From:	Gemignani, Helen S
To:	Amitkumar.Patel@pfizer.com
Subject:	COMIRNATY STN 125742 - PMR/PMC Communications
Date:	Thursday, September 30, 2021 4:49:00 PM
Attachments:	image002.png

Helen S. Gemignani -S

Digitally signed by Helen S. Gemignani -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=13000677794, cn=Helen S. Gemignani -S
Date: 2021.09.30 16:55:54 -04'00'

Good afternoon Dr. Patel,

We are in receipt of your 8/30/2021, PMR/PMC Correspondence Status Update submission, to your COMIRNATY BLA. This submission notified the BLA of the submission of study protocols to the IND for [PMR# 4, Study C4591009] and [PMC# 12, Study C4591012].

Please note, in the BLA Approval Letter, all of the PMRs and PMCs have been designated a sequential, specific PMR# or PMC#. For example:

POSTMARKETING REQUIREMENTS UNDER SECTION 505(o)

4. Study C4591009, entitled "A Non-Interventional Post-Approval Safety Study of the Pfizer-BioNTech COVID-19 mRNA Vaccine in the United States," to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY.

We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

Final Protocol Submission: August 31, 2021
Monitoring Report Submission: October 31, 2022
Interim Report Submission: October 31, 2023
Study Completion: June 30, 2025
Final Report Submission: October 31, 2025

POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

12. Study C4591012, entitled "Post-emergency Use Authorization Active Safety Surveillance Study Among Individuals in the Veteran's Affairs Health System Receiving Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine."

Final Protocol Submission: January 29, 2021
Study Completion: June 30, 2023
Final Report Submission: December 31, 2023

In your future correspondence, to the BLA and to the IND, please refer to the specific PMR # or PMC# to which the information pertains. This will mitigate confusion and maintain clarity of studies being discussed.

Please feel free to contact me via email if you have any questions.

Kind regards,
Helen

Helen Sullivan Gemignani
OVRR PMR/PMC Coordinator

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