

Patient Initials

--	--	--

Date of Birth

d	d	-	m	m	-	y	y	y	y
---	---	---	---	---	---	---	---	---	---

Site Number

0		
---	--	--

Trial Number

0		
---	--	--

1.1 BASELINE

Date of baseline assessment:

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

- Height (cm)

--	--	--

 .

--

 Weight (kg)

--	--	--

 .

--

 Body surface area (BSA) m²

--

 .

--	--
- ECOG performance status at randomisation

--

 0

--

 1

--

 2

--

 3

--

 4
- ECOG performance status 6 months prior to randomisation

--

 0

--

 1

--

 2

--

 3

--

 4
- Intention to perform Autologous Stem Cell Transplant Yes No (If no please give reason) →

--
- Date of diagnosis

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---
- Is patient on dialysis? Yes No If yes date started →

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---
- ISS stage I II III
- Has the patient had any Adverse Events since date of consent? Yes No If yes please complete section 1.16
- CKD stage 4 5
- Does patient have a pre-existing medical condition which may cause renal damage? Yes No
(please enter any pre-existing medical conditions in section 1.7)
If yes, did the GFR decline by a further ≥15 mls/min between previous steady state and study screening? Yes No

1.2 BONE DETAILS - Were any of the following imaging tests performed? (tick all that apply)

- Chest X-ray → Date

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

↓
Normal? → Yes No If no please specify →

--
- Skeletal Survey → Date

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

↓
Normal? → Yes No If no please specify below in Question 4
- MRI (Spine) → → Date

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

↓
 Not clinically indicated Normal? → Yes No If no please specify →

--
- Evidence of Myeloma Bone Disease? → Yes No
↓ *Tick all that apply*
 Vertebral fracture/collapse Lytic lesions Fractured rib Osteoporosis / Osteopenia (delete if not applicable)
 Other fracture (please specify)

--

 Other fracture(s)

--

Completed by:
(Print)

CRFs should only be completed by appropriately qualified personnel detailed on the site delegation log

Signature:

Date completed (ddmmyyyy):

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

For Office use only

Date form received: _____

Date form entered: _____

Initials: _____

Patient Initials

--	--	--

Date of Birth

d	d	-	m	m	-	y	y	y	y
---	---	---	---	---	---	---	---	---	---

Site Number

0		
---	--	--

Trial Number

0		
---	--	--

1.3 ECG Normal? → Yes No Date

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

1.4 PREGNANCY TEST Result
 1=Negative → Date

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

 2=Positive
 3=Not applicable

1.5 PERIPHERAL NEUROPATHY (CTCAE v 4.03) 0 1 2 3 4 5

1.6 CURRENT MEDICAL STATUS

	Disease/Symptom	Date of onset (dd/mm/yyyy)								
1.		<table border="1"><tr><td>d</td><td>d</td><td>m</td><td>m</td><td>y</td><td>y</td><td>y</td><td>y</td></tr></table>	d	d	m	m	y	y	y	y
d	d	m	m	y	y	y	y			
2.		<table border="1"><tr><td>d</td><td>d</td><td>m</td><td>m</td><td>y</td><td>y</td><td>y</td><td>y</td></tr></table>	d	d	m	m	y	y	y	y
d	d	m	m	y	y	y	y			
3.		<table border="1"><tr><td>d</td><td>d</td><td>m</td><td>m</td><td>y</td><td>y</td><td>y</td><td>y</td></tr></table>	d	d	m	m	y	y	y	y
d	d	m	m	y	y	y	y			
4.		<table border="1"><tr><td>d</td><td>d</td><td>m</td><td>m</td><td>y</td><td>y</td><td>y</td><td>y</td></tr></table>	d	d	m	m	y	y	y	y
d	d	m	m	y	y	y	y			
5.		<table border="1"><tr><td>d</td><td>d</td><td>m</td><td>m</td><td>y</td><td>y</td><td>y</td><td>y</td></tr></table>	d	d	m	m	y	y	y	y
d	d	m	m	y	y	y	y			
6.		<table border="1"><tr><td>d</td><td>d</td><td>m</td><td>m</td><td>y</td><td>y</td><td>y</td><td>y</td></tr></table>	d	d	m	m	y	y	y	y
d	d	m	m	y	y	y	y			

1.7 PREVIOUS MEDICAL HISTORY [continue on Additional Information Form (CRF 17), if required]

	Disease/Symptom	Date of onset (dd/mm/yyyy)								
1.		<table border="1"><tr><td>d</td><td>d</td><td>m</td><td>m</td><td>y</td><td>y</td><td>y</td><td>y</td></tr></table>	d	d	m	m	y	y	y	y
d	d	m	m	y	y	y	y			
2.		<table border="1"><tr><td>d</td><td>d</td><td>m</td><td>m</td><td>y</td><td>y</td><td>y</td><td>y</td></tr></table>	d	d	m	m	y	y	y	y
d	d	m	m	y	y	y	y			
3.		<table border="1"><tr><td>d</td><td>d</td><td>m</td><td>m</td><td>y</td><td>y</td><td>y</td><td>y</td></tr></table>	d	d	m	m	y	y	y	y
d	d	m	m	y	y	y	y			
4.		<table border="1"><tr><td>d</td><td>d</td><td>m</td><td>m</td><td>y</td><td>y</td><td>y</td><td>y</td></tr></table>	d	d	m	m	y	y	y	y
d	d	m	m	y	y	y	y			
5.		<table border="1"><tr><td>d</td><td>d</td><td>m</td><td>m</td><td>y</td><td>y</td><td>y</td><td>y</td></tr></table>	d	d	m	m	y	y	y	y
d	d	m	m	y	y	y	y			
6.		<table border="1"><tr><td>d</td><td>d</td><td>m</td><td>m</td><td>y</td><td>y</td><td>y</td><td>y</td></tr></table>	d	d	m	m	y	y	y	y
d	d	m	m	y	y	y	y			

Completed by: _____ *CRFs should only be completed by appropriately qualified personnel detailed on the site delegation log*
 (Print)

Signature: _____ **Date completed (ddmmyyyy):**

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

Patient Initials

--	--	--

Date of Birth

d	d	-	m	m	-	y	y	y	y
---	---	---	---	---	---	---	---	---	---

Site Number

0		
---	--	--

Trial Number

0		
---	--	--

1.8 MEDICATION (include current concomitant treatments and therapies used in previous 4 weeks). [Continue on Additional Information Form (CRF 17), if required.]

Medication	Date started	Continuing (tick)	Date Stopped																
	<table border="1"><tr><td>d</td><td>d</td><td>m</td><td>m</td><td>y</td><td>y</td><td>y</td><td>y</td></tr></table>	d	d	m	m	y	y	y	y		<table border="1"><tr><td>d</td><td>d</td><td>m</td><td>m</td><td>y</td><td>y</td><td>y</td><td>y</td></tr></table>	d	d	m	m	y	y	y	y
d	d	m	m	y	y	y	y												
d	d	m	m	y	y	y	y												
	<table border="1"><tr><td>d</td><td>d</td><td>m</td><td>m</td><td>y</td><td>y</td><td>y</td><td>y</td></tr></table>	d	d	m	m	y	y	y	y		<table border="1"><tr><td>d</td><td>d</td><td>m</td><td>m</td><td>y</td><td>y</td><td>y</td><td>y</td></tr></table>	d	d	m	m	y	y	y	y
d	d	m	m	y	y	y	y												
d	d	m	m	y	y	y	y												
	<table border="1"><tr><td>d</td><td>d</td><td>m</td><td>m</td><td>y</td><td>y</td><td>y</td><td>y</td></tr></table>	d	d	m	m	y	y	y	y		<table border="1"><tr><td>d</td><td>d</td><td>m</td><td>m</td><td>y</td><td>y</td><td>y</td><td>y</td></tr></table>	d	d	m	m	y	y	y	y
d	d	m	m	y	y	y	y												
d	d	m	m	y	y	y	y												
	<table border="1"><tr><td>d</td><td>d</td><td>m</td><td>m</td><td>y</td><td>y</td><td>y</td><td>y</td></tr></table>	d	d	m	m	y	y	y	y		<table border="1"><tr><td>d</td><td>d</td><td>m</td><td>m</td><td>y</td><td>y</td><td>y</td><td>y</td></tr></table>	d	d	m	m	y	y	y	y
d	d	m	m	y	y	y	y												
d	d	m	m	y	y	y	y												
	<table border="1"><tr><td>d</td><td>d</td><td>m</td><td>m</td><td>y</td><td>y</td><td>y</td><td>y</td></tr></table>	d	d	m	m	y	y	y	y		<table border="1"><tr><td>d</td><td>d</td><td>m</td><td>m</td><td>y</td><td>y</td><td>y</td><td>y</td></tr></table>	d	d	m	m	y	y	y	y
d	d	m	m	y	y	y	y												
d	d	m	m	y	y	y	y												
	<table border="1"><tr><td>d</td><td>d</td><td>m</td><td>m</td><td>y</td><td>y</td><td>y</td><td>y</td></tr></table>	d	d	m	m	y	y	y	y		<table border="1"><tr><td>d</td><td>d</td><td>m</td><td>m</td><td>y</td><td>y</td><td>y</td><td>y</td></tr></table>	d	d	m	m	y	y	y	y
d	d	m	m	y	y	y	y												
d	d	m	m	y	y	y	y												

Local Laboratory Test Results

1.9 HAEMATOLOGY

Date of test (dd/mm/yyyy)

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

Test Result

Date if different from above OR tick box if same as above

1. Haemoglobin

--	--

 .

--

 g/dL

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

--

2. Platelets

--	--	--

 x10⁹/L

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

--

3. White Blood cell (WBC) count

--	--

 .

--

 x10⁹/L

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

--

4. Haematocrit

--

 .

--	--	--

 L/L

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

--

Differential

5. Neutrophil Count

--	--

 .

--

 x10⁹/L

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

--

6. Lymphocytes

--	--

 .

--

 x10⁹/L

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

--

7. Monocytes

--	--

 .

--

 x10⁹/L

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

--

Completed by:
(Print)

CRFs should only be completed by appropriately qualified personnel detailed on the site delegation log

Signature:

Date completed (ddmmyyyy):

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

For Office use only

Date form received: _____

Date form entered: _____

Initials: _____

Patient Initials

--	--	--

Date of Birth

d	d	-	m	m	-	y	y	y	y
---	---	---	---	---	---	---	---	---	---

Site Number

0		
---	--	--

Trial Number

0		
---	--	--

Local Laboratory Test Results

1.10 BIOCHEMISTRY

Date of test (dd/mm/yyyy)

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

Test Result

Date if different from above OR tick box if same as above

- | | | | | | | |
|-----|----------------------|--|--|--|--|--------|
| 1. | Sodium | <table border="1" style="width: 30px; height: 20px;"> <tr><td style="width: 10px; height: 10px;"></td><td style="width: 10px; height: 10px;"></td><td style="width: 10px; height: 10px;"></td></tr> </table> | | | | mmol/L |
| | | | | | | |
| 2. | Potassium | <table border="1" style="width: 30px; height: 20px;"> <tr><td style="width: 10px; height: 10px;"></td><td style="width: 10px; height: 10px;"></td><td style="width: 10px; height: 10px;"></td></tr> </table> | | | | mmol/L |
| | | | | | | |
| 3. | Total Protein | <table border="1" style="width: 30px; height: 20px;"> <tr><td style="width: 10px; height: 10px;"></td><td style="width: 10px; height: 10px;"></td><td style="width: 10px; height: 10px;"></td></tr> </table> | | | | G/L |
| | | | | | | |
| 4. | Albumin | <table border="1" style="width: 30px; height: 20px;"> <tr><td style="width: 10px; height: 10px;"></td><td style="width: 10px; height: 10px;"></td><td style="width: 10px; height: 10px;"></td></tr> </table> | | | | G/L |
| | | | | | | |
| 5. | Bicarbonate | <table border="1" style="width: 30px; height: 20px;"> <tr><td style="width: 10px; height: 10px;"></td><td style="width: 10px; height: 10px;"></td><td style="width: 10px; height: 10px;"></td></tr> </table> | | | | mmol/L |
| | | | | | | |
| 6. | Adjusted Calcium | <table border="1" style="width: 30px; height: 20px;"> <tr><td style="width: 10px; height: 10px;"></td><td style="width: 10px; height: 10px;"></td><td style="width: 10px; height: 10px;"></td></tr> </table> | | | | mmol/L |
| | | | | | | |
| 7. | Phosphate | <table border="1" style="width: 30px; height: 20px;"> <tr><td style="width: 10px; height: 10px;"></td><td style="width: 10px; height: 10px;"></td><td style="width: 10px; height: 10px;"></td></tr> </table> | | | | mmol/L |
| | | | | | | |
| 8. | Serum Urea | <table border="1" style="width: 30px; height: 20px;"> <tr><td style="width: 10px; height: 10px;"></td><td style="width: 10px; height: 10px;"></td><td style="width: 10px; height: 10px;"></td></tr> </table> | | | | mmol/L |
| | | | | | | |
| 9. | Serum Creatinine | <table border="1" style="width: 30px; height: 20px;"> <tr><td style="width: 10px; height: 10px;"></td><td style="width: 10px; height: 10px;"></td><td style="width: 10px; height: 10px;"></td></tr> </table> | | | | µmol/L |
| | | | | | | |
| 10. | Uric Acid | <table border="1" style="width: 30px; height: 20px;"> <tr><td style="width: 10px; height: 10px;"></td><td style="width: 10px; height: 10px;"></td><td style="width: 10px; height: 10px;"></td></tr> </table> | | | | µmol/L |
| | | | | | | |
| 11. | Creatinine Clearance | <table border="1" style="width: 30px; height: 20px;"> <tr><td style="width: 10px; height: 10px;"></td><td style="width: 10px; height: 10px;"></td><td style="width: 10px; height: 10px;"></td></tr> </table> | | | | ml/min |
| | | | | | | |
| 12. | LDH | <table border="1" style="width: 30px; height: 20px;"> <tr><td style="width: 10px; height: 10px;"></td><td style="width: 10px; height: 10px;"></td><td style="width: 10px; height: 10px;"></td></tr> </table> | | | | iu/L |
| | | | | | | |
| 13. | Bilirubin | <table border="1" style="width: 30px; height: 20px;"> <tr><td style="width: 10px; height: 10px;"></td><td style="width: 10px; height: 10px;"></td><td style="width: 10px; height: 10px;"></td></tr> </table> | | | | µmol/L |
| | | | | | | |
| 14. | Glucose | <table border="1" style="width: 30px; height: 20px;"> <tr><td style="width: 10px; height: 10px;"></td><td style="width: 10px; height: 10px;"></td><td style="width: 10px; height: 10px;"></td></tr> </table> | | | | mmol/L |
| | | | | | | |
| 15. | C-Reactive Protein | <table border="1" style="width: 30px; height: 20px;"> <tr><td style="width: 10px; height: 10px;"></td><td style="width: 10px; height: 10px;"></td><td style="width: 10px; height: 10px;"></td></tr> </table> | | | | mg/L |
| | | | | | | |

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

1.11 LIVER FUNCTION TESTS

Date of test (dd/mm/yyyy)

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

Test Result

Date if different from above OR tick box if same as above

- | | | | | | | |
|----|-----------|--|--|--|--|--------|
| 1. | ALP | <table border="1" style="width: 30px; height: 20px;"> <tr><td style="width: 10px; height: 10px;"></td><td style="width: 10px; height: 10px;"></td><td style="width: 10px; height: 10px;"></td></tr> </table> | | | | µmol/L |
| | | | | | | |
| 2. | AST | <table border="1" style="width: 30px; height: 20px;"> <tr><td style="width: 10px; height: 10px;"></td><td style="width: 10px; height: 10px;"></td><td style="width: 10px; height: 10px;"></td></tr> </table> | | | | µmol/L |
| | | | | | | |
| 3. | ALT | <table border="1" style="width: 30px; height: 20px;"> <tr><td style="width: 10px; height: 10px;"></td><td style="width: 10px; height: 10px;"></td><td style="width: 10px; height: 10px;"></td></tr> </table> | | | | µmol/L |
| | | | | | | |
| 4. | Globulins | <table border="1" style="width: 30px; height: 20px;"> <tr><td style="width: 10px; height: 10px;"></td><td style="width: 10px; height: 10px;"></td><td style="width: 10px; height: 10px;"></td></tr> </table> | | | | iu/L |
| | | | | | | |

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

Completed by:
(Print)

CRFs should only be completed by appropriately qualified personnel detailed on the site delegation log

Signature:

Date completed (ddmmyyyy):

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

For Office use only

Date form received: _____

Date form entered: _____

Initials: _____

Patient Initials

--	--	--

Date of Birth

d	d	-	m	m	-	y	y	y	y
---	---	---	---	---	---	---	---	---	---

Site Number

0		
---	--	--

Trial Number

0		
---	--	--

Local Laboratory Test Results

1.12 IMMUNOLOGY

Date of test (dd/mm/yyyy)

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

Disease assessment

Date of test if different from above (dd/mm/yyyy)

Quantitative Immunoglobulin Results

1. IgA (g/L)

--

 1=Measureable, please complete result →

--	--

 .

--	--

2=Un-measureable
2. IgM (g/L)

--

 1=Measureable, please complete result →

--	--

 .

--	--

2=Un-measureable
3. IgG (g/L)

--

 1=Measureable, please complete result →

--	--

 .

--	--

2=Un-measureable
4. Sflc Kappa (mg/l)

--

 1=Done, please complete result →

--	--	--	--

 .

--	--

2=Not done
5. Sflc Lambda (mg/l)

--

 1=Done, please complete result →

--	--	--	--

 .

--	--

2=Not done
6. Sflc Kappa/Lambda ratio

--

 1=Done, please complete result →

--	--	--	--

 .

--	--

2=Not done

d	d	m	m	y	y	y	y
d	d	m	m	y	y	y	y
d	d	m	m	y	y	y	y
d	d	m	m	y	y	y	y
d	d	m	m	y	y	y	y
d	d	m	m	y	y	y	y

Protein Electrophoresis Results

8. Beta-2 microglobulin (mg/L)

--	--

 .

--	--
7. Specify Paraprotein (g/L)

--

↓

--

 1=Measureable, please complete result

--	--

 .

--	--

2=Immunofixation only
8. Specify Paraprotein (g/L) (if more than one type)

--

↓

--

 1=Measureable, please complete result

--	--

 .

--	--

2=Immunofixation only
10. If paraprotein cannot be measured please give monoclonal protein plus beta region (g/L):

--	--	--	--

 .

--	--

OR

--

 Not required
11. If 24 hour urine collection performed please give light chain load (g/L):

--	--

 .

--	--

OR

--

 Not done

d	d	m	m	y	y	y	y
d	d	m	m	y	y	y	y
d	d	m	m	y	y	y	y
d	d	m	m	y	y	y	y
d	d	m	m	y	y	y	y
d	d	m	m	y	y	y	y

Completed by:
(Print)

CRFs should only be completed by appropriately qualified personnel detailed on the site delegation log

Signature:

Date completed (ddmmyyyy):

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

For Office use only

Date form received: _____

Date form entered: _____

Initials: _____

Patient Initials

--	--	--

Date of Birth

d	d	-	m	m	-	y	y	y	y
---	---	---	---	---	---	---	---	---	---

Site Number

0		
---	--	--

Trial Number

0		
---	--	--

1.13 LOCAL LAB INVESTIGATIONS (Bone Marrow)

Tick samples collected

Bone Marrow Aspirate

Date of collection

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

Bone Marrow Trephine

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

1.14 CENTRAL LAB INVESTIGATION (Birmingham)

Tick all samples collected:

2 ml bone marrow aspirate

→

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

Sample Sent?

Yes →

Date Sent

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

No →

Reason for not sending:

5 ml blood (EDTA)

→

d	d	m	m	m	y	y	y
---	---	---	---	---	---	---	---

Yes →

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

No →

Reason for not sending:

10 ml clotted blood

→

d	d	m	m	m	y	y	y
---	---	---	---	---	---	---	---

Yes →

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

No →

Reason for not sending:

20 ml urine

→

d	d	m	m	m	y	y	y
---	---	---	---	---	---	---	---

Yes →

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

No →

Reason for not sending:

Is sample from 24 hour collection? No Yes →

Total vol. collected

--	--	--	--	--

ml

1.15 CENTRAL LAB INVESTIGATIONS (Oxford)

Tick all samples collected:

5 ml bone marrow aspirate

→

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

Sample Sent?

Yes →

Date Sent

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

No →

Reason for not sending:

2 unstained slides bone marrow aspirate

→

d	d	m	m	m	y	y	y
---	---	---	---	---	---	---	---

Yes →

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

No →

Reason for not sending:

Completed by:
(Print)

CRFs should only be completed by appropriately qualified personnel detailed on the site delegation log

Signature:

Date completed (ddmmyyyy):

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

For Office use only

Date form received: _____

Date form entered: _____

Initials: _____

Patient Initials

--	--	--

Date of Birth

d	d	-	m	m	-	y	y	y	y
---	---	---	---	---	---	---	---	---	---

Site Number

0		
---	--	--

Trial Number

0		
---	--	--

1.16 ADVERSE EVENTS (please use one line per AE)

AE key:
Severity Scale: 1. Mild, 2. Moderate, 3. Severe.
Outcome: 1. Resolved no sequelae, 2. Resolved with sequelae, 3. Death, 4. Continuing, 9. Not known.

AE Description	CTCAE Grade	Date (dd/mm/yyyy)	Ongoing Y/N	Severity (use key above)	Outcome (use key above)																
		Start <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> Stop <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>																			
		Start <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> Stop <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>																			
		Start <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> Stop <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>																			

Completed by:
(Print)

CRFs should only be completed by appropriately qualified personnel detailed on the site delegation log

Signature:

Date completed (ddmmyyyy):

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

For Office use only

Date form received: _____

Date form entered: _____

Initials: _____