

From: Naik, Ramachandra

Sent: Wednesday, July 28, 2021 4:37 PM

To: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>

Cc: Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>

Subject: STN 125742/0 - COMIRNATY (COVID-19 Vaccine, mRNA) – CBER comments regarding postmarketing safety study(ies)

Dear Ms. Harkins,

Our review of your pharmacovigilance plan for COMIRNATY (COVID-19 Vaccine, mRNA) under BLA 125742 is ongoing. We have the following comments regarding postmarketing safety study(ies):

1. Please propose postmarketing observational safety study(ies) to assess myo/pericarditis following administration of COMIRNATY to:
 - a. Quantify the magnitude of risk by age, sex, and dose
 - b. Include follow up cases (e.g., via a registry) for recovery status and long-term sequelae
2. Please also provide your plans to characterize subclinical cases of myocarditis.

Please include the following information for the postmarketing study(ies) proposal: study designs, sample sizes and justification of sample sizes including number of subjects ≤30 years of age, information to be collected at baseline, frequency and methods for follow-up data collection, plan for duration of long term follow-up and information to be collected in follow-up, study timeline and milestone dates (final protocol submission date, study completion date, and final study report submission date; please provide dates in mm/dd/yyyy format).

Please provide your responses in an amendment to STN 125742/0 by Tuesday, August 3, 2021. We recommend that you restate each item and follow it with your explanation or clarification. Use of this format helps organize the relevant information and provides a self-contained document that facilitates future reference.

Please confirm receipt of this email and let me know if you have any questions or need additional information.

Regards,

Ram

Ramachandra S. Naik, Ph.D.

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