

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

Visit Date / / Randomisation Month 15 Progression
 Week 16 Month 36 (please tick one)

This CRF should be completed (if the patient has consented) after Randomisation and prior to Day 1 infusion, at Week 16, Month 15, Month 36 and upon progression (if progression was before Month 36).

If progression occurs after Month 36, a QLQ-C30 CRF is not required.

A. QLQ-C30

We are interested in some things about you and your health. Please answer all of the questions yourself by ticking the number that best applies to you. There are no "right" or "wrong" answers.

The information that you provide will remain strictly confidential.

1 Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?

- 1 – Not at all
 2 – A little
 3 – Quite a bit
 4 – Very much

2 Do you have any trouble taking a long walk?

- 1 – Not at all
 2 – A little
 3 – Quite a bit
 4 – Very much

3 Do you have any trouble taking a short walk outside of the house?

- 1 – Not at all
 2 – A little
 3 – Quite a bit
 4 – Very much

During the past week:

6 Were you limited in doing either your work or other daily activities?

- 1 – Not at all
 2 – A little
 3 – Quite a bit
 4 – Very much

7 Were you limited in pursuing your hobbies or other leisure time activities?

- 1 – Not at all
 2 – A little
 3 – Quite a bit
 4 – Very much

8 Were you short of breath?

- 1 – Not at all
 2 – A little
 3 – Quite a bit
 4 – Very much

9 Have you had pain?

- 1 – Not at all
 2 – A little
 3 – Quite a bit
 4 – Very much

4 Do you need to stay in bed or a chair during the day?

- 1 – Not at all
 2 – A little
 3 – Quite a bit
 4 – Very much

5 Do you need help with eating, dressing, washing yourself or using the toilet?

- 1 – Not at all
 2 – A little
 3 – Quite a bit
 4 – Very much

10 Did you need to rest?

- 1 – Not at all
 2 – A little
 3 – Quite a bit
 4 – Very much

11 Have you had trouble sleeping?

- 1 – Not at all
 2 – A little
 3 – Quite a bit
 4 – Very much

12 Have you felt weak?

- 1 – Not at all
 2 – A little
 3 – Quite a bit
 4 – Very much

13 Have you lacked appetite?

- 1 – Not at all
 2 – A little
 3 – Quite a bit
 4 – Very much

For site staff use

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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A. QLQ-C30 – continued

During the past week:

14 Have you felt nauseated?

- 1 – Not at all
 2 – A little
 3 – Quite a bit
 4 – Very much

15 Have you vomited?

- 1 – Not at all
 2 – A little
 3 – Quite a bit
 4 – Very much

16 Have you been constipated?

- 1 – Not at all
 2 – A little
 3 – Quite a bit
 4 – Very much

17 Have you had diarrhoea?

- 1 – Not at all
 2 – A little
 3 – Quite a bit
 4 – Very much

18 Were you tired?

- 1 – Not at all
 2 – A little
 3 – Quite a bit
 4 – Very much

19 Did pain interfere with your daily activities?

- 1 – Not at all
 2 – A little
 3 – Quite a bit
 4 – Very much

20 Have you had difficulty in concentrating on things, like reading a newspaper or watching television?

- 1 – Not at all
 2 – A little
 3 – Quite a bit
 4 – Very much

21 Did you feel tense?

- 1 – Not at all
 2 – A little
 3 – Quite a bit
 4 – Very much

22 Did you worry?

- 1 – Not at all
 2 – A little
 3 – Quite a bit
 4 – Very much

23 Did you feel irritable?

- 1 – Not at all
 2 – A little
 3 – Quite a bit
 4 – Very much

24 Did you feel depressed?

- 1 – Not at all
 2 – A little
 3 – Quite a bit
 4 – Very much

25 Have you had difficulty remembering things?

- 1 – Not at all
 2 – A little
 3 – Quite a bit
 4 – Very much

26 Has your physical condition or medical treatment interfered with your family life?

- 1 – Not at all
 2 – A little
 3 – Quite a bit
 4 – Very much

27 Has your physical condition or medical treatment interfered with your social activities?

- 1 – Not at all
 2 – A little
 3 – Quite a bit
 4 – Very much

28 Has your physical condition or medical treatment caused you financial difficulties?

- 1 – Not at all
 2 – A little
 3 – Quite a bit
 4 – Very much

 Questions continue  overleaf.

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A. QLQ-C30 — continued

For the following questions, please tick the number between 1 and 7 that best applies to you.

29 How would you rate your overall health during the past week?

- 1 — Very poor
 2
 3
 4
 5
 6
 7 — Excellent

30 How would you rate your overall quality of life during the past week?

- 1 — Very poor
 2
 3
 4
 5
 6
 7 — Excellent

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