SUPPLEMENTARY DATA: ONLINE RESOURCE 2

Development and preliminary evaluation of an assessment of the age-appropriateness/age-inappropriateness of formulations used in children

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Figure S3. % of AaFs v AiFs identified across age groups at AH
Figure S4. % of AaFs v AiFs identified across age groups at LWH
Table S5. Final assessment outcome results across the age groups at AH (n = 1,758 MAEs)

| AaF Assessment Code | Term neonate (as % of n) | Infant (as % of n) | Toddler (as % of n) | Young child (as % of n) | Older child (as % of n) | Teenager (as % of n) | Adolescent (as % of n) | Total (N) |
|---------------------|--------------------------|-------------------|--------------------|------------------------|------------------------|---------------------|-----------------------|----------|
| Number of Patients  | 37                       | 102               | 33                 | 60                     | 49                     | 35                  | 18                    | 334      |
| AaF                 | 11 (10.4)                | 141 (29.7)        | 61 (30.2)          | 88 (24.4)              | 95 (37.0)              | 103 (50.0)          | 98 (64.1)             | 597 (34.0)|
| AiF (OL)            | 14 (13.2)                | 47 (9.9)          | 21 (10.4)          | 39 (10.8)              | 20 (7.8)               | 9 (4.4)             | 1 (0.7)               | 151 (8.6) |
| AiF (UL)            |                          | 12 (2.5)          | 5 (2.5)            | 23 (6.4)               | 8 (3.1)                | 2 (1.0)             |                       | 50 (2.8)  |
| M (OL)              | 50 (47.2)                | 179 (37.8)        | 90 (44.6)          | 143 (39.7)             | 94 (36.6)              | 65 (31.6)           | 28 (18.3)             | 649 (36.9)|
| M (UL)              | 30 (28.3)                | 85 (17.9)         | 22 (10.9)          | 64 (17.8)              | 30 (11.7)              | 24 (11.7)           | 21 (13.7)             | 276 (15.7)|
| MD                  |                          | 6 (1.3)           | 3 (1.5)            | 1 (0.3)                | 5 (1.9)                | 3 (1.5)             | 3 (2.0)               | 21 (1.2)  |
| U                   | 1 (0.9)                  | 4 (0.8)           |                    | 2 (0.6)                | 5 (1.9)                |                     | 2 (1.3)               | 14 (0.8)  |
| Total MAEs (n)      | 106                      | 474               | 202                | 360                    | 257                    | 206                 | 153                   | 1758     |
| Total AiF (as % of N)| 14 (7.0)                | 59 (29.4)         | 26 (12.9)          | 62 (30.8)              | 28 (13.9)              | 11 (5.5)            | 1 (0.5)               | 201      |
| Total AaF (as % of N)| 11 (1.8)                | 141 (23.6)        | 61 (10.2)          | 88 (14.7)              | 95 (15.9)              | 103 (17.3)          | 98 (16.4)             | 597      |
Table S6. Final assessment outcome results across the age groups at LWH (n = 441 MAEs)

| AaF Assessment Code | Age group                  | Total (N) |
|---------------------|----------------------------|-----------|
|                     | Extremely preterm neonate  | 93        |
|                     | (as % of n)                |           |
|                     | Very preterm neonate       |           |
|                     | (as % of n)                |           |
|                     | Moderate to late           |           |
|                     | preterm neonate (as % of n)|           |
|                     | Term neonate (as % of n)   |           |
|                     | Infant (as % of n)         |           |
| Number of Patients  | 8                         | 31        |
| AaF                 | 15 (34.9)                  | 39 (24.4) |
|                     | 19 (12.6)                  | 16 (24.2) |
|                     | 1 (4.8)                    | 90 (20.4) |
| AiF (OL)            | 7 (16.3)                   | 23 (14.4) |
|                     | 12 (7.9)                   | 9 (13.6)  |
|                     | 3 (14.3)                   | 54 (12.2) |
| AiF (UL)            | 4 (2.6)                    | 4 (0.9)   |
| M (OL)              | 16 (37.2)                  | 89 (55.6) |
|                     | 97 (64.2)                  | 30 (45.5) |
|                     | 10 (47.6)                  | 242 (54.9)|
| M (UL)              | 5 (11.6)                   | 7 (4.4)   |
|                     | 19 (12.6)                  | 11 (16.7) |
|                     | 7 (33.3)                   | 49 (11.1) |
| MD                  | 0 (0.0)                    | 2 (1.3)   | 2 (0.5)   |
| Total MAEs (n)      | 43                        | 160       |
|                     | 151                       | 66        |
|                     | 21                        | 441       |
| Total AiF (as % of N)| 7 (12.1)                  | 23 (39.7) |
|                     | 16 (27.6)                  | 9 (15.5)  |
|                     | 3 (5.2)                    | 58        |
| Total AaF (as % of N)| 15 (16.7)                 | 39 (43.3) |
|                     | 19 (21.1)                  | 16 (17.8) |
|                     | 1 (1.1)                    | 90        |