

29 June 2022

Dr. Jerzy Bialecki
 Samodzielnny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP
 Księda Stanisława Konarskiego 13
 05-400 Otwock
 Poland

RE: H-34 DELTA REVISION CUP Onsite Monitoring Visit or Monitoring Follow-up Letter

Dear Dr. Bialecki:

This letter is in follow-up to my monitoring visit, on behalf of LimaCorporate S.p.A. on 09 June 2022. I appreciate the opportunity to have worked with Dr. Julia Macias to discuss study progress and subject related issues. A new findings were identified during this visit. These items as well as recommendations for corrective actions are outlined below:

Findings identified during this review are noted below:

Issue Date	Finding	Action Required	Addressed to (Sponsor/Site/CRA)	Resolution date
09Jun2022	Consent process not documented in subjects notes from patients 101-07 to 101-014	To provide supplementary notes with the current date documenting the whole consenting process.	The site staff was instructed to provide supplementary notes.	Open
09Jun2022	Protocol Deviation log not updated	To update the PD log.	Site/CRA	
09Jun2022	The out of window visits of subject 101/7 FU 6 Months was noted.	The site should be reminded to perform the visit within the timeframe defined by the protocol	CRA	

Findings identified after the visit:

Issue Date	Finding	Action Required	Addressed to (Sponsor/Site/CRA)	Resolution date
17Jun2022	The SAE report for subject 101-014 was sent with a delay.	To retrain the site staff from safety reporting and to inform the EC	CRA	Open

Previous findings that remain open are noted below:

Issue Date	Finding	Action Required	Addressed to (Sponsor/Site/CRA)	Resolution date
18Nov2021	Lack of copies of current GCP certificates from the site staff.	To file the current GCP certificates in ISF. Update: Only GCP certificate of Dr. Macias was filed in ISF.	Site/CRA	
18Nov2021	Subject 101/4 did not	To check with the subject	Site	Partially

Issue Date	Finding	Action Required	Addressed to (Sponsor/Site/CRA)	Resolution date
	sign ICF	the reason why "Secondary use of data" part of the ICF was not signed.		closed on 03Feb2022
18Nov2021	Subjects 101-2 – 101-7 did not personally date the ICF.	To collect from the subject a statement confirming that the subject agreed to participate in the study. The statement should be signed with the current date by the subject. The missing signed statement that have not been collected so far for subjects 101-3, 101-5, and 101-6.	Site	
03Feb2022	Pending queries	To resolve pending queries	Site	
03Feb2022	eCRF was used as SD for some of the data. Including race, intensity of activity daily living, work status, smoking habits, alcohol drinking habits and radiographical description including presence of osteophytes and presence of cystis.	to provide a NTF clarifying that eCRF is the source document and for future patients it is requested to provide source documents (worksheet)	Site	

As a reminder I would like to kindly point out that all Serious Adverse Events are required to be reported to the Sponsor within 24 hours after learning of the event. In case of explantation of the components is performed, the explanted components need to be sent to the Sponsor after decontamination.

Dr. Jerzy Białecki, on behalf of LimaCorporate S.p.A., I would like to thank you and your staff for your cooperation in making this a successful monitoring review. If you have any questions please contact me at +48729107107 or akogut@namsa.com

Sincerely,

Adam Kogut
CRA

cc: Aissa Benyattou
Lisa Ciuffarin
Study File/Site File