

CANVAS Program

The **CANVAS Program** is the **largest, broadest, and longest** completed cardiovascular (CV) outcomes trial of any SGLT2 inhibitor and showed that **INVOKANA®** (canagliflozin) significantly reduces the **combined risk of CV death, myocardial infarction, and stroke** in patients with type 2 diabetes mellitus (T2DM) at high risk for CV events or established CV disease.

So what does this mean?

LARGEST

Placebo-controlled, randomized trial of

10,142 patients with T2DM

4,330 CANVAS

(since Dec. 2009)

5,812 CANVAS-R

(since Jan. 2014)



The **CANVAS Program** was a **global study**, reaching patients around the world.

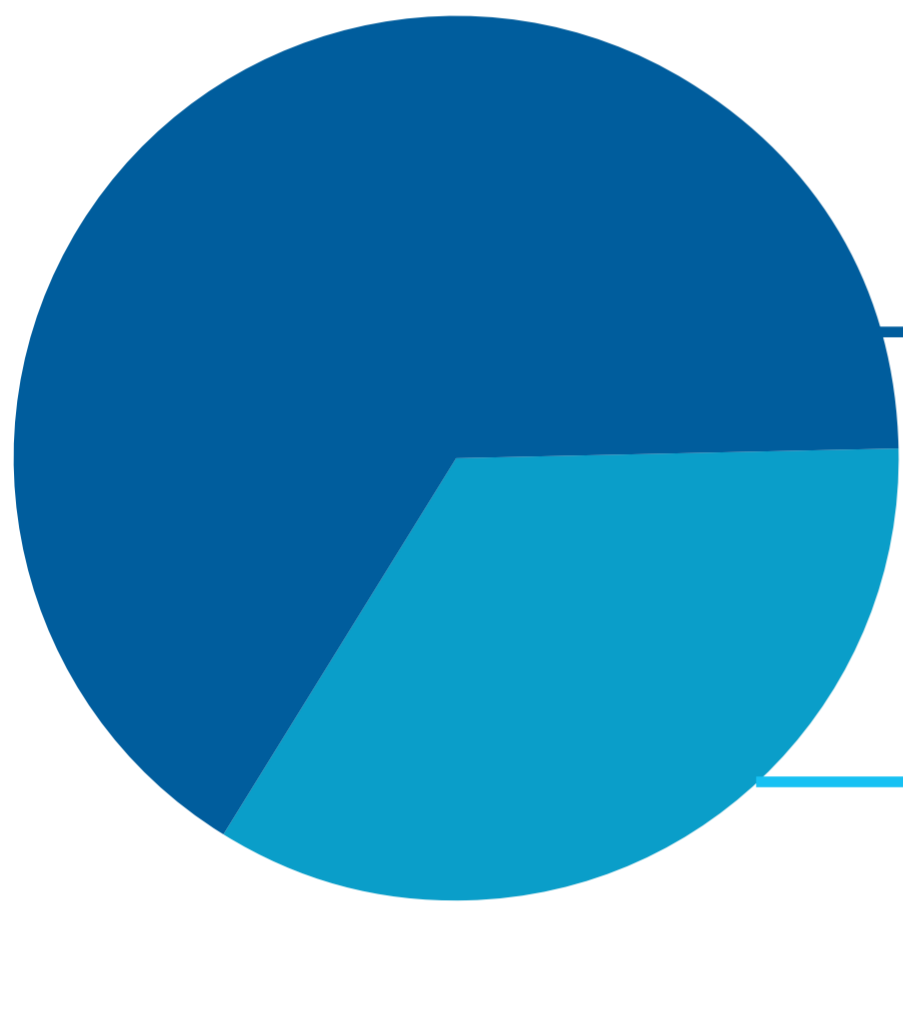
CANVAS reached patients in 25 countries:

United States, Argentina, Australia, Belgium, Canada, Colombia, Czech Republic, Estonia, France, Germany, Hungary, India, Israel, Luxembourg, Malaysia, Mexico, Netherlands, New Zealand, Norway, Poland, Russia, Spain, Sweden, Ukraine, United Kingdom

CANVAS-R reached patients in 24 countries:

United States, Argentina, Australia, Belgium, Brazil, Canada, China, Czech Republic, France, Germany, Hungary, Korea, Malaysia, Mexico, Netherlands, New Zealand, Poland, Puerto Rico, Russia, Spain, Sweden, Taiwan, Ukraine, United Kingdom

BROADEST



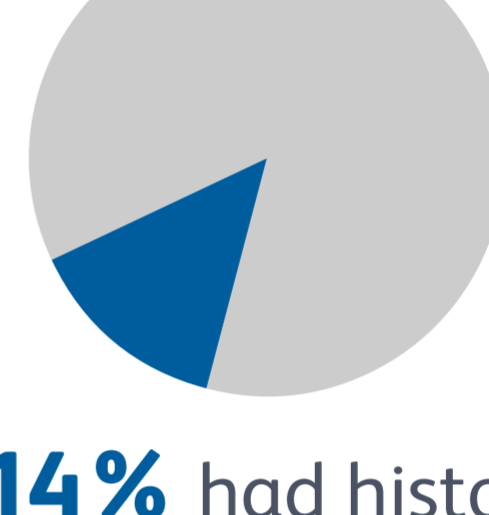
66 % of patients had a **history of CV disease**, secondary prevention

34 % of patients had at **≥2 risk factors for a CV event**, primary prevention

Additional baseline characteristics include:

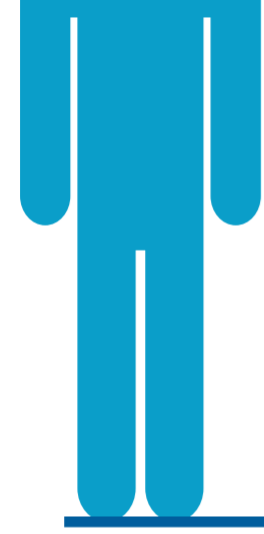


90% had history of **hypertension**



14% had history of **heart failure**

Adults & Seniors:



age ≥30 years with history of prior CV event

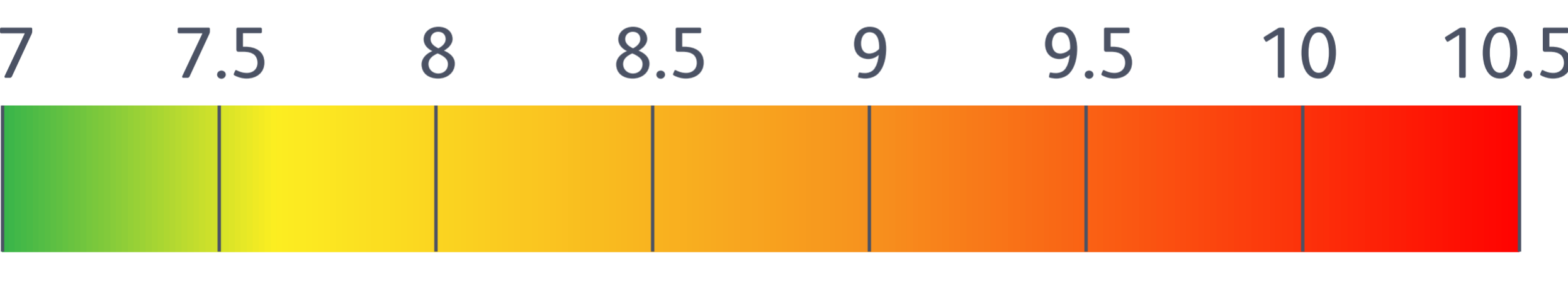
or



age ≥ 50 years with ≥2 risk factors for a CV event

Patients had high glycosylated hemoglobin levels

HbA1c ≥7.0% to ≤10.5%



LONGEST

CANVAS was initiated

CANVAS-R was initiated

Potential secondary presentations to follow including major cardiology and nephrology congresses

December 2009 November 2012 January 2014 June 2017 2017

FDA agreed to the CANVAS integrated analyses for a total of 10,000 patients across 2 studies to ensure the timely accrual of sufficient number of CV events

The results of the landmark CANVAS Program were presented in a special symposium at the American Diabetes Association's 77th Scientific Sessions

What is a CV outcomes trial (CVOT)?

A trial designed to determine that a therapy will not result in an unacceptable increase in CV risk, with the comparator as standard of care; however, most CVOTs are conducted to demonstrate a therapy's superiority over standard of care.

A closer look at diabetes and its most common comorbidities:

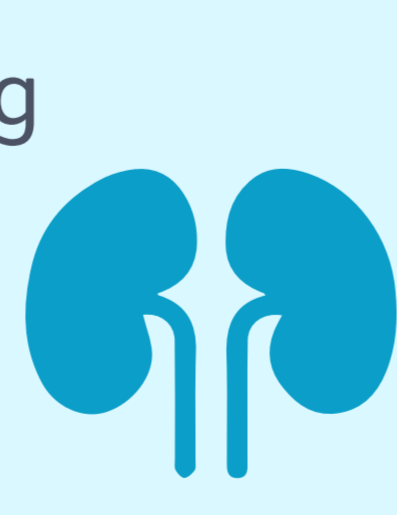


1 in 11 people or **415 million** people in the world have diabetes¹

Diabetes and its related complications result in an estimated **200,000+** deaths each year, making diabetes one of the major causes of mortality in the U.S.²

Diabetes is the leading cause of...

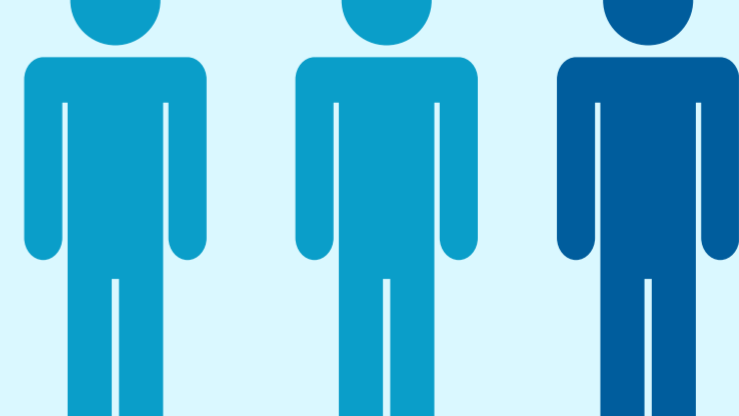
Kidney failure, accounting for **44%** percent of new cases³



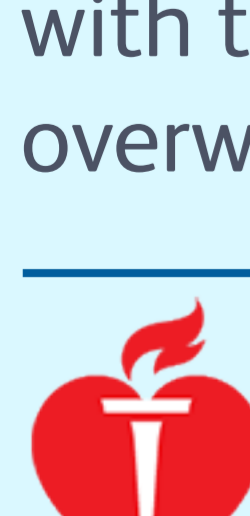
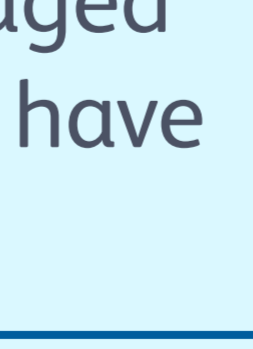
Kidney disease, affecting **25%** of adults with diabetes⁴

More than **35%** of people aged 20 years or older with diabetes have chronic kidney disease.³

2 in 3 people with diabetes have high blood pressure or take prescription medications to lower their blood pressure.⁶



More than **90%** of patients with type 2 diabetes are overweight or obese⁵



American Heart Association
life is why™

The AHA considers diabetes to be one of the **7 major controllable risk factors** for CV disease⁷

1 International Diabetes Federation (IDF). "Key Messages." Available at http://www.diabetesatlas.org/key-messages.html#keymessage_2. Last Accessed: June 2017.
 2 Obesity Society. "Your Weight and Diabetes." Available at: <http://www.obesity.org/content/weight-diabetes>. Last Accessed: May 2017.
 3 National Kidney Foundation. "Diabetes and Chronic Kidney Disease." Available at: <https://www.kidney.org/news/newsroom/factsheets/Diabetes-And-CKD>. Last Accessed: May 2017.
 4 National Institute of Diabetes and Digestive and Kidney Diseases. "Diabetic Kidney Disease." Available at <https://www.niddk.nih.gov/health-information/diabetes/overview/preventing-problems/diabetic-kidney-disease>. Last Accessed: May 2017.
 5 World Health Organization. "Obesity and Overweight." Available at: http://www.who.int/dietphysicalactivity/media/en/gsf_05_obesity.pdf. Last Accessed: May 2017.
 6 American Diabetes Association. "Are You at Risk: Lower Your Risk." Available at: <http://www.diabetes.org/are-you-at-risk/lower-your-risk/bloodpressure.html?referrer=https://www.google.com/>. Last Accessed: May 2017.
 7 American Heart Association. "Cardiovascular Disease & Diabetes." Available at: http://www.heart.org/HEARTORG/Conditions/More/Diabetes/WhyDiabetesMatters/Cardiovascular-Disease-Diabetes_UCM_313865_Article.jsp/#.WROB4PkrK01. Last Accessed: May 2017.