Conclusions

- Changes between the inclusion criteria for the original mITT analysis and the 2016 FDA guidance, particularly Nugent score, excluded a greater number of women.

- The COR rate, based on the 2016 FDA guidance, determined at days 7–14 vs days 21–30 was not significantly different (P=0.54).

- Despite excluding women with BV with intermediate Nugent scores, the COR rate was numerically higher with the 2016 FDA criteria.

Reference