

Thorin Demo	Eligibility and Demographics	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"/>
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SCREENING	Date of Screening <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"/> <div style="display: flex; justify-content: space-around; font-size: small;"> Day Month Year </div>
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Inclusion		Yes	No	
1. Inclusion item 1?.....		<input type="checkbox"/>	<input type="checkbox"/>	
2. Inclusion item 2?.....		<input type="checkbox"/>	<input type="checkbox"/>	
3. Inclusion item 3?.....	Date signed <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"/> <div style="display: flex; justify-content: space-around; font-size: small;"> Day Month Year </div>	<input type="checkbox"/>	<input type="checkbox"/>	
4. Is the subject ≥ 18 years of age?.....	Date of birth <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"/> <div style="display: flex; justify-content: space-around; font-size: small;"> Day Month Year </div>	<input type="checkbox"/>	<input type="checkbox"/>	
5. Is the subject willing to comply with all aspects of the treatment and evaluation schedule?		<input type="checkbox"/>	<input type="checkbox"/>	
6. Inclusion, item 6?.....		<input type="checkbox"/>	<input type="checkbox"/>	NA
7. If female subject and of childbearing potential, is the pregnancy test negative?.....	Date of pregnancy test <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"/> <div style="display: flex; justify-content: space-around; font-size: small;"> Day Month Year </div>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Inclusionr item 8?.....		<input type="checkbox"/>	<input type="checkbox"/>	
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?.....		<input type="checkbox"/>	<input type="checkbox"/>	
10. Exclusion item 10?.....		<input type="checkbox"/>	<input type="checkbox"/>	
11. Exclusion item 11?.....		<input type="checkbox"/>	<input type="checkbox"/>	
12. Exclusion item 12?.....		<input type="checkbox"/>	<input type="checkbox"/>	
13. Exclusion item 13?.....		<input type="checkbox"/>	<input type="checkbox"/>	
14. Exclusion item 10?.....		<input type="checkbox"/>	<input type="checkbox"/>	
15. Exclusion item 15?.....		<input type="checkbox"/>	<input type="checkbox"/>	
16. Exclusion item 16?.....		<input type="checkbox"/>	<input type="checkbox"/>	

DataFax #220

Plate #020

Visit #001

SCREENING	Eligibility, Demographics and Physical Examination	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"/>

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:
<input type="text"/> <input type="text"/>	_____	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
		Day Month Year
<input type="text"/> <input type="text"/>	_____	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
		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: _____

DataFax #220

Plate #030

Visit #001

SCREENING	Medical History and Medication	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"/>

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 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"/> Month Year	<input type="checkbox"/> Yes <input type="checkbox"/> No
_____	<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"/> Month Year	<input type="checkbox"/> Yes <input type="checkbox"/> No
_____	<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"/> Month Year	<input type="checkbox"/> Yes <input type="checkbox"/> No
_____	<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"/> Month Year	<input type="checkbox"/> Yes <input type="checkbox"/> No
_____	<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"/> 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 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"/> Month Year
_____	_____	<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"/> Month Year
_____	_____	<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"/> Month Year
_____	_____	<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"/> Month Year
_____	_____	<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"/> 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 #001

SCREENING	Laboratory Measurements	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

Note: Laboratory tests must be done **within 7 days** of surgery

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:40px; height:20px;" type="text"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Differential WBC	<input type="checkbox"/>	<input style="width:40px; height:20px;" type="text"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
RBC	<input type="checkbox"/>	<input style="width:40px; height:20px;" type="text"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
RDW	<input type="checkbox"/>	<input style="width:40px; height:20px;" type="text"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Hemoglobin	<input type="checkbox"/>	<input style="width:40px; height:20px;" type="text"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Hematocrit	<input type="checkbox"/>	<input style="width:40px; height:20px;" type="text"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MCH	<input type="checkbox"/>	<input style="width:40px; height:20px;" type="text"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MCHC	<input type="checkbox"/>	<input style="width:40px; height:20px;" type="text"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MCV	<input type="checkbox"/>	<input style="width:40px; height:20px;" type="text"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Platelet Count	<input type="checkbox"/>	<input style="width:40px; height:20px;" type="text"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Total bilirubin	<input type="checkbox"/>	<input style="width:40px; height:20px;" type="text"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Random glucose	<input type="checkbox"/>	<input style="width:40px; height:20px;" type="text"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Serum creatinine	<input type="checkbox"/>	<input style="width:40px; height:20px;" type="text"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
AST	<input type="checkbox"/>	<input style="width:40px; height:20px;" type="text"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Alkaline Phosphatase	<input type="checkbox"/>	<input style="width:40px; height:20px;" type="text"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
ALT	<input type="checkbox"/>	<input style="width:40px; 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:40px; height:20px;" type="text"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Sodium	<input type="checkbox"/>	<input style="width:40px; height:20px;" type="text"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Potassium	<input type="checkbox"/>	<input style="width:40px; height:20px;" type="text"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Chloride	<input type="checkbox"/>	<input style="width:40px; height:20px;" type="text"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Hb-A1c	<input type="checkbox"/>	<input style="width:40px; height:20px;" type="text"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

DataFax #220

Plate #046

Visit #001

SCREENING	Laboratory Measurements	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"/>	_____
Lymfocytes	<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 #001

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 #070

Visit #010

OPERATIVE DAY	Performance	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"/>

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



Hospital Discharge	Post Operative 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 Visit <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
		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: _____

Date of above procedure:

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 #040

Visit #030

2 Weeks	Follow-up	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:40px; height:20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Differential WBC	<input type="checkbox"/>	<input style="width:40px; height:20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
RBC	<input type="checkbox"/>	<input style="width:40px; height:20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
RDW	<input type="checkbox"/>	<input style="width:40px; height:20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Hemoglobin	<input type="checkbox"/>	<input style="width:40px; height:20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Hematocrit	<input type="checkbox"/>	<input style="width:40px; height:20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
MCH	<input type="checkbox"/>	<input style="width:40px; height:20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
MCHC	<input type="checkbox"/>	<input style="width:40px; height:20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
MCV	<input type="checkbox"/>	<input style="width:40px; height:20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Platelet Count	<input type="checkbox"/>	<input style="width:40px; height:20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Total bilirubin	<input type="checkbox"/>	<input style="width:40px; height:20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Random glucose	<input type="checkbox"/>	<input style="width:40px; height:20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Serum creatinine	<input type="checkbox"/>	<input style="width:40px; height:20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
AST	<input type="checkbox"/>	<input style="width:40px; height:20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Alkaline Phosphatase	<input type="checkbox"/>	<input style="width:40px; height:20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
ALT	<input type="checkbox"/>	<input style="width:40px; 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:40px; height:20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Sodium	<input type="checkbox"/>	<input style="width:40px; height:20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Potassium	<input type="checkbox"/>	<input style="width:40px; height:20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Chloride	<input type="checkbox"/>	<input style="width:40px; height:20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Hb-A1c	<input type="checkbox"/>	<input style="width:40px; height:20px;" type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____

DataFax #220

Plate #046

Visit #030

2 Weeks	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"/>

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"/>	_____
Lymfocytes	<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 #090

Visit #030

2 Weeks	Follow-up	Subject Number <input type="text"/> <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



	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"/> <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"/>
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"/> <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



	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"/>
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Adverse Events

Adverse Event no.

Description of Event _____

Startdate
Day Month Year

Stopdate
Day Month Year

Ongoing at Study end
 Yes
 No

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



	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"/>
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Adverse Events

Adverse Event no.

Description of Event _____

Startdate
Day Month Year

Stopdate
Day Month Year

Ongoing at Study end
 Yes
 No

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



	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"/>
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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
 Surgery
 Other

Update the Concomitant Medication section.

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



	Serious 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"/>
1. Adverse Event no. <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	Date SAE reported: <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"/>	
<small>Day Month Year</small>		

Clinical presentation of the Event _____

2. Why was the Adverse Event serious? *(check only one, the primary reason for seriousness)*

Resulted in Death Was an autopsy preformed? Yes No

Is life-threatening

Requires in patient hospitalisation or prolongation of existing hospitalisation

Results in persistent or significant disability/incapacity

Is a congenital anomaly/birth defect

Other medically important condition

3. Relevant medical history and/or current medical condition: _____

4. Concomitant medication or surgical procedures at the time the event started: _____

5. Relevant Laboratory data: _____

6. Treatment of the event: _____

7. Outcome of the event: _____

Investigator Sign-off

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

Investigator's Signature: _____ Date of Signature:

Day Month Year

DataFax #220

Plate #210

Visit #241

Serious Adverse Event

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

Subject Initials [][] [][]

1. Adverse Event no. [][]

Date SAE reported: [][] [][] [][][][]
Day Month Year

Clinical presentation of the Event _____

2. Why was the Adverse Event serious? (check only one, the primary reason for seriousness)

- Resulted in Death Was an autopsy preformed? Yes No
- Is life-threatening
- Requires in patient hospitalisation or prolongation of existing hospitalisation
- Results in persistent or significant disability/incapacity
- Is a congenital anomaly/birth defect
- Other medically important condition

3. Relevant medical history and/or current medical condition: _____

4. Concomitant medication or surgical procedures at the time the event started: _____

5. Relevant Laboratory data: _____

6. Treatment of the event: _____

7. Outcome of the event: _____

Investigator Sign-off

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

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

DataFax #220

Plate #210

Visit #242

Serious Adverse Event

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

Subject Initials [][] [][]

1. Adverse Event no. [][]

Date SAE reported: [][] [][] [][][][]
Day Month Year

Clinical presentation of the Event _____

2. Why was the Adverse Event serious? (check only one, the primary reason for seriousness)

- Resulted in Death —————> Was an autopsy preformed? Yes No
- Is life-threatening
- Requires in patient hospitalisation or prolongation of existing hospitalisation
- Results in persistent or significant disability/incapacity
- Is a congenital anomaly/birth defect
- Other medically important condition

3. Relevant medical history and/or current medical condition: _____

4. Concomitant medication or surgical procedures at the time the event started: _____

5. Relevant Laboratory data: _____

6. Treatment of the event: _____

7. Outcome of the event: _____

Investigator Sign-off

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

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



	Concomitant Medication	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"/>
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Please list all medication taken at the start of the study and/or during the study or Check 'none' None

1.	Medication (generic name) _____	Total dose (24 hours) _____	Units _____	Route _____	Reason for use <input type="checkbox"/> AE, specify AE# <input style="width: 20px; height: 20px;" type="text"/> <input type="checkbox"/> Other: _____
	Start date <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"/> <small>Day Month Year</small>	Stop date <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"/> <small>Day Month Year</small>	Ongoing at Study End <input type="checkbox"/> Yes <input type="checkbox"/> No		

2.	Medication (generic name) _____	Total dose (24 hours) _____	Units _____	Route _____	Reason for use <input type="checkbox"/> AE, specify AE# <input style="width: 20px; height: 20px;" type="text"/> <input type="checkbox"/> Other: _____
	Start date <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"/> <small>Day Month Year</small>	Stop date <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"/> <small>Day Month Year</small>	Ongoing at Study End <input type="checkbox"/> Yes <input type="checkbox"/> No		

3.	Medication (generic name) _____	Total dose (24 hours) _____	Units _____	Route _____	Reason for use <input type="checkbox"/> AE, specify AE# <input style="width: 20px; height: 20px;" type="text"/> <input type="checkbox"/> Other: _____
	Start date <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"/> <small>Day Month Year</small>	Stop date <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"/> <small>Day Month Year</small>	Ongoing at Study End <input type="checkbox"/> Yes <input type="checkbox"/> No		

4.	Medication (generic name) _____	Total dose (24 hours) _____	Units _____	Route _____	Reason for use <input type="checkbox"/> AE, specify AE# <input style="width: 20px; height: 20px;" type="text"/> <input type="checkbox"/> Other: _____
	Start date <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"/> <small>Day Month Year</small>	Stop date <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"/> <small>Day Month Year</small>	Ongoing at Study End <input type="checkbox"/> Yes <input type="checkbox"/> No		

5.	Medication (generic name) _____	Total dose (24 hours) _____	Units _____	Route _____	Reason for use <input type="checkbox"/> AE, specify AE# <input style="width: 20px; height: 20px;" type="text"/> <input type="checkbox"/> Other: _____
	Start date <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"/> <small>Day Month Year</small>	Stop date <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"/> <small>Day Month Year</small>	Ongoing at Study End <input type="checkbox"/> Yes <input type="checkbox"/> No		

DataFax #220

Plate #250

Visit #251

	Concomitant Medication	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"/>
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6.	Medication (generic name) _____	Total dose (24 hours) _____	Units _____	Route _____	Reason for use <input type="checkbox"/> AE, specify AE# <input style="width: 20px; height: 20px;" type="text"/> <input type="checkbox"/> Other: _____
	Start date <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"/> Day Month Year	Stop date <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"/> Day Month Year	Ongoing at Study End <input type="checkbox"/> Yes <input type="checkbox"/> No		

7.	Medication (generic name) _____	Total dose (24 hours) _____	Units _____	Route _____	Reason for use <input type="checkbox"/> AE, specify AE# <input style="width: 20px; height: 20px;" type="text"/> <input type="checkbox"/> Other: _____
	Start date <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"/> Day Month Year	Stop date <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"/> Day Month Year	Ongoing at Study End <input type="checkbox"/> Yes <input type="checkbox"/> No		

8.	Medication (generic name) _____	Total dose (24 hours) _____	Units _____	Route _____	Reason for use <input type="checkbox"/> AE, specify AE# <input style="width: 20px; height: 20px;" type="text"/> <input type="checkbox"/> Other: _____
	Start date <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"/> Day Month Year	Stop date <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"/> Day Month Year	Ongoing at Study End <input type="checkbox"/> Yes <input type="checkbox"/> No		

9.	Medication (generic name) _____	Total dose (24 hours) _____	Units _____	Route _____	Reason for use <input type="checkbox"/> AE, specify AE# <input style="width: 20px; height: 20px;" type="text"/> <input type="checkbox"/> Other: _____
	Start date <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"/> Day Month Year	Stop date <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"/> Day Month Year	Ongoing at Study End <input type="checkbox"/> Yes <input type="checkbox"/> No		

10.	Medication (generic name) _____	Total dose (24 hours) _____	Units _____	Route _____	Reason for use <input type="checkbox"/> AE, specify AE# <input style="width: 20px; height: 20px;" type="text"/> <input type="checkbox"/> Other: _____
	Start date <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"/> Day Month Year	Stop date <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"/> Day Month Year	Ongoing at Study End <input type="checkbox"/> Yes <input type="checkbox"/> No		

DataFax #220

Plate #250

Visit #252

Concomitant Medication

Subject Number

Subject Initials

11. Medication (generic name) Total dose (24 hours) Units Route Reason for use

 AE, specify AE#
 Other: _____

Start date Stop date Ongoing at Study End
Day Month Year Day Month Year Yes No

12. Medication (generic name) Total dose (24 hours) Units Route Reason for use

 AE, specify AE#
 Other: _____

Start date Stop date Ongoing at Study End
Day Month Year Day Month Year Yes No

13. Medication (generic name) Total dose (24 hours) Units Route Reason for use

 AE, specify AE#
 Other: _____

Start date Stop date Ongoing at Study End
Day Month Year Day Month Year Yes No

14. Medication (generic name) Total dose (24 hours) Units Route Reason for use

 AE, specify AE#
 Other: _____

Start date Stop date Ongoing at Study End
Day Month Year Day Month Year Yes No

15. Medication (generic name) Total dose (24 hours) Units Route Reason for use

 AE, specify AE#
 Other: _____

Start date Stop date Ongoing at Study End
Day Month Year Day Month Year Yes No

DataFax #220

Plate #250

Visit #253

	Concomitant Medication	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"/>
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16. Medication (generic name) _____ Total dose (24 hours) _____ Units _____ Route _____ Reason for use AE, specify AE# Other: _____

Start date Day Month Year Stop date Day Month Year Ongoing at Study End Yes No

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

Start date Day Month Year Stop date Day Month Year Ongoing at Study End Yes No

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

Start date Day Month Year Stop date Day Month Year Ongoing at Study End Yes No

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

Start date Day Month Year Stop date Day Month Year Ongoing at Study End Yes No

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

Start date Day Month Year Stop date Day Month Year Ongoing at Study End Yes No



	Comments	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"/>

Use this form to capture Study Information which cannot otherwise be collected in the Case Report Form (CRF). Indicate the CRF Visit number (just below the barcode) and the CRF Page number (lower right corner).

Comment #1
 Comment #2
 Comment #3
 Comment #4
 Comment #5
 Comment #6
 Comment #7
 Comment #8

Visit Number	Page Number	Item on CRF	Comment



	Comments	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"/>

Use this form to capture Study Information which cannot otherwise be collected in the Case Report Form (CRF). Indicate the CRF Visit number (just below the barcode) and the CRF Page number (lower right corner).

Comment #9
 Comment #10
 Comment #11
 Comment #12
 Comment #13
 Comment #14
 Comment #15
 Comment #16

Visit Number	Page Number	Item on CRF	Comment



	Comments	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"/>

Use this form to capture Study Information which cannot otherwise be collected in the Case Report Form (CRF). Indicate the CRF Visit number (just below the barcode) and the CRF Page number (lower right corner).

Comment #24
 Comment #23
 Comment #22
 Comment #21
 Comment #20
 Comment #19
 Comment #18
 Comment #17

Visit Number	Page Number	Item on CRF	Comment