

## Davidson, Mark

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**From:** Bross, Peter F (CBER)  
**Sent:** Monday, June 22, 2015 8:12 PM  
**To:** Pernice, Michelle  
**Cc:** Davidson, Mark  
**Subject:** RE: Type B Meeting Briefing Materials IND 12412 - another RFI

Michelle:

Thank you!

I have another IR request – could you please ask your stats folks to generate the following single composite Kaplan Meier plot:

An ITT analysis of the OS subgroups for combined Stage IIIB-C/IVM1a vs. combined Stage IV M1b and M1c (4 curves, T-Vec and GM-CSF)

Please use the updated OS information including the 3 missing persons.

Comparisons would be within the subgroups not between subgroups.

ASAP - preferably by the end of the week

Thanks

-Peter

Peter F. Bross, MD  
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[Important information regarding CBER's move \(25Apr – 18May\).](#)

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**From:** Pernice, Michelle [mailto:[mpernice@amgen.com](mailto:mpernice@amgen.com)]  
**Sent:** Monday, June 22, 2015 7:42 PM  
**To:** Bross, Peter F (CBER)  
**Cc:** Davidson, Mark  
**Subject:** RE: Type B Meeting Briefing Materials IND 12412 - RFI

Dear Peter,

Please see the attached response to the FDA information request received via e-mail on 09 June 2015 (below).

An electronic submission to the IND will follow. The content will remain exactly the same as the attached.

Please contact me with any questions.

Thank you.

Kind regards,  
Michelle

**Michelle Pernice, Pharm.D.**  
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**From:** Pernice, Michelle  
**Sent:** Tuesday, June 09, 2015 4:45 PM  
**To:** 'Bross, Peter F (CBER)'  
**Cc:** Davidson, Mark  
**Subject:** RE: Type B Meeting Briefing Materials IND 12412 - RFI

Hi Peter,

We will provide any available clinical data from Study 20110265 via email and to the IND as soon as possible. I will keep you updated on the anticipated timing of this submission.

I am looking forward to working with Mark to schedule regular teleconferences.

Thank you.

Kind regards,  
Michelle

**Michelle Pernice, Pharm.D.**  
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**From:** Bross, Peter F (CBER) [<mailto:Peter.Bross@fda.hhs.gov>]  
**Sent:** Tuesday, June 09, 2015 3:11 PM  
**To:** Pernice, Michelle  
**Cc:** Davidson, Mark  
**Subject:** Type B Meeting Briefing Materials IND 12412 - RFI

Hi Michelle:

As per our telephone discussion, you confirm that your type B meeting package contains minimal clinical information on the ongoing combo study 20110265. Please provide any available clinical safety and efficacy information and submit as an amendment to the IND preferably in time for us to review prior to the meeting.

Also we acknowledge the sensitivity of some information such as possible approval pathways that would not be appropriate for discussion in the type B meeting with representatives of Merck. I anticipate that Mark will be in touch with you soon regarding scheduling regular t'cons and you can clarify with him what topics you prefer to avoid during the Type B meeting.

It is very unusual to have two major pharmaceutical companies in the same room – I have not seen this in 15 years at FDA.

Thanks

-Peter

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*Important information regarding CBER's move (25Apr – 18May).*

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**From:** Pernice, Michelle [<mailto:mpernice@amgen.com>]  
**Sent:** Friday, June 05, 2015 10:49 AM  
**To:** Davidson, Mark  
**Subject:** Type B Meeting Briefing Materials IND 12412

Dear Mark,

Please see the attached Type B meeting briefing materials to be submitted electronically to the IND today. Hard copies of the briefing materials will also be delivered early next week. The Protocol 20110265 amendment 1 will also be included in the electronic IND submission but is too large for me to include in this e-mail (16MB).

The content in the attached document is identical to the content that will be electronically submitted to the IND.

Perhaps upon initial review of this document, you/your team will be able to confirm if a 90 minutes meeting would be feasible and appropriate, rather than 60 minutes.

Thank you. Have a nice weekend!

Kind regards,  
Michelle

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**From:** Pernice, Michelle

**Sent:** Thursday, June 04, 2015 11:20 AM

**To:** Davidson, Mark; 'Azari, Mehran'

**Subject:** RE: Meeting Confirmation IND 12412

Dear Mark and Mehran,

Per the meeting confirmation, the July 7<sup>th</sup> Type B meeting is scheduled for 1 hour (11:00-12:00 EST). Per the submitted meeting request, the proposed agenda may take 90 minutes for a complete discussion.

Please confirm if a 90 minute meeting would be feasible.

Thank you.

Kind regards,

Michelle

**Michelle Pernice, Pharm.D.**

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**From:** Azari, Mehran [<mailto:Mehran.Azari@fda.hhs.gov>]

**Sent:** Tuesday, May 19, 2015 12:00 PM

**To:** Pernice, Michelle

**Cc:** Davidson, Mark; Azari, Mehran

**Subject:** Meeting Confirmation IND 12412

Hi,

Please find the attached file meeting confirmation for IND 12412.

Thanks,

Mehran