

From: Polo, Stephanie
Sent: Wednesday, April 24, 2019 6:09 PM
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 your April 22, 2019 submission to STN 125682 (Amendment 47), and we have the following comments:

We note that you have modified your approach for collecting data on reported exposures to Dengvaxia during pregnancy. You have indicated that you will no longer conduct DNG16. Instead, you have proposed a new pregnancy registry to retrospectively collect data on reported exposures to Dengvaxia during pregnancy to evaluate maternal, pregnancy, birth, neonatal and infant outcomes using a hybrid design (i.e., primary data collection supplemented by the use of administrative health and mortality databases).

Pregnancy registry studies should be conducted using a prospective design. A retrospective design may introduce bias and is of limited usefulness. We reference the FDA Guidance for Industry "Establishing Pregnancy Exposure Registries." Therefore, we do not consider a retrospective pregnancy registry to be adequately designed.

Please revise your pregnancy registry to enroll women exposed to Dengvaxia during pregnancy prospectively.

Please submit a revised pregnancy registry in an amendment to STN 125682 by Friday, April 26, 2019. If you have any questions, please contact Kirk Prutzman, Stephanie Polo or Ramachandra Naik at (301) 796-2640.

Best regards,

Stephanie Polo

Primary Reviewer/Regulatory Project Manager

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