

From: [Yao, Michael \(CBER\)](#)
To: ["Margarita Aguilera"](#)
Cc: [Schneider, Bruce](#); [Gildner, Jean](#)
Subject: RE: Request for additional clinical information
Date: Monday, May 23, 2016 11:02:19 AM

APPROVED

By Jean Gildner at 10:15 am, Jul 19, 2016

Margarita,

Thanks for your response. BTW, we still have following questions to you:

1. Regarding subject screen and re-screen, please provide tabulation of reasons for screen failure in 45 or so subjects out of the original 189 subjects. Also, please provide details of rescreen (tabulation).
2. Please indicate where we can find information on the randomization procedure, in particular, how the surgeon was informed of the randomization assignment during the arthroscopy procedure.
3. Also, for those subjects with prior surgery to the index knee (prior to screening), please provide information regarding the type of surgery for each subject, along with subject number.

Thanks,

Michael

From: Margarita Aguilera [mailto:maguilera@vcel.com]
Sent: Sunday, May 22, 2016 10:04 PM
To: Yao, Michael (CBER)
Cc: Schneider, Bruce; Gildner, Jean
Subject: RE: Request for additional clinical information

Dear Dr. Yao,

This is to acknowledge receipt of your request for information. I will get back to you with additional information on Monday.

Regards,
Margarita

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From: Yao, Michael (CBER) [<mailto:Michael.Yao@fda.hhs.gov>]

Sent: Friday, May 20, 2016 9:02 PM

To: Margarita Aguilera

Cc: Schneider, Bruce; Gildner, Jean

Subject: Request for additional clinical information

Importance: High

Hi Aguilera,

Please provide following information for us:

1. Regarding clinical evaluation in SUMMIT study, do you have clinical data (KOOS pain and function) before visit 6 (week 24)? If so, please provide a summary for FDA review.
2. Please provide subgroup analysis by number of lesions and by subject age, using some reasonable cut-off determine "younger" vs "older."

Thanks.

Michael