

18 February 2022

Dr. Jerzy Białecki
Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP
Księdza Stanisława Konarskiego 13
05-400 Otwock
Poland

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

Dear Dr. Białecki:

This letter is in follow-up to my monitoring visit, on behalf of LimaCorporate S.p.A. on 03 Feb 2022. I appreciate the opportunity to have worked with Dr. Julia Macias to discuss study progress and subject related issues. As we discussed, overall your subject files and investigator site file are generally in good order. A few 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
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 the updated medical documentation signed with the current date to support the data completed in eCRF.	Site	

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 sign ICF	To check with the subject the reason why "Secondary use of data" part of the ICF was not signed.	Site	
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	Site	

Issue Date	Finding	Action Required	Addressed to (Sponsor/Site/CRA)	Resolution date
		<p>participate in the study. The statement should be signed with the current date by the subject.</p> <p>The missing signed statement that have not been collected during the recent visits of the patients at site, will be collected during their next visit at site.</p>		

Dr. Jerzy Białęcki, on behalf of LimaCorporate S.p.A., I would like to thank you and Dr. Macias 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