

From: [Dehdashti, Seameen \(Jean\)](#)
To: ["BDV \(Barbara Davies\)"](#)
Cc: [Dehdashti, Seameen \(Jean\)](#)
Subject: FDA Information Request (IR) RE: BLA 125671/0
Date: Thursday, March 15, 2018 8:40:05 AM
Attachments: [image002.png](#)
Importance: High

Good morning Barbara,

Reference is made to Novo Nordisk, Inc., original BLA 125671 submission, dated February 27, 2018. The FDA/CBER CDISC validation team has identified additional issues outlined below in **bold text**. Please provide a response no later than close-of-business (COB), Thursday, March 20, 2018. Please let me know if you are not able to meet this deadline.

FDA Information Request (CBER CDISC): We have identified several issues with the BLA datasets you have provided and are seeking some clarifications and or corrections.

-

1. **SDTM ~ ADaM Traceability:** there are 21 subjects in the 3859 extension 2 Study where their ARM values in the SDTM demographics domain (DM) do not match the ARM values in ADSL. Please correct the discrepancy.
2. **File names:** most supporting documents (e.g. reviewer's guides, protocols, etc.) hyperlinked within the define.xml files have the incorrect filename listed in the hyperlink. All the documents appear to be present, however, they can only be opened manually rather than using the hyperlinks in the define.xml). Please correct the documents so that the hyperlinks are functional.
3. **In some studies, comments are provided in SUPPQUAL instead of Comments (CO) domains.** Please provide all comments in the CO domains.
4. **In some studies, high percentage of screen failure subjects do not have information in IE domain.** Please make necessary corrections.
5. **In study 3885, 126 (3.6%) events are missing start date/time.** Please insert the missing information.
6. **In some studies, high percentage of subjects are missing Date/time of Informed Consent (RFICDTC).** Please submit the missing data.

Please confirm receipt of my e-mail, and do not hesitate to contact me, should you have any questions and/or concerns.

Warm regards,

Jean Dehdashti, MSc, RAC
Regulatory Project Manager

Center for Biologics and Evaluation
Office of Tissues and Advanced Therapies
U.S. Food and Drug Administration
Tel: 240-402-9146
Seameen.Dehdashti@fda.hhs.gov



THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.