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QuicDNA Max Research Programme – multi site, multi-centre, non-interventional, biomarker platform study. Assessing blood based ctDNA (circulating tumour) testing to guide cancer care across multiple cancer types

Submission date
16/04/2026

Recruitment status
Recruiting

Registration date
01/05/2026

Overall study status
Ongoing

Last Edited
29/04/2026

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
Cancer treatment often depends on finding changes in a tumour's genes. These changes are usually tested using a tissue biopsy, which involves taking a sample of the tumour. For some people, a tissue biopsy can be slow, difficult, or not possible. The QuicDNA Max programme is a new research programme that will explore how a simple blood test, called a liquid biopsy, can help doctors better understand and treat different types of cancer. This test looks for cancer-related DNA in the blood, which can help guide treatment decisions and track how the disease changes over time.
The main aim of the study is to see how useful blood-based DNA testing is for people with suspected or confirmed advanced cancer. The study will look at how well this blood test works compared with standard tissue tests, how quickly results are available, and whether the results can help guide treatment decisions.

Who can participate?
People may be able to take part if they are aged 16 years or older and have a suspected or confirmed diagnosis of cancer that is advanced or progressing. Participants must be well enough to attend clinic visits and provide a blood sample. Only people who are already receiving care in participating NHS hospitals and clinics will be invited to take part. Healthy volunteers cannot take part.

What does the study involve?
If someone agrees to take part, they will be asked to give a blood sample, usually during a routine hospital visit. The blood sample will be tested for small pieces of cancer DNA circulating in the blood. This test does not replace standard care and does not change treatment by itself. Doctors may still use tissue biopsy results if these are available.
The study team will also collect information from medical records, such as scan results and

treatments received, over time. Participants may be followed up for up to three years. Taking part is voluntary, and participants can withdraw at any time without affecting their usual care.

What are the possible benefits and risks of participating?
Some participants may benefit if the blood test finds genetic changes that help doctors choose treatments or identify clinical trials. The blood test may also provide results faster than standard tissue testing. However, there is no guarantee that taking part will benefit the participant directly.
The main risk is from giving a blood sample, which may cause brief discomfort, bruising, or, rarely, infection. The test may also find unexpected genetic information, which can sometimes be worrying. Participants will be given clear information about this before they consent and can choose which types of results they wish to receive.

Where is the study run from?
The study is run from NHS hospitals and clinics across Wales, including Velindre Cancer Centre. The study is coordinated by the Centre for Trials Research at Cardiff University (UK).

When is the study starting and how long is it expected to run for?
March 2026 to December 2028.

Who is funding the study?
The study is funded by a combination of organisations, including Eli Lilly and Company, Merck Sharp and Dohme UK, the Office of Life Sciences, and Menarini Stemline UK Ltd.

Who is the main contact?
QuicDNAMax@cardiff.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
Dr Magdalena Meissner

Contact details
Velindre University NHS Trust
Velindre Cancer Centre
Velindre Road
Cardiff
United Kingdom
CF14 2TL
+44 2920615888
magdalena.meissner@wales.nhs.uk

Type(s)
Public

Contact name
Mrs Georgina Gardner

ORCID ID
https://orcid.org/0000-0001-5886-8185

Contact details
Centre for Trials Research
College of Biomedical & Life Sciences
Cardiff University
6th Floor, Neuadd Meirionnydd
Heath Park
Cardiff
United Kingdom
CF14 4YS
+44 2920687950
QuicDNAMax@cardiff.ac.uk

Type(s)
Scientific

Contact name
Mrs Sian Morgan

Contact details
Cardiff & Vale University Health Board
Cardiff
United Kingdom
CF14 4XW
+44 29 20687950
sianmorgan602@yahoo.com

Additional identifiers

Integrated Research Application System (IRAS)
363293

Central Portfolio Management System (CPMS)
73332

Study information

Scientific Title
QuicDNA Max Research Programme (Multi- Site)

Study objectives
Primary objectives:
To evaluate the utility of liquid biopsy (ctDNA) genomic profiling across a range of tumour types in patients with either suspected or confirmed advanced cancer, including those already receiving treatment

Secondary objectives:
1. To evaluate the added detection capacity of ctDNA for clinically relevant mutations not

identified through tissue-based testing
2. To assess the failure rate of ctDNA testing in comparison to standard tissue molecular analysis (where tissue is available).
3. To determine the proportion of patients for whom ctDNA provides the only viable molecular profiling data due to inadequate or unavailable tissue
4. To measure the timeliness of ctDNA report delivery and its availability at the point of treatment decision-making
5. To assess whether ctDNA results can reduce the need for invasive tissue biopsy procedures
6. To quantify the frequency of failed or non-diagnostic tissue biopsies
7. To investigate the detection rate of somatic and potentially germline mutations through ctDNA, including scenarios where confirmatory
8. To evaluate the frequency and clinical significance of incidental germline findings identified through ctDNA testing, and to determine the proportion of patients requiring confirmatory germline testing and referral to by Clinical Genetics
9. To assess the utility of ctDNA results in stratifying patients into standard-of-care treatments, biomarker-driven clinical trials, therapies accessed through Individual Patient Funding Requests (IPFR), or compassionate access programmes
10. To evaluate clinical outcomes, including treatment response, progression-free survival, and overall survival, according to whether participants had treatment modification based on ctDNA results testing is indicated

Exploratory objectives: collection of additional biological samples and associated clinical data to support future research and technological innovation, including the potential for multi-omics integration and AI-driven cancer profiling
Evaluation of novel biomarkers, emerging genomic technologies, or unanticipated research questions that arise during or after the study

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 29/12/2025, Wales REC2 (Health and Care Research Wales Floor 4, Crown Building, Cardiff, CF10 3NQ, United Kingdom; +44 29 2294 0959; wales.rec2@wales.nhs.uk), ref: 25/WA /0307

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)

Health condition(s) or problem(s) studied
Individuals with radiologically suspected or confirmed advanced cancers, or those who have developed resistance to existing therapies and have radiological evidence of disease progression

Interventions
The QuicDNA Max programme is a platform-based, prospective, multi-centre, exploratory diagnostic study conducted
across NHS hospitals and clinics. The study is designed as an open-label, non-interventional

framework with a master protocol governing multiple tumour-specific sub-protocols.
Potential participants within each specific sub-study will be screened by their care team, who will use information already collected during routine care, such as scan results, lab reports, clinic notes, and electronic health records, to determine their eligibility. These records will only be accessed by staff who are allowed to see them as part of their job.
If a patient appears to meet the study criteria, a member of their care team will speak to them directly. They will explain the study, give written information (including a Participant Information Sheet and Consent Form), and offer the chance to take part.
Patients will be given time to think about whether they want to join and can ask questions before deciding. If they are interested, a trained member of the research team or clinical staff will go through the consent process with them.
Final checks to confirm eligibility will be made by the patient's main treating doctor, usually a consultant or specialist involved in their cancer care.
After they have read the QuicDNA Max PIS and signed the consent form, the participant will be registered on the study database and will donate a blood sample for ctDNA testing. Further assessments specific to each tumour type are listed in the relevant sub-protocols.
Every effort will be made to run the study assessments during the participant's routine hospital appointments in order to reduce the burden of attending hospital many times.
As QuicDNA Max includes ctDNA and blood-based genomic profiling, the study may generate results relevant to treatment as well as incidental findings. Patients will receive counselling before consent to understand these issues and may choose whether they wish to receive certain categories of results.
The study will adopt a flexible-default model of consent, where results directly relevant to the patient's cancer ("cancer of interest") will always be disclosed. Results unrelated to the patient's cancer, but with potential medical or familial significance, will be disclosed by default but patients may decline. Unknown or uncertain findings will not be disclosed. Any other or unanticipated findings that fall outside these categories will be considered on a case-by-case basis by the Trial Management Group (TMG), which will determine the appropriate approach to disclosure.

Intervention Type
Other

Primary outcome(s)
1. Turnaround time between ctDNA testing and tissue testing measured using study laboratory records and clinical reporting systems capturing dates of ctDNA sample collection, tissue sample collection, and delivery of validated genomic reports to the treating clinical team at Baseline (ctDNA sample collection), Baseline (tissue sample collection), report delivery date

2. Identification of clinically actionable biomarkers measured using ctDNA next generation sequencing assay with classification of actionable alterations based on established clinical guidelines or trial eligibility criteria recorded in study database at Baseline (ctDNA testing)

3. Concordance of key genomic alterations between ctDNA and tissue testing measured using Comparison of paired ctDNA next generation sequencing results and tissue based next generation sequencing results using predefined concordance criteria at Baseline (ctDNA testing), Baseline (tissue testing)

4. Feasibility of early integration of ctDNA testing measured using Study screening and laboratory records documenting successful completion of ctDNA testing at the intended early diagnostic time point at Baseline (early diagnostic time point such as radiological suspicion or initial colonoscopy)

5. Treatment modification informed by ctDNA results measured using Review of clinical decision making documented in medical records indicating changes to the treatment plan attributed to ctDNA findings at Baseline (ctDNA result availability), end of study

This is a non-interventional, exploratory study. Analyses will be mainly descriptive, focusing on metrics such as ctDNA turnaround time specified in the outcomes section including, concordance with tissue, and rates of actionable mutations. Outcomes will be analysed separately for each tumour-specific sub-protocol. Where appropriate, simple statistical tests (e. g. chi-square, t-tests) may be used. No safety analyses are required. Exploratory sub-group analyses (e.g. by cancer type or treatment status) will be detailed in sub-protocols. Interim analyses may be performed to assess feasibility, assay performance, or recruitment progress, but will not influence trial continuation decisions unless specified.

Primary outcomes tailored to specific tumour types and clinical settings will be defined in the corresponding sub-protocols

Key secondary outcome(s))
Secondary outcomes will be specified in each tumour-specific sub-protocol, according to clinical context and research objectives

Completion date
30/12/2028

Eligibility

Key inclusion criteria
1. Are willing and able to provide written informed consent
2. Are aged 16 years or older
3. Have an Eastern Cooperative Oncology Group (ECOG) performance status of 0–2
4. Have a suspected or confirmed diagnosis of cancer
5. Meet any additional tumour-specific eligibility criteria, as outlined in the relevant sub-protocols

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Upper age limit
85 years

Sex

All

Total final enrolment
0

Key exclusion criteria
1. Are unable or unwilling to comply with study procedures
2. Meet any tumour-specific exclusion criteria as defined in the relevant sub-protocols

Date of first enrolment
31/03/2026

Date of final enrolment
31/03/2028

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Centre for Trials Research
Centre for Trials Research
College of Biomedical & Life Sciences
Cardiff University
6th Floor, Neuadd Meirionnydd
Heath Park
Cardiff
Wales
CF14 4YS

Sponsor information

Organisation
Cardiff and Vale University Health Board

ROR
https://ror.org/0489f6q08

Funder(s)

Funder type

Funder Name
Eli Lilly and Company

Alternative Name(s)
Lilly, Eli Lilly & Company, Eli Lilly & Co., Eli Lilly And Co, Eli Lilly & Co

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Funder Name
Merck Sharp and Dohme United Kingdom

Alternative Name(s)
MSD United Kingdom, Merck Sharp & Dohme, Merck Sharp & Dohme Corp., MSD

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Funder Name
Office of Life Sciences

Funder Name
Menarini Stemline UK Ltd

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.0	23/10/2025	16/04/2026	No	No