

From: Polo, Stephanie
Sent: Tuesday, February 26, 2019 4:34 PM
To: 'Patrick.O'Neil@sanofi.com' <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 the following request for additional information regarding STN 125682 (Dengue Tetravalent Vaccine [Live, Attenuated]):

Please provide the following data on each case of severe dengue or DHF in each of the three trials, CYD15, CYD14 and CYD23, in tabular format. Please include only subjects who were at least 9 years of age and up to and through 16 years of age at the time of randomization into the trial. Row 3 is a mock template and rows 4-10 are abbreviated mock templates for the requested table.

Trial/Subj. I.D./sex/Dengvaxia or Placebo/age at randomization	Severe dengue by IDMC criteria	DHF by WHO criteria	Dengue Serotype at Diag. of severe or DHF: if not known, state Unknown	Age in years and months at time of diagnosis of severe or DHF	Baseline GMT for serotype identified in severe or DHF case: M=measured or I=imputed *	28 day post-inj. 3 GMT for serotype identified in severe or DHF case	GMT for serotype identified in severe or DHF case at time of diagnosis of that case	Number of months post-randomization until onset of severe or DHF case
CYD15								
Subject I.D. XXXXXXXX/male or female/9 years 1 month Dengvaxia	Yes or no	Yes or no If Yes, DHF Grade 1-4	1-4	10 y, 4 mo.	GMT=	GMT=	GMT=	34 months
Subject I.D. XXXXXXXX Placebo								
CYD14								

Subject I.D. XXXXXXX Dengvaxia								
Subject I.D.XXXXXX Placebo								
CYD23								
Subject I.D. XXXXXXX Dengvaxia								
Subject I.D. Placebo								

*If unknown, state Unknown

Please submit the requested information in an amendment to STN 125682 by Tuesday, March 5, 2019. If you have any questions, please contact Kirk Prutzman, Stephanie Polo or Ramachandra Naik at 301-796-2460.

Best regards,

Stephanie Polo

Primary Reviewer/Regulatory Project Manager

**Center for Biologics Evaluation and Research
Office of Vaccines Research and Review
U.S. Food and Drug Administration**

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