

ASA-BI Statistics Webinar Series



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**April 5th, Thursday
9-10 am EST**

For more information
regarding upcoming
webinar schedule,
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Title

EMPA-REG Outcome® - A Cardiovascular Outcome Trial Designed According to the FDA Guidance "Diabetes Mellitus – Evaluating Cardiovascular Risk in New Anti-diabetic Therapies to Treat Type 2 Diabetes"

Abstract

The Cardiovascular Outcome Trial (CVOT) EMPA-REG OUTCOME® was designed according to the FDA guideline released in 2008. The CVOT started in parallel to the phase project for the SGLT2 inhibitor Empagliflozin. The talk will present the challenges of designing a CVOT at that development stage and compare the assumptions used for designing the trial with the data observed in the trial. Furthermore, statistical aspects of the confirmatory statistical analysis as well as the exploratory analysis will be discussed.

Professional Biography

Dr. Hantel studied mathematics and econometrics at the Christian-Albrecht's-University in Kiel Germany. He received his PhD in 1993. Since 1993, he worked for several CROs and pharmaceutical companies. In 2004, he joined Boehringer Ingelheim and is now therapeutic area expert statistician for the therapeutic area cardiometabolics.

Sponsored by

- American Statistical Association (Boston, Connecticut, Florida, New Jersey, Princeton/Trenton, and Washington chapters)
- Boehringer Ingelheim Pharmaceuticals, Inc. (Biostatistics and Data Sciences Department)

