## What is a clinical research study?

A clinical trial, also called a clinical research study, is a carefully designed scientific evaluation of an investigational vaccine, medication or treatment. Clinical trials are conducted by doctors and researchers.

## The importance of diversity in clinical research studies

Research has shown that certain diseases, treatments and medications may impact people differently based on their age, gender and genetic background, including race and ethnicity.
It is important to conduct research studies with diverse populations to help ensure vaccines and medications are generally safe and effective (or the benefits outweigh the risks).

## Why is clinical research important?

Clinical research helps doctors and scientists determine if an investigational vaccine, medicine or therapy are safe and/or effective for use in humans to potentially treat or prevent a condition, disease or disorder. Clinical studies often require a large number of volunteers to participate in a single study; sometimes thousands are needed to obtain reliable information.

The image depicted contains models and is being used for illustrative purposes only.

## Can I change my mind?

Yes. You can leave the study at any time, for any reason. Even if you begin the study, you can change your mind at any point.

## See if you may be eligible to participate.

To learn more about this clinical research study, please contact the site at:

Email: rde-tr.prcexeter@nhs.net

Telephone: 01392 406289

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www.EmbraceVaccineStudy.com

Janssen Research & Development, LLC
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# Evaluating an Investigational Vaccine through Clinical Research

A clinical study to evaluate an investigational vaccine in adults 60 years of age or older who have had a urinary tract infection (UTI) in the past 2 years is now enroling.

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## What is Informed Consent?

Informed Consent is a process of information exchange before an adult agrees to participate in research. Potential research participants will be asked to read and sign an Informed Consent Form, but will also be given instructions, verbally and in writing, question/answer sessions and other reading materials to assure the potential study participants' understanding and willingness to voluntarily enrol in the research.

So, before you agree to volunteer for the study, the study doctor or staff is required to explain all the details of the study, which will include the potential risks and benefits, and address your questions. After all of your questions have been answered and if you wish to participate, then you will sign a document called the Informed Consent Form to ensure:

- You agree to volunteer.
- You understand the study, including the study procedures, risks and potential side effects of the study vaccine or medication.
- You understand that you can leave the study at any time, for any reason.

If you don't understand what is expected of you or the document, you should continue to ask questions and talk with the study doctor, your family or others that you trust, until you feel you understand.

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## Purpose of the E.mbrace Study

The purpose of this clinical research study is to assess the effectiveness and safety of an investigational vaccine in the prevention of a bloodstream infection caused by *E. Coli* bacteria. Currently there is no approved vaccine for bloodstream infection caused by *E. Coli* bacteria.

A vaccine is a type of medicine that may help prevent or lessen the severity of certain diseases by causing the human body to form a defensive response against the disease. This defensive response is called the immune response and it is your body's way to fight infections.

## Am I eligible?

You may be able to participate in this study if you:

- Are 60 years of age or older
- Have had a UTI in the past 2 years
- Feel comfortable, or have a caregiver who is comfortable, using a web-based programme on a computer or tablet, or an application on a smartphone

Additional eligibility criteria will be assessed by the study team during the screening process prior to being enroled. in the study and receiving any investigational vaccine. Not all individuals may qualify to participate in the research.

## About *E. coli* and IED

*Escherichia coli* (*E. coli*) are bacteria commonly found in the human gut. Some strains of *E. coli* bacteria can also go into the urinary tract and cause a urinary tract infection (UTI), an infection in any part of your urinary system – your kidneys, ureters, bladder and urethra. Sometimes for men, *E. coli* may cause an infection and inflammation of the prostate gland, a walnut-sized gland situated directly below the urinary bladder. This is called prostatitis.

The *E. coli* bacteria may also spread from the urinary tract to the bloodstream and other locations in the body and cause an infection called an invasive (also known as systemic) infection, often referred to as Invasive *E. coli* Disease (IED).

Although IED affects all ages, adults aged 60 years and older have an increased risk of developing IED,[1] which is further increased if you've had an UTI in the past.

## About the Mobile Health Platform (MHP)

Participants enroled. in the study and/or their caregivers will use either a web-based (laptop, computer or tablet) or smartphone application to enter information for the study team throughout the study. This technology will be referred to as the Mobile Health Platform (MHP) and will be used to record information about your participation throughout the study.

## What can I expect if I join the study?

If you qualify and choose to join the study and sign the Informed Consent Form, you will be asked to attend a screening visit with the study team. At this visit, you will undergo tests and procedures to determine if you are a good match for being in the study.

If eligible, you will be in the study for approximately 3 years. You will complete a minimum of 8 study visits, some in person and some remote, using a smartphone, computer or tablet.

You will be randomly assigned to one of two study groups. This means you may receive either a placebo (contains no active medicine) or the investigational vaccine. Neither you nor the study team will know which study group you are in.

The investigational vaccine or placebo will be given via a single injection on Day 1 of the study.

Qualified participants may receive the investigational vaccine or placebo and some study-required medical care at no cost.

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4871665/