FREQUENTLY ASKED QUESTIONS

What is a clinical research trial?
Clinical research trials (also known as ‘clinical research studies’) are scientific studies that help us learn more about investigational medications. Each follows a strict plan (also known as a ‘protocol’) to help us answer specific questions about the safety and effectiveness of an investigational medication. These plans are reviewed by groups of people whose job it is to protect the safety of participants.

Do I have to pay for anything?
Any trial-related investigational medications, laboratory tests and assessments (over and above standard of care) will be provided at no cost to you. Also, we will often reimburse reasonable study-related expenses (such as travel).

Do I have to take part?
No. We are asking for people to volunteer – no one has to take part if they do not want to. Their decision will not affect the usual healthcare to which they are entitled.

Will I be shown how to self-inject the study drug?
Yes. Our study team will show participants or their family members how to safely inject the study drug so that they are confident to self-inject throughout the duration of the study.

HOW TO TAKE PART
If you would like to take part in this trial, please contact the study staff on the details below. We will be happy to answer any questions that you may have and discuss the study with you. We can also schedule an appointment so that you can learn about the study in detail and we can check your suitability.

ABOUT THE SURPASS-CVOT TRIAL
Helping you and your family decide if this clinical research trial is right for you.

CONTACT DETAILS

www.LillyTrialGuide.com
SPDN.ALL-EN-PCB-10DEC19
THANK YOU FOR YOUR INTEREST

We are looking for volunteers to join SURPASS-CVOT – a clinical research trial that will investigate how effective an investigational study drug is on major cardiovascular events when compared to an approved diabetes medication (dulaglutide) in people:

• with type 2 diabetes (T2DM)
• who are 40 years of age or older
• who have a history of cardiovascular disease (CVD)

This leaflet will give you a brief introduction to the study and explain what participation involves. If you have any questions or would like more information, please contact the study staff. We will be happy to help.

AN OVERVIEW OF THE STUDY

Each participant will move through a dose escalation schedule every 4 weeks during the first six months of the study until the target dose is reached, dependent on the participant’s response to the study drug. If the target dose is not achieved by the end of the Dose-Escalation period, participants will be given another opportunity to reach the target dose during the Maintenance Period.

Throughout the trial, participants will have their health monitored during approximately 7 clinic appointments in the Dose-Escalation Period, plus the option of 6 additional telephone appointments, and 16 clinic appointments in the Maintenance Period. They will include assessments such as:

- Blood samples
- Urine samples
- Blood pressure and pulse rate measurements
- Weight and waist measurements
- Questionnaires

It is very important that participants attend all clinic appointments, as the data we gather will help us decide the future of the investigational medication.

During the study treatment period, participants will be assigned to one of the following groups:

• Investigational study drug
• Dulaglutide

This will be done randomly (by chance) and neither the participant nor the study staff will know which group they have been placed in.

Participants will receive their study treatment via a subcutaneous (under the skin) injection once a week which will need to be self-administered. The study team will show participants how to self-inject once their treatment is assigned, and will answer any questions they may have.