

RECORD OF TELEPHONE CONVERSATION

Submission Information

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| 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

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|---------------------------------|--|
| Telecon Date/Time | 27-APR-2016 09:28 PM |
| Author | SEN, GOUTAM |
| EDR | No |
| Post to Web | No |
| Outside Phone Number | 6507874406 |
| FDA Originated? | Yes |
| Communication Categories | IR - Information Request |
| Related STNs | None |
| Related PMCs | None |
| Telecon Summary | Clarification request on the randomization procedure used in Challenge Study |
| FDA Participants | Goutam Sen and Tina Mongeau |
| Applicant Participants | Kevin Smyth and Lisa Danzig |

Telecon Body: We called and ask PaxVax to explain how randomization occurred prior to vaccination of volunteers in trial PXVX-VC-200-003 and prior to selection of volunteers who were challenged in the trial in an amendment submission to the BLA.