

## Gloria Viti

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**Da:** Adam Kogut <adam@scra.pl>  
**Inviato:** giovedì 10 settembre 2020 11:53  
**A:** jerzybialecki@pro.onet.pl; Paweł Bartosz; maciasjulia@gmail.com  
**Cc:** Gloria Viti; Pierluigi Barzanti  
**Oggetto:** Confirmation of H-34 Pre-Study Visit

Dear Dr Bialecki, Dr Macias and Dr Bartosz,

I have the pleasure to confirm the scheduling of remote Pre-Study Visit through Zoom meeting on 11 September 2020 at 9:00 AM.

The following items will be discussed:

- 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 details about scheduled Zoom meeting:

Time: Sep 11, 2020 09:00 AM Warsaw

Join Zoom Meeting:

<https://zoom.us/j/96330626401?pwd=ZGxTWi8ydE85S05aK0IUcEpKSkJUT09>

Meeting ID: 963 3062 6401

Passcode: eL9YRG

Looking forward to working with you.

Kind regards,  
Adam Kogut  
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