

PREGNANCY IN CLINICAL STUDY INFORMED CONSENT FORM

A Phase 4, Open-Label Study to Evaluate Safety of Amivantamab in Combination With Chemotherapy in Indian patients with Locally Advanced or Metastatic Non-Small Cell Lung Cancer with EGFR Exon 19 del or Exon 21 L858R Mutations After Progression on Osimertinib

Study ID: 61186372NSC4018

Doctor Prashant Pandey is conducting this study, which is sponsored by

JOHNSON & JOHNSON PRIVATE LIMITED, HIGI House, LBS Marg, Mulund (West), Mumbai – 400080, a pharmaceutical company.

You are being asked to share medical information about your pregnancy and the outcome with the clinical staff and the sponsor. If you agree, the clinical staff will request this information from the doctor(s)/gynecologist, and/or the child's pediatrician after birth. This form explains what is involved if you agree to share this information.

Here are a few things to know:

- Sharing this medical information is entirely voluntary and is not part of routine medical care for the pregnancy nor the baby.
- Take your time to read this Informed Consent Form (ICF) carefully so that you understand why this is being requested and what it involves.
- Discuss this with your doctors, medical professionals, family, and friends.
- Ask questions to the clinical staff at the study site and request any additional information.
- Your participation does not enroll you in the research study.
- By participating, you will not get medical advice or treatment for pregnancy nor the baby (before or after birth). You should continue to see your own doctor(s).
- You are free to decide to share your/your baby's medical information or not and if you agree now, you can change your mind at any time. Whether or not you share it is up to you. Whatever choice you make, you will not lose access to the medical care you already receive, gain any penalty or give up any of your existing rights or benefits.

Thank you for taking the time to consider providing this information.

The sponsor may share sensitive company information with you to help you decide about sharing your/your baby's medical information. We kindly ask that you consider this when discussing details about the study with people other than your healthcare provider(s), family, and friends, or when using social media.

YOUR CONTACTS

Study sponsor Johnson & Johnson Private Limited	Represented by Johnson & Johnson Private Limited HIGI House, LBS Marg Mulund (West), Mumbai - 400080
Investigator's name: Dr. Prashant Pandey Address: TATA Medical Center, 14, MAR (E -W) New Town, Rajarhat, Kolkata-700160 Contact Number: +91-9804290687	
Independent Ethics Committee/Institutional Review Board (IEC/IRB) Contact: Dr. Indranil Mallick Clinician & Member Secretary Landline: 033 6605 7103/7447 IRB/IEC Name: Institutional Review Board TATA Medical Center, 14, MAR (E -W) New Town, Rajarhat, Kolkata - 700160	

OVERVIEW AND GENERAL INFORMATION

Why am I being asked to share information about my pregnancy and outcome?

We are asking for this information because your partner, the biological parent of your unborn baby, is (or was) participating in a clinical research study. They took an experimental drug called "amivantamab " which is being developed as a possible treatment for locally advanced or metastatic non-small cell lung cancer.

Since amivantamab is an experimental drug, researchers know little about its effects on pregnancy and the unborn baby or a nursing baby. So, the sponsor would like to collect information from you to learn more about amivantamab, and any possible effect it may have in this circumstance.

We will collect information about your pregnancy outcome and your baby's health for up to approximately 1 year after delivery.

WHAT ARE THE BENEFITS OF AGREEING TO SHARE THIS INFORMATION?

There is no direct benefit to you or the baby, but by sharing this information, you may help future patients who need to take this medicine.

You can change your mind about sharing this information at any time by telling the clinical staff. Please note that any information collected before you change your mind, will continue to be used by the sponsor. If you do not agree to share this information, it will not affect your partner's participation in the study. Please note that you will not receive any payment for sharing this information. There will be no costs to you but all your pregnancy-related expenses will be covered by you, your insurance, or a government health scheme as standard practice.

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Master Pregnancy in Clinical Study ICF Version Date: 04 May 2026 , ICF Version Number: 2.0

Site Pregnancy in Clinical Study ICF Version Date: 17-June-2026 , ICF Version Number: 2.1.0

PI : Dr. Prashant Pandey, Site: TMC, Kolkata

Back Translated from Hindi to English on 29 Jun 2026

HOW WILL PRIVACY BE PROTECTED?

The study staff and sponsor will manage your personal data (including information about your child) in compliance with applicable Indian data protection and privacy laws and in the manner described in this consent form. The "Privacy Appendix" in this document describes your rights about the use and protection of your personal data.

PRIVACY APPENDIX TO PREGNANCY INFORMED CONSENT

The sponsor and his representatives will use the information collected about your child for study purposes and for scientific research, such as study of your child's disease and genetic research [if applicable]. The sponsor and his representatives may also use this information to apply for permission to sell the drug in some countries. The information will be stored both on paper and on computer. To protect your privacy, the information will be labeled in a way that will not identify your child. If the study results are published your identity is kept confidential. By signing this form, you are permitting this use of your child's information.

Your study doctor will keep your child's personal medical records and a list that links each patient's name to his/her code number for at least 15 years.

Regulatory authorities, members of the ethics committee/institutional review board, employees at the study site, and representatives of the sponsor will have access to this list and be able to compare and check the study information collected about your child with the information in your child's medical records. As far as the law allows, your child's medical records will not be made public. By signing this form, you are allowing direct access to your child's medical records by those who have legitimate reason to look them.

The information collected may be sent to other members of the Johnson & Johnson group of companies, to contractors working for them, and to regulatory authorities.

You can arrange with your child's study doctor to see the information collected about your child, and you can ask for any mistakes to be corrected. The sponsor and his representatives may postpone your access to your child's information if it would interfere with the study itself. If you decide to leave from the study at any time, the sponsor and his representatives may still use the information collected about your child up to that point, if the law allows.

Medical Record – Information and data, including personal details, recorded by the clinical staff; stays on site.

Study Record - Medical record data from the study participant, pregnant partner, and child (without personal identifiers), which has been documented by the clinical staff and shared with the sponsor.

1. What personal data will the clinical staff collect?

If you agree, the clinical staff will collect and share your and your child's personal data for research purposes. **Personal data** may include:

- Information about your and your child's health. This may include medical images and written descriptions (including records about phone calls, visits, and examinations).
- Direct personal identifiers such as your and your child's name, initials, date of birth, address,
- Other sensitive data such as racial or ethnic origin, sex assigned at birth, gender identity, lifestyle, religious or philosophical beliefs, sexual behaviors or sexual orientation, are collected only when necessary to evaluate the study results.

2. Who will have access to my and/or my child's medical record?

Your and your child's medical records will be stored in paper files and electronic databases, including those that may be accessed remotely (if permitted in your country). The clinical staff will have access to your and your child's medical record. In addition, the people below may have direct access to your and your child's personal data (to ensure that the research study is being conducted properly).

- Monitors and auditors from the sponsor or the sponsor's representatives.
- The Institutional Review Board (IRB) or Independent Ethics Committee (IEC) (a group of people who review research studies to protect the rights and welfare of people participating in research).
- Regulatory authorities; local and outside your country.
- Other persons or groups, as required by law, who may be located outside of your country. The laws in other countries may have a different level of protection for your information.

3. How will my and my child's personal data be protected?

The clinical staff will also record information from you and your child's medical records into the **Study Record**. These data are provided to the sponsor for study purposes. This will only be identified by the study number and participant number. Direct personal identifiers such as your or your child's name, initials, date of birth will not be included in the Study Record. The clinical staff can match Study Record to your name, but this information will be kept confidential and will not be shared with the sponsor or anyone else, except where required by law.

4. How will my and my child's Study Record be used and shared?

The sponsor and other authorized parties described in this consent form will use and share your and your child's Study Record for scientific research and compatible research purposes such as:

- Evaluate and understand the study drug, the disease and associated health problems,
- Advance clinical science and medical knowledge.

Authorized parties may include organizations providing services for the sponsor (such as laboratories), researchers, collaborators, and companies who may share an interest in the study drug or disease.

The sponsor, other authorized parties, and Regulatory Authorities may be located outside of your country, where the laws may provide a different level of protection.

5. Data transfer

As required by applicable laws, there are safeguards in place to protect your and your child's personal data when it is transferred outside of your country. This also applies to people who have remote access to your and your child's data as well as when this is shared as described above.

6. How long will my and my child's personal data be kept?

According to local laws and requirements, clinical staff will retain your and your child's medical records at the site. The sponsor may retain your and your child's **Study Record** for as long as required in accordance with applicable laws.

7. What rights do I have concerning my and my child's personal data?

If you would like to review, correct, delete personal data, or make other requests in accordance with the laws in your country, you should contact the clinical staff

Name: **Dr. Prashant Pandey**

Contact details: **+91-9804290687**

You may not be able to review your data until after the end of the study. Your request to delete your personal data may not be allowed depending on regulations and laws that require clinical research and personal data to be retained.

YOUR CONSENT TO PARTICIPATE

If you consent (agree), please read and then sign below.

- I have read the information provided in this consent form (or it has been read to me).
- All my questions about sharing my and my child's health information have been answered to my satisfaction.
- By signing this form, I have not given up of my or my child's legal rights.
- I consent to share my and my child's health information with the study doctor for use by the sponsor for the research described in this form.
- I understand sharing this information is voluntary and I can change my mind at any time.
- I agree to the processing and transfer of my data as described in this consent form.
- I understand my rights and that I can withdraw at any time.

Signature (or Thumb impression) of Pregnant Partner of Male Subject/Legally Acceptable Representative:

Date: ____/ ____/ ____ (DD-MON-YYYY)

Name of Signatory: _____

Investigator's signature: _____

Date: ____/ ____/ ____ (DD-MON-YYYY)

Study investigator's name: _____

Legally Acceptable Representative

The signature of a legally acceptable representative is required below only if the male study participant's pregnant partner is a minor or an incapacitated adult. Relationship to pregnant partner MUST be included. _____

Printed Name of Legally Designated Representative, in full (if applicable)

Signature of the Legally Designated Representative _____

Date: ____/ ____/ (dd-MON-yyyy)

Relationship of Legally Designated Representative to pregnant partner of Male Study Participant:

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Master Pregnancy in Clinical Study ICF Version Date: 04 May 2026 , ICF Version Number: 2.0

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PI : Dr. Prashant Pandey, Site: TMC, Kolkata

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Impartial Witness Statement: I confirm that the information in the consent form was accurately explained to, and apparently understood by, Pregnant Partner of Male Subject, and that consent was freely given by the Pregnant Partner of Male Subject

Signature of the Witness _____

Date: ____/ ____/ ____ (DD-MON-YYYY)

Name of the Witness: _____

Copy of the duly filled Informed Consent Form shall be handed over to the Pregnant partner of male subject