

ACCEPT***ACCEPT – Pregnancy Information Sheet***

A phase Ib/II combination trial of acalabrutinib with rituximab, cyclophosphamide, doxorubicin, vincristine and prednisolone (R-CHOP) for patients with diffuse large B-cell lymphoma (DLBCL).

Why have I been approached?

You or your partner are or were participating in a clinical trial for treatment of cancer called the ACCEPT Trial. As you are pregnant and the effects of the study treatment are unknown on pregnancies and their outcomes, we would like to follow your pregnancy and collect medical information about your pregnancy and its outcomes. Please read further regarding how this information will be collected and what is involved.

Do I have to agree to be followed-up?

If you decide to take part in this follow-up you are still free to withdraw at any time without giving a reason. If you decide not to participate in this follow-up your ante-natal and post-natal care will not be adversely affected. This will also not affect your or your partner's continued participation in this study or future studies.

What will happen to me if I agree for my pregnancy to be followed up?

If you choose to take part in this follow-up, you will be asked to meet with a study doctor or nurse to give information related to the progress of your pregnancy and again when the outcome of the pregnancy is known. This may include information related to the date your pregnancy was confirmed, expected delivery date, the outcome of your pregnancy and the health of your child at birth.

How will my pregnancy information be used and disclosed?

In compliance with the requirements of the study noted above, you or your partner has informed the study doctor that you are pregnant. Regulatory agencies recommend that information be collected about pregnancy in women; women who are pregnant or become pregnant while they or their partner are participating in a clinical trial. You are therefore invited to participate in an important safety monitoring activity. This may help to understand the effects, if any, that the trial drugs may have or have had on your pregnancy or your unborn child. We would also like to collect information as to whether the pregnancy went to term or not. Although the study doctor will collect information about your pregnancy and outcome, the study doctor will not be responsible for any expenses related to this pregnancy.

Will my taking part in the pregnancy follow-up be kept confidential?

Yes. The University Hospital Southampton NHS Foundation Trust is the sponsor for this study. The Southampton Clinical Trials Unit (SCTU) manage the trial on their behalf. The SCTU will use information about you and the outcome of your pregnancy as part of the study they are conducting and will act as the data controller for the study. This means that SCTU are responsible for looking after your information and using it properly. University Hospital Southampton NHS Foundation Trust will keep identifiable information about you for 25 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the follow up, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at <https://www.southampton.ac.uk/ctu/about/index.page>

[Insert name of NHS site] will collect information from you and your medical records about your pregnancy outcome for this research study in accordance with our instructions.

[Insert name of NHS site] will keep your contact details confidential and will not pass this information to the Southampton Clinical Trials Unit (SCTU). [Insert name of NHS site] will use this information as needed, to contact you about your pregnancy, and make sure that relevant information about the outcome of your pregnancy is recorded for your care, and to oversee the quality of the study. Certain individuals from the Southampton Clinical Trials Unit (SCTU) and regulatory organisations may look at your medical records to check the accuracy of the research study. The people who analyse the information will not be able to identify you and will not be able to find out your name, or contact details.

[Insert name of NHS site] will keep identifiable information about you from this study for 25 years after the study has finished.

You can be assured that any data collected about your pregnancy and the outcome of the pregnancy published will not identify you personally. Your medical records will only be available to the research doctors, your hospital consultant, responsible individuals from the Sponsor or sponsor delegates from the Southampton Clinical Trials Unit, and regulatory authorities. Information collected relating to your pregnancy will be held on the trial specific database located on servers within or outside of the European Economic Area. Trial Sponsor (University Hospital Southampton NHS Foundation Trust) is responsible for ensuring compliance with current data protection regulations and the protection of your privacy.

Access to non-identifiable data, managed by the Southampton Clinical Trials Unit, held on servers located in the EU and USA, will be strictly controlled. At the end of the trial the non-identifiable data that has been collected will be archived and held securely for up to 25 years.

Right to withdraw authorisation to release information

Your participation is voluntary and you are free to withdraw your authorisation at any time by informing the study doctor. If you revoke your authorisation the study doctor will not collect any new health information about you or your child. Refusal to participate in this safety monitoring activity will not adversely affect your ante-natal and post-natal care or you or your partner's continued participation in this study or future studies.

Who is organising and funding this research?

The trial that you or your partner is participating in is being coordinated by Southampton Clinical Trials Unit. The trial is being funded by Acerta Pharma with endorsement from Cancer Research UK. The trial drugs are being provided free of charge by Acerta Pharma. None of the doctors or other staff conducting the research are being paid directly for recruiting patients into the study.

Who has reviewed this study?

The clinical study that you or your partner is participating in has been reviewed by number of medical specialists during its development, the National Cancer Research Institute Clinical Studies Group, Cancer Research UK and Acerta Pharma. The study has been reviewed and approved by the, Medicines and Healthcare Regulatory Authority (MHRA), Local Research and Development Department and the Research Ethics Committee to confirm that this study considered the patients' rights and protection of patients' health.

If I would like to take part, what do I need to do?

If you sign the ACCEPT Pregnancy Informed Consent Form, you are giving permission for the study team to undertake pregnancy follow-up with you for the purposes of the safety monitoring activity. You do not have to give this permission. Your original consent form will be filed at the hospital securely and kept separate from any non-identifiable information, a copy provided to you and a copy will be sent to the Southampton Clinical Trials Unit (SCTU) via secure e-mail and held securely. At the end of the trial the original consent form will be archived by the hospital who took the consent for a period of 25 years and will be stored separately from any non-identifiable information provided. The copy sent to the SCTU will be destroyed as confidential waste prior to the trial being archived.

Contact for further information

If you have further questions about taking part, please discuss them with you or your partner's doctor or nurse.

If you would like independent advice of further information you may also find it useful to contact Macmillan Cancer Support, an independent patient advisory group (Freephone 0808 808 0000; address: 89 Albert Embankment, London, SE1 7UQ or the Cancer Research UK website (<http://www.cancerresearchuk.org>)).

If during the course of your participation you have any questions or would like further information before making your decision please contact:

Doctor: [insert local information here]

Name: [insert local information here]

Telephone Number [insert local information here]

Research Nurse: [insert local information here]

Name: [insert local information here]

Telephone number: [insert local information here]

If you find the wording difficult to understand or would like us to explain things to you once more, please feel free to ask you or your partners doctor or nurse.

Thank you for taking the time to read this information sheet. If you wish to take part you will be given a copy of this information sheet and a signed consent form to keep.