

DataFax #220

Plate # 010

Visit #

Thorin Demo

Eligibility and Demographics

Subject Number [][] [][][][]

Subject Initials [][] [][]

SCREENING

Date of Screening [][] [][] [][][][]
Day Month Year

Inclusion

Yes No

1. Inclusion item 1?.....

2. Inclusion item 2?.....

3. Inclusion item 3?.....

Date signed [][] [][] [][][][]
Day Month Year

4. Is the subject ≥ 18 years of age?.....

Date of birth [][] [][] [][][][]
Day Month Year

5. Is the subject willing to comply with all aspects of the treatment and evaluation schedule?

6. Inclusion, item 6?..... NA

7. If female subject and of childbearing potential, is the pregnancy test negative?.....

Date of pregnancy test [][] [][] [][][][]
Day Month Year

8. Inclusionr item 8?.....

Exclusion

Yes No

9. Is the subject a participant in another clinical research study which the Investigator believes may interfere with the purpose of this study?.....

10. Exclusion item 10?.....

11. Exclusion item 11?.....

12. Exclusion item 12?.....

13. Exclusion item 13?.....

14. Exclusion item 10?.....

15. Exclusion item 15?.....

16. Exclusion item 16?.....

DataFax #220

Plate # 020

Visit #

SCREENING

**Eligibility, Demographics and
Physical Examination**

Subject Number

Subject Initials

Eligibility criteria discussed

If the subject does not meet all eligibility criteria, but requests to be enrolled in the study, please contact Thorin

Eligibility
criterion #

Discussed with and subject enrollment authorized by:

Discussion date:

Day

Month

Year

Day

Month

Year

Demographics

Gender:

Male

Female

Physical Examination

From the subject's pre-study medical history and physical exam, answer the following questions.
Use Comments Form for any written comments.

1. Does the subject smoke? Currently Never Stopped; quit date:

Month

Year

2. Does the subject have a known disease? Yes No

If YES, describe: _____

3. Does the subject have hypertension? Yes No
If YES, are medications taken for hypertension? Yes No

4. Does subject have hypercholesterolemia? Yes No
If YES, are medications taken for hypercholesterolemia? Yes No

5. Does subject have diabetes? Yes No
If YES, check type: IDDM NIDDM

6. Does subject have a history of events? Yes No
If YES, check type: Type 1 Type 2 Type 3 Type 4 Other: _____

SCREENING	Medical History and Medication	Subject Number <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
		Subject Initials <input type="text"/> <input type="text"/> <input type="text"/>

Medical History

7. Does the subject have medical history affecting vascular system or coagulation? Yes No
 If YES, please list below

Diagnosis

Date of Diagnosis

Active

	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Year	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Year	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Year	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Year	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Year	<input type="checkbox"/> Yes <input type="checkbox"/> No

Prior surgeries/procedures

8. Does the subject have prior surgeries/procedures? Yes No
 If YES, please list below

Surgery/Procedure

Indication

Date of Surgery

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

Medication

9. Did the subject take any medication within 1 week prior to surgery that may affect outcome? Yes No

If YES, indicate which apply:

- | | |
|---------------------------------------|---------------------------------------|
| <input type="checkbox"/> Medication 1 | <input type="checkbox"/> Medication 5 |
| <input type="checkbox"/> Medication 2 | <input type="checkbox"/> Medication 6 |
| <input type="checkbox"/> Medication 3 | <input type="checkbox"/> Medication 7 |
| <input type="checkbox"/> Medication 4 | |

List all current Concomitant Medications (generic name) on the Concomitant Medication Form

DataFax #220

Plate # 040

Visit #

		Subject Number <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>
		Subject Initials <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>

Laboratory Measurements

List only when parameter is 'out of range' OR parameter is 'not done'

Date sample taken for Hematology:

Day Month Year

Date sample taken for Biochemistry:

Day Month Year

Parameter	Check if Not done	Result	Unit	Out of range		Clinically significant		Comment
				Yes	No	Yes	No	
WBC	<input type="checkbox"/>	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Differential WBC	<input type="checkbox"/>	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
RBC	<input type="checkbox"/>	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
RDW	<input type="checkbox"/>	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Hemoglobin	<input type="checkbox"/>	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Hematocrit	<input type="checkbox"/>	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
MCH	<input type="checkbox"/>	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
MCHC	<input type="checkbox"/>	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
MCV	<input type="checkbox"/>	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Platelet Count	<input type="checkbox"/>	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Total bilirubin	<input type="checkbox"/>	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Random glucose	<input type="checkbox"/>	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Serum creatinine	<input type="checkbox"/>	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
AST	<input type="checkbox"/>	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Alkaline Phosphatase	<input type="checkbox"/>	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
ALT	<input type="checkbox"/>	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Blood urea nitrogen	<input type="checkbox"/>	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Sodium	<input type="checkbox"/>	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Potassium	<input type="checkbox"/>	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Chloride	<input type="checkbox"/>	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Hb-A1c	<input type="checkbox"/>	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____

DataFax #220

Plate # 046

Visit #

		Subject Number	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
		Subject Initials	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Laboratory Measurements (continued)

Parameter	Check if Not done	Result	Unit	Out of range		Clinically significant		Comment
				Yes	No	Yes	No	
Eosinophils	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Basophils	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Neutrophils	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Monocytes	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Lymphocytes	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____

DataFax #220

Plate # 050

Visit #

SCREENING

**Baseline Measurements /
Investigator Sign-off**

Subject Number

Subject Initials

Duplex Doppler Flow

Is a Duplex Doppler Flow taken?

Yes No

If **YES**, please note the diameter and describe the results below:

Results

mm. _____

Date Duplex Doppler Flow

Day Month Year

Angiography

Is an Angiography taken?

Yes No

If **YES**, please note the diameter and describe the results below:

Results

mm. _____

Date Angiography

Day Month Year

Investigator Sign-off

I have personally reviewed all data recorded at **Screening** for completeness and accuracy.

Investigator's Signature: _____ Date of Signature: Day Month Year

DataFax #220

Plate # 060

Visit #

OPERATIVE DAY

Treatment Record

Subject Number

Subject Initials

Date of Surgery Day Month Year

1. Surgery start time: :
(first cut) Hours Minutes

Time surgery ends: :
(last stitch) Hours Minutes

2. Name and location of sites: _____

3. Diameter . mm. Type: _____ Catalog number:: _____

4a. Does the subject require assistance? Yes No
→ if YES, stop enrollment into this study !

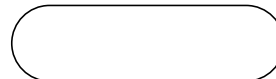
4b. Is complete surgery achieved ? Yes No
→ if NO, stop enrollment into this study !

5. Time surgery finished: :
Hours Minutes

6. Is the patient allocated to the treatment Group? Yes No

If YES, time randomised: : Number: _____
Hours Minutes

Affix randomization label to each copy of this treatment form:



7. Medication 1 used? Yes No **Units**
→ If YES, total dose: _____

8. Medication 2 used? Yes No
→ If YES, total dose: _____

9. Is an Angiography in 2 taken ? Yes No
→ If YES, please note the diameter and describe the results:
. mm. _____

10. Were any other procedures applied / measurements conducted during surgery? Yes No
→ If YES, please specify and note the results:

11. Is a digital image taken? Yes No

Record all Adverse Events on the Adverse Events Form

DataFax #220

Plate # 070

Visit #

OPERATIVE DAY

Performance

Subject Number

Subject Initials

Please document all items immediately after operation!

Surgery Ratings

If this subject was treated, please rate the following items of performance

Excellent	Good	Fair	Poor	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1. item 1
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2. item 2
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	3. item 3
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	4. item 4

Operating Room Comments

Please note ANY comments, positive or negative, by surgeon or Operating Room staff. Indicate the role of the person who made the comments.

Role	Comments
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

Investigator Sign-off

I have personally reviewed all data recorded at **Operative Day** for completeness and accuracy.

Investigator's Signature: _____ Date of Signature:
Day Month Year

DataFax #220

Plate # 080

Visit #

Hospital Discharge

Post Operative Follow-up

Subject Number

Subject Initials

Date of Visit

Day

Month

Year

Post operative experience

1. Was surgery used at the treatment site:

Yes No

If **YES**, date of surgery:

Day

Month

Year

Total volume

mL.

2. Did the subject return to surgery:

Yes No

If **YES**, surgical procedure performed:

Day

Month

Year

Complete Adverse Event Form and fax to Thorin

3. Date Duplex Doppler Flow:

Day

Month

Year

Please note the diameter and describe the results:

Diameter mm. Results _____

List changes in medication on Concomitant Medication Form

4. Did any of the following complications occur at the operative site?

Infection Yes No

Infection Yes No

Infection Yes No

Other Yes No If **YES**, specify: _____

If any YES, Record all Adverse Events on the Adverse Event Form

Investigator Sign-off

I have personally reviewed all data recorded for this **Visit** for completeness and accuracy.

Investigator's Signature: _____

Date of Signature:

Day

Month

Year

DataFax #220

Plate # 090

Visit #

	Follow-up	Subject Number <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
		Subject Initials <input type="text"/> <input type="text"/> <input type="text"/>
		Date of Follow-up visit <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
		<small>Day Month Year</small>

Adverse Events and Concomitant Medication Changes

1. Did the subject develop any adverse events during the post-discharge period? Yes No

Record any Adverse Events the subject experienced after the previous visit on the Adverse Event Form.

List all changes in medication on the Concomitant Medication Form.

2. Is the subject taking prescribed medications as directed? Yes No

If **NO**, please explain: _____

Duplex Doppler Flow

Is a Duplex Doppler Flow taken for this visit? Yes No

If **YES**, please note the diameter and describe the results below:

Results

mm. _____

Date Duplex Doppler Flow

Day Month Year

Angiography

Is an Angiography taken since last visit? Yes No

If **YES**, please note the diameter and describe the results below:

Results

mm. _____

Date Angiography

Day Month Year

Investigator Sign-off

I have personally reviewed all data recorded for this **Follow-up Visit** for completeness and accuracy.

Investigator's Signature: _____ Date of Signature:

Day Month Year

DataFax #220

Plate # 100

Visit #

	Study Termination	Subject Number <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> Subject Initials <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>
Date of Study Completion/Termination		<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <small style="display: flex; justify-content: space-around; width: 100%;">Day Month Year</small>

Study Completion / Termination

1. Did the subject complete all study visits to date? Yes No

If **NO**, please check the one most appropriate reason below:

a. Protocol violation, please explain:

b. Lost to follow-up after 3 attempts to contact. Please provide dates for each of these 3 attempts:

1st telephone contact, date:
Day Month Year

2nd telephone contact, date:
Day Month Year

3rd contact by certified mail, dated:
Day Month Year

Certified mail #: _____

c. Adverse Event, #

d. Death Date of Death:
Day Month Year

➔ **Any death must be reported within 24 hours of the Investigator's first knowledge of it.**

➔ **Complete SAE Form and fax within 24 hours of death to Thorin**

e. Other, please explain:

Investigator Sign-off

I have personally reviewed all data recorded for this **Termination Visit** and for **Concomitant Medication** for completeness and accuracy.

Investigator's Signature: _____ Date of Signature:
Day Month Year

DataFax #220

Plate # 200

Visit #

	Adverse Event	Subject Number <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> Subject Initials <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>
--	----------------------	--

Adverse Events

Adverse Event no.

Description of Event _____

Startdate
Day Month Year

Ongoing at Study end
 Yes
 No

Stopdate
Day Month Year

Severity (maximum)?
 Mild
 Moderate
 Severe

Pattern?
 Once
 Continuous
 Intermittent

Action taken?
 None
 Medication → *Update the Concomitant Medication section.*
 Surgery
 Other → *Please describe at Details of AE*

Was Event related to Treatment?
 Definitely
 Likely
 Unlikely
 Definitely not

Serious Adverse Event?
 Yes
 No

Outcome?
 Recovered
 Recovering
 Recovered with sequelae
 Not recovered
 Death
 Unknown

Details of Adverse Event:

Investigator Sign-off

I have personally reviewed all data recorded for this **Adverse Event** for completeness and accuracy.

Investigator's Signature: _____ Date of Signature:
Day Month Year

Concomitant Medication

Subject Number

Subject Initials

Medication (generic name) _____ Total dose (24 hours) _____ Units _____ Route _____ Reason for use AE, specify AE# Other: _____

Start date Stop date Ongoing at Study End Yes No

Day Month Year Day Month Year

Medication (generic name) _____ Total dose (24 hours) _____ Units _____ Route _____ Reason for use AE, specify AE# Other: _____

Start date Stop date Ongoing at Study End Yes No

Day Month Year Day Month Year

Medication (generic name) _____ Total dose (24 hours) _____ Units _____ Route _____ Reason for use AE, specify AE# Other: _____

Start date Stop date Ongoing at Study End Yes No

Day Month Year Day Month Year

Medication (generic name) _____ Total dose (24 hours) _____ Units _____ Route _____ Reason for use AE, specify AE# Other: _____

Start date Stop date Ongoing at Study End Yes No

Day Month Year Day Month Year

Medication (generic name) _____ Total dose (24 hours) _____ Units _____ Route _____ Reason for use AE, specify AE# Other: _____

Start date Stop date Ongoing at Study End Yes No

Day Month Year Day Month Year

