

**Table 1.** Anthropometric outcomes per study group in the per protocol population (mean  $\pm$  SD).

|                           | <b>Experimental Group</b><br>[N = 71] | <b>Control Group</b><br>[N = 74] | <b>Breastfed reference</b><br>[N = 86] |
|---------------------------|---------------------------------------|----------------------------------|--|
| <b>Body weight (g)</b>    |                                       |                                  |  |
| Baseline                  | 3619 $\pm$ 587                        | 3561 $\pm$ 540                   | 3810 $\pm$ 526                         |
| 4 wks                     | 4090 $\pm$ 422                        | 4147 $\pm$ 495                   | 4082 $\pm$ 402                         |
| 8 wks                     | 5026 $\pm$ 593                        | 5060 $\pm$ 561                   | 5030 $\pm$ 569                         |
| 13 wks                    | 5976 $\pm$ 689                        | 6006 $\pm$ 723                   | 5940 $\pm$ 634                         |
| 17 wks                    | 6544 $\pm$ 775                        | 6681 $\pm$ 806                   | 6607 $\pm$ 651                         |
| <b>Body length (cm)</b>   |                                       |                                  |  |
| Baseline                  | 51.7 $\pm$ 2.4                        | 51.3 $\pm$ 2.1                   | 52.3 $\pm$ 2.2                         |
| 4 wks                     | 53.8 $\pm$ 2.0                        | 53.2 $\pm$ 1.8                   | 53.9 $\pm$ 1.9                         |
| 8 wks                     | 56.9 $\pm$ 2.0                        | 56.7 $\pm$ 2.4                   | 57.0 $\pm$ 2.2                         |
| 13 wks                    | 60.5 $\pm$ 2.2                        | 60.4 $\pm$ 2.0                   | 60.6 $\pm$ 2.3                         |
| 17 wks                    | 62.8 $\pm$ 2.1                        | 62.6 $\pm$ 2.1                   | 63.2 $\pm$ 2.4                         |
| <b>Head circumference</b> |                                       |                                  |  |
| Baseline                  | 35.7 $\pm$ 1.7                        | 35.8 $\pm$ 1.6                   | 36.7 $\pm$ 1.5                         |
| 4 wks                     | 36.7 $\pm$ 1.2                        | 37.0 $\pm$ 1.3                   | 37.3 $\pm$ 0.9                         |
| 8 wks                     | 38.8 $\pm$ 1.4                        | 38.9 $\pm$ 1.3                   | 39.1 $\pm$ 1.1                         |
| 13 wks                    | 40.6 $\pm$ 1.5                        | 40.5 $\pm$ 1.3                   | 40.6 $\pm$ 1.2                         |
| 17 wks                    | 41.6 $\pm$ 1.8                        | 41.6 $\pm$ 1.3                   | 41.5 $\pm$ 1.3                         |

\*P<0.05; significant difference between Experimental and Control group.

**Table 2.** Summary of crying frequency per week of age (episodes/ day)<sup>1</sup>

| Age      |                | Experimental Group | Control Group   | Breastfed reference |
|----------|----------------|--------------------|-----------------|---------------------|
|          |                | N = 77             | N = 86          | N = 90              |
| Baseline | Min-Max (n)    | 0.0 - 10.0 (69)    | 0.0 - 12.0 (83) | 0.0 - 24.0 (84)     |
|          | Median (Q1-Q3) | 6.0 (3.0 - 8.0)    | 5.0 (1.0 - 8.0) | 5.0 (2.0 - 8.0)     |
| 4 wks    | Min-Max (n)    | 0.0 - 11.5 (55)    | 0.0 - 13.0 (61) | 0.0 - 10.8 (68)     |
|          | Median (Q1-Q3) | 2.5 (1.0 - 4.6)    | 2.6 (1.0 - 5.2) | 2.8 (1.3 - 4.6)     |
| 5 wks    | Min-Max (n)    | 0.0 - 14.1 (67)    | 0.0 - 12.0 (74) | 0.0 - 10.4 (84)     |
|          | Median (Q1-Q3) | 2.7 (1.0 - 4.7)    | 2.8 (1.0 - 5.4) | 2.7 (1.4 - 4.1)     |
| 6 wks    | Min-Max (n)    | 0.0 - 15.6 (66)    | 0.0 - 14.0 (77) | 0.0 - 11.0 (84)     |
|          | Median (Q1-Q3) | 2.5 (1.3 - 4.3)    | 2.3 (1.1 - 4.4) | 2.3 (0.8 - 4.2)     |
| 7 wks    | Min-Max (n)    | 0.0 - 17.4 (67)    | 0.0 - 12.9 (75) | 0.0 - 9.2 (80)      |
|          | Median (Q1-Q3) | 2.4 (0.9 - 4.3)    | 2.0 (0.6 - 3.7) | 1.9 (0.7 - 3.8)     |
| 8 wks    | Min-Max (n)    | 0.0 - 15.8 (65)    | 0.0 - 11.3 (76) | 0.0 - 8.7 (78)      |
|          | Median (Q1-Q3) | 2.0 (0.7 - 4.3)    | 1.8 (0.7 - 4.1) | 1.7 (0.7 - 3.5)     |
| 9 wks    | Min-Max (n)    | 0.0 - 11.6 (66)    | 0.0 - 11.4 (76) | 0.0 - 8.6 (73)      |
|          | Median (Q1-Q3) | 1.9 (0.5 - 3.9)    | 1.6 (0.4 - 4.6) | 1.3 (0.6 - 2.5)     |
| 10 Wks   | Min-Max (n)    | 0.0 - 9.1 (64)     | 0.0 - 9.3 (75)  | 0.0 - 9.1 (71)      |
|          | Median (Q1-Q3) | 1.7 (0.6 - 4.1)    | 1.4 (0.4 - 3.4) | 1.3 (0.1 - 2.4)     |
| 11 wks   | Min-Max (n)    | 0.0 - 11.3 (64)    | 0.0 - 9.9 (75)  | 0.0 - 9.7 (68)      |
|          | Median (Q1-Q3) | 1.6 (0.4 - 3.7)    | 0.9 (0.3 - 3.4) | 0.9 (0.3 - 2.4)     |
| 12 wks   | Min-Max (n)    | 0.0 - 8.9 (64)     | 0.0 - 9.0 (75)  | 0.0 - 10.6 (67)     |
|          | Median (Q1-Q3) | 1.3 (0.4 - 2.9)    | 1.0 (0.3 - 3.4) | 1.0 (0.3 - 2.6)     |
| 13 wks   | Min-Max (n)    | 0.0 - 10.7 (63)    | 0.0 - 10.3 (74) | 0.0 - 10.7 (67)     |
|          | Median (Q1-Q3) | 1.5 (0.5 - 3.1)    | 0.9 (0.0 - 3.6) | 1.1 (0.2 - 2.2)     |
| 14 wks   | Min-Max (n)    | 0.0 - 9.0 (64)     | 0.0 - 8.0 (70)  | 0.0 - 9.5 (64)      |
|          | Median (Q1-Q3) | 1.1 (0.3 - 2.8)    | 0.8 (0.1 - 3.6) | 0.8 (0.3 - 2.7)     |
| 15 wks   | Min-Max (n)    | 0.0 - 8.4 (63)     | 0.0 - 7.4 (72)  | 0.0 - 11.6 (63)     |
|          | Median (Q1-Q3) | 1.3 (0.3 - 3.0)    | 0.6 (0.0 - 3.6) | 0.9 (0.0 - 2.7)     |
| 16 wks   | Min-Max (n)    | 0.0 - 9.6 (62)     | 0.0 - 7.7 (72)  | 0.0 - 11.7 (63)     |
|          | Median (Q1-Q3) | 1.4 (0.4 - 3.8)    | 0.8 (0.0 - 3.0) | 0.9 (0.2 - 2.6)     |
| 17 wks   | Min-Max (n)    | 0.0 - 7.3 (29)     | 0.0 - 6.5 (40)  | 0.0 - 11.1 (43)     |
|          | Median (Q1-Q3) | 1.3 (0.2 - 2.6)    | 0.5 (0.0 - 2.5) | 0.7 (0.1 - 2.0)     |

<sup>1</sup>Based on parent-reported data in the PPi population (per protocol for diary data on tolerance (related) outcomes). \* Statistical difference vs Control  $P < 0.05$  †Trend for statistical difference vs Control  $0.05 < P < 0.10$ .

**Table 3.** Summary of crying duration per week of age (hours/ day)<sup>1</sup>.

| Age      |                | Experimental group | Control group   | Breastfed reference |
|----------|----------------|--------------------|-----------------|---------------------|
|          |                | N = 77             | N = 86          | N = 90              |
| Baseline | Min-Max (n)    | 0.0 - 6.0 (71)     | 0.0 - 8.5 (84)  | 0.0 - 3.0 (87)      |
|          | Median (Q1-Q3) | 0.7 (0.2 - 1.3)    | 0.6 (0.2 - 1.8) | 0.5 (0.2 - 1.0)     |
| 4 wks    | Min-Max (n)    | 0.0 - 7.1 (55)     | 0.0 - 5.2 (61)  | 0.0 - 4.3 (68)      |
|          | Median (Q1-Q3) | 1.2 (0.5 - 2.6)    | 1.2 (0.5 - 2.1) | 1.1 (0.4 - 1.7)     |
| 5 wks    | Min-Max (n)    | 0.0 - 5.6 (67)     | 0.0 - 5.4 (74)  | 0.0 - 5.1 (84)      |
|          | Median (Q1-Q3) | 1.3 (0.5 - 2.3)    | 1.3 (0.5 - 2.2) | 0.9 (0.4 - 1.8)     |
| 6 wks    | Min-Max (n)    | 0.0 - 6.7 (66)     | 0.0 - 5.0 (77)  | 0.0 - 5.6 (84)      |
|          | Median (Q1-Q3) | 1.0 (0.5 - 2.0)    | 1.3 (0.5 - 2.1) | 0.8 (0.3 - 1.4)     |
| 7 wks    | Min-Max (n)    | 0.0 - 5.8 (67)     | 0.0 - 4.5 (75)  | 0.0 - 4.7 (80)      |
|          | Median (Q1-Q3) | 1.0 (0.4 - 1.8)    | 0.8 (0.3 - 2.0) | 0.7 (0.2 - 1.4)     |
| 8 wks    | Min-Max (n)    | 0.0 - 7.9 (65)     | 0.0 - 5.5 (76)  | 0.0 - 4.4 (78)      |
|          | Median (Q1-Q3) | 0.8 (0.3 - 1.6)    | 0.8 (0.3 - 1.7) | 0.6 (0.2 - 1.2)     |
| 9 wks    | Min-Max (n)    | 0.0 - 5.5 (66)     | 0.0 - 3.9 (76)  | 0.0 - 3.1 (73)      |
|          | Median (Q1-Q3) | 0.8 (0.2 - 1.6)    | 0.6 (0.2 - 1.6) | 0.5 (0.2 - 0.9)     |
| 10 wks   | Min-Max (n)    | 0.0 - 2.9 (64)     | 0.0 - 2.9 (75)  | 0.0 - 3.4 (71)      |
|          | Median (Q1-Q3) | 0.7 (0.2 - 1.5)    | 0.6 (0.2 - 1.3) | 0.4 (0.1 - 0.8)     |
| 11 wks   | Min-Max (n)    | 0.0 - 3.5 (64)     | 0.0 - 3.1 (75)  | 0.0 - 2.8 (68)      |
|          | Median (Q1-Q3) | 0.5 (0.2 - 1.5)    | 0.4 (0.1 - 1.1) | 0.3 (0.1 - 0.8)     |
| 12 wks   | Min-Max (n)    | 0.0 - 2.5 (64)     | 0.0 - 2.8 (75)  | 0.0 - 2.8 (67)      |
|          | Median (Q1-Q3) | 0.7 (0.2 - 1.1)    | 0.4 (0.1 - 1.2) | 0.3 (0.1 - 0.9)     |
| 13 wks   | Min-Max (n)    | 0.0 - 2.8 (63)     | 0.0 - 2.6 (74)  | 0.0 - 2.9 (67)      |
|          | Median (Q1-Q3) | 0.5 (0.2 - 1.3)    | 0.3 (0.0 - 1.1) | 0.3 (0.1 - 0.8)     |
| 14 wks   | Min-Max (n)    | 0.0 - 2.7 (64)     | 0.0 - 2.3 (70)  | 0.0 - 2.5 (64)      |
|          | Median (Q1-Q3) | 0.4 (0.1 - 1.1)    | 0.3 (0.0 - 1.1) | 0.3 (0.1 - 0.9)     |
| 15 wks   | Min-Max (n)    | 0.0 - 2.1 (63)     | 0.0 - 3.5 (72)  | 0.0 - 3.7 (63)      |
|          | Median (Q1-Q3) | 0.5 (0.1 - 1.1)    | 0.3 (0.0 - 1.0) | 0.3 (0.0 - 0.9)     |
| 16 wks   | Min-Max (n)    | 0.0 - 2.6 (62)     | 0.0 - 1.9 (72)  | 0.0 - 3.2 (63)      |
|          | Median (Q1-Q3) | 0.6 (0.1 - 1.2)    | 0.3 (0.0 - 1.2) | 0.3 (0.1 - 0.8)     |
| 17 wks   | Min-Max (n)    | 0.0 - 2.0 (29)     | 0.0 - 1.9 (40)  | 0.0 - 3.0 (43)      |
|          | Median (Q1-Q3) | 0.5 (0.1 - 0.9)    | 0.2 (0.0 - 0.8) | 0.2 (0.0 - 0.6)     |

<sup>1</sup>Based on parent-reported data in the PP<sub>t</sub> population (per protocol for diary data on tolerance (related outcomes)). \* Statistical difference vs Control P < 0.05 †Trend for statistical difference vs Control 0.05 < P < 0.10.

**Table 4.** Summary of sleeping frequency per week of age (episodes/ day)<sup>1</sup>.

| Age      |                | Experimental Group | Control Group   | Breastfed reference |
|----------|----------------|--------------------|-----------------|---------------------|
|          |                | N = 77             | N = 86          | N = 90              |
| Baseline | Min-Max (n)    | 0.0 - 10.0 (66)    | 0.0 - 12.0 (79) | 0.0 - 24.0 (81)     |
|          | Median (Q1-Q3) | 8.0 (5.0 - 8.0)    | 7.0 (5.0 - 8.0) | 8.0 (6.0-8.0)       |
| 4 wks    | Min-Max (n)    | 1.8 - 10.3 (55)    | 2.6 - 10.9 (61) | 4.6 - 13.0 (68)     |
|          | Median (Q1-Q3) | 7.2 (6.3 - 8.5)    | 7.3 (6.0 - 8.0) | 7.5 (6.3 - 8.7)     |
| 5 wks    | Min-Max (n)    | 3.4 - 12.3 (67)    | 3.0 - 11.0 (74) | 4.6 - 13.4 (84)     |
|          | Median (Q1-Q3) | 7.5 (6.3 - 8.1)    | 7.2 (6.7 - 8.3) | 7.6 (6.7 - 8.9)     |
| 6 wks    | Min-Max (n)    | 3.4 - 11.4 (66)    | 2.7 - 10.7 (77) | 4.1 - 14.7 (84)     |
|          | Median (Q1-Q3) | 7.0 (6.0 - 8.1)    | 7.3 (6.6 - 8.0) | 8.0 (6.6 - 9.0)     |
| 7 wks    | Min-Max (n)    | 3.8 - 13.0 (67)    | 2.1 - 10.7 (75) | 3.3 - 12.0 (80)     |
|          | Median (Q1-Q3) | 7.1 (6.1 - 8.3)    | 7.0 (6.1 - 7.7) | 7.6 (6.9 - 9.0)     |
| 8 wks    | Min-Max (n)    | 3.8 - 16.0 (65)    | 2.1 - 9.8 (76)  | 3.9 - 12.2 (78)     |
|          | Median (Q1-Q3) | 6.7 (5.3 - 7.8)    | 6.9 (6.3 - 7.8) | 7.7 (6.3 - 9.0)     |
| 9 wks    | Min-Max (n)    | 3.7 - 11.3 (66)    | 2.9 - 10.0 (76) | 3.7 - 11.9 (73)     |
|          | Median (Q1-Q3) | 6.7 (5.6 - 8.2)    | 7.0 (6.3 - 7.6) | 7.6 (6.6 - 8.7)     |
| 10 wks   | Min-Max (n)    | 3.9 - 11.7 (64)    | 2.8 - 9.6 (75)  | 3.4 - 11.6 (71)     |
|          | Median (Q1-Q3) | 6.6 (5.5 - 7.9)    | 6.7 (5.9 - 7.6) | 7.7 (6.4 - 8.7)     |
| 11 wks   | Min-Max (n)    | 3.4 - 11.1 (64)    | 3.0 - 9.3 (75)  | 3.9 - 12.1 (68)     |
|          | Median (Q1-Q3) | 6.7 (5.5 - 7.6)    | 6.7 (6.0 - 7.3) | 7.4 (6.3 - 8.7)     |
| 12 wks   | Min-Max (n)    | 3.9 - 9.6 (64)     | 3.6 - 8.5 (75)  | 4.0 - 12.9 (67)     |
|          | Median (Q1-Q3) | 6.5 (5.6 - 7.6)    | 6.7 (6.0 - 7.4) | 7.3 (6.7 - 8.4)     |
| 13 wks   | Min-Max (n)    | 3.0 - 11.2 (63)    | 3.7 - 10.5 (74) | 3.6 - 12.8 (67)     |
|          | Median (Q1-Q3) | 6.5 (5.4 - 7.5)    | 6.5 (5.7 - 7.3) | 7.5 (6.2 - 8.2)     |
| 14 wks   | Min-Max (n)    | 3.0 - 9.1 (64)     | 3.8 - 8.9 (70)  | 4.0 - 11.1 (64)     |
|          | Median (Q1-Q3) | 6.1 (5.1 - 6.9) *  | 6.7 (5.7 - 7.4) | 7.0 (6.0 - 7.9)     |
| 15 wks   | Min-Max (n)    | 3.6 - 9.7 (63)     | 4.0 - 9.1 (72)  | 3.5 - 10.7 (63)     |
|          | Median (Q1-Q3) | 6.1 (5.0 - 6.9) ‡  | 6.4 (5.6 - 7.1) | 6.9 (6.0 - 7.9)     |
| 16 wks   | Min-Max (n)    | 3.9 - 8.7 (62)     | 3.4 - 8.8 (72)  | 3.6 - 11.0 (63)     |
|          | Median (Q1-Q3) | 5.8 (5.0 - 7.1) ‡  | 6.4 (5.6 - 7.2) | 7.0 (6.0 - 7.9)     |
| 17 wks   | Min-Max (n)    | 4.0 - 9.3 (29)     | 3.0 - 9.0 (40)  | 3.3 - 11.0 (43)     |
|          | Median (Q1-Q3) | 5.5 (5.0 - 6.3) *  | 6.2 (5.7 - 6.8) | 6.7 (6.0 - 8.3)     |

<sup>1</sup>Based on parent-reported data in the PP<sub>t</sub> population (per protocol for diary data on tolerance (related outcomes)). \* Statistical difference vs Control  $P < 0.05$  ‡Trend for statistical difference vs Control  $0.05 < P < 0.10$ .

**Table 5.** Summary of sleeping duration per week of age (hours/ day)<sup>1</sup>

| Age      |               | Experimental Group   | Control Group      | Breastfed reference |
|----------|---------------|----------------------|--------------------|---------------------|
|          |               | N = 77               | N = 86             | N = 90              |
| Baseline | Min-Max (n)   | 3.0 - 23.0 (71)      | 7.0 - 23.0 (83)    | 2.0 - 24.0 (85)     |
|          | Median(Q1-Q3) | 20.0 (17.0 - 21.0)   | 20.0 (18.0 - 22.0) | 18.5 (16.0 - 20.0)  |
| 4 wks    | Min-Max (n)   | 10.9 - 22.2 (55)     | 9.6 - 19.3 (61)    | 9.3 - 18.2 (68)     |
|          | Median(Q1-Q3) | 15.0 (12.5 - 16.7)   | 15.0 (13.5 - 16.3) | 14.0 (12.8 - 15.0)  |
| 5 wks    | Min-Max (n)   | 10.6 - 21.2 (67)     | 10.5 - 18.4 (74)   | 10.6 - 18.4 (84)    |
|          | Median(Q1-Q3) | 14.4 (12.7 - 15.5) * | 15.3 (14.0 - 16.1) | 14.2 (12.9 - 15.4)  |
| 6 wks    | Min-Max (n)   | 10.2 - 19.8 (66)     | 10.0 - 19.3 (77)   | 8.6 - 17.9 (84)     |
|          | Median(Q1-Q3) | 14.1 (12.8 - 16.0)   | 14.9 (13.5 - 16.0) | 14.3 (12.8 - 15.4)  |
| 7 wks    | Min-Max (n)   | 8.7 - 20.5 (67)      | 10.7 - 19.4 (75)   | 8.2 - 17.5 (80)     |
|          | Median(Q1-Q3) | 14.2 (12.6 - 15.9)   | 14.8 (12.7 - 15.6) | 13.8 (12.9 - 15.5)  |
| 8 wks    | Min-Max (n)   | 11.7 - 19.4 (65)     | 9.4 - 19.5 (76)    | 6.9 - 18.0 (78)     |
|          | Median(Q1-Q3) | 14.1 (13.1 - 15.9)   | 14.5 (13.4 - 16.3) | 14.2 (13.1 - 15.3)  |
| 9 wks    | Min-Max (n)   | 10.6 - 18.0 (66)     | 11.5 - 18.4 (76)   | 7.6 - 16.7 (73)     |
|          | Median(Q1-Q3) | 14.4 (13.2 - 15.6)   | 14.7 (13.1 - 15.8) | 14.1 (13.1 - 15.2)  |
| 10 wks   | Min-Max (n)   | 11.0 - 18.9 (64)     | 10.2 - 18.8 (75)   | 8.4 - 17.4 (71)     |
|          | Median(Q1-Q3) | 14.1 (13.0 - 15.5)   | 14.2 (13.0 - 15.6) | 14.1 (12.8 - 14.9)  |
| 11 wks   | Min-Max (n)   | 11.4 - 18.7 (64)     | 10.8 - 19.4 (75)   | 8.5 - 17.2 (68)     |
|          | Median(Q1-Q3) | 14.1 (12.8 - 15.6)   | 14.2 (12.7 - 15.6) | 13.9 (12.9 - 15.0)  |
| 12 wks   | Min-Max (n)   | 10.5 - 19.0 (64)     | 11.2 - 19.2 (75)   | 8.8 - 18.0 (67)     |
|          | Median(Q1-Q3) | 14.0 (13.1 - 15.3)   | 14.2 (12.8 - 15.6) | 13.8 (13.0 - 15.0)  |
| 13 wks   | Min-Max (n)   | 11.5 - 17.1 (63)     | 10.0 - 18.0 (74)   | 9.0 - 17.9 (67)     |
|          | Median(Q1-Q3) | 14.2 (13.2 - 15.3)   | 14.1 (12.9 - 15.1) | 13.7 (12.7 - 15.0)  |
| 14 wks   | Min-Max (n)   | 11.1 - 17.3 (64)     | 8.8 - 17.9 (70)    | 8.1 - 16.2 (64)     |
|          | Median(Q1-Q3) | 14.2 (13.3 - 15.2)   | 14.0 (12.9 - 14.5) | 13.4 (12.4 - 14.4)  |
| 15 wks   | Min-Max (n)   | 12.0 - 17.1 (63)     | 2.4 - 17.6 (72)    | 8.3 - 16.7 (63)     |
|          | Median(Q1-Q3) | 13.7 (12.9 - 14.9)   | 14.1 (12.9 - 15.0) | 13.4 (12.5 - 14.2)  |
| 16 wks   | Min-Max (n)   | 11.3 - 16.8 (62)     | 2.3 - 17.7 (72)    | 8.3 - 15.6 (63)     |
|          | Median(Q1-Q3) | 13.8 (13.0 - 14.8)   | 13.8 (12.7 - 14.8) | 13.3 (12.5 - 13.9)  |
| 17 wks   | Min-Max (n)   | 11.7 - 16.8 (29)     | 3.1 - 17.8 (40)    | 9.6 - 16.4 (43)     |
|          | Median(Q1-Q3) | 13.9 (13.0 - 15.3)   | 13.9 (13.2 - 14.7) | 13.4 (12.7 - 14.2)  |

<sup>1</sup>Based on parent-reported data in the PP<sub>t</sub> population (per protocol for diary data on tolerance (related outcomes)). \* Statistical difference vs Control P < 0.05 ‡Trend for statistical difference vs Control 0.05 < P < 0.10.