

From: [Jarvis, Candace](#)
To: [James L'Italien, PhD \(jlitalien@avexis.com\)](#)
Cc: [Jarvis, Candace](#); [Byrnes, Andrew](#); [Lin, Xue \(Mary\)](#); [Singer, Mike](#); [Xu, Lei \(CBER\)](#)
Subject: BLA 125694/0| AveXis, Inc| Information Request 9 (PLEASE RESPOND BY COB NOVEMBER 8, 2018)
Date: Tuesday, November 06, 2018 12:36:12 PM **Attachments:**
[image002.png](#)

Good Afternoon Dr. L'Italien,

We have the following request for information regarding dataset ADVT as provided in BLA 125694/0. PLEASE RESPOND TO THIS EMAIL BY COB NOVEMBER 8, 2018.

1. In the SAS program ad-advt, you imported an excel spreadsheet 'acute_pt'. Acute_pt was used in the derivation of advt dataset. However, it seems that you did not provide this data in your submission. Please provide this data.
2. The CRF recorded three types of ventilator support: cough assist, non-invasive (BiPAP and other) and invasive ventilator supports. It seems only BiPAP noninvasive ventilator support counts toward the primary endpoint of permanent ventilation free survival, but not the other types of ventilator support. Please explain why cough assist, other type of non-invasive ventilator support and invasive ventilator support do not count toward permanent ventilation free survival.

Please confirm receipt of this email.

Regards,

Candace N. Jarvis
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