INFORMED CONSENT FORM (ICF)

Product Code/Name	Zoliflodacin, ceftriaxone and azithromycin
Protocol Title	A multi-center, randomized, open-label, non-inferiority trial to evaluate the efficacy and safety of a single, oral dose of zoliflodacin compared to a combination of a SINGLE intramuscular dose of ceftriaxone and a SINGLE oral dose of azithromycin in the treatment of patients with uncomplicated gonorrhoea.
Protocol Number Version/Date	STI_Zoli001 / v4.0 / 22 October 2021 ClinicalTrials.gov identifier: NCT0395927
Principal Investigator	*Enter Name and Address of Principal Investigator at relevant trial site*
Sponsor	Global Antibiotic Research and Development Partnership (GARDP), Geneva, Switzerland

Why have I been given this form?

You are being invited to take part in a clinical research study on gonorrhoea. This form is called an informed consent form; it describes the purpose of the study, the study procedures, the risks, the benefits and the alternatives to participating in this study that are available to you.

You are invited to take part in this study because:

- you may have gonorrhoea
- you are at least twelve (12)-years-old and weigh more than thirty-five (35) kilograms *<<Insert for US sites only:* (77 pounds)>>
- if you are a female, you are not pregnant or intend to be in the next thirty (30) days. You are on highly effective contraception and agree to remain on such contraception and use a condom until the end of your participation in the study.
- if you are a male, you agree to use a condom and delay conception with a female partner until the end of your participation in the study.

Please note you cannot participate in this study if:

- you have undergone sex reassignment surgery involving your penis or vagina
- you were involved in a clinical study where you received an experimental drug within the past 30 days
- you have already participated in this research study and been assigned treatment.

It is not obligatory for you to take part in this research, your **participation** in this research study is **free** and completely **voluntary**. If you decide not to participate in this research study, you will be offered the treatment that is routinely offered in this hospital/clinic for gonorrhoea infection. You can also start the study and change your mind later and decide to stop participating at any time; this will not affect your ongoing treatment at this hospital/clinic.

There may be words that you do not understand. Please ask as many questions as you have to the study doctor or the medical staff before making any decision, to help you to decide whether you want to take part in the study and please take as long as you need to decide whether to participate. We will ask you additional questions to check if we have explained everything to you clearly.

If you do agree to participate in this study, you will be asked to write your name, sign and personally date the page at the end.

If you have a personal insurance policy, review its terms and restrictions carefully to confirm that study participation does not interfere with the policy you have.

We will provide you with an original signed copy of this form to keep.

You do not give up any legal rights by signing this form.

What is the purpose of the study?

Gonorrhoea is a sexually transmitted disease from bacterial origin that is transmitted through unprotected oral, anal, or vaginal sex. Uncomplicated gonorrhoea infects the urethra (the tube inside the penis that drains urine from the urinary bladder), the female reproductive tract, eyes, throat, vagina, and anus. Gonorrhoea can cause: discharge in your genital tract, pelvic or testicular pain, burning sensation when urinating, pain during sexual intercourse, and/or vaginal bleeding. It can also cause problems in your rectum and throat if they are infected and finally, it can also be asymptomatic. Women who have gonorrhoea can pass the disease on to their baby during delivery. Untreated gonorrhoea can also increase the risk of acquiring and transmitting HIV. Gonorrhoea can also be complicated: it means the infection has spread to other organs and/or your blood circulation. Complicated gonorrhea is not evaluated in this study.

The standard treatment for uncomplicated gonorrhoea is antibiotics: ceftriaxone and azithromycin are the most commonly used. When this treatment is effective, symptoms should improve within 2-3 days. However, antibiotics treatments are increasingly failing to cure gonorrhoea because the bacteria responsible for the disease has learned to resist to them. This is called antimicrobial resistance. This resistance can spread rapidly and there is a high risk that one day, a reliable treatment won't be available to cure gonorrhoea.

The Global Antibiotic Research and Development Partnership (GARDP) Foundation is a not-for-profit organization that works on discovering new antibiotic treatments. You are being invited to take part in this study from GARDP which evaluates if a new antibiotic called zoliflodacin is a suitable treatment for gonorrhoea. Your participation is likely to help GARDP provide the necessary evidence to support use of zoliflodacin to treat gonorrhea. To know if zoliflodacin is approximately as good and safe as the currently recommended therapies, we need to compare both treatments. Therefore, if you participate in this study, you will be given either zoliflodacin or a combination of ceftriaxone and azithromycin, a standard treatment for uncomplicated gonorrhoea.

This research study has been reviewed and approved by an accredited research ethics committee, which is a committee whose task is to make sure research participants are protected from harm.

What is the size and duration of the study?

Approximately 1092 participants from the Netherlands, Belgium, South Africa, Thailand and the USA will be recruited into this study, of which *<<enter expected number of patients to be enrolled in the relevant country>>* will be recruited in *<<enter name of relevant country>>*. The study will last until the required number of participants are recruited.

How long will my participation in the study last for?

If you decide to take part in the study, your participation in the trial will consist of one (1) day of treatment (today), followed by one (1) phone call in one (1) or two (2) days and two (2) follow-up visits at the hospital/clinic over a total of thirty (30) days.
Today's visit should take approximately *<<enter time of relevant site>>*, and each follow-up visit to the hospital/clinic should take approximately *<<enter time of relevant site>>*. The phone call should last approximately *<<enter time of relevant site>>*,

In total your participation will last approximately 30 days.

<<insert if site participates to PK sub-study: If you agree to participate in this study, you could also be invited to participate in a sub-study which will investigate how much time it takes for zoliflodacin (the study drug) to be absorbed into your body and how long it stays in your body after it has been absorbed. Please discuss it further with your doctor if you are interested.>>

What are my responsibilities during the study?

If you take part in this study, you are committing to follow the study procedures:

- You must make every effort to attend all the study visits and answer to the phone call.
- You must report any health problems you experience to the medical staff
- You must report all medication you take (name of drug, dose taken, when it was taken) to the medical staff.
- You must not take any drug that is forbidden during the study. The medical staff will explain to you which drugs are not allowed.
- You must agree not to have anal, oral or vaginal sex, **or** to protect yourself using a condom during all anal, oral or vaginal sexual contacts during the 30 days of the study. This is important to minimize risk of being infected again and to avoid getting pregnant or getting your partner pregnant whilst you are in the study because the risks of zoliflodacin on pregnancy have not been tested yet, and there is limited data on the impact of ceftriaxone and azithromycin on pregnancy. The medical staff will discuss the appropriate contraception methods with you.
- If you or your partner become pregnant during the study, you must tell the medical staff **immediately.** This is important to check the health of both you and your unborn baby. The medical staff will ask your permission to obtain information on your pregnancy and on your baby from the doctor following your pregnancy.
- You are prohibited from participating simultaneously in another clinical study in which medications are prescribed.
- You are prohibited from participating in this same study at a different hospital/clinic, or in this study again after you have already completed it at this hospital.

What are the procedures during the study?

	Today (and possibly tomorrow) ***Clinic visit***	Day 2 or 3 ***Phone call***	Between Day 4 and 8 ***Clinic visit***	Between Day 27 and 33 ***Clinic visit***
Discussion with doctor/medical staff	X	X	X	X
Pregnancy test (for females)	X		X	X
HIV test (if you agree)	X			
Physical examination	X		X	X
Blood tests	X		X	X
Swab tests	X		X	X
Drug treatment	X			

Day 1: today

1. Screening

The first step will be to evaluate if you qualify to participate in the study.

- You will be asked questions about your life situation such as your age, sex at birth, gender and ethnicity. You will also be asked questions about your medical history, sexual history and about medical treatment you have received over the past 30 days. We will also ask you to provide us with your contact details. Your answers will be kept confidential.

- Trained medical staff will conduct a physical examination to assess your general health and will ask you if you are currently taking any medication. The examination includes: temperature, weight, skin examination, oral examination, rectal examination and external genital examination (including pelvic examination for females).

- If you are a female that can have children, you will be asked to give a urine sample for a pregnancy test.

2.Tests

Medical staff will then proceed to a series of tests to learn about your health.

- *HIV test*

If you agree, the medical staff will test you for HIV infection, except if your HIV status or HIV treatment regimen is known and documented, or if you received testing directly prior to being asked to participate in the study. <<*insert if site participates to PK sub-study*: If you don't want to be tested for HIV, you can still participate in the study, but you will not be able to participate to the PK sub-study.>>
This test will usually give a result in 15-60 minutes.
A positive result from an HIV test always needs to be confirmed by a different laboratory test. This result is usually available in <<insert time at specific site>> days, and this will not affect your participation in the study. If you are confirmed HIV positive, the hospital/clinic staff will make sure that you will be followed up as per standard guidelines in your country and that you access appropriate care. HIV treatment is not part of the research study and the cost will not be covered by GARDP. If you have HIV infection, you will still be able to participate in this study.
If you agree to be tested for HIV, the medical staff will <<*Choose one of the following as appropriate*: take a maximum of 5 mL of blood through venous blood draw *OR* collect a few drops of blood by pricking one of your fingers *OR* use a small sample of a blood tube collected from you for other blood tests>>.

- *Blood tests*

Medical staff will take a maximum of 15 mL (about 3 teaspoons) of blood through blood draw using a needle in your arm. A bandage will be put on your arm that will need to stay in place for a short time (approximately 15 minutes).

Three types of tests will be performed with your blood sample:

- *A full blood count*: this is a very common test measuring cells in your blood such as red blood cells, white blood cells and platelets to help the doctor rule out serious health problems,
- *Liver function tests* which will tell us how well your liver is working,
- *Kidney function tests* that will tell us how well your kidneys are functioning.

- *Swab tests*

Swab tests are normal routine procedures to detect bacterial infections. In this study, swab samples will be collected for *Neisseria gonorrhoeae* and *Chlamydia trachomatis* testing, which are two bacteria that cause sexually transmitted diseases. The medical staff will use a sterile << insert type of kit e.g.: plastic loop, polyester swab…>> to collect:

- two samples from your throat << *insert if applicable*: (to minimize the risk of COVID-19 transmission, you might be asked to collect this sample yourself under guidance and supervision of the study staff'),>>
- two samples from your rectum,
- two samples from your urethra if you have a penis (if you have a discharge, the tip is gently placed into the top of the penis to collect bacteria. If you don't have a discharge, the tip will be inserted 2 to 4 cm inside your penis and rotated for 3 to 5 seconds),
- OR two samples from your uterine cervix during the pelvic exam (with help of a speculum inserted into your vagina) if you have a cervix.

3.Study treatment

Neither the doctor, nor you will choose which treatment you will receive. You will be assigned by chance (like flipping a coin) by a computer program, to a group of participants that will receive zoliflodacin (group 1) or to a group of participants that will receive ceftriaxone plus azithromycin (group 2). You will have 2 out of 3 chances to receive zoliflodacin, and 1 out of 3 chances to receive the ceftriaxone plus azithromycin treatment. This process is called 'unequal randomisation'. Both you and the medical staff will know which treatment you are getting.

The study staff will check that you have eaten before you take/receive the study treatment. If you have not eaten, you will be asked to take a snack/light meal, which will be provided by the study staff. This will help make sure the treatment is effective.
Then, you will be given the study treatment in one dose and you will need to stay in the hospital/clinic for 30 minutes after taking the medicine.

- **For group 1** (zoliflodacin 3 grams [g]), the treatment will be granules mixed into potable water which you will have to drink.
- **For group 2** (ceftriaxone and azithromycin), you will have to swallow four (4) tablets of 250 mg azithromycin with water. Then you will receive an injection of 2 mL containing 500 mg of ceftriaxone with a needle into your muscle. Ceftriaxone will be mixed with a drug (lidocaine) which numbs the area of injection.

NOTE: if there is no time to do everything mentioned above on the first day you visit the clinic, if your physician deems this is appropriate and if you agree, you might undergo some of the above-mentioned procedures today and the rest, including taking the blood and swab tests as well as receiving the study treatment tomorrow morning.

Day 3 (-1 day): phone call

You will receive a phone call from the hospital/clinic one (1) or two (2) days from today to ask if you have experienced any health problems and if you have been taking other medications. You will also be asked about your sexual behaviour since your previous visit to the hospital/clinic.

Day 6 (+/- 2 days): clinic visit

You will be asked to verify your contact information that was collected on Day 1.

- The medical staff will ask you how you are feeling and if you have had any health problems and if you have been taking other medications since the first visit. They will also discuss with you about your sexual behavior.
- The medical staff will:
  - perform a physical examination
  - collect a blood sample about a maximum of 15 mL (about 3 teaspoons) for *full blood count*, *liver function tests and kidney function tests*
  - depending on the results of the swab tests taken at your first visit and/or if some of the results have not yet been received, the medical staff will:
    - collect a maximum of two urethral (if you have a penis) or cervical (if you have a cervix) samples
    - collect a maximum of two throat samples << *insert if applicable*: (to minimise the risk of COVID-19 transmission, you might be asked to collect this sample yourself under guidance and supervision of the study staff)>>
    - collect a maximum of two rectal samples.

- if you are a female that can have children, the medical staff will also perform a urine pregnancy test.

If your test results for *Chlamydia trachomatis* from Day 1 show that you have a chlamydia infection, and you were assigned to the group of participants that received zoliflodacin (Group 1), you will be treated for chlamydia infection according to standard of care. If you were assigned to ceftriaxone and azithromycin (Group 2), there is no need to treat as azithromycin works against *Chlamydia trachomatis*.

Day 30 (+/- 3 days): clinic visit

You will be asked to verify your contact information.

- The medical staff will ask you how you are feeling and if you have had any health problems and if you have been taking other medications since the previous visit. They will also discuss with you about your sexual behavior.
- The medical staff will:
    - perform a physical examination
    - collect a blood sample of a maximum of 15 mL (about 3 teaspoons) for *full blood count, liver function tests and kidney function tests*
    - depending on the results of the swab tests taken at your previous visit and/or if you have symptoms, the medical staff will:
        - collect a maximum of two urethral (if you have a penis) or cervical (if you have a cervix) samples
        - collect a maximum of two throat samples << *insert if applicable*: (to minimise the risk of COVID-19 transmission, you might be asked to collect this sample yourself under guidance and supervision of the study staff)>>
        - collect a maximum of two rectal samples
- If you are a female that can have children, the medical staff will also perform a urine pregnancy test.

NOTE: The maximum amount of blood that will be drawn during the study is 50 mL (about 10 teaspoons).

May I withdraw, at a future date, my consent for participation in this research study?

You may decide to stop your participation in the study before the end at any time without providing any justification.

If you decide to withdraw your participation in this study, it will not affect the quality of your care. Information collected up to your withdrawal cannot be removed from the study data. This includes samples collected up until the date of withdrawal which will be kept and analyzed. However, you have the right to request that bacterial isolates from previously collected samples meant for storage and future analysis are destroyed.
No new information will be collected from you or added to existing data or database unless you agree to it.

The medical staff also have the right to withdraw you from the study if:

- in their opinion the study would impose a health risk to you,

- you fail to follow your responsibilities,
- the study is stopped.

In the case of your withdrawal from the study by a study doctor, you will be treated according to standard of care in this hospital/clinic.
In this event, you will be asked to come back one last time to the hospital/clinic to make sure that you are safe with the treatment you already took, if you agree; this is called an early withdrawal visit.

Early withdrawal visit:

- You will be asked if you had any health problems since the beginning of the treatment, if you have been taking other medications. They will also discuss with you about your sexual behavior.
- The medical staff will perform a physical examination.

The medical staff will collect a blood sample of a maximum of 15 mL (about 3 teaspoons) for *full blood count, liver function tests and kidney function tests.*

- If you are a female that can have children, a urine pregnancy test will be performed.

If you wish to withdraw at the time of the first or second follow-up visit, you will discuss with your study doctor whether you agree that the planned samples for assessing the infections are taken.

Sometimes during the course of a research project, new information becomes available about the treatment/drug that is being studied. If this happens, the medical staff will tell you about it and discuss whether you want to, or should, continue in the study. If you decide not to carry on, the medical staff will make arrangements for your care to continue. If you decide to continue in the study, you will be asked to sign an updated consent form.

What will happen with my samples and the results of my tests?

You have the possibility to discuss with the medical staff the use of the collected data at any time.

- *Blood tests*

The blood samples will be sent to a local laboratory. When these results are available, the medical staff will discuss them with you if an abnormality is detected. They will assess the best treatments for you or refer you to a doctor/hospital if needed. The blood samples will be destroyed as per local standard practices.

- *Swab tests*

The swabs will be sent to local laboratories to see if bacteria are present, and if the bacteria are likely to be gonorrhoea. If so, these bacteria will be sent to a laboratory in the USA to confirm if they are gonorrhoea, and to learn if the bacteria are resistant to common antibiotics. This will be very useful information for the researchers to compare if zoliflodacin kills the bacteria as well as ceftriaxone and azithromycin do, and learn more about how the disease is evolving.
The bacteria will also be sent to a laboratory in Sweden after the end of the study to study their genetic code to try and understand why the bacteria may have become resistant to antibiotics.

No blood or urine samples will be sent for genetic analyses; only bacteria will be shipped and analysed. No genetic analyses will be performed on your DNA.
Results from the analyses performed in Sweden will not be made available to the medical staff as they are intended for research purposes only and will not impact your clinical care.

Throughout the study, and until the end, some of the bacteria collected from your samples (called bacterial isolates) will be stored in a local laboratory as a back-up (in case some shipments to the central laboratory in the USA get lost or destroyed). Bacterial isolates will also be stored in the central laboratories in the USA and in Sweden until completion of all study analyses.
<< *Insert for SA and Thailand where long term storage in US or Sweden is not allowed:*
After the end of the study, the bacteria collected from your samples that will be sent to the USA and Sweden will be destroyed. The bacteria collected from your samples that will be kept in a local laboratory will also be destroyed at the end of the study, except if you agree to long term storage of those bacterial isolates.>>
<< *Insert for US, South Africa and NL:* They will be destroyed at the end of the study, except if you agree to long-term storage of those bacterial isolates.>>
<< *Insert if long term storage is to be included in main ICF:* If you agree, bacterial isolates will be kept for a maximum of 5 years after the end of the study for future research on gonorrhoea. Please check this box to certify that you agree to this ☐ >>

Swabs will also be analyzed to see if you have another common sexually transmitted infection *Chlamydia trachomatis*.

What are the possible risks of taking part in this study?

- *Social risks*

<< To remove or keep sentences below as required at country level>>
Although the clinic staff will make every effort to ensure the confidentiality of your records, it is possible that your participation in this study could become known to others, and that a social impact may result of it.
During the study visits, you may also feel embarrassed or uncomfortable with some of the questions you will be asked, some of the procedures that will be done, or some of the test results that you will receive. The questions you will be asked about your sexual behavior may make you feel uneasy. However, you do not have to answer any questions that you do not want to, and you can stop answering the questions at any time.
Study staff will help you deal with any feelings or questions you have.

- *Risks associated with zoliflodacin*

As of today, five clinical studies in healthy participants and one clinical study in participants with gonorrhoea have been conducted with zoliflodacin. In completed studies as of as of 5th September 2021, 324 people have received at least one dose of zoliflodacin, most of them receiving at least one dose ≥3 g, the dose that is given in this study. Most commonly reported side effects of zoliflodacin were headache, diarrhoea, and nausea. Vomiting was reported by one participant receiving zoliflodacin. Unpleasant taste was commonly reported in healthy participants when the drug was previously presented as a powder rather than granules.

- *Risks associated with ceftriaxone and azithromycin*

Ceftriaxone: The main risk is severe allergic reactions, which can occur in around 3 % of people and can be fatal. The most frequently reported side effects for ceftriaxone are abnormal counts of some blood cells, loose stools or diarrhea, rash, and effect on liver function. Ceftriaxone will be mixed with a drug (lidocaine) which has the property to numb the area of injection.
Possible reactions to lidocaine include flushing, redness of skin, small red or purple spots on the skin, hives, swelling at the site of injection or unusually warm skin. A reaction such as itching, bruising, burning, pain, or bleeding at the site of injection is very common.

Azithromycin: Rare serious allergic reactions such as skin rash and liver damage (hepatotoxicity) have been reported. The most frequently reported side effects when taking a single dose are diarrhea/loose stools, nausea, abdominal pain, vomiting and indigestion.

- There is a risk that your disease will not get better after treatment. In that case, you will receive additional treatment after Day 6, in accordance with the local standard of care.

- *Risks associated with medical procedures*

Physical examination*:* It is rare to have a problem during a physical examination. You may feel uncomfortable or feel some pressure during examination of your genital area. If you need a pelvic exam, this could be uncomfortable due to the speculum.

Blood sampling (venepuncture): You may feel a slight discomfort or even feel like fainting when the needle is inserted to your vein. You may have a small bruise where the needle went in. Bruises can be painful but are usually harmless and fade over the next few days. A risk of infection is possible where the needle is inserted, though very rare.

Swab tests*:* There may be some mild discomfort associated with taking vaginal, throat or rectal swab. If there is no discharge, urethral swab << is a painful procedure OR can cause slight discomfort – choose one option as required as per local standard>>.

- *Risks associated with exposure during pregnancy*

If you are a female participant:
Zoliflodacin has not been studied in pregnant females, and there is limited data on ceftriaxone and azithromycin in pregnancy. Therefore, it is important that you do not become pregnant during the study.
If you may be able to have children, you will be given a pregnancy test at screening. If the result is positive, you will not be able to participate in the study. If you are breastfeeding, you cannot participate in the study.
Your partner(s) or you must use an accepted form of birth control throughout the study until at least 28 days after receiving treatment, so you do not become pregnant. Acceptable forms of birth control include:

- For yourself: combined (estrogen and progestogen containing) hormonal contraception, or progestogen-only hormonal contraception, or mechanical products, such as an intrauterine device.
- For your male partner(s): vasectomy.

These methods **must** be combined with a condom to avoid being re-infected during the study. The medical staff will discuss with you methods of birth control.
If you become pregnant during the course of the study, **please contact the medical staff immediately**.

The medical staff must make every effort to follow up and document the course and the outcome of all pregnancies until delivery and until the newborn child reaches 2 years old, even if you withdraw from the study or if the study has finished, if you agree to this.

If you are a male participant:
If you have (a) female partner(s) that is (are) able to have children, you must inform them that the effects of the investigational products on sperm are unknown. Your partner(s) and yourself must agree to delay conception for at least 28 days. This is best achieved by using an accepted form of birth control until at least 28 days after receiving treatment. Acceptable forms of birth control include:

- For yourself: condom, vasectomy
- For your female partner(s): combined (estrogen and progestogen containing) hormonal contraception, or progestogen-only hormonal contraception, or mechanical products, such as an intrauterine device.

These methods **must** be combined with a condom to avoid being re-infected during the study.
The medical staff will discuss with you appropriate methods of birth control for you and your partner.
If your partner(s) become pregnant during the course of the study, **please contact the medical staff immediately**.
The medical staff must make every effort to follow up and document the course and the outcome of all pregnancies until delivery and until the newborn child reaches 2 years old. They will ask your partner if they agree to this.

- *Unknown risks*

In addition, there may be uncommon or previously unknown risks that might occur. You should report any problems to the medical staff immediately. Contact details are provided at the end of this form.

What are the benefits to participating in this study?

- By participating into the study, you will benefit from close and frequent medical care.
- If you are found to be positive for HIV or chlamydia, you will be rapidly referred for treatment and follow up according to the standard of care in your country. Treatment will not be provided by GARDP.
- Since antibiotic resistance to the standard treatment already exists and may rapidly grow, new antibiotics are crucially needed. Your participation will help determine if zoliflodacin can be used in future to treat gonorrhoea. This will be of benefit for future patients.

What about confidentiality?

Your identity, medical records and your participation in this research study will be strictly confidential. Your name will not be mentioned on any sample leaving the hospital/clinic, nor on any data collected during the study, except in records here at the hospital/clinic. Upon enrollment in the study, you will be attributed a unique number, which will be used to identify the samples and data collected from you. The number list will be kept secure at the hospital/clinic.

Your data will only be collected by and shared with personnel authorized at GARDP and GARDP's representatives (study team, monitors, auditors). None of this data will allow to identify you. At the end of the study, we will write a report about the results of the study and publish the results of this study on publicly available databases and in medical journals so that other doctors can learn about it. These reports will not include any information relating to you personally (for example name or where you live). We ask your permission for authorised medical staff, clinical monitors or auditors and ethics committee to have access to your information to ensure that the study is being conducted correctly.

GARDP may also give your data to the US Food and Drug Administration (FDA) (the USA Health Agency), and other governmental health agencies in the USA and other countries involved in the trial or in which an approval for zoliflodacin may be sought. This may be part of the process to try to get the treatment approved by the FDA and/or foreign government authorities. Each of these organisations will be under an obligation to keep data confidential.

Your data will be used as long as is needed for the study and may be retained for longer, wherever required by law. GARDP will retain data from clinical trials for up to 25 years.

You have the possibility to access your personal information by asking your medical doctors, and you have the right to correct the data collected from you if there is an error.

A description of this clinical trial will be available on http://www.clinicaltrials.gov as required by U.S. law. This Website will not include information that can identify you. The Website will include a summary of the final study results. You can access this Website at any time.

<<Insert for Europe sites only: If your data is transferred, we will always ensure appropriate measures will be taken to protect your personal information. Along with coding your personal information as detailed above with a unique number, we also make sure we have contracts and other protections in place before we share your personal information. These measures comply with data protection and privacy laws.
Your data may be transferred to trusted persons in other countries. Data protection and privacy laws may not be as strong in these countries as the laws in your home country. When personal information is transferred, GARDP makes sure that appropriate and suitable safeguards are used.
Your coded personal information may be transmitted to:

- GARDP who is based in Switzerland
- the ICON GPHS group to help us complete the study, which is based in the USA
- laboratories or clinical facilities which help us to conduct analysis on samples you give us as part of the study
- couriers or transport companies to enable us to deliver the samples to external laboratories.

For questions or requests regarding how your personal information is handled, or if you required additional information, please contact *Insert DPO contact >>*

<<Insert for US sites only: There are United States federal laws and regulations related to privacy. These laws can be found under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). These laws apply to certain personal health information collected in connection with this study. Your permission to use this

information is required. In addition to this form, you will be asked to give your permission to use your personal health information. This is done by signing the HIPAA Authorization Form attached to this form. Please ask the study site if you have any questions about the HIPAA Authorization Form.>>

How much will it cost you if you are participating in this study?

The medical treatments and tests that you get as part of this study will be provided free of charge. There will be no cost to you for taking part in the study. If you have a private insurance, your insurance will not be billed for any of the study procedures.
In the event that you suffer an injury or illness related to participating in this trial, GARDP will pay all costs relating to treatment of the injury or illness. GARDP have subscribed appropriate clinical trial insurance to cover for such event. If you wish to find out more about the insurance, the medical staff will be happy to provide more information.

Will you be paid if you decide to participate in this study?

If you agree to participate in the study, you will receive << to adapt per country/site >> per visit to the hospital/clinic to compensate for your time and travel to and from the hospital/clinic.

Contact persons

For further information regarding the study or in the event of a study related injury, please contact:

1. *Insert name, address and tel of study site investigator*

If you have any questions on your rights as study participant, please contact:

2. *Insert name, address and tel of someone independent of the study (e.g. Ethics Committee Chair, patient's representative)*

You will be given an original of this information to keep.

Site Number: *<<Insert Site Identifier>>*
Participant Identification Number for this trial:

CONSENT FORM

Product Code/Name	Zoliflodacin, ceftriaxone and azithromycin
Protocol Title	A multi-center, randomized, open-label, non-inferiority trial to evaluate the efficacy and safety of a single, oral dose of zoliflodacin compared to a combination of a SINGLE intramuscular dose of ceftriaxone and a SINGLE oral dose of azithromycin in the treatment of patients with uncomplicated gonorrhoea.
Protocol Number Version/Date	STI_Zoli001 v4.0 22 October 2021

Name of Investigator: <<Insert>>

I have read the information in this form, or it has been read to me in a language that I understand well. I have had the opportunity to ask questions about it and all my questions have been answered to my satisfaction.
I know that I can refuse to participate in the study without penalty or loss of benefits to which I would have been otherwise entitled, or that if I agree to participate, I can withdraw at any time without losing benefits or services to which I or my family are entitled.
I agree to participate in the study. By signing this form, I agree that the personal information collected about me will be accessible to GARDP's representatives (study team, monitors, auditors), ethics committees or the Food and Drug Administration or other regulatory agencies.

Name of Participant: _____

Signature: _____**Date**:_____**Time**:_____

I have explained the study to the participant and answered all of his/her questions. I believe that he/she understands the information described in this form and freely consents to participate. A copy of this form has been provided to the participant.

Name of Investigator/Clinic staff_____

Signature:_____**Date**:_____**Time**:_____

If applicable:

I have witnessed the accurate reading of the form to the participant. I confirm that the participant has had the opportunity to ask questions. I confirm that the participant agrees to be part of the study.

Name of Impartial Witness<<*>>: _____

Signature: _____**Date**:_____Time:_____

<<If applicable locally: add this definition: *A witness is a person who is independent from the research team or any team member and who was not involved in obtaining consent.>>
Be reminded that two originals of the form have to be signed (depending of country requirements). Once completed and signed, one original is for the participant and the other one is to be kept as source documentation. (e.g.: investigator site file)

Site Number: *<<Insert Site Identifier>>*
Participant Identification Number for this trial:

PARENT/GUARDIAN CONSENT FORM (FOR MINORS)

Product Code/Name	Zoliflodacin, ceftriaxone and azithromycin
Protocol Title	A multi-center, randomized, open-label, non-inferiority trial to evaluate the efficacy and safety of a single, oral dose of zoliflodacin compared to a combination of a SINGLE intramuscular dose of ceftriaxone and a SINGLE oral dose of azithromycin in the treatment of patients with uncomplicated gonorrhoea.
Protocol Number Version/Date	STI_Zoli001 v4.0 22 October 2021

Name of Investigator: <<Insert>>

I, as the parent / guardian of <<*Insert minor participant name*>> have read the information in this form, or it has been read to me in a language that I understand well. I have had the opportunity to ask questions about it and all my questions have been answered to my satisfaction.
I know that I can refuse to allow my child/ward to participate in the study without suffering any penalty or loss. If I agree to their participation, they can be withdrawn at any time without losing benefits or services to which they or my family are entitled.
I agree that my child / ward can participate in the study. By signing this form, I agree that the personal information about my child/ward will be accessible to GARDP, GARDP's representatives (study team, monitors, auditors), ethics committees or the Food and Drug Administration or other US or foreign regulatory agencies.

Parent/Guardian's full name: _____

Signature: _____**Date**: _____Time:_____

I have explained the study to the participant and answered all of his/her questions. I believe that he/she understands the information described in this form and freely consents to participate. A copy of this form has been provided to the participant.

Name of Investigator/Clinic staff: _____

Signature: _____**Date**: _____Time:_____

If applicable:

I have witnessed the accurate reading of the form to the participant. I confirm that the participant has had the opportunity to ask questions. I confirm that the participant agrees to be part of the study.

Name of impartial witness<<*>>: _____

Signature: _____**Date**:_____Time: _____

<<If applicable locally: add this definition: *A witness is a person who is independent from the research team or any team member and who was not involved in obtaining consent.>>
Be reminded that two originals of the form have to be signed (depending on country requirements). Once completed and signed, one original is for the participant and the other original is to be kept as source documentation. (e.g.: investigator site file)

Site Number: *<<Insert Site Identifier>>*
Patient Identification Number for this trial:

ASSENT FORM (FOR MINORS)

(To be completed in addition to the parental consent for minors. This may not always be required, but it is good practice and should be included in the ethics submission for their review)

Product Code/Name	Zoliflodacin, ceftriaxone and azithromycin
Protocol Title	A multi-center, randomized, open-label, non-inferiority trial to evaluate the efficacy and safety of a single, oral dose of zoliflodacin compared to a combination of a SINGLE intramuscular dose of ceftriaxone and a SINGLE oral dose of azithromycin in the treatment of patients with uncomplicated gonorrhoea.
Protocol Number Version/Date	STI_Zoli001 v4.0 22 October 2021

Name of Investigator: <<Insert>>

I have had chance to read or had read to me the information in this form and the study has been explained to me in a language that I understand. I have been able to ask all the questions I wanted to and my questions have been answered to my satisfaction.
I know I do not have to take part in the study and that I can change my mind at any time during the study if I want to. I know that if I don't take part in the study, I will still receive the best treatment available at the site.
I agree to participate.

Name of Minor:_____

Minor's Signature (*If able*):_____**Date**:_____Time:_____

I have explained the study to the participant and answered all of his/her questions. I believe that he/she understands the information described in this form and freely consents to participate. A copy of this form has been provided to the participant.

Name of Investigator/Clinic staff: _____

Signature:_____**Date**:_____Time:_____

If applicable:

I have witnessed the accurate reading of the form to the participant. I confirm that the participant has had the opportunity to ask questions. I confirm that the participant agrees to be part of the study.

Name of Impartial Witness<<*>>:_____

Signature:_____**Date**:_____Time:_____

<<If applicable locally: add this definition: *A witness is a person who is independent from the research team or any team member and who was not involved in obtaining consent.>>*
Be reminded that two originals of the form have to be signed (depending on country requirement). Once completed and signed, one original is for the participant and the other original is to be kept as source documentation (e.g.: investigator site file)

<<For US sites only>>

Site Number: *<<Insert Site Identifier>>*
Patient Identification Number for this trial:

HIPAA Research Authorization

Authorization to Use and Disclose Health Information

I agree to permit [Name of Institution] and any of my doctors or other health care providers (together "Providers"), study doctor, and [his/her/their/its] collaborators and medical staff (together "Researchers"), to obtain, use, and disclose health information about me as described below.

The health information that may be used and disclosed includes:

1. All information collected during the research and procedures described in the Informed Consent Form (the "Research"); and
2. Personal health information in my medical records that is relevant to the Research, which includes my past medical history, medical information from my primary care physician, and other medical information relating to my participation in the study.

The Providers may disclose health information in my medical records to:

1. The Researchers;
2. Representatives of government agencies, review boards, and other persons who watch over the safety, effectiveness, and conduct of research; and
3. Global Antibiotic Research and Development Partnership, and its affiliates, agents and contractors assisting in the conduct or completion of the study (together, "Sponsor").

The Researchers may use and share my health information:

1. Among themselves, with the Sponsor, and with the other participating Researchers to conduct the Research; and
2. As permitted by the Informed Consent Form.

The Sponsor may use and share my health information for purposes of the Research and as permitted by the Informed Consent Form.

Once my health information has been disclosed to a third party, federal privacy laws may no longer protect it from further disclosure.

Please note that:

1. You do not have to sign this Authorization, but if you do not, you may not participate in the Research. If you do not sign this Authorization, your right to other medical treatment will not be affected.

2. You may change your mind and revoke (take back) this Authorization at any time for any reason. To revoke this Authorization, you must write to the study team at:

NAME:
ADDRESS:
PHONE:

3. However, if you revoke this Authorization, you will not be allowed to continue taking part in the Research. Also, even if you revoke this Authorization, the Providers, Researchers, and the Sponsor may continue to use and disclose the information they have already collected to protect the integrity of the Research or as permitted by the Informed Consent Form.

4. While the Research is in process, you may not be allowed to see your health information that is created or collected during the course of the Research. After the Research is finished, however, you may inspect and obtain a copy of this information.

5. The expiration date for this Authorization is 25 years after the study is completed.

6. You will be given a copy of this Authorization after you have signed it.

Signature of Participant or authorized representative*	Date	Time (hh:mm)
Printed Name of Participant or authorized representative	Date	Time (hh:mm)

*If this Authorization is signed by an authorized representative, please describe the basis of your authority to act for the Participant: