THIS IS AN IMPORTANT DOCUMENT – KEEP FOR FUTURE REFERENCE

PARTICIPANT INFORMATION AND CONSENT FORM

Sponsor / Study Title:	**Rousselot, BV / A randomized, triple-blind, placebo controlled, parallel clinical trial to investigate the efficacy and safety of chronic exposure to Nextida GC-B on glycemic control in adults with normoglycemia or prediabetes**
Protocol Number:	**25RSCFA01**
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You are invited to participate in a clinical research study. Participation in this study is strictly voluntary. To make an informed decision about participating in this study, it is important that you understand the potential risks and benefits of the study. This process, known as informed consent, ensures you have all the information needed to decide. This consent form outlines the study's purpose, procedures, potential benefits, risks, and how your medical information will be handled.

Take your time to thoroughly read all the details about the study, and do not hesitate to ask any questions you may have regarding the information given and about the study. Study staff will answer all your questions. You have access to this form and can review it at your leisure before making a decision.

You should not sign this form until you fully understand the information provided, feel comfortable with your decision to participate, and have had all your questions about the study answered to your satisfaction. You will be provided with a signed copy of this form and are expected to keep it for your record. Once consent has been obtained, the study assessments will proceed.

If you wish to contact the study staff, please use the phone number or email address provided at the top of this page.

Background And Purpose

Prediabetes is a condition where a person's blood sugar levels are higher than normal but not high enough to be diagnosed as Type 2 diabetes. People with prediabetes are at increased risk of developing diabetes in the future. Even people with normal blood sugar levels (called normoglycemia) may want to maintain healthy levels of blood sugar to avoid problems later in life.

Lifestyle changes like healthy eating and exercise can help manage blood sugar, but sometimes they're not enough. While medications exist, they can come with unwanted side effects. Recently, natural products like hydrolyzed collagen have gained attention for their possible benefits on blood sugar control.

The investigational product used in this study (Nextida GC-B), is a dietary supplement made from hydrolyzed collagen (regular collagen broken down into smaller, easily absorbable pieces). The purpose of this study is to explore Nextida GC-B's safety and efficacy in supporting blood sugar control in adults with either normal blood sugar or prediabetes.

Study Population

This study will include 60 males and females 18 years of age and older, with either normal blood sugar levels or prediabetes.

How Long Is The Study?

If eligible after the screening visit, your participation in this study will last approximately 105 days.

Important Things To Note

- If you voluntarily agree to participate in this study, you must be willing to:
  1. Fast for at least 12 hours prior to Visits 2, 3, 4 and 5 (No food or drinks except water)
  2. Complete questionnaires, records and diaries associated with the study and complete all study visits following specific study instructions
  3. Maintain current lifestyle habits (such as diet, physical activity, medications, supplements, sleep, and skin, nail and hair habits) throughout the study
  4. Eat the full standardized meals given in-clinic to continue in the study
  5. Eat the standardized meals both at home (prior to the visit) and in clinic during the visit before baseline visit, visit 3, visit 4 and visit 5
- To determine your eligibility to participate in this study, detailed information about your lifestyle, medications, and medical history will be collected. This information will help determine if you meet the necessary inclusion and/or exclusion criteria for this study.
- By signing this consent form, you are not guaranteed to be enrolled in the study. Your participation depends on meeting the study's specific eligibility criteria, which will be determined through a series of questions and assessments.
- This study uses competitive enrollment. This means that once (60) participants have enrolled and started the study, no additional participants will be accepted. Therefore, if you complete the screening phase and are found eligible, you may still be withdrawn from the study without your consent if the enrollment limit has already been reached. Since no official study enrollment would take place, you would not be eligible for study compensation.
- You should not participate in the study if you have metal implants in the spine, hip, or limbs—such as joint replacements, rods, screws, or plates.

Study Design

The study design describes the overall plan for how the study is conducted. This is a *randomized, triple-blind, placebo controlled, parallel* study.

- **Randomized** — During Visit 2, if you are eligible to participate, you will be randomly assigned by chance (like flipping a coin) to 1 of 2 study groups:
  - Nextida GC-B group
  - Placebo group

  Neither you nor the study staff will be able to choose which group you are in, ensuring that the random assignment is fair and unbiased.

  Any reference to the term "study product**"** refers to what you will take as part of your participation. This may be the active product (Nextida GC-B) or placebo.

- **Triple-blind** — Neither you, the study staff, nor the researchers analyzing the data will know which group you have been assigned to. However, if needed for your safety, the study staff can find out this information.
- **Placebo controlled** — A placebo is an inactive substance that looks like Nextida GC-B but has no active/medicinal ingredients. It is used in research to help determine whether the active product has real effects beyond what might happen by chance or expectation.
- **Parallel** — You stay in the same randomly assigned group for the entire study. For example, if you are assigned to the Nextida GC-B group or placebo group, you stay in that group throughout the entire study.

What Will Happen During The Study?

The following section provides an overview of the assessments, procedures, and schedule of study visits.

Assessments and Procedures

Blood Samples – Visit 1, 2, 3, 4, and 5

- The total blood volume collection will be approximately 547 mL (approximately 37 tablespoons), over the period from screening (Visit 1) to the end of the study (Visit 5) (which can range from 97 to 135 days). At any study visit, blood volume collected is not expected to exceed 150 mL (approximately 10 tablespoons). Additional blood samples may be collected during the study, if necessary, such as in cases of abnormal test results or processing errors, to conduct or repeat laboratory tests.
- At Visit 2, 3, 4 and 5, an intravenous catheter will be placed to help facilitate multiple blood draws. The catheter will be flushed with saline to keep it clear and working properly throughout the visits. Conventional phlebotomy (blood draw from a vein using a needle) will also be used in this study, such as at Visit 1, and may also be used during Visits 2, 3, 4 and 5 if the catheter is not working properly.

Urine Samples – Visit 1, 2 and 5

- If you are of child-bearing potential, you will be required to provide a urine sample for a urine pregnancy test. You will be provided with a collection container and instructed on how to provide the sample.

Standardized meals (Carbohydrate-Rich Test Meal) – Visit 2, 3, 4 and 5

The evening before Visit 2, 3, 4 and 5 (at home):

- Before Visit 2, you will eat a low-fiber dinner around 6:00 p.m. This meal will be white pasta with any sauce you like. You will eat the same meal at about the same time before Visits 3, 4 and 5.
- If you feel hungry later in the evening, between 9:00 and 10:00 p.m., you can eat 1 to 4 slices of white bread. You can add any spread or topping you like and choose any drink.
- You will record the number of slices of bread consumed before Visit 2 in the study diary. You will be required to consume the identical number of slices of bread with the same spread and drink before Visit 3, 4 and 5.
- After this meal you will fast for at least 12 hours and not eat or drink anything, except water.

During Visit 2, 3, 4 and 5 (in-clinic):

- You will be given a standardized meal which will include a white toast, butter, and strawberry jam.
- The meal is to be consumed steadily and finished within a 12–14-minute period.

- Water (150 mL) and decaffeinated coffee or tea (150 mL) will be offered with the meal. You can select your preferred beverage(s) at Visit 2 and you will consume the same beverage(s) at each Visit thereafter.
- You will be required to consume the entire meal at the designated visits to continue in the study.

Continuous Glucose Monitoring (CGM) – Days -7 to 7 and Days 83 to 96
The device will monitor your blood sugar levels on days -7 to 7 (7 days before and 7 days after your Visit 3) and 83 to 96 (7 days before and 7 days after your Visit 5) You will receive instructions on how to use the device.

Dual-Energy X-Ray Absorption (DEXA) Scan – Visit 2 and 5
- This test uses X-rays to assess body composition. The amount of radiation used in the DEXA scan is extremely small. The estimated amount of exposure from participation in this study will be comparable to that of a single east to west coast flight within the USA and similar to the normal background radiation received over the course of a single day.

Corneometer®, Cutometer®, and VISIA® – Visit 2 and 5
These tests will be done to check the condition of your skin:
- **Corneometer®**: This test measures how hydrated your skin is by checking the moisture levels on your cheek.
- **Cutometer®**: This test measures how firm and elastic your skin (cheek and underarm area) is by gently pulling it and seeing how well it returns to its normal shape.
- **VISIA®**: This imaging system takes high-quality pictures of your face to look at wrinkles, skin texture, spots, pores, sun damage, and other skin features.

RAND Short-Form Health Survey (SF-36) – Visit 2, 4 and 5
This questionnaire is used to capture your self-reported perception of your health-related quality of life.

Product Perception Questionnaire (PPQ) – Visit 5
This questionnaire will be used to evaluate your perception of the study product.

Hair, Nail and Skin Self-Assessment Questionnaires – Visit 2, 4 and 5
You will be asked to rate changes in some specific hair, nail, and skin health parameters.

Hunger and satiety Visual Analogue Scale (VAS) – Visit 2, 3, 4 and 5
This scale will ask you to rate your hunger and how satisfied you feel before and after the **Carbohydrate-Rich Test Meal** in clinic. This will be administered prior to meal consumption as well as after test meal consumption.

Food Records
- You will report your food and drink intake using your food records:
  - You will complete daily food records for 7 days before, the day of, and 7 days after Visits 3 and 5.
  - You will complete 3 days of food records during the week prior to Visit 4. These food records will include two weekdays and one weekend day.

Study Diary
- You will complete an online daily study diary throughout the study. Questions about study product use, how you have been wearing the CGM (when applicable), lifestyle habits and any changes in medications and/or health will be included.

Schedule of Study Visits

You are required to fast for at least 12 hours prior to Visits 2, 3, 4 and 5.

Visit 1 – Screening (Day -45 to Day -11) *Some portions of this visit may occur virtually*
After informed consent is obtained, visit assessments will include: • Review of your medical history, medications, and current health status • Seated blood pressure (BP) and heart rate (HR) will be measured • Weight and height measurements (including calculation of Body Mass Index, also referred to as BMI) • Urine pregnancy test (If you are of childbearing potential) • You will be asked to confirm your willingness to eat the full standardized meal at Visit 2, Visit 3, Visit 4, and Visit 5. • Blood samples will be collected • Review of any changes in your health • Your eligibility will be reviewed *If you are potentially eligible for this study, you will be scheduled for a Baseline and Day 1 visit.*
Visit 2 (Baseline, Day -10, Day -9 or Day -8)

You will return to the clinic fasting for 12 hours for baseline blood collection and your eligibility for the study will be reviewed.
• Review of your medical history, medications, and current health status
• Seated blood pressure (BP) and heart rate (HR) will be measured
• Weight and height measurements (including calculation of Body Mass Index, also referred to as BMI)
• Urine pregnancy test (If you are of childbearing potential)
• Corneometer®, Cutometer® and VISIA® assessments, and DEXA scan will be done.
• SF-36, Hunger and satiety VAS, and Hair, Nail and Skin Self-Assessments Questionnaires will be administered
• A CGM, 7 daily food records, and study diary will be provided to you, along with instructions on how to use and complete them
• If you continue to be eligible for the study, you will be randomized (assigned to a study group) and enrolled into the study
• Blood samples will be collected before the standardized meal
• You will eat the standardized meal
• 15 min, 30 min, 60 min, 120 min and 180 min after eating the standardized meal:
  ○ Blood samples will be collected
  ○ Hunger and satiety VAS will be administered
• You will receive instructions to wear the CGM for seven days prior to your Visit 3.
• You will be asked to complete 7-day food records and a daily diary. Your diaries will capture any changes in your health or medications, and if you have been wearing the CGM as instructed.
 	
Your next visit will be scheduled for Visit 3 (Day 1)

Visit 3 (Day 1)

You will return to the clinic fasting for 12 hours and with your completed daily study diary, 7-day food record and CGM device.
• Review of your study diaries, 7-day food records, and any changes in your health or medications
• Study staff will confirm if you have been using the CGM device as directed
• Hunger and satiety VAS questionnaire will be administered and blood samples will be collected before you take the study product. There will be two blood draws before the standardized meal: one before taking the study product and one before eating the standardized meal.
• You will take the study product (Nextida GC-B or placebo) 30 minutes before eating the standardized meal
• Blood samples will be collected and Hunger and satiety VAS will be administered before you eat the standardized meal
• You will eat the standardized meal
• 15 min, 30 min, 60 min, 120 min and 180 min after eating the standardized meal:
  ○ Blood samples will be collected
  ○ Hunger and satiety VAS will be administered
• You will receive the study product to take home and instructions on use.
• You will receive your study diary, 7-day food records (to complete for 7 consecutive days starting the day of this visit), and 3-day food records (to complete the week before your next visit) with instructions on completion
• Instructions to continue wearing CGM will be given to you
• Your next visit will be scheduled for Day 30 (+3 days)

Visit 4 (Day 30 + 3 days)
You will return to the clinic with unused study product, completed daily study diaries, completed 7 day and 3 day food records and the CGM device. • Review of your study diaries, completed 7 day and 3 day food records, and any changes in your health or medications • Study staff will confirm if you have been using the CGM device as directed • You will return the unused study product in its original packaging so we can confirm that you have been taking it as directed • Seated BP, HR and weight measurements will be taken (BMI will be calculated). • SF-36, Hunger and satiety VAS, and Skin, Hair and Nail Self-Assessments will be administered • Blood samples will be collected before you take the study product • You will take the study product (Nextida GC-B or placebo) 30 minutes before eating the standardized meal • Blood samples will be collected and Hunger and satiety VAS will be administered before you eat the standardized meal • You will eat the standardized meal

- 15 min, 30 min, 60 min, 120 min and 180 min after eating the standardized meal:
  - Blood samples will be collected
  - Hunger and satiety VAS will be administered
- You will receive new study product to take home.
- You will receive your study diary and 7-day food record with instructions on completion.
- Instructions to wear CGM before visit 5 will be given to you.
- Your next Visit will be scheduled for Day 90 +3 days.

Between Visit 4 and Visit 5, you will receive email reminders on the following days:

- **Day 60:** A reminder to complete your study diaries daily, along with information about upcoming study assessments.
- **Day 82:** A reminder about upcoming study procedures, including instructions to:
  - Begin wearing the CGM device.
  - Start recording your food and beverage intake in your 7-day food record starting on Day 83.
  - Prepare for your scheduled Visit 5.

Visit 5 (End of Study, Day 90 + 3 days)

You will return to the clinic with the completed daily study diary, 7-day food record and CGM device.

- Review of your study diaries, 7-day food records, and any changes in your heath or medications.
- Study staff will confirm if you have been using the CGM device as directed.
- You will return the unused study product in its original packaging so we can confirm that you have been taking it as directed.
- Urine pregnancy test (If you are of childbearing potential).
- Seated BP, HR and weights measurement will be taken (BMI will be calculated).
- Corneometer®, Cutometer® and VISIA® assessments, and DEXA scan will be done.
- SF-36, Hunger and satiety VAS, and Hair, Nail and Skin Self-Assessments Questionnaires will be administered.
- Blood samples will be collected before you take the study product
- You will take the study product (Nextida GC-B or placebo) 30 minutes before eating the standardized meal.
- Blood samples will be collected and Hungry and satiety VAS will be administered before you eat the standardized meal
- You will eat the standardized meal.
- 15 min, 30 min, 60 min, 120 min and 180 min after eating the standardized meal:
  - Blood samples will be collected.
  - Hunger and satiety VAS will be administered.
- Product Perception Questionnaire (PPQ) will be done
- You will receive your study diary and 7-day food record with instructions on completion.
- Instructions to continue wearing the CGM will be given to you for 7 days during the follow-up period. Study staff will give you a pre-paid shipping label to send back the CGM device once the 7-day follow-up period is complete.

Follow-up Period (Day 97)
During the seven-day follow up period, you will: • Continue wearing the CGM. • Complete the 7-day food record and study diaries. Study staff will review your completed diaries, food records, and any changes in your health or medications. Once the follow-up period is complete, you will ship back the CGM device using the pre-paid shipping label, unless you are able to return it in person

Medications, Supplements, And Food/Drinks

If you are taking any prescribed medications, you must agree to maintain your dosing regimen during the study, unless otherwise recommended by your general/nurse practitioner. If they recommend any medication or dose changes, please notify the study staff immediately. You should not discontinue your regular medications unless explicitly instructed by your general/nurse practitioner. Stopping regular medications without medical advice to join this study may worsen your health. If you stop your regular medications, inform the study staff immediately.

- If you are taking any prescribed medications and/or treatments which may affect the study outcomes, you may only be assessed for eligibility if you have been taken off these therapies by your general/nurse practitioner. The study doctor will recommend an appropriate washout period prior to enrollment in the study.
- If you use any over-the-counter medications, supplements and/or foods and drinks which may affect the study outcomes, you must be willing to stop taking them and agree not to consume these items during the study. The study doctor will recommend an appropriate washout period prior to enrollment in the study.

Washout Period: This is a period of time recommended by the study doctor to allow restricted substances (such as medications, supplements, foods or drinks) to clear from the body before the study begins. If you have recently taken or stopped any restricted substances or participated in activities that conflict with the study, a washout period may be required before enrollment.

Birth Control, Pregnancy, And Breastfeeding

The effect of the study products on pregnancy and breast milk is not known. You must not participate if you are pregnant, breastfeeding or planning to become pregnant during the study. Individuals able to become pregnant (not post-menopausal, have had a menstrual period in the past 1 year, or have not had any of the following surgeries: hysterectomy, bilateral oophorectomy, complete endometrial ablation, or bilateral tubal ligation) must have a negative screening and baseline/enrollment urine pregnancy test and agree to use a medically approved method of birth control for the duration of the study. If you are using hormonal birth control, you must have been using it for at least 3 months prior to screening.

Some examples of approved methods of birth control include:

- Hormonal contraceptives including oral contraceptives, hormone birth control patch, vaginal contraceptive ring, injectable contraceptives, or hormone implant
- Double-barrier method
- Intrauterine devices (IUD)

- Non-heterosexual lifestyle or agree to use contraception if planning on changing to heterosexual partner(s)
- Vasectomy of partner at least 6 months prior to screening
- Abstinence and agree to use contraception if planning on becoming sexually active during the study

If you become pregnant during the study, you must stop taking the study product immediately and contact the study staff. You will be withdrawn from the study and the study doctor will follow up with you until the child's birth, collect information about your pregnancy, its outcome, and the health of your child.

Since the study products are investigational, there may be other risks that are unknown. Additionally, there may be unknown risks to a pregnancy, embryo, or fetus if you become pregnant.

Study Product Information

The study products will be in liquid form.

Nextida GC-B

Medicinal Ingredient	Quantity
Collagen hydrolysate	5 g

g = grams

Non-medicinal ingredients: water (solvent), Erythritol, Citric Acid, DL-Malic Acide, Natural Apples Flavor, Steviol Glycosides

Placebo Ingredients:

Non-medicinal ingredients: water (solvent), Erythritol, Citric Acid, DL-Malic Acid, Natural Apples Flavor, Steviol Glycosides

Directions:

- Starting Day 2 (Day after visit 3) you will be instructed to take one liquid shot of 5 g of **Nextida GC-B** or placebo approximately 30 minutes before your two main meals (breakfast and lunch or breakfast and dinner) daily until Day 89.
- On Day 1, Day 30 and Day 90 you will consume the first dose of study product in clinic under supervision, and the second dose will be consumed at home prior to your lunch or dinner.
- You will need to take the study product 30 minutes before the same mealtimes you chose (either breakfast and lunch, or breakfast and dinner) every day during the study.
- Store the study product at room temperature, do not expose it to direct sunlight, heat or moisture.
- If you miss a dose, take the missed dose prior to your next meal or snack.If you miss the dinner dose do not take it on the next day.
- Do not take more than two liquid shots (10 g) daily.
- Save all unused and open study product packaging and return them to the clinic at each study visit.

Alternative Treatments

This study is not designed to diagnose, treat, or prevent any disease. Your alternative is to not take part in the study.

Additional Safeguards

If you need regular medical care for current medical conditions, you should continue with this medical care unless otherwise instructed by your regular physician or other healthcare professional. For your safety, you must discuss your current medical care with the study staff, as well as changes in medical conditions during the study. In addition, all new medications including supplements and natural health products (NHPs) that are taken during the study must be reported to the study staff.

Risks To You

It is possible that you could have problems or side effects from the study product that nobody knows about yet. There may be unknown risks with taking the study product. Potential side-effects of taking the study product may include:

- Gastrointestinal discomfort, such as nausea

Some risks associated with blood collection may include pain, bruising, and infection at the site. Alcohol swabs and proper blood collection procedures will be followed to minimize the risk of infection. Fainting during a blood draw can occur, though it is not common. Please advise the study staff if you normally faint with blood draws.

Fasting for 12 hours may cause temporary symptoms such as hunger, light-headedness, or fatigue.

Could I Have An Allergic Reaction?

It is possible for people to have allergic reactions to the study products. If you have a serious allergic reaction, you could die. Read the study products ingredients carefully to make sure you are not allergic to any of them. Some effects of an allergic reaction that could be a sign of a life-threatening (anaphylaxis) include:

- Rash
- Difficulty of Breathing
- Wheezing
- Sudden drop in blood pressure (making you feel dizzy or lightheaded)
- Swelling around the mouth, throat, or eyes
- Fast pulse
- Sweating

If you experience any of the above-listed effects or any other side effects during the study, you should get medical help or go to the emergency room immediately and then contact the study staff. Refer to section "Whom To Contact About This Study" for instructions on what to do in case of an emergency.

Contact the study staff if you have questions about the signs or symptoms of any side-effects you read about in this consent form. Inform the study staff right away if you experience any side-effect, problems with your health or the way you feel during the study, and whether you think these problems are related to the study products or not.

Potential Risks From E-Consent

You may receive a link via email/text message to download a PDF copy of this signed consent form. There may be risks of loss of privacy and confidentiality if the PDF copy of this consent form is viewed and/or stored on a personal electronic device (PED), especially if that PED is shared with other users or is lost, hacked, or subject to a search warrant or subpoena. Also, the PDF copy of the consent may not be able to be permanently removed from a PED.

Risks Related to Using the CGM:

The CGM is a small sensor worn on the skin to estimate your glucose levels. Possible risks include:

- **Incorrect readings:** The sensor may sometimes show glucose levels that are higher or lower than your actual blood sugar. This is more likely when glucose levels are changing quickly. Acting on an incorrect reading could lead you to take too much sugar.
- **Delay compared to finger sticks:** The CGM measures glucose in body fluid under the skin, not directly from blood, so readings may lag behind finger-stick tests.
- **Skin reactions:** You may have redness, itching, rash, discomfort, or minor bleeding where the sensor is worn. In rare cases, skin irritation may require removing the sensor.
- **Device or signal problems:** The sensor may stop working early, lose signal, or fall off, which could temporarily limit glucose information.
- **Need for confirmation:** If the CGM reading does not match how you feel, you may need to check your blood sugar with a finger-stick meter before making treatment decisions.

You should not rely on the CGM alone if you feel symptoms of low or high blood sugar that do not match the device reading.

Withdrawal From The Study

- Your participation in this research is strictly voluntary. You have the right to choose not to be in the study or leave at any time, for any reason, without affecting your relationship with the study doctor or study staff and without penalty or loss of benefits to which you are otherwise entitled.
- If you discontinue the study for whatever reason, you are expected to return all study materials, such as study product, to the clinic.
- You may be asked to undergo some final visit procedures. These may include returning to the clinic to provide a final blood sample to test your markers of general health, any end-of-study assessments or questionnaires.
- If the study doctor or study staff finds out any related information that may greatly affect your well-being (for example, information related to your health), they will share it with you immediately.

The Sponsor has the right to stop the study at any time.

The study doctor may also stop your participation in the study at any time without your consent, but you will be informed about the reason. Reasons for this may include, but are not limited to:

- Missing scheduled study visits
- Not taking study product as directed
- Not completing required assessments or procedures
- Development of medical conditions or serious side-effects that may pose a health risk to you or the study outcomes
- The need for restricted medication(s) during the study
- If you become pregnant during the study

New Findings

Any significant findings that become available during the study which may influence your continued participation in the study will be disclosed to you as soon as possible.

Benefits

There may be no immediate benefit to you. Your participation in this study supports the research that is required to ensure the science behind the study products.

Costs To You

- All the tests, study products, examinations, and medical care required as part of this study are provided at no cost to you, the public health plan (OHIP), or your private medical insurance. All costs will be paid for by the Sponsor of this study.
- You, OHIP, or your personal medical insurance (if any) should continue to pay for expenses for your current medical care and/or prescriptions. These expenses will not be paid as part of your participation in this study.
- The Sponsor of this study is paying your study doctor for the time, effort, and expenses to conduct this study.

Compensation For Participation

For your time and participation in the study, you will be compensated a total of $1,000.00 if you complete the entire study and all associated requirements.

You will receive your compensation after completion of the study (provided that you have returned the CGM device at no cost to you and in working condition) on a ClinCard, which can be used like a prepaid Mastercard. It can be used anywhere that accepts Mastercard, or the funds can be withdrawn from an ATM (ATM fees apply). Compensation will be processed and received approximately 20 business days from the date you complete the study. Processing times may apply before funds become available on your ClinCard.

If you are enrolled (completed visit 2 and were randomly assigned to one of the study groups), the compensation breakdown is as follows:

- Screening Visit 1: $0
- Visit 2 (Randomization): $175
- Visit 3: $200
- Visit 4: $250
- Visit 5: $275
- Follow up: $100

Once enrolled, for any case in which you or the study doctor determine you cannot complete all the study visits and assessments, you will receive compensation for the visits you have completed. An early termination visit will be requested where you will bring back all study-related materials and be requested to complete some blood work and visit procedures if you consent to doing so. If you complete the early termination visit, you will be compensated $50.

Important to note: You are responsible for shipping the CGM device back to KGK Science (at no cost to you) in its original working condition, upon finalization of your follow-up period. Failure to return the device as instructed may result in loss of any applicable compensation.

Compensation And Treatment For Injury

- In case of an injury or illness suffered while, and solely as a result of participating in this study, you will receive appropriate medical care. The Sponsor will cover necessary medical costs not covered by the provincial health plan or your private medical insurance (if any). By signing this form, you are not giving up your legal rights, nor releasing the study doctor or Sponsors from their legal and professional obligations.
- Be aware that the provincial health plan or your health care payer/insurer might not cover the costs of study-related injuries or illnesses.

Confidentiality Of Records

- Staff at KGK Science (the contract research organization managing this study) will keep all your medical information confidential to the extent permitted by law.
- All research data (health information, past medical history, and test results from this study) will be kept in a secured location. Forms on which your information is entered will not contain your name (except for the study intake form and/or external requisitions if applicable)
- Any of your personal information that is stored electronically will be password protected, accessible only to authorized personnel and coded wherever possible. Electronic data may be stored on secure servers which are physically located in Canada and/or the United States.
- You will not be identified in any publication that might result from the study. Unless required by law, only the following may have access to confidential study data (not your personal information) at the study site:
    - The study doctor and study staff
    - The Sponsor (including its monitors and auditors)
    - Members of the Research Ethics Board - Univo REB (an independent ethics committee that reviewed the ethical aspects of this study to help ensure that the rights and welfare of participants are protected and that the study is carried out in an ethical manner)
    - Government regulatory authorities including Health Canada and other foreign regulatory agencies.
- While the Sponsor will not have access to your personal identifying information, the study doctor, study staff, monitors, auditors, REB, and regulatory authorities may review study records, which could include your personal identifying information (such as the signed consent form) for compliance and verification purposes.
- All study data will be archived for a minimum of 15 years from the date of completion of the study in accordance with Health Canada regulatory requirements.
- Information from this study will be submitted to the Sponsor. Information sent from the study site will not contain your name.
- You have the right to check your study records and request changes if the information is incorrect.
- While every effort will be made to protect the privacy of your information, absolute confidentiality cannot be guaranteed. This does not limit the duty of the researchers and others to protect your privacy.

- As part of this research, you may be required to use one or more of the following: a phone or web app/site, an electronic study diary (eDiary), or a device that tracks information about you. While using these, information about you may be collected and shared with the researchers or people outside of the study. This data might include personal health information, location, call logs, text message history, web browsing history, or social media use. A complete description of the data collection and sharing for an app, eDiary, or device can commonly be found in the Terms of Use, End User License Agreement, or Privacy Policy associated with the device. If you would like to read these documents, request a copy or instructions about how to access this information from the study doctor.
- While the Terms of Use, End User License Agreement, or Privacy Policy may include statements limiting your rights if you are harmed as a result of your use of the app, eDiary, or device in this study, you do not release the investigator, sponsor, institution, or agents for responsibilities from mistakes. You also do not waive any of your rights as a research participant.

By signing and dating the consent form, you give your consent to collect, use and disclose your health information as described above.

A description of this clinical trial will be available on https://www.ClinicalTrials.gov as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Future Use Of Data And Specimens

- Your personal information and/or biospecimens collected during this study may be stored and used for future research. If so, any personal identifiers will be removed so that the information or samples cannot be linked back to you. As a result, we will no longer be able to identify them or identify you.
- Study doctors, including study doctors from collaborating institutions, can request this data and samples for new research. Samples and data may also be shared with outside non-profit academic study doctors as well as with for-profit study doctors or commercial entities, with whom we collaborate.
- You will not be asked to provide additional informed consent for the use of your de-identified information or samples in future research.
- Future research studies may include genetic research. Your genes are unique to you. At this time, you cannot be identified through this research. There is a risk that you might be reidentified in the future as genetic research progresses.

Future Contact

By participating in this study, you agree that the study staff may contact you in the future should additional information be needed. This contact would only occur if more data specifically related to your participation in this study were required after you have completed the study, or the study has concluded/expired. Any additional information gathered will be handled with the same confidentiality and privacy protections outlined in this consent form. You may choose not to provide additional information if contacted in the future, without any penalty or effect on the care or benefits you receive.

Whom To Contact About This Study

You can contact the study staff via email or by telephone listed on the first page of this consent form during the study if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The study doctor's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study and inform the KGK Science study staff.

A research ethics board (REB) is an independent committee that helps to protect the rights and welfare of research participants. If you have any questions about your rights and welfare as a research participant, or have concerns or complaints regarding this research study, please contact Univo REB at (919) 910-7743 or via email at info@univo-group.com.

Voluntary Consent To Participate

By signing and dating this document I agree that I have been provided enough time to read and consider whether to participate. I have reviewed and understand all pages of the consent form and information it contains regarding the study in a language I understand. I have been given the opportunity to ask all my questions regarding the study with answers to my satisfaction. I understand that I may consult with the study staff, should anything become unclear or if I have further questions.

I volunteer to be in this study at my own free will and without being pressured by the study doctor or the study staff knowing I have the opportunity to leave at any time without giving a reason and without affecting my health care. I understand that if I choose to withdraw from the study, I must notify the study staff. The risks involved with participating in this study are clear to me. I agree to follow the study instructions provided to me by the study staff and understand I may not participate in another study while I am enrolled in this study.

It is clear to me that my data derived from this study will be kept anonymous and may be reviewed by the Sponsor, their agents, the Research Ethics Board, Health Canada and other foreign regulatory agencies. I understand that all my personal information will be treated as strictly confidential, except where disclosure is required by law, and will not be made publicly available; however, absolute confidentiality cannot be guaranteed.

By signing and dating this document, I do not waive any of my rights under the law or release the study doctor or Sponsor from their legal and professional obligations.

I know that the study product is for my use only. I will not share it with anyone, and I will store it in a safe place away from children, pets, or others for whom it is not intended. I understand that I am required to return the CGM device at the end of my participation in the study, and that I will be compensated once the device has been returned. Failure to return the device may result in loss of any applicable compensation.

I understand that I am expected to keep a copy of this signed and dated consent form for my record.

IN THE EVENT THAT ELECTRONIC CONSENT IS NOT AVAILABLE:

By signing this informed consent document, you acknowledge that you have read and fully understand all pages of the information presented in it, had enough time to consider this information, had an opportunity to ask questions, and voluntarily agree to be in this study.

_____
Printed Name of Participant

_____ _____ _____AM/PM
Signature of Participant Date (MMM,DD,YYYY) Time (HH:MM)

THIS IS AN IMPORTANT DOCUMENT – KEEP FOR FUTURE REFERENCE

I attest that the participant named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

_____
Printed Name of Person Explaining Consent

_____ _____ _____AM/PM
Signature of Person Explaining Consent Date (MMM,DD,YYYY) Time (HH:MM)

FOR ELECTRONIC CONSENT:

For electronic consent, your name, digital signature, date and time of consenting will be added below by the consenting software. By adding your electronic signature, you consent to the material provided as if you were physically signing a hard copy of this document. By signing this informed consent document, you acknowledge that you have read and fully understand all pages of the information presented in it.

Participant

I voluntarily agree to
participate in this study
↓