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Cc: sebastian.gascon@grifols.com; [Ananyeva, Natalya](#); [Do, Yu](#)
Subject: RE: BLA 125640/0; IPSP: Pediatric Study IG1405
Date: Monday, August 21, 2017 7:32:26 AM

Good Morning,

I am the clinical review for BLA 125640. Regarding the agreed iPSP (Pediatric study protocol IG1405), please submit a statement summarizing the grounds for deferring the studies, a brief description of the planned study, evidence that the study will be conducted with due diligence and at the earliest possible time, and a timeline for the completion of the study. Please contact me by email if you have any questions.

Please respond by email by 2:00pm EST today, 8/21/2017.

Regards,

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