

16 November 2021

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

RE: H-34 DELTA REVISION CUP Onsite Monitoring Visit Confirmation Letter

Dear Dr. Bialecki:

The purpose of this letter is to confirm my upcoming onsite monitoring visit at your site for the H-34 DELTA REVISION CUP study. The monitoring visit is scheduled for 18 November 2021 beginning at 9 AM.

The following items must be available for my review during the visit:

- Investigator Site File/Regulatory Binder
- Subject Case Report Forms & Informed Consent Forms for all subjects
- Hospital Files
- Adverse Event and Protocol Deviation reporting policies
- Any other source documents.

Please allow time during my visit to meet with the Investigator and discuss the study progress and any issues or concerns noted during this monitoring visit.

After the monitoring visit is complete, I will follow-up with you and your research coordinator to review and discuss issues identified during the monitoring review, corrective actions, and any other outstanding issues.

If you have any questions please contact me at 729107107 or adam@scra.pl.

Sincerely,



Adam Kogut
CRA

cc: Aissa Benyattou
Lisa Ciuffarin
Study File/Site File