From: Gottschalk, Laura
Sent: Monday, July 26, 2021 2:06 PM
To: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>; Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>
Subject: STN 125742/0: IR RE disposition of participants in safety populations who experienced pregnancy

Dear Ms. Harkins,

The review team has comments for you regarding the disposition of participants in safety populations who experienced pregnancy. Please complete and submit the following table to your BLA by this Friday, July 30, 2021:

Table X: Disposition of Participants 16 Years of age and Older, Safety Populations who Experienced Pregnancy through 13 March 2021

Treatment Group	BNT162b2 (N=) n (%)	Placebo (N=) n (%)	Total (N=) n (%)
Total number of pregnancies			
Withdrawal from study due to pregnancy			
Timing of pregnancy			
Completed 1 dose			
Completed 2 doses			
Completed 3 doses			
Completed 4 doses			
Spontaneous Abortions			
Elective Abortions			
Miscarriage			
Fetal demise			
Birth outcomes known			
Unknown pregnancy outcomes			
Ongoing pregnancy			
Major birth defect			

Please provide the timing of the last dose (BNT162b2) , relative to LMP: study vaccination occurred prior to LMP, within 30 days of LMP and >30 days after LMP. This may be expressed as a percentage of total pregnancies.

Please acknowledge receipt of this message and let me know if you have any questions.

Best,
Laura

Laura Gottschalk, PhD
Regulatory Project Manager/Primary Reviewer

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