Hispanic Representation

in Diabetes Cardiovascular Outcomes Trials

**APPENDIX**

**NIH Definition for Race and Ethnicity** (found at https://grants.nih.gov/grants/guide/notice-files/not-od-15-089.html)**:**

* **American Indian or Alaska Native.** A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment.
* **Asian.** A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.
* **Black or African American.** A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American."
* **Hispanic or Latino.** A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. The term, "Spanish origin," can be used in addition to "Hispanic or Latino."
* **Native Hawaiian or Other Pacific Islander.** A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.
* **White.** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

**Search Strategy:** Cardiovascular Outcome Trials (CVOTs) for New Type 2 Diabetes Medications

Part I: CVOT identification

*Inclusion Criteria*

1. Any CVOT listed on clinicaltrials.gov completed with a publication of primary findings between January 1, 2008 and October 31, 2018

*Exclusion Criteria*

1. Trials that did not use an oral or injectable antidiabetic drug as the primary intervention (*n* = 1). The DEVOTE trial studied subcutaneously injected degludec insulin.
2. Trials that contained primary data collected before 2008 (*n* = 1). The IRIS trial used retrospective data to ascertain cardiovascular safety for pioglitazone, a thiazolidinedione approved for use in 1999.
3. Trials that excluded subjects from the United States (*n* = 1). The ACE trial studied acarbose with research subjects entirely outside of the United States.

*Trials Included*

1. Albiglutide [HARMONY](2)
2. Alogliptin [EXAMINE](3)
3. Canagliflozin [CANVAS)](4)
4. Empagliflozin [EMPA-REG](5)
5. Exenatide [EXSCEL](6)
6. Liraglutide [LEADER](7)
7. Lixisenatide [ELIXA](8)
8. Saxagliptin [SAVOR-TIMI](9)
9. Semaglutide [SUSTAIN-6](10)
10. Sitagliptin [TECOS](11)

NOTE: FREEDOM-CVO was a qualifying CVOT completed within the specified time period; however, no results were published in a peer-reviewed academic journal.

Part II: Secondary studies from CVOTs relating to race/ethnicity

69 results

1 Book

1 not in English

24 not related to diabetes treatment

6 not related to CVOTs

37 studies mentioning CVOTs + race/ethnicity/Hispanic/minority/demographics

*PubMed Search*

Search ((((((((randomized controlled trial [pt] OR controlled clinical trial [pt] OR randomized [tiab] OR placebo [tiab] OR clinical trials as topic [mesh] OR randomly [tiab] OR trial\*[tiab] OR cardiovascular[text word] OR “cardiovascular diseases”[mesh] OR heart[mesh]) AND (“examine investigators”[text word] OR exscel[text word] OR “leader investigators”[text word] OR SAVOR-TIMI[text word] OR SUSTAIN-6[text word] OR tecos[text word] OR canvas[text word] OR elixa[text word] OR empa-reg[text word] OR harmony[text word] OR “examine investigators”[corporate author] OR exscel[corporate author] OR “leader investigators”[corporate author] OR SAVOR-TIMI[corporate author] OR SUSTAIN-6[corporate author] OR tecos[corporate author] OR canvas[corporate author] OR elixa[corporate author] OR empa-reg[corporate author] OR harmony[corporate author]))) AND ("2008/01/01"[Date - Publication] : "2018/10/31"[Date - Publication])) AND Humans[Mesh])) AND (((race) OR (ethnicity) OR (Hispanic) OR (demographic) OR (minority)))) AND Humans[Mesh]) Filters: Humans

1 study identifies Hispanic by gender for TECOS(1)

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