

From: Polo, Stephanie
Sent: Wednesday, September 26, 2018 4:55 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]):

Under 21st Century Cures Act, FDA is required to “make public a brief statement regarding the patient experience data and related information, if any, submitted and reviewed as part of the application.”

You may either:

- 1) Confirm that no patient experience data was submitted with the application. **OR**
- 2) Identify all patient experience data, as defined in section 3001 of the 21st Century Cures Act that are included in the application. (See <https://www.congress.gov/114/plaws/publ255/PLAW-114publ255.pdf>).

Some examples of patient experience data might include the following, but are not limited to:

- Clinical outcome assessment data
- Qualitative studies (e.g., individual patient/caregiver interviews, focus group interviews, expert interviews, Delphi Panel, etc.)
- Patient-focused drug development or other stakeholder meeting summary reports
- Observational survey studies designed to capture patient experience data (e.g., disease burden, treatment burden, etc.)
- Natural history studies
- Patient preference studies

Please include a summary table with patient experience data type and reference the section in the application where the data is described in detail. A sample table has been provided below:

<input type="checkbox"/>	The patient experience data that was submitted as part of the application, include:	Section(s) and if applicable file names where data are located and discussed in the application
<input type="checkbox"/>	Clinical outcome assessment (COA) data, such as	

<input type="checkbox"/>	Patient reported outcome (PRO)	
<input type="checkbox"/>	Observer reported outcome (ObsRO)	
<input type="checkbox"/>	Clinician reported outcome (ClinRO)	
<input type="checkbox"/>	Performance outcome (PerfO)	
<input type="checkbox"/>	Qualitative studies (e.g., individual patient/caregiver interviews, focus group interviews, expert interviews, Delphi Panel, etc.)	
<input type="checkbox"/>	Patient-focused drug development or other stakeholder meeting summary reports	
<input type="checkbox"/>	Observational surveys studies designed to capture patient experience data	
<input type="checkbox"/>	Natural history studies	
<input type="checkbox"/>	Patient preference studies (e.g., submitted studies or scientific publications)	
<input type="checkbox"/>	Other: (Please specify)	

Please submit your response as an amendment to STN 125682.

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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