

From: [Patel, Manisha](#)
To: [Giordano, Erica](#); [Oleary, Maura](#)
Cc: [Ahmed, Narin](#)
Subject: RE: BLA 125646 - Follow-up from today's call
Date: Friday, August 25, 2017 9:47:21 AM
Sensitivity: Confidential

Thank you

From: Giordano, Erica [mailto:Erica.Giordano@fda.hhs.gov]
Sent: Friday, August 25, 2017 9:46 AM
To: Patel, Manisha <manisha.patel@novartis.com>; Oleary, Maura <Maura.Oleary@fda.hhs.gov>
Cc: Ahmed, Narin <narin.ahmed@novartis.com>
Subject: RE: BLA 125646 - Follow-up from today's call
Sensitivity: Confidential

Good morning,

We agree with you on abdominal pain and on renal. We are still reviewing bleeding but the clinical team used bleeding on ADAERISK.

Thanks
Erica

From: Patel, Manisha [<mailto:manisha.patel@novartis.com>]
Sent: Wednesday, August 23, 2017 10:19 PM
To: Giordano, Erica; Oleary, Maura
Cc: Ahmed, Narin
Subject: BLA 125646 - Follow-up from today's call

Hi Erica & Maura,

Please see below list of patients as requested this afternoon:

- ABDOMINAL PAIN: there are 11 patients with ABDOMINAL PAIN when preferred term includes both Abdominal Pain and Abdominal Pain Upper. This is not consistent with the Agency's result (n=10).

(b) (6)


- ACUTE KIDNEY INJURY: there are 15 patients with ACUTE KIDNEY INJURY when the following preferred terms are included: ACUTE KIDNEY INJURY, ANURIA, AZOTAEMIA, RENAL FAILURE, RENAL TUBULAR DYSFUNCTION, and RENAL TUBULAR NECROSIS. This is not consistent with the Agency's result (n=14).

(b) (6)

- BLEEDING: Under Section 6.1 Table 2, about bleeding episodes, there are 21/68 (30.9%)

patients who had bleeding events based on SMQ term 'Hemorrhage terms (excl laboratory terms)'. This is not consistent with the Agency's result (40%). Can you please clarify your search criteria?

(b) (6)

A large rectangular area of the document is redacted with a solid grey fill. The redaction covers the signature and any text that might have been present below the signature line.

Kind regards,

Manisha

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