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**Inviato:** venerdì 2 ottobre 2020 23:58  
**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](mailto:adam@scra.pl)

Looking forward to working with you.

Kind regards,

Adam Kogut  
CRA