

Gloria Viti

Da: Adam Kogut <adam@scra.pl>
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A: jerzybialecki@pro.onet.pl; maciasjulia@gmail.com; Paweł Bartosz
Cc: Gloria Viti; Pierluigi Barzanti
Oggetto: H-34 Pre-Study Visit Follow-up Letter

Dear Dr Bialecki, Dr Macias and Dr Bartosz,

I would like to take this opportunity to thank you and your team for attending the Pre-Study Visit performed on 11 September 2020.

At the time of visit we discussed and reviewed the following:

- Study overview
- Study protocol and procedure
- Investigator and site personnel updates
- Enrollment expectations
- Principal Investigator responsibilities
- Equipment and facilities
- Device use and application
- Device accountability and storage
- e-CRF
- EC/RA procedure and regulatory requirements
- GCP/ISO-14155 guidelines
- Safety reporting requirements
- Contract and compensation
- Study updates

Please see below the answers to your questions raised during the visit:

1. Participation of other hospital clinics in the study.

At this study's stage, instead of joining the other hospital clinics into the study it is recommended that other hospital clinics refer their patients to the study staff.

2. Possibility to avoid putting additional surgeons on the Delegation List.

Considering that the study is observational, other surgeons can perform Delta revision cup implantations and not be listed in the delegation list if the following conditions are both respected:

1. study team and/or PI has to assist to the surgery;
2. PI has to countersign the medical charts related to the implant.

If the both above mentioned items cannot be respected, the other surgeons have to be included in the delegation log.

3. Submission of Polish version of study scores to the EC.

The Polish versions of OHS scores (only) will be submitted to EC within the EC submission for the amendment of protocol to be done within 20 Nov 2020; site staff will be informed as soon as the Sponsor will receive the EC approval.

Should you have any questions, please do not hesitate to contact me at 729107107 or by email at adam@scra.pl

Looking forward to working with you.

Kind regards,

Adam Kogut
CRA