

**CENTER FOR DRUG EVALUATION AND
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APPLICATION NUMBER:

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STATISTICAL REVIEW(S)



U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Translational Sciences
Office of Biostatistics

STATISTICAL REVIEW AND EVALUATION

CLINICAL STUDIES

NDA/BLA #: NDA 209091
Drug Name: Saxagliptin/Dapagliflozin Fixed-Dose Combination (5 mg/10 mg)
Indication(s): Type 2 diabetes mellitus
Applicant: AstraZeneca Pharmaceuticals
Date(s): Stamp: 4/27/2016
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Biometrics Division: II

Statistical Reviewer: Anna Kettermann, Dipl. Math, MA

Concurring Reviewers: Mark Rothmann, PhD, Team leader

Medical Division: Metabolism and Endocrinology Products

Clinical Team: Frank Pucino, Pharm. D, Medical reviewer
William Chong, MD, Clinical team leader

Project Manager: Abolade Adeolu

Keywords: Missing data, subgroup analyses, regional differences, sensitivity analyses

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