

CONSENT FOR A-V RECORDING OF THE INFORMED CONSENT PROCESS

Study Protocol:	TAK-226-3001
Study Title:	A Phase 3, Multicenter, Open Label, Randomized Trial to Compare the Efficacy and Safety of Elritercept versus Epoetin Alfa for the Treatment of Anemia Due to IPSS-R Very Low, Low, or Intermediate Risk Myelodysplastic Syndromes in ESA-naïve Adult Participants Who Require Red Blood Cell Transfusions ("Study")
Study Drug:	Elritercept (TAK-226), referred throughout the document as the "study drug"
Sponsor of the study:	Takeda Development Center Americas, Inc. 500 Kendall Street Cambridge, MA 02142 USA
Phase of the study:	III

Investigator:	Dr. Arijit Nag
Site Number (if applicable):	24003
Site Name & Address:	Tata Medical Center, 14 Major Arterial Road (EW) New Town, Rajarhat, Kolkata-700160, West Bengal, India.
Country:	India

As per New Drugs and Clinical Trials Rules ("New Rules"), 2019 (Gazette Notification G.S.R. 227(E), dated 19th March 2019 issued by the Ministry of Health and Family Welfare), Audio-Video (A-V) recording of the informed consent process for the participation in the Study is for all vulnerable subjects who will take part in the Study in India.

If you agree to this A-V recording of the informed consent process for the participation in this Study, you will be given the trial specific informed consent form (ICF), which describes in detail the trial and the potential risks and benefits of participation. The informed consent procedure with the Investigator for your participation in the Study will be recorded and securely stored at the trial site along with other study documentation for a period of not less than 15 years after the completion/termination of this clinical trial and then for as long as necessary to fulfil legal, regulatory, scientific or other requirements of the countries or regions where the study drug will be launched ("Retention Period"). After the above Retention Period, the recording will be destroyed. The A-V recording will normally only be reviewed on-site by the Investigator, Ethics Committee and Regulatory Authority representative, and your confidentiality will be maintained by these parties.

Taking part in the study is entirely voluntary. However, if you do not agree to this required A-V recording of the informed consent process, you will not be able to participate in the Study.

You may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which you are otherwise entitled. It is up to you if you do or do not want to take part. The Study specific ICF will provide details regarding the risks and benefits of participation in the Study, how the personal information will be collected, used, processed, stored and disclosed in the Study, the withdrawal process from the Study, and your rights in the Study, etc. Please read the Study ICF carefully for these details and please discuss with your study doctor for the details of the Study ICF.

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Additionally, in the event the Sponsor sells or licenses out Elritercept to another company,, your coded data collected as part of this study may be shared with that company as part of that transaction.

Study Participant Name:		Study Participant Initials:	
Date of Birth / Age:		Study Participant ID:	
Study Participant Address:			

STATEMENT OF VOLUNTARY CONSENT TO THE AUDIO-VISUAL RECORDING OF INFORMED CONSENT PROCESS

By signing this form, I hereby give permission to perform the audio-video recording of my image, voice, etc. for recording the informed consent process of my participation in the Study, and the process of the A-V recording and all information contained in and/or associated to it pursuant to this Consent for A-V Recording of the Informed Consent Process.

I have read and fully informed myself of the content of this Consent for A-V Recording of the Informed Consent Process before signing it.

Sr.	Statement	Initial (Study Participant)
(i)	I confirm that I have read this consent form for A-V recording of the informed consent process, and have had the opportunity to ask questions, which were answered to my satisfaction.	
(ii)	I agree that the Investigator, Ethics Committee, Regulatory Authorities, sponsor and/or its representative and/or its business partner will not need my permission to look at the A-V recording, even if I later withdraw from the trial. I agree to this access. However, I understand that my confidentiality will be maintained and my identity will not be revealed in any information released to third parties other than those mentioned above or published, unless otherwise required by any applicable laws and regulations or may be used in courts.	
(iii)	I agree that the said A-V recording and other related documents (including but not limited to this document) shall be preserved safely for a period of not less than 25 years after the completion/termination of this clinical trial and then for as long as necessary to fulfil legal, regulatory, scientific or other requirements of the countries or regions where the study drug will be launched.	
(iv)	I agree that nothing contained herein shall preclude any judicial officer from viewing the said A-V recording without my consent.	

I agree to the audio-visual recording of consenting process.

Study Participant Name (print):	
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Signature (or Thumb impression) of the Study Participant

Date

Name of the Investigator	
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Signature of the Investigator

Date

(* If a study participant has limited ability to read and write, a witness should be present during the entire informed consent discussion).

In these instances, the study participant places his/ her left thumb impression in the place of the signature.

Study Participant 's Legally Acceptable Representative's Statement

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Not Applicable

I, as the study participant 's legally acceptable representative, was present during the consenting procedure for the audio-video recording of informed consent and understand the preceding information.

Name of the Legally Acceptable Representative (print):	
Relationship to the Study Participant:	
Address of the legally acceptable representative:	
Phone No:	

Signature of the Legally Acceptable Representative

Date

Witness Declaration of Study Participant 's Informed Consent

☐

Not Applicable

By signing this consent form, I attest that the information was explained to and apparently understood by the subject and the legally acceptable representative (if applicable) and that informed consent was freely given by the subject.

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Name of the Witness: (print):			
Address of the Witness:			
Phone No:			
Signature of the Witness		Date	

(Copy of the Consent for Audio-Visual (A-V) Recording of the Informed Consent Process shall be handed over to the study participant or his/her attendant)