CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

209091Orig1s000

<u>STATISTICAL REVIEW(S)</u>

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
	Due date 23/01/2016
Review Priority:	Standard
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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