

7 December 2021

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 18 Nov 2021. 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
18Nov2021	Subject 101/3 doubled in the e-CRF	Subject 101/3 should be removed from e-CRF	Sponsor	01Dec2021
18Nov2021	Subject 101/4 did not sign 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.	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 participate in the study. The statement should be signed with the current date by the subject.	Site	
18Nov2021	Updated insurance policy not filed in the ISF	To file the updated version of the insurance policy.	CRA	
18Nov2021	Lack of copies of current GCP certificates from the site staff.	To file the current GCP certificates in ISF.	Site/CRA	
18Nov2021	Lack of printed out SD.	To print out the SD of all subjects.	Site	
18Nov2021	Consent process not documented in subjects notes.	To provide supplementary notes with the current date documenting the whole consenting process.	Site	

Previous findings that remain open are noted below:

Issue Date	Finding	Action Required	Addressed to (Sponsor/Site/CRA)	Resolution date
11Jun2021	Missing laboratory certificates.	To collect the missing laboratory certificates from the site local laboratory.	Site/CRA	

Dr. Jerzy Białecki, 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 adam@scra.pl

Sincerely,



Adam Kogut
CRA

cc: Aissa Benyattou
Lisa Ciuffarin
Study File/Site File