Investigator: Dr Emer MacSweeney

Centre number: 2501

Contact for queries

If you have any questions about this study, you can contact:

Daytime: Re:Cognition Health – London on

+44 (0) 20 3355 3536

Out of hours: Dr Emer MacSweeney on

+44 (0) 7540 802222

Re:Cognition Health - London

45 Queen Anne Street

London

W1G 9JF

United Kingdom

COLLECTION OF DATA FROM PREGNANT FEMALE PARTNERS OF MALE PATIENTS PARTICIPATING IN A RESEARCH STUDY WITH REMIBRUTINIB/ TERIFLUNOMIDE

You are asked

… to provide pregnancy information because you have become pregnant while your partner was / is taking part in a research study with remibrutinib and teriflunomide. This information sheet is to let you know about the information that Novartis would like to collect about your pregnancy.

This Information Sheet is in two sections:

- questions and answers
- a Consent Form

Please take as much time as you need to read it carefully. Discuss it with your family, friends and GP if you wish, before making up your mind. If anything in this Information Sheet and Consent Form is not clear, or if you have more questions, please ask the doctor who gave it to you.

About the information

Novartis would like to collect pregnancy information from females who become pregnant while their male partners are taking part in a clinical trial that may include a Novartis drug.

The risks associated with an unborn foetus from the medications taken in the research study are unknown.

Your participation is voluntary (up to you). If you decide to stop participating it will not change you or your baby's medical care. If you decide not to take part in this safety monitoring, it will not affect your partner's continued participation in this study or future Novartis studies.

You are being asked to provide information relating to your pregnancy and its outcome for the purposes set out in this Information Sheet.

QUESTIONS AND ANSWERS

1 *What is the purpose of providing pregnancy information?*

We are asking you to provide information (personal data) concerning your pregnancy and its outcome. Only information relating to your pregnancy and the outcome will be collected.

The information you provide will be collected by Novartis, the sponsor of the clinical trial your partner is taking part in. This information may help Novartis: (i) to understand the effect that a study drug can have on a pregnancy; (ii) to identify risks and side effects related to the study drugs and pregnancy; and (iii) to help doctors and other healthcare professionals provide advice to women who become pregnant of associated risks and side effects in the future.

Novartis acts as the data controller as it independently determines why and how the personal data collected is used.

2 *What are the risks to my unborn baby?*

As with any new drug, the risk to the unborn foetus is unknown. By collecting information from pregnant women, this may help doctors or other health care professionals advise pregnant mothers in the future.

You will not be paid or reimbursed for providing your information.

3 *Do I have to provide my information?*

No — your agreement to provide information on your pregnancy and its outcome is voluntary.

If you do decide to provide this information, you will be given a copy of the Information Sheet and Consent Form that you will be asked to sign.

You are free to change your mind at any time, with or without giving a reason. Should you choose to change your mind, no further information will be collected. However, the information collected prior to this will continue to be used in future analyses of the data for the study drug.

You are free to discuss this information sheet and consent form with your partner, family, friends or own doctor before making a decision.

4 *Personal Pregnancy Follow-up Data*

Your partner's study doctor will only collect limited personal data about you and your baby. The personal data obtained about your pregnancy and your baby's health (if appropriate) will remain confidential to the extent provided by law.

The people listed below are trained to keep data confidential. They ensure that the data collection was run properly and make sure that this data is correct:

What is personal data?	**Who can see it?**
Some examples include: You and your baby's name, full date of birth, sex You and your baby's address and phone number	The study doctor/study staff Institutional Review Boards/Ethics Committees who are responsible for protecting participants' rights A few people authorised by the sponsor (such as the sponsor's study monitors and auditors) who

You and your baby's health information Images (such as X-rays, Scan results photographs).	need to check that all of the data is correct. The study monitors may review your data from a location other than the study site. Vendors (people who work on the study for the sponsor, such as Contract Research Organisations) An entity acquiring the sponsor or part of its business Health Authorities (government groups who make sure that clinical studies are conducted according to established quality and safety standards)

All of thesethe people are trained to keep your data confidential. They use your personal data to ensure the study was run properly and make sure these data are correct. Your "Personal Data" will be kept confidential at the Study Site.

5 *Coded Pregnancy Follow-up Data*

The study doctor will replace the parts of the "Personal Pregnancy Follow-Up Data" above that can identify you or your baby, such as names and addresses with your partner's study Participant ID. This ensures that the information about you or your baby becomes "Coded Pregnancy Follow-up Data". By using Coded Pregnancy Follow-up Data it is very unlikely that anyone other than the study doctor and study staff can identify you or your baby. Your and your baby's Personal and Coded Pregnancy Follow-up Data will not be used for further purposes than as described in this consent form. However, your or your baby's Coded Pregnancy Follow-up Data may be disclosed to the following people, organisations or agencies:

What is Coded pregnancy follow-up data?	**Who can see it?**
Some examples may include: Your age and your baby's sex and age The data and images collected where information that can identify you and your baby have been replaced by your partners' Participant ID.	The study doctor/study staff Ethics Committees or Institutional Review Boards The sponsor and their staff The sponsor's collaborators and partners (such as researchers who work with the sponsor or commercial partners and staff at scientific journals) Vendors (see examples in previous table) Health Authorities' employees located in different countries around the world. Another company potentially buying the sponsor or part of the sponsors business

You will **not** be notified every time the Coded Data is used or shared.

The Sponsor keeps your and your baby's coded follow-up pregnancy data to comply with its legal and safety obligations of monitoring any effects of your partner's use of study treatment on your pregnancy and the health of your baby. The Sponsor may submit the coded follow-up

pregnancy data to the Health Authorities. This coded data will also help the Sponsor to continue to enhance the safety profile of its treatments. Your and your baby's coded follow up pregnancy data cannot be used to contact you or affect other decisions about your life.

The people/organisations listed in the table above may be located in countries outside of the United Kingdom ("UK"), but during the transfer, the Sponsor will ensure the protection and privacy of the pregnancy follow-up Coded Data as required by law. Pregnancy follow-up Personal data may be transferred outside of the UK, where data protection laws may not be as strict as your home country. If we transfer your pregnancy follow-up personal data to overseas jurisdictions, where required, we will put in place appropriate measures to protect your personal data by: (i) applying the level of protection required under the local data protection/privacy laws applicable; and (ii) acting in accordance with our policies and standards.

If you wish to request additional information in relation to international transfers of personal data and/or obtain a copy of the adequate safeguard put in place, please contact privacy_uk.ireland@novartis.com.

By law, the Sponsor must keep all pregnancy follow-up data for at least 25 years after study completion.

Subject to laws and regulations, you have the right to:

- Review, correct certain pregnancy follow-up data, and obtain a copy at the end of the study
- Get the pregnancy follow-up data you provided in a standard electronic format (the law calls it right of portability)
- Oppose the use of the pregnancy follow-up data if appropriately justified
- Withdraw your consent to collect and use the pregnancy follow-up data
- Lodge a complaint with the Information Commissioner's Office

It is not possible to erase you or your baby's Personal or Coded pregnancy follow-up data which has already been collected as the pregnancy follow-up data needs to be complete, correct, and available for Health Authority purposes. Please remember that the Sponsor does not keep Personal pregnancy follow-up data. The Sponsor only keeps the Coded pregnancy follow-up data. If you wish to exercise any rights regarding Personal pregnancy follow-up data, you should contact your Study Doctor.

For any queries related to Coded pregnancy follow-up data, you can contact the Study Doctor/site staff.

6 *What will happen if I choose to stop participating in this monitoring?*

Your participation is voluntary (up to you). If you provide access to you and your baby's medical information, you are free to change your mind at any time by informing the study doctor in writing at the contact address provided. The study doctor will not collect any new health information about you or your baby from that point onwards. However, Novartis and its representatives may continue to use and disclose any information already collected. If you decide to stop participating it will not change you or your baby's medical care. If you decide not to take part in this safety monitoring, it will not affect your partner's continued participation in this study or future Novartis studies.

Your signature below means, that you agree to have the study doctor contact you during your pregnancy and after the birth of your baby to ask about the health of your baby.

If you have any further questions about this monitoring or your rights, you may contact Dr Emer MacSweeney, +44 (0) 20 3355 3536.

7 *What rights do I have over my personal data?*

You may ask to review your personal data. However, during the study, access to the personal data may be limited to protect the integrity of the study. You may have access to your personal data at the end of the study.

You should ask the study doctor if you have any questions about the collection and use of information.

Subject to laws and regulations, you have the right to:

- Review and correct certain pregnancy follow-up data, and obtain a copy of it at the end of the study
- Get the pregnancy follow-up data you provided in a standard electronic format (referred to as the right of portability)
- Oppose the use of the pregnancy follow-up data if appropriately justified

It is not possible to erase your or your baby's Personal or Coded pregnancy follow-up data which has already been collected as this data needs to be complete, correct and available for Health Authority purposes. Please remember that the sponsor does not keep Personal Pregnancy Follow-up Data. The sponsor only keeps the Coded Pregnancy Follow-up Data. If you wish to exercise any rights regarding the Personal Pregnancy Follow-up Data, you should contact the study doctor.

For any queries related to the Coded Pregnancy Follow-up Data, you can contact the study doctor/site staff.

In any case, you may also lodge a complaint with the Information Commissioners Office (ICO).

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CONSENT FORM

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Please initial the boxes below to confirm that you have read, understood and agreed each numbered point.

1	I have read and understood this Information Sheet and Consent Form version 02.01.02 dated 05-Sep-2022. I have had the time to consider it and the opportunity to ask questions.	1
2	I understand that providing my data is voluntary and that I am free to change my mind any time, without giving any reason, and without my medical care or legal rights being affected.	2
3	I have read and understood the information on the use of my and my baby's Personal and Coded pregnancy follow-up data as described in this document.	3
4	I agree that my and my baby's confidential medical records can be accessed for the study. I also agree to the study doctor contacting my GP for this information.	4

When you have initialled the boxes above, please complete the first box below (including the date) yourself:

Name of partner (CAPITALS):	Signature:	Date:
Name of doctor taking consent (BLOCK CAPITALS):	Signature:	Date:

Partner initials: _____

Original to be kept in the study Investigator Folder; Second original or a copy of the original to be given to the patient. The Information Sheet and Consent Form are one entire document and must not be separated