

02 June 2021

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

Re: H-34 DELTA REVISION CUP Study Site Initiation Visit

Dear Dr. Bialecki:

This letter is to confirm the Site Initiation Visit for the LimaCorporate S.p.A. An open label, observational, prospective, longitudinal cohort study to evaluate safety, clinical and radiographic outcomes of total hip arthroplasty with DELTA Revision cup Study scheduled with you and your staff on 11 June 2021 beginning at 10 AM at Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP, Księda Stanisława Konarskiego 13, 05-400 Otwock. Please plan on approximately 4 hours for training. Dr. Bialecki, if your schedule does not permit for full attendance at the training, the items listed below and identified with an asterisk will require your direct participation. This should take approximately 60 minutes. If possible, please ensure that as many participating sub-investigators and research support staff, including at a minimum, the primary research coordinator for this study, are present during the initiation visit.

During the visit the following agenda will be covered:

- H-34 DELTA REVISION CUP Study Team, their role and tasks performed in this study*
- Study Device introduction/training*
- Study Objectives and Design*
- Subject Screening & Enrollment
- Procedure and Follow-Up Assessments
- Adverse Events / Deviations*
- Devices: Ordering, Return, Accountability
- Core Lab
- Data Management and data collection requirements
- Monitoring
- Review of Investigator Responsibilities*
- Discussion of Source Documents for this study

Please contact me with any additional questions at 729107107 or adam@scra.pl.

We look forward to your site's initiation!

Regards,



Adam Kogut
CRA

cc: Aissa Benyattou
Pierluigi Barzanti