

From: Smith, Michael (CBER)
Sent: Monday, August 9, 2021 12:06 PM
To: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>
Subject: STN 125742.0: Clinical IR RE sequencing data

Elisa,

The review team has the below clinical questions for you regarding study C4591001. Please respond as soon as possible and no later than Thursday, August 12, 2021.

One subject in the vaccine group, (Site No: 1252, Subject No: 12521010): 80-year-old white, non-Hispanic male who received two doses of BNT162b2 (17 Aug 2020 and 08 September 2020), died from COVID pneumonia.

If available, please provide sequencing data for the virus isolated from this patient.

If there is available genomic sequencing data for any other COVID-19 case, especially those with fatal outcomes, and those from HIV positive subjects, please submit that information.

Regards,

Mike

- Please confirm receipt of this e-mail and let us know if you have any questions.

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Captain, USPHS

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