ISRCTN50943319 https://doi.org/10.1186/ISRCTN50943319

UKHSA framework study for evaluating the safety and effectiveness of devices and new testing methods for diagnosing COVID-19 and other infectious diseases

Submission date
13/12/2022

Recruitment status
Recruiting

Registration date
27/01/2023

Overall study status
Ongoing

Last Edited
20/01/2025

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
During the early stages of the SARS-CoV-2 pandemic, The UK Health Security Agency (UKHSA) introduced a national infectious disease (including Covid-19) testing programme. This involved the UKHSA directly delivering Covid-19 testing across the UK population. In the beginning, there were no licensed tests for Covid-19 and therefore, UKHSA worked with manufacturers and suppliers of test kit components to manufacture new testing devices. Since then, UKHSA has worked in collaboration with the UK biotechnology industry to develop national diagnostics manufacturing capabilities. The aim of which was to ensure that the UK had a continuous supply of high-quality in-vitro diagnostic tests to meet the demands of a national pandemic.

The rapid development of tests in response to an urgent public health threat may mean that new tests need to be developed quickly. As such, the tests do not have the normal checks /studies to confirm the degree of accuracy of the tests in larger populations or over longer periods of time, and those studies that are conducted by manufacturers may be based on small numbers of samples, so it is important to confirm that they perform adequately when used in larger populations and as diseases change or mutate over time. It is also essential to ensure that we have the capability to rapidly develop and validate tests for public use in future infectious disease outbreaks where there are no suitable commercially available tests.

We aim to ensure that the tests used in national infectious diseases testing programmes are of a high standard of diagnostic accuracy and that UK resources are used wisely.

We will do this by studying:
The accuracy of the tests used or planned to be used, within national testing programmes.
The effectiveness of the ways in which we deliver testing.
Whether the tests or where relevant sample collection kits, are safe and relatively easy for people to use.

This framework protocol ensures that these studies can be delivered quickly and safely, under one standardised ethical and governance framework, to inform key policy decisions, support the development of improved testing approaches and provide assurance of the clinical effectiveness of UKHSA testing programmes.

Who can participate?
Individuals who are known, or suspected, to have an infectious disease which is the subject of a UKHSA National Testing Programme, contacts of such individuals, or any individual who is at risk of contracting the disease in question (e.g. healthcare workers, hospital inpatients, etc)

What does the study involve?
Participants are asked to take part in an evaluation study which will allow the research team to check the performance of tests and improve how they are used. We will provide participants with some tests or sampling kits, together with a step-by-step guide on how to take the test or provide a sample. The test may need to be registered and some additional information provided but the requirement for extra testing or information collection has been kept to a minimum and will be as close to normal care as possible. Laboratory studies completed using the provided samples may also help researchers understand more about the disease which can assist them in developing new vaccines, treatments, tests and other public health responses.

What are the possible benefits and risks of participating?
By taking part in this study, you will be helping the research team check the accuracy of these tests and the effectiveness of UKHSA testing services. This information will help decide how to test for Covid-19 or other infectious diseases in the future, and whether how well tests work is affected by changes in testing approaches or changes to the disease itself.

Taking part may involve doing extra tests which may require some additional time to complete and register. The requirement for extra testing or information collection has been kept to a minimum and will be as close to normal care as possible. The process of collecting the sample can sometimes cause some pain or discomfort depending on the type of sample required.

Where is the study run from?
UK Health Security Agency (UK)

When is the study starting and how long is it expected to run for?
November 2022 to November 2027

Who is funding the study?
UK Health Security Agency (UK)

Who is the main contact?
Dr Edward Blandford, edward.blandford@ukhsa.gov.uk

Contact information

Type(s)
Scientific

Contact name
Dr Edward Blandford

ORCID ID
https://orcid.org/0000-0002-8846-2650

Contact details
4th Floor – Zone A
Nobel House
17 Smith Square
London
United Kingdom
SW1P 3JA
+44 (0)7974 019145
edward.blandford@ukhsa.gov.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
317913

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 53887, IRAS 317913

Study information

Scientific Title
UK Health Security Agency (UKHSA) standardised protocol for clinical studies evaluating the safety and performance of In-Vitro Diagnostic Devices (IVDD) for use in the Covid-19 and other national infectious diseases testing programmes

Acronym
UKHSA IVDD Testing Evaluation Framework

Study objectives
We aim to ensure that the tests used in national infectious diseases testing programmes are of a high standard of diagnostic accuracy and that UK resources are used wisely. We will do this by studying:
• The accuracy of the tests used, or planned to be used, within national testing programmes.
• The effectiveness of the ways in which we deliver testing.
• Whether the tests, or where relevant sample collection kits, are safe and relatively easy for people to use.

This framework protocol ensures that these studies can be delivered quickly and safely, under one standardised ethical and governance framework, to inform key policy decisions, support the development of improved testing approaches and to provide assurance of the clinical effectiveness of UKHSA testing programmes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/11/2022, South Central - Oxford C Research Ethics Committee (Health Research Authority (Bristol), Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, UK; +44 (0) 2071048241; oxfordc.rec@hra.nhs.uk), ref: 22/SC/0340

Study design
Randomized cohort study

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
COVID-19 and other infectious diseases

Interventions
This framework incorporates both prospective observational cohort studies and performance evaluation studies of in-vitro diagnostic devices (IVDDs), methodologies or testing regimens for SARS-CoV-2 and other infectious diseases.

Fundamentally, studies will be designed to either evaluate a different testing option within a standardised process (new device, new testing regimen) or to explore the use of a standardised test in a new context (e.g. new sampling technique, a new variant of concern [VoC], new infectious disease).

IVDD's, sampling methods or testing regimens under evaluation used may be randomly allocated to individuals, organisations, or test sites through a computerised randomisation procedure. This approach will only be used where there is a requirement to control other confounding factors which may affect study validity. Examples of these include swabbing order, geographical location, and sociodemographic factors. However, all participants will receive standard-of-care diagnostic testing appropriate for the use case/setting.

Potential designs falling within the scope of this framework also include:
1. Participants doing two or three tests simultaneously or within a few hours of each other
2. Participants doing daily, regular or follow-up testing for a set period (e.g., the incubation period)
3. Participants using different sample collection methods or materials (e.g., saliva versus nose and throat swab, viral inactivation versus viral transport medium)
4. Participants providing samples to be used for in-vitro validation of IVDDs in the laboratory or other service-based functions (such as viral characterisation) as part of the health protection response.

If a proposed study requires the introduction of new requirements beyond the scope of this protocol, amendments may be submitted describing these additional requirements which may include informed consent procedures, safety characteristics, and any other relevant considerations.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
In-vitro diagnostic devices for SARS-CoV-2 and other infectious diseases

Primary outcome(s)
Standard Diagnostic Accuracy is calculated using PCR CT (Cycle Threshold) values at sub-study completion

Key secondary outcome(s))
Measured at sub-study completion for each new arm:
1. Sensitivity is calculated using PCR CT (Cycle Threshold) values
2. Usability is demonstrated using the MHRA Guidance on applying human factors to medical devices

Completion date
15/11/2027

Eligibility

Key inclusion criteria
1. Individuals able to give consent to participate in the evaluation, or in the case of an adult who lacks capacity or a minor (< 16 years), their identified personal or professional consultee, who is willing and able to give consent.
2. Individuals who are known, or suspected, to have an infectious disease which is the subject of a UKHSA National Testing Programme, contacts of such individuals, or any individual who is at risk of contracting the disease in question (e.g. healthcare workers, hospital inpatients, etc)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
1. Participants who cannot provide informed consent and do not have an identified caregiver who can provide consent on their behalf.
2. Individuals for whom the caregiver, healthcare worker, or physician stipulates the process of sample collection is clinically unsuitable.

Date of first enrolment
30/01/2023

Date of final enrolment
15/06/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University College London Hospital
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
United Kingdom
NW1 2PG

Study participating centre
Chelsea & Westminster Hospital
369 Fulham Road
London
United Kingdom
SW10 9NH

Study participating centre
St Thomas' Hospital
249 Westminster Bridge Road
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
UK Health Security Agency

Funder(s)

Funder type
Government

Funder Name
UK Health Security Agency

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 PHCOServiceEvaluations@ukhsa.gov.uk. Each sub-study may use different consent arrangements and may generate different categories of data. UKHSA are committed to transparency and all reasonable requests for anonymised data will be reviewed on a case-by-case basis at the fortnightly Scientific Advisory Group meeting.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Interim results article		13/01/2025	20/01/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 2	19/10/2022	26/01/2023	No	No
Protocol file	version 4	19/09/2023	30/04/2024	No	No