PARTICIPANT INFORMATION AND INFORMED CONSENT FORM

Sponsor/Study Title:	**Crestone, Inc. / A Phase 1, Single-Center, Open-Label, Randomized, Single-Dose, 2 Period, Crossover Study to Evaluate the Potential Impact of High-Fat Meal on the Pharmacokinetics of CRS3123 200 mg Capsule in Healthy Adult Participants**
Protocol number:	**242021 (Sponsor Study Number: 24-3123-FE, DMID Study Number 25-0002)**
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A research study looking into the safety and blood levels of CRS3123 capsules in healthy participants.

Before a new drug can be prescribed by doctors, it must be tested. This is to see if it is safe and if it works as we expect it to. This is called a clinical research study. You are invited to take part in a clinical research study. In this document we will call it a "study".

Before you decide if you want to take part, it is important for you to understand why the study is being done and what it will involve. Take time to read the following information carefully and discuss it with friends and relatives if you wish. Ask the study doctor or study staff if anything is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

Before you decide if you want to take part in the study, it is important that you understand:

- Why the study is being done,
- The possible risks and benefits,
- What you will have to do if you take part.

Please read the rest of this Participant Information and Informed Consent Form. It gives you more information about the study.

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Important things that you need to know

This is a summary of the important things that you need to know about the study.

- The study looks at the safety and blood levels of a new study drug called CRS3123 in healthy participants.
- Many healthy individuals are motivated by the opportunity to support scientific progress and help develop medications that could prevent or treat infections in others.
- Even healthy individuals may worry about how their body will react to a new, investigational medication such as diarrhea, abdominal pain, headache, and nausea.
- CRS3123 is an experimental drug and has not been approved by the US Food and Drug Administration (FDA).
- CRS3123 is being developed as a new drug for the treatment of *Clostridioides difficile* (bacterial) infection.
- The study consists of 2 treatment periods during which you will receive CRS3123 under fasting (Study Treatment A) or fed (Study Treatment B) conditions. You will participate in both periods, meaning you will take the study drug twice, once soon after a high-fat, high-calorie meal and once without a meal
- You will get a single oral capsule of 200 mg of CRS3123 in each period at the clinical site. The administration will be done by mouth with a capsule you will have to swallow with approximately 240 mL of water.
- Like all drugs, this study drug may have side effects.
- The study will last for about 6 weeks including screening through the follow-up phone call. If you are selected and choose to volunteer, you will check-in to the clinic and remain there for both periods for a total of 9 days, including 8 nights.
- You will have 2 scheduled visits: the screening visit, and the clinic visit with the study staff or the study doctor.
- At the visits, you will have clinical checks done and several blood samples taken.
- Your urine will be collected several times during the study.
- You will be asked about your health, medical history, and habits.
- You cannot take part in this study if you participate in another research study.
- Women: Women who are not able to become pregnant or women of childbearing potential who are non-pregnant and non-lactating and are willing to comply with the birth control requirements can take part in the study.
- Men: Only men who do not plan to father a child and are willing to comply with birth control requirements during the study period can take part in the study.

Please read the rest of this Participant Information Sheet. It gives you more information about the study.

What is this study about?

What is the purpose of the study?

Clostridioides difficile infection (CDI) in the gastrointestinal tract causes symptoms ranging from severe diarrhea to toxic megacolon, a rare but life-threatening complication of intestinal disease or infection. It is caused by toxins produced by the bacteria *Clostridioides difficile*. CRS3123 drug is an antibacterial compound which is being developed for the treatment of CDI because it is very specific for *Clostridioides difficile*.

The purpose of this study is to assess the effect of food on the safety (if any side effects occur) and pharmacokinetics (PK, the amount of study drug in your blood) of the study drug CRS3123 in healthy adult participants. To achieve this, the study drug will be administered on Day 1 (Period 1) and Day 6 (Period 2), under fasting (Study Treatment A) or fed (Study Treatment B) conditions. Each participant will be included in both periods to provide the highest quality data. Based on the results of this study, recommendations on dosing with or without food can be made for future clinical trials or product labeling.

How many participants will take part?

In total, there will be approximately 18 healthy adult male and female participants in this study.

Do I have to take part?

Your participation in this study is voluntary. You have the right to decide not to participate or to withdraw at any time without penalty or loss of benefits to which you are otherwise entitled. However, please note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

Why have I been chosen?

You are being asked to take part in this study because you are interested in taking part in, and contributing to research and have no medical conditions that would make you not eligible.

What will happen if I say "yes"?

First, you need to sign and date this form saying you agree to take part. We call this an 'Informed Consent Form'. You will sign this form at the end of this document, and this will designate your consent to participate.

You will be given a copy of this Participant Information Sheet and the signed and dated Informed Consent Form to take home and keep.

What will happen if I say "no"?

You are free to say no; the choice is yours. Your decision will not affect your current and future medical care. Do not sign this consent form if you do not want to participate in the study.

What will I need to do if I take part?

General Overview of the Study

The study should last approximately 6 weeks (including 4 weeks of screening). The study consists of 2 study treatment periods. You will be asked to come to the clinical site one day before the scheduled dosing on Period 1. You will be administered the study drug on Day 1 and Day 6 (once in fasting and once in fed condition). You will stay at the clinical site for 9 days (8 nights).

During your stay you will not be allowed to leave the clinical site or receive visitors. There will be a period of at least 5 days between each drug administration to ensure that the study drug you took during one period is no longer in your body when you begin the next period. In addition, you will receive a follow-up phone call, approximately 3 days (Day 11) after being discharged from the clinic to check on your health status.

Outings may be permitted during confinement. The scheduling of these outings will depend on the ongoing study procedures and will remain limited to the grounds surrounding the clinic. Every outing will need to be approved and supervised at all times by a member of the study staff.

What will happen at the different visits in the study?

Screening Procedures

To participate in this study the following screening procedures will be done:

- Complete medical questionnaire (for example, past surgery, current condition, medications you are taking)
- General physical examination
- Recording of your demographic data (age, sex, race)
- Recording of your body measurements (height, weight, body mass index [BMI])
- Measurement of your vital signs (blood pressure, heart rate, respiration rate [breathing rate], and temperature by mouth)
- Recording of the electrical activity of your heart (electrocardiogram [ECG]).
- Follicle stimulating Hormone (FSH) test - for female participants only to determine postmenopausal status
- A blood sample is necessary to verify your general health status and to detect a possible HIV, Hepatitis B or Hepatitis C infection. A positive result for any of these tests must be reported to the Public Health authorities, as required by law.
- If you are a post-menopausal female, blood sample will be collected to confirm your post-menopausal status.
- A urine sample is necessary to verify your health status and to screen for drugs or medications of abuse, or to see if you smoke. Urine sample will also be used to test if you are pregnant (for female participants). An alcohol breath test will also be performed.

If your screening procedure results are adequate, you will be contacted and asked to participate. You will be given specific instructions at that time.

Study Visit - Check-In

If you agree to continue you will have to show up at the clinical site at a time specified by the study staff for admission to your in-house stay where tests and exams may be done to confirm your eligibility. This is called the check-in.

Randomization (choosing participants completely by chance, like flipping a coin)

You will be administered the study drug as a CRS3123 capsule of 200 mg once under fasting and once under fed condition. In which condition (fasting or fed) you will receive the study drug first is determined by chance (like the flip of a coin).

Study Treatment A (Fasting)

During the fasted period, no food will be allowed from at least 10 hours before the administration of the study drug to at least 4 hours after.

Study Treatment B (Fed)

During the fed period, after fasting overnight for at least 10 hours, you will receive a high-fat, high-calorie breakfast of approximately 800 to 1000 calories (approximately 50% of the total caloric content of the meal will be derived from fat) on the morning of Day 1 of that study period.

This breakfast will be served to you approximately 30 minutes before you take the study drug. An example breakfast will include 2 eggs fried in butter, 2 strips of bacon, 2 slices of toast with butter, 4 ounces of hash brown potatoes and 8 ounces of whole milk. This entire breakfast must be eaten within a period of about 30 minutes or less.

Please tell the study staff if there are foods that you are unwilling or unable to eat or if you have food allergies and/or food sensitivities. Also, if you don’t think you will be able to finish the entire breakfast within approximately 30 minutes, you should not take part in this study.

During the fasting period, no food will be allowed from at least 10 hours before you take the study drug until at least 4 hours after dosing.

Study Drug

When you have completed this study, you will have received a total of 400 mg (2 x 200 mg) of CRS3123. Access to water will be restricted and controlled by the study staff from at least 1 hour before to at least 1 hour after taking the study drug.

Except for the high-fat, high-calorie meal, a standard diet will be offered during your stay at the clinical site.

Additional Study Procedures

At different times during the study, these tests will be performed:

- Vital signs measurement
- Body weight and height measurement
- ECG (electrocardiogram; measure of the electrical activity of your heart)
- General physical examination
- Urine and serum pregnancy test (for all females only)
- Blood draws (to measure the amount of study drug in your body and to check your health status)

Blood Sample Collection

A total of 32 blood samples will be collected to measure the amount of study drug in your body. Blood draws are done using needle puncture or a catheter. A catheter (IV) is a flexible tube inserted into the vein that allows taking several blood samples without repeated needle insertion into the skin. The total volume of blood collected should not exceed 250 mL (about 1 cup) for the whole study. In comparison, blood donation represents 450 mL (about 2 cups or 1 pint) of blood, and it is done in 1 day.

What are my responsibilities?

Tell the truth about your medical history, current conditions and all the drugs you are currently taking.

Tell the study doctor about any problems or symptoms you may have during the study.

Follow the instructions given by the study staff regarding use of prescription and non-prescription drugs:

- Do not to take illegal drugs or any nicotine product (such as tobacco and vape) during the study.
- Do not take prescription medications (except those medications as approved by the study doctor) and any vaccine, for 14 days prior to dosing until study discharge.
- Do not take antibiotics administered by mouth or injection within 30 days of screening.
- Do not take digoxin within 7 days of screening
- Do not take any drugs that can speed up or slow down how the liver processes medicines, or that can affect enzymes that play a key role in how the body processes various substances, including drugs, toxins, and even natural compounds for 30 days prior to dosing until the end of the study.
- Do not get depot injection or implant of any drug or hormonal contraceptive for 3 months prior to dosing until study discharge.
- Do not take over-the-counter (OTC) medications and natural health products (including herbal medicines such as St. John’s wort, homeopathic and traditional medicines,

probiotics, food supplements such as vitamin, minerals, amino acids, essential fatty acids, and protein supplements used in sports) from 7 days prior to dosing (with the exception of the occasional use of acetaminophen/paracetamol up to 2 g/day).
- Do not take any drug (OTC or prescription) that may affect how they are absorbed in the stomach or how they're broken down and removed from the body.

Follow the instructions given by the study staff regarding meals and liquids:

- Do not consume food or beverages containing curcumin (turmeric), grapefruit, grapefruit related citrus fruits, Seville orange, starfruit, pomegranate, pineapple, or pomelo from 7 days prior to first dosing and throughout the study.
- Do not consume food or beverages containing xanthine derivatives or xanthine-related compounds (coffee, black/green tea, chocolate, gum) or energy drinks from 48 hours prior to first dosing and throughout the study.
- Do not consume food containing poppy seeds from 24 hours prior to admission to the clinic.
- Do not take consume alcohol-based products from 24 hours prior to admission and until after the last PK blood sample collection of the last dosing. Red wine should not be consumed from 7 days prior to dosing and throughout the study.

Follow the instructions given by the study staff regarding activities:

- Avoid lying down (except when required for procedures) or sleeping for the first 4 hours after study drug administration.
- Avoid vigorous activity (heavy lifting, weight training, calisthenics, aerobics, etc.) at least 48 hours before your stay at the clinic and at all times during your clinical stay. Walking at a normal pace will be permitted.
- You will be confined to the procedure room for the first 4 hours after study drug administration on Day 1 and Day 6, except to use the bathroom.

Do not donate plasma within 7 days prior to dosing or donate or have a blood loss of 500 mL or more of whole blood within 8 weeks prior to dosing

Keep in contact with the study staff during the entire study.

What are the possible side-effects of taking part?

Risk associated with participating in the study

Participation in a clinical research study involves some unforeseeable risks of side effects. Like all drugs, CRS3123 can cause side effects, although not everybody gets them. They are usually mild to moderate in intensity. However, some participants may experience severe side effects which may require treatment or even be life-threatening.

The side effects associated with the use of CRS3123 have been experienced by other participants who have taken the drug in previous studies and are listed in the section "**Risk associated with study drug administration**" below.

The frequencies listed below are not predictive of what could happen during the study. Please be aware that the side effects mentioned below could occur at a frequency higher or lower than indicated, and some side effects not indicated below could also occur. Unless otherwise stated, the side effects listed below are anticipated to be temporary, and it is anticipated that they will disappear by the end of the study.

Risks associated with study drug administration

CRS3123 has been given to a total of 83 participants in clinical trials. About 30 healthy volunteers have received it as a single dose at different dose levels. About 24 healthy volunteers have received it twice a day for 10 days at different dose levels. About 29 patients with CDI have received it twice each day for 10 days. The side effects listed may or may not be due to CRS3123, but they happened during the previous studies.

The most frequently (greater than or equal to1%) reported side effects in patients associated with the use of CRS3123, are listed below:

- Headache
- Vomiting
- Feeling abnormal
- Muscle spasms
- Gastric reflux
- Decreased blood calcium
- Increased alanine aminotransferase (liver enzyme that can signal liver damage)
- Decreased hemoglobin
- Abnormal urine analysis
- Abdominal pain
- Nausea
- Asthenia (generalized weakness or fatigue)
- Malaise (general feeling of discomfort, illness, or being unwell)
- Dry mouth
- Rash
- Increased aspartate aminotransferase (liver enzyme that can signal liver damage)
- Increased alkaline phosphatase
- Positive urine leukocyte esterase (white blood cells present in your urine)
- Diarrhea

Allergic Reaction

With any drug, there is a small but real risk of allergic reactions that can be fatal. These reactions usually start shortly after taking the study drug. If you have a very serious allergic reaction, you may be at risk of death. Some symptoms of allergic reactions are:

- Skin itching, redness, rash
- Difficulty breathing

- Dizziness and fainting
- Swelling around the mouth, throat, or eyes
- A fast pulse
- Sweating

If you experience any of the reactions mentioned above, you must immediately inform the study staff. Outside of your clinical stay, if you seek emergency care or hospitalization is required, alert the treating physician that you are participating in this research study. **Please contact the study doctor at the telephone number listed on the first page of this consent document.**

Risks associated with pregnancy

Since the risks to a developing human fetus or a nursing infant following exposure to the study drug are unknown at this time, only male and non-pregnant, non-lactating female participants will be enrolled in this study.

Women

Female participants are required to avoid becoming pregnant while participating in this study since there may be risks to the participant or the fetus associated with the use of CRS3123 during pregnancy. Pregnant or breastfeeding females are not allowed to participate in this study.

Females participating in this study must either:

- Be of non-childbearing potential by being surgically sterile (hysterectomy [uterus removal] or tubal ligation [a procedure to block the fallopian tubes]) at least 3 months prior to dosing.
- Be postmenopausal (with no menstrual bleeding for more than 1 year [no menses for 12 consecutive months]).
- If fertile, you are required to use one of the following contraceptive methods from screening until 30 days after the last dose.
    - Simultaneous use of non-hormonal intrauterine device placed at least 4 weeks prior to first dosing and condom for the male partner.
    - Simultaneous use of diaphragm or cervical cap with spermicide and condom for the male partner, started at least 21 days prior to first dosing.

Except abstinence, no method of contraception is 100% effective. If you think you may have become pregnant even though you used required contraception while in the study, you should contact the study doctor or the study staff immediately (see telephone number at the first page of this form). Follow-up information about the pregnancy and the outcome will be collected and documented.

Men

If you are sexually active with a female partner of childbearing potential and if you are not vasectomized for at least 3 months, you must discuss the risks to her and the fetus with your female

partner(s) and you must avoid heterosexual intercourse if the acceptable contraception methods for this study are not used.

Since CRS3123 may have an effect on sperm, female partner(s) of male participants have to avoid becoming pregnant during the duration of the study and for 90 days after the last study drug administration.

- Simultaneous use of male condom and, for the female partner, hormonal contraceptives (for example: oral, patch, depot injection, implant, vaginal ring, intrauterine device) or non-hormonal intrauterine device, used since at least 4 weeks before sexual intercourse.
- Simultaneous use of male condom and, for the female partner, a diaphragm or cervical cap with spermicide.

In addition, you must not donate sperm starting from the first dose and for 90 days after the last dose or ovum starting from the first dose and for 30 days after the last dose.

If your partner is pregnant, you must use a condom, even if you are vasectomized, until at least 90 days after the last study drug administration.

Except abstinence, no method of contraception is 100% effective. If your female partner thinks she may have become pregnant even though you used required contraception while in the study, you should contact the study staff immediately (see telephone number at the end of this form).

Are there any other possible risks or inconveniences?

Among other known risks of side effects in a study, there are those related to the use of needles for blood collection and catheter insertion: pain, bruising and swelling at the site of blood collection, fainting for a short period, and, very rarely, nerve damage or infection at the needle insertion site.

There is no pain or risks related to having an ECG. However, electrodes (small sticky patches) will be placed on your body. Removing the electrodes may cause skin irritation. In some areas, it may be necessary to shave a small spot of body hair so the adhesive patches can be properly placed on your body.

Finally, although we try to make sure that all volunteers are healthy upon participation in the study, the risk of contagious infection is increased because you will be in contact with several participants during your stay at the site.

You will be monitored for the duration of your time in the study, and you should tell your study doctor about any changes in your health while taking part in the study.

There may be other risks that are unknown.

What are the possible benefits of taking part?

No benefits can be anticipated from participating in this study, except for a health evaluation. This study may help doctors and scientists learn things about the study drug that will help others.

You will be informed of any significantly abnormal result obtained during the screening session or during the study and, if necessary, you will be referred to a health professional.

What are the alternatives for treatment?

The option is not to take part in this study.

Who is involved and more information about taking part

Who is organizing and funding the research?

Crestone, Inc., is the company sponsoring this research study with support from the National Institutes of Health, National Institute of Allergy and Infectious Diseases (NIH/NIAID).

The policy of the NIH is to evaluate investigators at least yearly for any conflicts of interest. You may review the system for assessing conflicts of interest by checking the web site link: http://ethics.od.nih.gov/forms/Protocol-Review-Guide.pdf. Copies of the standards may also be requested by research subjects.

Will I be paid for taking part?

If you complete the entire study and all related procedures, you will be compensated will a total amount of $3,540 for the time and inconveniences related to your participation in the study. During the study, you will receive an amount of money at pre-set times and the remaining amount will be paid to you upon completion of the study.

As compensation for the time and inconveniences related to your participation in this study, you could receive up to $3,540 for the entire study. Compensation will be allocated as follows:

Compensation schedule	
Amount for confinement ($170/12 hours confinement period)	$2,720
Amount for Phone Call Visit ($120 per each visit)	$120
Amount allowed for completing the study*	$700
Total	**$3,540**

**This amount will be allocated only to participants completing the whole study. Completing the whole study means completing all planned procedures, providing all required samples, and attending all call-back/follow-up visits of the study.*

You will receive $25 as compensation for the screening visit, if applicable. Please note, if your drug, alcohol, smoking screens or pregnancy tests (for female participants) are positive, this fee will not be applicable. Please note that compensation will only be provided if the Informed Consent Form (ICF) is signed. This ensures that participants fully understand the study and agree to participate voluntarily.

You will receive $25 as compensation for each unscheduled visit during the screening period if applicable. You will receive $40 as compensation for each unscheduled visit during the on-study period.

You may be selected as a stand-by participant and should be ready to fully participate in the study as a replacement.

- If you are called to a walk-in visit, you will receive $50.
- If you are selected as a stand-by participant and are not called upon to spend the night you will receive $100.
- If you are selected as a stand-by participant, you will receive $200 if you are asked to stay onsite until the first drug administration of Day 1 is completed.

In return for your participation in this study, compensation will be issued in the form of a clincard (pre-loaded debit card). In the event of loss or damage to the card, a $5 replacement fee will be charged.

The amounts mentioned above may be subject to tax withholding and reporting as per Federal and State laws.

If you do not complete the study, the amount you receive will depend on the portion of the study you completed, even if the study is cancelled or stopped by the sponsor or Syneos Health.

What happens if I get sick or injured?

In case of injury or disease because of your participation in this study, you will receive appropriate medical care. The sponsor is committed to covering all necessary and related medical costs not covered by your private medical insurance (if any).

If you suffer a serious or lasting injury as a result of participation in this study, it may affect your ability to obtain private health insurance, your employability, and/or quality of life. No compensation other than that mentioned in this Participant Information and Informed Consent Form is planned. No long-term medical care or financial compensation for research related injury will be provided by the NIH or the Federal Government.

To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

Will there be any cost to me for taking part?

There are no costs for you, your private medical insurance (if applicable), or the public health insurance plan, associated with the tests and examinations planned for the study.

What if new information about the study treatment becomes available during the study?

During the study, you will be informed as soon as possible of any new information on the study drug that might affect whether you want to continue participating in the study. This new information may mean that you can no longer participate in this study. It could also mean that the sponsor may suspend or prematurely end the study. If this occurs, the study staff supervising the study will stop your participation.

Can I be withdrawn from the study?

The study doctor or a designated study staff member can decide to withdraw you from the study, without your consent, if they decide that it would be better for your health, if you do not follow the instructions given to you, or for other reasons. If you are withdrawn from the study by the study doctor or study staff, the reason for your withdrawal will be explained to you.

What will happen if I don't want to carry on with the study?

If you decide to withdraw from the study, or if the study doctor or a study staff decides to withdraw you from the study for safety reasons, for not following the requirements of the study, or for any other reason, the data and sample collected up to the time of your withdrawal from the study remains part of the study and may not be removed.

At the time of your withdrawal from the study, you may be asked to undergo additional tests for your safety; one last blood sample may also be collected to measure the amount of study drug in your body.

What will happen when the study stops?

Your overall health will be checked before you are discharged from the study. Even after the study is completed, the clinical site may contact you within a few weeks after the last study day to clarify information or to ask you to come back for additional tests for your safety.

What if something goes wrong?

A study doctor will be reachable 24 hours a day / 7 days a week during the study. If deemed necessary by the study staff, additional tests or blood draws could be performed to ensure your safety and you will receive appropriate medical care.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this study.

In addition, should you require medical care or hospitalization during the study, Clinical site's representative may contact the treating physician with your consent, except that consent may not be requested if there is an emergency situation. If you don't agree for Syneos to proceed with this contact in case of emergency situation, you should not take part in this study.

How will information collected about you be used and who can see it?

As part of your participation in this study you will be monitored by closed-circuit television (CCTV) during screening, any stay and follow-up visits including exit visit. CCTV cameras are located throughout the screening center, the clinical unit and the eating area/recreation room. CCTV cameras are not placed in the restrooms/washrooms or showers. The purpose of CCTV is to maintain close watch of your health condition while participating in the study to make certain you are safe. By signing and dating this Informed Consent Form you agree to be monitored by closed-circuit television.

Will my taking part in this study be kept confidential?

The clinical site will take necessary steps to protect the privacy of your personal information in accordance with applicable law.

Outside of the clinical site, you will be identified at all times by a number unless there is an emergency situation and/or a representative of the clinical site has to communicate with your primary doctor. Your information will only be used for the purpose of this research study, and it will only be disclosed with your permission, except as required by law. Regardless of whether the results of the study are published, your identity will remain confidential.

While every effort is made to protect the privacy of your information, absolute confidentiality cannot be guaranteed. This does not limit the duty of the study doctor and the study staff to protect your privacy.

<u>Certificate of Confidentiality</u>

This research is covered by a Certificate of Confidentiality from the NIH. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the U.S. Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

How long will my information be stored?

The study data will be available for confidential consultation and may be accessed by representatives of the clinical site in the United States and outside of United States, by representatives of the study sponsor, various regulatory agencies such as the U.S. Food and Drug Administration (FDA) as well as the Institutional Review Board, Advarra.

All information from this study will be stored for at least 15 years at the clinical site after the end of the study.

Blood and other samples will be sent to different laboratories for testing. Samples will be destroyed either after they have been tested or when the 'Clinical Study Report' - this contains the full results of the study - is finished, or when otherwise decided by the study sponsor.

Left over samples may be used for further CRS3123 research to check for breakdown products of the study drug, compounds related to the effects of the study drug, or control of the analysis methods used or may be used to check for additional safety markers. These leftover samples may be stored for up to 15 years.

What will happen with the study results?

A description of this clinical trial could be available on http://www.ClinicalTrials.gov. 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.

Some results from the study can be made publicly available sometime after the study finishes.

What else do I need to know about this study?

Future Research Studies

Identifiers might be removed from your identifiable private information or identifiable biospecimens collected during this study **and could then be used for future research studies or distributed to another investigator for future research studies** without additional informed consent.

Commercial Profit

Your biospecimens collected during this study may be used for commercial profit (even if identifiers are removed) and **you will not share in this profit**.

Clinically Relevant Research Results

Research results that are clinically relevant, including individual research results, will not be disclosed to you.

Genome Sequencing

Researchers can look closely at large amounts of your genetic information by sequencing, or "reading," every letter in your DNA (your genome). Reading a person's entire genetic code is called whole genome sequencing. The research **will not include** whole genome sequencing (for example, sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Who can I talk to for more information?

How can I get answers to my questions or concerns about the study?

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns, or complaints about the study, please contact the study doctor or study staff at the telephone number listed on the first page of this Consent document.

Whom to contact about this study?

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;

Please contact the study doctor at the telephone number listed on the first page of this consent document.

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

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact:

• By **mail**:

Study Subject Adviser
Advarra IRB
6100 Merriweather Drive, Suite 600
Columbia, MD 21044

• or call **toll free**: 877-992-4724

• or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00085452.

Thank you for taking the time to read this Participant Information Sheet.

If you have decided to take part, please fill in the "Informed Consent Form" on the next pages.

Informed Consent Form

By signing and dating this form, I agree with all the following statements:

I acknowledge the following points:

- I have been given spoken and written information about this study.
- I have read and understood the information given to me.
- I have had enough time to think about taking part.
- I have had the chance to ask questions, and all my questions have been answered adequately.

I understand the following points:

- I do not have to take part and that I am free at any time to stop taking part. Also, that I do not have to give a reason.
- A number of the study site staff can see my personal medical file. This is to make sure that the study is done correctly, and that all information is recorded correctly. All personal details will be treated as strictly confidential by all of these people.
- All information collected during the study is stored electronically in a database and may be shared with other researchers who are not working on this study. The information can also be sent to other countries in the world. The information will never have my name on it.
- If I decide to stop taking part during the study, information already collected cannot be deleted. This is required by the national medicine authorities to make sure that the results for the entire study can still be used.
- The results of this study may be made publicly available.
- I accept that the study staff may get information related to the study from individuals like my family doctor. They may also look at publicly available information.
- If I require urgent medical care or hospitalization during the course of the study, I authorize Syneos to contact such urgent care provider and to provide my personal information and clinical research study data to the treating physician.

About this form

- I will get a copy of this signed and dated Participant Information and Informed Consent Form.
- I agree to take part in this research study.

To be completed by you, the participant

The study doctor has my permission to contact my family doctor about my participation in this study:

YES _____ NO _____

First and last name of the family doctor to contact: _____

I consent to the study sponsor using my information for other purposes in accordance with the study protocol, and further CRS3123 research in the field of *Clostridioides difficile* infection: infections:

YES _____ NO _____

I agree with all of the statements on this form and would like to take part in the study as described in this document:

_____ _____
Signature Date

_____
Printed name

To be completed by the study staff seeking the informed consent

(to be signed by the study doctor or appropriately qualified designee)

By signing and dating this form, I confirm that the entire informed consent process has been conducted before any study procedures have taken place:

_____ _____
Signature Date

_____
Printed name

By signing and dating this document you do not waive any of your legal rights, nor release the study doctor or sponsor from their legal and professional obligations. Signature of this document confirms you have been informed about the nature of the study you are participating in.