

DataFax #220

Plate # 010

Visit #

<b>Thorin Demo</b>	<b>Eligibility and Demographics</b>	Subject Number <b>7.SUBJID</b>
		Subject Initials <b>8.SUBNAM</b>

<b>SCREENING</b>	Date of Screening <b>9.VISITDTM</b>
	Day Month Year

<b>Inclusion</b>		Yes	No
1.	Inclusion item 1?.....	<b>10.IESTRESC</b>	
2.	Inclusion item 2?..... <b>13.SJOUKE</b>	<b>11.IESTRESC</b>	
3.	Inclusion item 3?.....	<b>12.IESTRESC</b>	
	Date signed <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		
4.	Is the subject ≥ 18 years of age?.....	<b>14.IESTRESC</b>	
	Date of birth <b>15.BRTHDTM</b>		
5.	Is the subject willing to comply with all aspects of the treatment and evaluation schedule?	<b>16.IESTRESC</b>	
6.	Inclusion, item 6?.....	<b>17.IESTRESC</b>	
7.	If female subject and of childbearing potential, is the pregnancy test negative?.....	<b>18.IESTRESC_7</b>	
	Date of pregnancy test <b>19.DMPTDTM</b>		
8.	Inclusionr item 8?.....	<b>20.IESTRESC</b>	
<b>Exclusion</b>		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?.....	<b>21.IESTRESC</b>	
10.	Exclusion item 10?.....	<b>22.IESTRESC</b>	
11.	Exclusion item 11?.....	<b>23.IESTRESC</b>	
12.	Exclusion item 12?.....	<b>24.IESTRESC</b>	
13.	Exclusion item 13?.....	<b>25.IESTRESC</b>	
14.	Exclusion item 10?.....	<b>26.IESTRESC</b>	
15.	Exclusion item 15?.....	<b>27.IESTRESC</b>	
16.	Exclusion item 16?.....	<b>28.IESTRESC</b>	

<b>SCREENING</b>	<b>Eligibility, Demographics and Physical Examination</b>	Subject Number <b>7.SUBJID</b>
		Subject Initials <b>8.SUBNAM</b>

**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:
<b>9.IESEQ_1</b>	<b>10.EDDESC</b>	<b>11.EDDTM</b>
		Day Month Year
<b>12.IESEQ_2</b>	<b>13.EDDESC</b>	<b>14.EDDTM</b>
		Day Month Year

**Demographics**

Gender: **15.SEX**

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? **16.SUSTAT** Stopped; quit date: **17.SUENDTM**

2. Does the subject have a known disease? **18.PESTAT** No  
If YES, describe: **19.PEDESC**

3. Does the subject have hypertension? **20.PESTAT** No  
If YES, are medications taken for hypertension? **21.PEYN** No

4. Does subject have hypercholesterolemia? **22.PESTAT** No  
If YES, are medications taken for hypercholesterolemia? **23.PEYN** No

5. Does subject have diabetes? **24.PESTAT** No  
If YES, check type: **25.PEDM** NIDDM

6. Does subject have a history of events? **26.PESTAT** No  
If YES, check type: **27.PETE**  Type 3  Type 4  Other: **28.PEDESC**

<b>SCREENING</b>	<b>Medical History and Medication</b>	Subject Number <span style="border: 1px solid black; padding: 2px;">7.SUBJID</span>
		Subject Initials <span style="border: 1px solid black; padding: 2px;">8.SUBNAM</span>

**Medical History**

7. Does the subject have medical history affecting vascular system or coagulation? [ 9.MHSTAT ] No  
 If YES, please list below

Diagnosis	Date of Diagnosis	Active
<span style="border: 1px solid black; padding: 2px;">10.MHTERM</span>	<span style="border: 1px solid black; padding: 2px;">11.MHSTDTM</span> <small>Month Year</small>	<span style="border: 1px solid black; padding: 2px;">12.MHONGO</span> <small>Yes No</small>
<span style="border: 1px solid black; padding: 2px;">13.MHTERM</span>	<span style="border: 1px solid black; padding: 2px;">14.MHSTDTM</span> <small>Month Year</small>	<span style="border: 1px solid black; padding: 2px;">15.MHONGO</span> <small>Yes No</small>
<span style="border: 1px solid black; padding: 2px;">16.MHTERM</span>	<span style="border: 1px solid black; padding: 2px;">17.MHSTDTM</span> <small>Month Year</small>	<span style="border: 1px solid black; padding: 2px;">18.MHONGO</span> <small>Yes No</small>
<span style="border: 1px solid black; padding: 2px;">19.MHTERM</span>	<span style="border: 1px solid black; padding: 2px;">20.MHSTDTM</span> <small>Month Year</small>	<span style="border: 1px solid black; padding: 2px;">21.MHONGO</span> <small>Yes No</small>
<span style="border: 1px solid black; padding: 2px;">22.MHTERM</span>	<span style="border: 1px solid black; padding: 2px;">23.MHSTDTM</span> <small>Month Year</small>	<span style="border: 1px solid black; padding: 2px;">24.MHONGO</span> <small>Yes No</small>

**Prior surgeries/procedures**

8. Does the subject have prior surgeries/procedures? [ 25.SPSTAT ] No  
 If YES, please list below

Surgery/Procedure	Indication	Date of Surgery
<span style="border: 1px solid black; padding: 2px;">26.MHTERM</span>	<span style="border: 1px solid black; padding: 2px;">27.MHDESC</span>	<span style="border: 1px solid black; padding: 2px;">28.MHSTDTM</span> <small>Month Year</small>
<span style="border: 1px solid black; padding: 2px;">29.MHTERM</span>	<span style="border: 1px solid black; padding: 2px;">30.MHDESC</span>	<span style="border: 1px solid black; padding: 2px;">31.MHSTDTM</span> <small>Month Year</small>
<span style="border: 1px solid black; padding: 2px;">32.MHTERM</span>	<span style="border: 1px solid black; padding: 2px;">33.MHDESC</span>	<span style="border: 1px solid black; padding: 2px;">34.MHSTDTM</span> <small>Month Year</small>
<span style="border: 1px solid black; padding: 2px;">35.MHTERM</span>	<span style="border: 1px solid black; padding: 2px;">36.MHDESC</span>	<span style="border: 1px solid black; padding: 2px;">37.MHSTDTM</span> <small>Month Year</small>
<span style="border: 1px solid black; padding: 2px;">38.MHTERM</span>	<span style="border: 1px solid black; padding: 2px;">39.MHDESC</span>	<span style="border: 1px solid black; padding: 2px;">40.MHSTDTM</span> <small>Month Year</small>

**Medication**

9. Did the subject take any medication within 1 week prior to surgery that may affect outcome? [ 41.MDSTAT ] No  
 If YES, indicate which apply:

<span style="border: 1px solid black; padding: 2px;">42.FUMD1</span> on 1	<span style="border: 1px solid black; padding: 2px;">46.FUMD5</span> on 5
<span style="border: 1px solid black; padding: 2px;">43.FUMD2</span> on 2	<span style="border: 1px solid black; padding: 2px;">47.FUMD6</span> on 6
<span style="border: 1px solid black; padding: 2px;">44.FUMD3</span> on 3	<span style="border: 1px solid black; padding: 2px;">48.FUMD7</span> on 7
<span style="border: 1px solid black; padding: 2px;">45.FUMD4</span> on 4	

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

		Subject Number <b>7.SUBJID</b>
		Subject Initials <b>8.SUBNAM</b>

**Laboratory Measurements**

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

Date sample taken for Hematology: **9.LBDTM\_1**

Day      Month      Year

Date sample taken for Biochemistry: **10.LBDTM\_2**

Day      Month      Year

Parameter	Check if Not done	Result	Unit	Out of range		Clinically significant		Comment
				Yes	No	Yes	No	
WBC	<b>11.LBND</b>	<b>12.LBORRES</b>	<b>13.LBORRESU</b>	<b>14.LBOR</b>		<b>15.LBCS</b>		<b>16.LBREAS</b>
Differenti	<b>17.LBND</b>	<b>18.LBORRES</b>	<b>19.LBORRESU</b>	<b>20.LBOR</b>		<b>21.LBCS</b>		<b>22.LBREAS</b>
RBC	<b>23.LBND</b>	<b>24.LBORRES</b>	<b>25.LBORRESU</b>	<b>26.LBOR</b>		<b>27.LBCS</b>		<b>28.LBREAS</b>
RDW	<b>29.LBND</b>	<b>30.LBORRES</b>	<b>31.LBORRESU</b>	<b>32.LBOR</b>		<b>33.LBCS</b>		<b>34.LBREAS</b>
Hemoglo	<b>35.LBND</b>	<b>36.LBORRES</b>	<b>37.LBORRESU</b>	<b>38.LBOR</b>		<b>39.LBCS</b>		<b>40.LBREAS</b>
Hematoc	<b>41.LBND</b>	<b>42.LBORRES</b>	<b>43.LBORRESU</b>	<b>44.LBOR</b>		<b>45.LBCS</b>		<b>46.LBREAS</b>
MCH	<b>47.LBND</b>	<b>48.LBORRES</b>	<b>49.LBORRESU</b>	<b>50.LBOR</b>		<b>51.LBCS</b>		<b>52.LBREAS</b>
MCHC	<b>53.LBND</b>	<b>54.LBORRES</b>	<b>55.LBORRESU</b>	<b>56.LBOR</b>		<b>57.LBCS</b>		<b>58.LBREAS</b>
MCV	<b>59.LBND</b>	<b>60.LBORRES</b>	<b>61.LBORRESU</b>	<b>62.LBOR</b>		<b>63.LBCS</b>		<b>64.LBREAS</b>
Platelet C	<b>65.LBND</b>	<b>66.LBORRES</b>	<b>67.LBORRESU</b>	<b>68.LBOR</b>		<b>69.LBCS</b>		<b>70.LBREAS</b>
Total bilir	<b>71.LBND</b>	<b>72.LBORRES</b>	<b>73.LBORRESU</b>	<b>74.LBOR</b>		<b>75.LBCS</b>		<b>76.LBREAS</b>
Random	<b>77.LBND</b>	<b>78.LBORRES</b>	<b>79.LBORRESU</b>	<b>80.LBOR</b>		<b>81.LBCS</b>		<b>82.LBREAS</b>
Serum cr	<b>83.LBND</b>	<b>84.LBORRES</b>	<b>85.LBORRESU</b>	<b>86.LBOR</b>		<b>87.LBCS</b>		<b>88.LBREAS</b>
AST	<b>89.LBND</b>	<b>90.LBORRES</b>	<b>91.LBORRESU</b>	<b>92.LBOR</b>		<b>93.LBCS</b>		<b>94.LBREAS</b>
Alkaline Phospha	<b>95.LBND</b>	<b>96.LBORRES</b>	<b>97.LBORRESU</b>	<b>98.LBOR</b>		<b>99.LBCS</b>		<b>100.LBREAS</b>
ALT	<b>101.LBND</b>	<b>102.LBORRES</b>	<b>103.LBORRESU</b>	<b>104.LBOR</b>		<b>105.LBCS</b>		<b>106.LBREAS</b>
Blood ure nitrogen	<b>107.LBND</b>	<b>108.LBORRES</b>	<b>109.LBORRESU</b>	<b>110.LBOR</b>		<b>111.LBCS</b>		<b>112.LBREAS</b>
Sodium	<b>113.LBND</b>	<b>114.LBORRES</b>	<b>115.LBORRESU</b>	<b>116.LBOR</b>		<b>117.LBCS</b>		<b>118.LBREAS</b>
Potassium	<b>119.LBND</b>	<b>120.LBORRES</b>	<b>121.LBORRESU</b>	<b>122.LBOR</b>		<b>123.LBCS</b>		<b>124.LBREAS</b>
Chloride	<b>125.LBND</b>	<b>126.LBORRES</b>	<b>127.LBORRESU</b>	<b>128.LBOR</b>		<b>129.LBCS</b>		<b>130.LBREAS</b>
Hb-A1c	<b>131.LBND</b>	<b>132.LBORRES</b>	<b>133.LBORRESU</b>	<b>134.LBOR</b>		<b>135.LBCS</b>		<b>136.LBREAS</b>

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		Subject Number <input type="text" value="7.SUBJID"/>
		Subject Initials <input type="text" value="8.SUBNAM"/>

**Laboratory Measurements (continued)**

Parameter	Check if Not done	Result	Unit	Out of range		Clinically significant		Comment
				Yes	No	Yes	No	
Eosinophils	<input type="checkbox"/> 9.LBND	<input type="text" value="10.LBORRES"/>	<input type="text" value="11.LBORRESU"/>	<input type="checkbox"/> 12.LBOR	<input type="checkbox"/>	<input type="checkbox"/> 13.LBCS	<input type="checkbox"/>	<input type="text" value="14.LBREAS"/>
Basophils	<input type="checkbox"/> 15.LBND	<input type="text" value="16.LBORRES"/>	<input type="text" value="17.LBORRESU"/>	<input type="checkbox"/> 18.LBOR	<input type="checkbox"/>	<input type="checkbox"/> 19.LBCS	<input type="checkbox"/>	<input type="text" value="20.LBREAS"/>
Neutrophils	<input type="checkbox"/> 21.LBND	<input type="text" value="22.LBORRES"/>	<input type="text" value="23.LBORRESU"/>	<input type="checkbox"/> 24.LBOR	<input type="checkbox"/>	<input type="checkbox"/> 25.LBCS	<input type="checkbox"/>	<input type="text" value="26.LBREAS"/>
Monocytes	<input type="checkbox"/> 27.LBND	<input type="text" value="28.LBORRES"/>	<input type="text" value="29.LBORRESU"/>	<input type="checkbox"/> 30.LBOR	<input type="checkbox"/>	<input type="checkbox"/> 31.LBCS	<input type="checkbox"/>	<input type="text" value="32.LBREAS"/>
Lymphocytes	<input type="checkbox"/> 33.LBND	<input type="text" value="34.LBORRES"/>	<input type="text" value="35.LBORRESU"/>	<input type="checkbox"/> 36.LBOR	<input type="checkbox"/>	<input type="checkbox"/> 37.LBCS	<input type="checkbox"/>	<input type="text" value="38.LBREAS"/>

<b>SCREENING</b>	<b>Baseline Measurements / Investigator Sign-off</b>	Subject Number <span style="float: right;">7.SUBJID</span>
		Subject Initials <span style="float: right;">8.SUBNAM</span>

**Duplex Doppler Flow**

Is a Duplex Doppler Flow taken?

[ 9.IMSTAT ] No

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

**Results**

[ 10.IMORRES\_1 ] mm. [ 11.IMDESC ]

**Date Duplex Doppler Flow**

[ 12.IMDTM ]

Day      Month      Year

**Angiography**

Is an Angiography taken?

[ 13.IMSTAT ] No

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

**Results**

[ 14.IMORRES\_2 ] mm. [ 15.IMDESC ]

**Date Angiography**

[ 16.IMDTM ]

Day      Month      Year

**Investigator Sign-off**

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

Investigator's Signature: \_\_\_\_\_ [ 17.ISSTAT ] signature: [ 18.ISDTM ]

Day      Month      Year

<b>OPERATIVE DAY</b>	<b>Treatment Record</b>	Subject Number <b>7.SUBJID</b>
		Subject Initials <b>8.SUBNAM</b>
Date of Surgery <b>9.VISITDTM</b>		Day Month Year

1. Surgery start time (first cut) **10.EXST\_HH** Hours : **11.EXST\_MM** Minutes Time surgery ended (last stitch) **12.EXEN\_HH** Hours : **13.EXEN\_MM** Minutes

2. Name and location of sites: **14.EXLOC**

3. Diameter **15.EXORRES** mm. Type: **16.EXMAN** Catalog number: **17.EXCNO**

4a. Does the subject require assistance? **18.EXVS** ] No  
 if YES, stop enrollment into this study !

4b. Is complete surgery achieved ? **19.EXHS** ] No  
 if NO, stop enrollment into this study !

5. Time surgery finished: **20.EXHS\_HH** Hours : **21.EXHS\_MM** Minutes

6. Is the patient allocated to the treatment Group? **22.TRTGRP** No  
 If YES, time randomise **23.TRT\_HH** Hours : **24.TRT\_MM** Minutes Number: **25.EXLOT**

Affix randomization label to each copy of this treatment form:

**26.TRTCD**

7. Medication 1 used? **27.ASSTAT** ] No Units  
 If YES, total dose **28.ASORRES** **29.ASORRESU**

8. Medication 2 used? **30.ASSTAT** ] No  
 If YES, total dose **31.ASORRES** **32.ASORRESU**

9. Is an Angiography in 2 taken ? **33.ASSTAT** ] No  
 If YES, please note the diameter and describe the results:  
**34.ASORRES** mm. **35.ASDESC**

10. Were any other procedures applied / measurements conducted during surgery? **36.ASSTAT** ] No  
 If YES, please specify and note the results:  
**37.ASDESC**

11. Is a digital image taken? **38.ASSTAT** ] No

**Record all Adverse Events on the Adverse Events Form**

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<b>OPERATIVE DAY</b>	<b>Performance</b>	Subject Number <b>7.SUBJID</b>
		Subject Initials <b>8.SUBNAM</b>

**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"/>	1. item 1
			<input type="checkbox"/>	2. item 2
			<input type="checkbox"/>	3. item 3
			<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
<b>13.PCNAM</b>	<b>14.PCDESC</b>
<b>15.PCNAM</b>	<b>16.PCDESC</b>
<b>17.PCNAM</b>	<b>18.PCDESC</b>
<b>19.PCNAM</b>	<b>20.PCDESC</b>
<b>21.PCNAM</b>	<b>22.PCDESC</b>

### Investigator Sign-off

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

Investigator's Signature: \_\_\_\_\_ **23.ISSTAT** signature: **24.ISDTM**

Day      Month      Year

<b>Hospital Discharge</b>	<b>Post Operative Follow-up</b>	Subject Number <b>7.SUBJID</b>
		Subject Initials <b>8.SUBNAM</b>
		Date of Visit <b>9.VISITDTM</b> Day Month Year

**Post operative experience**

1. Was surgery used at the treatment site: **10.PODRAIN** ] No

If **YES**, date of surgery: **11.POENDTM**  
Day Month Year

Total volume **12.POORRES** mL.

2. Did the subject return to surgery: **13.POHOSP** ] No

If **YES**, surgical procedure performed: **14.POTERM**

Date of above procedure: **15.POSTDTM**  
Day Month Year

**Complete Adverse Event Form and fax to Thorin**

3. Date Duplex Doppler Flow: **16.IMDTM**  
Day Month Year

Please note the diameter and describe the results:

Diameter **17.IMORRES** mm. Results **18.IMDESC**

**List changes in medication on Concomitant Medication Form**

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

Infection **19.POAE1** ] No

Infection **20.POAE2** ] No

Infection **21.POAE3** ] No

Other **22.POAE4** ] No If **YES**, specify: **23.POAEDESC**

**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: \_\_\_\_\_ **24.ISSTAT** signature: **25.ISDTM**  
Day Month Year

	<b>Follow-up</b>	Subject Number <input type="text" value="7.SUBJID"/> Subject Initials <input type="text" value="8.SUBNAM"/>
		Date of Follow-up visit <input type="text" value="9.VISITDTM"/> <small>Day      Month      Year</small>

**Adverse Events and Concomitant Medication Changes**

1. Did the subject develop any adverse events during the post-discharge period?  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?  No  
 If **NO**, please explain:

**Duplex Doppler Flow**

Is a Duplex Doppler Flow taken for this visit?  No  
 If **YES**, please note the diameter and describe the results below:

Results <input type="text" value="14.IMORRES"/> mm. <input type="text" value="15.IMDESC"/>	Date Duplex Doppler Flow <input type="text" value="16.IMDTM"/> <small>Day      Month      Year</small>
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**Angiography**

Is an Angiography taken since last visit?  No  
 If **YES**, please note the diameter and describe the results below:

Results <input type="text" value="18.IMORRES"/> mm. <input type="text" value="19.IMDESC"/>	Date Angiography <input type="text" value="20.IMDTM"/> <small>Day      Month      Year</small>
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**Investigator Sign-off**

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

Investigator's Signature:  signature:   
Day      Month      Year

	<b>Study Termination</b>	Subject Number <span style="border: 1px solid black; padding: 2px;">7.SUBJID</span> Subject Initials <span style="border: 1px solid black; padding: 2px;">8.SUBNAM</span>
Date of Study Completion/Termination		<span style="border: 1px solid black; padding: 2px;">9.VISITDTM</span> <div style="display: flex; justify-content: space-between; width: 100%; font-size: small;"> <span>Day</span> <span>Month</span> <span>Year</span> </div>

**Study Completion / Termination**

1. Did the subject complete all study visits to date? 10.STSTAT No

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

11.STREAS

a. Protocol violation, please explain:

12.STPVDESC

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

1<sup>st</sup> telephone contact, date:

13.STCTDTM1

Day
Month
Year

2<sup>nd</sup> telephone contact, date:

14.STCTDTM2

Day
Month
Year

3<sup>rd</sup> contact by certified mail, dated:

15.STCTDTM3

Day
Month
Year

Certified mail #: 16.STCTDESC

c. Adverse Event, # 17.STAESEQ

d. Death

Date of Death:

18.DTHDTM

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:

19.STOTHC

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**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: \_\_\_\_\_

20.ISSTAT

Signature: \_\_\_\_\_

21.ISDTM

Day Month Year

	<b>Adverse Event</b>	Subject Number <span style="border: 1px solid black; padding: 2px;">7.SUBJID</span> Subject Initials <span style="border: 1px solid black; padding: 2px;">8.SUBNAM</span>
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**Adverse Events**

Adverse Event no. 9.AESEQ

Description of Event 10.AETERM

Startdate 11.AESTDTM

Day	Month	Year	
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Ongoing at Study end

13.AEONGO

No

Stopdate 12.AEENDTM

Day	Month	Year	
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Severity (maximum)?

14.AESEV

- Moderate
- Severe

Pattern?

15.AEPAT

- Continuous
- Intermittent

Action taken?

16.AEACN

- Medication →
- Surgery
- Other →

*Update the Concomitant Medication section.*

*Please describe at Details of AE*

Was Event related to Treatment?

17.AEREL ✓

- Likely
- Unlikely
- Definitely not

Serious Adverse Event?

18.AESER

- No

Outcome?

19.AEOUT d

- Recovering
- Recovered with sequelae
- Not recovered
- Death
- Unknown

Details of Adverse Event:

20.AECOM

**Investigator Sign-off**

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

Investigator's Signature: \_\_\_\_\_ 21.ISSTAT Signature: 22.ISDTM

	Day	Month	Year
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	<b>Serious Adverse Event</b>	Subject Number <span style="border: 1px solid black; padding: 2px;">7.SUBJID</span> Subject Initials <span style="border: 1px solid black; padding: 2px;">8.SUBNAM</span>
1. Adverse Event no. <span style="border: 1px solid black; padding: 2px;">9.AESEQ</span>	Date SAE reported:	<span style="border: 1px solid black; padding: 2px;">10.AESDTM</span> Day      Month      Year

Clinical presentation of the Event \_\_\_\_\_  
11.AESDESC

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

- 12.AESDTH in Death            Was an autopsy preformed? 13.AESAUT  No
- 14.AESLIFE threatening
- 15.AESHOSP in patient hospitalisation or prolongation of existing hospitalisation
- 16.AESDISAB persistent or significant disability/incapacity
- 17.AESCONG congenital anomaly/birth defect
- 18.AESOTH medically important condition

3. Relevant medical history and/or current medical condition: \_\_\_\_\_  
19.AESMHIS

4. Concomitant medication or surgical procedures at the time the event started: \_\_\_\_\_  
20.AESMED

5. Relevant Laboratory data: \_\_\_\_\_  
21.AESLAB

6. Treatment of the event: \_\_\_\_\_  
22.AESTRT

7. Outcome of the event: \_\_\_\_\_  
23.AESOUT

**Investigator Sign-off**

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

Investigator's Signature: \_\_\_\_\_ 24.ISSTAT signature: 25.ISDTM  
 Day      Month      Year

### Concomitant Medication

Subject Number **7.SUBJID**

Subject Initials **8.SUBNAM**

Medication (generic name) <b>9.CMTRT</b>	Total dose (24 hours) <b>10.CMDOSTOT</b>	Units <b>11.CMDOSU</b>	Route <b>12.CMROUTE</b>	Reason for use <input type="checkbox"/> <b>14.CMREAS</b> AE# <b>15.AESEQ</b> <input type="checkbox"/> <b>13.CMSTR</b> <input type="checkbox"/> Other: <b>16.CMRSOTH</b>
Start date <b>17.CMSTDTM</b> Day Month Year	Stop date <b>18.CMENDTM</b> Day Month Year	Ongoing at Study End <input type="checkbox"/> <b>19.CMONGO</b> <input type="checkbox"/> No		

Medication (generic name) <b>20.CMTRT</b>	Total dose (24 hours) <b>21.CMDOSTOT</b>	Units <b>22.CMDOSU</b>	Route <b>23.CMROUTE</b>	Reason for use <input type="checkbox"/> <b>25.CMREAS</b> AE# <b>26.AESEQ</b> <input type="checkbox"/> <b>24.CMSTR</b> <input type="checkbox"/> Other: <b>27.CMRSOTH</b>
Start date <b>28.CMSTDTM</b> Day Month Year	Stop date <b>29.CMENDTM</b> Day Month Year	Ongoing at Study End <input type="checkbox"/> <b>30.CMONGO</b> <input type="checkbox"/> No		

Medication (generic name) <b>31.CMTRT</b>	Total dose (24 hours) <b>32.CMDOSTOT</b>	Units <b>33.CMDOSU</b>	Route <b>34.CMROUTE</b>	Reason for use <input type="checkbox"/> <b>36.CMREAS</b> AE# <b>37.AESEQ</b> <input type="checkbox"/> <b>35.CMSTR</b> <input type="checkbox"/> Other: <b>38.CMRSOTH</b>
Start date <b>39.CMSTDTM</b> Day Month Year	Stop date <b>40.CMENDTM</b> Day Month Year	Ongoing at Study End <input type="checkbox"/> <b>41.CMONGO</b> <input type="checkbox"/> No		

Medication (generic name) <b>42.CMTRT</b>	Total dose (24 hours) <b>43.CMDOSTOT</b>	Units <b>44.CMDOSU</b>	Route <b>45.CMROUTE</b>	Reason for use <input type="checkbox"/> <b>47.CMREAS</b> AE# <b>48.AESEQ</b> <input type="checkbox"/> <b>46.CMSTR</b> <input type="checkbox"/> Other: <b>49.CMRSOTH</b>
Start date <b>50.CMSTDTM</b> Day Month Year	Stop date <b>51.CMENDTM</b> Day Month Year	Ongoing at Study End <input type="checkbox"/> <b>52.CMONGO</b> <input type="checkbox"/> No		

Medication (generic name) <b>53.CMTRT</b>	Total dose (24 hours) <b>54.CMDOSTOT</b>	Units <b>55.CMDOSU</b>	Route <b>56.CMROUTE</b>	Reason for use <input type="checkbox"/> <b>58.CMREAS</b> AE# <b>59.AESEQ</b> <input type="checkbox"/> <b>57.CMSTR</b> <input type="checkbox"/> Other: <b>60.CMRSOTH</b>
Start date <b>61.CMSTDTM</b> Day Month Year	Stop date <b>62.CMENDTM</b> Day Month Year	Ongoing at Study End <input type="checkbox"/> <b>63.CMONGO</b> <input type="checkbox"/> No		

	<b>Comments</b>	Subject Number <span style="border: 1px solid black; padding: 2px;">7.SUBJID</span>
		Subject Initials <span style="border: 1px solid black; padding: 2px;">8.SUBNAM</span>

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).

Visit Number	Page Number	Item on CRF	Comment
9.CRFVISIT	10.CRFPAGE	11.CRFITEM	12.ACDESC
13.CRFVISIT	14.CRFPAGE	15.CRFITEM	16.ACDESC
17.CRFVISIT	18.CRFPAGE	19.CRFITEM	20.ACDESC
21.CRFVISIT	22.CRFPAGE	23.CRFITEM	24.ACDESC
25.CRFVISIT	26.CRFPAGE	27.CRFITEM	28.ACDESC
29.CRFVISIT	30.CRFPAGE	31.CRFITEM	32.ACDESC
33.CRFVISIT	34.CRFPAGE	35.CRFITEM	36.ACDESC
37.CRFVISIT	38.CRFPAGE	39.CRFITEM	40.ACDESC