

**From:** [Jarvis, Candace](#)  
**To:** [James L'Italien, PhD \(jlitalien@avexis.com\)](#)  
**Cc:** [Nancy Boman](#); [Byrnes, Andrew](#); [Jarvis, Candace](#); [Lin, Xue \(Mary\)](#)  
**Subject:** 125694/0| AveXis, Inc| Information Request 28 ( PLEASE RESPND BY JANUARY 18, 2019)  
**Date:** Tuesday, January 15, 2019 1:24:24 PM  
**Attachments:** [image013.png](#) **Importance:** High

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Good afternoon Dr. L'Italien,

We have the following Statistical comment for BLA 125694/0. Please respond to this request by COB January 8, 2019. If you are unable to meet this deadline, please let us know so that a new timeline can be negotiated.

We found the following discrepancies in your clinical study report for study AVXS101-CL-101. Please explain.

1. Listing 16.2.6.6-24 indicates that 7 subjects could prone: hold head to vertical axis and legs extended, however, in Table 14.2.3.1.1-24, the number of subjects reached this milestone was 8.
2. Listing 16.2.6.6-24 indicates that 10 subjects could supine: rolls over back to front, however, in Table 14.2.3.1.1-24, the number of subjects reached this milestone was 9.
3. Listing 16.2.6.6-24 indicates that nine subjects could sit alone for at least 10 seconds, however, Table 14.2.3.3.1-24 shows ten subjects can sit alone for at least 10 seconds.
4. Listing 16.2.6.6-24 indicates that six subjects could sit alone for at least 30 seconds, however, Table 14.2.3.3.1-24 shows nine subjects can sit alone for at least 30 seconds.
5. In the case report form submitted in amendment #27 on Nov 27, subject (b) (6) was enrolled in The Royal Children's Hospital Melbourne in Australia. However, the demographic data indicates that this subject was enrolled in the U.S.

Please acknowledge receipt of this email.

Regards,

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