

AstraZeneca – Call For Grant Applications (CGA T2D 1803)

Submission / Review Timeline:	Accepting applications until 9 AM EST on April 1, 2019; internal review will be ongoing during this time period
Primary Area of Focus	Endocrinology
Therapeutic Area	Type 2 Diabetes
Educational Design	Accredited medical education programs / initiatives designed to address knowledge and competence gaps and attitudinal barriers to improve clinical performance and person care experience
Educational Audience:	Cardiologists, Endocrinologists, Primary Care Physicians, NPs, PAs, and nurses
Program Cost:	≤ \$800,000.00
CGA Code	CGA T2D 1803
Website URL	https://www.astrazenecagrants.com/us-grants.html

Background on Cardiovascular Outcomes in Type 2 Diabetes

In 2008, the FDA mandated that the cardiovascular safety of new glucose-lowering medications must be systematically studied in outcomes trials.¹ While the primary objective of these studies was to demonstrate CV safety, several have shown superiority in reducing CV and renal risk, including studies with the SGLT-2 inhibitor class.^{2,3,4} As the clinical trials have differed greatly in design, patient populations and outcomes, it is imperative that clinicians are well versed in the data and are able to apply the findings to clinical practice when making treatment decisions for their patients with type 2 diabetes (T2D) and CVD or at elevated risk for CVD.

Given this, healthcare professionals who manage patients with T2D patients could benefit from evidence-based education on:

- The new and emerging SGLT-2 inhibitor cardiovascular outcome trial (CVOT) data
- Recent guideline updates for the treatment of T2D and their recommendations regarding the importance of considering comorbidities, including atherosclerotic cardiovascular disease (ASCVD), heart failure (HF) and chronic kidney disease (CKD)⁵
- Clinical and real-world evidence of the SGLT-2 inhibitor class for use in prevention of hospitalization for HF and renal outcomes as well as future ongoing studies in the treatment of HF and CKD
- The interrelationships linking diabetes, HF, CVD, and CKD
- The potential cardio-renal mechanisms of the SGLT-2 inhibitor class in reducing the risk of CV, including HF, and renal events

References

1. US Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER). Guidance for industry diabetes mellitus – evaluating cardiovascular risk in new antidiabetic therapies to treat type 2 diabetes. <https://www.fda.gov/downloads/Drugs/.../Guidances/ucm071627.pdf>. Accessed Nov 7, 2018
2. Zinman B, Wanner C, Lachin JM, et al, for the EMPA-REG OUTCOME Investigators. Empagliflozin, cardiovascular outcomes, and mortality in type 2 diabetes. *New Engl J Med*. 2015;373:2117-2128.
3. Neal B, Perkovic V, Mahaffey KW, et al, for the CANVAS Program Collaborative Group. Canagliflozin and cardiovascular and renal events in type 2 diabetes. *New Engl J Med*. 2017;377:644-657.
4. Wiviott SD, Raz I, Bonaca MP, et al, for the DECLARE-TIMI 58 Investigators. Dapagliflozin and Cardiovascular Outcomes in Type 2 Diabetes [published online ahead print]. *New Engl J Med*. 2018. <https://www.nejm.org/doi/pdf/10.1056/NEJMoa1812389>.
5. Davies MJ, D'Alessio DA, Fradkin J et al. Management of Hyperglycemia in Type 2 Diabetes, 2018. A consensus report by the American Diabetes Association (ADA) and the European Association for the Study

Program Requirements:

The Program must be accredited and fully compliant with the criteria and/or standards of commercial support for ACCME, AAFP, AOA, ACPE, ANCC, AANP, or NCCPA. Furthermore, the program will be educational and non-promotional in nature and will be planned, designed and implemented in accordance with the U.S. Food and Drug Administration's Guidance on Industry-Supported Scientific and Educational Activities ("Policy Statement").

The Policy Statement and the ACCME Standards require, among other things, that (i) Institution conduct the Program independently and without control or influence by AstraZeneca over the Program's planning, content (including the selection of speakers or moderators), or execution; (ii) the Program be free of commercial bias for or against any product; (iii) Institution make meaningful disclosure of AstraZeneca support of the Program and any prior relationship between Institution and AstraZeneca, and the relationship, if any, between AstraZeneca and the speakers selected by Institution; and (iv) AstraZeneca not engage in, and Institution not permit any other sponsor to engage in, promotional activities in or near the Program room or advertise its products in any materials disseminated as part of the Program.

In addition, Institution is required by the Policy Statement and the ACCME Standards to ensure that any product discussions at the Program be accurate, objective, balanced and scientifically rigorous. This includes a balanced discussion of each product and of treatment alternatives, that limitations on data be disclosed, that unapproved uses be identified as such, and that for live presentations there be opportunities for questioning or debate.