Green Light Approval for Site Activation

Study ID:	H-34
Protocol short title:	DELTA REVISION
Principal Investigator:	Dr. Jerzy Białecki
Study site ID:	01

Guidance:
The CMCL/RMCL must confirm that the following documents are present and complete prior to the investigational site activation.

	Document Type	Present (Yes, No, NA)	Date and version of Document	Comments
1	Signed protocol and amendments (if any) [signed and dated by the Principal Investigator (PI)]	Yes	v. 1.1 dated 28 Sep 2020	
2	Informed Consent Form (ICF) (including all applicable translations)	Yes	v. 1.0 dated 04 Feb 2020	
3	Other written information given to subjects	NA		
4	Financial aspects of the clinical trial (i.e., financial agreement between the site and the sponsor)	Yes		
5	Dated, documented approval/favourable opinion of Institutional Review Board (IRB)/Independent Ethics Committee (IEC) of the following: • protocol and any amendments • Case Report Form (CRF) (if applicable) • ICF(s) and other consents where applicable • any other written information to be provided to the subject(s) • advertisement for subject recruitment (if used) • subject compensation (if any) • any other documents given approval/ favourable opinion	Yes	EC approval from 09 Sep 2020	
6	IRB/IEC Composition (Membership)	Yes		
7	Regulatory Authority (RA) authorization/approval/notification of protocol and amendments (if any) (where required)	NA		.
8	PI current Curriculum Vitae (CV) and documents evidencing qualifications of PI	Yes	08 Jun 2020	
9	eCRF training date completion and access	Yes	Training performed on 11 Jun 2021	
10	Laboratory Reference Ranges	NA		

	Document Type	Present (Yes, No, NA)	Date and version of Document	Comments
11	Medical/laboratory/technical procedures/tests (where required) • certification or • accreditation or • established quality control and/or external quality assessment or • other validation (where required)	NA		
12	Instructions for handling, storage, package, dispensing and disposition of investigational device(s) and clinical trial related materials	NA		
13	Decoding procedures for blinded trials	NA		
14	Qualification site assessment report	Yes	Site assessment performed on 11 Sep 2020	
15	Verification that site initiation activities have been completed with no outstanding issues (including Site Duty Delegation Log)	Yes		
16	If additional local requirements for investigational site activation exist, documented verification that all local requirements have been met	NA		

	Role	Name and Surname	Date	Signature
Written by:	CRA	Adam Kogut	14/7/2021 | 10:13 CEST	DocuSigned by: Adam Kogut Signer Name: Adam Kogut Signing Reason: I am the author of this do Signing Time: 14/7/2021 | 10:12 CEST F835E6799B83473F870B4E7D9B3504(
Approved by:	RMCL	Federica Azzimonti	14/7/2021 | 11:22 CEST	DocuSigned by: Federica Azzimonti Signer Name: Federica Azzimonti Signing Reason: I approve this documer Signing Time: 14/7/2021 | 11:22 CEST F76117269A994B43A353A3F6CBA0F(