

# THE LANCET

## **Supplementary webappendix**

This webappendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

Supplement to: Seymour MT, Thompson LC, Wasan HS, et al, on behalf of the FOCUS2 Investigators and the National Cancer Research Institute Colorectal Cancer Clinical Studies Group. Chemotherapy options in elderly and frail patients with metastatic colorectal cancer (MRC FOCUS2): an open-label, randomised factorial trial. *Lancet* 2011; published online May 12. DOI:10.1016/S0140-6736(11)60399-1.

# Baseline Comprehensive Health Assessment

## *FOCUS2* Trial

### Baseline Comprehensive Health Assessment (CHA)

#### Notes for Research Nurse/Data Manager:

This baseline health assessment is an indispensable part of the *FOCUS2* trial. It must be completed **after** obtaining the patient's consent, but **before** telephoning the MRC CTU to register and randomise the patient. The CHA is in two parts, (a) a nurse-administered assessment of physical parameters, mental state and medical history, and (b) a patient-completed questionnaire dealing with various aspects of quality of life. **Randomisation will not be performed until both parts of the CHA have been completed.**

#### CHA Nurse-Administered Section:

For this section of the CHA, you need a quiet, private environment where the patient can answer questions without feeling pressurised or "on trial". Ensure the patient is comfortable and not hungry, thirsty or in need of the toilet or analgesia. Hearing aids, if used, should be working. The patient may have a carer present, but if so ask them not to answer questions on the patient's behalf. If an interpreter is required, use a professional interpreter in preference to a relative.

You will need: a blank sheet of paper; scales and a measure for height and weight; a tape measure for arm circumference. This assessment includes a timed 20-metre walk. For this, a straight 20-metre distance should be marked out, for example in the clinic corridor, and you will need a watch or stopwatch.

Patient initials	Date form completed	Trial N°. (complete after registering)
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#### **Section P – Physical tests**

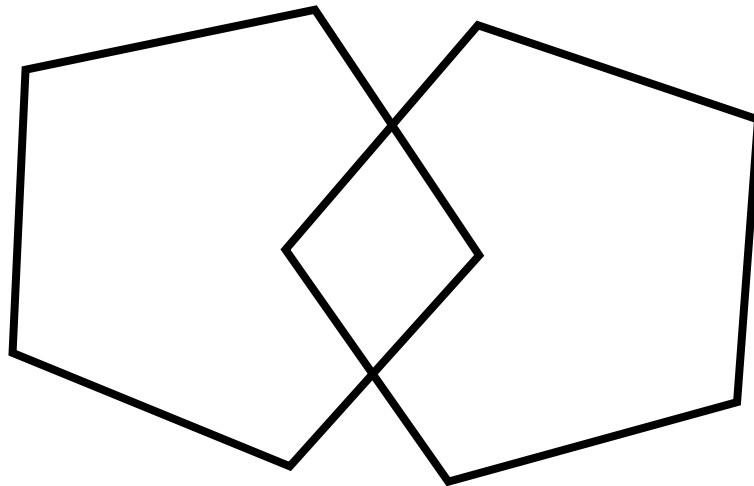
P.1) height in cm:	P.2) weight in kg:	P.3) right arm circumference in cm (midway between elbow and shoulder):
<p>P.4) approximate weight change in past 3 months:</p> <p>Ask the patient if they are aware of having lost or gained weight:</p> <p><input type="checkbox"/> don't know</p> <p><input type="checkbox"/> weight loss. If so, how much? Approx .....kg (½ stone = 3 kg)</p> <p><input type="checkbox"/> weight gain If so, how much? Approx .....kg (½ stone = 3 kg)</p>		

If no, give reason:

☐ declined test

☐ unable to walk

M.16-18) <b>“Now keep going until I ask you to stop”</b> (score each correct if difference is 7, even if previous answer was wrong)	first: <input type="checkbox"/>	<input type="checkbox"/>
	second: <input type="checkbox"/>	<input type="checkbox"/>
	third: <input type="checkbox"/>	<input type="checkbox"/>
	correct	incorrect
M.19-21) <b>“What were the three words I asked you to repeat a little while ago?”</b> (there should be no prompting)	Apple: <input type="checkbox"/>	<input type="checkbox"/>
	Table: <input type="checkbox"/>	<input type="checkbox"/>
	Penny: <input type="checkbox"/>	<input type="checkbox"/>
	correct	incorrect
M.22) <b>“What is this?”</b> (show a pencil)	<input type="checkbox"/>	<input type="checkbox"/>
	correct	incorrect
M.23) <b>“What is this?”</b> (show a watch)	<input type="checkbox"/>	<input type="checkbox"/>
	correct	incorrect
M.24) <b>“I am going to say something and I would like you to repeat it after me: NO IFS, ANDS OR BUTS”</b> (read this only once)	<input type="checkbox"/>	<input type="checkbox"/>
	correct	incorrect
M.25-27) <b>“I am going to ask you to carry out some actions. Please listen to the whole command before trying: Take this piece of paper, fold it in half and put it on the floor”</b> (offer a sheet of paper)	take paper: <input type="checkbox"/>	<input type="checkbox"/>
	fold in half: <input type="checkbox"/>	
	put on floor: <input type="checkbox"/>	<input type="checkbox"/>
	correct	incorrect
M.28) <b>“Please do this”</b> (close your eyes)	<input type="checkbox"/>	<input type="checkbox"/>
	correct	incorrect
M.29) <b>“Please write a sentence of your choice on this piece of paper”</b> (grammar and spelling not important; accept any sentence with a subject (real or implied) and verb. “Help” or “Go away” are acceptable)	<input type="checkbox"/>	<input type="checkbox"/>
	correct	incorrect
M.30) <b>“Copy this drawing on a piece of paper”</b> (show the patient the following drawing. To score correct, they must draw two intersecting pentagons, and the intersection should be a diamond shape)	<input type="checkbox"/>	<input type="checkbox"/>
	correct	incorrect



### **Section C (Charlson Co-Morbidity Index)**

This section is completed from the medical notes, although it is helpful to do so whilst the patient is still present so that you can clarify any missing data (using lay terms). Record whether there is a past or current history of any of the following medical conditions (if in doubt, consult the doctor responsible):

C.1) Myocardial infarct <i>History of medically documented myocardial infarction</i>	<input type="checkbox"/> present	<input type="checkbox"/> absent
C.2) Congestive heart failure <i>Symptomatic CHF with response to specific treatment</i>	<input type="checkbox"/> present	<input type="checkbox"/> absent
C.3) Peripheral vascular disease <i>Intermittent claudication, peripheral arterial bypass for insufficiency, gangrene, acute arterial insufficiency, untreated aneurysm (&gt;6cm)</i>	<input type="checkbox"/> present	<input type="checkbox"/> absent
C.4) Cerebrovascular disease (except hemiplegia) <i>History of TIA, or CVA with no or minor sequelae</i>	<input type="checkbox"/> present	<input type="checkbox"/> absent
C.5) Dementia <i>Chronic cognitive deficit</i>	<input type="checkbox"/> present	<input type="checkbox"/> absent
C.6) Chronic pulmonary disease <i>Symptomatic dyspnoea due to chronic respiratory conditions (including asthma)</i>	<input type="checkbox"/> present	<input type="checkbox"/> absent
C.7) Connective tissue disease <i>SLE, polymyositis, mixed CTD, polymyalgia rheumatica, moderate to severe RA.</i>	<input type="checkbox"/> present	<input type="checkbox"/> absent
C.8) Ulcer disease <i>Patients who have required treatment for PUD</i>	<input type="checkbox"/> present	<input type="checkbox"/> absent
C.9) Mild liver disease <i>Cirrhosis without PHT, chronic hepatitis</i>	<input type="checkbox"/> present	<input type="checkbox"/> absent
C.10) Diabetes (without complications) <i>Diabetes with medication</i>	<input type="checkbox"/> present	<input type="checkbox"/> absent
C.11) Diabetes with end organ damage <i>Retinopathy, neuropathy, nephropathy</i>	<input type="checkbox"/> present	<input type="checkbox"/> absent
C.12) Hemiplegia <i>Hemiplegia or paraplegia</i>	<input type="checkbox"/> present	<input type="checkbox"/> absent
C.13) Moderate or severe renal disease <i>Creatinine &gt; 265 umol/l, dialysis, transplantation, uraemic syndrome</i>	<input type="checkbox"/> present	<input type="checkbox"/> absent
C.14) 2 <sup>nd</sup> Solid tumour (non metastatic) <i>Initially treated in the last 5 years. Excl non-melanomatous skin ca, and in situ cervical ca.</i>	<input type="checkbox"/> present	<input type="checkbox"/> absent
C.15) Leukaemia <i>CML, CLL, AML, ALL, PV</i>	<input type="checkbox"/> present	<input type="checkbox"/> absent
C.16) Lymphoma, Multiple myeloma <i>Non Hodgkin's Lymphoma (NHL), Hodgkins, Waldenstrom, multiple myeloma</i>	<input type="checkbox"/> present	<input type="checkbox"/> absent
C.17) Moderate or severe liver disease <i>Cirrhosis with PHT +/- variceal bleeding</i>	<input type="checkbox"/> present	<input type="checkbox"/> absent
C.18) 2 <sup>nd</sup> Metastatic solid tumour	<input type="checkbox"/> present	<input type="checkbox"/> absent
C.19) AIDS <i>AIDS and AIDS related complex</i>	<input type="checkbox"/> present	<input type="checkbox"/> absent
<b>NB Now please go back and check that patient ID and date are completed at the top of this form, then ask the patient to complete the patient questionnaire section of the CHA.</b>		

## CHA Patient Questionnaire Section:

This section of the CHA is a patient-completed questionnaire. Please ensure the patient has a relaxed, private environment such as a clinic room, **not a public waiting area**. Ensure they are comfortable and not hungry, thirsty or in need of the toilet or analgesia. The patient may have a carer present, but if so ask them not to answer questions on the patient's behalf. If an interpreter is required, use a professional interpreter rather than a relative, if possible.

Some patients will require help reading or interpreting the questions, or ticking the response boxes. The research nurse or data manager should offer to sit with the patient and help if they wish, but if so should not change the patient's initial "gut reaction" responses. **When the patient has finished, the research nurse or data manager should look through the questionnaire before the patient leaves, check that there are no missing or unclear answers and check that the patient ID and date are complete.**

Dear Patient,

As part of our research into finding the best chemotherapy for your condition, we'd like to ask you some questions about your activities, symptoms and feelings. Would you please go through this questionnaire and, for each question, tick the answer that fits most closely, even if it is not exact. If there are questions you cannot answer, please ask the nurse for help (or, if you would prefer, the nurse can sit with you and read out all the questions).

Thank you!

<b>Your initials</b>	<b>/ /</b> <b>Today's Date</b>	<b>Trial N<sup>o</sup>. (Nurse to complete)</b>
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***First, some questions about what activities you can manage currently:***

A.1) Do you walk around outside?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily
A.2) Do you climb stairs?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily
A.3) Do you get in and out of the car?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily
A.4) Do you walk over uneven ground?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily
A.5) Do you cross roads?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily
A.6) Do you travel on public transport?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily
A.8) Do you manage to feed yourself?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily
A.9) Do you manage to make yourself a hot drink?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily
A.10) Do you take hot drinks from one room to another?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily
A.11) Do you do the washing up?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily

A.12) Do you make yourself a hot snack?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily
A.14) Do you manage your own money when you are out?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily
A.15) Do you wash small items of clothing?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily
A.16) Do you do your own shopping?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily
A.17) Do you do a full clothes wash?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily
A.19) Do you read newspapers or books?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily
A.20) Do you use the telephone?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily
A.21) Do you write letters?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily
A.22) Do you go out socially?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily
A.23) Do you manage our own garden?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily
A.24) Do you drive a car?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily

E.1) Over the past <b>6 weeks</b> how many times has your GP visited you?	<input type="checkbox"/> not at all	or: How many times?:.....	
E.2) Over the past <b>6 weeks</b> how many times have you visited your GP?	<input type="checkbox"/> not at all	or: How many times?:.....	
E.3) Over the past <b>6 weeks</b> how often have you been visited by a district nurse?	<input type="checkbox"/> not at all	or: How many times?:.....	
E.4) Over the past <b>6 weeks</b> , have you been visited by a MacMillan nurse?	<input type="checkbox"/> not at all	or: How many times?:.....	
E.5) Which best describes your mobility <b>today</b> ?	<input type="checkbox"/> I have no problems walking about	<input type="checkbox"/> I have some problems walking about	<input type="checkbox"/> I am confined to bed
E.6) Which best describes your self-care <b>today</b> ?	<input type="checkbox"/> I have no problems with self care	<input type="checkbox"/> I have some problems washing or dressing	<input type="checkbox"/> I am unable to wash or dress myself
E.7) Which best describes your activities <b>today</b> ?	<input type="checkbox"/> I have no problems performing my usual activities	<input type="checkbox"/> I have some problems performing my usual activities	<input type="checkbox"/> I am unable to perform my usual activities
E.8) Do you have any pain <b>today</b> ?	<input type="checkbox"/> I have no pain or discomfort	<input type="checkbox"/> I have some pain or discomfort	<input type="checkbox"/> I have extreme pain or discomfort
E.9) Which best describes your mood <b>today</b> ?	<input type="checkbox"/> I am not anxious or depressed	<input type="checkbox"/> I am moderately anxious or depressed	<input type="checkbox"/> I am extremely anxious or depressed

**Now some questions about your symptoms over the past week.**

**During the past week...**

Q.8) ...were you short of breath?	<input type="checkbox"/> not at all	<input type="checkbox"/> a little	<input type="checkbox"/> quite a bit	<input type="checkbox"/> very much	
Q.9) ...have you had pain?	<input type="checkbox"/> not at all	<input type="checkbox"/> a little	<input type="checkbox"/> quite a bit	<input type="checkbox"/> very much	
Q.10) ...did you need to rest?	<input type="checkbox"/> not at all	<input type="checkbox"/> a little	<input type="checkbox"/> quite a bit	<input type="checkbox"/> very much	
Q.11) ...have you had trouble sleeping?	<input type="checkbox"/> not at all	<input type="checkbox"/> a little	<input type="checkbox"/> quite a bit	<input type="checkbox"/> very much	
Q.12) ...have you felt weak?	<input type="checkbox"/> not at all	<input type="checkbox"/> a little	<input type="checkbox"/> quite a bit	<input type="checkbox"/> very much	
Q.13) ...have you lacked appetite?	<input type="checkbox"/> not at all	<input type="checkbox"/> a little	<input type="checkbox"/> quite a bit	<input type="checkbox"/> very much	
Q.14) ...have you felt nauseated?	<input type="checkbox"/> not at all	<input type="checkbox"/> a little	<input type="checkbox"/> quite a bit	<input type="checkbox"/> very much	
Q.15) ...have you vomited?	<input type="checkbox"/> not at all	<input type="checkbox"/> a little	<input type="checkbox"/> quite a bit	<input type="checkbox"/> very much	
Q.16) ...have you been constipated?	<input type="checkbox"/> not at all	<input type="checkbox"/> a little	<input type="checkbox"/> quite a bit	<input type="checkbox"/> very much	
Q.17) ...have you had diarrhoea?	<input type="checkbox"/> not at all	<input type="checkbox"/> a little	<input type="checkbox"/> quite a bit	<input type="checkbox"/> very much	
Q.18) ...were you tired?	<input type="checkbox"/> not at all	<input type="checkbox"/> a little	<input type="checkbox"/> quite a bit	<input type="checkbox"/> very much	
Q.31)...have you had a dry and/or sore mouth?	<input type="checkbox"/> not at all	<input type="checkbox"/> a little	<input type="checkbox"/> quite a bit	<input type="checkbox"/> very much	
Q.32)...have you had problems eating or drinking because of a sore mouth?	<input type="checkbox"/> not at all	<input type="checkbox"/> a little	<input type="checkbox"/> quite a bit	<input type="checkbox"/> very much	
Q.33)...have you had soreness or redness of your hands or feet?	<input type="checkbox"/> not at all	<input type="checkbox"/> a little	<input type="checkbox"/> quite a bit	<input type="checkbox"/> very much	
Q.34) ...have you had difficulty handling small objects (eg buttons or zips)?	<input type="checkbox"/> not at all	<input type="checkbox"/> a little	<input type="checkbox"/> quite a bit	<input type="checkbox"/> very much	
Q.35) ...have you lost any hair?	<input type="checkbox"/> not at all	<input type="checkbox"/> a little	<input type="checkbox"/> quite a bit	<input type="checkbox"/> very much	
Q.36) ...if you have a colostomy, have you had trouble with it (soreness of skin, increased frequency, leakage)?	<input type="checkbox"/> not applicable	<input type="checkbox"/> not at all	<input type="checkbox"/> a little	<input type="checkbox"/> quite a bit	<input type="checkbox"/> very much
G.1) How was your <b>overall health</b> during the past week? <i>(put a circle round the score)</i>	<div> <div>1</div> <div>2</div> <div>3</div> <div>4</div> <div>5</div> <div>6</div> <div>7</div> </div> <div> <div>Very poor</div> <div></div> <div></div> <div></div> <div></div> <div></div> <div>Excellent</div> </div>				
G.2) And how was your <b>overall quality of life</b> during the past week?	<div> <div>1</div> <div>2</div> <div>3</div> <div>4</div> <div>5</div> <div>6</div> <div>7</div> </div> <div> <div>Very poor</div> <div></div> <div></div> <div></div> <div></div> <div></div> <div>Excellent</div> </div>				



**Finally, please answer these questions about your feelings. For each statement please mark the box which best describes how you have been feeling over the past week:**

H.1) "I feel tense or 'wound up'..."	<input type="checkbox"/> most of the time	<input type="checkbox"/> a lot of the time	<input type="checkbox"/> time-to-time, occasionally	<input type="checkbox"/> not at all
H.2) "I still enjoy the things I used to enjoy..."	<input type="checkbox"/> definitely as much	<input type="checkbox"/> not quite so much	<input type="checkbox"/> only a little	<input type="checkbox"/> hardly at all
H.3) "I get a sort of frightened feeling as if something awful is about to happen..."	<input type="checkbox"/> very definitely and quite badly	<input type="checkbox"/> yes, but not too badly	<input type="checkbox"/> a little but it doesn't worry me	<input type="checkbox"/> not at all
H.4) "I can laugh and see the funny side of things..."	<input type="checkbox"/> as much as I always could	<input type="checkbox"/> not quite so much now	<input type="checkbox"/> definitely not so much now	<input type="checkbox"/> not at all
H.5) "Worrying thoughts go through my mind..."	<input type="checkbox"/> a great deal of the time	<input type="checkbox"/> a lot of the time	<input type="checkbox"/> time to time but not too often	<input type="checkbox"/> only occasionally
H.6) "I feel cheerful..."	<input type="checkbox"/> not at all	<input type="checkbox"/> not often	<input type="checkbox"/> sometimes	<input type="checkbox"/> most of the time
H.7) "I can sit at ease and feel relaxed..."	<input type="checkbox"/> definitely	<input type="checkbox"/> usually	<input type="checkbox"/> not often	<input type="checkbox"/> not at all
H.8) "I feel as if I am slowed down..."	<input type="checkbox"/> nearly all the time	<input type="checkbox"/> very often	<input type="checkbox"/> sometimes	<input type="checkbox"/> not at all
H.9) "I get a sort of frightened feeling like 'butterflies' in the stomach..."	<input type="checkbox"/> not at all	<input type="checkbox"/> occasionally	<input type="checkbox"/> quite often	<input type="checkbox"/> very often
H.10) "I have lost interest in my appearance..."	<input type="checkbox"/> definitely	<input type="checkbox"/> I take less care than I should	<input type="checkbox"/> I may not take quite as much care	<input type="checkbox"/> I take just as much care as ever
H.11) "I feel restless as if I have to be on the move..."	<input type="checkbox"/> very much indeed	<input type="checkbox"/> quite a lot	<input type="checkbox"/> not very much	<input type="checkbox"/> not at all
H.12) "I look forward with enjoyment to things..."	<input type="checkbox"/> as much as I ever did	<input type="checkbox"/> rather less than I used to	<input type="checkbox"/> definitely less than I used to	<input type="checkbox"/> hardly at all
H.13) "I get sudden feelings of panic..."	<input type="checkbox"/> very often indeed	<input type="checkbox"/> quite often	<input type="checkbox"/> not very often	<input type="checkbox"/> not at all
H.14) "I can enjoy a good book or radio or TV programme..."	<input type="checkbox"/> often	<input type="checkbox"/> sometimes	<input type="checkbox"/> not often	<input type="checkbox"/> very seldom

**Many thanks for helping us by filling in this questionnaire. Please now hand it to the research nurse. You may feel that you wish to discuss some of the issues which it has raised – please feel free to do so.**

# Limited Health Assessment (LHA)

## FOCUS2 Trial

### Limited Health Assessment (LHA)

#### Notes for Research Nurse/Data Manager:

This health assessment, along with the baseline CHA, is an indispensable part of the *FOCUS2* trial. It is completed once after the first 12 weeks of chemotherapy (during week 12-14), and once again 6 months after trial entry. These forms will provide some of the most important data for the trial. Like the CHA, the LHA is in two sections, (a) a nurse-administered assessment of physical parameters, and (b) a patient-completed questionnaire dealing with various aspects of quality of life.

#### **LHA Nurse-Administered Section:**

You will need: scales and a measure for height and weight; a tape measure for arm circumference. This assessment includes a timed 20-metre walk. For this, a straight 20-metre distance should be marked out, for example in the clinic corridor, and you will need a watch or stopwatch.

Patient initials	Date form completed	Trial N°.
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#### **Section P – Physical tests**

P.1) height in cm:	P.2) weight in kg:	P.3) right arm circumference in cm (midway between elbow and shoulder):
<b>P.4) approximate weight change in past 3 months:</b>  Ask the patient if they are aware of having lost or gained weight: <input type="checkbox"/> don't know <input type="checkbox"/> weight loss. If so, how much? Approx .....kg (½ stone = 3 kg) <input type="checkbox"/> weight gain If so, how much? Approx .....kg (½ stone = 3 kg)		
<b>P.5) timed 20-metre walk.</b> Use an unobstructed straight 20-metre distance (this should be marked off, for example, in the clinic corridor). Ask the patient to walk as fast as they can without running, starting at the start line and continuing for a few steps beyond the finish line. If they normally use a walking stick or frame, this should be used. Gentle support (e.g. holding elbow) may be given.  Did the patient walk 20 metres? Yes <input type="checkbox"/> No <input type="checkbox"/>  If yes, time taken in seconds: .....seconds  If no, give reason: <input type="checkbox"/> declined test <input type="checkbox"/> unable to walk		

## LHA Patient Questionnaire Section:

This section of the LHA is a patient-completed questionnaire. Please ensure the patient has a relaxed, private environment such as a clinic room, **not a public waiting area**. Ensure they are comfortable and not hungry, thirsty or in need of the toilet or analgesia. The patient may have a carer present, but if so ask them not to answer questions on the patient's behalf. If an interpreter is required, use a professional interpreter rather than a relative, if possible.

Some patients will require help reading or interpreting the questions, or ticking the response boxes. The research nurse or data manager should offer to sit with the patient and help if they wish, but if so should not change the patient's initial "gut reaction" responses. **When the patient has finished, the research nurse or data manager should look through the questionnaire before the patient leaves, check that there are no missing or unclear answers and check that the patient ID and date are complete.**

Dear Patient,

As part of our research into finding the best chemotherapy for your condition, we would like to ask you the same questions that we did at the start of your treatment, about your activities, symptoms and feelings. For each question, tick the answer which fits most closely, even if it is not exact. If there are questions you cannot answer, please ask the nurse for help (or, if you would prefer, the nurse can sit with you and read out all the questions).

Thank you!

<b>Your initials</b>	<b>/ /</b> <b>Today's Date</b>	<b>Trial N<sup>o</sup>. (Nurse to complete)</b>
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***First, some questions about what activities you can manage currently:***

A.1) Do you walk around outside?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily
A.2) Do you climb stairs?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily
A.3) Do you get in and out of the car?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily
A.4) Do you walk over uneven ground?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily
A.5) Do you cross roads?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily
A.6) Do you travel on public transport?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily
A.8) Do you manage to feed yourself?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily
A.9) Do you manage to make yourself a hot drink?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily
A.10) Do you take hot drinks from one room to another?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily

A.11) Do you do the washing up?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily
A.12) Do you make yourself a hot snack?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily
A.14) Do you manage your own money when you are out?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily
A.15) Do you wash small items of clothing?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily
A.16) Do you do your own shopping?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily
A.17) Do you do a full clothes wash?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily
A.19) Do you read newspapers or books?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily
A.20) Do you use the telephone?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily
A.21) Do you write letters?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily
A.22) Do you go out socially?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily
A.23) Do you manage our own garden?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily
A.24) Do you drive a car?	<input type="checkbox"/> not at all	<input type="checkbox"/> with help	<input type="checkbox"/> alone with difficulty	<input type="checkbox"/> alone easily

E.1) Over the past <b>6 weeks</b> how many times has your GP visited you?	<input type="checkbox"/> not at all	or: How many times?:.....	
E.2) Over the past <b>6 weeks</b> how many times have you visited your GP?	<input type="checkbox"/> not at all	or: How many times?:.....	
E.3) Over the past <b>6 weeks</b> how often have you been visited by a district nurse?	<input type="checkbox"/> not at all	or: How many times?:.....	
E.4) Over the past <b>6 weeks</b> , have you been visited by a MacMillan nurse?	<input type="checkbox"/> not at all	or: How many times?:.....	
E.5) Which best describes your mobility <b>today</b> ?	<input type="checkbox"/> I have no problems walking about	<input type="checkbox"/> I have some problems walking about	<input type="checkbox"/> I am confined to bed
E.6) Which best describes your self-care <b>today</b> ?	<input type="checkbox"/> I have no problems with self care	<input type="checkbox"/> I have some problems washing or dressing	<input type="checkbox"/> I am unable to wash or dress myself
E.7) Which best describes your activities <b>today</b> ?	<input type="checkbox"/> I have no problems performing my usual activities	<input type="checkbox"/> I have some problems performing my usual activities	<input type="checkbox"/> I am unable to perform my usual activities
E.8) Do you have any pain <b>today</b> ?	<input type="checkbox"/> I have no pain or discomfort	<input type="checkbox"/> I have some pain or discomfort	<input type="checkbox"/> I have extreme pain or discomfort
E.9) Which best describes your mood <b>today</b> ?	<input type="checkbox"/> I am not anxious or depressed	<input type="checkbox"/> I am moderately anxious or depressed	<input type="checkbox"/> I am extremely anxious or depressed

**Now some questions about your symptoms. Over the past week....**

Q.8) ...were you short of breath?	<input type="checkbox"/> not at all	<input type="checkbox"/> a little	<input type="checkbox"/> quite a bit	<input type="checkbox"/> very much			
Q.9) ...have you had pain?	<input type="checkbox"/> not at all	<input type="checkbox"/> a little	<input type="checkbox"/> quite a bit	<input type="checkbox"/> very much			
Q.10) ...did you need to rest?	<input type="checkbox"/> not at all	<input type="checkbox"/> a little	<input type="checkbox"/> quite a bit	<input type="checkbox"/> very much			
Q.11) ...have you had trouble sleeping?	<input type="checkbox"/> not at all	<input type="checkbox"/> a little	<input type="checkbox"/> quite a bit	<input type="checkbox"/> very much			
Q.12) ...have you felt weak?	<input type="checkbox"/> not at all	<input type="checkbox"/> a little	<input type="checkbox"/> quite a bit	<input type="checkbox"/> very much			
Q.13) ...have you lacked appetite?	<input type="checkbox"/> not at all	<input type="checkbox"/> a little	<input type="checkbox"/> quite a bit	<input type="checkbox"/> very much			
Q.14) ...have you felt nauseated?	<input type="checkbox"/> not at all	<input type="checkbox"/> a little	<input type="checkbox"/> quite a bit	<input type="checkbox"/> very much			
Q.15) ...have you vomited?	<input type="checkbox"/> not at all	<input type="checkbox"/> a little	<input type="checkbox"/> quite a bit	<input type="checkbox"/> very much			
Q.16) ...have you been constipated?	<input type="checkbox"/> not at all	<input type="checkbox"/> a little	<input type="checkbox"/> quite a bit	<input type="checkbox"/> very much			
Q.17) ...have you had diarrhoea?	<input type="checkbox"/> not at all	<input type="checkbox"/> a little	<input type="checkbox"/> quite a bit	<input type="checkbox"/> very much			
Q.18) ...were you tired?	<input type="checkbox"/> not at all	<input type="checkbox"/> a little	<input type="checkbox"/> quite a bit	<input type="checkbox"/> very much			
Q.31)...have you had a dry and/or sore mouth?	<input type="checkbox"/> not at all	<input type="checkbox"/> a little	<input type="checkbox"/> quite a bit	<input type="checkbox"/> very much			
Q.32)...have you had problems eating or drinking because of a sore mouth?	<input type="checkbox"/> not at all	<input type="checkbox"/> a little	<input type="checkbox"/> quite a bit	<input type="checkbox"/> very much			
Q.33)...have you had soreness or redness of your hands or feet?	<input type="checkbox"/> not at all	<input type="checkbox"/> a little	<input type="checkbox"/> quite a bit	<input type="checkbox"/> very much			
Q.34) ...have you had difficulty handling small objects (eg buttons or zips)?	<input type="checkbox"/> not at all	<input type="checkbox"/> a little	<input type="checkbox"/> quite a bit	<input type="checkbox"/> very much			
Q.35) ...have you lost any hair?	<input type="checkbox"/> not at all	<input type="checkbox"/> a little	<input type="checkbox"/> quite a bit	<input type="checkbox"/> very much			
Q.36) If you have a colostomy, have you had trouble with it (soreness of skin, increased frequency, leakage)?	<input type="checkbox"/> not applicable	<input type="checkbox"/> not at all	<input type="checkbox"/> a little	<input type="checkbox"/> quite a bit	<input type="checkbox"/> very much		
Q.37) ...how much has your chemotherapy treatment interfered with your normal daily activities?	<input type="checkbox"/> not applicable	<input type="checkbox"/> not at all	<input type="checkbox"/> a little	<input type="checkbox"/> quite a bit	<input type="checkbox"/> very much		
Q.38) <b>Since you started chemotherapy,</b> how worthwhile do you think your treatment has been?	<input type="checkbox"/> not applicable	<input type="checkbox"/> not at all	<input type="checkbox"/> a little	<input type="checkbox"/> quite a bit	<input type="checkbox"/> very much		
G.1) How was your <b>overall health</b> during the past week? <i>(put a circle round the score)</i>	1 Very poor	2	3	4	5	6	7 Excellent
G.2) And how was your <b>overall quality of life</b> during the past week?	1 Very poor	2	3	4	5	6	7 Excellent

**Finally, please answer these questions about your feelings. For each statement please mark the box which best describes how you have been feeling over the past week:**

H.1) "I feel tense or 'wound up'..."	<input type="checkbox"/> most of the time	<input type="checkbox"/> a lot of the time	<input type="checkbox"/> time-to-time, occasionally	<input type="checkbox"/> not at all
H.2) "I still enjoy the things I used to enjoy..."	<input type="checkbox"/> definitely as much	<input type="checkbox"/> not quite so much	<input type="checkbox"/> only a little	<input type="checkbox"/> hardly at all
H.3) "I get a sort of frightened feeling as if something awful is about to happen..."	<input type="checkbox"/> very definitely and quite badly	<input type="checkbox"/> yes, but not too badly	<input type="checkbox"/> a little but it doesn't worry me	<input type="checkbox"/> not at all
H.4) "I can laugh and see the funny side of things..."	<input type="checkbox"/> as much as I always could	<input type="checkbox"/> not quite so much now	<input type="checkbox"/> definitely not so much now	<input type="checkbox"/> not at all
H.5) "Worrying thoughts go through my mind..."	<input type="checkbox"/> a great deal of the time	<input type="checkbox"/> a lot of the time	<input type="checkbox"/> time to time but not too often	<input type="checkbox"/> only occasionally
H.6) "I feel cheerful..."	<input type="checkbox"/> not at all	<input type="checkbox"/> not often	<input type="checkbox"/> sometimes	<input type="checkbox"/> most of the time
H.7) "I can sit at ease and feel relaxed..."	<input type="checkbox"/> definitely	<input type="checkbox"/> usually	<input type="checkbox"/> not often	<input type="checkbox"/> not at all
H.8) "I feel as if I am slowed down..."	<input type="checkbox"/> nearly all the time	<input type="checkbox"/> very often	<input type="checkbox"/> sometimes	<input type="checkbox"/> not at all
H.9) "I get a sort of frightened feeling like 'butterflies' in the stomach..."	<input type="checkbox"/> not at all	<input type="checkbox"/> occasionally	<input type="checkbox"/> quite often	<input type="checkbox"/> very often
H.10) "I have lost interest in my appearance..."	<input type="checkbox"/> definitely	<input type="checkbox"/> I take less care than I should	<input type="checkbox"/> I may not take quite as much care	<input type="checkbox"/> I take just as much care as ever
H.11) "I feel restless as if I have to be on the move..."	<input type="checkbox"/> very much indeed	<input type="checkbox"/> quite a lot	<input type="checkbox"/> not very much	<input type="checkbox"/> not at all
H.12) "I look forward with enjoyment to things..."	<input type="checkbox"/> as much as I ever did	<input type="checkbox"/> rather less than I used to	<input type="checkbox"/> definitely less than I used to	<input type="checkbox"/> hardly at all
H.13) "I get sudden feelings of panic..."	<input type="checkbox"/> very often indeed	<input type="checkbox"/> quite often	<input type="checkbox"/> not very often	<input type="checkbox"/> not at all
H.14) "I can enjoy a good book or radio or TV programme..."	<input type="checkbox"/> often	<input type="checkbox"/> sometimes	<input type="checkbox"/> not often	<input type="checkbox"/> very seldom

**Many thanks for helping us by filling in this questionnaire. Please now hand it to the research nurse. You may feel that you wish to discuss some of the issues which it has raised – please feel free to do so.**

## Overall Treatment Utility (OTU)

OTU is a novel clinical outcome measure incorporating objective and subjective measures of anticancer efficacy, tolerability and acceptability, assessed 12 weeks after starting treatment and condensed into a simple 3-point score.

OTU may be regarded as asking the clinician: *"With the benefit of hindsight, are you glad you gave this treatment?"* and asking the patient: *"With the benefit of hindsight, are you glad you received it?"*: OTU is scored as good, intermediate or poor, corresponding to "yes", "uncertain" or "no" replies to these questions.

To score OTU, the patient is assessed 12 weeks after randomisation (acceptable window 10-14 weeks), using the following criteria:

### 1. Clinical benefit? Categorised as:

- a. Both radiologically progression-free (RECIST response or stable disease) and no clinical deterioration<sup>1</sup>, as assessed by treating consultant
- b. Either radiological progression (RECIST progressive disease) or clinical deterioration, as assessed by treating consultant

### 2. Tolerable and acceptable? Categorised as:

- a. All of the following:
  - no SAE or SUSAR attributed to treatment
  - no episodes of grade  $\geq 3$  non-haematological toxicity
  - patient response to LHA<sup>2</sup> Q37 ("How much has your treatment interfered with your normal daily activities?") is not "Very much"
  - patient response to LHA<sup>2</sup> Q38 ("How worthwhile do you think your treatment has been?") is not "Not at all"
- b. Any of the following:
  - an SAE or SUSAR attributed to treatment
  - an episode of grade  $\geq 3$  non-haematological toxicity
  - patient response to LHA<sup>2</sup> Q37 ("How much has your treatment interfered with your normal daily activities?") is "Very much"
  - patient response to LHA<sup>2</sup> Q38 ("How worthwhile do you think your treatment has been?") is "Not at all"

### Scoring:

Good OTU:	Patient is alive and scores 1a/2a
Intermediate OTU:	Patient is alive and scores 1a/2b or 1b/2a
Poor OTU:	Patient is alive and scores 1b/2b, or patient is dead

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<sup>1</sup> Clinical deterioration = clear clinical evidence of cancer progression which has not been confirmed radiologically.

<sup>2</sup> LHA = Limited Health Assessment. Please see webappendix pages 9-13 for full details of the LHA.