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# Testing tumour genetics in patients with cancers resistant to standard-of-care therapy

**Submission date**
06/01/2020

**Recruitment status**
Recruiting

**Registration date**
13/01/2020

**Overall study status**
Ongoing

**Last Edited**
04/04/2025

**Condition category**
Cancer

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

## Plain English summary of protocol

Background and study aims
We are now in the era where we aspire to make cancer treatment decisions based not only on the location and microscopic type of disease, but also on the molecular tumour characteristics in order to match the right treatment to the right patient.

The Clinical Research Unit at Beatson West of Scotland Cancer Centre provides access to experimental cancer treatments for patients who have exhausted the current approved treatments for their condition. Many of these experimental treatments allow patients with cancer in different locations to enter the same clinical trial depending on the molecular tumour characteristics (also called tumour profile).

The aim of the IMAGINE study is to build the framework and processes that will make it possible to obtain tumour profile results in a much quicker timeframe than it takes at present. The aim is to reduce the time from consenting to the study until the time the results of the tumour profile are available to less than 6 weeks. It is hoped that over the course of the study this timeframe will become even shorter. The study is expected to recruit patients over 5 years, after which time we would hope to be able to obtain tumour profiles in a timeframe that could help direct treatment decisions more precisely to maximise patient benefit.

Who can participate?
Male and female patients aged 18 years and over who have been referred to the early-phase cancer clinic.

What does the study involve?
The IMAGINE study will collect tumour samples that were taken at the time of cancer diagnosis, take new samples of tumour (where possible) and take blood samples. Samples will then be examined in order to establish a profile of the tumour.

Biopsy
A biopsy is the removal of a small piece of tissue. In this study, the biopsy will be taken from an area where the cancer has come back. The doctor taking the biopsy may use a CT scanner or ultrasound machine to help guide the biopsy needle to the tumour. You will be given a local

anaesthetic to numb the area before the biopsy is taken. The biopsy site may have some stitches that need to be removed after a few days.

In you start on an anti-cancer treatment we may ask to take another biopsy and blood sample in the event of an exceptional response or on progression of the cancer. However, this part of the study is optional and you may say no to this second biopsy and subsequent blood tests.

Blood tests
We will take blood samples to examine cancer DNA in your blood. This sample will be taken before the biopsy (if scheduled to have one). If the participant is not having a biopsy, the blood test will be taken within a few weeks of signing the consent form.

We will also take a blood sample for storage. This is because we may identify mutations in genes that are inherited from parents and might have caused the cancer to develop. If this happens, we would want to send a sample for a confirmatory test in a clinical (rather than research) laboratory. Together, these samples will involve taking up to 30ml of blood (approximately 6 teaspoons) in addition to the usual blood tests that would be taken routinely.

In addition, if the participant is having any anti-cancer treatment in the future, we would like to take a blood sample immediately before the first two doses of anti-cancer treatment. In total this will involve another 20 ml (approximately 4 teaspoons) of blood. However, this part of the study is optional and it is not compulsory to give these extra blood samples.

Some participants may already have had their tumour profile examined as part of another clinical trial or as part of private care. These participants will be asked to consent to provide their data and the results of their tumour profile, so that this information can be included on the study database. Blood and tumour samples would not be collected from these participants.

What are the benefits and risks of participating?
There may or may not be any direct medical benefits to taking part in the study. Some participants benefit from increased monitoring and regular contact with the study team. Although in the early stages of IMAGINE the tumour profile results will not be available quickly enough to be used when making treatment decisions, the aim of the study is to gradually improve the speed with which these results can be obtained.

Where is the study run from?
The study is being carried out by researchers at the Beatson West of Scotland Cancer Centre (BWoSCC), Glasgow (UK), and is supported and sponsored by NHS Greater Glasgow & Clyde (UK).

When is the study starting and how long is it expected to run for?
December 2017 to March 2026

Who is funding the study?
The study is funded by grants from Cancer Research UK Glasgow Centre (UK) and the University of Glasgow (UK)

Who is the main contact?
Ann Shaw, Ann.Shaw@glasgow.ac.uk

# Contact information

### Type(s)
Public

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Scientific

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## Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### Integrated Research Application System (IRAS)
242738

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
IRAS: 242738, IMAGINE2018

## Study information

### Scientific Title
IMAGINE: Integrating Medically Actionable Genomics INto Early-phase trials

## Acronym
IMAGINE

## Study objectives
This study aims to test the feasibility of obtaining molecular profiles in a clinically useful timeframe (<6 weeks).

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 27/03/2019, East of Scotland Research Ethics Services (Tayside medical science centre, Residency block level 3, George Pirie Way, Ninewells Hospital and Medical School, Dundee, DD1 9SY;+44 1382383878; eosres.tayside@nhs.net), ref: 19/ES/0021

## Study design
Single-centre non-randomized feasibility study

## Primary study design
Interventional

## Study type(s)
Screening

## Health condition(s) or problem(s) studied
Cancer patients who are referred for an early-phase clinical trial.

## Interventions
Patients that are referred to the early-phase trials clinic at the Beatson West of Scotland Cancer Centre and are assessed as being potential early-phase clinical trial participants will be given a patient information sheet regarding this study and will be given the opportunity to consent to study participation. After written informed consent has been obtained, image-guided/other suitable biopsies will be performed according to local standard management where possible. Since patients referred for an early phase clinical trial are not restricted to defined tumour sites, biopsies may be obtained from a variety of anatomical locations. Archival tissue will be obtained where a biopsy is not feasible or when the biopsy tissue failed to lead to generation of a molecular profile.

Blood samples will also be taken for isolation of DNA and to examine circulating tumour markers.

Inclusion Criteria 3b
eIMAGINE is the database that has been developed to capture the molecular and clinical data generated in the IMAGINE study. Patients who are referred to the early-phase trials clinic who have already had tumour sequencing performed (and are not fit/willing to have a research biopsy) will instead be able to contribute their clinical and sequencing data to eIMAGINE via inclusion certiate 3b. Although these patients will not contribute to the primary or secondary objectives their clinical and sequencing data will make a valuable contribution to translational research studies examining associations between molecular aberrations and response and

resistance.
Patients who enter the study under inclusion criteria 3b will not be asked to provide tumour or blood samples.

Patient's who have consented to blood and tissue collection will remain on study until the last blood sample is collected at progressive disease. The median time for this is approximately 5 months. With the exception of patients attending for additional biopsy, visits will be conducted as per standard of care for the early-phase trial that the participant takes part in, these can vary in frequency depending on the particular trial. Patients will be followed up for response to subsequent therapies and to assess survival outcomes. The maximum length of follow up is 8 months following the last patient recruited.

### Intervention Type
Other

### Primary outcome(s)
To establish a mechanism and framework in which tumour samples can be obtained and molecular profiles generated in a clinically useful timeframe (<6 weeks).

### Key secondary outcome(s))
1. Proportion of patients experiencing an adverse event due to tumour biopsy as measured by Common Terminology Criteria for Adverse Events (CTCAE) and calculated at 5 years
2. Proportion of patients where biopsy contained adequate tumour measured by histological observation and calculated at 5 years
3. Proportion of patients where adequate DNA was isolated using DNA isolation assay and calculated at 5 years
4. Proportion of patients where an actionable biopsy was identified by genomic analysis and calculated at 5 years
5. Proportion of patients where appropriate therapy was accessible as assessed at molecular tumour board and calculated at 5 years

### Completion date
31/03/2026

## Eligibility

### Key inclusion criteria
1. Adult patients aged 18 years or over
2. Patients referred for an early-phase clinical trial with histologically confirmed advanced solid tumours
3. Patient meets one of the following criteria:
3.1. Willing and fit to have a tumour biopsy aimed at obtaining sufficient tissue for molecular profiling
3.2. Not willing/fit to have a tumour biopsy and had prior tumour molecular profiling
4. Patient deemed a suitable candidate for further systemic anti-cancer therapy
5. Willing and able to provide signed informed consent

### Participant type(s)
Patient

### Healthy volunteers allowed

No

**Age group**
Adult

**Lower age limit**
18 years

**Sex**
All

**Key exclusion criteria**
Does not meet the inclusion criteria

**Date of first enrolment**
07/01/2020

**Date of final enrolment**
31/03/2026

# Locations

**Countries of recruitment**
United Kingdom

Scotland

**Study participating centre**
**Beatson West of Scotland Cancer Centre**
1053 Great Western Road
Glasgow
United Kingdom
G12 0YN

# Sponsor information

**Organisation**
Greater Glasgow & Clyde NHS Board

**ROR**
https://ror.org/05kdz4d87

# Funder(s)

**Funder type**
Charity

**Funder Name**
Cancer Research UK

**Alternative Name(s)**
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Other non-profit organizations

**Location**
United Kingdom

**Funder Name**
Beatson Cancer Charity

**Alternative Name(s)**

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Other non-profit organizations

**Location**
United Kingdom

# Results and Publications

**Individual participant data (IPD) sharing plan**
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Patricia Roxburgh, email: Patricia.Roxburgh@glasgow.ac.uk

**IPD sharing plan summary**
Available on request

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| HRA research summary | | | 26/07/2023 | No | No |
| | Participant information sheet | | | | |

| | | | | | |
|---|---|---|---|---|---|
| Participant information sheet | | 11/11/2025 | 11/11/2025 | No | Yes |
| Protocol file | version 4 | 08/02/2023 | 04/01/2024 | No | No |