

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

Visit Date / /

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

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 B and C only.

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.

Basophils	1a <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Value	1b <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> LLN	1c <input type="checkbox"/> $\times 10^9/L$
Eosinophils	2a <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Value	2b <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> LLN	2c <input type="checkbox"/> $\times 10^9/L$
Haematocrit	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
Haemoglobin	4a <input type="text"/> <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"/> <input type="text"/> ULN	4c <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> LLN
			4d <input type="checkbox"/> g/dL <input type="checkbox"/> g/L <input type="checkbox"/> mmol/L
Lymphocytes	5a <input type="text"/> <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	5c <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> LLN
			5d <input type="checkbox"/> $\times 10^9/L$ <input type="checkbox"/> mm^3
Mean corpuscular haemoglobin	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
Mean corpuscular haemoglobin concentration	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
Mean corpuscular volume	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
Monocytes	9a <input type="text"/> <input type="text"/> Value	9b <input type="text"/> <input type="text"/> LLN	9c <input type="checkbox"/> $\times 10^9/L$

Signature Printed Name Date Completed / /

Please return a copy to RAMPART Trial, MRC Clinical Trials Unit at UCL, 90 High Holborn, 2nd Floor, London WC1V 6LJ

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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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