**From:** Smith, Michael (CBER)
**Sent:** Tuesday, June 29, 2021 3:47 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 Study C4591001

Elisa,

The clinical team has the below IR regarding Study C4591001. The review team would prefer a response by July 2, 2021.

Please provide the maximum date (latest date) of randomization for participants included in the reactogenicity subset for Study C4591001. Our evaluation of the datasets indicates that the maximum date of randomization (RANDDT) and vaccination date 01 (VAX101DT) for participants included in the reactogenicity subset is January 8, 2021. If based on your analyses, this date should be different, please provide guidance to the datasets and the appropriate flags we can use to confirm your results within the datasets.

Regards,

Mike

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

**Mike Smith, Ph.D.**
**Captain, USPHS**

**Senior Regulatory Review Officer**
**Food and Drug Administration**
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