FOxTROT 5 Supplementary Information

This additional information is provided for potential FOxTROT 5 participants who would like to read it after they have considered the essential information given in the main FOxTROT 5 Patient Information Sheet.

Part 1: More information about this research

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

You can stop taking part in all of this research, or in any part of it, at any time and without giving a reason. However, we would like to know the reason if you are willing to say, as this will help us understand if there are common reasons for participants to stop taking part in research.

- If you decide to stop taking your neoadjuvant research treatment (before surgery), you are likely to proceed to an operation after a period of recovery. Research follow up visits and assessments can still go ahead if you agree to this.
- If you tell us that you want to stop completing quality of life questionnaires, we will stop asking you to complete them. You can still take part in the research if you stop these, and you can change your mind later and start completing them again, if you want.
- If you decide to stop research follow up visits or assessments, to make sure the research is still reliable, we will need to keep the information we have already collected about you and include it in the research analysis.

An important aim of the research is to find out how many participants complete their treatment and how people get on if they withdraw from treatment. For this reason, your data and samples would remain on file and be included in the final research analysis.

Finally, we may be legally required to collect information about any side-effects you have following your research treatment, even if you have told us you did not want to provide further data for the research. We will collect this information from your healthcare team, you will not have to attend any additional visits in order for us to do this.

What will happen to any samples I give?

Blood and tissue samples you agree to have taken or collected for the research will be sent to the study research laboratories. These will be labelled with your research number and a local laboratory number; they will not contain your name and address. These samples will be used to increase our understanding of which patients respond to treatment and the underlying reasons for different responses to treatment.

All samples will be sent to the laboratories using your hospital's standard processes or by a courier. When your samples are sent to the laboratories for further tests, there may be some of your samples left over once all the tests have been done. We will ask your permission to keep any of these left-over samples in storage so that they may be used for future cancer research. Any future research projects asking to use your samples will firstly need to be

approved by an ethics committee. If you do not consent to your samples being stored and used for future research, blood samples will be destroyed at the end of this research. Your cancer tissue samples will be sent back to your local hospital for storage.

Who has organised, reviewed and funded the research?

The FOxTROT research was developed by the National Cancer Research Institute's Colorectal Cancer Clinical Studies Group. The FOxTROT 5 research is being funded by the company GlaxoSmithKline PLC (GSK), who will also provide the dostarlimab drug. GSK is not involved in the day-to-day running of the research, and the responsibility for making decisions about the research design and how it is run will always remain with the doctors, statisticians, and research experts.

University of Leeds is the Sponsor and has reviewed and approved this research and will be responsible for the management and conduct of the whole research. The day-to-day running of this research will be carried out by the Clinical Trials Research Unit (CTRU) at the University of Leeds.

All research in the NHS is reviewed by an independent group of people called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This research has been reviewed and given a favourable opinion by a Research Ethics Committee. The project has also received approval by the Health Research Authority (HRA) and Medicines and Healthcare products Regulatory Agency (MHRA).

The Chief Investigator of all the FOxTROT research is Professor Jenny Seligmann (Consultant Medical Oncologist) who is based at St James's University Hospital, Leeds. The Medical Lead of FOxTROT 5 is Professor Campbell Roxburgh (Consultant Surgeon) who is based at the Glasgow Royal Infirmary.

What if I have a concern or complaint?

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 research, the normal National Health Service complaints mechanisms are available to you. Your healthcare team will give you further information if necessary. If you are unhappy about anything to do with this research and wish to complain formally, you can do this at the Patient Advice and Liaison Service (PALS). You can find your nearest PALS office on the NHS Choices website: http://www.nhs.uk/Service-Search/Patient-advice-and-liaison-services-(PALS)/LocationSearch/363. You can also ask your GP surgery, hospital, or phone NHS 111 for details of your nearest PALS.

Part 2: More about how your information will be used

This optional extra section of the participant information gives more detail about how your information will be used if you agree to take part in this study. It is in the same order as the quick access guide in the main participant information sheet, so that you can easily find what you need. If you have questions or concerns after reading the quick access guide, you should look at this optional appendix, or the sections of it that interest you.

If you still have questions after reading this supplementary information, or would like more detail about anything, you should look through our **comprehensive guide** to how your information is used. You do not have to read it before taking part in this study, but you might want to look at specific sections if you have particular concerns. It is available at https://ctru.leeds.ac.uk/ctru-comprehensive-privacy-guide/ or you can ask for a printed copy from your study doctor or nurse. This can also be made available in large print or other formats, if you need them.

1. What information will be collected, and what will it be used for?

If you agree to take part in this study, we will need to collect and use some information about you and your health. We will only use what we need to run the study, to produce the results of the study and to make sure you and other people taking part in the study are safe.

This research is in the public interest, which means our results will be used to improve the healthcare of patients in the future. Because of this, if you agree to take part in the study, we will be able to use information about you, including sensitive information about your health, ethnicity, and your genetic characteristics (this means information about your DNA from biological samples you will have given).

Specifically, the ways we will use information about you are:

- We will use information from you and your medical notes to run the study, to produce the study results and to confirm it is safe and appropriate for you to join the study. We will also collect information about your health from your study doctor or nurse and your medical notes to help make sure you and others are safe.
- We will collect a copy of your signed consent form so that we can be sure you have agreed to take part in the study.
- We will collect information about you and your health directly from you on study questionnaires. We will use this information to produce the study results.
- We will collect information about you held in NHS databases managed by NHS Digital**.** To do this, we will securely send a limited amount of your identifiable data (for example, initials, data of birth, and NHS/CHI number)**,** and they will return the information about you that we need for the study. We do this because it means we can do the study while taking up less of your time, and less of your hospital's time.
- We will collect information about biological samples **(tumour and blood)** you will give in the study. These samples will be sent to labs at the University of Leeds and University of Birmingham with **your research number.**
    - When your samples are sent to the laboratories for further tests, there may be some of your samples left over once all the tests have been done. If you agree to provide these samples for future research, they will be retained by

the study laboratories**.** If other researchers in the future want to use the samples for worthwhile research in the public interest, they will be sent the samples and your unique research number. The other researchers may also ask us for other information about you for their research (see section 5, below), but they would not be able to see who you are from the information they have, even when they combine the results of analysing your samples with the other information we share with them.

- Sometimes we need to ask doctors who work with us to give us advice on specific medical situations. To help the doctors do this, we might need to collect copies or scans of parts of your medical notes. These will have any details that could identify you removed before they are sent to us.
- In this study, we need to **check that your CT scans are being recorded consistently.** In order to do this, we will need to collect **the scan images.** CT scans collected during the course of the research will be provided to Leeds Teaching Hospital Trust (LTHT) labelled with your name, date of birth, NHS/CHI number, the date of the CT scan and hospital name. The purpose of collecting this data along with the scan, is so that we can be sure the CT scan being reviewed is for you and of the correct date. This data will be provided by a secure and encrypted method and once received at LTHT the scan will be pseudonymised – this means your personal identifiers will be removed and your CT scan will be saved with only your research number. The pseudonymised scans will be stored within the NHS and the University of Leeds.

If you want to find out more about any of these, please refer to the **comprehensive guide** to how your information is used.

2. Who is collecting my information?

Your information will be collected by the Clinical Trials Research Unit within the Leeds Institute of Clinical Trials Research, University of Leeds. You can find out more about our work at https://ctru.leeds.ac.uk/.

University of Leeds has overall responsibility for what information is collected, how it is collected, and making sure people's information is used securely and correctly. If you want to contact someone within the University about how your information has been or will be used, you can see section 9, below. See the **comprehensive guide** for more about what this means for you.

We will make sure we follow the principles of data protection in everything we do. This means we will keep your information secure, keep it only for as long as we need it, only use the minimum information we need for specific, necessary purposes, and we will be open, transparent and fair with you about how we use your information. You can find out more about how we follow the principles of data protection in the **comprehensive guide.**

3. Will my information be kept secure?

We will take all necessary measures to ensure that information about you is sent and stored securely by us or by anyone acting on our behalf.

Your study doctor or nurse will enter most of the information needed for the study directly into our secure study database. You will be allocated a research number, which will be used along with your date of birth and initials to identify you on each form. Your study doctor or nurse may also send us some information by post – this could include your consent form.

Sometimes we will also get information about you by email. Emails will never contain your name, only your study identifying number and sometimes your initials and date of birth.

Finally, some particularly sensitive documents, such as **the consent form** may be sent to us via a 'secure file transfer'. This means information is sent by the internet in a very secure way.

Information stored in our databases or other electronic storage locations is held very securely, in a way that would make it very difficult for any unauthorised people to access it.

4. Who will see my information in the research team?

We will make sure that the only people at the University of Leeds who can see your information are people who need to run or analyse the study.

See **Section A** of the information sheet for more on who may see your medical notes and other confidential information if you agree to take part in this study.

5. Who else will see my information?

There are some specific situations where we need to share information with other people or other organisations. We will always do this carefully and only when it's really necessary. We will avoid sharing information that could identify you whenever possible. We will never sell your information, or pass it on to people who will sell it. We will only share information when it is necessary for the study, necessary to protect your safety or the safety of others, or in the public interest. Information we share will not be used to make decisions about future services available to you, such as insurance.
We will share your information for the following reasons. You can find out more about these in the **comprehensive guide.**

- To run and analyse parts of the study, we need to share your information with collaborators (such as doctors, statisticians or other experts) outside the University of Leeds.
- To keep you and other people safe, we will need to share some information about health-related events you may have with authorised organisations. None of these organisations will be able to identify you from this information.
- To report to authorised people about the progress of the study, we will need to share some basic information with some authorised organisations, including the Research Ethics Committee that has approved this study. None of these organisations will be able to identify you from this information.
- To allow other researchers to carry out future research in the public interest. We will only share your information for worthwhile research with all appropriate

approvals. We will only share your information in such a way that researchers outside the University of Leeds will not be able to identify you. Your information will not be shared if you have explicitly said you did not want this to happen.

- We may also use study information for additional research projects within the University of Leeds. We will only agree to do this for worthwhile projects with all appropriate approvals, and we will not share any clearly identifiable information with researchers outside the original study team.
- Due to storage space limitations, we will store information securely away from the University of Leeds for a period after the main part of the study is over. The archiving companies we use to do this for us will only store your information and will not access it or see your details.

See **Section A** of the information sheet for more on who may see your medical notes and other confidential information if you agree to take part in this study.

6. Can I see my information, or ask you to correct it?

Usually, when an organisation or a company has information about you, you can ask to have access to that information at any time, or ask them to correct it if it needs correcting. However, this does not apply in the same way to information used for research in the public interest, because allowing people to access or change their information could harm the quality of the research. You therefore cannot ask to access or correct information we have about you. However, most of the information we will collect will also be in your medical notes, which you can get access to if you want to. You should speak to your study doctor and nurse if you would like more information about care you have received.

7. How long will my information be stored for?

If you agree to take part in this study, we will need to keep your information for at least **25 years** after the end of the study. We need to do this in order to comply with laws and other rules about research, which say it must be possible to check the results of the research for a period of time after it has finished. We will keep your information secure during all this time. For practical reasons, we may ask reputable archiving companies to store information securely on our behalf, away from the University of Leeds.

At the end of this period, we will securely destroy your information.

8. What will happen if I stop taking part in the study?

If you decide you would like to stop all your study visits for any reason, we will need to keep the information we have about you to make sure the results of the study are reliable.

Usually, when an organisation or a company has information about you, you can ask them to delete it, or not use it for a certain purpose. However, this does not apply in the same way to information used for research, because it would harm the quality of the research if people could delete or remove their information. We also need to comply

with laws and other rules about research that say we need to keep all information used in research for a period of time after the research finishes. If you agree to take part in this study, it will therefore not be possible for us to remove or delete your information later on, although you can ask us to collect no further information after a given time.

Some other things you should know about what will happen to your information if you stop taking part:

- If you stop all study visits, you should discuss with your study doctor and nurse. If you still occasionally go to your hospital for routine visits, we would like to hear from your study doctor or nurse about these visits, if they are relevant to this study. This way, you can still contribute to the study and help make the study results more reliable, without giving any more of your time. However, you can tell your study doctor or nurse that you do not want any more information sent to us, and they will make sure your wishes are respected.
- If you tell us you do not want us to collect any more information about you, we will still be legally required to collect information about any serious side-effects you experience, or health events that might be related to the treatment you have received. This is so that doctors using the same treatment have all the information they need about possible side-effects.
- If you stop attending your study visits without telling anyone at your hospital, or you change your contact details or move house and do not tell your hospital, they will lose contact with you. If this happens, we may ask your study doctor or nurse to contact your GP to check if you are OK and still happy to take part in the study.

If you want to know more about what might happen to your information if you stop taking part in the study, including *why* we need to use your information in the ways we do, please see the **comprehensive guide.**

9. What if I have concerns about how my information is being used?

Your study doctor or nurse should be your first contact for any questions about your participation in this study. If you still have questions that they cannot answer, and which are not answered by any of these documents, you can contact the University of Leeds Data Protection Officer (the University's main contact for anything to do with how your information is used, https://dataprotection.leeds.ac.uk/). You can do this using any of the details below. If you do contact them, please mention the name of this study 'FOxTROT 5' and the Clinical Trials Research Unit.

- Email: DPO@leeds.ac.uk
- Telephone number: +44 (0)113 343 7641
- Postal address for data protection issues: University of Leeds, Room 11.72 EC Stoner Building, Leeds, LS2 9JT

If you are not happy with the response to any queries or complaints, or believe your information is being used incorrectly or unlawfully, you should contact the Information Commissioner's Office:

- General website: https://ico.org.uk/
- ICO contact webpage: https://ico.org.uk/global/contact-us
- Telephone number: 0303 123 1113

- Postal address: Information Commissioner’s Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF