

## RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: 125510/0 Office: OVRR

Product:  
Influenza Vaccine, Adjuvanted

Applicant:  
Novartis Vaccines and Diagnostics, Inc.

Telecon Date/Time: 17-Dec-2014 03:00 PM Initiated by FDA? Yes

Telephone Number: (617) 871-8325

Communication Category(ies):  
1. Information Request

Author: THEODORE GARNETT

Telecon Summary:  
Information regarding the trial sites used in pivotal trail V70\_27

FDA Participants: Theodore Garnett, Brenda Baldwin, Kirk Prutzman, Sarah Browne

Non-FDA Participants: Matthew Gollwitzer

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

The 1<sup>st</sup> e-mail provided below was a follow-up to a telephone conversation between CBER staff and Mr. Gollwitzer regarding CBER's request for information about the trial sites used in pivotal trail V70\_27. (The table template referred to in this e-mail is attached.)

On December 18, 2014, CBER agreed to modify their request per Novartis' proposal (see 2<sup>nd</sup> e-mail; the statistics analysis plan referred to in the e-mail is also attached to this document).

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**From:** Baldwin, Brenda

**Sent:** Wednesday, December 17, 2014 3:35 PM

**To:** Gollwitzer, Matthew

**Cc:** Garnett, Theodore; Prutzman, Kirk C; Browne, Sarah  
**Subject:** BLA 125510 FLUAD

Hi Matt,

As we discussed today, I am providing a document containing a table template of the information we need regarding the trial sites used in your pivotal trial V70\_27. We will need this information NLT 2 pm on Tuesday, December 23, 2014. You can submit this table unofficially via e-mail initially. Please respond to all in this e-mail as we want to ensure that this information is reviewed rapidly. Thank you.

Regards,  
Brenda

Dr. Brenda R. Baldwin  
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**From:** Gollwitzer, Matthew [mailto:matthew.gollwitzer@novartis.com]  
**Sent:** Thursday, December 18, 2014 11:51 AM  
**To:** Baldwin, Brenda  
**Cc:** Garnett, Theodore; Prutzman, Kirk C; Browne, Sarah  
**Subject:** RE: BLA 125510 FLUAD

Hi Brenda and Sarah,

I shared the request and was able to discuss with our Clinical and Stats team. Columns A through D can be provided, but our stats team can't provide the information requested in column E of the attached document as they said it is not compatible with our primary objective. However, they have put together a proposal attached. Essentially, instead of % subjects meeting primary endpoints for superiority and noninferiority, we are proposing the following breakdown below. Please also review the attached MSWord document for more specifics. Can you please get back to me today if you are fine with the proposal? Our stats group needs to run the program tonight/tomorrow as they will all be on vacation next week.

Broken down by site, strain (homologous strains only), and vaccination group:

1. SC rates, between vaccine group differences (TIV-ADJ-TIV-NONADJ)

## 2. GMTs, vaccine group ratios (TIV-ADJ/TIV-NONADJ)

Please let me know if you would like to discuss or if you have any questions. If so, let me know a specific time so I can have a clinical colleague join me for any questions.

Kind Regards,

Matt