

Patient Initials     Date of Birth   /    /     Trial Number **R**

Visit Date   /    /

Visit Time  Randomisation  Week 2  Week 6  Week 12  Week 20  Week 28  Week 36  Week 44  Week 52 (Tick one)  
Point  Day 1  Week 4  Week 8  Week 16  Week 24  Week 32  Week 40  Week 48  Month 15

This CRF should be completed for any protocol laboratory investigations which are not listed on the Treatment CRF. Any abnormal results which qualify as an adverse event according to CTCAE v4.03 should be added to Form 06—Adverse Events Log.

This CRF should be completed for every visit up until month 15 for patients on Arms A, B and C.

**A. Haematology Laboratory Investigations**

Transcribe the required information for the completed haematology investigations in the boxes provided. The lower and upper limits of normal should be provided as required.

<b>Basophils</b>	1a <input type="text"/> <input type="text"/> <input type="text"/> Value	1b <input type="text"/> <input type="text"/> <input type="text"/> LLN	1c <input type="checkbox"/> x10 <sup>9</sup> /L
<b>Eosinophils</b>	2a <input type="text"/> <input type="text"/> <input type="text"/> Value	2b <input type="text"/> <input type="text"/> <input type="text"/> LLN	2c <input type="checkbox"/> x10 <sup>9</sup> /L
<b>Haematocrit</b>	3a <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Value	3b <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> LLN	3c <input type="checkbox"/> L/L
<b>Haemoglobin</b>	4a <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Value	4b <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> ULN	4d <input type="checkbox"/> g/dL
		4c <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> LLN	<input type="checkbox"/> g/L
			<input type="checkbox"/> mmol/L
<b>Lymphocytes</b>	5a <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Value	5b <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> ULN	5d <input type="checkbox"/> x10 <sup>9</sup> /L
		5c <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> LLN	<input type="checkbox"/> mm <sup>3</sup>
<b>Mean corpuscular haemoglobin</b>	6a <input type="text"/> <input type="text"/> <input type="text"/> Value	6b <input type="text"/> <input type="text"/> <input type="text"/> LLN	6c <input type="checkbox"/> pg
<b>Mean corpuscular haemoglobin concentration</b>	7a <input type="text"/> <input type="text"/> <input type="text"/> Value	7b <input type="text"/> <input type="text"/> <input type="text"/> LLN	7c <input type="checkbox"/> g/l
<b>Mean corpuscular volume</b>	8a <input type="text"/> <input type="text"/> <input type="text"/> Value	8b <input type="text"/> <input type="text"/> <input type="text"/> LLN	8c <input type="checkbox"/> fl
<b>Monocytes</b>	9a <input type="text"/> <input type="text"/> Value	9b <input type="text"/> <input type="text"/> LLN	9c <input type="checkbox"/> x10 <sup>9</sup> /L

Signature  Printed Name  Date Completed   /    /

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**A. Haematology Laboratory Investigations - continued**

<b>Neutrophils</b>	10a	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Value	10b	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> ULN	10d	<input type="checkbox"/> x10 <sup>9</sup> /L <input type="checkbox"/> mm <sup>3</sup>
			10c	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> LLN		
<b>Platelet count</b>	11a	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Value	11b	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> LLN	11c	<input type="checkbox"/> x10 <sup>9</sup> /L <input type="checkbox"/> mm <sup>3</sup>
<b>Red blood cell count</b>	12a	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Value	12b	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> LLN	12c	<input type="checkbox"/> x10 <sup>12</sup> /L
<b>Total white cell count</b>	13a	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Value	13b	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> ULN	13d	<input type="checkbox"/> x10 <sup>9</sup> /L <input type="checkbox"/> mm <sup>3</sup>
			13c	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> LLN		

**B. Biochemistry Laboratory Investigations**

Transcribe the results of any completed biochemistry laboratory investigations. Upper and lower limits of normal should be provide where applicable.

① Bicarbonate, calcium, chloride, creatinine clearance, gamma glutamyltransferase and magnesium tests are only required at screening, day 1 and if clinically indicated.

<b>Albumin</b>	1a	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Value	1b	<input type="text"/> <input type="text"/> ULN	1c	<input type="checkbox"/> g/L <input type="checkbox"/> g/dL <input type="checkbox"/> mmol/L <input type="checkbox"/> µmol/L
<b>Bicarbonate</b>	2a	<input type="text"/> <input type="text"/> <input type="text"/> Value	2b	<input type="text"/> <input type="text"/> ULN	2c	<input type="checkbox"/> mmol/L
<b>Calcium</b>	3a	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Value	3b	<input type="text"/> <input type="text"/> <input type="text"/> ULN	3d	<input type="checkbox"/> mmol/L <input type="checkbox"/> mg/dL
			3c	<input type="text"/> <input type="text"/> <input type="text"/> LLN		
<b>Chloride</b>	4a	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Value	4b	<input type="text"/> <input type="text"/> <input type="text"/> ULN	4c	<input type="checkbox"/> mmol/L
<b>Creatinine clearance</b>	5a	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Value	5b	<input type="text"/> <input type="text"/> <input type="text"/> ULN	5c	<input type="checkbox"/> ml/min
<b>GGT</b>	6a	<input type="text"/> <input type="text"/> <input type="text"/> Value	6b	<input type="text"/> <input type="text"/> ULN	6c	<input type="checkbox"/> IU/L

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**B. Biochemistry Laboratory Investigations - continued**

**Glucose**

7a     Value

7b     ULN

7c     LLN

7d  mmol/L  
 mg/dL

**Lactate dehydrogenase**

8a     Value

8b     ULN

8c  IU/L

**Magnesium**

9a    Value

9b   ULN

9c   LLN

9d  mmol/L  
 mg/dL

**Potassium**

10a    Value

10b   ULN

10c   LLN

10d  mmol/L

**Random cortisol**

11a     Value

11b     ULN

11c  nmol/L  
 µg/dL

**Sodium**

12a    Value

12b     ULN

12c     LLN

12d  mmol/L

**TSH**

13a    Value

13b    ULN

13c  µU/L

**Total protein**

14a    Value

14b    ULN

14c  g/L

**Urea**

15a    Value

15b    ULN

15c  mmol/L

**Uric acid**

16a     Value

16b     ULN

16c  µmol/L  
 mmol/L  
 mg/dL

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