On page 27 of the clinical briefing document please make the following changes:

In the current document replace the highlighted numbers.

Reviewer: The differential in incidence in myocardial infarction is probably overestimated due to changes in the manner of collection of this data over the course of the study (see Reviewer note pg 77 for details). If all prevalent serious cardiac diseases are analyzed the prevalence was actually highest in Eastern Europe. The baseline prevalence was 39.6, 39.9, 65.6, 41.4, and 32.7 in the US, Asian, Eastern European, Western European, and Other populations, respectively

The corrected numbers are highlighted below:

Reviewer: The differential in incidence in myocardial infarction is probably overestimated due to changes in the manner of collection of this data over the course of the study (see Reviewer note pg 75 for details). If all prevalent cardiac diseases are analyzed the prevalence was actually highest in Eastern Europe. The baseline prevalence was 33.4,16.6, 41.6, 28.1, and 23.2 in the US, Asian, Eastern European, Western European, and Other populations, respectively

On page 75 of the briefing document the highlighted sentence should be removed.

There are 3274 conditions labeled as "Cardiovascular". However, over 1000 of the entries are for uncomplicated hypertension, peripheral vascular disease, and a miscellany including palpitations, heart murmur, and migraine headaches. If these conditions are removed, the remaining cardiovascular diagnoses were valvular disease, arrhythmia, coronary artery disease, ischemic cardiovascular disease, and heart failure. The distribution of these more serious conditions was uniform across the treatment groups (45.7, 47.7, 42.1, and 43.7% of the patients in the placebo, SAL, FP, and FSC groups respectively). However, the distribution across the regions was quite skewed. By this definition, 66% of the Eastern Europeans had a serious cardiovascular condition at entry to the study compared to 39.6, 39.9, 41.4, and 32.7% of the US, Asian, Western European, and "Other" patients, respectively.

Corrected copy.

There are 3274 conditions labeled as "Cardiovascular". However, over 1000 of the entries are for uncomplicated hypertension, and hyperlipidemia. If these conditions are removed, the remaining cardiovascular diagnoses were valvular disease, arrhythmia, coronary artery disease, ischemic cardiovascular disease, and heart failure. The distribution of these more serious conditions was uniform across the treatment groups (29.4, 31.4, 27.7, and 30.4% of the patients in the placebo, SAL, FP, and FSC groups respectively). However, the distribution across the regions showed more events in the Eastern Europeans (41.6 compared to 33.4, 16.6, 28.1, and 23.2% of the US, Asian, Western European, and "Other" patients, respectively).