Supplemental Appendix 2. The detail for the sample size and statistical analysis method

The planned study cohort was 70 individuals (35 cases per study group). Based on data from our retrospective pilot study, the sample size was calculated using the assumption that the mean ± SD change in body weight would be −4.38 kg ± 2.33 kg in switching from pioglitazone to dapagliflozin and 0.66 kg ± 1.77 kg for pioglitazone continuation. It was determined that only eight patients would be needed in each group to detect a significant difference, with 80% power and at a significance level of 0.05 for superiority in body weight. Regarding non-inferiority in the improvement of the HbA1c level, the mean ± SD change in the HbA1c level was 0.05 ± 0.43% in switching from pioglitazone to dapagliflozin and 0.04 ± 0.38% for pioglitazone continuation. Sixty-four patients would be needed to detect a significant difference with a power of ≥80% and significance of 0.05, with a non-inferiority margin for the HbA1c level of 0.4%; this calculation was based on guidance from the US Food and Drug Administration, which specifies a non-inferiority margin for the HbA1c level of 0.3–0.4%.

Results are the mean ± SD, median (range) or number (%). Differences in baseline characteristics between the two groups were evaluated using the unpaired *t*-test or the Mann–Whitney *U*-test for continuous variables, and the chi-square test or Fisher's exact test for categorical variables. The Kolmogorov–Smirnov test for normality was used for the appropriate statistical test for continuous variables. The correlation was evaluated by Spearman rank-order correlation analysis. Data were analyzed using JMP Pro v13.1.0 (SAS Institute, Cary, NC, USA). p < 0.05 was considered significant.