



Our Reference: BLA 125668/0

Octapharma Pharmazeutika Produktionsges.m.b.H.

Attention: Mr. Stanley Ammons

February 5, 2018

Sent by email

Dear Mr. Ammons:

We are reviewing your December 28, 2017, biologics license application (BLA), for Immune Globulin Subcutaneous (Human). We determined that the following information is necessary to continue our review:

M5 File for SCGAM-01 study

EX Domain:

1. Please explain why the EX domain has so many records. There are three EXCAT: "PRIOR IVIG TREATMENTS", "EXPOSURE", and "INFUSION SITES". Please explain the difference between these three records.
2. Some of the values in EXSTDTC are not in ISO8601 format, "-----T19:00". Please correct.
3. EXSTDY has a missing value. Please correct.
4. Some of the records in EX appear to be duplicate records, see example below. Please confirm if they are duplicate records, if so, please remove all duplicates.

Abdomen, right      10      mL      490      Week 49      -----T18:59

Abdomen, right      10      mL      490      Week 49      -----T18:59

5. There are 9899 records missing timing information (EXSTDTC/EXENDTC is missing). Please provide the missing information.
6. Temperature information should be recorded in the VS domain instead of the EX domain.

PC Domain:

7. PCORNRLO, PCORNRHI, PCSTNRLO, PCSTNRHI, PCNRIND should be in the PC domain instead of the SUPPPC domain.

LB Domain:

8. The following LBTESTCD LBTESTs have a standardized result (LBSTRESN). However, the standardized upper range (LBSTNRHI) is null:
  - a. BASOLE Basophils/Leukocytes 346 records (73.5% of 471 total records)
  - b. EOSLE Eosinophils/Leukocytes 355 records (75.4% of 471 total records)
  - c. LYMLE Lymphocytes/Leukocytes 355 records (75.4% of 471 total records)
  - d. MONOLE Monocytes/Leukocytes 355 records (75.4% of 471 total records)
  - e. NEUTLE Neutrophils/Leukocytes 355 records (75.4% of 471 total records)
9. There is an incorrect SDTM implementation. The results (LBORRES) and units (LBORRESU) for these records should have been copied over to the standardized result (LBSTRESC) and standardized unit (LBSTRESU) even if the standard results and unit are not available. Please fix the error "Missing value for LBSTRESC, when LBORRES is provided".

The review of this submission is on-going and issues may be added, expanded upon, or modified.

Please submit your response to this information request as an amendment to this file by February 19, 2018, referencing the date of this request. If you anticipate you will not be able to respond by this date, please contact the Agency immediately so a new response date can be identified.

If we determine that your response to this information request constitutes a major amendment, we will notify you in writing.

The action due date for this file is December 29, 2018.

Please send an email message acknowledging receipt of this request.

If you have any questions, please contact me.

Sincerely,  
Edward Thompson  
Regulatory Project Manager  
FDA/CBER/OBRR/PPMS