Details of randomization

Randomization codes were generated by the sponsor and administered centrally by an interactive web-based response system (IWRS). The randomization was stratified by region (Japan and all other countries), sex (male and female) and diabetic status (diagnosed with diabetes vs not diagnosed with diabetes). Patient randomization numbers were allocated sequentially in the order in which the patients were enrolled. Patients were enrolled by the investigators, who could access the IWRS at any time via the internet or telephone.