

**From:** Smith, Michael (CBER)

**Sent:** Wednesday, June 9, 2021 2:12 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 1275742.0: Request for dates associated with PREA deferred studies

Elisa,

The clinical team has an information request regarding the dates associated with the PREA deferred studies – see below. Please submit this information to the BLA by Friday, June 18<sup>th</sup>.

Please provide the following dates for your PREA deferred studies:

Study C4591001: Ages 12 Through 17 Years

Final Protocol Submission: xx-xx-xxxx

Study Completion: xx-xx-xxxx

Final Report Submission: xx-xx-xxxx

Study C4591007: 11 years of age and younger

Final Protocol Submission: xx-xx-xxxx

Study Completion: xx-xx-xxxx

Final Report Submission: xx-xx-xxxx

Regards,

Mike

- Please confirm receipt of this e-mail

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

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