

Record of Telephone Conversation, December 16, 2009 - Flublok

- Submission Type: BLA Submission ID: 125285/0 Office: OVRR
 Product:
 Influenza Vaccine
 Applicant:
 Protein Sciences Corporation
 Telecon Date/Time: 16-Dec-2009 08:36 AM Initiated by FDA? Yes
 Telephone Number:
 Communication Category(ies):
 1. Information Request

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Telecon Summary:

Clarification of disposition for Study PSC04.

FDA Participants: Timothy Fritz

Non-FDA Participants: Penny Post

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

Dr. Post-

Our review of Protein Sciences Corporation FluBlok BLA 125285 is ongoing. We have the following request for clarification:

- Please clarify your disposition of subjects at Day 28 and Day 180.

From the Interim Study Report (ISR), original BLA Module 5, Volume 19, pp 52-54, Table 4 p 53 and Table 14.1.1 p 105, and the corresponding electronic datasets, the disposition of subjects at Day 28 appears to be as presented in Table 1:

Table 1: Subject Disposition through Day 28 Contact – ISR-PSC04

| | Number of Subjects (%) | | |
|-------------|------------------------|------------------|---|
| | Treatment Group | | |
| Disposition | Placebo n (%) | FluBlok n (%) | FluBlok Immunogenicity Subset n(%) |
| Randomized | 2325 (100) | 2323 (100) | 391 (100) |
| Vaccinated* | 2304 (100) | 2344 (100) | 391 (100) |
| Completed** | 2211 (96%) | 2249 (96%) | 0 |

| | Number of Subjects (%) | | |
|---------------------------------------|------------------------|---------|-----|
| Discontinued | 93 (4%) | 95 (4%) | 0 |
| Due to AE | 0 | 0 | |
| Lost to follow-up | 85 (4%) | 88 (4%) | |
| Withdrew consent | 2 (<1) | 7 (<1) | |
| Death | 0 | 0 | |
| Randomized, not Vaccinated | 0 | 0 | |
| Other reasons | 6 (<1) | 0 | |
| | | | |
| Safety Population | 2304 | 2344 | |
| Evaluable Population (Immunogenicity) | | 391 | 391 |

In the Complete (Final) Study Report (CSR), Complete Response Module 5, Volume 2, pp 55-58, Table 4 p56 and Table 14.1.1 p 158, and corresponding electronic datasets, the disposition of subjects at Day 180 appears to be as presented in Table 2:

Table 2: CSR – Final Disposition of Subjects through Day 180 – PSC04

| | #subjects(%) | | | |
|---------------------------------------|---------------|---------------|------------|------------------------------------|
| | Tx Gp | | | |
| Disposition | Placebo n (%) | FluBlok n (%) | Overall | FluBlok Immunogenicity Subset n(%) |
| Randomized | 2325 (100) | 2323 (100) | 4648 (100) | 480 (100) |
| Vaccinated* | 2304 (100) | 2344 (100) | 4648 (100) | 480 (100) |
| Completed** | 2022 (88) | 2049 (87) | 4071 (88) | 402 (84) |
| Discontinued | 282 (12) | 295 (13) | 577 (12) | 78 (16) |
| Due to AE | 3 (<1) | 3 (<1) | 6 (<1) | 0 |
| Lost to follow-up | 251 (11) | 260 (11) | 511 (11) | 73 (15) |
| Withdrew consent | 14 (1) | 22 (1) | 36 (1) | 5 (1) |
| Death | 1 (<1) | 1 (<1) | 2 (<1) | 0 |
| Randomized, not Vaccinated | 0 | 0 | 0 | 0 |
| Other reasons | 13 (1) | 9 (<1) | 22 (<1) | 0 |
| | | | | |
| Safety Population | 2304 | 2344 | 4648 | |
| Evaluable Population (Immunogenicity) | | 448 | | 448 |

***Serology available for immunogenicity analysis post database lock

Although the CSR appears to present the data through the end of the study, the report states in Section 10.1, paragraph 1, p55, Mod 5 Vol 2, that “The disposition of the 4648 subjects enrolled in the study as of the **Day 28** contact is summarized in Table 4”, and then in paragraph 2, “No subjects died, and no subjects were discontinued due to AEs”. This latter sentence appears to refer to the Day 28 data, but paragraph 3 appears to describe subject disposition at the end of the study. Additionally, although Table 4, CSR p 56, Mod 5, Vol 2, is labeled “Subject Disposition through **Day 28** Contact”, the data appears to represent the end of study data (Day 180).

Please comment and provide a table(s) that presents the Disposition of Subjects at Day 28 versus Day 180. Please categorize discontinuations according to reason for discontinuation including:

- Due to AE
- Lost to follow-up
- Withdrew consent
- Death
- Randomized, not vaccinated
- Other

If you have any questions, please contact the Regulatory Project Managers, Katherine Matrakas or Timothy Fritz, at 301-827-3070.

Thank you.

Timothy A. Fritz, Ph.D.

Microbiologist

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