

**From:** Polo, Stephanie  
**Sent:** Thursday, April 18, 2019 11:31 AM  
**To:** Patrick.O'Neil@sanofi.com  
**Cc:** Prutzman, Kirk C <Kirk.Prutzman@fda.hhs.gov>; Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>  
**Subject:** STN 125682-Information Request

Dear Mr. O'Neil,

We have reviewed the Risk Management Plan (version 5.0, dated August 1, 2018) submitted to your biologics license application for Dengue Tetravalent Vaccine, Live (STN 125682) and we have the following request for additional information:

1. Please confirm the information below regarding your proposed pregnancy registry (DNG16) and provide the requested dates:

To establish a pregnancy registry to prospectively collect data on reported exposures to Dengvaxia during pregnancy and evaluate pregnancy outcomes. The registry will enroll a minimum of 350 evaluable subjects.

Final protocol submission: [INSERT DATE when the protocol will be submitted to the IND]

Study/Clinical trial completion: [INSERT DATE]

Final Report Submission: December 31, 2023 [Please confirm]

Please submit your response as an amendment to STN 125682 by Monday, April 22, 2019. If you have any questions about this communication, please contact Kirk Prutzman, Stephanie Polo or Ramachandra Naik at (301) 796-2640.

Best regards,

**Stephanie Polo**

*Primary Reviewer/Regulatory Project Manager*

Center for Biologics Evaluation and Research  
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