

**From:** Mineo, Gosia (b) (6)  
**Sent:** Tuesday, April 26, 2022 4:14 PM  
**To:** Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>  
**Cc:** Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; MaguireThon, Meghan <Meghan.MaguireThon@fda.hhs.gov>; Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>; Collins, Kathleen Mary Catherine (b) (6)  
**Subject:** RE: [EXTERNAL] RE: STN 125742/45 & IND 19736: IR RE request for a revised study protocol for Study C4591022 - pregnancy registry study (postmarketing commitment (PMC) #10 as described in the STN 125742/0 approval letter)

Michael J. Smith -S4  
Digitally signed by Michael J. Smith -S4  
Date: 2022.04.26 16:22:07 -04'00'

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Thank you very much, Mike.

Yes, I confirm we will provide the response by May 6<sup>th</sup>, likely sooner.

Thank you and kind regards,  
Gosia

**From:** Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>  
**Sent:** Tuesday, April 26, 2022 3:35 PM  
**To:** Mineo, Gosia (b) (6)  
**Cc:** Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; MaguireThon, Meghan <Meghan.MaguireThon@fda.hhs.gov>; Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>; Collins, Kathleen Mary Catherine (b) (6)  
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Gosia,

Pfizer's proposal to submit the revised protocol and SAP to IND 19736 by May 20<sup>th</sup> is acceptable. However, please submit an IR response to STN 125742.45 by May 6<sup>th</sup> (sooner if possible) confirming your intention to revise the pregnancy registry study protocol and SAP to include pregnant individuals of all ages.

Regards,

Mike

**From:** Mineo, Gosia (b) (6)  
**Sent:** Tuesday, April 26, 2022 2:08 PM  
**To:** Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>

**Cc:** Naik, Ramachandra <[Ramachandra.Naik@fda.hhs.gov](mailto:Ramachandra.Naik@fda.hhs.gov)>; Gottschalk, Laura <[Laura.Gottschalk@fda.hhs.gov](mailto:Laura.Gottschalk@fda.hhs.gov)>; MaguireThon, Meghan <[Meghan.MaguireThon@fda.hhs.gov](mailto:Meghan.MaguireThon@fda.hhs.gov)>; Harkins Tull, Elisa <[Elisa.HarkinsTull@pfizer.com](mailto:Elisa.HarkinsTull@pfizer.com)>; Devlin, Carmel M <[Carmel.Devlin@pfizer.com](mailto:Carmel.Devlin@pfizer.com)>; Collins, Kathleen Mary Catherine (b) (6)

**Subject:** [EXTERNAL] RE: STN 125742/45 & IND 19736: IR RE request for a revised study protocol for Study C4591022 - pregnancy registry study (postmarketing commitment (PMC) #10 as described in the STN 125742/0 approval letter)

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Hi Mike –

In the below communication, you requested we submit the revised final study Protocol and SAP for C4591022 to IND 19736 by May 6, 2022.

Unfortunately, it will take some time to turn around these documents and thus we won't be able to meet this date. We can submit the protocol and SAP amendments on May 20. Would this please be acceptable?

Thank you,  
Gosia