

Gloria Viti

Da: Gloria Viti
Inviato: venerdì 25 settembre 2020 13:09
A: Adam Kogut
Cc: Pierluigi Barzanti
Oggetto: R: H-34 DELTA REVISION Pre-study visit 11 September 2020
Allegati: H34 PSV Report Bialecki 09Sep20 signed 25Sep20.pdf

Hi Adam,
Please find attached the PSV report with my signature.
Thank you very much!
Have a nice weekend
Gloria



Gloria Viti
Clinical Trial Lead
M +39 337 1532539
gloria.viti@limacorporate.com

Limacorporate S.p.A.
Via Nazionale, 52
33038 Villanova di San Daniele del Friuli
Udine - Italy
limacorporate.com



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Da: Adam Kogut <adam@scra.pl>
Inviato: venerdì 25 settembre 2020 12:19
A: Gloria Viti <gloria.viti@limacorporate.com>
Cc: Pierluigi Barzanti <pierluigi.barzanti@limacorporate.com>
Oggetto: Re: H-34 DELTA REVISION Pre-study visit 11 September 2020

Dear Gloria,

many thanks for sending the final version of the PSV report. Please find attached the signed and dated signature page.

Have a great day.

Kind regards,
Adam

On 25 Sep 2020, at 08:59, Gloria Viti <gloria.viti@limacorporate.com> wrote:

Hi Adam,
Just a reminder to send to me the signed and dated PSV report in order to finalize it within timelines.
Thank you very much in advance.
Have a nice day
Gloria

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Gloria Viti
Clinical Trial Lead
M +39 337 1532539
gloria.viti@limacorporate.com

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Via Nazionale, 52
33038 Villanova di San Daniele del Friuli
Udine - Italy
limacorporate.com

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Da: Gloria Viti
Inviato: giovedì 24 settembre 2020 08:43
A: Adam Kogut <adam@scra.pl>
Cc: Pierluigi Barzanti <pierluigi.barzanti@limacorporate.com>
Oggetto: R: H-34 DELTA REVISION Pre-study visit 11 September 2020

Hi Adam,
Please find attached the final report: as soon as you will send the signed and dated and report (within today, maximum tomorrow morning), I will sign the report and I will forward the finalized the report to you and I will archive it in TMF.
Have a nice day,
Gloria

<image001.png>

Gloria Viti
Clinical Trial Lead
M +39 337 1532539
gloria.viti@limacorporate.com

Limacorporate S.p.A.
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Da: Adam Kogut <adam@scra.pl>
Inviato: mercoledì 23 settembre 2020 20:45
A: Gloria Viti <gloria.viti@limacorporate.com>
Cc: Pierluigi Barzanti <pierluigi.barzanti@limacorporate.com>
Oggetto: Re: H-34 DELTA REVISION Pre-study visit 11 September 2020

Dear Gloria,

many thanks for your review and I agree with your comments. Please find attached the revised report with accepted changes and updated answer to the question no. 5.

Have a nice evening!

Kind regards,
Adam

On 21 Sep 2020, at 19:31, Gloria Viti <gloria.viti@limacorporate.com> wrote:

Hi Adam,
First of all, I would like to thank you for the prompt and good PSV report!
Please find:

- below in blu my comments;
- Attached the PSV report with my comments: if my comments are fine for you please accept my revisions and add only some comments according to my suggestions (question n.5).

Could you send the report within 23 Sep 2020 in order to finalize it in time, please?

Have a nice evening,
Gloria

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Gloria Viti
Clinical Trial Lead
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gloria.viti@limacorporate.com

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Da: Adam Kogut <adam@scra.pl>
Inviato: venerdì 18 settembre 2020 22:06
A: Gloria Viti <gloria.viti@limacorporate.com>
Cc: Pierluigi Barzanti <pierluigi.barzanti@limacorporate.com>
Oggetto: Re: H-34 DELTA REVISION Pre-study visit 11 September 2020

Dear Gloria,

please find attached the PSV report for your review as well as responses to below questions (in red).

Have a nice weekend.

Kind regards,
Adam

> Based on the feasibility questionnaire and key inclusion/exclusion criteria, **do you confirm to enroll 2 patients per month?**

The site staff stated they can enrol 2-3 patients per week (on average, sometimes

less and sometimes more). OK,
Thanks!

> Based on my email dated 04.Sep.2020, **could you confirm that your site implants delta revision cups only for the revision** according to the IFU and not for the primary reasons, please?

The site staff confirmed they are using these implants for the revision only. It does not change their recruitment plans. **It's perfect! Thank you**

> I'm going to enter **Jarosław Czubak, Professor M.D in the Financial Agreement as person responsible for the Hospital administration** in order to start the process of signature: do you confirm that Jarosław Czubak is the correct person with name and title, please?

Prof. dr hab n. med. Jarosław Czubak is the Director and represents hospital as well as signs financial agreements. **Great!**

> Do you prefer to have Oxford Hip Score (OHS) in Polish language or English? I believe that the site staff is more comfortable to have it in Polish and I'm going to finalize the license but I would like to be sure

The site staff prefers Polish version. In addition, they asked if Polish versions of study scores can be submitted to EC for review. Having EC approved Polish versions would allow the staff to provide each subject with paper scores for subject's completion instead of reading questions to the subject. **The Polish OHS will be submitted to EC within amendment to be done within 20 Nov 2020**

<Site Selection Report H-34 Dr Bialecki_GV.docx>

<Site Selection Report H-34 Dr Bialecki_final.pdf>