[redacted]

(PRONUNCIATION KEY)
[redacted]
CGM = “cee-gee-em” (pronounce each letter)
IQVIA = “aye-kew-vee-uh” (pronounce I, Q, and via)

Introduction
(VOICEOVER)
This video contains a brief overview of the Dexcom G6 CGM Device and how it will be used in the [redacted] Trial. For more detailed information, please reference the IQVIA Connected Devices Investigators Manual.

About the CGM Device
(VOICEOVER)
The Dexcom G6 CGM Device is made up of 3 parts: a receiver, a sensor, and a transmitter. The transmitter is attached to the sensor, which is attached to the abdomen and sits above the skin. The sensor uses a needle to sip fluid from the interstitial space, which is the fluid-filled space between cells and blood vessels, to gather glucose information that the transmitter sends to the receiver. The receiver is a handheld device, separate from the transmitter, that records continuous glucose values when it's in range.

Device Enrollment
(VOICEOVER)
Once devices and supplies have been verified, internet connectivity has been confirmed, and training materials have been reviewed, site personnel should log in to the trial participant’s IQVIA-provisioned laptop at the screening visit. The ClinSpark study portal on the participant’s laptop can be accessed using the login credentials shared by IQVIA.

To enroll a new participant for data collection, site personnel must ensure they are logged in to the participant-provisioned laptop only using their ClinSpark credentials. Navigate from Data Collection to Subject Search and click “Enroll.” On this page, the participant’s demographic information may be entered and saved. After this, the participant will be ready for data collection across all visits. For more detailed instructions, see pages 26 and 27 of the IQVIA Connected Devices Investigators Manual.

Device Initialization
(VOICEOVER)
To initialize the CGM device for the participant, connect the device to the laptop and open the Device Initialization Form by selecting “Collect.” Once the form has opened, click on the “Invoke Device” button, and device details will appear in the form. Save and close the form. Once the initialization process is completed, the device can be disconnected. The participant will now be enabled to remotely upload data.

After the device has been disconnected, test the connectivity by reconnecting the device to the participant’s laptop. The screen should display a message indicating successful connection for the remote upload process.

Once the device has been initialized, the participant can begin the receiver setup, sensor application, and transmitter attachment process.

Receiver Setup
(VOICEOVER)

Sensor Application
(VOICEOVER)
The sensor is applied with a sterile, single-use, disposable unit. Trial participants will apply the sensor to their lower abdomen or upper buttocks. The applicator is to be placed horizontally on the skin and pressed down firmly. Once the adhesive is secure on the skin, the safety guard can be folded, broken, and thrown away. Next, the button on the applicator should be pushed to insert the sensor. Once complete, the applicator can be removed and disposed of following local guidelines for blood-contacting components.

Transmitter Attachment
(VOICEOVER)
Before the transmitter is attached, it is important to check that the transmitter serial number is correctly entered in the receiver device. The transmitter serial number can be found on the bottom of the transmitter.

Trial participants will begin by wiping the bottom of the transmitter device with an alcohol wipe and letting it dry, being careful not to touch any metal components or scratch the device. The transmitter tab can then be slid into the slot at the narrow end of the holder. Next, the wide end of the transmitter can be pressed until it clicks into the holder. The transmitter can be secured by rubbing fingers around the patch 3 times. Additional medical adhesive tape may be applied around the edges of the white patch if a participant has trouble keeping the sensor and transmitter in place. Medical adhesive tape, also called overpatches, is not provided in the CGM kit but may be requested from your CRA if needed.

Once the receiver is set up and the participant has inserted the sensor and attached the transmitter, the transmitter will automatically pair with the receiver. This may take up to 30 minutes. Once paired, the sensor will automatically start for a warm-up session, during which the receiver must be kept within 20 feet of the sensor. There is an out-of-range alert that will sound if the participant moves too far away. Sites must ensure that the receiver's out-of-range signal alert is always turned on in the device settings.

Once the warm-up session is complete, the CGM device application and setup are done.

Sensor Sessions
(VOICEOVER)
After the sensor warm-up session is finished, the Start Sensor option disappears from the menu on the receiver, and the Stop Sensor option will appear instead. This indicates that a session is ongoing.

When the 10-day sensor session is almost over, the participant will receive multiple notifications on the receiver at different timepoints before sensor expiration. These alerts can be muted; however, this does not extend the life of the sensor. Glucose data will not be collected after expiration. Once the session is over, the used sensor must be removed and replaced before starting a new session.

Transmitter Sessions
(VOICEOVER)
Each transmitter has a battery life of 3 months. Three weeks before the end of its battery life, the participant will start receiving an alert warning count down until the transmitter battery life has only 10 days left. If the transmitter battery has 10 days or less remaining, one cannot start a new sensor session. The participant must remove and replace the transmitter and sensor before its battery runs out.

Thank You
(VOICEOVER)
For additional information and more detailed instructions, please reference pages 11 to 30 in the IQVIA Connected Devices Investigators Manual. If additional troubleshooting is needed, please reach out to the IQVIA Help Desk.

Thank you for taking the time to learn about the use of the Dexcom G6 CGM Device in the [redacted] Trial.

(LOGOS)
[redacted] Trial

(FOOTER)

[redacted]