

From: [Janice Castillo](#)
To: [Gildner, Jean](#)
Subject: RE: BLA 125586 - Clarification of IR
Date: Thursday, January 04, 2018 4:28:03 PM
Attachments: [image007.png](#)

Receipt acknowledged.

Janice

From: Gildner, Jean [mailto:Jean.Gildner@fda.hhs.gov]
Sent: Thursday, January 04, 2018 1:13 PM
To: Janice Castillo
Subject: BLA 125586 - Clarification of IR

Dear Janice,

Please see the following clarification. Please acknowledge receipt of this email.

Since our expectation for the ADAE dataset is just to have investigator assessed AEs, we consider EAC adjudicated AEs whether they are TEs or other AEs as optional to our review. So as long as you confirm that ALL investigator assessed AEs are included that is fine. In other words if the EAC did not identify a TE but an investigator did this information should be included in the dataset.

In addition CBER CDISC did not send us an analysis but just notified us of the inquiry by Portola. I will leave it up to them to respond to you as to what they found.

Sincerely, Jean

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