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EMT2: EPA for Metastasis Trial 2
Extended follow-up phase

PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT DOCUMENT

A large-print version of this sheet is available on request.

You have been taking part in a research study called EMT2, funded by Yorkshire Cancer Research. You will soon have completed the period when you will have been expected to take capsules. There is now an opportunity to take part in an extension phase of EMT2. Before you decide if you want to take part, we would like to explain why the research is continuing, how we will use the information we have about you, and what the extension phase of the study will involve.

Please read this information carefully and discuss it with others, if you like. Ask us if anything is unclear, or if you would like more information.

Once you have read this information, your doctor or research nurse will talk to you about the study again and you can ask any questions you like.

- Part 1 tells you the purpose of this part of the study and what will happen if you take part.
- Part 2 gives you more detailed information about the conduct of the study.

Take time to decide whether or not you wish to provide consent.

How to contact us

If you have any questions about this study, please talk to your doctor at

<<Enter PI, nurse name >>

<< Contact details for site>>

Thank you for reading this information sheet.

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Part 1

What is the purpose of the extended follow-up phase of the EMT2 study?

The purpose of the EMT2 study that you are taking part in is to find out if there is benefit from taking EPA capsules after liver surgery for colorectal cancer spread to the liver. The longer that we monitor people in the trial, the more detailed information that we will have about the effects of EPA. Even though you are nearing the end of the part of the trial when you are expected to take capsules, there is still important information to be obtained by reviewing your medical records for up to two more years after the phase taking trial medication is over.

Why have I been chosen?

You have been invited because you have been taking part in the EMT2 trial and are coming to the end of the time in the trial when participants were expected to take capsule medication (intervention phase). It does not matter whether you are still taking capsules or have had to stop taking them earlier in the EMT2 trial.

Do I have to take part?

No, however we hope that you will provide your consent for this phase of the trial. You may withdraw your consent at any time, without giving us a reason.

If you decide to take part, you will be given this information document to keep. You will be asked to sign a consent form, but you are still free to withdraw at any time and without giving a reason.

What would taking part involve?

You will not need to attend hospital for any further visits and you will not be contacted by a Research Nurse or Doctor. Information on future hospital tests that you undergo and changes to your health will be obtained from your hospital records without the need to contact you.

What will happen during the extended follow-up phase?

At the end of the intervention phase in EMT2 (at Visit 10), your research nurse or doctor will contact you by telephone to ask how you have been feeling since they last spoke to you, about any other medications that you are taking and if you have attended hospital or your GP for any reason.

From that point onwards, you will enter the extended follow-up phase and there will be no further contact with your research nurse or doctor. You will not need to attend the hospital for any further visits. With your consent, they will access your hospital records annually and collect medical information about your health.

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How long does the extended follow-up phase go on?

The extended follow-up phase will continue until the last participant who enters the EMT2 trial has completed at least 2 years' follow up, but no longer than 3 years in total.

What happens when the research study stops?

When the extended follow-up phase of the EMT2 trial finishes, the trial team will stop accessing your hospital records.

1. Intervention phase		
Assessment type and timing	**Duration of visit**	**Visit details**
Visit 10 (End of Intervention Phase)	2 hours	• Review of CT scan • Complete 5 questionnaires
Phone call (60 days after visit 10 if still taking capsules at visit 10)	Phone call only	
2. Extended follow up phase		
• Remote data collection annually up to 3 years post after the end of the Intervention phase		

Will my taking part be kept confidential?

If you decide to participate in the EMT2 extended follow-up, the information collected about you will be handled strictly in accordance with the consent that you have given and also the Data Protection Act 2018. Please refer to Part 2 for further details.

Contact Details

If you have any further questions about your illness or clinical studies, please discuss them with your doctor or research nurse. You may also find it helpful to contact Macmillan Cancer Support, an independent cancer information charity (freephone: **0808 808 00 00**; address: 89 Albert Embankment, London, SE1 7UQ; website www.macmillan.org.uk) or CancerHelp, an information service about cancer and cancer care for people with cancer and their families by Cancer Research UK (Tel: 020 7061 8355; website www.cancerhelp.org.uk). If you would like further information about clinical research, the UK Clinical Research Collaboration (a partnership of organisations working together on clinical research in the UK) have published a booklet entitled 'Understanding Clinical Trials'. Contact UKCRC: Tel: 0207 670 5452; website www.ukcrc.org

This completes Part 1 of the Information Sheet. If the Information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

Part 2

What will happen if I don't want to carry on with the study?

If you withdraw consent for further information to be collected from you, your data will remain on file and will be included in the final study analysis. In line with Good Clinical Practice guidelines, at the end of the study, your data will be securely archived for a minimum of 15 years. Arrangements for confidential destruction will then be made.

Who has organised, reviewed and funded the research and who will be supervising it?

The Chief Investigator is Professor Mark Hull who is based at the University of Leeds. He is a Consultant Gastroenterologist and an expert in the molecular basis of colorectal cancer development and colorectal cancer prevention. The study is being sponsored by the University of Leeds and is organised on its behalf by the Clinical Trials Research Unit (CTRU) at the University of Leeds. The study is taking place in at least 13 different hospitals in the UK. The study has been reviewed and funded by Yorkshire Cancer Research (YCR). It has also been reviewed by North-East: Newcastle and Tyneside 2 Research Ethics Committee.

Complaints:

If you wish to complain, or have concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms should be available to you. Your doctor will give you further information if necessary.

Will my taking part in this study be kept confidential?

If you decide to participate in the extension phase of the EMT2 Study, the information collected about you will be handled in accordance with the consent that you have given and also the Data Protection Act 2018. The information needed for study purposes will be collected on paper forms and sent (usually using standard Royal Mail post but in some cases by fax or email) from the hospital to the CTRU.

Your allocated EMT2 study number, will be used along with your date of birth and initials to identify you on each paper form. Your full name will be included on your consent form and a copy of this will be sent to the CTRU by fax, post or email. Every effort will be made to ensure that any further information about you that leaves the hospital will have your name and address removed so that you cannot be recognised from it; this information will usually be removed by a member of the study team at your hospital, but may also be removed by the CTRU upon receipt.

Your data will be entered onto a secure database held at the CTRU in accordance with the Data Protection Act 2018.

Your healthcare records may be looked at by authorised individuals from the research team, the University of Leeds (the study Sponsor) or the regulatory authorities to

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check that the study is being carried out correctly.

Your name, date of birth, and NHS number may be submitted to standard NHS registries such as Hospital Episodes Statistics (a standard NHS patient registry held by the Health and Social Care Information Centre and other central UK NHS bodies). This is so that information about your health status and hospital attendance may be obtained by the CTRU.

The information collected about you may be shared with other research teams to answer new research questions in the future. This may include information from the NHS registries on how you are doing after you finished participating in the trial. Wherever possible, information will be anonymised (for example; your full name will not be disclosed).

Your data may be passed to other organisations (possibly in other countries where the data protection standards and laws are different to the UK) to monitor the safety of the treatment(s) that you are receiving; these data will have your name removed.

What will happen to the results of the research study?

When the study is complete the results will be published in a medical journal, but no individual participants will be identified. If you would like to obtain a copy of the published scientific results, please ask your doctor. The trial team also aim to write a summary of the trial results for the public and publicise the results in the media. If at the end of the trial, once the results of the study are available, you would like to know which treatment you received you should speak to your doctor who will be able to obtain that information for you. You will not be told which treatment you received before then unless your doctor feels that there is a medical reason to do so.

Thank you very much for reading this information sheet.

If you have any questions, please ask us.

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Delete this line, then print on Trust/Hospital headed paper

Participant ID:	Initials:
Date of Birth:	NHS/Hospital Number:
EudraCT Number: *2016-000628-24*	Principal Investigator:

EMT2: EPA for Metastasis Trial 2

Extended follow-up phase

PARTICIPANT CONSENT FORM

Please initial each box

1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation in this study is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected. I understand that even if I withdraw from the above study, the data and samples collected from me will be used in analysing the results of the study and in some cases further information about any unwanted effects of my treatment may need to be collected by the study team. ☐

3. I understand that strict confidentiality will be maintained at all times ☐

4. I understand that my healthcare records may be looked at by authorised individuals from the study team, regulatory bodies or Sponsor (University of Leeds) in order to check that the study is being carried out correctly. ☐

5. I agree to a copy of this Consent Form being sent to the CTRU. ☐

6. I agree to take part in the extended follow-up phase of the study. ☐

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Patient:

Signature……

Name (block capitals)……

Date……

Investigator:

I have explained the study to the above-named patient and he/she has indicated his/her willingness to participate.

Signature……

Name (block capitals)……

Date……

(If used)Translator:

Signature……

Name (block capitals)……

Date……

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(1 copy for patient; 1 for the CTRU; 1 held in patient notes, original stored in Investigator Site File)