

**From:** Gottschalk, Laura  
**Sent:** Thursday, July 29, 2021 6:22 PM  
**To:** Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>  
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**Subject:** STN 125742/0 – COMIRNATY (COVID-19 Vaccine, mRNA) – Comment regarding analyses for safety for the two age groups

Dear Ms. Harkins:

Our review of the information provided in your BLA STN 125742/0 for COMIRNATY (COVID-19 Vaccine, mRNA), for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older, is ongoing. We have the following request for additional information:

Please submit the analyses as presented in Table 7 (page 116) of the Summary of Clinical Safety for the following age groups: 1) 16 through 55 years, 2) 56 years and older.

Please provide your response in an Amendment to STN 125742/0 by COB August 2, 2021. If you have any questions about this communication, please feel free to contact me.

Best regards,  
Laura

**Laura Gottschalk, PhD**

*Regulatory Project Manager/Primary Reviewer*

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