Table 1-Characteristics of subjects

|  | **PT 103 Study (FA)** | |
| --- | --- | --- |
|  |  | **All Cohorts** |
| Mean Age (years) |  | 60.4±9.72 (33.2-80.3) |
| Age group |  |  |
| <50 |  | 20 (18.0%) |
| 51-60 |  | 22 (19.8%) |
| 61-70 |  | 58 (52.3%) |
| 71-80 |  | 11 (9.9%) |
|  |  |  |
| Mean Weight (Kg) |  | 69.9±12.59 (54-100) |
| Mean height (cm) |  | 164.5±6.46 (145-176) |
| Mean BMI |  | 25.8±4.46 (19.0-40.6) |
| Deliveries |  | **151** |
| spontaneous |  | 108 |
| Instrumental |  | 39 |
| Caesarean |  | 4 |
| Mean newborn Weight (gr) |  | 3662±449 (2600-4850) |
| Menopausal status |  |  |
| postmenopausal |  | 90 (81.1%) |
| perimenopausal |  | 1 (0.9%) |
| premenopausal |  | 20 (18%) |
| Mean length of amenorrhea (Y) |  | 14.2 (1-28) |
| HRT usage (# of users) |  | 13 (11.7%) systemic,  6 (5.4%) local vaginal |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

Table 2-All Cohorts - comparison of POP-Q stages before (screening) and while using (V5) the Device, (FA (red) PP (black), p<0.0001)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Visit** | **POPQ stage 0** | **POPQ stage 1** | **POPQ stage 2** | **POPQ stage 3** | **POPQ stage 4** |
| **1 (baseline)** |  |  | ***35 (31.5%)***  **28 (29.8%)** | ***76 (68.5%)***  **66 (70.2%)** |  |
| **Visit 3** | *93 (96.9%)*  89 (96.7%) | *3 (3.1%)*  3 (3.3%) |  |  |  |
| **Visit 4** | *93 (96.9%)*  91 (96.8%) | *1 (1.0%)*  1 (1.1%) | *2 (2.1%)*  2 (2.1%) |  |  |
| **Visit 5** | *90 (97.8%)*  **90 (97.8%)** | *2 (2.2%)*  **2 (2.2%)** |  |  |  |

Table 4-Number & percentage of device-related and non-device related adverse events (FA,All Cohort)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Population | Total AE | Non-Device Related AE  (NDRAE) | Device Related Adverse Events (DRAE) | | | |
| Remotely | Possibly | Probably | Total DRAE |
| All Cohorts | 124 | 33 (26.6%) | 8 (6.5%) | 17 (13.7%) | 66 (53.2 %) | 91 (73.3%) |