PARTICIPANT INFORMATION SHEET SUMMARY

This summary page provides an overview of the study.
Please make sure you read all the information in the full Participant Information Sheet.

Study Number	**BDD25432**
Study Title	A proof-of-concept, open-label, two-arm scintigraphic crossover study in healthy adult volunteers to investigate the *in vivo* performance of two novel orally administered duodenal targeted drug-delivery formulations.
IRAS ID	**366901**
Sponsor Name	**BDD Pharma**

What is the study?

This is a placebo study, meaning no active medication is involved. The tablets used in this study are designed to pass through the stomach and break down in the first part of the small intestine (the duodenum). In future, tablets like these could be used to deliver medicines to this area, which may be helpful for drug absorption. This study is checking whether the tablets break down in the correct place. There is no medication inside the tablets used in this study.

We are aiming to recruit 8 healthy adult volunteers.

How is the treatment tested?

To see where the tablet breaks down, the tablet is 'radiolabelled' which means a small amount of radiation is added. A special camera called a 'gamma camera' is then used to track the tablet as it moves through your digestive system and to see where it breaks down.

To take these images, you will need to stand still at the camera for up to **20 minutes at a time**.

What will the study involve?

The study will involve 5 visits to the BDD clinical trial site at Glasgow Royal Infirmary. The first visit is a screening visit, lasting about one hour, to check whether you are suitable to take part. There are then 3 assessment visits:

- At the first assessment visit, you will not take any tablets. Instead, you will drink a radiolabelled liquid, and the gamma camera is used to map the shape and position of your stomach and small intestine.
- At the second and third assessment visits, you will be given one of the study tablets (Treatment A or Treatment B). The gamma camera will then be used to track how the tablet moves through your body and where it breaks down.

The final visit is a follow-up visit where safety assessments will take place, this will last approximately 30 minutes.

This study mainly uses imaging to measure the results. No blood samples will be taken during the study visits, other than routine safety blood tests taken at the screening visit.

Data

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.
At the end of the study, we will save some of the data in case we need to check it. We will make sure no-one can work out who you are from the reports we write. The information in the rest of this document tells you more about this.

Please make sure you read all the information in the remainder of the Participant Information Sheet.

PARTICIPANT INFORMATION SHEET

BDD Pharma Ltd
Bio-Imaging Centre
Basement Medical Block
Within Glasgow Royal Infirmary
84 Castle Street
Glasgow G4 0SF
UK
www.bddclinicaltrials.com
Registered in Scotland
Nº. 212868

Study Number	**BDD25432**
Study Title	A proof-of-concept, open-label, two-arm scintigraphic crossover study in healthy adult volunteers to investigate the *in vivo* performance of two novel orally administered duodenal targeted drug-delivery formulations.
IRAS ID	**366901**
Sponsor Name	**BDD Pharma**

INVITATION

You are invited to take part in a research study investigating new placebo tablet formulations. These tablets are being developed to improve delivery of medicines to the start of the small intestine. For this study, the tablets will contain no active medication.

The study aims to recruit 8 healthy, non-smoking adults, who do not take alcohol excessively and who do not take illicit drugs; we will test for your compliance with this throughout the study.

Before you decide to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your General Practitioner (GP) if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part.

This study will take place at BDD's clinical trial site: the Bio-Imaging Centre at Glasgow Royal Infirmary.

WHAT IS THE PURPOSE OF THE STUDY?

BDD have developed a new oral tablet formulation designed to release its contents after leaving the stomach and entering the start of the small intestine (the duodenum). This area of the small intestine has a rich blood supply and is one of the most effective places for medicines to be absorbed into the bloodstream. In future, these new tablets could be used to deliver medication to this area, however, the two formulations in this study are placebo tablets and contain no active medications.

The aim of this study is to assess how well the tablet can release its contents at the intended time and in the correct location using imaging to assess this.

In carrying out the study, we will be looking at:

- The length of time it takes for the tablets to leave the stomach.
- When, where and how quickly the tablets break up in the body.
- Comparing the performance of Treatment A and Treatment B

WHY HAVE I BEEN INVITED?

You have been invited because you have expressed an interest in taking part in studies. You also appear to meet the study criteria, which mainly relate to your age and general health.

DO I HAVE TO TAKE PART?

No. It is up to you to decide whether or not to take part. If you decide to take part, you will be asked to sign a consent form. You will be given a copy of the signed form and this information sheet to keep. If you decide to take part you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive.

WHAT ARE THE FORMULATIONS THAT ARE BEING TESTED?

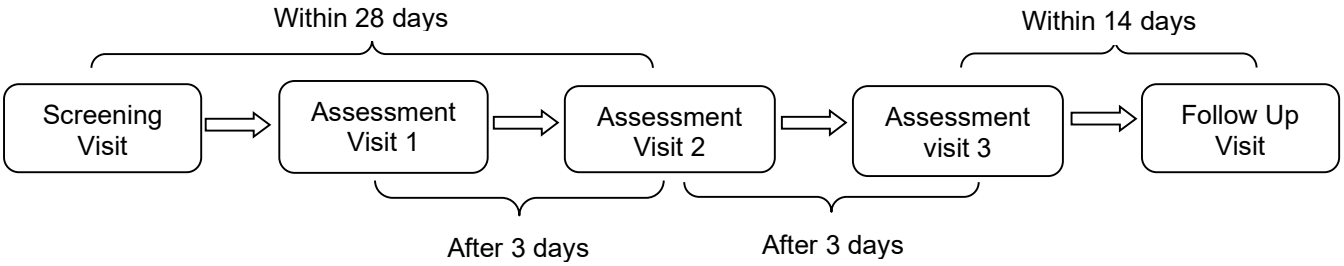
There are 2 formulations being tested:

Treatment A: One radiolabelled placebo P1 (Prototype 1) tablet

Treatment B: One radiolabelled placebo P2 (Prototype 2) tablet

WHAT WILL HAPPEN TO ME IF I TAKE PART?

Your participation will last between 3 to 7 weeks in total. During this time, you will be asked to visit the clinical unit up to 5 times. The following flow chart shows the order in which each visit would happen.



At the screening visit we assess if you are suitable for the trial, this visit will last approximately 1 hour.

The purpose of Assessment Visit 1 is to map out the position and structure of your stomach and small intestine. You will be given a radiolabelled liquid to drink and asked to stand at the camera for up to 20 minutes at a time. The visit should last approximately 3 hours.

Assessment Visit 2 and 3 are when you will be given one of the study placebo tablets (Treatment A or B). Each of these visits will last approximately 5 hours with regular imaging during that time.

You will attend a follow-up visit which will last approximately 30 minutes to carry out safety assessments.

For a full summary of the study procedures at each visit please refer to **Appendix 1**

RADIATION AND GAMMA IMAGING

This study requires exposure to ionising radiation to monitor how each tablet behaves in your body after being swallowed. The radiation emitted will be detected by taking images using a device known as a gamma camera (known as 'imaging').

The gamma camera itself does not give off any radiation. Gamma cameras allow us to produce a picture of where the radiation is in your body and to follow this as the day progresses. The process is painless and simply involves you standing in front of the camera. You are not required to undress, although clothing containing metal should not be worn, e.g. underwire bra, braces or tops with zips.

In this study we will be using a type of radioactive material (known as **technetium-99m**) which is routinely used for imaging studies and for diagnostic purposes. The amount of extra radiation you will be exposed to in this study is 0.26mSv (millisieverts). This amount of radiation is equivalent to approximately 1 month of average background radiation in the UK or equivalent to 3.25 transatlantic flights or 19 chest x-rays.

The risks relating to radiation are discussed in the section below.

WHAT ARE THE POTENTIAL SIDE EFFECTS OF THE TREATMENT RECEIVED?

Placebo tablets

All materials used in the tablets are standard pharmaceutical ingredients which are generally regarded as safe. They are included in quantities typically used in approved medicines.

Potential risk from radiation exposure

If you take part in this study, you will have up to 3 radiolabelled doses (radiolabelled liquid, Treatment A and Treatment B). All of these will be extra to those that you would have if you did not take part. These procedures use ionising radiation to form images of your body.

Ionising radiation may cause cancer many years or decades after the exposure.

We are all at risk of developing cancer during our lifetime. 50% of the population is likely to develop one of the many forms of cancer at some stage during our lifetime. Taking part in this study will add only a very small chance of this happening to you (0.001 %).

The chance of this happening to you as a consequence of taking part in this study is extremely small.

<u>Risk of harm to the unborn child due to radiation</u>

For male participants:

Please share this information with your partner if appropriate.

It is not known whether the radiation dose could affect sperm or semen. You must not father a child during this study or for a safety period of 90 days after your last assessment visit. For this reason, you must only take part in this study if you agree to follow the contraception advice previously described. If your partner becomes pregnant, you should inform the BDD site staff as soon as possible to allow appropriate follow up. An information sheet will be provided to your partner and follow up of the pregnancy and child will only occur with their consent.

For female participants:

It is not known if the radiation dose could affect a developing embryo or foetus and, therefore, you must not be planning to become pregnant during this study. You must only take part in this study if you agree to use reliable contraceptive

methods. If you become pregnant during the study or shortly after we will ask for your consent to collect information on your pregnancy and the baby's health until around 8 weeks after your expected delivery date.

Please refer to **Appendix 2** for further information on contraception and family planning.

WHAT ARE THE OTHER POSSIBLE DISADVANTAGES OF TAKING PART?

Blood sampling

A small needle will be placed into a vein (usually in your arm) for blood sampling at your screening visit (about 20-25mL). You may feel brief discomfort when the needle is inserted. Some people feel faint during or after the procedure.

Minor bruising, redness, swelling, or tenderness may occur at the site. There is a small risk of bleeding, infection, or inflammation of the vein (phlebitis).

Insurance

Some insurance companies regard participation in medical research as a "material fact" which must be declared when applying for or updating health-related insurance, or which could influence their judgement in consideration of claims made under existing insurance policies. You should check that participation in this research does not affect any existing policy or a policy you might be thinking about taking out.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

There are no direct benefits to you in taking part in this study other than receiving information about your general health at your screening visit, however the results obtained could be important for the development of medicinal products which will benefit others.

EXPENSES AND PAYMENTS

For the time and inconvenience involved in participating in this study you will receive inconvenience payments as follows:

£ 650 if you complete the entire study

Travel expenses are covered per mile as per HMRC guidance or public transport costs covered up to a maximum of £20 per visit (reimbursable with receipts).

£ 10 for any additional visits per site outside those scheduled above

You will be paid via bank transfer after completion of your final follow up visit. If you choose to withdraw from the study, do not attend assessment visits, do not comply with study restrictions, do not take the products as directed and/or do not participate in all scheduled procedures you will be paid for the period that you have completed. If, however, having started the study (received any study treatments), the study doctor decides you should no longer take part for medical reasons (e.g. the doctor decides you are at risk), you will receive the full amount.

If you are withdrawn from the study or do not meet the eligibility criteria at the screening visit due to a positive urine test for drugs of abuse or cotinine (test for nicotine use) or a positive breath alcohol test, then you may not receive any financial compensation.

If the investigator or other members of site staff or managerial team have reason to believe that misinformation was deliberately provided at any point during the pre-screening period, screening visit or study duration in order to meet eligibility criteria then you may not receive any financial compensation.

WHAT DO I HAVE TO DO

On your screening visit you will need to bring a form of photographic identification i.e., passport or driving licence and evidence of your national insurance number. A digital photo will be taken of you at your screening visit so you will not need to provide this information at every visit. This digital photo will be securely stored on an electronic server. This will only be accessible by designated individuals on BDD's clinical site.

On each visit, we will ask you to sign an attendance form. It is very important that you attend all scheduled appointments on time.

Restrictions

You must not be taking part in any other clinical studies while taking part in this study. You must also tell us if you have taken part in any other clinical studies in the last year.

You will also be expected to agree to the following restrictions. You will be asked if you have followed these restrictions when you arrive for the assessment visit. If you have not, you may not be allowed to take part in the study.

Lifestyle

- You must fast for at least 5 hours prior to dosing at each assessment visit.
- You must not consume any fluids for 1 hour before or 1 hour after dosing at each assessment visit.
- During the assessment visit, you will not be allowed any food or fluids other than those provided by the study site staff
- You must avoid eating spicy foods (such as food containing chili, jalapeno peppers or cayenne pepper) for 48 hours prior to each assessment visit.
- You must not carry out any strenuous physical activity (such as running, HIIT or other cardiovascular exercise resulting in an increased heart rate) for 24 hours prior to each assessment visit.
- You must abstain from alcohol consumption for 24 hours prior to the assessment visit.
- You must not consume any caffeine or xanthine-containing beverages or foods (i.e., tea, coffee, chocolate, cola, etc.) for 24 hours prior to each assessment visit.

Medications and Treatments

- If you start prescribed medication which has not been approved by the study doctor, you may be withdrawn from the study.
- You must abstain from over-the-counter medication (medication you can get without a prescription) from 48 hours prior to each assessment visit, unless previously agreed with the study doctor.

WHAT IF RELEVANT NEW INFORMATION BECOMES AVAILABLE?

Sometimes during a research project, new information becomes available about the study treatment. If this happens, you will be informed, and it will be discussed with you whether you want to or should continue with the study. If you decide not to carry on, arrangements will be made to complete your study follow up visit. If you decide to continue with the study, you will be asked to sign an updated consent form.

If the study is stopped for reasons not known now, the situation will be fully explained to you.

WHAT WILL HAPPEN IF I DON'T WANT TO CARRY ON WITH THE STUDY?

You are free to withdraw from the study at any time without giving a reason. You will be paid for the part of the study you have completed. If you have taken part in an assessment visit, we would like you to attend for a post study medical examination. All data collected up to this point will be used.

The study doctor can at any time decide to withdraw you from the study, e.g., if:

- Your continued participation involves a risk to you
- You do not show up for the scheduled visits
- You do not take the study products as directed
- You do not participate in all scheduled assessment visit procedures
- You do not follow the study restrictions

The study doctor, Sponsor, or regulatory authorities can also stop the study at any time if new information that could justify such a decision should occur. You will be told if this happens and given the reason.

If, after receiving study treatment, the study doctor withdraws you for safety reasons you will receive the full study payment amount. If you are withdrawn or choose to withdraw for any other reason, you will be compensated for the time you have completed.

WHAT IF I LOSE CAPACITY TO CONSENT DURING THE STUDY?

If, during this study, events occur that result in you being unable to continue to consent to participating in this study, the research team reserves the right to retain the data and personal information collected up to that point. We will continue to use it confidentially to achieve the study objectives. Blood samples would be retained for analysis and then destroyed.

WHAT IF SOMETHING GOES WRONG?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed.

Complaints:

If you have a concern about any aspect of this study, you should ask to speak to the researchers, who will do their best to answer your questions. Please speak to study staff onsite or telephone 0141 552 0126 during normal working hours.

If you remain unhappy and wish to complain formally, you can do this through our complaints procedure. You may discuss your complaint with a member of study staff or with a member of the Site Management Team. All complaints will be taken seriously and handled in strict confidence. In any case, a complaint record will be completed documenting the nature and specific details of your complaint and any follow-up measures to be taken. We may conduct interviews with members of staff in the course of the complaint investigation. We will also document the outcome of the complaint and inform you of this. Complaints may also be sent in writing to the following address:

Complaints, BDD Pharma Ltd, Bio-Imaging Centre, Basement Medical Block, Within Glasgow Royal Infirmary, 84 Castle Street, Glasgow, G4 0SF or e-mail: enquiries@bddpharma.com.

If you wish to raise a complaint on how the research organisation has handled your personal data, you can contact the BDD Pharma Chief Operations Officer who will investigate the matter. If you are not satisfied with their response or believe they are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

Harm:

The Sponsor will provide compensation for any injury caused by taking part in this study in accordance with the guidelines of the Association of the British Pharmaceutical Industry (ABPI). Compensation will be paid where the injury is determined by the Sponsor or the principal investigator Dr Ewen Brennan to have resulted from:

- A drug being tested or administered as part of the trial protocol
- Any test or procedure you received as part of the trial

Any payment would be without legal commitment (Please ask if you wish more information on this). The Sponsor is not bound by these guidelines to pay compensation where the injury resulted from a drug or procedure outside the trial protocol or where the study instructions were not followed by you.

You are not waiving any rights by signing this form.

Medical Concerns:

You are requested to report any adverse event that happens after you receive the treatments to BDD Pharma, either in person or via telephone (numbers below) within 24 hours of the occurrence.

An adverse event means any undesirable signs or symptoms that occur in a participant after receiving the treatment. Examples of adverse events may include but are not limited to headaches, fever, or discomfort.

For medical concerns during working hours:	Please telephone 0141 552 0126
For medical concerns out of hours:	Please telephone 07752 591 796

Leave your full telephone number, including dialling code, and you will be contacted within 30 minutes.

A study team member will discuss your medical concerns and advise you on what you should do. They will also update the study doctor who may call you to discuss the concerns.

In the case of a **medical emergency**, at any time, please **telephone 999 immediately.**

HOW WILL WE USE INFORMATION ABOUT YOU?

We will need to use information from you, from your medical records, and your GP for this research project.

This information will include your:

- Full name
- Date of birth
- Sex
- Home address
- Telephone number(s)
- Email address
- Emergency contact details
- GP name and contact details
- Copy of your ID
- Photographs
- National Insurance Number
- As well as information on your medical history and any clinical data collected during the study

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

BDD Pharma is responsible for looking after your information. We will share your information related to this research project with the following types of organisations:

- BDD Pharma staff who are responsible for coordinating and conducting the trial.
- South West – Cornwall and Plymouth Research Ethics Committee.
- Administration of Radioactive Substances Advisory Committee (ARSAC).
- Nuffield Glasgow laboratory

Blood samples sent for safety analysis will be labelled with your study code, your sex and your date of birth as these details are required for the laboratory to complete their analysis and interpretation.

We will keep all information about you safe and secure by:

- Limiting access to authorised study personnel only
- Storing your data in secure, access-controlled systems
- Using coded study identifiers instead of your name whenever possible
- Keeping paper records in locked, restricted-access areas

International transfers

Your data will not be shared outside the UK.

HOW WILL WE USE INFORMATION ABOUT YOU AFTER THE STUDY ENDS?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data archived in a secure location for a maximum of 25 of years. The study data will then be fully anonymised and securely archived or destroyed

WHAT ARE YOUR CHOICES ABOUT HOW YOUR INFORMATION IS USED?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records or your GP. If you do not want this to happen, tell us and we will stop. We require this request to be in writing or via email.

You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

WHAT WILL HAPPEN TO ANY SAMPLES I GIVE?

The blood and urine samples which are taken will be analysed by the relevant laboratories and then destroyed. All results from these samples are stored on a secure computer system. A paper copy of the results is stored in your confidential file.

INVOLVEMENT OF THE GENERAL PRACTITIONER/FAMILY DOCTOR (GP)

Your general practitioner will be informed of your participation in this study and we will also inform them of any abnormal medical results that may be detected during the study. By signing the consent form you are giving your consent for them to be informed.

WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED?

You can find out more about how we use your information:

- At **www.hra.nhs.uk/information-about-patients**

- At **www.hra.nhs.uk/patientdataandresearch** **(a print out of this page can be provided on request)**

- by asking one of the research team
- by sending an email to contact@bddpharma.com or
- by ringing us on 0141 552 0126.

OVER VOLUNTEERING

You must not take part in too many studies because it may not be good for you. BDD keep a database of healthy volunteers and details of when they take part in studies. The database BDD will enter your details into is 'TOPS – The Over Volunteering Prevention System'.

BDD will add your national insurance number or passport and country of origin if you're not a UK citizen and the date of your last study treatment. If you withdraw from the study before you receive any study treatment, the database will show that you never received a dose.

WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?

The results of this study will be published in an internal report. They may also be presented at scientific meetings and published in scientific journals. You will not be personally identified in any publication or presentation.

BDD will send you information about the trial results and which treatment you have received (where applicable) once the study is completed. If you do not wish to be informed of the trial results or your treatment, please discuss this with a member of staff.

WHO IS ORGANISING AND FUNDING THE RESEARCH?

The study is being organised by BDD Pharma The study will be funded by BDD Pharma and Scottish Enterprise.

Insurance will be arranged and provided for this study by CNA Insurance Company Limited.

WHO HAS REVIEWED THE STUDY?

This study has been looked at by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinions by:

- South West – Cornwall and Plymouth Research Ethics Committee.
- Administration of Radioactive Substances Advisory Committee (ARSAC).

You will be given a copy of this information sheet, a Participant Contact Card (detailing emergency contact numbers and assessment visit restrictions) and the signed consent form to keep.

Thank you for considering taking part and taking time to read this information sheet.

CONTACT DETAILS

For any further information you require about this study, please contact:

BDD Pharma Ltd
Bio-Imaging Centre
Basement Medical Block
Within Glasgow Royal Infirmary
84 Castle Street
Glasgow, G4 0SF
Phone: 0141 552 0126
E-mail: contact@bddpharma.com

APPENDIX 1

Screening Visit

You will be asked to attend BDD's clinical unit, located within Glasgow Royal Infirmary for your screening visit. During this visit, we will:

- Explain the purpose of the study, what will happen, and any possible effects or risks.
- Answer any questions you have before you decide whether to take part.

If you agree to participate, you will be asked to sign a consent form. The full visit will take approximately 45 minutes

Screening Visit Procedures

The doctor will ask you questions about your current and previous medical history, and it is important that you give the doctor as much information as you can, particularly with regards to any allergies or problems you may have had after taking medicines. Please let the doctor know if you have had any recent investigations involving radiation (e.g., X-rays).

You should also inform the doctor of any medications you are currently taking, including vitamins and supplements. The doctor will also conduct a brief physical examination, calculate your Body Mass Index (BMI), check your temperature, blood pressure, and pulse and perform an electrocardiogram (ECG).

Blood samples will be taken for testing to assess your health. These tests will include blood biochemistry and haematology. The amount of blood taken will be about 20-25 mL, which is about 4-5 teaspoons.

A urine sample will be taken for routine analysis, to test for recreational drugs, and to test for nicotine use and to conduct a pregnancy test (where applicable). Please note that passive smoking (being exposed to second hand smoke) can result in a positive urine nicotine test and may result in your exclusion from the study. A breath alcohol sample will also be taken by blowing into a tube.

If your pregnancy test is positive, you will not be able to participate in the study.

If you test positive for HIV, Hepatitis B or Hepatitis C infection you will be contacted by a member of the medical team from BDD Pharma. These are viruses which can persist in your blood and bodily fluids. Under the Public Health Scotland Act 2008, Hepatitis B and Hepatitis C are *"notifiable infections"* which means that there is a statutory (legal) duty to notify Public Health Scotland of a positive test result and some of your personal details including your name, date of birth, ethnicity and postcode.

If any other abnormal results are found that your GP should be informed of, with your agreement, we will send your GP a letter to advise him/her to follow up with you. A letter to confirm this will also be sent to you for your information.

The study doctor will review all your results to decide if you are eligible to take part. You may be asked to return for repeat tests if any results are outside the normal range.

Assessment Visit 1

The first assessment visit will be to use imaging to outline the structure and position of your stomach and small intestine.

On arrival, we will:

- Ask whether you have followed the study restrictions (explained on page 5) and whether you have felt unwell or taken any medicines since your last visit.
- Collect a urine sample (for recreational drug, nicotine, and pregnancy testing where applicable) and you will take a breath alcohol test.

If these tests are abnormal and/or you test positive for pregnancy, you will not be able to participate in the assessment visit and may be excluded from the study.

Imaging (Gamma Camera)

Small markers (containing a small amount of technetium-99m) will be attached to your chest and back to help position you correctly for imaging. These are stuck on using medical tape and are painless.

You will not receive any study treatment during this visit. You will be asked to drink 600 mL of a radiolabelled liquid. Immediately afterwards, you will be positioned at the gamma camera. You will need to stand upright at the camera for approximately 20 minutes while continuous images are taken.

Following this initial period, a brief image will be taken every 5 minutes for up to 2 hours. Each image will take around 25 seconds to capture, during which you will stand at the camera. Imaging may finish earlier if the required images are obtained sooner, as determined by BDD site staff.

You will be free to move around between images. You will be requested to refrain from reclining or lying down during the time between dosing and the end of imaging.

This visit may last up to 3 hours in total.

Assessment Visit 2 and 3

At assessment visit 2 and 3, you will be dosed with Treatment A at assessment visit 2 and Treatment B at assessment visit 3.

On arrival, we will:

- Ask whether you have followed the study restrictions (explained on page 5) and whether you have felt unwell or taken any medicines since your last visit.
- Collect a urine sample (for recreational drug, nicotine, and pregnancy testing) and a breath alcohol test.

If these tests are abnormal and/or you test positive for pregnancy, you will not be able to participate in the assessment visit and may be excluded from the study.

If you are eligible to participate in the study, you will be given a wristband to identify you.

Imaging (Gamma Camera)

Small markers (containing a small amount of technetium-99m) will be attached to your chest and back to help position you correctly for imaging. These are stuck on using medical tape and are painless.

Immediately after dosing, we will ask you to stand at the gamma camera so that we can take an image, facing the camera. The image will last 25 seconds.

Images will be taken every 5 minutes for up to 4 hours. Imaging may finish earlier if the required images are obtained sooner, as determined by BDD site staff.

You will be free to move around between images. You will be requested to refrain from reclining or lying down during the time between dosing and the end of imaging.

Food and Drink

There will be no meals provided during the visits. Water will be available 1-hour post-dose.

Entertainment facilities

You may have only short intervals between imaging procedures (approximately 5–10 minutes). However, you are welcome to bring a book or magazine. Entertainment facilities are available when time permits, including Wi-Fi access should you wish to bring a laptop or tablet.

You may leave the centre when all imaging and study procedures are complete, providing the study doctor decides you do not require further monitoring.

After the study

Within 14 days of your final assessment visit, you will be asked to return for a follow up medical examination (lasting approximately 30 minutes). This will include:

- A physical examination
- Blood pressure and pulse checks
- Urine samples for pregnancy testing (where applicable)

If any results are outside the normal range, you may be asked to return for repeat tests. You will be paid an allowance for any additional visits to the unit

APPENDIX 2: FAMILY PLANNING AND CONTRACEPTION

For male participants

If your partner is of child-bearing potential you must be willing to abstain from penile-vaginal intercourse OR agree to use a condom with spermicide in addition to your female partner using a highly effective form of contraception such as an IUD, oral contraceptives, injectable progesterone, subdermal implants or a tubal ligation the time of the first assessment visit until 90 days following the last assessment visit

The study doctor will discuss acceptable methods of contraception with you at the screening visit if applicable.

You must agree not to donate sperm during the study period and for a period of 90 days following the study.

For female participants:

If you are of child-bearing potential (could become pregnant) you must be willing to use one of the following highly effective forms of contraception:

- an intrauterine device (IUD)
- oral contraceptives
- injectable progesterone
- subdermal implants
- a tubal ligation

The use of one of these forms of contraception is in addition to having your male partner use a condom/spermicide.

You must adhere to these measures from the time of the first Treatment Visit until the end of the study. Methods of contraception will be discussed with you at screening by the study medic if appropriate.

You must agree not to donate eggs (ova, oocytes) for the purpose of reproduction during this period.