

# RECORD OF TELEPHONE CONVERSATION

## Submission Information

<b>Application Type</b>	BLA
<b>STN</b>	125510/0.0
<b>Review Office</b>	OVRR
<b>Applicant</b>	Novartis Vaccines and Diagnostics, Inc. / Lic. # 1751
<b>Product</b>	Influenza Vaccine, Adjuvanted
<b>Trans-BLA Group:</b>	No

## Telecon Details

<b>Telecon Date/Time</b>	06-MAY-2015 03:26 PM
<b>Author</b>	BALDWIN, BRENDA
<b>EDR</b>	No
<b>Post to Web</b>	No
<b>Outside Phone Number</b>	
<b>FDA Originated?</b>	No
<b>Communication Categories</b>	IR - Information Request
<b>Related STNs</b>	None
<b>Related PMCs</b>	None
<b>Telecon Summary</b>	request for recalculated HAI titers
<b>FDA Participants</b>	Brenda Baldwin, Theodore Garnett
<b>Applicant Participants</b>	Mayuresh Garnett

**From:** GADRE, MAYURESH  
**Sent:** Wednesday, May 06, 2015 1:23 PM  
**To:** 'Brenda.Baldwin@fda.hhs.gov'  
**Subject:** STN 125510 - Revised SDTM datasets

Dear Brenda,

## RECORD OF TELEPHONE CONVERSATION

Further to our conversation on the phone, I wanted to clarify that the files for SDTM datasets for V70\_27 (lb.xpt and supplb.xpt) were with the old data. However, all other information provided in Module 1 (tables and listings, analysis) was correct and based on the revised data.

I will send an email shortly outlining our proposal for providing SDTM datasets to the eCTD and the content of the datasets.

Please let me know if you have any questions.

I am very sorry for the inconvenience.

Best Regards,  
Mayuresh

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**From:** GADRE, MAYURESH [<mailto:mayuresh.gadre@novartis.com>]  
**Sent:** Wednesday, May 06, 2015 3:07 PM  
**To:** Baldwin, Brenda  
**Subject:** RE: STN 125510 - Revised SDTM datasets

Dear Brenda,

Novartis proposes to provide revised SDTM datasets which include both old and recalculated HAI titer data (derived by dividing by a factor of (b) (4)). The old and the recalculated HAI titers within the individual datasets can be filtered using the variable, "LBMETHOD":

LBMETHOD=" HEMAGGLUTINATION INHIBITION " = old results  
LBMETHOD= " HEMAGGLUTINATION INHIBITION RECALCULATION - TITERS  
DIVIDED BY (b) (4) = recalculated results

Novartis proposes to replace the incorrect datasets (lb.xpt and supplb.xpt) provided in Sequence 0008, with the correct, revised datasets which contain both old and recalculated HAI titers. The operator "replace" would be used when providing the eCTD sequence with revised datasets, as an amendment to the BLA.

As proposed, Novartis can provide the revised datasets by email today, and submit formally by eCTD by the end of this week. Is this acceptable to CBER?

Please let me know if you have any questions.

Best Regards,  
Mayuresh

Mayuresh Gadre  
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## RECORD OF TELEPHONE CONVERSATION

**From:** Baldwin, Brenda [<mailto:Brenda.Baldwin@fda.hhs.gov>]

**Sent:** Wednesday, May 06, 2015 4:10 PM

**To:** GADRE, MAYURESH

**Cc:** Garnett, Theodore

**Subject:** RE: STN 125510 - Revised SDTM datasets

Hi Mayuresh,

We will accept the revised dataset to include both the old and recalculated HAI titer as noted below. We also will accept the replacement of the incorrect datasets provided in sequence 0008 as noted below. I look forward to receiving the corrected revised datasets today by e-mail as long as it is condensed into ZIP file as previously done.

Regards,  
Brenda