QSC300553

PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FORM

(MEL-DEL-101-3727-1)

TITLE: A study in healthy volunteers to assess how the test medicine is taken up by the body in comparison to an existing tablet formulation and to assess the taste of the test medicine

(A Phase 1, Single Part, Partially Randomised, Open-Label Study to Evaluate the Relative Bioavailability of a Taste-Masked Delafloxacin Powder for Oral Suspension with Oral Delafloxacin Tablet Reference in Healthy Subjects)

We're inviting you to take part in a research study. This study is for research purposes only and you will receive no medical benefit by taking part.

- Before you decide to volunteer it is important for you to understand why we are doing the research and what it involves.
- Please take time to read the following information carefully. Talk to your friends, relatives and whoever you feel is appropriate about the study if you want to.
- When you visit the unit one of our team will go through this information sheet with you to help you decide if you would like to take part or not.
- Please ask us if there is anything that is not clear or if you would like more information. Feel free to ask any questions at any time.
- It's entirely up to you if you want to take part in the study. Take your time to decide whether or not you wish to take part.
- Any reference to gender specific requirements (e.g., contraceptive requirements, female pregnancy/menopause tests, etc) will need to be followed in line with your biological sex, however volunteers of any gender identity can be involved in the study.

A brief summary of the study design is as follows:

- This is a study in healthy volunteers to assess how the test medicine it is taken up by the body in comparison to an existing tablet formulation (reference tablet) and also assess the taste of the test medicine.
- The new test medicine is being developed to treat community acquired bacterial pneumonia in paediatric patients (target age group 2 months to less than 18 years).
- This is a new formulation (recipe) of the test medicine.
- You will be asked to take the test medicine and existing tablet formulation on up to 4 occasions, whilst you are resident in our clinical unit. This will require up to 4 visits to our unit, including screening.
- You may be eligible to take part in this study if you are a healthy male or non-pregnant, non-lactating female and between the ages of 18 to 55 years.
- The study will be conducted at our clinical unit in Nottingham, UK.

- The study will last approximately 14 weeks and is planned to take place in June to August 2024. These dates could be subject to change.

If you receive an invitation for vaccination, please inform the study team.

If you are invited to have a COVID-19 vaccine within 2 days of admission to the clinical unit, please postpone the vaccine, this is due to possibilities of side effects. You are permitted to have the vaccine up to 2 days before admission and at any point after discharge from the trial (after follow up).

We've split this information sheet into 3 Sections.

- Section A will tell you about the purpose of the study and what will happen to you if you decide to take part.
- Section B will give you information on confidentiality, what will happen to the samples that you give, what to do if you have a problem and any contact details you may need.
- Section C contains the Informed Consent Form which you must sign if you would like to take part in the study. This is a form to confirm that you have read and understand all of the information that we have given to you and that you want to take part in the research study.

Quotient Sciences Recruitment Department Contact

0330 303 1000

Table of Contents

Section A

1 Why Are We Doing This Study?

Melinta Therapeutics (the Sponsor) is developing a new test medicine recipe of an approved drug called delafloxacin to treat community acquired bacterial pneumonia in paediatric patients (target age group 2 months to less than 18 years) and is paying Quotient to conduct the study.

Delafloxacin, the active ingredient in the test medicine, is a component of marketed products in the USA, UK and EU. It is available in the USA as Baxdela®, where it is used as either an intravenous (IV; into the vein) or oral tablet (by mouth) antibiotic treatment for adults with skin infections and community acquired bacterial pneumonia. Marketed products containing delafloxacin are marked with a Black Box warning in the USA, which applies to certain medications that carry serious risks for the person taking them. In the UK, these products are part of the Black Triangle Scheme, denoted by an inverted Black Triangle symbol (▼), which means it is being monitored more intensively than other medicines for its side effects. More information on the side effects can be found in Section 8. You will receive a single dose of the US marketed product in this study. As of December 2023, approximately 3117 people have received delafloxacin as an oral or IV treatment across 32 completed trials and approximately 21,000 people have taken marketed delafloxacin worldwide. Delafloxacin works by killing the bacteria that cause infections.

Worldwide, bacterial infections have increased in hospital and community settings, and other current treatments have begun to be ineffective. Delafloxacin remains effective in treating bacterial infections in adults. However, as the medicine is only available only as tablets or IV, the Sponsor is developing a liquid form that will be easier for children to swallow.

This study will also aim to assess the taste of this new recipe of the test medicine, which is a liquid. You will be given a questionnaire on one dosing occasion to complete, to let us know your opinion after dosing with the liquid test medicine.

We are doing this study in healthy people to answer these questions:

- How much test medicine gets into the bloodstream and how quickly does the body get rid of it?
- When the test medicine is given as the new liquid and the current tablet form (reference tablet), how do blood levels of the test medicine compare?
- Optionally, does food affect how the test medicine gets into the bloodstream?
- To assess the taste of the new liquid test medicine

To study the effect of food on how the test medicine gets into the bloodstream, in study visits 2 or 3, we may give you a high-fat breakfast (see Section 3.3) containing bacon, eggs, butter, and milk.

You should only agree to take part in the study only if you are willing to eat the breakfast.

We will also monitor your safety and wellbeing throughout the study.

2 Why Am I Being Asked To Take Part?

You have been invited to be screened to take part in this study because the information we have about you on file seems to match the requirements for the study. We need to perform a medical check to make sure that you can take part (detailed in Section 3.1).

To be able to take part in this study, you must:

- Be a healthy biological man or be a healthy biological woman who is not pregnant and not breastfeeding;
- Not have a pregnant or breastfeeding partner (male only);
- Be between 18 and 55 years of age;
- Have a BMI of 18 to 32 kg/m^2 and weigh at least 50.0 kg;
- Not have participated (received another test medicine) in a clinical research study in the 90 days before the first planned dose;
- Not consume more than 21 units of alcohol per week for men and 14 units of alcohol per week for women (1 Unit = ½ pint beer or a 25 mL shot of 40% spirit, 1.5 to 2 units = 125 mL glass of wine, depending on type);
- Follow the contraception requirements of the study with your partner, as detailed in Section 12.3;
- Not to have any history of drug or alcohol abuse within the past 2 years;
- Be willing to eat the breakfast described in Section 3.3 (which includes pork and dairy);
- Not have donated blood or lost a lot of blood (e.g. through surgery or an accident) in the last 3 months;
- Agree not to donate blood or plasma during the 90 days after the last dose on the study;
- Not have taken any medicines within 14 days before dosing including herbal medicines and vitamins (including those with zinc and iron), antibacterial medicines and antacids (you are allowed up to 4 g of paracetamol per day, as well as hormonal contraception and hormone replacement therapy (HRT));
- Not have had a COVID-19 vaccine within 2 days (48 hours) prior to admission;
- Be a non-smoker or should not have smoked in the last 12 months;
- Not be using e-cigarettes or nicotine containing products and not have used these in the last 12 months;
- Never have had a severe allergic reaction;
- Never have had a history of hypersensitivity to delafloxacin or any other fluoroquinolones, or history of tendon disorders related to fluoroquinolones;
- Not have any diarrhoea or constipation in the 7 days before dosing;
- Not have a disorder of the heart, blood vessels, kidneys, liver, airways and lungs, stomach, small or large intestine, brain or nerves (including psychiatric);
- Not have a medical condition that affects your sense of taste or smell, including mouth ulcers, significant gum disease, airway and/or sinus infection or cold;
- Not have a history of gall stones or had your gall bladder removed;
- Not be an employee, or an immediate relative of an employee, of either Quotient Sciences or the Sponsor company;
- Not have any holidays planned during the study (study dates can be obtained from the recruitment department);
- Be able to understand and follow the requirements of the study.

3 What Will Happen To Me Before, During, And After The Study?

The study will involve up to 4 visits to the Quotient Sciences unit, as follows:

Visit	Fasting Required on Arrival
Screening Up to 28 days before dosing	Yes
Study Visit 1[a] Admission in the morning of Day -1 followed by 7 overnight stays.	Yes
Study Visit 2 and 3[b] Admission in the evening of Day -1 followed by 3 overnight stays at each visit	No
Discharge 2 days after final dose at each study visit	N/A
Follow-Up Phone Call 5 to 7 days after your final dose	N/A

[a] You will be dosed twice at Study Visit 1. There will be a gap of at least 4 days between dosing.

[b] Study Visit 3 may not go ahead. The decision to conduct Study Visit 3 will be based on the information collected at the prior study visit, you will be informed in advance if you are required to take part in Study Visit 3, however you must be available to take part.

The total time you will be involved in this study is expected to be 14 weeks from the screening visit until the follow up phone call. There will be a gap of at least 14 days between study visits.

3.1 Screening Visit

You will attend Quotient Sciences for a medical assessment to check you are suitable to take part in the study: this is known as “screening”.

You must arrive at your screening visit having not eaten or drunk anything other than water for at least 8 hours, so that you have an empty stomach. Any food or drink might affect blood tests such as your blood glucose (blood sugar) levels.

The screening visit will be 1 visit of about 4 hours to check if you are suitable for the study. We might ask you to watch a video before your screening visit, to introduce you to the study – if so, we will give you instructions on how to access and view the video. Alternatively, we might introduce you to the study via a group information session with other volunteers at your screening visit. You will also have the opportunity to ask any questions 1 to 1 with a study doctor.

After you have had enough time to consider the information and ask any questions, we will ask you to sign the informed consent form in Section C of this information sheet. Signing this form confirms that you understand what will happen to you and what you will have to do during the study and that you are happy to take part.

After this, a study doctor will ask you questions about any medicines you have taken, and about your surgical and medical history.

Your GP will be informed of your intent to participate in this trial.

We need a medical report from your GP to confirm your surgical and medical history. If you are a new volunteer, we will request a new medical report from your GP that is dated within 12 months of your screening visit. If you are a volunteer that has previously taken part in a trial at Quotient, we will request a new medical history report from your GP at least every 24 months (2 years). By signing the consent form in Section C, you agree that Quotient can tell your GP that you have volunteered to take part in this study and request a report if one is not already on file.

This medical report will include, but is not limited to:

- Medical and surgical problems you have had in the past or that are ongoing
- Any allergies you have
- Any medicines you have been given
- Any operations or procedures (e.g. X-rays) you have had
- Your reproductive status/contraception

This report might be a full print out of your records held by the GP so might include everything recorded in your medical history. If you tell us about any visits to the GP or hospital or if something is noted in your medical history that we think might be important, we will ask your GP for more details.

You will have the following routine tests at your screening visit:

- A medical, including an electrocardiogram (ECG – a painless test that records heart rhythm) and blood and urine tests, to check that you are healthy.
- Your blood pressure, heart rate and temperature (measured using a thermometer placed in your mouth)
- Blood and urine pregnancy test and/or blood test to see if you have been through the menopause, if you are a woman
- Breath tests for alcohol and smoking, and urine tests for drugs of abuse
- Blood tests for HIV and hepatitis (see Section 13)

We might need to repeat the screening for reasons including, for example, the study is delayed, your results show something unexpected, or there are technical problems. We may contact you to arrange an extra visit if we need to repeat any of the screening tests or if we cannot do all the tests at your scheduled screening visit. We will contact you to arrange an extra visit or confirm if the tests can be repeated at admission.

In cases where medical tests show something unexpected, for safety reasons we might have to perform extra tests to confirm or clarify the test result. Before we do any extra tests, we will discuss them with you and, with your permission, we will inform your GP of any important results during screening that show something unexpected.

The screening procedures could find underlying health conditions that you didn't know you had. They might reveal something you would prefer not to know about, or something that is upsetting or that has implications for your long-term health and lifestyle. We will discuss anything we find with you, and your study doctor will arrange appropriate treatment and/or, with your permission, refer you to your GP.

If we find an unexpected problem during your medical check, this could affect any private insurance policies you may have. If you have any queries, please contact your insurance provider(s).

Once you have had your medical check and we have all your results and reports, the study doctor will decide if you are suitable to take part in the study. You will be contacted by the Recruitment Department to confirm that you should attend for admission to the study visit (see Section 3.2).

3.2 Admission

If you are accepted into the study, you should arrive at the clinical unit for admission in the morning on the day before dosing for Study Visit 1 and in the evening on the day before dosing for Study Visit 2 and 3. Please ensure you eat a meal before arriving at the unit for your evening admission. An evening snack will be provided later in the evening prior to bedtime. The exact time will be arranged with you before you attend. Sometimes we have to change the dates of our studies at short notice. If this happens, we will discuss the new dates with you.

You should arrive having not eaten or drunk anything other than water for at least 8 hours for Study Visit 1 only.

When you arrive at the clinical unit, we will do a bag search to check for any items that are not permitted in the unit during the study, such as medicines, food, and drinks. CCTV is also used to monitor the entry and exit to the clinical unit.

We will ask about your health since your last visit. We will do some extra tests at admission to make sure that you are still suitable to take part in the study. These tests are listed in the table in Section 3.7. If there are any problems with these tests, the study doctor may decide that you are not suitable to be dosed. We will give you meals at appropriate times on the day of admission.

3.2.1 Reserve Volunteers

We need to have extra volunteers on standby just in case of non-attendance, exclusion, or last-minute withdrawal. All volunteers who are invited will be admitted to the clinical unit on the day before dosing. The decision on who will be dosed will be based on your eligibility and other logistical reasons, for example, availability and willingness to participate in other groups or studies. We can't promise you a place on the study.

You should not come to the clinical unit until a member of the Recruitment Department has spoken to you and confirmed that you should attend.

Reserve volunteers usually need to stay overnight in the clinical unit until all the included volunteers in the group have been dosed. This means you may be asked to stay up to lunch time on the dosing day.

You must make sure you are available for the whole study in case we need you to take part.

Reserve volunteers are reimbursed for their time and inconvenience (see Section 11.1.1).

In every case, the final decision on "included" and "reserve" volunteers will be made by the study doctor at Quotient Sciences.

3.3 Study Visit(s)

If you are accepted into the study, you will attend the clinical unit for up to 3 study visits where you will be dosed with the test medicine and reference tablet on up to 4 occasion(s). When we admit you to the clinical unit, we will ask you about your health and any medicines you have taken since your last visit. You will have many procedures at your visits, detail of this can be found in Section 3.7.

3.3.1 Food and Fluid Requirements

You must eat the food we give you, and nothing else, because we need to ensure that what you are eating doesn't contain ingredients that might interfere with the test medicine.

<u>Fasted dosing</u>

On the evening before each dosing day, you will be given a light snack before bedtime and then you will not be allowed to eat or drink anything other than water for at least 10 hours before dosing until 4 hours after dosing.

You will have lunch at about 4 hours after dosing, an evening meal at about 10 hours after dosing and an evening snack at about 14 hours after dosing. On days when you do not receive test medicine, meals will be provided at appropriate times. The standard menu at Quotient Sciences includes vegetarian options, although there may not be options suitable for all restricted diets.

We might ask you to fast more often or for longer than we planned, but we won't ask you to fast for longer than 18 hours.

Fed dosing

Fed dosing may be selected in Study Visit 2 and/or 3.

On the evening of admission (Day -1), you will be given a light snack before bedtime and then you will not be allowed to eat or drink anything other than water for at least 10 hours until breakfast. You will have a high fat breakfast on the morning of dosing, 30 minutes before you take the test medicine.

You must eat all the breakfast provided within 25 minutes. Meals served before dosing must be eaten on the ward so that clinical staff can keep track of how much you eat and how long it takes.

The high fat breakfast will consist of the following;

- 1 fried egg
- 2 strips of unsmoked bacon
- 2 slices of sliced white bread with unsalted butter
- 1 hash brown
- A glass of whole milk (240 mL)

You should agree to take part in the study only if you are willing to eat this breakfast.

Lunch will be provided at about 4 hours after dosing, an evening meal at about 10 hours after dosing and an evening snack at about 14 hours after dosing. On days when you do not receive test medicine, meals will be provided at appropriate times. The standard menu at Quotient Sciences includes vegetarian options, although there may not be options suitable for all restricted diets.

Fluid requirements

You will not be allowed to drink water for 1 hour before dosing until 1 hour after dosing (except for the water provided with your dose). You will be allowed to drink water freely from 1 hour after dosing and decaffeinated drinks from around lunchtime on the day of dosing.

3.3.2 Details of Dosing and Post Dose Requirements

At Study Visit 1 you will be dosed with a single oral dose of the test medicine and reference tablet on Days 1 and 5. The order in which you receive the test medicine or reference tablet will be randomly allocated (by chance) meaning you might receive it in a different order to the person next to you.

You will be asked to swallow the test medicine in the form of an oral suspension (liquid) in a bottle. The dosing bottle will then be rinsed with water and given to you to drink. The total liquid volume consumed will be 240 mL. The reference tablet will be given to you to swallow with 240 mL of water.

At Study Visit 2 and 3 you will be dosed with the test medicine in the form of the oral suspension (liquid) on Day 1 only. All volunteers are these visits will be given the same treatment.

You will receive your morning dose at any time before lunch time on the day of dosing. Subsequent procedures will be calculated from the time of your first dose.

During Study Visit 1, following dosing with the oral suspension (liquid) only, you will be asked to fill out a questionnaire to assess the smell, sweetness, bitterness, flavour, mouthfeel/texture, grittiness, and aftertaste of the test medicine. It is important you complete your questionnaire in private and do not discuss the results or tastes with anyone as it may influence other volunteers' opinions and impact the study results.

At each study, visit you must stay on site for 2 days after your final dose for more study procedures (see table in Section 3.7).

The study doctor can withdraw you from the study at any time. You can be withdrawn because of safety reasons or if you fail to follow the study instructions or restrictions, or if the study is stopped by the Sponsor or terminated at the Quotient study site.

3.4 Blood Samples

We will collect blood samples (for measurement of the test medicine and for safety assessments) often while in the clinical unit.

In total, we will collect blood from you on approximately 40 occasions on study visit 1 and 20 occasions at study visits 2 and 3 (a total of approximately 80 occasions throughout the whole study). Multiple blood samples may be taken at each occasion.

The total amount of blood taken from you during the whole study, including the screening visit and follow-up will be approximately 350 mL over the whole study and is not expected to exceed 550 mL in a 4-week period. For comparison, the amount taken during a single blood donation is about 470 mL, which is just under a pint.

On days where there are several blood samples (e.g. Day 1 and all busy PK/PD blood sampling days), we prefer to take blood samples using a cannula (small plastic tube) placed in a vein in your arm, which stays there until we have finished taking samples. This is so that we don't have to keep using needles on days when multiple blood samples are needed. On days when there are only 1 or 2 blood samples, we will use a needle.

No blood samples for genetic testing will be taken in this study.

3.5 Discharge

Before leaving the clinical unit (2 days after your last dose at each study visit), we will perform another bag search to check for items that are not permitted to be taken home. We will also do some tests before you leave to check that you have come to no harm. These tests are listed in the table in Section 3.7. If we have any concerns about your safety, we may ask you to stay for extra safety tests. You could be discharged from the clinical unit around lunchtime after we have finished all the required tests.

The exact date and time will be discussed with you before you leave the clinical unit.

3.6 Follow Up Phone Call

Once you have finished the study, or if you withdraw from the study, we will give you a short phone call to check on your wellbeing. This will be between 5 and 7 days after you receive your final dose of test medicine and will last about 10 minutes. A date and time will be arranged with you before you leave the unit.

If you experience any side effects of concern, you may be asked to attend an unscheduled follow up visit to the clinical unit to check on your wellbeing. During this visit you will have the following procedures:

- blood and urine safety tests
- ECG
- blood pressure and heart rate.

3.7 Summary Of Study Tests

During your stay on the ward, you will have many tests and procedures. We will often: ask you how you are feeling; measure your heart rate, blood pressure, temperature and breathing rate; do medical examinations; ask you to complete taste questionnaires and record ECGs.

During the study, we will take many samples of your blood to:

- Measure levels of the study medicine (and its breakdown products)
- Do safety tests to check that you have come to no harm

We will also ask you to collect urine samples for safety tests.

Your study tests are summarised below.

Test	Admission	Day 1	Day 2	Discharge Day 3
Breath test for smoking and alcohol, urine tests for drugs of abuse	X			
Urine Pregnancy test (if female)	X			X
Blood samples [d]	◄———	———	———	———►
Urine samples	X[b]	X[c]		X
Questions about how you are feeling; heart rate, blood pressure, temperature, breathing rate; medical examinations; and ECGs	◄———	———	———	———►
Taste Questionnaire (liquid test medicine only)		X		
Administration of test medicine [a]		X		

[a] You will be dosed twice at Study Visit 1. There will be a gap of at least 4 days between dosing and Days 1 to 3 will be repeated where you will remain in the clinical unit discharging on Day 7.
[b] Study Visit 1 only.
[c] Study Visit 2 and 3 only
[d] Blood Samples at Admission will be taken on Study Visit 1 only

We might do some of the tests described above more or less often than we planned, or change the times of the tests. We might do extra, unplanned tests to find out if you have come to any harm, or to investigate possible side effects of the test medicine. If this is the case, we will tell you what these tests are before we do them.

3.8 Your Study Design Explained

It is planned you will be 1 of about 16 volunteers involved in this study.

This is an open label, partially randomised study. You will take part in up to 3 Study Visits and may be dosed with different dose levels of the test medicine. In Study Visit 1, you will be dosed twice, once with 450 mg of the new liquid test medicine and once with 450 mg of the reference tablet, to see how they compare when given at the same dose level. Study Visits 2 and 3 may look at changing the dose of the test medicine or may keep the dose level the same and look at the effect of giving the test medicine with food. On all occasions, both you and the clinical team will know what treatment you are receiving.

During Study Visit 2 and/or 3 it is possible you could receive the test medicine fasted or following a high fat breakfast. There will be a decision made after Study Visit 1 and 2 to determine which dose amount you will receive in the coming Study Visit and if you will be fed or fasted before dosed.

There will be a break of at least 4 days between dosing in Study Visits 1 and at least 14 days between dosing between Study Visits 3 and 4. This will allow your body to get rid of the test medicine before you receive another treatment.

All the treatments will be compared at the end of the study.

4 Do I Have To Take Part?

No, it is entirely up to you if you take part or not. If you decide not to take part this will not affect whether we include you in future studies at Quotient Sciences.

5 What Happens If I Change My mind?

If you do decide to take part, you can withdraw from the study at any time without giving a reason. If you withdraw, we will stop collecting information about you and you can ask us to destroy any samples we have taken but not yet analysed (see Section 17). We will strongly advise you to attend a follow-up visit for your own benefit and to ensure your safety. If you agree to the follow up, we will collect more information and results from you that will be processed as part of the study results (see Section 17).

Withdrawing from the study will not affect the standard of care you will receive or the benefits to which you are otherwise entitled. You should only volunteer if you have time to complete the whole study.

6 Can I Be Taken Off The Study?

The study doctor can withdraw you from the study at any time (from screening to final visit). You can be withdrawn because of safety reasons or if you fail to follow the study instructions or restrictions which you have agreed to.

7 What If New Information Becomes Available?

Sometimes we may be given new information during the study about the test medicine being studied after you have given consent or during the study. If this happens your study doctor will tell you about it and discuss with you if you want to continue in the study. Your study doctor might also decide you should not continue in the study. If you and the doctor are happy for you to continue in the study, you will be asked to sign an updated informed consent form.

8 Will There Be Any Side Effects?

Delafloxacin, the active medicine in the test medicine, is already available in multiple countries and is known in the USA as Baxdela®, where it is used as either an intravenous (IV; into the vein) or oral tablet (by mouth) antibiotic treatment for adults with skin infections and community acquired bacterial pneumonia. Delafloxacin is also a market authorised medicine in the UK, known as Quofenix®, for the treatment of acute bacterial skin and skin structure infections and community-acquired pneumonia.

Many people worldwide have taken the medicine. As of December 2023, approximately 3117 people have received delafloxacin across 32 Phase 1 to Phase 3 clinical studies. The active medicine in the test product has been well tolerated in all studies.

Currently, oral tablets of delafloxacin are licensed for use at the dose of 450 mg twice a day. So far, approximately 1115 healthy volunteers have taken single doses of test medicine of up to 1600 mg and repeated doses of up to 1200 mg in previous Phase I clinical trials. In this study, we plan to test single doses of the test medicine which will achieve a level 2 to 3-fold below the level seen in the body with the maximum dose tested in previous Phase I clinical trials. This dose is expected to be safe and well tolerated in the liquid test medicine form and will help develop a dose with similar amounts of medicine available within the body as the 450 mg tablet.

Like all medicines, delafloxacin has side effects. The following side effects were reported by people participating in clinical studies for this test medicine, including patients.

Common side effects that may affect up to 1 in 10 people are:

- Fungal infection
- Headache
- Vomiting
- Increase in the amount of enzymes produced by your liver
- Itching

Uncommon side effects (may affect up to 1 in 100 people):

- Reduction in the number of white cells in the blood (leukopenia)
- Low haemoglobin level (anaemia)
- Allergic reaction

- High blood glucose levels
- Decreased appetite
- Difficulty sleeping (Insomnia)
- Muscle weakness in the arms and legs
- Sensations like numbness, tingling, pins and needles
- Reduced tactile sensation
- Change in taste
- Feeling your heart beat (palpitation)
- High blood pressure
- Flushing (e.g. redness of the face or neck)
- Inflammation of the lining of the stomach, inflammation of the internal tissues of the mouth, abdominal pain, stomach discomfort/pain or indigestion, dry mouth, flatulence
- Abnormal sweat
- Allergic skin reaction
- Itchiness, red rash
- Joint pain
- Pain and swelling of the tendons
- Muscle and musculoskeletal pain (e.g. pain in extremity, back pain, neck pain), muscle weakness
- Increased level of creatine phosphokinase in blood (an sign of muscle damage)
- Reduced kidneys function
- Feeling tired
- Blood test changes related to liver function (blood alkaline phosphatase increased)
- Raised body temperature (pyrexia)
- Lower limb swelling

Rare side effects (may affect up to 1 in 1000 people):

- Urinary tract infection
- Inflammation of the nasal mucosa tract
- Decrease of special blood cells necessary for blood clotting
- Changes in tests which measure how well your blood clots
- Seasonal allergy
- Low blood glucose levels
- High level of uric acid
- High level of blood potassium
- Low level blood potassium
- Hearing things that do not exist (auditory hallucination)
- Anxiety
- Abnormal dreams
- Confusion
- Drowsiness (Somnolence)

- Feeling lightheaded or faint, usually because of a drop in blood pressure
- Dry eye
- Dizziness or loss of balance (vertigo)
- Ringing or buzzing in the ears (tinnitus)
- Alteration of the sense of balance
- Irregular or rapid heart beats, decrease of heart beat
- Swollen, red, irritated veins (phlebitis)
- Blood clot, known as a thrombus in the deep vein
- Heartburn/acid regurgitation
- Reduced or loss of tactile sensation at the mouth
- Burning sensation in the mouth
- Discoloured poo (faeces)
- Blood test changes related to liver function (blood albumin decreased and gamma- glutamyltransferase increased)
- Cold sweat
- Night sweat
- Abnormal hair loss
- Muscle spasm
- Muscle inflammation/pain
- Inflammation of joints, pain in hands or feet, back pain
- Blood in urine
- Cloudy urine because of the presence of solid component
- Chills
- Worsening of a wound
- Swelling in the limbs (Oedema peripheral)

Serious side effects are rare, but delafloxacin and this type of medicine can cause:

- Joint pain and damage
- Muscle aches and pain
- Pain, numbness and tingling of hands, arms or feet
- Low mood
- Severe headaches
- Confusion
- Serious and fatal allergic reaction

Please notify the study staff immediately if you experience any symptoms, whether or not you think they are caused by the test medicine.

There may be delayed side effects associated with delafloxacin which could not be present whilst you are in the clinical unit and may occurs weeks after dosing. Some of these include, but are not limited to:

- Tendinitis (inflammation of the tendons particularly in the ankle or calf)

- Tendon rupture (tearing/damage of tendons)
- Muscle & joints weakness and pain
- Diarrhoea
- Central Nervous System effects (such as hallucinations, anxiety, depression, trouble sleeping, severe headaches and confusion)

If you experience any delayed side effects after the completion of the study, please report these to your GP and the study staff. Contact details and details of the test medicine are present on the Trial Participation Card which can be used if you experience any delayed side effects.

As with any new medicine, the test medicine might affect an unborn child. So, you must not take part in the study if you are pregnant or planning to start a family in the next few months. Please refer to Section 12.3 for more information on contraception and pregnancy.

All medicines have the potential to cause severe isolated reactions, which may be life-threatening. As with any medicine, there is a risk that a rare or previously unknown side effect will occur. The clinical unit is fully equipped to care for you if you should suffer a severe reaction. Additionally, the unit is very close to the Queen's Medical Centre, a large hospital in Nottingham and you can be taken here within 10 minutes in the case of an emergency.

9 What Are The Possible Disadvantages And Risks Of Taking Part?

- **Blood sampling -** During the study you will have frequent blood samples taken. This is a standard procedure which is unlikely to cause you any problems but can sometimes cause discomfort. Collecting a blood sample from a vein may cause pain, swelling, bruising, light headedness, fainting, and very rarely, clot formation, nerve damage and/or infection at the site of the needle stick.
- **ECG monitoring -** You may have minor discomfort, like removing a plaster, when we remove the electrodes taped to your chest to measure your heart's electrical signals. A reaction to the electrode tape may cause redness or swelling of your skin.
- **Test medicine -** The formulation (recipe) used for delivery of the test medicine in the study is new and are still being tested to see if they behave as expected and are safe to use.
- **Loss of sleep -** During the study we will have to perform some tests early in the morning or during the night, which we will have to wake you up for. You may be on a ward with up to 19 other people which could mean that your sleep is interrupted.
- **Private medical insurance -** If you have private medical insurance you should check with the company if taking part in the study is considered a 'material fact' that should be reported to the insurance company before agreeing to take part in this study. You will need to do this to ensure that taking part in the study will not affect your medical insurance.

10 What Are The Possible Benefits Of Taking Part?

You will get no medical benefit from the test medicine, however development of a treatment for paediatric bacterial infection and community acquired pneumonia may benefit the population as a whole.

11 What Expenses and Payments Will I Receive?

11.1 Inconvenience Allowance for Completing the Study

You will be given an inconvenience allowance of £4,186 plus travel allowance for taking part in the whole study (as compensation for your time, inconvenience and lifestyle restrictions).

If you are replacing a volunteer who dropped out of the study, you might not complete all of the study periods. We will pay you only for the study periods you attend. We will pay you the same amount per study period as volunteers who do the whole study. We will tell you before you start the study how many periods you will do and how much you will be paid if you finish them all as this may be less than the amount stated above.

This allowance may be reduced if;

- you do not complete the whole study for non-medical reasons or medical reasons not related to the test medicine, but in this instance, payment will be in proportion with the amount of time you have spent in the trial;
- you do not follow the requirements and restrictions of the study;
- you do not follow the rules of the clinic (please refer to your copy of the House Rules).

The allowance will not be increased if study days are delayed.

Travel allowances are calculated on distance travelled. If your travel expenses exceed the calculated travel allowance, a receipt may be required for Quotient to consider whether they can reimburse you in full.

11.1.1 Inconvenience Allowance for Reserve Volunteers

If you are a reserve volunteer you will receive up to £500 plus travel allowance if you are not required for dosing.

11.1.2 Inconvenience Allowance for Volunteers Not Eligible at Screening

If you attend a screening visit but we can't offer you a place on this study, you will receive a screening fee of up to £110 plus travel expenses. If you are offered a place, this is included within the study/reserve expenses listed above.

11.2 If You Are in Receipt of Any Benefits

If you are in receipt of any benefits, you should seek further advice from your benefits provider as to whether the payment that you receive from taking part in this study will affect your eligibility for those benefits.

There may be circumstances when we are required by law to disclose such payments to the relevant authorities when requested.

11.3 If You Are a UK Taxpayer

Depending on your personal circumstances, part of this payment may be classed as income by HMRC. Volunteers are reminded that they are responsible for their own tax affairs.

If you test positive for drugs of abuse (illegal use of drugs) at any time during this study you will NOT be entitled to receive your inconvenience allowance or travel expenses and we reserve the right to remove you from the volunteer panel.

12 What Restrictions Will I Have to Follow?

12.1 General Requirements

You must follow the restrictions we give you before and during the study. This is for your safety and to ensure the data we collect from you during the study is accurate:

- You should be able to attend all study days and stay for the whole length of time;
- You should tell us about any special dietary requirements (e.g. vegetarian, vegan, dislike of certain foods) before you volunteer. The clinic has a fixed menu but vegetarian options are available;
- If you are taking a medicine prescribed by your GP, you must not stop taking it in order to be eligible to participate in this study;
- You must use appropriate contraception (see Section 12.3);
- Please wear appropriate clothing such as trousers and a top, as a physical examination or ECG may require removal of an all-in-one outfit, such as a dress.

12.2 Summary of Study Restrictions

Restricted Item / Activity	How Long For	Why?
Prescription or non-prescription/over the counter medication*	14 days before dosing until discharge from the clinical unit	Other medicines might interfere with the test medicine
Food containing poppy seeds (i.e. poppy seed topped bread)	48 hours before screening and each admission until discharge from the clinical unit	This could cause a positive result on our drugs of abuse test as it is very sensitive
Spicy or high fat foods (e.g. curry or fish and chips or food of a high fibre content, such as All Bran)	24 hours before each admission until discharge from the clinical unit	These types of food can change how fast the test medicine is absorbed into the blood stream
Food or drink containing grapefruit, and cranberry	24 hours before each admission until discharge from the clinical unit	A chemical in these fruits can slow down how long it takes your body to break down and remove the test medicine
Unaccustomed or strenuous exercise	72 hours before screening and each admission until discharge from the clinical unit	This could cause an abnormal blood test
Alcohol	24 hours before screening and each admission until discharge from the clinical unit	Alcohol might interfere with the test medicine and can also cause other side effects
Caffeine or xanthines or products containing these (e.g. chocolate, tea, coffee, carbonated drinks)	24 hours before each admission until discharge from the clinical unit	These chemicals can affect how long it take your body to break down and remove the test medicine

*up to 4g of paracetamol per day, hormonal contraception, and HRT is allowed.

12.3 Contraception Requirements

There is little information available about the effect of the test medicine on an unborn child and so we don't know if it may harm the baby as it grows during pregnancy.

Please note that you must discuss these contraception requirements with your partner.

Male Volunteers

If you are a sexually active man, you must use a condom, even if you have been sterilised (had a vasectomy) or your sexual partner is unable to have a baby (e.g. if they are post-menopausal, already pregnant or you're in a same-sex relationship). This is because your partner could be exposed to the test medicine via sexual intercourse. However, the contraception rules you must follow are based on whether your partner is able to have a baby, as follows.

Men who have NOT had a vasectomy, with partners who could become pregnant

If you have not had a vasectomy (i.e. are not surgically sterilised) and you are sexually active with a female partner who could become pregnant, you must use a condom and your female partner must use an additional method of contraception, from the following list, from the time of informed consent until 93 days after the last time you took the test medicine:

- Combined (oestrogen and progestogen-containing) hormonal contraception that stops the woman's eggs being released: These contraceptives may be given:
  - orally
  - into the vagina
  - patch
- Progestogen-only hormonal contraception that stops the woman's eggs being released. These contraceptives may be given:
  - orally
  - by injection / implant
  - as an intrauterine hormone-releasing system (IUS)
- Implantable intrauterine device (IUD)
- Documented bilateral tubal occlusion

Men who have had a vasectomy, with partners who could become pregnant

If you have had a vasectomy (surgical sterilisation) and you are sexually active with a female partner who could become pregnant, then your partner does not need to use one of the above methods. However, you must still use a condom from the time of informed consent until 93 days after the last time you took the test medicine.

Men with pregnant partners

If your partner is pregnant, you are not eligible to take part in this study.

Men with partners who are unable to become pregnant

If your partner is not able to have a baby (not of childbearing potential) then you must use a condom from your first dose of the test medicine, until the final follow-up call to prevent exposure of your partner to the test medicine.

Men who do not have sex as part of their usual lifestyle

If you do not normally have sex (abstinence), this will be acceptable, but only if this is what you normally do. Periodic abstinence (not having sex occasionally) and withdrawal are not acceptable methods of contraception.

All men

You must not donate sperm from the time of informed consent until 93 days after you last took the test medicine.

Women who are able to have a baby (women of childbearing potential)

If you are a woman who is able to have a baby, and you are sexually active with a male partner, you must use a method of contraception, from the following list, from the time of informed consent until 33 days after you last took the test medicine:

- Combined (oestrogen and progestogen-containing) hormonal contraception that stops the woman's eggs being released: These contraceptives may be given:
  - orally
  - into the vagina
  - patch
- Progestogen-only hormonal contraception that stops the woman's eggs being released. These contraceptives may be given:
  - orally
  - by injection / implant
  - as an intrauterine hormone-releasing system (IUS)
- Implantable intrauterine device (IUD)

You do not have to use any of the above contraceptive methods if you have had your tubes tied (bilateral tubal occlusion) or have had an operation to remove your womb, both ovaries or both fallopian tubes. You also do not need to use any of the above contraceptive methods if your sexual partner has been surgically sterilised by a vasectomy or you are in a same-sex relationship.

Women who do not have sex as part of their usual lifestyle

Alternatively, if you do not normally have sex (abstinence), this will be acceptable, but only if this is what you normally do. Periodic abstinence (not having sex occasionally) and withdrawal are not acceptable methods of contraception.

All Women

Women of childbearing potential should not donate eggs from the time of dosing, throughout the study and for at least 33 days after you last took the test medicine.

Women who are unable to have a baby (Women not of childbearing potential)

Women who are unable to have a baby do not need to use any methods of contraception. A woman is considered to be able to have a baby, unless she is has been through the menopause or she has had surgery that permanently prevents pregnancy, including:

- Hysterectomy (removal of the womb)
- Bilateral salpingectomy (removal of both fallopian tubes)
- Bilateral oophorectomy (removal of both ovaries)

Women who are unable to have a baby should not donate eggs from the time of dosing, throughout the study and for at least 33 days after you last took the test medicine.

All Volunteers

If you or your partner become pregnant after you take the test medicine and during the study, including confirmed after completion of the study, you must inform the study doctor immediately. For safety reasons, it is important for the Sponsor and the study doctor to follow up the pregnancy until the end, to check if there are any effects on the child. Please refer to Section 17 for information on what would happen to information we collect about the pregnancy.

13 HIV and Hepatitis B and C Testing

During the screening visit you will be tested for HIV and Hepatitis B and C.

13.1 HIV (Human Immunodeficiency Virus)

HIV is the virus which causes AIDS (Acquired Immune Deficiency Syndrome). It is a serious disease which decreases the body's resistance to infections and other illnesses.

13.2 Hepatitis B and C

Hepatitis B and C are viral infections that cause inflammation of the liver. They are serious diseases that both may lead to long term liver damage and eventually liver failure. These might also result in the development of liver cancer.

13.3 How are HIV and Hepatitis B and C Transmitted?

HIV and Hepatitis B and C are almost always transmitted from infected blood or other infected body fluids (e.g. semen, vaginal secretions, breast milk). The most common way of passing these on are through sexual intercourse or through contact with blood.

People who test positive for HIV or Hepatitis B or C cannot take part in the study because they might be at greater risk of side effects from the test medicine. We need to test your blood for these viruses to ensure that you do not currently have an active infection with one of these viruses, and are free from these infections. If you think that you are at risk of infection with HIV or Hepatitis B or C, you should discuss this matter with your own GP or by visiting the Genito-Urinary Medicine (GUM) clinic in Nottingham (located at Nottingham City Hospital; Tel: 0115 969 1169) or a clinic nearer to you.

13.3.1 How Will I Be Tested?

You will be asked to give your consent for a HIV and Hepatitis B and C test to be carried out. A sample of blood will be taken from your arm during your screening visit, which will be tested for all these viruses.

13.3.2 I've Never had Hepatitis. Why Do I Need To Be Tested For Hepatitis B or C?

The initial infection with Hepatitis B or C virus may cause only a very mild illness or even no illness at all. Some people may acquire the Hepatitis B infection from their mothers before birth and so never realise that they have been infected. Even if the initial infection was very mild, people can still become long term carriers of the virus. Infection can be difficult to detect without a blood test as carriers may appear to be perfectly fit and well for many years, although some of them may develop severe liver disease eventually.

13.3.3 What If I've Had a Hepatitis B Vaccine?

We will still need to check for infection as the vaccine is not always 100% effective. If you have had the vaccine, this won't interfere with the results of the test for infection.

13.3.4 Who Will Know The Result Of The HIV And Hepatitis Tests?

Your test results will be reviewed by the study team. Your results will be filed with your study notes and handled in a confidential manner. Your GP will only be told if a result is positive. By signing the informed consent form (Section C), you are giving us your permission to notify your GP but we would try to let you know first, before doing this. Only if we were unsuccessful in contacting you for follow up after several attempts, would we notify your GP without speaking to you first. In this case, all correspondence with your GP will be strictly confidential. Hepatitis B and Hepatitis C are notifiable diseases in England which means that the UK Health Security Agency (UKHSA) must be notified if a positive result is confirmed.

13.3.5 What Happens If I Do Not Give Consent For The Test?

The test forms part of the study requirements therefore if you do not want to have the sample taken, if you are not willing to provide consent and/or do not want us to inform your GP of a positive result, this would mean you will not be eligible to proceed onto the study.

13.3.6 What Happens If A Result Is Positive?

If you have a positive Hepatitis B, C or HIV result, you cannot take part in this study. If this result is confirmed, you will also not be able to participate in any future healthy volunteer studies. This is for your own safety and wellbeing. As with any new medicine, the side effects of the test medicine are not known. The test medicine could worsen the harmful effects of the viruses and the viruses could increase the risk of side effects of the test medicine.

You will be informed of the result by a study doctor. The study doctor will refer you to a GUM clinic or your GP as appropriate. Hepatitis B and C are notifiable diseases in the UK which means that, by law, the UKHSA must be notified of any positive result. Quotient will report any positive Hepatitis B and C test results to the UKHSA along with your personal details including: your full name, home address, date of birth, sex, ethnicity, and contact telephone number. By signing the informed consent form (Section C), you are giving us your permission to notify all relevant parties including your GP or your local GUM clinic, depending on your preference, but we would try to let you know first.

A negative HIV test does not necessarily mean that you are not infected, as a test may not reveal the presence of infection for 3 months after exposure.

14 COVID-19 Monitoring and Prevention.

COVID-19 is an infectious disease that can affect your airways and lungs. The most common symptoms are a high temperature, a new continuous cough and a loss or change to your sense of smell or taste. Other symptoms can include: shortness of breath, feeling tired, aching body, sore throat, blocked or runny nose.

Quotient will decide what procedures are appropriate for the monitoring and prevention of COVID-19, based on current infection rates and government guidance. Quotient staff will inform you of any COVID-19 control measures in place when you visit the unit. Those measures may include social distancing, increased hand-washing, use of face masks and / or COVID-19 testing, which is described below.

14.1 COVID-19 Antigen Test

You may need to have antigen tests for COVID-19, to check whether you are currently infected with the virus. The antigen test involves taking a swab from your nose. The test may cause momentary discomfort, because the back of the nose is a sensitive area, but it should not be painful.

14.1.1 What if I Test Positive

If you test positive on the antigen test or the results are not certain, we may ask you to take another antigen test to confirm that the first result was truly positive. If your result is positive, you are considered to have an active COVID-19 infection and can pass on the virus to other people. You may not be able to take part in the study, but we may be able to move or delay your study visits so that you can take part when you are no longer infected. You should follow any advice from the UK government on COVID-19 infection.

14.1.2 What will Happen to My Test Samples?

Nose swab samples will be labelled with your volunteer panel number, initials and date of birth. The samples will be tested immediately at Quotient. Your sample will be discarded after the test has been done.

Testing sites must provide your COVID-19 test results and the following details to the United Kingdom Health Security Agency (UKHSA): your full name, home address, date of birth, sex, contact telephone number and email address.

14.1.3 Who Will Know the Results of My Test Samples and How Will My Data Be Handled?

If your samples have been sent to a UK laboratory for analysis, they will know the results of the test and will send the results to Quotient. Your test results will be reviewed by the study team at Quotient. Your results will be filed with your study notes and handled in a confidential manner. Access at Quotient is restricted to staff with a need-to-know.

By signing the informed consent form (Section C), you are giving us your permission to notify all relevant parties, including your GP, of your results, but we would try to let you know first. If you do not give consent, you may not be able to take part in the study if COVID-19 testing is a current requirement.

Your COVID-19 test results will not be included in the study results. Quotient will be the data controller and the legal basis for the processing of your results and information will be Quotient's legitimate interest. You can ask us for a copy of your information and request corrections. You can object to our processing your records, or ask us to restrict our processing or erase your records. We may not be able to comply with all your requests – for example, we must, by law, share COVID-19 test results with the UKHSA. Also, if you object to our processing or ask us to restrict our processing or erase your records, there is a possibility you will not be able to take part in a study at Quotient if COVID-19 testing is a requirement due to current infection rates and government guidance.

The legal basis for collecting and sharing the information required by the UKHSA is legal obligation. Your test data will be used by test laboratories and by Quotient for only as long is needed to comply with the law, or for the study, if you are later enrolled. If you have any questions, please see Section 17.9 or details of whom to contact.

15 What Happens When The Study Stops?

There will be no continued provision for your care after the trial as this is a healthy volunteer study.

Section B

16 What If There Is A Problem?

16.1 If You Feel Unwell

When you are discharged from the clinical unit after you have taken the test medicine, you will be given a trial participation card which will have a 24 hour phone number that you can use to contact the study doctor.

Please carry this card with you and, if you feel unwell at any time after discharge, please contact the unit in the first instance. If you prefer to visit your GP, please take your trial participation card with you and tell your GP that you have recently taken part in a study at Quotient Sciences. If in the unlikely event that you need to attend the A&E Department of your nearest hospital, please ensure your trial participation card is with you.

16.2 Complaints

If you have any medical queries about this study after you have been discharged from the clinical unit, you should contact 0330 303 1000 and ask to speak to the study doctor. For any out of hours queries see your trial participation card.

If you have any concerns about the way you have been dealt with, please contact the Recruitment Department, Quotient Sciences, Mere Way, Ruddington Fields, Nottingham, NG11 6JS (see Page 2 for contact telephone number).

16.3 Harm

If your health or wellbeing is affected as a result of taking part in the study, the Sponsor will provide compensation to you in accordance with the Association of the British Pharmaceutical Industry "Guidelines for Phase I Clinical Trials 2018 Edition".

The Sponsor will pay compensation for any injury resulting from participation in the trial, without the need to prove fault on the part of the Sponsor or anyone else connected with the trial.

Any payment would be without legal commitment (please ask if you wish for more information on this). The Sponsor would not be bound by these guidelines to pay compensation where the injury resulted from a medicine or procedure outside the study or where you did not follow the restrictions laid out in this document. Quotient have appropriate insurance to cover incidents outside of the study which may cause harm.

The amount of compensation shall be calculated by reference to the amount of damages that would commonly have been awarded for similar injuries by an English court had liability been admitted. The amount of compensation will be reduced if you are partly responsible for the injury or if you have been compensated under another insurance policy.

You and the Sponsor shall refer to an independent person any dispute or disagreement about the compensation undertaking. If you and the Sponsor cannot agree on the identity of an independent person, the President of the Royal College of Physicians, London will be invited to appoint an independent person with the power to consult an advocate of not less than 10 years standing on any issue of law including the amount of damages to be paid.

The contractual commitment to compensate you shall follow the laws in England and, subject to the provisions above, the English courts shall have sole jurisdiction over any dispute that may arise out of it. You are not giving up any of your legal rights by taking part in the study.

If you would like an explanation of these legal terms please feel free to ask.

If you want to contact us regarding a study-related injury, please contact the Recruitment Department on 0330 303 1000.

For more information on insurance and compensation in the event of injury in Phase I clinical trials, please see the Association for the British Pharmaceutical Industry (APBI) guidelines that can be found online using the following link:

https://www.abpi.org.uk/publications/ct-compensation

You can also contact the ABPI for independent help and advice (2nd Floor Goldings House, 2 Hay's Lane, London SE1 2HB: telephone 020 7930 3477).

17 How Will My Personal Information be Handled?

17.1 What Happens to My Personal Information?

Your personal information will be used to help the Sponsor and Quotient to conduct the study and understand more about the study drug.

Quotient will record baseline measurements and test results which may include blood pressure, heart rate, body temperature, breathing rate, blood tests, ECG, and lists of medical conditions and medicines you have taken, to document your health before you were given a study drug or underwent a procedure. This information will be added to your volunteer record at Quotient to enable comparisons with any study data which may be generated in future.

17.2 What Personal Information is Collected About Me for the Study?

The study doctor and other study staff will collect your personal information. This may include:

- your name, address and telephone number, along with your passport or national insurance number and photograph;

- your initials, age, date of birth, sex and ethnic background;
- lifestyle information, health and medical history;
- your study treatments and response to study treatments; and
- results of tests on your biological samples (e.g. blood, urine).

17.3 Who Has Access to My Personal Information?

All your personal information collected for this study will be stored in the study medical records at the Quotient site.

Sponsor staff, representatives of companies who work with or for the Sponsor, and others may check the study records. This is done to make sure that the study is being run properly.

Regulatory agencies, such as the Medicines and Healthcare products Regulatory Agency (MHRA), US Food and Drug Administration (FDA), European Medicine Agency (EMA), or others, review and approve new medicines. These agencies will be granted direct access to your information if required. This is so they can verify clinical trial procedures and/or data.

Only people who really need to will be able to see information that could identify you.

Each of these people or organisations will be under an obligation to keep your personal information confidential.

17.4 How is My Personal Information Protected?

Your personal information will be given a numbered code (such as 123456). Once it is coded, linking it to you is only possible through a code list. The code list is kept secure and confidential at the Quotient study site – Quotient will not send that code list anywhere else. Information that directly identifies you (e.g. name and address) will not be sent to the Sponsor with the study results. We will send information that identifies you only to medical professionals responsible for your care, to experts working with us on the study, or to UKHSA (because we must do that by law, see Section 14).

17.5 How Long Will My Personal Information be Used?

Your personal information will be used for only as long is needed for the study and may be retained for longer, where required by law. Sponsors must usually keep data from clinical trials for at least 25 years after the trial has ended. The study data must also be kept for a minimum of 2 years after development of the test medicine has stopped or if all marketing authorisations planned for the test medicine are in place.

17.6 Will My Data be Transferred?

If your data are transferred, we will always ensure appropriate measures will be taken to protect your personal information. Along with coding your personal information as detailed above, 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 study results 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 your coded information is transferred, the Sponsor makes sure that appropriate and suitable safeguards are used.

We may transfer your coded personal information to:

- the Sponsor who is based in the USA;
- BARDA (Biomedical Advanced Research and Development Authority), who are providing funding for the study and are based in the USA;
- laboratories or clinical facilities which help us to conduct analysis on samples you give us as part of the study some of which are in the USA, and
- couriers or transport companies to enable us to deliver the samples to external laboratories.

Because the information is coded, people who receive it will not be able to work out that it came from you. We will not transfer to anyone more information than they need.

We also need to log your involvement in the study on a national database called The Overvolunteering Prevention System (TOPS). This information will be available to other clinical units and contains the following information:

- your National Insurance number (if you're a UK citizen); or
- your passport number and country of origin (if you're not a UK citizen or have a non-UK passport); and
- the date of your last dose of study medicine (but only if you go on to take part in a study).

For your own safety, your GP will be told if any of the test results show that something might be wrong or if you become unwell as a result of taking part in the study.

17.7 What Right Do I Have to Access My Personal Information?

At any time, you may ask the study doctor to see your personal information. In certain circumstances, you may request:

- to learn more about what is done to your personal information;
- a copy of your personal information; and
- to correct and/or delete your personal information (subject to certain conditions).

You may also:

- object to what is done to your personal information although the sponsor may still be able to carry on processing your information even if you object;
- complain to your local data protection authority (the Information Commissioner's Office in the UK), if your privacy rights are violated; and
- claim compensation for damages or distress incurred or suffered from unlawful use of your personal information, through the courts.

17.8 Who Owns the Study Results?

The Sponsor will be the owner of the study results. The Sponsor plans to use the results, and may get patents, or sell the product in the future, or make profits in other ways. You will not be paid for any part of this.

17.9 Who Should I Contact With Questions about my Personal Information?

For questions or requests regarding how your personal information is handled, or if you want additional information, please contact Quotient's Data Protection Officer, by email: DPO@quotientsciences.com.

Melinta Therapeutics has appointed Willans Data Protection Services (WDPS) whose offices are located at 34 Imperial Square, Cheltenham GL50 1RH as its local Data Privacy Representative in the UK to assist with any queries you may have.

You can contact WDPS at https://www.willansdataprotectionservices.com/subject-access-requests/. But, to retain your anonymity, we recommend that you contact the Quotient Data Protection Officer in the first instance.

17.10 What is a Data Controller?

A data controller collects and processes personal information. It determines why and how it is processed. Melinta Therapeutics is the data controller for this study.

18 What Will Happen To The Samples I Give?

All samples (for example, urine and blood) will be collected on the ward by a trained member of the clinical team. These samples will be analysed and processed in secure laboratories in the UK and USA.

The samples (as described in Section 3.7) you provide in this study will be used only for the development of this test medicine. There are no plans for long-term storage of these samples. Your samples will be destroyed once there is a final study report. This will be about one year after the end of the trial. Any storage of these samples will be in accordance with local law.

Blood and urine samples for safety analysis are labelled with the study number, sample type, date of sample, date of birth, sex and your volunteer panel number.

Blood samples for analysis of levels of test medicine are labelled with the study number, subject number, date of sample and time of blood draw.

19 What Will Happen To The Results Of The Research Study?

Pseudonymised data (information that doesn't identify you directly) from this study may be used to support future development of the test medicine. Quotient will substitute any personally identifiable information (such as your name) with a numbered code (such as 123456); this process is called pseudonymisation. The list which links your information back to the numbered code is kept secure but could be used by Quotient to identify you in the future – for example, if the Sponsor asked Quotient to pass on some important information to participants.

20 Who Has Approved The Study?

The study has been reviewed and approved by the South Central- Berkshire REC.

The clinical study has also been reviewed and approved by the Medicine and Healthcare products Regulatory Agency (MHRA), the government appointed agency for United Kingdom. The MHRA are also responsible for evaluating Quotient Sciences' unit and granting the unit approval to carry out clinical studies.

21 Contact Details For Further Information

If you want any further information on clinical research, please see the UK Clinical Research Collaboration (UKCRC) booklet called 'Understanding Clinical Trials' (http://www.ukcrc.org/wp-content/uploads/2014/03/iCT_Booklet.pdf).

If you require any further information or advice on whether to participate in this study you should contact the Recruitment Department at Quotient Sciences, the contact telephone number for this can be found on Page 2.

If you are unhappy with anything on the study, please follow the complaints advice in Section 16.2.

You will be provided with a signed and dated copy of this information and consent form.

The sponsor will not make the results of the study freely available. If you would like to see a summary of the results of the study, please ask the clinic staff at Quotient. We would not be able to give you a summary until all the results have been analysed, which may be quite a long time after you finish the study.

Thank you for considering taking part in this study.

Volunteer Number

Volunteer initials

Section C

INFORMED CONSENT FORM (QSC300553, SPONSOR STUDY NUMBER MEL-DEL-101-3727-1)

Initials

1. I confirm that I have read and understood the information in this document for the above study. I have had the opportunity to consider the information and ask questions. Any questions I have asked have been answered to my satisfaction. ☐
2. I understand that my participation is voluntary and I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that relevant sections of my medical notes and data collected during the study may be looked at as described in Section 17. ☐
4. I acknowledge that my personal information will be used in the manner and for the purposes set out in this document. This information may include my initials and date of birth and my full name and/or address. In particular, I understand and agree that information about me that is a result of me taking part in the study will be processed by Quotient Sciences Limited and its group companies and data that does not identify me may be used to support future research. Quotient will: ☐
   - Analyse my clinical data during and after the trial, to assess the test medicine and to produce reports;
   - Send coded data which cannot readily be linked back to myself, to the Sponsor to the USA where data protection laws are not as comprehensive as in Europe, for central analysis. Such data may be seen by government regulatory authorities outside of Europe;
   - Hold my data on file and provide to government regulatory authorities in accordance with the government's requirements for clinical trials.
   - I understand that, if I withdraw from the study, I will be asked to have a follow up to check that I have come to no harm. If I agree to attend the follow up, the results and information collected during the follow up will be used as described above.
5. I understand that my GP will be informed of my intent to participate, and I give consent for my GP to send Quotient a report of my medical history (which may be a full print out), which will be used by the study team to assess my eligibility for the study. ☐
6. I understand it is important to tell Quotient Sciences about all medical problems for which I needed to see a GP or nurse, and all medicines I have taken since the date of the last report from my GP. ☐
7. I understand that samples will be screened for HIV and Hepatitis B and C and the implications of a positive result. In the event of a positive result this will be referred to my GP and / or Genito-Urinary Medicine (GUM) clinic (whichever is my preference). ☐

Volunteer Number

Volunteer initials

8. I understand that depending on current infection rates and government guidance, I may be required to undergo COVID-19 antigen testing and I give my consent for this testing. I understand the implication of a positive result and how my data will be handled. ☐
9. I consent to provide blood and urine samples for this trial, and understand what will happen to the samples I provide and the data they generate. ☐
10. I confirm I understand the importance of following the contraception guidance in Section 12.3 and have had the opportunity to consider the information and ask questions. Any questions I have asked have been answered to my satisfaction ☐
11. I agree to take part in the above study ☐

_____	_____	Time ☐☐.☐☐ (24 h clock)	Date ☐☐ ☐☐☐ ☐☐☐☐ Day Month Year
Full Name of Volunteer	Signature		
_____	_____	Date ☐☐ ☐☐☐ ☐☐☐☐ Day Month Year	
Name of Physician / Nurse Giving Information	Signature		

This information and consent form cannot be reproduced without the permission of Quotient Sciences. If you require extra copies to discuss with family, friends or your GP, please contact the recruitment department on 0330 303 1000.