

RECORD OF TELEPHONE CONVERSATION

Submission Information

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

Telecon Details

Telecon Date/Time	02-FEB-2016 04:04 PM
Author	SEN, GOUTAM
EDR	No
Post to Web	No
Outside Phone Number	
FDA Originated?	Yes
Communication Categories	IR - Information Request
Related STNs	None
Related PMCs	None
Telecon Summary	To submit detailed pediatric study plan
FDA Participants	Goutam Sen
Applicant Participants	Kevin Smyth

Telecon Body: I called Kevin Smyth of PaxVax and requested him to submit a detailed deferred pediatric study plan/protocol (which was agreed during IND) to the BLA. PaxVax has submitted a synopsis of their pediatric study plan in the original BLA submission. PaxVax agreed to submit the details of the pediatric study design and associated logistics and more detailed protocol to the BLA as an amendment.