STATEMENT FOR STUDY PROTOCOL AVAILABILITY

Detailed Title:	Effectiveness of maternal immunization with *Boostrix* at preventing pertussis among infants <2 Months old in the United States: analysis of a dataset from a case-control study conducted by the Centre for Disease Control.
eTrack study number and Abbreviated Title:	210031 (EPI-PERTUSSIS-052 VE US DB)
Statement for study protocol availability:	The initial study on the effectiveness of Tdap maternal immunization at preventing pertussis in infants was conducted by the Emerging Infections Program Network. This is a collaborative network between the Centers for Disease Control and Prevention and state and local health departments, academic institutions, and laboratories that serves as a national resource for surveillance, prevention, and control of emerging infectious diseases. The results of this study have been published in Clinical Infectious Diseases in 2017 (*Skoff TH, Blain AE, Watt J, Scherzinger K, McMahon M, Zansky SM, Kudish K, Cieslak PR, Lewis M, Shang N, Martin SW. Impact of the US Maternal Tetanus, Diphtheria, and Acellular Pertussis Vaccination Program on Preventing Pertussis in Infants <2 Months of Age: A Case-Control Evaluation. PMID:29028938*). Within the frame of a data use agreement, GSK performed a brand-specific post-hoc analysis of a limited data set to estimate the effectiveness of the *Boostrix* Tdap vaccine. Considering the specificities of this project, developing both a protocol and a statistical analysis plan would have been redundant and of no added value. GSK therefore described the planned analysis in a single document, which was a detailed statistical analysis plan.
Date of Statement:	24 June 2020