

From: Sen, Goutam
To: [Kevin Smyth \(KSmyth@paxvax.com\)](mailto:Kevin.Smyth@paxvax.com)
Subject: Information request to submit a concept protocol for pregnancy registry, STN: 125597
Date: Wednesday, April 06, 2016 11:34:00 AM

Dear Kevin,

While reviewing your Pharmacovigilance Plan submitted to your original BLA submission, we note that you have proposed a Pregnancy Registry to monitor pregnancy outcomes in women exposed to VAXCHORA during pregnancy. You have also indicated that the Pregnancy Registry will be initiated on licensure and launch of VAXCHORA.

Please submit a Concept Protocol for the proposed Pregnancy Registry to your BLA. You may refer to the FDA Guidance for Establishing Pregnancy Registries at www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm071639.pdf

Please submit a Concept Protocol to your BLA by April 20, 2016. Also, please provide the projected dates and justification of the proposed dates for the following events pertaining to the pregnancy registry:

Final Protocol Submission
Study Completion
Final Report Submission

Please let me know if you have any questions.

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