Participant Informed Consent Form
And Authorization To Use And Disclosed Protected Health Information

Sponsor / Study Title:	**Argenx BV / "A WORLDWIDE PREGNANCY SAFETY STUDY TO ASSESS MATERNAL, FETAL, AND INFANT OUTCOMES FOLLOWING EXPOSURE TO EFGARTIGIMOD DURING PREGNANCY AND/OR BREASTFEEDING"**
Protocol Number:	**ARGX-113-PAC-2206**
Principal Investigator:	**Amy Miller, RPh, PharmD**
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Address:	**United BioSource Corporation** **933 Canyon Road** **Morgantown, WV 26508**

This form is for use in a research study that may involve participants who may or may not have the capacity to consent to take part in the study. When the participant cannot legally consent to take part, pronouns "you" and "your" should be read as referring to the participant rather than the person (legally authorized representative) who is signing and dating this form for the participant. In cases where the participant's representative gives consent, the participant should be informed about the study to the extent possible given his/her understanding. During the course of the study, if the participant regains the capacity to consent, informed consent will be obtained from the participant and the participant offered the ability to leave the study if desired.

INTRODUCTION

argenx BV, the study sponsor, has set up this voluntary pregnancy study to collect valuable information on pregnancies and their outcomes in those exposed to efgartigimod.

This pregnancy safety study will apply to pregnant participants who have received either Vyvgart® (efgartigimod alfa-fcab) or Vyvgart Hytrulo® (efgartigimod alfa and hyaluronidase - qvfc) – referred to as "efgartigimod" or "Vyvgart" interchangeably throughout this document.

This study is required by U.S. Food and Drug Administration (FDA) and other regulatory agencies. Argenx BV developed the study in collaboration with the regulatory agencies to assess maternal, fetal, and infant outcomes following exposure to efgartigimod within 25 days before conception or during pregnancy and breastfeeding. During the development of pharmaceutical products, pregnant women are typically excluded from clinical trials, and therefore, limited information is available on the use of efgartigimod during pregnancy. Information obtained from this study may assist healthcare providers and future pregnant women in weighing the risks and benefits of being treated with efgartigimod during pregnancy and breastfeeding. It is anticipated that approximately 265 pregnancies will be collected over the data collection period.

You are being asked to participate in this study because you have been exposed to efgartigimod during pregnancy, 25 days before conception, or your infant has been exposed to efgartigimod during breastfeeding. The health of your baby will be followed until 12 months of age. This form will explain the purpose of this study and other important information. You need to provide only your written or verbal consent to enroll in the study; therefore, we want to obtain your consent to participate. Please get in touch with the VYVGART® Pregnancy Study Coordinating Center (SCC) if you are interested in verbally consenting. This center is the central site for collecting your information.

RISKS

This is an observational pregnancy study, meaning there will be no change to your current treatment or medical care as a consequence of participating in this study. All data collected as part of this study is taken from the information that your doctor has documented in your medical notes during your regular doctor's visits and the results of any tests performed during these visits.

You or your baby have no additional medical risks when participating in this observational pregnancy study. There may be risks which are currently unknown.

Notify your health care provider right away if you become pregnant or plan to become pregnant while taking efgartigimod.

BENEFITS

There is no direct benefit for you or your baby by you volunteering to be in this study. Information learned from the study may help other people in the future.

PARTICIPATION

Your participation in this study is strictly voluntary. Choosing not to participate in the study, or leaving the study after you join will not result in any penalty or loss of benefits to which you are otherwise entitled. You will be asked to do the following if you are in this study:

- State that you want to participate in the study through written or verbal consent. If you choose to provide your consent verbally, we will need to create an audio recording of your conversation with the SCC and keep a copy of such audio recording in your participant study's files for compliance and auditing purposes.
- In addition to the Participant Informed Consent Form, the SCC will send you a Medical Information Release (MIR) form for you to sign, date, and return after you provide your informed consent. In signing and dating the MIR form, you allow the SCC to contact your doctor or other licensed medical practitioner and your baby's doctor or other licensed medical practitioner for medical information.
- Provide information to the SCC at the time of enrollment and additional information around the following timepoints:
    - Once per trimester during your pregnancy
    - Pre-natal follow-up visit at 34 weeks after conception (Obstetric health care provider will be contacted)
    - At the estimated date of delivery

- When your baby is 3, 6, 9, and 12 months of age

INFORMATION

During enrollment, the Health Care Professional (HCP) or SCC will ask you questions about your health and pregnancy and your contact information, including your address and phone number. You will also be asked to identify secondary contacts inside and outside your home. The secondary contacts must be someone who can contact you if the HCP or SCC cannot. The SCC will collect the following information:

- Any anticipated changes in the contact information you provided at enrollment
- Any changes in the status of your pregnancy
- Any changes in your health status
- Efgartigimod administration dates
- Any changes in efgartigimod treatment, if applicable, and changes in other medications
- Any pre-natal testing at the pre-natal follow up visit
- Any changes to your baby's health status

In addition, subject to your prior permission, your doctor or other licensed medical practitioner caring for you during pregnancy will be contacted at the initial pregnancy report, around 34 weeks of your pregnancy and, again, within 2 weeks of your estimated delivery date. The SCC will also contact, subject to your prior permission, your baby's doctor or other licensed medical practitioner when your baby is approximately 3, 6, 9, and 12 months old to determine if there are any changes in your baby's health status.

COMPENSATION AND STUDY-RELATED EXPENSES

Argenx BV is sponsoring the Vyvgart Pregnancy Study and is paying the SCC to conduct the study. You will not be paid for your participation in this study. There are no additional costs for your participation in this study. While you are in this study, the cost of your usual medical care, procedures, medications, and doctor visits, will continue to be billed to you or your insurance.

POSTING OF RESEARCH STUDY ON WEB

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

A description of this study will be available on the Food and Drug Administration (FDA) Women's Health Research website https://www.fda.gov/science-research/womens-health-research/list-pregnancy-exposure-registries and European Network of Centres for Pharmacoepidemiology and Pharmacovigilance website https://www.encepp.eu/encepp/studiesDatabase.jsp .

PRIVACY

Information about your health collected while you are in this study will be kept in confidence according to applicable privacy laws and regulations (for example, Health Information Portability and Accountability Act (HIPAA)). As is customary, the study's sponsor, argenx BV, may be required to provide certain safety information to the Institutional Review Board (IRB), Ethics Committee, National Health Authorities, and the FDA, including personal medical

information. There is a small risk that your and your baby's information could be improperly disclosed. This means absolute confidentiality cannot be guaranteed. Your identity will remain anonymous and confidential in any presentation of the study's results at meetings or in publications.

ALTERNATIVES TO PARTICIPATION
This research study is for research purposes only. The only alternative is to not participate in this study.

WITHDRAWAL
You may leave the study for any reason at any time. If you stop participating, the quality of your and your baby's medical care will not be affected. You and your baby will not be penalized or lose any benefits to which you and your baby are entitled. If you leave the study before your participation has ended, argenx BV will still use the information collected before your withdrawal. The request for withdrawal from the study must be made to the SCC by you or your health care provider in your name and on your behalf. The sponsor may stop the study at any time without your consent.

NEW FINDINGS
Any new important information discovered during the study that could impact your willingness to continue participating in the study will be provided to you.

WHOM TO CONTACT ABOUT THIS STUDY
During the study, if you have questions, concerns or complaints about the study such as:

- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The Study Investigator's or study site's decision to withdraw you from participation;

Please contact the Study Investigator at the telephone number listed on the first page of this consent document.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00075324.

A copy of this Participant Informed Consent Form will be mailed to you for your records. If you choose to sign and date this form and return it to the SCC, please make a copy of it for your records before mailing it.

We will also include the MIR form you must sign, date, and return in the self-addressed and pre-stamped envelope.

I do not give up any of my legal rights by signing this consent document or agreeing to participate in this study.

Signatures:

_____
Participant's Printed Name

_____ _____
Participant's Signature Date

_____
Printed Name of Legally Authorized Representative

_____ _____
Signature of Legally Authorized Representative Date

_____
Authority of Legally Authorized Representative to act on behalf of Participant

_____
Printed Name of SCC Representative

_____ _____
SCC Representative Signature Date

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide for you and your newborn child to be in this study, the Study Investigator and research team will use and share health data about you and your newborn child to conduct the study. Health data can include:

- Name
- Address
- Phone number
- Date of birth
- Medical history
- Information from your doctor visits, including test results

Health data can come from you and your newborn child's study records or existing medical records kept by you or your doctor and your newborn child's doctor or other health care workers.

The research team can share health data about you and your newborn child with authorized users. Authorized users include:

- Representatives of argenx BV
- United BioSource (UBC) / Study Coordinating Center (SCC)
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- Government agencies to which information about certain diseases (like HIV, hepatitis, and STDs) must be reported
- Governmental agencies of other countries
- Outside individuals and companies, such as laboratories and data storage companies, that need to access your information to conduct this study and work with the sponsor and researchers of this study
- Other research doctors and medical centers participating in this research, if applicable
- A teratologist (specialist in the study of malformations or serious deviations from the normal type in developing organisms), or similar subject matter expert

You and your newborn child's health data will be used to conduct and oversee the research, including for instance:

- Describe and estimate the frequency of pregnancy complications in women exposed to at least 1 dose of efgartigimod during pregnancy and/or breastfeeding and fetal and infant outcomes in infants through 1 year of age.
- Describe and estimate the frequency of adverse events affecting women and infants through 1 year of age in women exposed to at least 1 dose of efgartigimod during pregnancy or breastfeeding.

Once you and your newborn child's health data have been shared with authorized users, it may no longer be protected by federal privacy law and could be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you and your newborn child will end in 50 years unless you revoke it (take it back) sooner.

You can revoke (take back) your permission to use and share health data about you and your newborn child at any time by writing to the Study Investigator at the address listed on the first page of this form. If you do this, you and your newborn child cannot stay in this study. No new health data identifying you or your newborn child will be recorded after receiving your written request. However, health data about you and your newborn child that has already been recorded can still be used and given to others as described in this form.

You have the right to request access and/or rectify your and your newborn child's data at any time, as well as get a copy of your data from your Study Investigator. However, please note that some of your privacy rights including your right to deletion and objection to the processing of your and your newborn child's health data in the study records may be restricted to the extent necessary to ensure the integrity of the study results.

I voluntarily agree to allow study staff to collect, use, and share my and my newborn child's health data as specified in this form. I am not giving up any of my or my newborn child's legal rights by providing this authorization.

Signatures For Authorization to Use and Disclose Protected Health Information:

_____
Participant's Printed Name

_____ _____
Participant's Signature Date

_____
Printed Name of Legally Authorized Representative

_____ _____
Signature of Legally Authorized Representative Date

_____
Authority of Legally Authorized Representative to act on behalf of Participant

_____
Printed Name of SCC Representative

_____ _____
SCC Representative Signature Date