Optional Real World Data Collection Consent Form

Sponsor / Study Title:	**Janssen Research & Development, LLC / "A Phase 3, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Study to Demonstrate the Efficacy and Safety of Milvexian, an Oral Factor XIa Inhibitor, for Stroke Prevention after an Acute Ischemic Stroke or High-Risk Transient Ischemic Attack LIBREXIA-STROKE"**
Protocol Number:	**70033093STR3001**
Principal Investigator: (Study Doctor)	**Brett Cucchiara, MD**
Telephone:	**215-662-6738 General Questions** **215-349-5990 (24Hr.) Emergencies**
Address:	**Hospital Of the University of Pennsylvania** **3400 Spruce Street, 3 West Gates Building** **Philadelphia, PA 19104**

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

INTRODUCTION

You have already read and signed the main Informed Consent Form to participate in the 70033093STR3001 study ("A Phase 3, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Study to Demonstrate the Efficacy and Safety of Milvexian, an Oral Factor XIa Inhibitor, for Stroke Prevention after an Acute Ischemic Stroke or High-Risk Transient Ischemic Attack LIBREXIA-STROKE").

The purpose of this form is to tell you about Optional Real World Data Collection so you can decide if you want to participate in this data collection option. If you choose not to agree to this, it will not affect your main study participation.

ADDITIONAL STUDY INFORMATION AND OPTION TO PARTICIPATE

The following information and consent wording is in addition to the original Informed Consent form you signed and dated. All text in the original main Informed Consent Form you signed and dated remains the same.

Optional Real-World Data Collection

With your consent, limited personal data from your medical records (for example, name and birth date) may be shared with and used by Sponsor or its service providers to generate a unique string of letters and characters called a "*token*" that can be used to combine your Study Record with de-identified data sets about you from third parties. We refer to this combined data as "Tokenized Data." Tokenized Data is considered "de-identified" because we have removed information that can be used to identify you. By combining and de-identifying data from your Study Record together with, for example, clinical and claims data from third parties, this process may enable novel insights and provide opportunities to study and understand milvexian and Ischemic Stroke or Transient Ischemic Attack.

Five (5) years after the study ends (or upon withdrawal of your consent), the Sponsor will stop combining new data from third-party sources with your Tokenized Data, but the existing Tokenized Data may continue to be used for research and other purposes described in this consent form. These records will be accessed from up to Five (5) years before you started your participation in the study, and for up to Five (5) years after the study ends. To withdraw your consent to creation of Tokenized Data, please notify your study doctor.

By signing the form I agree to the use of personal data from my medical records to create Tokenized Data, including for example, Tokenized Data that combines my Study Record with de-identified clinical and claims data from third parties to better understand milvexian and Ischemic Stroke or Transient Ischemic Attack. I understand that I do not have to agree to this use of my personal data in order to participate in the Study and that I may change my mind about allowing the creation of Tokenized Data at any time.

If you agree to PARTICIPATE IN THIS DATA COLLECTION OPTION, PLEASE READ AND THEN SIGN BELOW.

If you still have questions, please ask the study doctor or study staff, **before** you sign this form.

YOUR AGREEMENT TO PARTICIPATE

- I have read this information.
- It is written in a language that I can read and understand.
- The informed consent has been explained to me.
- All of my questions about the information captured in this form have been answered to my satisfaction.
- Based on this information, I agree to the use of my personal data as described in the section **"Optional Real-World Data Collection"**

You will receive a copy of this signed and dated Informed Consent Form Addendum.

Printed Name of subject in full	
Signature of subject	Date (dd-MON-yyyy) Time (HH:MM)
Printed Name of Person Obtaining Consent	
Signature of Person Obtaining Consent	Date (dd-MON-yyyy) Time (HH:MM)
Printed Name of study doctor, if different from the person obtaining consent	
Signature of study doctor, if different from the person obtaining consent	Date (dd-MON-yyyy) Time (HH:MM)

Legally Authorized Representative Signature, if applicable:

Printed Name of Legally Authorized Representative, in full

Signature of Legally Authorized Representative | Date (dd-MON-yyyy)

Time (HH:MM)

Relationship of Legally Authorized Representative to the subject

Impartial witness statement

At least one **impartial** witness is mandatory when the patient, parent, legal guardian, or legally acceptable representative is unable to read or write. An **impartial** witness must be present during the entire informed consent discussion.

I confirm that the information in the consent form was accurately explained to, and apparently understood by, the patient and/or the patient's legally acceptable representative, and that consent was freely given by the patient and/or the patient's legally acceptable representative.

Printed Name of Impartial Witness, in full

Signature of Impartial Witness | Date (dd-MON-yyyy)

Time (HH:MM)