

LIST A. Relevant interactions with CBER regarding the PREA study V72_57

GSK has diligently pursued development of Bexsero in children from the time of approval of Bexsero to the present time. Below lists the several submissions and interactions with CBER (excluding TCs and email correspondence with CBER PM) that GSK has made:

- December 19, 2014: Original protocol V72_57 submitted as seq# 0237 to IND 011561
- December 02, 2015: GSK submits a revised V72_57 Protocol (Version 2) as seq# 0253 to IND 011561 in response to CBER comments received March 04, 2015
- May 16, 2016: GSK submits its response to some comments received from CBER referencing protocol V72_57 (version 2) as seq# 0259 to IND11561
- August 9, 2016: GSK responds to additional comments received from CBER for protocol V72_57 (version 2) and submits revised V72_57 Protocol (version 4) as seq# 0264 to IND 011561
- January 06, 2017: White Paper titled “Meningococcal Group B Vaccine Bexsero Overview of CDP in pediatric population (2 months to 10 year of age)” submitted as seq# 0266 to IND 011561
- June 29, 2017: Type C Meeting on pediatric development and Licensure (CRMTS #10734)
- December 19, 2017: Breakthrough Therapy Designation status granted for development of Bexsero in children 2-10 years of age
- February 21, 2018: GSK submits revised V72_57 protocol as agreed with CBER at Type C meeting (CRMTS #10734; June 29, 2017) as seq# 0292 to IND 011561

The following are submissions that were also made to propose study completion revision dates and provide explanation for these revisions which affected three milestones, PMR#2, PMR#3 and PMR#5.

- March 21, 2016: Bexsero Annual Report for PMC submitted as seq# 083 to BLA 125546
- December 20, 2016: PMC/PMR Status report and Good Cause Argument to extend PMCs submitted as seq# 0123 to BLA 125546
- March 23, 2017: Bexsero Annual Report for PMC submitted as seq#0143 to BLA 125546
- March 23, 2018: Bexsero Annual Report for PMC submitted as seq#0203 to BLA 125546

LIST B. CBER correspondence with GSK regarding the PREA study V72_57

- March 04, 2015: CBER responds with comments to GSK's submission of the original V72_57 protocol (December 19, 2014; IND 011561 seq# 0237)
- January 20, 2016: Teleconference with GSK; included discussion on study V72_57 protocol
- February 12, 2016: CBER provided some comments on study protocols V72_57, V72_79 and V72_58
- February 29, 2016: CBER responds with comments to GSK's submission of revised study V72_57 protocol (version 2) (December 02, 2015, IND 011561, seq# 0253).
- November 22, 2016: CBER email requesting more details of GSK's Clinical Development Program for use of Bexsero in infants
- January 24, 2017: CBER responds to GSK's submission of further revised V72_57 protocol (August 9, 2016, IND 011561 seq# 264) and White Paper titled 'Meningococcal Group B Vaccine Bexsero Overview of CDP in pediatric population (2 months to 10 year of age)' (January 06, 2017, IND 011561 seq#269).
- June 29, 2017: Type C Meeting on pediatric development and Licensure (CRMTS #10734)
- April 19, 2018: Request to GSK for additional information and a teleconference on final revised V72_57 protocol (February 21, 2018, IND 011561 seq# 0292)