOBIN		G/DL
WBC		10E9/L
NEUTROPHILS		10E9/L
PLATELET COUNT (THROMBOCYTE COUNT)		10E9/L

Confidential Information



AVE5026EFC6521

X500

45

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Country Center Subject

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LABORATORY TESTS BIOCHEMISTRY

TO BE FILLED IN ONLY FOR UNRESOLVED ABNORMAL PARAMETERS AT END OF TREATMENT VISIT

Data No Data

DO NOT COMPLETE CROSSED OUT FIELDS

Date
DD-MMM-YYYY

Time
24-hour clock

Test	Value	Unit	NORMAL RANGES Upper limit
AST		IU/L	
ALT		IU/L	
ALKALINE PHOSPHATASE		IU/L	
TOTAL BILIRUBIN		UMOL/L	
CONJUGATED BILIRUBIN (DIRECT)		UMOL/L	
CREATININE		UMOL/L	X

Confidential Information



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X500

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0

Country Center Subject

Page No.

Repeat No.

Visit Name FOLLOW UP

CENTRAL VENOUS CATHETER

Data No Data

Since the last visit, was there any change in the CVC status? Yes No

IF YES,

Was CVC removed? Yes No

IF YES: Date of removal
DD-MMM-YYYY

Was CVC inserted? Yes No

IF YES: Date of insertion
DD-MMM-YYYY

Side of insertion Left Right

Type of catheter

Confidential Information



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X500

519.1

0

Country Center Subject

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SUBJECT STATUS

Data No Data

Date of last contact

DD-MMM-YYYY

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

- Alive
- Lost to follow-up
- Dead *

* If the subject died, please complete an adverse event form,
safety complementary form and death report form

Confidential Information



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Country Center Subject

Page No.

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Visit Name FOLLOW UP

CLINICAL STATUS

Data No Data

Since the last visit, did the subject experience any of the following events (1-2) or performed any scheduled lung tumor evaluation imaging test (3)?

1. Suspected VTE (DVT and/or PE)

If Yes, complete the specified form

Yes No Unknown

If occurred up to 3 days after last investigational product injection: Diagnostics test for suspected VTE, p. 754

If occurred after: AE/Safety complementary form (if serious), p. 601, p. 631

2. Bleeding

Yes No Unknown

Bleeding event form, Bleeding specific form/Safety complementary form (if serious), p. 611, p. 612, p. 631

3. Scheduled lung tumor evaluation imaging test

Yes No Unknown

If occurred up to 3 days after last investigational product injection: Tumor evaluation (scheduled lung imaging tests), p. 755

If occurred after and PE diagnosed: AE/Safety complementary form (if serious), p. 601, p. 631

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SUBJECT STATUS

Data No Data

Date of last contact
DD-MMM-YYYY

Subject condition (tick one box only)

- Alive
- Lost to follow-up
- Dead

Visit Name **VISIT 99****CODE BREAKING (ON SITE)**Data No Data

The code has been broken by Investigator
 Pharmacist
 Study Nurse
 Other (site staff)

If other, specify _____

Name _____

Performed by: Central randomization system Date performed

DD-MMM-YYYY

Time performed

24-HR CLOCK

Reason of code breaking AE / SAE
 Other

AE Form Number

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

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.**



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Country Center Subject

Page No.

Repeat No.

Visit Name VISIT 99

SUBJECT STATUS

Data No Data

Date of last contact

DD-MMM-YYYY

Subject condition (tick one box only)

- Alive
- Lost to follow-up
- Dead *

* If the subject died, please complete an adverse event form,
safety complementary form and death report form

Confidential Information

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Country Center Subject

Page No.

Repeat No.

Visit Name VISIT 99

CLINICAL STATUS

Data No Data

Since the last visit, did the subject experience any of the following events (1-2) or performed any scheduled lung tumor evaluation imaging test (3)?

If Yes, complete the specified form

1. Suspected VTE (DVT and/or PE)

Yes No Unknown

If occurred up to 3 days after last investigational product injection: Diagnostics test for suspected VTE, p. 754

If occurred after: AE/Safety complementary form (if serious), p. 601, p. 631

2. Bleeding

Yes No Unknown

Bleeding event form, Bleeding specific form/Safety complementary form (if serious), p. 611, p. 612, p. 631

3. Scheduled lung tumor evaluation imaging test

Yes No Unknown

If occurred up to 3 days after last investigational product injection: Tumor evaluation (scheduled lung imaging tests), p. 755

If occurred after and PE diagnosed: AE/Safety complementary form (if serious), p. 601, p. 631

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Country Center Subject

Page No.

Repeat No.

Visit Name VISIT 99 MED

MEDICATION: ANTI-THROMBOTIC

Data No Data

Record all anti-thrombotic medications that the subject has taken within two weeks before randomization and until the end of the study

OR

Drug/Medication (brand or generic name)	Reason	Dosage (Total Daily Dose)	Unit	Route	Start Date <i>DD-MMM-YYYY</i>	End Date <i>DD-MMM-YYYY</i>	Ongoing
--	--------	------------------------------	------	-------	----------------------------------	--------------------------------	---------

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

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Country Center Subject

Page No.

Repeat No.

Visit Name

VISIT 99 MED

MEDICATION: OTHER THAN ANTI-THROMBOTIC

Data No Data

Record all non anti-thrombotic medications that the subject has taken within two weeks before randomization and until the end of study

OR

Drug/Medication
(brand or generic name)

Reason

Start Date

DD-MMM-YYYY

End Date

DD-MMM-YYYY

Ongoing

Confidential Information



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Country Center Subject

Page No.

Repeat No.

Visit Name VISIT 99 MED

MEDICATION: OTHER THAN ANTI-THROMBOTICData No Data

Record all non anti-thrombotic medications that the subject has taken from randomization and until the end of the study

Drug/Medication (brand or generic name)	Reason	Start Date DD-MMM-YYYY	End Date DD-MMM-YYYY	Ongoing

OR

Confidential Information



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Country Center Subject

Page No.

Repeat No.

Visit Name VISIT 99 MED

MEDICATION: FLUSHING SOLUTIONS WITH HEPARIN OR THROMBOLYTICS

Data No Data

Record any flushing solutions with heparin or thrombolytic for CVC maintenance that the subject has taken within 2 weeks before randomization and until the end of the study.

Drug/Medication	Dosage	Dose Units	Route	Start Date	Start Time

Confidential Information

List of Adverse Events

Subevent	Adverse Event Term
0	.
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
19	

List of Adverse Events

Subevent	Adverse Event Term
20	.
21	
22	
23	
24	
25	
26	
27	
28	
29	
30	
31	
32	
33	
34	
35	
36	
37	
38	
39	

List of Adverse Events

Subevent	Adverse Event Term
40	.
41	
42	
43	
44	
45	
46	
47	
48	
49	
50	
51	
52	
53	
54	
55	
56	
57	
58	
59	

List of Adverse Events

Subevent	Adverse Event Term
60	.
61	
62	
63	
64	
65	
66	
67	
68	
69	
70	
71	
72	
73	
74	
75	
76	
77	
78	
79	

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Country Center Subject

Page No.

Repeat No.

Visit Name VISIT 99 AE

ADVERSE EVENT FORM

Data No Data

Category

AE Form Number

1. Adverse Event (Diagnosis)

2. Status of Adverse Event New

Date of Start

DD-MMM-YYYY

Ongoing with change

AE Reference No

Date of worsening intensity

DD-MMM-YYYY

3. Intensity

Mild Moderate Severe

4. Corrective treatment/therapy

Yes No

5. Action Taken with Investigat. Product

Yes No

6. Relationship to: Is there a reasonable possibility that the AE was caused by:

Investigational Product Yes No

Chemotherapy Yes No

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Country Center Subject

Page No.

Repeat No.

Visit Name VISIT 99 AE

7. Outcome

Date of Recovery

DD-MMM-YYYY

Specify sequelae

Date of Death

DD-MMM-YYYY

8. Seriousness Criteria Yes* No

If Yes - Date event became serious

DD-MMM-YYYY

- Complete this section (tick all criteria that apply)

Results in Death Requires or prolongs hospitalization Congenital anomaly or Birth Defect Life Threatening Persist./signif. disability/incapacity Other medically important event **9. Is it an even such as:**Overdose of the IP Yes* No Pregnancy Yes* No

* If yes, please complete the Safety Complementary Form

Confidential Information

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Country Center Subject

Page No. Repeat No.

Visit Name VISIT 99 AE

SAFETY COMPLEMENTARY FORM

AE/Specific Event Form number

1. DEMOGRAPHIC INFORMATION Weight (kg)

.

2. DETAILED DESCRIPTION OF THE ADVERSE EVENT

3. DATE OF START OF EVENT

DD-MMM-YYYY

4. INVESTIGATIONAL PRODUCTS Date of the FIRST admission of:

Treatment INVESTIGATIONAL PRODUCT Start date
DD-MMM-YYYY

Current Treatment Number Ongoing Yes No

5. IN CASE OF HOSPITALIZATION Date of Admission

DD-MMM-YYYY

6. IN CASE OF DEATH Autopsy report Yes No

7. CORRECTIVE TREATMENT / THERAPY

Confidential Information

List of Bleeding Events

Subevent	Bleeding term
0	.
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
19	

Confidential Information

List of Bleeding Events

Subevent Bleeding term

20	.	
21		
22		
23		
24		
25		
26		
27		
28		
29		
30		
31		
32		
33		
34		
35		
36		
37		
38		
39		

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Country Center Subject

Page No.

Repeat No.

Visit Name VISIT 99 BLEED

BLEEDING EVENT FORM

Data No Data

Category

AE Form Number

1. Bleeding Event (Diagnosis)

2. Status of Bleeding Event

New

Date of Start

DD-MMM-YYYY

Ongoing with change

Bleeding Reference No

DD-MMM-YYYY

Date of worsening in intensity

DD-MMM-YYYY

3. Intensity

Mild Moderate Severe

4. Corrective treatment/therapy

Yes No

5. Action Taken with Investigat. Product

Yes No

6. Relationship to: Is there a reasonable possibility that the Bleeding was caused by:

Investigational Product

Yes No Chemotherapy

Yes No

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Country Center Subject

Page No.

Repeat No.

Visit Name: VISIT 99 BLEED

7. Outcome

Date of Recovery

DD-MMM-YYYY

Specify Sequelae

Date of Death

DD-MMM-YYYY

8. Seriousness Criteria Yes No

If yes, Date event became serious

DD-MMM-YYYY

- Complete this section (tick all criteria that apply)

Results in Death

Requires or prolongs hospitalization

Congenital anomaly or Birth Defect

Life Threatening

Persist./signif. disability/incapacity

Other medically important event

* If yes please complete the Safety Complementary Form

Confidential Information

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Country Center Subject

Page No.

Repeat No.

Visit Name

VISIT 99 BLEED

BLEEDING SPECIFIC FORM

Data No Data

Bleeding form number

1. Overt Bleeding Yes No

2. Bleeding Context (Tick one box only)

Spontaneous	<input type="checkbox"/>
Post-traumatic	<input type="checkbox"/>
Post procedural	<input type="checkbox"/>

If Post Procedural:

Drug injection site	<input type="checkbox"/>
Vessel puncture	<input type="checkbox"/>
Other procedure	<input type="checkbox"/>
Other puncture	<input type="checkbox"/>
Surgery	<input type="checkbox"/>

If surgery, blood loss more than expected Yes No

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Country Center Subject

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Visit Name **VISIT 99 BLEED**

3. Did bleeding lead to an unscheduled contact with a Health Care Professional? Yes No

4. THERAPEUTIC INTERVENTIONS

Did bleeding require intervention? Yes No If YES, specify below:

Compression

Drainage without major surgery

Major surgery

Surgical repair/ligation of a vessel without surgery

Any transfusions *

Other invasive or medical procedure **

* If ticked, please complete the Transfusion page, p.753

** If ticked, please complete the Procedures page, p.756

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Country Center Subject

Page No.

Repeat No.

Visit Name VISIT 99 BLEED

SAFETY COMPLEMENTARY FORM

AE/Specific Event Form number

1. DEMOGRAPHIC INFORMATION Weight (kg) .**2. DETAILED DESCRIPTION OF THE ADVERSE EVENT****3. DATE OF START OF EVENT**

DD-MMM-YYYY

4. INVESTIGATIONAL PRODUCTS Date of the FIRST admission of:

Treatment

 INVESTIGATIONAL PRODUCT

Start date

DD-MMM-YYYY

Current Treatment Number

Ongoing Yes No **5. IN CASE OF HOSPITALIZATION** Date of Admission

DD-MMM-YYYY

6. IN CASE OF DEATH Autopsy reportYes No **7. CORRECTIVE TREATMENT / THERAPY**

Confidential Information



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Country Center Subject

Page No.

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Visit Name VISIT 99 LAB

LABORATORY TESTS HEMATOLOGY

UNSCHEDULED

Data No Data

Date
DD-MMM-YYYY

Time
24-hour clock

Test	Value	Unit
HEMOGLOBIN	<input type="text"/>	G/DL
WBC	<input type="text"/>	10E9/L
NEUTROPHILS	<input type="text"/>	10E9/L
PLATELET COUNT (THROMBOCYTE COUNT)	<input type="text"/>	10E9/L

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Country Center Subject

Page No.

Repeat No.

Visit Name VISIT 99 LAB

LABORATORY TESTS BIOCHEMISTRY

UNSCHEDULED

Data No Data

DO NOT COMPLETE CROSSED OUT FIELDS

Date
DD-MMM-YYYYTime
24-hour clock

Test	Value	Unit	NORMAL RANGES Upper limit
AST		IU/L	
ALT		IU/L	
ALKALINE PHOSPHATASE		IU/L	
TOTAL BILIRUBIN		UMOL/L	
CONJUGATED BILIRUBIN (DIRECT)		UMOL/L	
CREATININE		UMOL/L	X
ALBUMIN		G/L	X

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Country Center Subject

Page No.

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Visit Name VISIT 99 LAB

LABORATORY TESTS COAGULATION

UNSCHEDULED

Data No Data

DO NOT COMPLETE CROSSED OUT FIELDS

Date

DD-MMM-YYYY

Time

24-hour clock

Test	Value	Unit	NORMAL RANGES	
			Lower limit	Upper limit
INR		RATIO	X	X
APTT	.	S		
APTTC	.	S	X	X
APTR	.	RATIO	X	X

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Country Center Subject

Page No.

Repeat No.

Visit Name VISIT 99 LAB

LABORATORY TESTS PREGNANCY TEST

UNSCHEDULED

Data No Data Date

DD-MMM-YYYY

Test type

Serology
Urinalysis

Result

Negative
Positive

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Country Center Subject

Page No.

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Visit Name V99 ANTIBODIES

MEDICATION: PREVIOUS EXPOSURE TO HEPARIN OR HEPARIN DERIVATIVES

Record previous exposure to Heparin or Heparin derivatives

PAGE TO BE COMPLETED IN CASE OF SUSPICION OF STUDY DRUG-INDUCED THROMBOCYTOPENIAData No Data

Drug/Medication

Not Taken

End Date

Year

Confidential Information

CENTRALIZED DATA ANTIPLATELET ANTIBODIES SAMPLES

PAGE TO BE COMPLETED IN CASE OF SUSPICION OF STUDY DRUG-INDUCED THROMBOCYTOPENIA

Data No Data

Date performed
DD-MMM-YYYY



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Country Center Subject

Page No.

Repeat No.

Visit Name V99 TRANSFUSION

TRANSFUSION

Data No Data

Administration

Date DD-MMM-YYYY	Time 24-hour clock	Transfusion Type	Prescribed Dose	Administered Dose	Unit <i>If Other Unit,, specify</i>	Indication for Use
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

*For "Other Procoagulant Factors", no dose or unit need be specified.

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Country Center Subject

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Visit Name V99 DIAG VTE

DIAGNOSTIC TESTS FOR SUSPECTED VTE

Data No Data

Date of first symptoms of the VTE episode

DD-MMM-YYYY

1. There is a suspicion of PE

DVT

On Leg

Side of symptoms

Right

Arm

Left

Bilateral

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Country Center Subject

Page No.

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Visit Name V99 DIAG VTE

2. Examinations performed

Not done

OR

Date performed

DD-MMM-YYYY

SPIRAL CT SCAN
PERFUSION LUNG SCAN
VENTILATION LUNG SCAN
PULMONARY ANGIOGRAPHY
ULTRASOUND OF UPPER LIMBS
VENOGRAPHY OF UPPER LIMBS
COMPRESSION ULTRASOUND OF LOWER LIMBS
VENOGRAPHY OF LOWER LIMBS

.

OTHER DIAGNOSTIC TEST

.

Please specify other test

[Redacted]

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3. According to the result of these tests, was the subject treated for VTE? Yes No

IF YES, complete page 551



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Visit Name V99 PROC

PROCEDURES

Data No Data

Procedure	Date DD-MMM-YYYY	Purpose	Does it lead to a bleeding?
			Yes <input type="checkbox"/> No <input type="checkbox"/>
			Yes <input type="checkbox"/> No <input type="checkbox"/>
			Yes <input type="checkbox"/> No <input type="checkbox"/>
			Yes <input type="checkbox"/> No <input type="checkbox"/>
			Yes <input type="checkbox"/> No <input type="checkbox"/>

Confidential Information

Visit Name V99 HOSP

HOSPITALIZATION

Data No Data

Reason for hospitalization PE
(tick one box only) DVT
Bleeding
Other

Date of admission
DD-MMM-YYYY

Date of discharge
DD-MMM-YYYY OR Ongoing

Number of hospitalization days per ward:

ER (Emergency Room)

ICU (Intensive Care Unit)



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Country Center Subject

Page No.

Repeat No.

Visit Name V99 CANCER THER

ANTI-CANCER THERAPY (CONCOMITANT TREATMENT)

Data No Data

Intent

Reason for Discontinuation

If Other, specify

Regimen No.

Drug per Regimen

Therapy Type

Cumulative Dose

Unit

Start Date

End Date

Ongoing

.

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Country Center Subject

Page No.

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Visit Name V99 RADIAT THER

RADIATION THERAPY CONCOMITANT

Data No Data

Lesion location	Start date	Stop date
	DD-MMM-YYYY	DD-MMM-YYYY

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Country Center Subject

Page No.

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Visit Name V99 TUMOR EVAL

TUMOR EVALUATION (SCHEDULED LUNG IMAGING TEST)

Data No Data

Seq	Method of Assessment	If Other, specify	Date DD-MMM-YYYY	PE Diagnosed	If Yes, subject treated for PE
				Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
				Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
				Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
				Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
				Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>

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Centre No.

 □□□

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VISIT V99

V 99

DEATH ADJUDICATION

ADJDE_01_STU

• Date of death: □□□ / □□□ / □0□□
 day month year

• Death (tick "✓" one box only):

- Fatal PE
- Fatal bleeding
- Death not associated with VTE or bleeding (other)

• CIAC comments: _____

• Date of adjudication: □□□ / □□□ / □0□□
 day month year

Signature: _____

Signature: _____

NO 951

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EFC6521	Country No.		Centre No.	Subject No.
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DEATH ADJUDICATION ADJDE_01_STU

• Date of death: / /
 day month year

• Death (tick "✓" one box only):

- Fatal PE
- Fatal bleeding
- Death not associated with VTE or bleeding (other)
- ↳ If other, please specify: Cardiovascular death
Non cardiovascular death

• CIAC comments: _____

• Date of adjudication: / /
 day month year

Signature: _____

Signature: _____

NO 951.01

AVE5026

EFC6521

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VTE ADJUDICATION

ADJVT 02 STU

- Date of the first examination performed: / / 20
day month year
 - Diagnostic tests for suspected VTE form number: 754.
 - VTE (*tick all that apply*):

PE: Yes No

Acute DVT: Yes No

 IF YES, SPECIFY:

	LEFT	RIGHT
Proximal leg	Not Done <input type="checkbox"/>	Not Done <input type="checkbox"/>
	DVT <input type="checkbox"/>	DVT <input type="checkbox"/>
	No DVT <input type="checkbox"/>	No DVT <input type="checkbox"/>
Distal leg	Not Done <input type="checkbox"/>	Not Done <input type="checkbox"/>
	DVT <input type="checkbox"/>	DVT <input type="checkbox"/>
	No DVT <input type="checkbox"/>	No DVT <input type="checkbox"/>
Arm	Not Done <input type="checkbox"/>	Not Done <input type="checkbox"/>
	DVT <input type="checkbox"/>	DVT <input type="checkbox"/>
	No DVT <input type="checkbox"/>	No DVT <input type="checkbox"/>

- Date of adjudication: / /
 day month year

Signature: _____

Signature: _____

Signature: _____

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EFC6521	Country No.			Centre No.	Subject No.	Page
VISIT V99	V <input type="text"/> <input type="text"/>					

BLEEDING ADJUDICATION ADJBL_02_STU

• DATE OF EVENT ONSET: / /
day month year

• BLEEDING EVENT FORM NUMBER: 611 611 611

• BLEEDING:

CRITERIA FOR MAJOR BLEEDING:

- Fatal bleeding? Yes No
- Symptomatic bleeding into a critical area or organ? Yes No

↳ If Yes, please tick all that apply:

Intracranial Intraspinal Intraocular Retroperitoneal
Intraarticular Pericardial Intramuscular with compartment syndrome

- Fall in hemoglobin \geq of 2 g/dL? Yes No
- Transfusion of two or more units of whole blood or red cells? Yes No

CRITERIA FOR CLINICALLY RELEVANT NON-MAJOR BLEEDING:

- Overt bleeding requiring a medical intervention? Yes No

• OVERALL CLASSIFICATION:

Major bleeding Clinically relevant non major bleeding Non clinically relevant bleeding

• Date of adjudication: / /
day month year

Signature: _____

Signature: _____

AVE5026	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	XT	954	<input type="text"/> 01
EFC6521	Country No.			Centre No.	Subject No.	Page
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PE ADJUDICATION ADJPE_01_STU

DIAGNOSED ON SCHEDULED LUNG IMAGING TEST

- Date of the examination performed: / / 20
day month year
 - Diagnostic tests form number: 755.
 - Row number:
 - VTE:
- PE: Yes No

• Date of adjudication: <input type="text"/> / <input type="text"/> / <input type="text"/> 20 <input type="text"/> day month year	Signature: _____
Signature: _____	Signature: _____

XT 954 AVE5026 EFC6521

DEATH

Data No Data

Date of Death

DD-MMM-YYYY

Reason for Death

Progression

Adverse Event

Other

If Other, specify



Adjudication of a case of combined liver test abnormalities: ALT>3 ULN and Total Bilirubin (TBL) >2 ULN

AVE5026 - Study EFC

Country N°

Center N°

Patient N°

TYPE OF LIVER INJURY:

Cholestatic

Hepatocellular

Mixed

Chronic liver disease specify:

SEVERITY OF LIVER INJURY:

Hy's Law Case Yes No Non-evaluable

If Non-Evaluable, please specify reason:

Lack of information: Yes Specify:

No

Other, specify:.....

Adjudicator's Comments:

AVE5026 - Study EFC

Country N°

Center N°

Patient N°

ASSESSMENT of the association between the study drug and the liver injury

Method:

Unrelated/Excluded specify the most likely cause of the liver injury:

Possible

Probable

Unlikely

Definite

Adjudicator's Comments:

.....
.....
.....
.....
.....
.....
.....
.....

Date of adjudication: / /
Day Month Year

Adjudicator's Signature