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

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