

From: Hooban, Christopher
To: [Ammons, Stanley](#)
Cc: [Cagungun, Nannette](#)
Subject: BL 125587/0 - NGAM-01 Clarification Request
Date: Friday, May 22, 2015 10:32:00 AM
Attachments: [image001.png](#)

Our Reference: BL 125587/0

Mr. Ammons,

Good morning. One of the reviewers had the following clarification requests related to NGAM-01:

1. Table 27 of the protocol, pg. 117/11678:
 - a. The value given for "Any AEs" is less than the sum of the sub-rows for columns 2 (Children), 5 (3-week schedule) and 7 (Total All Patients). Please provide an explanation.
 - b. Please distinguish the difference between the numbers in bold and the numbers that are not in bold.

Table 27: Infusional Adverse Events (within 72 Hours of the End of Infusion) (Frequency >3.0% of Total Patients) by Time-Point, MedDRA System Organ Class and Preferred Term, Treatment Schedule and Age Group (Safety Set, N = 51)

| Number of patients with infusional AEs (within 72 hours) by time-point | Children ≥2 Years <12 Years N = 13 N (%) | Adolescents ≥12 Years <16 Years N = 12 N (%) | Adults ≥16 Years ≤75 Years N = 26 N (%) | 3-week schedule N = 21 N (%) | 4-week schedule N = 30 N (%) | Total All Patients N = 51 N (%) |
|---|--|--|---|---------------------------------------|---------------------------------------|---|
| Month 0 (Infusion # 1) | | | | | | |
| <i>Any AE</i> | 2 (15.4) | 1 (8.3) | 1 (3.8) | 1 (4.8) | 3 (10.0) | 4 (7.8) |
| General disorders and administration site conditions | 1 (7.7) | 1 (8.3) | 1 (3.8) | 1 (4.8) | 2 (6.7) | 3 (5.9) |
| Month 1 (Infusion # 2) | | | | | | |
| <i>Any AEs</i> | 3 (23.1) | 0 (0.0) | 3 (11.5) | 1 (4.8) | 5 (16.7) | 6 (11.8) |
| Infections and infestations | 1 (7.7) | 0 (0.0) | 2 (7.7) | 1 (4.8) | 2 (6.7) | 3 (5.9) |
| Month 3 (Infusion #5) | | | | | | |
| <i>Any AEs</i> | 2 (15.4) | 2 (16.7) | 4 (15.4) | 3 (14.3) | 5 (16.7) | 8 (15.7) |
| Infections and infestations | 2 (15.4) | 1 (8.3) | 2 (7.7) | 2 (9.5) | 3 (10.0) | 5 (9.8) |
| Gastrointestinal disorders | 0 (0.0) | 1 (8.3) | 1 (3.8) | 1 (4.8) | 1 (3.3) | 2 (3.9) |
| Nervous system disorders | 1 (7.7) | 0 (0.0) | 1 (3.8) | 1 (4.8) | 1 (3.3) | 2 (3.9) |
| Month 6 (Infusion #9 – 3-week schedule / Infusion #7 – 4-week schedule) | | | | | | |
| <i>Any AEs</i> | 2 (15.4) | 0 (0.0) | 3 (11.5) | 1 (4.8) | 4 (13.3) | 5 (9.8) |
| General disorders and administration site conditions | 1 (7.7) | 0 (0.0) | 1 (3.8) | 0 (0.0) | 2 (6.7) | 2 (3.9) |
| Pyrexia | 1 (7.7) | 0 (0.0) | 1 (3.8) | 0 (0.0) | 2 (6.7) | 2 (3.9) |
| Month 12 (Infusion #17 – 3-week schedule / Infusion #13 – 4-week schedule) | | | | | | |
| <i>Any AEs</i> | 1 (7.7) | 1 (9.1) | 3 (11.5) | 2 (9.5) | 3 (10.3) | 5 (10.0) |
| Nervous system disorders | 1 (7.7) | 0 (0.0) | 3 (11.5) | 2 (9.5) | 2 (6.9) | 4 (8.0) |
| Headache | 1 (7.7) | 0 (0.0) | 3 (11.5) | 2 (9.5) | 2 (6.9) | 4 (8.0) |

Source: Section 14.3, Table 14.3.1.10

N = number of patients

AE = treatment-emergent adverse events

2. Please clarify what the values provided in table 14.3.1.10, pg. 1683/11678, represent:
 - a. Please distinguish what each of the three values (#, %, #) represent for each column.
 - b. Please clarify if a value represents the number of adverse events or the number of patients.

Please provide a response by May 29, 2015. Thanks for your time and please feel free to email or call me if you have

any questions.

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