

DONOR

INFORMATION



Thanks for signing-up

You are invited to take part in the Number 2 Donor Programme. Before you decide whether to become a donor, it is important for you to understand what is involved in being a donor and what your donations are being used for. Please take time to read the following information carefully, talk to others about the programme if you wish, and please do not hesitate to contact us (see p. 7 for details) if there is anything that is not clear to you or if you would like more information.

What is the purpose of our Number 2 Donor Programme?

The Number 2 Donor Programme is the trading name of a biopharmaceutical company called EnteroBiotix Limited (EBX) and is responsible for recruiting stool donors. Number 2 supplies EBX with stool from healthy donors which is rigorously screened by EBX. EBX was established to develop novel medicinal products based on a medical treatment called intestinal microbiome transfer (IMT) (also known as faecal microbiota transplantation (FMT)). IMT involves the transfer of whole community microbiota, derived from the donated stool of rigorously screened human donors, into the intestinal tract of a person suffering from a disease or infection.

Our aim is to maintain an active pool of stool donors who are engaged and motivated to donate on a frequent basis for as long as they wish to remain on the donor registry. The registry is held and controlled by EBX. The stool processing laboratory complies with Good Manufacturing Practice (GMP) and is based at EBX headquarters in Aberdeen. These facilities are licensed by the Medicines and Healthcare Products Regulatory Agency (MHRA), which enables EBX to manufacture medicinal products from donated stool. These products are classed as 'specials' for use in FMT. At present, the Company produces two 'specials' products, FM125 and FM250. These are a suspension of whole community microbiota, derived from a healthy donor, that are stored frozen, thawed when required for treatment, and then administered by clinicians to the recipient through an invasive medical procedure. Moving forward, we wish to develop additional products that can be stored at room temperature and that are administered orally using a capsule. Oral administration will expand access to patients and simplify the future research and design of clinical trials.

The ambition of the Company is now evolving beyond its initial concept. Indeed, the exponential growth of research into the microbiome has now linked imbalances in the gut microbiome with intestinal diseases, ranging from acute infections, caused by e.g. *C. difficile*, to more complicated chronic conditions such as inflammatory bowel disease and irritable bowel syndrome. The gut microbiome can be described as the totality of microorganisms, bacteria, viruses, protozoa, and fungi, their collective genetic material, and their repertoire of activity, found in the gastrointestinal tract. We also seek to undertake experiments that allow us to better understand the composition and mechanism of action of our products, with a view to one day potentially creating more standardised therapies.

The stool samples that you donate may be used to treat patients, or healthy volunteers in a clinical setting, or be used for research into the microbiome. By donating your stool, you are helping us to develop new processes and technology that will support future product development. Ultimately these donations may allow us to create new products that will be of benefit to vulnerable patient groups.

Why have I been chosen?

We are looking for fit and healthy non-smokers over the age of 18; males and females, who can donate a stool sample approximately 3-4 times a week.

You cannot be a donor if you meet any of the following exclusions:

- Under the age of 18
- Body mass index (BMI) under 18.5
- Current tobacco user (vaping is not an exclusion)
- In receipt of certain regularly prescribed medication (certain medications are accepted, for example, the oral contraceptive pill, this can be assessed at the screening interview)
- Currently receiving medication for depression, anxiety, or any other medical health issue diagnosed by a doctor
- A personal or family history of gastrointestinal malignancy or known polyposis syndrome
- Known to be infected with HIV, HTLV or Hepatitis A, B, C, D, or E
- Known exposure to HIV, HTLV or Hepatitis A, B, C, D, or E in the last 12 months
- Recurring diarrhoea (≥ 3 loose or watery stools per day for at least 2 consecutive days per week)
- Sexual contact with known HIV or hepatitis patients, men who have had sex with men either protected or unprotected, sexual contact for drugs/money in the past 12 months
- Incarceration or history of incarceration within the past 12 months
- Any, or family, history of gastrointestinal disease or disorders such as inflammatory bowel disease and irritable bowel syndrome
- Currently being treated for cancer

EnteroBiotix are committed to unlocking the full potential of the human gut microbiome by researching and developing new products and medicines. Please do get in touch using the contact details provided if you are interested in participating, even if you think you may not be eligible.

Do I have to take part?

No. It is up to you to decide whether to take part or not. If you do decide to take part, you will be asked to sign a consent form. If you initially think you would like to participate but change your mind, you are free to withdraw at any time, without providing a reason. If you withdraw you will not be penalised or lose any benefits to which you are already entitled. You will be informed of any new information about the donation programme that might affect your decision to continue.

What will happen to me if I take part?

Before you are enrolled into the donation programme, we will need to establish whether you are eligible. Our Number 2 online questionnaire allows us to complete an initial assessment on your eligibility. If suitable, you will be invited by EBX's Donor Manager to take part in a one on one screening session.

At this visit the Donor Manager will go through the Number 2 Donation Programme Information Sheet and discuss any questions you may have. If you are happy to do so, you will be asked to complete and sign a consent form and a General Data Protection Regulation (GDPR) document.

Your medical screening questionnaire, which you will have completed on the Number 2 website, is reviewed by a Doctor, who is independent of EBX, and registered with the General Medical Council (GMC). The Doctor will assess your overall health status and determine your eligibility for participating in the donor programme. The Donor Manager can arrange a meeting with you, and the Doctor, in conjunction with the screening session, or on another date if preferred. This allows the Doctor to review the questionnaire with you and give you an opportunity to ask any questions you may have.

Assuming the previous medical review is satisfactory, and you remain happy to become a stool donor, you will be assigned an anonymised donor number. This number is unique to you and will be used to identify you and track any of your donations within the EBX donor programme, instead of using any personal identifiable information.

To minimise the biological risk to the individuals who will come into contact with your stool, we require you to have your blood and stool tested as part of the initial screening process. Your blood and stool will be sent, anonymised, to selected third party reference and screening laboratories who will test for viruses, bacteria, parasites, and ova. This testing is repeated

approximately every 30 days to ensure ongoing risk reduction and protection. For each blood test, a small needle will be inserted into your arm and approximately 22 mL of blood will be withdrawn. For your stool test, you are issued a stool donation kit containing all the equipment required to provide a sample.

NOTE: Stool donations/blood for testing can only be collected Monday to Thursday due to shipping restrictions to EBX's selected laboratories.

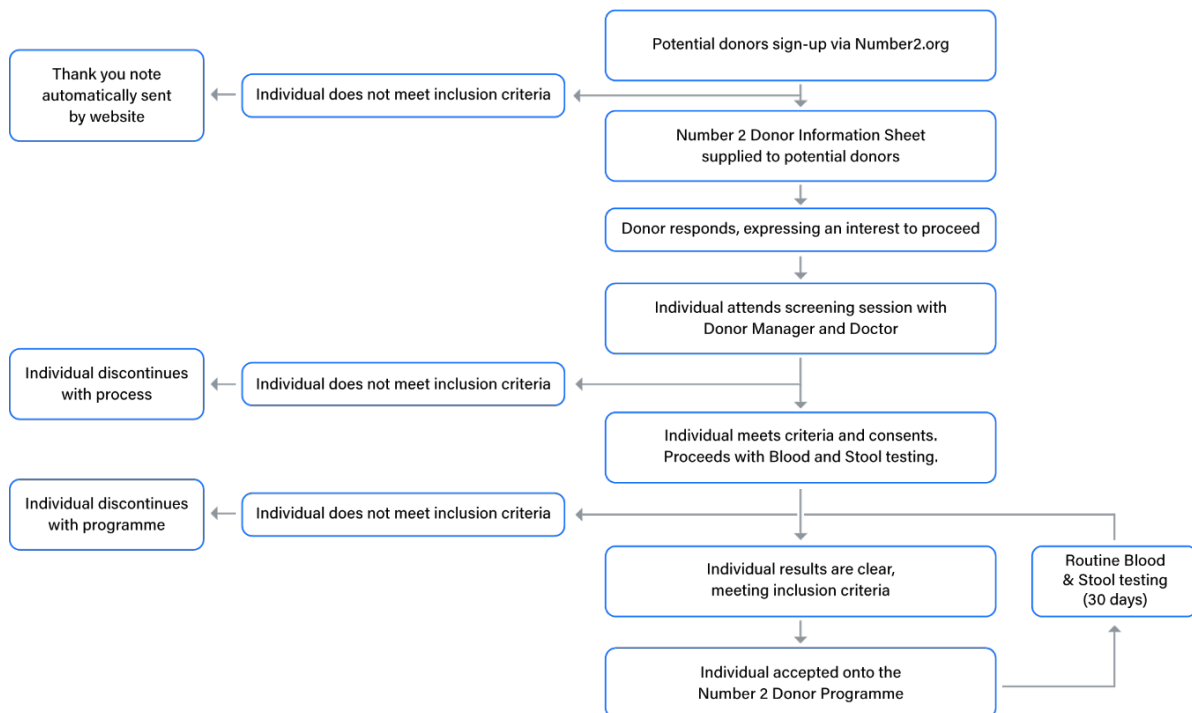
Results from the blood and stool screening tests can take 2-4 weeks to be analysed, interpreted, and collated, by the various laboratories involved. Only after all results are reviewed, and are found to meet the acceptable criteria, will you be approved to start donating on a regular basis.

To make those regular stool donations, you will be supplied with the relevant instruction sheets. They may be donated at The Rowett Institute, or with our home donation system. The frequency of the stool donations required is, on average, 3-4 times per week for as long as you wish to participate.

Your blood and stool samples are collected for testing approximately every 30 days and are sent to several UK accredited laboratories to test for a variety of potentially harmful pathogens, such as bacteria, viruses, parasite's or other microorganisms that can cause disease. If you require further details on this testing, or your results, please contact the Donor Manager at donors@number2.org

At each donation you will complete a short questionnaire to confirm any changes to your medical conditions/treatments/lifestyle - Pre-donation Review FRM EUR F103. You will be informed by the Donor Manager of any dates that donations cannot be received. Further instructions are detailed in the Donor Instruction Leaflet FRM EUR F137 & Home Donation Instruction Leaflet FRM EUR F149.

Consent Diagram



What will happen to the donations I give, and bloods/stool results received?

Your stool donations are transported to EBX laboratories where they are processed for research & development purposes, or to manufacture products which may be used to treat patients in hospital, or involved in clinical trials. Your personal information will not be transferred and will remain secure with EBX. EBX, and its partner laboratories, will perform certain DNA identifying methods with the intention of gathering information about the bacteria in the sample. However, it is possible that some of your own DNA (human) will be profiled due to the presence of your own cells in your stool. It is not our intention to profile your DNA, and that data will not form part of the analysis.

Expenses and payments

We will reimburse your travel costs and expenses up a maximum of £20 per day. This will be gifted as £10 for each stool donation. Similarly, £15 will be offered for each blood sample provided. These expenses are transferred directly into your bank account at the end of each month. You will be asked to complete the FRM EUR F136 Donor Expenses Form after your meeting with the independent General Medical Council (GMC) registered medical professional.

What are the possible benefits of taking part in the programme?

Participating in this programme may not benefit you directly, however your donations may benefit certain patients, help develop new novel products and deepen the understanding of how these products work.

What are the possible disadvantages and risks of taking part?

The safety of donors will always be paramount to EBX, who operate to strict standard operating procedures, established by Number 2, EnteroBiotix and The Rowett Institute.

Our Donor Manager, or a highly trained phlebotomist at the Rowett Institute, will collect your blood samples. On occasion, this may cause minimal bruising or mild discomfort at the puncture site. Less common side effects include, fainting, swelling of the vein, infection and/or bleeding from where the needle is inserted.

You and your GP will be notified of any incidental findings or any out of range results detected during your participation in the stool donation programme. There is a risk that the pathogen testing that is undertaken on your blood and stool samples may return significant results e.g. a positive result for an infectious pathogen. There is a risk that a positive result may not actually be positive, a phenomenon known as a 'false positive'. In both cases, you may experience distress when the results are relayed to you. Number 2/EBX cannot provide medical advice, and in the case of positive results, EBX will contact your GP who should follow up any treatment that you may require.

What will happen to the data of the screening?

All your data is stored safely and securely and collected in line with the Data Protection Act 2018. Members of the Number 2 Clinical Team, and external Regulatory Agencies, may review the test results from time to time. Any reports/results generated from the programme will be anonymised, protecting your identity.

If a positive test from your initial or routine blood and stool screening is identified, the Donor Manager will contact you. The GMC registered clinician may need to notify your GP, who in turn will provide you with further medical advice as required. Under the Public Health (Scotland) Act 2008, certain positive results require Grampian Health Protection to be informed, and may result in them contacting you directly to offer advice.

What if there is a problem?

At any time during the programme, if you have a complaint or a concern, you may contact the Donor Manager using the contact details outlined at the end of this document.

Will my taking part be kept confidential?

Number 2 and EBX are committed to protecting the privacy and security of your personal information. Your participation in the programme will remain confidential. EBX employ practises that are designed to maintain that confidentiality and anonymity e.g. a unique non identifying donor number. EBX employ measures to ensure robust data security e.g. secure paper record storage with restricted access.

Number ②

We will provide you with a privacy notice during your initial screening process that describes how we collect and use personal information about you during and after your participation in the stool donation programme, in accordance with the General Data Protection Regulation, 2018 (GDPR). To allow EBX access to the information generated from your donation for selected purposes, we are required to obtain your explicit consent, which we will do so via our initial screening process.

You have the right to review, verify, correct, or request erasure of your personal information, object to the processing of your personal data, or request that we transfer a copy of your personal information to another party. Please contact the Donation Manager in writing, or via email, if you wish to exercise your rights in connection with your personal information.

Contacts for the programme

Claire Kidd

Tel: 01224 690373 / 07870 101718

Email: donors@number2.org

EnteroBiotix Ltd
Aberdeen Blood Transfusion Centre
Foresterhill Road
Aberdeen
AB25 2ZW

Donor:

Signature

Date

Print name

Donor Manager/Designee:

Signature

Date

Print name

Job title