

## Secondary efficacy outcome 7: Paediatric Quality of Life (PedsQL)

**Table 6.6-22: Paediatric Quality of Life (PedsQL) – Completeness of data (ITT)**

*Note: 1 CSII patient that DNA 6-month visit provided a completed child PedsQL questionnaire; The parents/carers of 1 CSII patient and 1 MDI patient that DNA their 6-month visit provided a completed parent/carer PedsQL questionnaire*

|                                     | 6 months    |             |             | 12 months   |             |             |
|-------------------------------------|-------------|-------------|-------------|-------------|-------------|-------------|
|                                     | CSII        | MDI         | Total       | CSII        | MDI         | Total       |
| <b>Child (Diabetes)</b>             |             |             |             |             |             |             |
| N                                   | 144         | 149         | 293         | 144         | 149         | 293         |
| Included                            | 100 (69.4%) | 108 (72.5%) | 208 (71%)   | 108 (75%)   | 107 (71.8%) | 215 (73.4%) |
| DNA 6 months                        | 7 (4.9%)    | 7 (4.7%)    | 14 (4.8%)   | 0 (0%)      | 0 (0%)      | 0 (0%)      |
| No questionnaire completed          | 6 (4.2%)    | 6 (4%)      | 12 (4.1%)   | 7 (4.9%)    | 8 (5.4%)    | 15 (5.1%)   |
| Only 5/11 questions answered        | 0 (0%)      | 0 (0%)      | 0 (0%)      | 1 (0.7%)    | 0 (0%)      | 1 (0.3%)    |
| Questionnaire section not completed | 1 (0.7%)    | 1 (0.7%)    | 2 (0.7%)    | 1 (0.7%)    | 3 (2%)      | 4 (1.4%)    |
| Too young for questionnaire         | 30 (20.8%)  | 27 (18.1%)  | 57 (19.5%)  | 26 (18.1%)  | 26 (17.4%)  | 52 (17.7%)  |
| WD from study prior to 12 months    | 0 (0%)      | 0 (0%)      | 0 (0%)      | 1 (0.7%)    | 5 (3.4%)    | 6 (2%)      |
| <b>Child (Treatment I)</b>          |             |             |             |             |             |             |
| N                                   | 144         | 149         | 293         | 144         | 149         | 293         |
| Included                            | 100 (69.4%) | 107 (71.8%) | 207 (70.6%) | 109 (75.7%) | 107 (71.8%) | 216 (73.7%) |
| DNA 6 months                        | 7 (4.9%)    | 7 (4.7%)    | 14 (4.8%)   | 0 (0%)      | 0 (0%)      | 0 (0%)      |
| No questionnaire completed          | 6 (4.2%)    | 6 (4%)      | 12 (4.1%)   | 7 (4.9%)    | 8 (5.4%)    | 15 (5.1%)   |
| Questionnaire section not completed | 1 (0.7%)    | 2 (1.3%)    | 3 (1%)      | 1 (0.7%)    | 3 (2%)      | 4 (1.4%)    |
| Too young for questionnaire         | 30 (20.8%)  | 27 (18.1%)  | 57 (19.5%)  | 26 (18.1%)  | 26 (17.4%)  | 52 (17.7%)  |
| WD from study prior to 12 months    | 0 (0%)      | 0 (0%)      | 0 (0%)      | 1 (0.7%)    | 5 (3.4%)    | 6 (2%)      |
| <b>Child (Treatment II)</b>         |             |             |             |             |             |             |
| N                                   | 144         | 149         | 293         | 144         | 149         | 293         |
| Included                            | 100 (69.4%) | 107 (71.8%) | 207 (70.6%) | 108 (75%)   | 107 (71.8%) | 215 (73.4%) |
| DNA 6 months                        | 7 (4.9%)    | 7 (4.7%)    | 14 (4.8%)   | 0 (0%)      | 0 (0%)      | 0 (0%)      |
| No questionnaire completed          | 6 (4.2%)    | 6 (4%)      | 12 (4.1%)   | 7 (4.9%)    | 8 (5.4%)    | 15 (5.1%)   |

|                                     | 6 months   |             |             | 12 months   |             |            |
|-------------------------------------|------------|-------------|-------------|-------------|-------------|------------|
|                                     | CSII       | MDI         | Total       | CSII        | MDI         | Total      |
| Only 3/7 questions answered         | 0 (0%)     | 0 (0%)      | 0 (0%)      | 1 (0.7%)    | 0 (0%)      | 1 (0.3%)   |
| Questionnaire section not completed | 1 (0.7%)   | 2 (1.3%)    | 3 (1%)      | 1 (0.7%)    | 3 (2%)      | 4 (1.4%)   |
| Too young for questionnaire         | 30 (20.8%) | 27 (18.1%)  | 57 (19.5%)  | 26 (18.1%)  | 26 (17.4%)  | 52 (17.7%) |
| WD from study prior to 12 months    | 0 (0%)     | 0 (0%)      | 0 (0%)      | 1 (0.7%)    | 5 (3.4%)    | 6 (2%)     |
| <b>Child (Worry)</b>                |            |             |             |             |             |            |
| N                                   | 144        | 149         | 293         | 144         | 149         | 293        |
| Included                            | 99 (68.8%) | 106 (71.1%) | 205 (70%)   | 109 (75.7%) | 105 (70.5%) | 214 (73%)  |
| DNA 6 months                        | 7 (4.9%)   | 7 (4.7%)    | 14 (4.8%)   | 0 (0%)      | 0 (0%)      | 0 (0%)     |
| No questionnaire completed          | 6 (4.2%)   | 6 (4%)      | 12 (4.1%)   | 7 (4.9%)    | 8 (5.4%)    | 15 (5.1%)  |
| Only 1/3 questions answered         | 1 (0.7%)   | 1 (0.7%)    | 2 (0.7%)    | 0 (0%)      | 0 (0%)      | 0 (0%)     |
| Questionnaire section not completed | 1 (0.7%)   | 2 (1.3%)    | 3 (1%)      | 1 (0.7%)    | 5 (3.4%)    | 6 (2%)     |
| Too young for questionnaire         | 30 (20.8%) | 27 (18.1%)  | 57 (19.5%)  | 26 (18.1%)  | 26 (17.4%)  | 52 (17.7%) |
| WD from study prior to 12 months    | 0 (0%)     | 0 (0%)      | 0 (0%)      | 1 (0.7%)    | 5 (3.4%)    | 6 (2%)     |
| <b>Child (Communication)</b>        |            |             |             |             |             |            |
| N                                   | 144        | 149         | 293         | 144         | 149         | 293        |
| Included                            | 98 (68.1%) | 106 (71.1%) | 204 (69.6%) | 106 (73.6%) | 105 (70.5%) | 211 (72%)  |
| DNA 6 months                        | 7 (4.9%)   | 7 (4.7%)    | 14 (4.8%)   | 0 (0%)      | 0 (0%)      | 0 (0%)     |
| No questionnaire completed          | 6 (4.2%)   | 6 (4%)      | 12 (4.1%)   | 7 (4.9%)    | 8 (5.4%)    | 15 (5.1%)  |
| Only 1/3 questions answered         | 1 (0.7%)   | 0 (0%)      | 1 (0.3%)    | 0 (0%)      | 0 (0%)      | 0 (0%)     |
| Questionnaire section not completed | 2 (1.4%)   | 3 (2%)      | 5 (1.7%)    | 4 (2.8%)    | 5 (3.4%)    | 9 (3.1%)   |
| Too young for questionnaire         | 30 (20.8%) | 27 (18.1%)  | 57 (19.5%)  | 26 (18.1%)  | 26 (17.4%)  | 52 (17.7%) |
| WD from study prior to 12 months    | 0 (0%)     | 0 (0%)      | 0 (0%)      | 1 (0.7%)    | 5 (3.4%)    | 6 (2%)     |
| <b>Child (Overall)</b>              |            |             |             |             |             |            |
| N                                   | 144        | 149         | 293         | 144         | 149         | 293        |
| Included                            | 98 (68.1%) | 104 (69.8%) | 202 (68.9%) | 104 (72.2%) | 104 (69.8%) | 208 (71%)  |

|                                     | 6 months    |             |             | 12 months   |             |             |
|-------------------------------------|-------------|-------------|-------------|-------------|-------------|-------------|
|                                     | CSII        | MDI         | Total       | CSII        | MDI         | Total       |
| 1/5 incomplete sections             | 1 (0.7%)    | 3 (2%)      | 4 (1.4%)    | 5 (3.5%)    | 2 (1.3%)    | 7 (2.4%)    |
| 2/5 incomplete sections             | 1 (0.7%)    | 0 (0%)      | 1 (0.3%)    | 0 (0%)      | 1 (0.7%)    | 1 (0.3%)    |
| 3/5 incomplete sections             | 0 (0%)      | 1 (0.7%)    | 1 (0.3%)    | 0 (0%)      | 0 (0%)      | 0 (0%)      |
| DNA 6 months                        | 7 (4.9%)    | 7 (4.7%)    | 14 (4.8%)   | 0 (0%)      | 0 (0%)      | 0 (0%)      |
| No questionnaire completed          | 6 (4.2%)    | 6 (4%)      | 12 (4.1%)   | 7 (4.9%)    | 8 (5.4%)    | 15 (5.1%)   |
| Questionnaire section not completed | 1 (0.7%)    | 1 (0.7%)    | 2 (0.7%)    | 1 (0.7%)    | 3 (2%)      | 4 (1.4%)    |
| Too young for questionnaire         | 30 (20.8%)  | 27 (18.1%)  | 57 (19.5%)  | 26 (18.1%)  | 26 (17.4%)  | 52 (17.7%)  |
| WD from study prior to 12 months    | 0 (0%)      | 0 (0%)      | 0 (0%)      | 1 (0.7%)    | 5 (3.4%)    | 6 (2%)      |
| <b>Parent (Diabetes)</b>            |             |             |             |             |             |             |
| N                                   | 144         | 149         | 293         | 144         | 149         | 293         |
| Included                            | 127 (88.2%) | 128 (85.9%) | 255 (87%)   | 132 (91.7%) | 125 (83.9%) | 257 (87.7%) |
| DNA 6 months                        | 7 (4.9%)    | 6 (4%)      | 13 (4.4%)   | 0 (0%)      | 0 (0%)      | 0 (0%)      |
| No questionnaire completed          | 10 (6.9%)   | 14 (9.4%)   | 24 (8.2%)   | 11 (7.6%)   | 17 (11.4%)  | 28 (9.6%)   |
| Questionnaire section not completed | 0 (0%)      | 1 (0.7%)    | 1 (0.3%)    | 0 (0%)      | 2 (1.3%)    | 2 (0.7%)    |
| WD from study prior to 12 months    | 0 (0%)      | 0 (0%)      | 0 (0%)      | 1 (0.7%)    | 5 (3.4%)    | 6 (2%)      |
| <b>Parent (Treatment I)</b>         |             |             |             |             |             |             |
| N                                   | 144         | 149         | 293         | 144         | 149         | 293         |
| Included                            | 127 (88.2%) | 127 (85.2%) | 254 (86.7%) | 131 (91%)   | 125 (83.9%) | 256 (87.4%) |
| DNA 6 months                        | 7 (4.9%)    | 6 (4%)      | 13 (4.4%)   | 0 (0%)      | 0 (0%)      | 0 (0%)      |
| No questionnaire completed          | 10 (6.9%)   | 14 (9.4%)   | 24 (8.2%)   | 11 (7.6%)   | 17 (11.4%)  | 28 (9.6%)   |
| Only 1/4 questions answered         | 0 (0%)      | 0 (0%)      | 0 (0%)      | 1 (0.7%)    | 0 (0%)      | 1 (0.3%)    |
| Questionnaire section not completed | 0 (0%)      | 2 (1.3%)    | 2 (0.7%)    | 0 (0%)      | 2 (1.3%)    | 2 (0.7%)    |
| WD from study prior to 12 months    | 0 (0%)      | 0 (0%)      | 0 (0%)      | 1 (0.7%)    | 5 (3.4%)    | 6 (2%)      |
| <b>Parent (Treatment II)</b>        |             |             |             |             |             |             |
| N                                   | 144         | 149         | 293         | 144         | 149         | 293         |

|                                     | 6 months    |             |             | 12 months   |             |             |
|-------------------------------------|-------------|-------------|-------------|-------------|-------------|-------------|
|                                     | CSII        | MDI         | Total       | CSII        | MDI         | Total       |
| Included                            | 126 (87.5%) | 128 (85.9%) | 254 (86.7%) | 131 (91%)   | 125 (83.9%) | 256 (87.4%) |
| DNA 6 months                        | 7 (4.9%)    | 6 (4%)      | 13 (4.4%)   | 0 (0%)      | 0 (0%)      | 0 (0%)      |
| No questionnaire completed          | 10 (6.9%)   | 14 (9.4%)   | 24 (8.2%)   | 11 (7.6%)   | 17 (11.4%)  | 28 (9.6%)   |
| Only 3/7 questions answered         | 1 (0.7%)    | 0 (0%)      | 1 (0.3%)    | 1 (0.7%)    | 0 (0%)      | 1 (0.3%)    |
| Questionnaire section not completed | 0 (0%)      | 1 (0.7%)    | 1 (0.3%)    | 0 (0%)      | 2 (1.3%)    | 2 (0.7%)    |
| WD from study prior to 12 months    | 0 (0%)      | 0 (0%)      | 0 (0%)      | 1 (0.7%)    | 5 (3.4%)    | 6 (2%)      |
| <b>Parent (Worry)</b>               |             |             |             |             |             |             |
| N                                   | 144         | 149         | 293         | 144         | 149         | 293         |
| Included                            | 127 (88.2%) | 128 (85.9%) | 255 (87%)   | 131 (91%)   | 125 (83.9%) | 256 (87.4%) |
| DNA 6 months                        | 7 (4.9%)    | 6 (4%)      | 13 (4.4%)   | 0 (0%)      | 0 (0%)      | 0 (0%)      |
| No questionnaire completed          | 10 (6.9%)   | 14 (9.4%)   | 24 (8.2%)   | 11 (7.6%)   | 17 (11.4%)  | 28 (9.6%)   |
| Only 1/3 questions answered         | 0 (0%)      | 0 (0%)      | 0 (0%)      | 1 (0.7%)    | 0 (0%)      | 1 (0.3%)    |
| Questionnaire section not completed | 0 (0%)      | 1 (0.7%)    | 1 (0.3%)    | 0 (0%)      | 2 (1.3%)    | 2 (0.7%)    |
| WD from study prior to 12 months    | 0 (0%)      | 0 (0%)      | 0 (0%)      | 1 (0.7%)    | 5 (3.4%)    | 6 (2%)      |
| <b>Parent (Communication)</b>       |             |             |             |             |             |             |
| N                                   | 144         | 149         | 293         | 144         | 149         | 293         |
| Included                            | 124 (86.1%) | 127 (85.2%) | 251 (85.7%) | 130 (90.3%) | 123 (82.6%) | 253 (86.3%) |
| DNA 6 months                        | 7 (4.9%)    | 6 (4%)      | 13 (4.4%)   | 0 (0%)      | 0 (0%)      | 0 (0%)      |
| No questionnaire completed          | 10 (6.9%)   | 14 (9.4%)   | 24 (8.2%)   | 11 (7.6%)   | 17 (11.4%)  | 28 (9.6%)   |
| Questionnaire section not completed | 3 (2.1%)    | 2 (1.3%)    | 5 (1.7%)    | 2 (1.4%)    | 4 (2.7%)    | 6 (2%)      |
| WD from study prior to 12 months    | 0 (0%)      | 0 (0%)      | 0 (0%)      | 1 (0.7%)    | 5 (3.4%)    | 6 (2%)      |
| <b>Parent (Overall)</b>             |             |             |             |             |             |             |
| N                                   | 144         | 149         | 293         | 144         | 149         | 293         |
| Included                            | 124 (86.1%) | 125 (83.9%) | 249 (85%)   | 128 (88.9%) | 123 (82.6%) | 251 (85.7%) |
| 1/5 incomplete sections             | 2 (1.4%)    | 3 (2%)      | 5 (1.7%)    | 3 (2.1%)    | 2 (1.3%)    | 5 (1.7%)    |

|                                     | 6 months  |           |           | 12 months |            |           |
|-------------------------------------|-----------|-----------|-----------|-----------|------------|-----------|
|                                     | CSII      | MDI       | Total     | CSII      | MDI        | Total     |
| 2/5 incomplete sections             | 1 (0.7%)  | 0 (0%)    | 1 (0.3%)  | 1 (0.7%)  | 0 (0%)     | 1 (0.3%)  |
| 4/5 incomplete sections             | 0 (0%)    | 1 (0.7%)  | 1 (0.3%)  | 0 (0%)    | 0 (0%)     | 0 (0%)    |
| DNA 6 months                        | 7 (4.9%)  | 6 (4%)    | 13 (4.4%) | 0 (0%)    | 0 (0%)     | 0 (0%)    |
| No questionnaire completed          | 10 (6.9%) | 14 (9.4%) | 24 (8.2%) | 11 (7.6%) | 17 (11.4%) | 28 (9.6%) |
| Questionnaire section not completed | 0 (0%)    | 0 (0%)    | 0 (0%)    | 0 (0%)    | 2 (1.3%)   | 2 (0.7%)  |
| WD from study prior to 12 months    | 0 (0%)    | 0 (0%)    | 0 (0%)    | 1 (0.7%)  | 5 (3.4%)   | 6 (2%)    |

**Table 6.6-23: Paediatric Quality of Life (PedsQL) – Results summary at 6m and 12m (ITT)**

| Questionnaire Summary<br>age-group                |                            | 6 months                        |                                  |                                  | 12 months                         |                                   |                                   |
|---|----------------------------|---------------------------------|----------------------------------|----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|
|   |                            | CSII                            | MDI                              | Total                            | CSII                              | MDI                               | Total                             |
| Children 5-7 years old (6 & 12 month follow-up)   | Child (Diabetes)           |                                 |                                  |                                  |                                   |                                   |                                   |
|   | N                          | 12                              | 22                               | 34                               | 14                                | 19                                | 33                                |
|   | Mean (SD)                  | 56.8 (13.4)                     | 61 (10.4)                        | 59.5 (11.5)                      | 66.7 (16.9)                       | 59.6 (16)                         | 62.6 (16.5)                       |
|   | Median (IQR)<br>(Min, Max) | 54.5 (50, 63.6)<br>(31.8, 81.8) | 59.1 (50, 72.7)<br>(40.9, 77.3)  | 56.8 (50, 68.2)<br>(31.8, 81.8)  | 68.2 (63.6, 79.3)<br>(27.3, 90.9) | 63.6 (50, 72.7)<br>(22.7, 77.3)   | 63.6 (54.5, 72.7)<br>(22.7, 90.9) |
| Children 8-12 years old (6 & 12 month follow-up)  | Child (Diabetes)           |                                 |                                  |                                  |                                   |                                   |                                   |
|   | N                          | 59                              | 55                               | 114                              | 57                                | 55                                | 112                               |
|   | Mean (SD)                  | 63 (16.9)                       | 62.3 (15)                        | 62.7 (15.9)                      | 68.7 (15.8)                       | 63.9 (16.1)                       | 66.4 (16.1)                       |
|   | Median (IQR)<br>(Min, Max) | 65.9 (49.6, 77.3)<br>(25, 100)  | 63.6 (50, 74.4)<br>(29.5, 100)   | 63.6 (50, 75)<br>(25, 100)       | 70.5 (54.5, 79.5)<br>(36.4, 100)  | 61.4 (50, 77.3)<br>(37.2, 93.2)   | 65.9 (52.3, 79.5)<br>(36.4, 100)  |
| Children 13-16 years old (6 & 12 month follow-up) | Child (Diabetes)           |                                 |                                  |                                  |                                   |                                   |                                   |
|   | N                          | 29                              | 31                               | 60                               | 37                                | 33                                | 70                                |
|   | Mean (SD)                  | 68.2 (16.4)                     | 64.3 (15.3)                      | 66.2 (15.8)                      | 62.9 (16.8)                       | 61.6 (17.3)                       | 62.3 (16.9)                       |
|   | Median (IQR)<br>(Min, Max) | 65.9 (56.8, 75)<br>(40.9, 100)  | 61.4 (56.8, 72.7)<br>(40.9, 100) | 63.6 (56.8, 73.9)<br>(40.9, 100) | 61.4 (54.5, 71.9)<br>(27.3, 100)  | 59.1 (52.3, 72.7)<br>(29.5, 90.9) | 61.1 (52.3, 72.7)<br>(27.3, 100)  |

| Questionnaire age-group Summary                   |                            | 6 months                         |                                  |                                  | 12 months                       |                                  |                                  |
|---|----------------------------|----------------------------------|----------------------------------|----------------------------------|---------------------------------|----------------------------------|----------------------------------|
|   |                            | CSII                             | MDI                              | Total                            | CSII                            | MDI                              | Total                            |
| Children 5-7 years old (6 & 12 month follow-up)   | Child (Treatment I)        |                                  |                                  |                                  |                                 |                                  |                                  |
|   | N                          | 12                               | 22                               | 34                               | 14                              | 19                               | 33                               |
|   | Mean (SD)                  | 77.3 (18.3)                      | 79.8 (16.1)                      | 79 (16.7)                        | 81.3 (16.8)                     | 75.7 (22.2)                      | 78 (20)                          |
|   | Median (IQR)<br>(Min, Max) | 76.6 (62.5, 93.8)<br>(50, 100)   | 82.8 (75, 87.5)<br>(37.5, 100)   | 78.1 (75, 87.5)<br>(37.5, 100)   | 75 (75, 100)<br>(50, 100)       | 75 (62.5, 87.5)<br>(12.5, 100)   | 75 (62.5, 100)<br>(12.5, 100)    |
| Children 8-12 years old (6 & 12 month follow-up)  | Child (Treatment I)        |                                  |                                  |                                  |                                 |                                  |                                  |
|   | N                          | 59                               | 54                               | 113                              | 57                              | 55                               | 112                              |
|   | Mean (SD)                  | 79.3 (17.9)                      | 74.7 (19.6)                      | 77.1 (18.8)                      | 83.7 (15.5)                     | 77.2 (20.5)                      | 80.5 (18.3)                      |
|   | Median (IQR)<br>(Min, Max) | 87.5 (68.8, 93.8)<br>(31.3, 100) | 75 (68.8, 87.5)<br>(12.5, 100)   | 81.3 (68.8, 93.8)<br>(12.5, 100) | 87.5 (75, 93.8)<br>(25, 100)    | 81.3 (62.5, 93.8)<br>(18.8, 100) | 81.3 (75, 93.8)<br>(18.8, 100)   |
| Children 13-16 years old (6 & 12 month follow-up) | Child (Treatment I)        |                                  |                                  |                                  |                                 |                                  |                                  |
|   | N                          | 29                               | 31                               | 60                               | 38                              | 33                               | 71                               |
|   | Mean (SD)                  | 79.7 (21.2)                      | 79.5 (14.2)                      | 79.6 (17.8)                      | 76.6 (21.2)                     | 74.8 (15.3)                      | 75.8 (18.6)                      |
|   | Median (IQR)<br>(Min, Max) | 87.5 (75, 93.8)<br>(6.3, 100)    | 81.3 (75, 87.5)<br>(43.8, 100)   | 81.3 (75, 93.8)<br>(6.3, 100)    | 81.3 (68.8, 93.8)<br>(25, 100)  | 75 (62.5, 87.5)<br>(31.3, 100)   | 75 (68.8, 87.5)<br>(25, 100)     |
| Children 5-7 years old (6 & 12 month follow-up)   | Child (Treatment II)       |                                  |                                  |                                  |                                 |                                  |                                  |
|   | N                          | 12                               | 22                               | 34                               | 13                              | 19                               | 32                               |
|   | Mean (SD)                  | 80.1 (19.3)                      | 83.2 (12.9)                      | 82.1 (15.3)                      | 82.3 (18.1)                     | 79.9 (15.3)                      | 80.9 (16.3)                      |
|   | Median (IQR)<br>(Min, Max) | 85.7 (67.9, 95.4)<br>(42.9, 100) | 83.7 (73.5, 92.9)<br>(57.1, 100) | 85.7 (71.4, 92.9)<br>(42.9, 100) | 85.7 (73.5, 100)<br>(35.7, 100) | 78.6 (71.4, 92.9)<br>(55.1, 100) | 80.1 (72.4, 95.4)<br>(35.7, 100) |
| Children 8-12 years old (6 & 12 month follow-up)  | Child (Treatment II)       |                                  |                                  |                                  |                                 |                                  |                                  |
|   | N                          | 59                               | 54                               | 113                              | 57                              | 55                               | 112                              |
|   | Mean (SD)                  | 87.9 (11.9)                      | 83.7 (14.5)                      | 85.9 (13.3)                      | 89.6 (11.6)                     | 84.8 (17.6)                      | 87.2 (15)                        |
|   | Median (IQR)<br>(Min, Max) | 92.9 (82.1, 96.4)<br>(45.9, 100) | 85.7 (77.6, 96.4)<br>(39.3, 100) | 89.3 (78.6, 96.4)<br>(39.3, 100) | 92.9 (82.1, 100)<br>(53.1, 100) | 92.9 (75, 100)<br>(16.3, 100)    | 92.9 (82.1, 100)<br>(16.3, 100)  |
| Children 13-16 years old (6 & 12 month follow-up) | Child (Treatment II)       |                                  |                                  |                                  |                                 |                                  |                                  |
|   | N                          | 29                               | 31                               | 60                               | 38                              | 33                               | 71                               |

| Questionnaire Summary<br>age-group                |                       | 6 months         |                   |                 | 12 months       |                   |                 |
|---|-----------------------|------------------|-------------------|-----------------|-----------------|-------------------|-----------------|
|   |                       | CSII             | MDI               | Total           | CSII            | MDI               | Total           |
| 12 month follow-up)                               | Mean (SD)             | 90.1 (13.8)      | 87.2 (10.7)       | 88.6 (12.3)     | 84 (16.7)       | 85.3 (12.4)       | 84.6 (14.8)     |
|   | Median (IQR)          | 96.4 (87.2, 100) | 85.7 (82.1, 96.4) | 92.9 (82.1, 98) | 91.3 (75, 96.4) | 85.7 (78.6, 96.4) | 89.3 (75, 96.4) |
|   | (Min, Max)            | (50, 100)        | (60.7, 100)       | (50, 100)       | (42.9, 100)     | (50, 100)         | (42.9, 100)     |
| Children 5-7 years old (6 & 12 month follow-up)   | Child (Worry)         |                  |                   |                 |                 |                   |                 |
|   | N                     | 11               | 21                | 32              | 14              | 19                | 33              |
|   | Mean (SD)             | 74.2 (26.2)      | 77.8 (24.9)       | 76.6 (25)       | 77.4 (31.1)     | 68.4 (28.8)       | 72.2 (29.7)     |
| Children 8-12 years old (6 & 12 month follow-up)  | Child (Worry)         |                  |                   |                 |                 |                   |                 |
|   | N                     | 59               | 54                | 113             | 57              | 53                | 110             |
|   | Mean (SD)             | 81.2 (16.8)      | 75.8 (20.7)       | 78.6 (18.9)     | 82.5 (17.7)     | 78 (23.4)         | 80.3 (20.6)     |
| Children 13-16 years old (6 & 12 month follow-up) | Child (Worry)         |                  |                   |                 |                 |                   |                 |
|   | N                     | 29               | 31                | 60              | 38              | 33                | 71              |
|   | Mean (SD)             | 80.5 (22.1)      | 77.2 (17.9)       | 78.8 (19.9)     | 73 (23.2)       | 74.5 (23.3)       | 73.7 (23.1)     |
| Children 5-7 years old (6 & 12 month follow-up)   | Child (Communication) |                  |                   |                 |                 |                   |                 |
|   | N                     | 11               | 22                | 33              | 14              | 18                | 32              |
|   | Mean (SD)             | 56.1 (38.2)      | 77.3 (23.9)       | 70.2 (30.5)     | 57.1 (33.1)     | 80.6 (25.7)       | 70.3 (31)       |
| Children 8-12 years old (6 & 12 month follow-up)  | Child (Communication) |                  |                   |                 |                 |                   |                 |
|   | N                     | 58               | 55                | 113             | 54              | 54                | 108             |
|   | Mean (SD)             | 82.2 (18.3)      | 72 (25.3)         | 77.2 (22.5)     | 79.7 (23.7)     | 75.6 (26.6)       | 77.6 (25.2)     |

| Questionnaire age-group                                 |                            | 6 months                          |                                   |                                   | 12 months                         |                                   |                                   |
|---|----------------------------|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|
|   |                            | CSII                              | MDI                               | Total                             | CSII                              | MDI                               | Total                             |
| Children 13-16 years old (6 & 12 month follow-up)       | Median (IQR)<br>(Min, Max) | 83.3 (75, 100)<br>(16.7, 100)     | 75 (58.3, 91.7)<br>(0, 100)       | 83.3 (66.7, 100)<br>(0, 100)      | 91.7 (66.7, 100)<br>(8.3, 100)    | 83.3 (58.3, 100)<br>(0, 100)      | 83.3 (58.3, 100)<br>(0, 100)      |
|   | Child (Communication)<br>N | 29                                | 29                                | 58                                | 38                                | 33                                | 71                                |
|   | Mean (SD)                  | 86.2 (15.5)                       | 81.6 (19.7)                       | 83.9 (17.7)                       | 81.6 (18.1)                       | 76.8 (26.4)                       | 79.3 (22.3)                       |
|   | Median (IQR)<br>(Min, Max) | 91.7 (75, 100)<br>(50, 100)       | 83.3 (75, 100)<br>(16.7, 100)     | 87.5 (75, 100)<br>(16.7, 100)     | 83.3 (66.7, 100)<br>(33.3, 100)   | 83.3 (66.7, 100)<br>(0, 100)      | 83.3 (66.7, 100)<br>(0, 100)      |
| Children 5-7 years old (6 & 12 month follow-up)         | Child (Overall)<br>N       | 11                                | 21                                | 32                                | 13                                | 18                                | 31                                |
|   | Mean (SD)                  | 67.3 (15.4)                       | 73 (9)                            | 71 (11.7)                         | 72.6 (15.5)                       | 70 (15.2)                         | 71.1 (15.1)                       |
|   | Median (IQR)<br>(Min, Max) | 75 (51.5, 80.4)<br>(41.1, 83.4)   | 70.9 (67.9, 80.4)<br>(55.4, 87.5) | 71.4 (67, 80.4)<br>(41.1, 87.5)   | 78.6 (60.7, 85.7)<br>(39.3, 89.3) | 76.4 (60.7, 81.6)<br>(30.4, 85.7) | 76.8 (60.7, 82.1)<br>(30.4, 89.3) |
| Children 8-12 years old (6 & 12 month follow-up)        | Child (Overall)<br>N       | 58                                | 54                                | 112                               | 54                                | 53                                | 107                               |
|   | Mean (SD)                  | 75.9 (12.6)                       | 71.8 (13.2)                       | 73.9 (13)                         | 79 (12)                           | 74.4 (14.3)                       | 76.7 (13.3)                       |
|   | Median (IQR)<br>(Min, Max) | 79.1 (66.6, 84.8)<br>(45.5, 94.1) | 71.5 (64.3, 80.4)<br>(40.2, 99.1) | 75.9 (66.3, 83.6)<br>(40.2, 99.1) | 81.7 (70.7, 88.4)<br>(44.6, 100)  | 76.8 (64.3, 85.7)<br>(39.8, 96.4) | 77.7 (70.5, 87.8)<br>(39.8, 100)  |
| Children 13-16 years old (6 & 12 month follow-up)       | Child (Overall)<br>N       | 29                                | 29                                | 58                                | 37                                | 33                                | 70                                |
|   | Mean (SD)                  | 78.6 (13)                         | 75.9 (11.6)                       | 77.2 (12.3)                       | 73.7 (13.8)                       | 72.4 (14.4)                       | 73.1 (14)                         |
|   | Median (IQR)<br>(Min, Max) | 79.5 (71.4, 87.6)<br>(43.8, 99.1) | 75.9 (67, 82.1)<br>(50, 98.2)     | 76.9 (69.6, 85.7)<br>(43.8, 99.1) | 75 (63.4, 84.8)<br>(47.3, 95.5)   | 73.2 (60.7, 79.3)<br>(35.7, 94.6) | 74.7 (60.7, 84.8)<br>(35.7, 95.5) |
| Parents / carers 2-4 years old (6 & 12 month follow-up) | Parent (Diabetes)<br>N     | 25                                | 18                                | 43                                | 22                                | 18                                | 40                                |
|   | Mean (SD)                  | 62 (16)                           | 58.1 (11.1)                       | 60.4 (14.1)                       | 62.7 (17.1)                       | 56.2 (16.2)                       | 59.8 (16.8)                       |
|   | Median (IQR)               | 62 (54.5, 65.9)                   | 58.1 (47.7, 65.9)                 | 61.4 (47.7, 65.9)                 | 59.1 (47.7, 75)                   | 56.8 (43.2, 68.2)                 | 56.8 (46.6, 72.7)                 |

| Questionnaire age-group                                   |                      | 6 months          |                   |                   | 12 months         |                   |                   |
|---|----------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|
|   |                      | CSII              | MDI               | Total             | CSII              | MDI               | Total             |
| Parents / carers 5-7 years old (6 & 12 month follow-up)   | (Min, Max)           | (27.3, 97.7)      | (38.6, 75)        | (27.3, 97.7)      | (33.1, 97.7)      | (27.3, 81.8)      | (27.3, 97.7)      |
|   | Parent (Diabetes)    |                   |                   |                   |                   |                   |                   |
|   | N                    | 14                | 23                | 37                | 17                | 18                | 35                |
|   | Mean (SD)            | 66.2 (12)         | 61.4 (13.9)       | 63.2 (13.2)       | 68.3 (15.4)       | 60.8 (15.7)       | 64.5 (15.8)       |
|   | Median (IQR)         | 65.9 (59.1, 77.3) | 59.1 (50, 72.7)   | 61.4 (54.5, 72.7) | 65.9 (56.8, 77.3) | 61.4 (53.7, 72.7) | 65.9 (53.7, 75)   |
| Parents / carers 8-12 years old (6 & 12 month follow-up)  | (Min, Max)           | (43.2, 84.1)      | (38.6, 90.9)      | (38.6, 90.9)      | (45.5, 95.5)      | (13.6, 81.8)      | (13.6, 95.5)      |
|   | Parent (Diabetes)    |                   |                   |                   |                   |                   |                   |
|   | N                    | 58                | 58                | 116               | 55                | 55                | 110               |
|   | Mean (SD)            | 62.9 (14.9)       | 62.7 (15.3)       | 62.8 (15)         | 66.2 (14.6)       | 60.8 (16.2)       | 63.5 (15.6)       |
|   | Median (IQR)         | 63.6 (52.3, 75)   | 61.4 (52.3, 72.7) | 61.4 (52.3, 72.7) | 65.9 (52.3, 75.2) | 61.4 (47.7, 74.4) | 63.6 (52.3, 75)   |
| Parents / carers 13-16 years old (6 & 12 month follow-up) | (Min, Max)           | (25, 93.2)        | (36.4, 95.5)      | (25, 95.5)        | (43.2, 100)       | (29.5, 97.7)      | (29.5, 100)       |
|   | Parent (Diabetes)    |                   |                   |                   |                   |                   |                   |
|   | N                    | 30                | 29                | 59                | 38                | 34                | 72                |
|   | Mean (SD)            | 63.9 (17.4)       | 60.3 (18.1)       | 62.1 (17.7)       | 60.3 (17.7)       | 61.5 (14)         | 60.9 (15.9)       |
|   | Median (IQR)         | 58 (52.3, 81.8)   | 61.4 (50, 72.7)   | 59.1 (52.1, 75)   | 59.1 (47.7, 68.2) | 61.4 (54.5, 70.5) | 61.4 (50, 70.5)   |
| Parents / carers 2-4 years old (6 & 12 month follow-up)   | (Min, Max)           | (36.4, 97.7)      | (24.8, 100)       | (24.8, 100)       | (27.3, 100)       | (22.7, 90.9)      | (22.7, 100)       |
|   | Parent (Treatment I) |                   |                   |                   |                   |                   |                   |
|   | N                    | 25                | 18                | 43                | 21                | 18                | 39                |
|   | Mean (SD)            | 79.8 (20.5)       | 69.8 (20.7)       | 75.6 (20.9)       | 80.7 (18.9)       | 73.6 (20.8)       | 77.4 (19.9)       |
|   | Median (IQR)         | 87.5 (62.5, 100)  | 68.8 (56.3, 93.8) | 75 (56.3, 100)    | 87.5 (68.8, 93.8) | 81.3 (68.8, 87.5) | 81.3 (68.8, 87.5) |
| Parents / carers 5-7 years old (6 & 12 month follow-up)   | (Min, Max)           | (37.5, 100)       | (31.3, 100)       | (31.3, 100)       | (31.3, 100)       | (18.8, 100)       | (18.8, 100)       |
|   | Parent (Treatment I) |                   |                   |                   |                   |                   |                   |
|   | N                    | 14                | 23                | 37                | 17                | 18                | 35                |
|   | Mean (SD)            | 63.8 (28.4)       | 69.3 (19.2)       | 67.2 (22.9)       | 72.8 (21.5)       | 69.8 (21.1)       | 71.3 (21.1)       |
|   | Median (IQR)         | 62.5 (50, 87.5)   | 68.8 (56.3, 81.3) | 68.8 (56.3, 81.3) | 81.3 (56.3, 87.5) | 71.9 (56.3, 87.5) | 75 (56.3, 87.5)   |
|   | (Min, Max)           | (0, 100)          | (31.3, 100)       | (0, 100)          | (37.5, 100)       | (25, 100)         | (25, 100)         |

| Questionnaire age-group                                   |                            | 6 months                       |                                  |                                  | 12 months                        |                                  |                                  |
|---|----------------------------|--------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|
|   |                            | CSII                           | MDI                              | Total                            | CSII                             | MDI                              | Total                            |
| Parents / carers 8-12 years old (6 & 12 month follow-up)  | Parent (Treatment I)       |                                |                                  |                                  |                                  |                                  |                                  |
|   | N                          | 58                             | 57                               | 115                              | 55                               | 55                               | 110                              |
|   | Mean (SD)                  | 71.3 (20.3)                    | 67.9 (20.8)                      | 69.6 (20.5)                      | 69.1 (18.7)                      | 66.9 (19.6)                      | 68 (19.1)                        |
|   | Median (IQR)<br>(Min, Max) | 75 (56.3, 87.5)<br>(25, 100)   | 68.8 (56.3, 87.5)<br>(12.5, 100) | 68.8 (56.3, 87.5)<br>(12.5, 100) | 68.8 (56.3, 81.3)<br>(25, 100)   | 62.5 (56.3, 81.3)<br>(25, 100)   | 68.8 (56.3, 81.3)<br>(25, 100)   |
| Parents / carers 13-16 years old (6 & 12 month follow-up) | Parent (Treatment I)       |                                |                                  |                                  |                                  |                                  |                                  |
|   | N                          | 30                             | 29                               | 59                               | 38                               | 34                               | 72                               |
|   | Mean (SD)                  | 65.2 (22.3)                    | 61.3 (18.1)                      | 63.3 (20.3)                      | 67.3 (22.1)                      | 62.3 (21.9)                      | 64.9 (22)                        |
|   | Median (IQR)<br>(Min, Max) | 68.8 (43.8, 81.3)<br>(25, 100) | 62.5 (50, 75)<br>(31.3, 100)     | 62.5 (50, 81.3)<br>(25, 100)     | 68.8 (50, 81.3)<br>(25, 100)     | 62.5 (43.8, 81.3)<br>(12.5, 100) | 68.8 (50, 81.3)<br>(12.5, 100)   |
| Parents / carers 2-4 years old (6 & 12 month follow-up)   | Parent (Treatment II)      |                                |                                  |                                  |                                  |                                  |                                  |
|   | N                          | 25                             | 18                               | 43                               | 22                               | 18                               | 40                               |
|   | Mean (SD)                  | 85.4 (13.6)                    | 74.2 (16.6)                      | 80.8 (15.7)                      | 88.6 (10.9)                      | 82.7 (14.8)                      | 85.9 (13)                        |
|   | Median (IQR)<br>(Min, Max) | 91.8 (82.1, 96.4)<br>(49, 100) | 73.2 (61.2, 85.7)<br>(40.8, 100) | 82.1 (69.4, 96.4)<br>(40.8, 100) | 92.3 (85.7, 92.9)<br>(59.7, 100) | 87.8 (75, 93.9)<br>(45.9, 100)   | 90.8 (80.4, 93.4)<br>(45.9, 100) |
| Parents / carers 5-7 years old (6 & 12 month follow-up)   | Parent (Treatment II)      |                                |                                  |                                  |                                  |                                  |                                  |
|   | N                          | 14                             | 23                               | 37                               | 16                               | 18                               | 34                               |
|   | Mean (SD)                  | 84.2 (14.4)                    | 82.8 (9.8)                       | 83.3 (11.6)                      | 84.8 (14.3)                      | 77.6 (15.3)                      | 81 (15.1)                        |
|   | Median (IQR)<br>(Min, Max) | 91.3 (75, 96.4)<br>(57.1, 98)  | 82.1 (75, 92.9)<br>(64.3, 100)   | 85.7 (75, 93.9)<br>(57.1, 100)   | 85.7 (70.2, 100)<br>(64.3, 100)  | 76.8 (64.3, 92.9)<br>(50, 98)    | 82.1 (65.3, 96.4)<br>(50, 100)   |
| Parents / carers 8-12 years old (6 & 12 month follow-up)  | Parent (Treatment II)      |                                |                                  |                                  |                                  |                                  |                                  |
|   | N                          | 58                             | 58                               | 116                              | 55                               | 55                               | 110                              |
|   | Mean (SD)                  | 86.4 (12.7)                    | 80.9 (15.3)                      | 83.7 (14.3)                      | 86.8 (13.5)                      | 81.1 (16.6)                      | 83.9 (15.3)                      |
|   | Median (IQR)               | 87.2 (77.6, 98)                | 82.1 (71.4, 92.9)                | 85.7 (73.5, 96.4)                | 89.3 (81.6, 100)                 | 85.7 (67.9, 92.9)                | 89.3 (75, 96.4)                  |

| Questionnaire Summary<br>age-group                        |                       | 6 months          |                   |                   | 12 months         |                   |                   |
|---|-----------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|
|   |                       | CSII              | MDI               | Total             | CSII              | MDI               | Total             |
| Parents / carers 13-16 years old (6 & 12 month follow-up) | (Min, Max)            | (50, 100)         | (39.3, 100)       | (39.3, 100)       | (44.9, 100)       | (16.3, 100)       | (16.3, 100)       |
|   | Parent (Treatment II) |                   |                   |                   |                   |                   |                   |
|   | N                     | 29                | 29                | 58                | 38                | 34                | 72                |
|   | Mean (SD)             | 84.6 (15.1)       | 79.4 (15)         | 82 (15.1)         | 80.7 (16.4)       | 77.7 (19.6)       | 79.3 (17.9)       |
|   | Median (IQR)          | 85.7 (77.6, 98)   | 82.1 (64.3, 92.9) | 85.7 (73.5, 93.9) | 81.9 (64.3, 96.4) | 78.6 (67.9, 92.9) | 81.6 (67.9, 96.4) |
|   | (Min, Max)            | (42.9, 100)       | (55.1, 100)       | (42.9, 100)       | (39.3, 100)       | (32.1, 100)       | (32.1, 100)       |
| Parents / carers 2-4 years old (6 & 12 month follow-up)   | Parent (Worry)        |                   |                   |                   |                   |                   |                   |
|   | N                     | 25                | 18                | 43                | 21                | 18                | 39                |
|   | Mean (SD)             | 63 (29.5)         | 45.4 (28.6)       | 55.6 (30.1)       | 47.9 (28.1)       | 48.6 (31.9)       | 48.2 (29.5)       |
|   | Median (IQR)          | 58.3 (33.3, 91.7) | 41.7 (25, 58.3)   | 50 (33.3, 83.3)   | 41.7 (33.3, 75)   | 54.2 (25, 66.7)   | 50 (25, 75)       |
|   | (Min, Max)            | (8.3, 100)        | (0, 100)          | (0, 100)          | (0, 100)          | (0, 100)          | (0, 100)          |
| Parents / carers 5-7 years old (6 & 12 month follow-up)   | Parent (Worry)        |                   |                   |                   |                   |                   |                   |
|   | N                     | 14                | 23                | 37                | 17                | 18                | 35                |
|   | Mean (SD)             | 61.3 (26.7)       | 75.4 (22)         | 70 (24.5)         | 61.3 (29.3)       | 67.1 (25.2)       | 64.3 (27)         |
|   | Median (IQR)          | 58.3 (33.3, 83.3) | 83.3 (58.3, 91.7) | 75 (50, 91.7)     | 66.7 (33.3, 83.3) | 75 (50, 83.3)     | 75 (41.7, 83.3)   |
|   | (Min, Max)            | (25, 100)         | (25, 100)         | (25, 100)         | (16.7, 100)       | (0, 100)          | (0, 100)          |
| Parents / carers 8-12 years old (6 & 12 month follow-up)  | Parent (Worry)        |                   |                   |                   |                   |                   |                   |
|   | N                     | 58                | 58                | 116               | 55                | 55                | 110               |
|   | Mean (SD)             | 72.1 (20.1)       | 64.4 (21.3)       | 68.2 (21)         | 68.2 (24.3)       | 67.7 (25.3)       | 68 (24.7)         |
|   | Median (IQR)          | 75 (58.3, 83.3)   | 66.7 (50, 83.3)   | 66.7 (50, 83.3)   | 75 (50, 91.7)     | 66.7 (50, 91.7)   | 70.8 (50, 91.7)   |
|   | (Min, Max)            | (25, 100)         | (25, 100)         | (25, 100)         | (8.3, 100)        | (0, 100)          | (0, 100)          |
| Parents / carers 13-16 years old (6 & 12 month follow-up) | Parent (Worry)        |                   |                   |                   |                   |                   |                   |
|   | N                     | 30                | 29                | 59                | 38                | 34                | 72                |
|   | Mean (SD)             | 69.2 (24.4)       | 65.2 (23.5)       | 67.2 (23.8)       | 71.9 (21)         | 66.9 (23.6)       | 69.6 (22.3)       |
|   | Median (IQR)          | 75 (50, 91.7)     | 66.7 (50, 83.3)   | 66.7 (50, 83.3)   | 75 (50, 83.3)     | 75 (50, 83.3)     | 75 (50, 83.3)     |
|   | (Min, Max)            | (8.3, 100)        | (16.7, 100)       | (8.3, 100)        | (33.3, 100)       | (8.3, 100)        | (8.3, 100)        |

| Questionnaire age-group                                   |                            | 6 months                          |                                   |                                 | 12 months                       |                                   |                                   |
|---|----------------------------|-----------------------------------|-----------------------------------|---------------------------------|---------------------------------|-----------------------------------|-----------------------------------|
|   |                            | CSII                              | MDI                               | Total                           | CSII                            | MDI                               | Total                             |
| Parents / carers 2-4 years old (6 & 12 month follow-up)   | Parent (Communication)     |                                   |                                   |                                 |                                 |                                   |                                   |
|   | N                          | 24                                | 19                                | 43                              | 21                              | 17                                | 38                                |
|   | Mean (SD)                  | 83.7 (25.2)                       | 74.1 (28.7)                       | 79.5 (26.9)                     | 81.3 (25.7)                     | 70.6 (34)                         | 76.5 (29.8)                       |
|   | Median (IQR)<br>(Min, Max) | 100 (75, 100)<br>(0, 100)         | 75 (58.3, 100)<br>(0, 100)        | 91.7 (66.7, 100)<br>(0, 100)    | 91.7 (75, 100)<br>(25, 100)     | 83.3 (50, 100)<br>(0, 100)        | 91.7 (50, 100)<br>(0, 100)        |
| Parents / carers 5-7 years old (6 & 12 month follow-up)   | Parent (Communication)     |                                   |                                   |                                 |                                 |                                   |                                   |
|   | N                          | 13                                | 23                                | 36                              | 17                              | 17                                | 34                                |
|   | Mean (SD)                  | 82.7 (22.4)                       | 84.1 (22.5)                       | 83.6 (22.1)                     | 72.5 (32.1)                     | 80.9 (18.8)                       | 76.7 (26.3)                       |
|   | Median (IQR)<br>(Min, Max) | 100 (66.7, 100)<br>(41.7, 100)    | 91.7 (75, 100)<br>(16.7, 100)     | 95.8 (75, 100)<br>(16.7, 100)   | 83.3 (50, 100)<br>(0, 100)      | 83.3 (66.7, 100)<br>(41.7, 100)   | 83.3 (66.7, 100)<br>(0, 100)      |
| Parents / carers 8-12 years old (6 & 12 month follow-up)  | Parent (Communication)     |                                   |                                   |                                 |                                 |                                   |                                   |
|   | N                          | 58                                | 57                                | 115                             | 54                              | 55                                | 109                               |
|   | Mean (SD)                  | 78.7 (22.4)                       | 75.7 (26.2)                       | 77.2 (24.3)                     | 80.1 (22.8)                     | 67.2 (26.3)                       | 73.6 (25.4)                       |
|   | Median (IQR)<br>(Min, Max) | 83.3 (66.7, 100)<br>(16.7, 100)   | 83.3 (58.3, 100)<br>(0, 100)      | 83.3 (58.3, 100)<br>(0, 100)    | 87.5 (75, 100)<br>(0, 100)      | 75 (50, 91.7)<br>(0, 100)         | 75 (58.3, 100)<br>(0, 100)        |
| Parents / carers 13-16 years old (6 & 12 month follow-up) | Parent (Communication)     |                                   |                                   |                                 |                                 |                                   |                                   |
|   | N                          | 29                                | 28                                | 57                              | 38                              | 34                                | 72                                |
|   | Mean (SD)                  | 77 (28.9)                         | 67.3 (24.1)                       | 72.2 (26.9)                     | 73.2 (26.1)                     | 72.8 (30.7)                       | 73 (28.2)                         |
|   | Median (IQR)<br>(Min, Max) | 83.3 (75, 100)<br>(0, 100)        | 66.7 (50, 91.7)<br>(25, 100)      | 83.3 (50, 100)<br>(0, 100)      | 75 (50, 100)<br>(0, 100)        | 79.2 (58.3, 100)<br>(0, 100)      | 75 (58.3, 100)<br>(0, 100)        |
| Parents / carers 2-4 years old (6 & 12 month follow-up)   | Parent (Overall)           |                                   |                                   |                                 |                                 |                                   |                                   |
|   | N                          | 24                                | 18                                | 42                              | 20                              | 17                                | 37                                |
|   | Mean (SD)                  | 72.5 (13)                         | 64 (11.5)                         | 68.9 (12.9)                     | 73 (12.7)                       | 67 (15.7)                         | 70.2 (14.3)                       |
|   | Median (IQR)<br>(Min, Max) | 72.8 (62.9, 77.2)<br>(54.5, 98.6) | 61.8 (55.5, 74.1)<br>(46.7, 81.6) | 68.8 (57, 76.8)<br>(46.7, 98.6) | 75 (62.1, 82.1)<br>(52.4, 99.1) | 70.5 (54.7, 79.5)<br>(40.2, 90.2) | 73.2 (60.7, 80.4)<br>(40.2, 99.1) |

| Questionnaire age-group                                   | Summary                    | 6 months                          |                                   |                                   | 12 months                         |                                   |                                   |
|---|----------------------------|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|
|   |                            | CSII                              | MDI                               | Total                             | CSII                              | MDI                               | Total                             |
| Parents / carers 5-7 years old (6 & 12 month follow-up)   | Parent (Overall)           |                                   |                                   |                                   |                                   |                                   |                                   |
|   | N                          | 13                                | 23                                | 36                                | 16                                | 17                                | 33                                |
|   | Mean (SD)                  | 72.5 (12.8)                       | 71.8 (8.6)                        | 72 (10.1)                         | 73.1 (15.8)                       | 71 (9.3)                          | 72 (12.7)                         |
|   | Median (IQR)<br>(Min, Max) | 70.5 (63.5, 85.7)<br>(51.8, 90.2) | 69.6 (65.2, 80.4)<br>(54.7, 84.4) | 69.8 (65.1, 80.8)<br>(51.8, 90.2) | 75.6 (60.4, 86.6)<br>(45.5, 94.6) | 72.3 (64.7, 76)<br>(49.1, 86.6)   | 73.2 (63.4, 81.3)<br>(45.5, 94.6) |
| Parents / carers 8-12 years old (6 & 12 month follow-up)  | Parent (Overall)           |                                   |                                   |                                   |                                   |                                   |                                   |
|   | N                          | 58                                | 56                                | 114                               | 54                                | 55                                | 109                               |
|   | Mean (SD)                  | 72.7 (12.7)                       | 69.9 (13)                         | 71.3 (12.8)                       | 73.9 (11.9)                       | 68.2 (14.9)                       | 71 (13.8)                         |
|   | Median (IQR)<br>(Min, Max) | 73.2 (65.2, 84.2)<br>(31.3, 94.6) | 68.8 (63.4, 78.8)<br>(34.8, 95.8) | 70.5 (64.3, 81.5)<br>(31.3, 95.8) | 74.5 (65.9, 81.3)<br>(39.5, 100)  | 67.9 (57.1, 77.7)<br>(34.2, 99.1) | 70.5 (61.6, 80.4)<br>(34.2, 100)  |
| Parents / carers 13-16 years old (6 & 12 month follow-up) | Parent (Overall)           |                                   |                                   |                                   |                                   |                                   |                                   |
|   | N                          | 29                                | 28                                | 57                                | 38                                | 34                                | 72                                |
|   | Mean (SD)                  | 71.7 (15.4)                       | 66.7 (16.1)                       | 69.3 (15.8)                       | 69 (14.5)                         | 67.5 (15.7)                       | 68.3 (15)                         |
|   | Median (IQR)<br>(Min, Max) | 73.2 (59.8, 84.3)<br>(42, 99.1)   | 67.6 (55.6, 74.9)<br>(35.1, 98.2) | 69.6 (58.9, 80.4)<br>(35.1, 99.1) | 67.3 (58, 80.7)<br>(41.1, 96.4)   | 67.4 (59.8, 79.5)<br>(19.6, 91.1) | 67.3 (58.9, 80.1)<br>(19.6, 96.4) |

**Table 6.6-24: Paediatric Quality of Life (PedsQL) – Modelling results at 6m and 12m (ITT)**

| Type                | Least Squares Mean Difference between treatment groups (CSII-MDI) across all questionnaire age-groups | p-value |
|---------------------|---|---------|
| Child Self-Report   | 3.1 (-0.6, 6.8)   | 0.10    |
| Parent/Carer Proxy* | 4.1 (0.6, 7.6)  | 0.02    |

\* The Estimated G matrix was not positive definite which indicates that the variance component in the RANDOM statement (site) are estimated to be zero so were removed from the model.

**Table 6.6-25: Paediatric Quality of Life (PedsQL) – Mean profile plot inclusion status (ITT)**

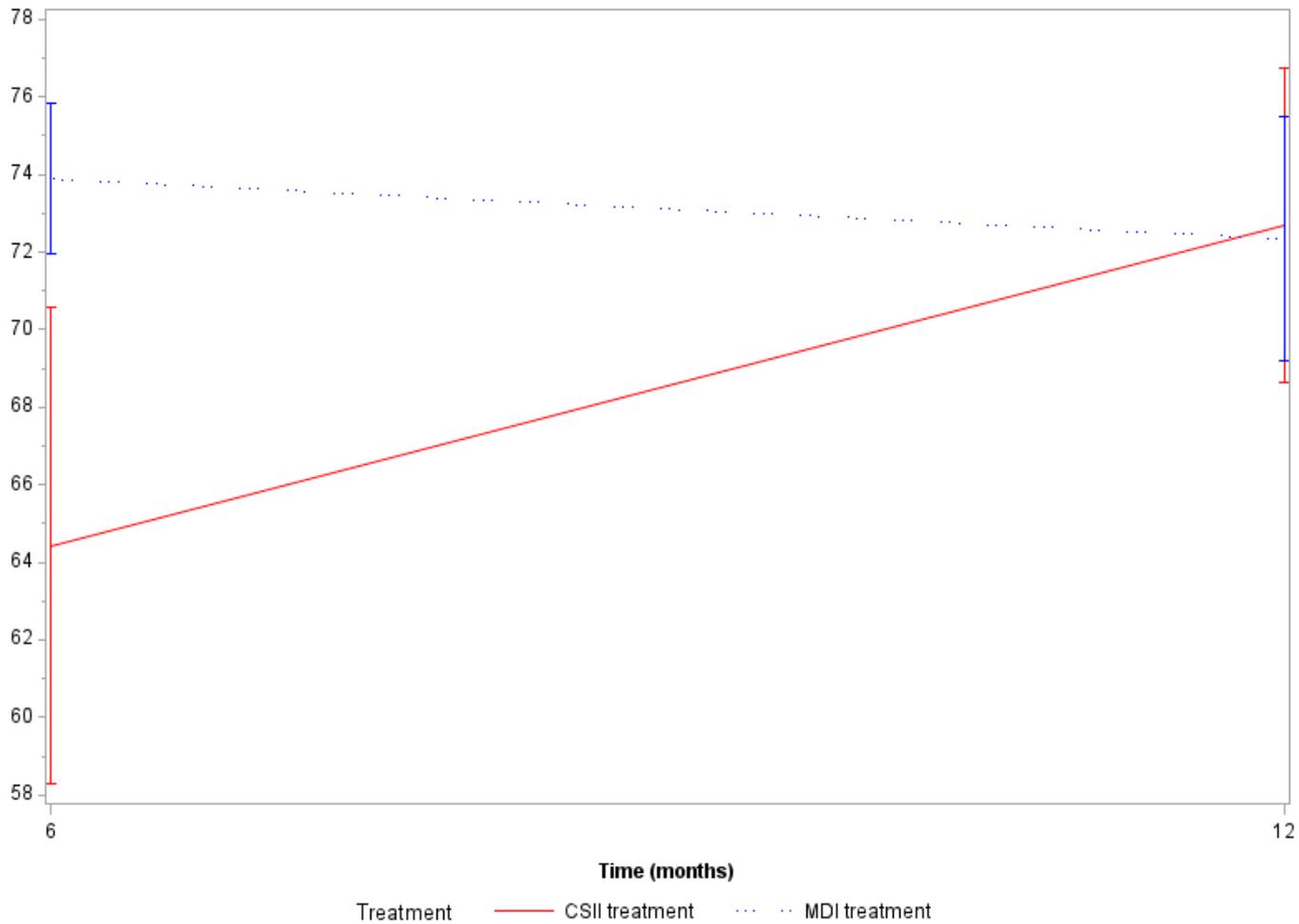
*Note: Only Patients that completed the same questionnaire age-group at both 6m and 12m are included in the mean profile plots*

|   | <b>Mean profile plot inclusion status</b>                                 | <b>6-month questionnaire status</b> | <b>12-month questionnaire status</b> | <b>CSII</b> | <b>MDI</b> | <b>Total</b> |
|---|---|-------------------------------------|--------------------------------------|-------------|------------|--------------|
| Child   | Included  | Children 13-16 years old            | Children 13-16 years old             | 27 (18.8%)  | 25 (16.8%) | 52 (17.7%)   |
|   |   | Children 5-7 years old              | Children 5-7 years old               | 8 (5.6%)    | 14 (9.4%)  | 22 (7.5%)    |
|   |   | Children 8-12 years old             | Children 8-12 years old              | 46 (31.9%)  | 45 (30.2%) | 91 (31.1%)   |
|   | Excluded  | 1/5 incomplete sections             | 1/5 incomplete sections              | 1 (0.7%)    | 1 (0.7%)   | 2 (0.7%)     |
|   |   | 1/5 incomplete sections             | Included                             | 0 (0%)      | 2 (1.3%)   | 2 (0.7%)     |
|   |   | 2/5 incomplete sections             | Included                             | 1 (0.7%)    | 0 (0%)     | 1 (0.3%)     |
|   |   | 3/5 incomplete sections             | Included                             | 0 (0%)      | 1 (0.7%)   | 1 (0.3%)     |
|   |   | DNA 6 months                        | 1/5 incomplete sections              | 1 (0.7%)    | 0 (0%)     | 1 (0.3%)     |
|   |   | DNA 6 months                        | Included                             | 6 (4.2%)    | 3 (2%)     | 9 (3.1%)     |
|   |   | DNA 6 months                        | No questionnaire completed           | 0 (0%)      | 2 (1.3%)   | 2 (0.7%)     |
|   |   | DNA 6 months                        | WD from study prior to 12 months     | 0 (0%)      | 2 (1.3%)   | 2 (0.7%)     |
|   |   | Included                            | 1/5 incomplete sections              | 2 (1.4%)    | 1 (0.7%)   | 3 (1%)       |
|   |   | Included                            | 2/5 incomplete sections              | 0 (0%)      | 1 (0.7%)   | 1 (0.3%)     |
|   |   | Included                            | No questionnaire completed           | 4 (2.8%)    | 5 (3.4%)   | 9 (3.1%)     |
|   |   | Included                            | Questionnaire section not completed  | 0 (0%)      | 3 (2%)     | 3 (1%)       |
|   |   | Included                            | WD from study prior to 12 months     | 0 (0%)      | 3 (2%)     | 3 (1%)       |
|   |   | No questionnaire completed          | Included                             | 3 (2.1%)    | 5 (3.4%)   | 8 (2.7%)     |
|   |   | No questionnaire completed          | No questionnaire completed           | 1 (0.7%)    | 1 (0.7%)   | 2 (0.7%)     |
|   |   | No questionnaire completed          | Questionnaire section not completed  | 1 (0.7%)    | 0 (0%)     | 1 (0.3%)     |
|   |   | No questionnaire completed          | WD from study prior to 12 months     | 1 (0.7%)    | 0 (0%)     | 1 (0.3%)     |
| Questionnaire completed but different age questionnaires at 6m and at 12m | Questionnaire completed but different age questionnaires at 6m and at 12m | 11 (7.6%)                           | 7 (4.7%)                             | 18 (6.1%)   |            |              |
| Questionnaire section not completed                                       | Included  | 1 (0.7%)                            | 1 (0.7%)                             | 2 (0.7%)    |            |              |

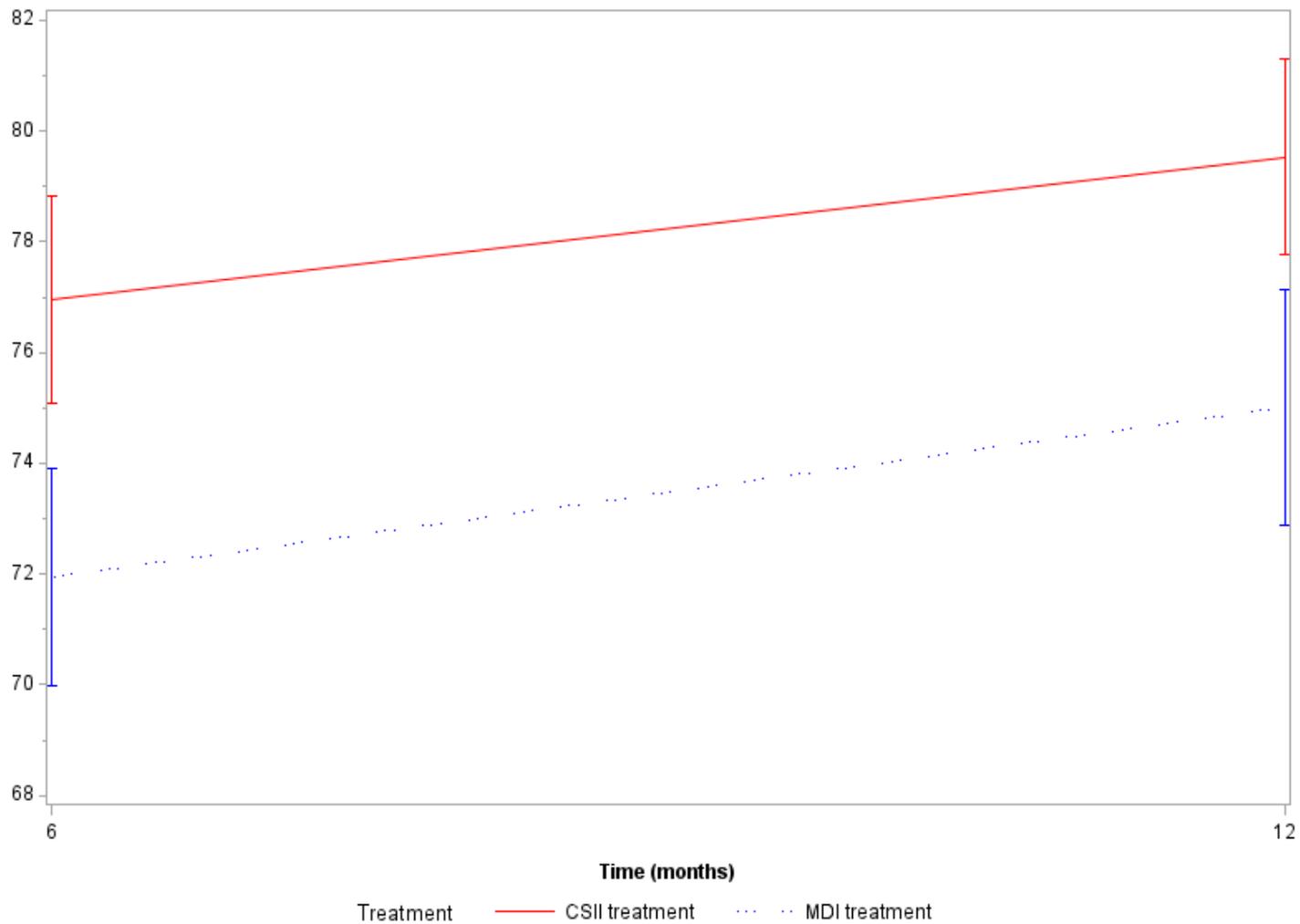
|                | Mean profile plot inclusion status | 6-month questionnaire status                              | 12-month questionnaire status                             | CSII       | MDI        | Total      |
|----------------|------------------------------------|---|---|------------|------------|------------|
|                |                                    | Too young for questionnaire                               | Now old enough and included                               | 1 (0.7%)   | 1 (0.7%)   | 2 (0.7%)   |
|                |                                    | Too young for questionnaire                               | Now old enough but: 1/5 incomplete sections               | 1 (0.7%)   | 0 (0%)     | 1 (0.3%)   |
|                |                                    | Too young for questionnaire                               | Now old enough but: No questionnaire completed            | 2 (1.4%)   | 0 (0%)     | 2 (0.7%)   |
|                |                                    | Too young for questionnaire                               | Too young for questionnaire                               | 26 (18.1%) | 26 (17.4%) | 52 (17.7%) |
| Parent / Carer | Included                           | Parents / carers 13-16 years old (6 & 12 month follow-up) | Parents / carers 13-16 years old (6 & 12 month follow-up) | 28 (19.4%) | 26 (17.4%) | 54 (18.4%) |
|                |                                    | Parents / carers 2-4 years old (6 & 12 month follow-up)   | Parents / carers 2-4 years old (6 & 12 month follow-up)   | 18 (12.5%) | 13 (8.7%)  | 31 (10.6%) |
|                |                                    | Parents / carers 5-7 years old (6 & 12 month follow-up)   | Parents / carers 5-7 years old (6 & 12 month follow-up)   | 10 (6.9%)  | 15 (10.1%) | 25 (8.5%)  |
|                |                                    | Parents / carers 8-12 years old (6 & 12 month follow-up)  | Parents / carers 8-12 years old (6 & 12 month follow-up)  | 45 (31.3%) | 47 (31.5%) | 92 (31.4%) |
|                | Excluded                           | 1/5 incomplete sections                                   | 2/5 incomplete sections                                   | 1 (0.7%)   | 0 (0%)     | 1 (0.3%)   |
|                |                                    | 1/5 incomplete sections                                   | Included  | 1 (0.7%)   | 1 (0.7%)   | 2 (0.7%)   |
|                |                                    | 1/5 incomplete sections                                   | No questionnaire completed                                | 0 (0%)     | 1 (0.7%)   | 1 (0.3%)   |
|                |                                    | 1/5 incomplete sections                                   | Questionnaire section not completed                       | 0 (0%)     | 1 (0.7%)   | 1 (0.3%)   |
|                |                                    | 2/5 incomplete sections                                   | Included  | 1 (0.7%)   | 0 (0%)     | 1 (0.3%)   |
|                |                                    | 4/5 incomplete sections                                   | No questionnaire completed                                | 0 (0%)     | 1 (0.7%)   | 1 (0.3%)   |
|                |                                    | DNA 6 months  | Included  | 6 (4.2%)   | 3 (2%)     | 9 (3.1%)   |
|                |                                    | DNA 6 months  | No questionnaire completed                                | 1 (0.7%)   | 2 (1.3%)   | 3 (1%)     |
|                |                                    | DNA 6 months  | WD from study prior to 12 months                          | 0 (0%)     | 1 (0.7%)   | 1 (0.3%)   |
|                |                                    | Included  | 1/5 incomplete sections                                   | 2 (1.4%)   | 1 (0.7%)   | 3 (1%)     |
|                |                                    | Included  | No questionnaire completed                                | 8 (5.6%)   | 10 (6.7%)  | 18 (6.1%)  |
|                |                                    | Included  | Questionnaire section not completed                       | 0 (0%)     | 1 (0.7%)   | 1 (0.3%)   |
| Included       | WD from study prior to 12 months   | 0 (0%)  | 4 (2.7%)  | 4 (1.4%)   |            |            |
|                | No questionnaire completed         | 1/5 incomplete sections                                   | 1 (0.7%)  | 1 (0.7%)   | 2 (0.7%)   |            |

|  | <b>Mean profile plot inclusion status</b> | <b>6-month questionnaire status</b>                                       | <b>12-month questionnaire status</b>                                      | <b>CSII</b> | <b>MDI</b> | <b>Total</b> |
|--|---|---|---|-------------|------------|--------------|
|  |   | No questionnaire completed  | Included  | 6 (4.2%)    | 10 (6.7%)  | 16 (5.5%)    |
|  |   | No questionnaire completed  | No questionnaire completed  | 2 (1.4%)    | 3 (2%)     | 5 (1.7%)     |
|  |   | No questionnaire completed  | WD from study prior to 12 months  | 1 (0.7%)    | 0 (0%)     | 1 (0.3%)     |
|  |   | Questionnaire completed but different age questionnaires at 6m and at 12m | Questionnaire completed but different age questionnaires at 6m and at 12m | 13 (9%)     | 8 (5.4%)   | 21 (7.2%)    |

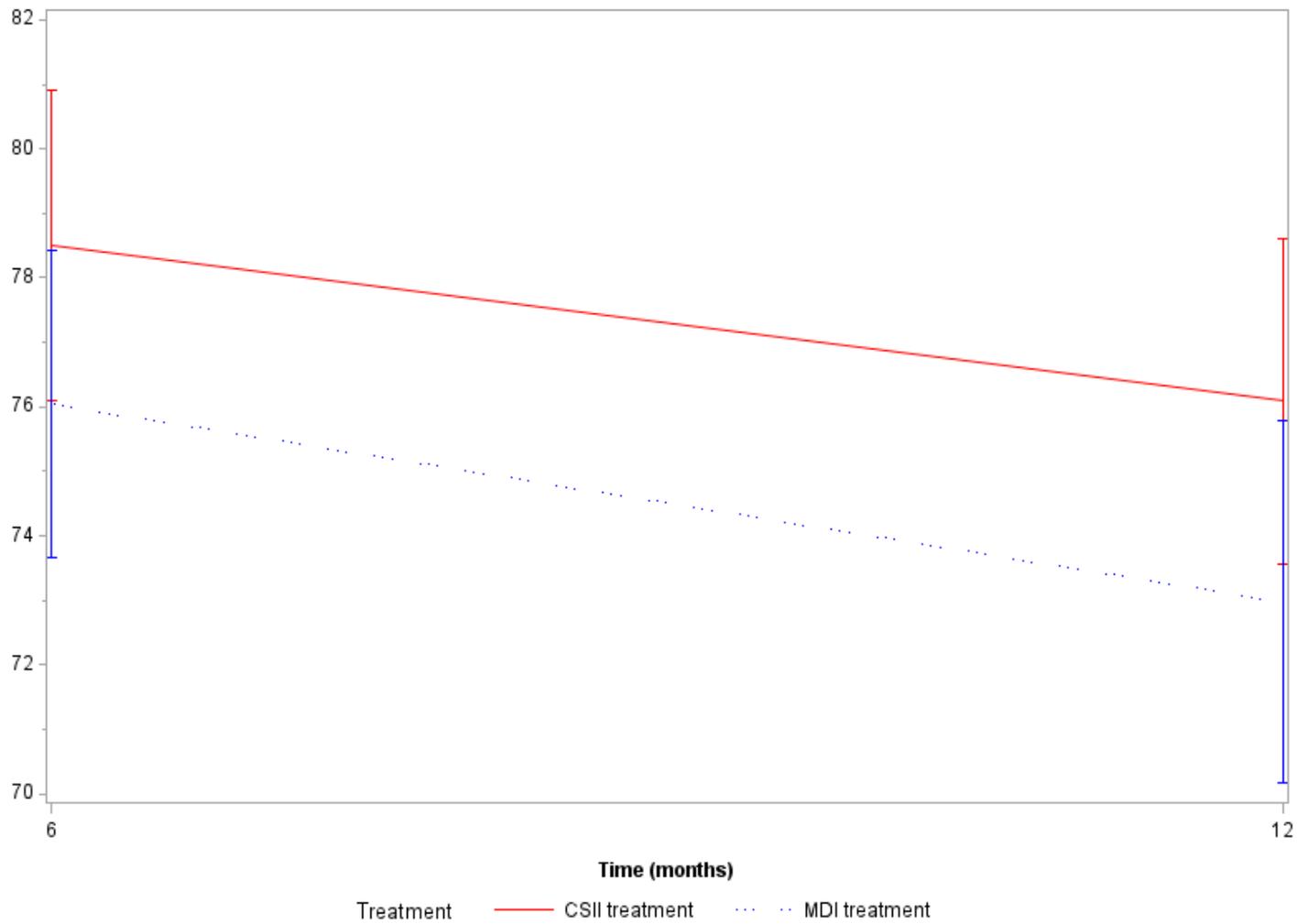
**Figure 6.6-5: Paediatric Quality of Life (PedsQL) – Child mean profile plots (5-7 years old) (ITT)**  
PedsQL Overall Score Mean Profile Plots For Children That Completed a 5-7 Years Old questionnaire at both 6m and 12m  
PedsQL Overall Score



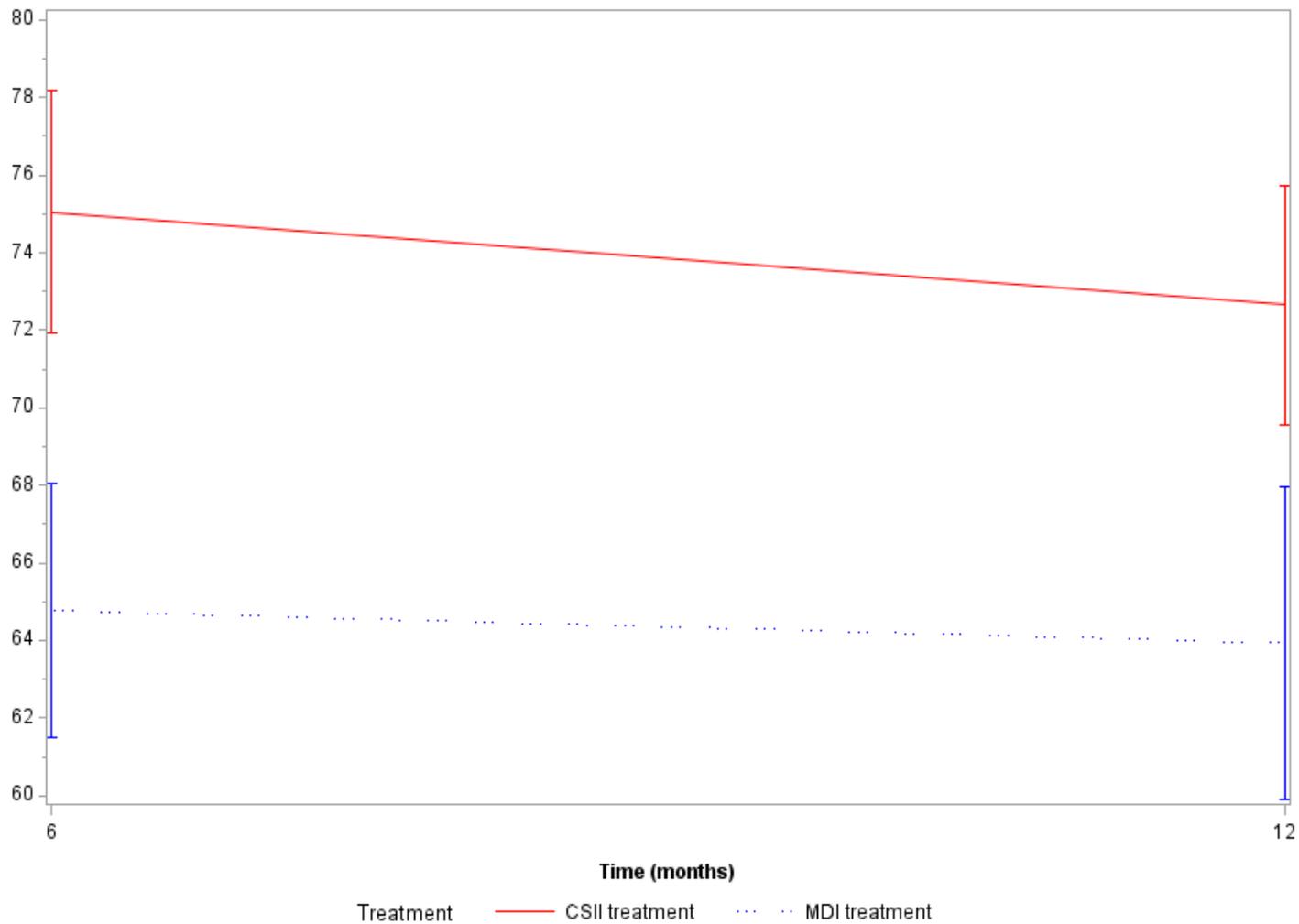
**Figure 6.6-6: Paediatric Quality of Life (PedsQL) – Child mean profile plots (8-12 years old) (ITT)**  
PedsQL Overall Score Mean Profile Plots For Children That Completed a 8-12 Years Old questionnaire at both 6m and 12m  
PedsQL Overall Score



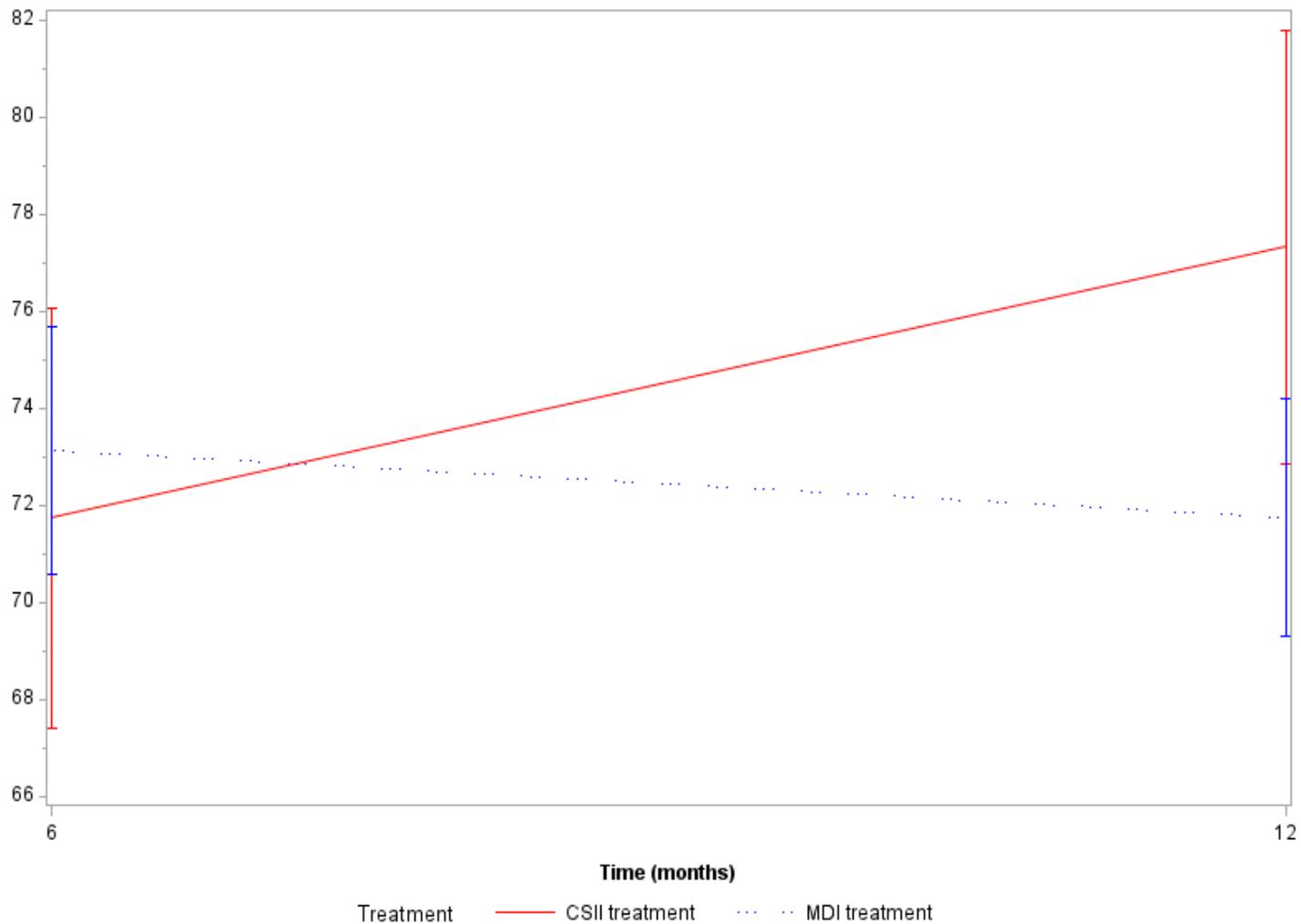
**Figure 6.6-7: Paediatric Quality of Life (PedsQL) – Child mean profile plots (13-16 years old) (ITT)**  
PedsQL Overall Score Mean Profile Plots For Children That Completed a 13-16 Years Old questionnaire at both 6m and 12m  
PedsQL Overall Score



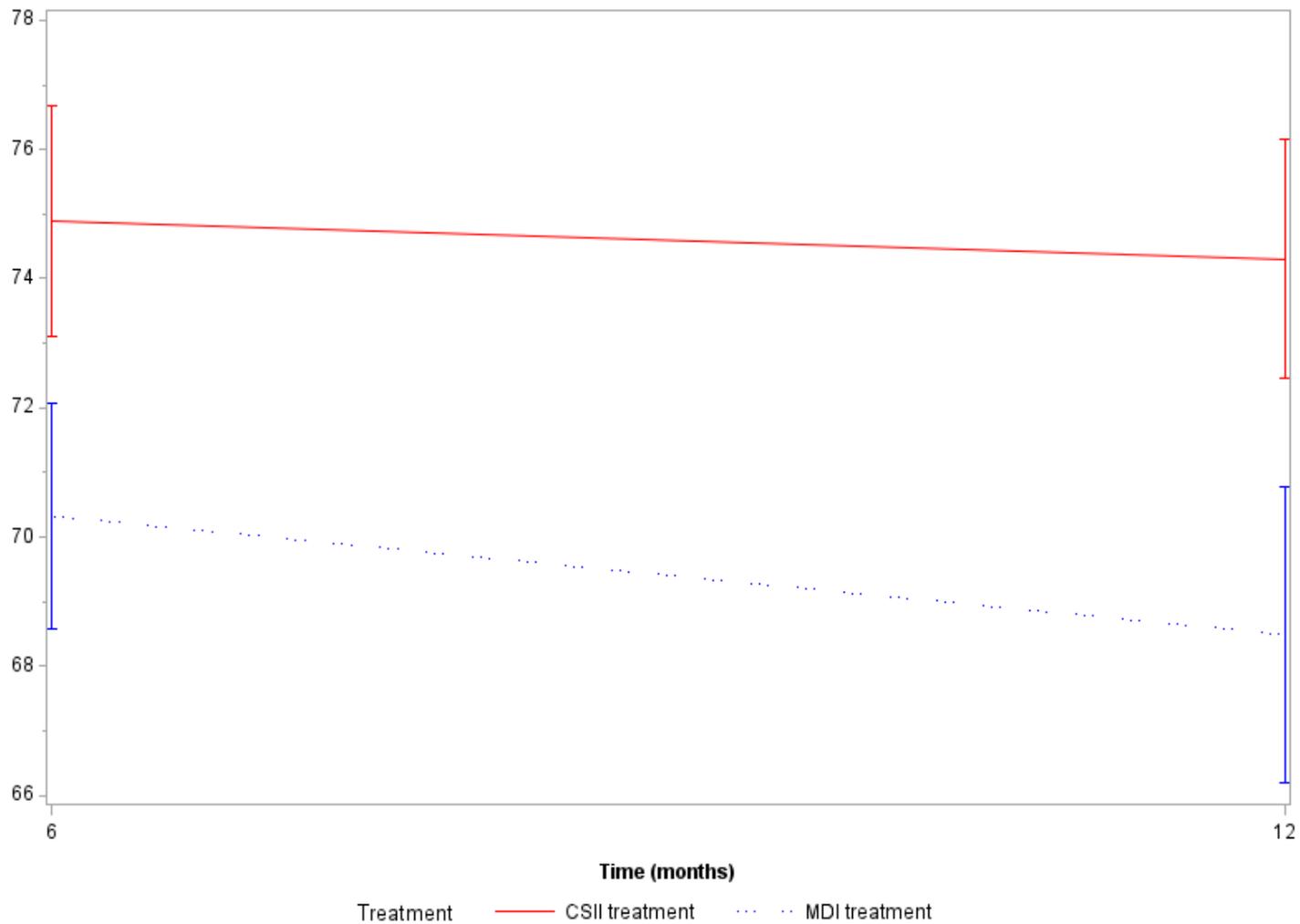
**Figure 6.6-8: Paediatric Quality of Life (PedsQL) – Parent/carer mean profile plots (2-4 years old) (ITT)**  
PedsQL Overall Score Mean Profile Plots For Parents/Carers Of Children That Completed a 2-4 Years Old questionnaire at both 6m and 12m  
PedsQL Overall Score



**Figure 6.6-9: Paediatric Quality of Life (PedsQL) – Parent/carer mean profile plots (5-7 years old) (ITT)**  
PedsQL Overall Score Mean Profile Plots For Parents/Carers Of Children That Completed a 5-7 Years Old questionnaire at both 6m and 12m  
PedsQL Overall Score



**Figure 6.6-10: Paediatric Quality of Life (PedsQL) – Parent/carer mean profile plots (8-12 years old) (ITT)**  
PedsQL Overall Score Mean Profile Plots For Parents/Carers Of Children That Completed a 8-12 Years Old questionnaire at both 6m and 12m  
PedsQL Overall Score



**Figure 6.6-11: Paediatric Quality of Life (PedsQL) – Parent/carer mean profile plots (13-16 years old) (ITT)**  
PedsQL Overall Score Mean Profile Plots For Parents/Carers Of Children That Completed a 13-16 Years Old questionnaire at both 6m and 12m  
PedsQL Overall Score

