

# RECORD OF TELEPHONE CONVERSATION

## Submission Information

<b>Application Type</b>	BLA
<b>STN</b>	125597/0.0
<b>Review Office</b>	OVRR
<b>Applicant</b>	Pax Vax Bermuda Ltd. / Lic. # 2041
<b>Product</b>	Cholera Vaccine Live Oral
<b>Trans-BLA Group:</b>	No

## Telecon Details

<b>Telecon Date/Time</b>	17-MAR-2016 11:45 AM
<b>Author</b>	HOFFMAN, KELSY
<b>EDR</b>	No
<b>Post to Web</b>	Yes
<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 revised timeline for deferred pediatric study
<b>FDA Participants</b>	Kelsy Hoffman, Christina Houck, Goutam Sen
<b>Applicant Participants</b>	Kevin Smyth

## Telecon Body:

**From:** Kevin Smyth [mailto:KSmyth@paxvax.com]

**Sent:** Thursday, March 17, 2016 11:45 AM

**To:** Hoffman, Kelsy

**Cc:** Houck, Christina M; Sen, Goutam

**Subject:** RE: Clarification for BLA 125597

## RECORD OF TELEPHONE CONVERSATION

Dear Ms. Hoffman,

Thank you for your information request. A corrected submission will be transmitted by March 21, 2016.

Regards, Kevin

**Kevin Smyth**

Vice President

Regulatory Affairs and Pharmacovigilance

**PaxVax**

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**From:** Hoffman, Kelsy [<mailto:Kelsy.Hoffman@fda.hhs.gov>]

**Sent:** Thursday, March 17, 2016 08:22

**To:** Kevin Smyth

**Cc:** Houck, Christina M; Sen, Goutam

**Subject:** RE: Clarification for BLA 125597

Mr Smyth,

Also, in your March 4, 2016 submission (amendment 17) to your BLA 125597/0, we note that your timeline for your deferred pediatric study provides an estimated month and year for the protocol submission, study initiation and final report submission. Please provide the estimated month, day and year for the final protocol submission, study completion date, and final report submission. Please also provide just one estimated date for the submission of your protocol (month, day and year). Please submit this information no later than March 21, 2016.

Thank you,

Kelsy

Kelsy F. Hoffman, Ph.D.

LCDR, USPHS

Primary Reviewer/Regulatory Project Manager

FDA/CBER/OVRR/DVRPA

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## RECORD OF TELEPHONE CONVERSATION

Fax- 301-595-1124

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**From:** Hoffman, Kelsy  
**Sent:** Thursday, March 17, 2016 10:16 AM  
**To:** 'Kevin Smyth'  
**Cc:** Houck, Christina M; Sen, Goutam  
**Subject:** Clarification for BLA 125597

Mr. Smyth,

In your March 4, 2016, submission (amendment 17) to your BLA 125597/0, you provided an updated timeline for your deferred pediatric study. You indicate that the estimated study completion date is Dec 2018 and the final report submission date is June 2019. However, you also indicate that the BLA supplement for 2-17 yr olds will be submitted December 2018. Please clarify if this date is an error.

Thank you,  
Kelsy

Kelsy F. Hoffman, Ph.D.  
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