

# Artificial intelligence project for improved sarcoma diagnoses for patient benefit

<b>Submission date</b> 06/12/2024	<b>Recruitment status</b> Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 09/01/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 17/12/2024	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Cancer treatment is determined by how tumours are classified by pathologists, who provide diagnoses which encompass prognoses and predictions of responses to therapies.

Reaching a tissue diagnosis today requires more time than hitherto allocated to pathologists, driven by the rapidly increasing knowledge of important prognostic factors, an understanding of the molecular basis of disease and the availability of targeted and personalised treatments. Diagnoses must be highly specific and accurate, distinguishing cancer subtypes from each other and from other diseases such as bone and soft tissue tumours versus regenerative /degenerative musculoskeletal (MSK) disease.

The increasing workload and complexity in reaching pathological diagnoses is compounded by a declining workforce: 29% of all UK-based pathologists are aged 55 and over. MSK pathology is specifically affected as there is a serious shortfall in pathologists in this subspecialty area. Although primary MSK sarcomas represent about 2% of all cancers, there are over 100 subtypes described, as well as many common conditions that mimic sarcoma. The diagnosis has huge treatment implications and therefore crucially important to get right. Sarcomas can occur anywhere in the body (e.g. breast, lung) so they are frequently first encountered by non-expert MSK pathologists. This often leads to excessive consultant time in reaching diagnoses, and ordering inappropriate and excessive immunohistochemical and genetic tests. This protracts patients' journeys to treatment, resulting in unnecessary costs.

This study aims to find out whether artificial intelligence (AI) is a solution to these challenges and can help support (not replace) pathologists as already shown for common cancers (e.g. prostate and bowel).

### Who can participate?

Patients who had a diagnosis of sarcoma or a mimic of sarcoma and whose tissue has been processed as part of their clinical care. The study is fully inclusive of all genders, age ranges, ethnicities and members of all socio-economic groups.

### What does the study involve?

As AI requires large numbers of cases and pathology slides must be digitised to generate whole-slide images (WSIs). The availability of digital scanners across the UK has made this possible. This study will gather large numbers of sarcoma cases using archived slides/data from the last 40

years and prospectively. Members of direct clinical care teams will gather pathology images /data from up to 50,000 patients. The project will run for 10 years (collecting images/data for 5 years and 5 years follow-up).

What are the possible benefits and risks of participating?

The study aims to produce an AI algorithm to aid sarcoma diagnosis in the future. There are no direct benefits or risks to current patients.

Where is the study run from?

University College London (UK)

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

March 2023 to December 2033

Who is funding the study?

The majority of the funding has been secured from UK Research and Innovation (UKRI) along with smaller grants from Tom Prince Cancer Trust, Skeletal Cancer Trust, Sarcoma UK, Chordoma UK and Bone Cancer Research Trust (UK)

Who is the main contact?

Prof. Adrienne M Flanagan, a.flanagan@ucl.ac.uk

## Contact information

### Type(s)

Public, Scientific, Principal Investigator

### Contact name

Prof Adrienne Flanagan

### ORCID ID

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### Contact details

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

328987

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

EDGE 161548

## Study information

**Scientific Title**

An artificial intelligence solution for diagnosing, prognosticating as well as predicting the outcome of sarcomas and their mimics: a multi-centre study

**Acronym**

AI-SCOPE

**Study objectives**

It is hypothesised that artificial intelligence (AI) can be used to support pathologists in classifying sarcomas (rare cancers of bone and soft tissue) and their mimics and provide improved or similar classification performance compared to pathologists.

It is hypothesised that the AI Classifier will save pathologists' time and improve the patients' diagnostic pathways and that cost efficiencies can be made.

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

Approved 12/12/2023, Health and Social Care Research Ethics Committee B (HSC REC B) (Office for Research Ethics Committee Northern Ireland (ORECNI), Lissue Industrial Estate West, 5 Rathdown Walk, Lisburn, BT28 2RF, United Kingdom; +44 (0)28 95 361400; info.orecni@hscni.net), ref: 23/NI/0166

**Study design**

Multi-centre observational pseudonymised cohort study

**Primary study design**

Observational

**Secondary study design**

Cohort study

**Study setting(s)**

Hospital, University/medical school/dental school

**Study type(s)**

Diagnostic

**Participant information sheet**

Not available in web format, please use the contact details to request a participant information sheet

## **Health condition(s) or problem(s) studied**

Bone and soft tissue tumours and their mimics

## **Interventions**

This study involves a large-scale collection of digitised whole slide images (WSI), together with related demographic and clinical data, from a cohort of 35,000 - 50,000 patients which will be obtained from multiple hospital sites.

There is no recruitment to the study and no intervention.

Because of the rarity of sarcoma, this can only be achieved using retrospective cases archived over many years. The identification and preparation of the WSI and related clinical data, including its deidentification and pseudonymisation, will be undertaken at each collaborating pathology site by the direct clinical care team. Only de-identified and pseudonymised data will be accessible to researchers. The diagnoses given by the resulting algorithm will be compared with the diagnosis given by a panel of pathologists.

## **Intervention Type**

Other

## **Primary outcome measure**

The primary outcome measure is whether the algorithm has predicted the diagnosis correctly. The algorithm ranks the diagnosis in order of likelihood with the highest ranking being compared to the diagnosis agreed on by a panel of pathologists and/or additional molecular tests and is categorised as being correct or incorrect and a confusion table will be constructed. Measured at a single timepoint.

## **Secondary outcome measures**

Measured at a single timepoint:

1. Diagnostic pathway efficiency and speed, measured as the rate at which a patient receives a diagnosis
2. The number of ancillary tests required, measured as the numbers requested by pathologists prior to reaching a diagnosis
3. Pathologist diagnostic efficiency, measured as the number of pathologists able to make accurate diagnoses without the need for excessive tests and referrals
4. Pathological and epidemiological insights into sarcomas, measured through the review of a large number of retrospective cases along with the development of an algorithm to improve diagnosis prospectively.
5. Prognosis and prediction of response to treatment, assessed by linking the algorithm's predictions with demographic and clinical outcome data ranging from the patient's initial date of diagnosis to either their date of death or date last seen.

Following exploratory data analysis with correlation plots, histograms and frequency tables, statistical modelling will be performed using survival analysis with Cox proportional hazard estimates and log-rank test as appropriate. Statistical significance will be set at 5%. Further statistical methods and machine learning techniques such as the random forest algorithm may be used to improve prediction of prognosis.

## **Overall study start date**

01/03/2023

**Completion date**

31/12/2033

## Eligibility

**Key inclusion criteria**

Patients who had a diagnosis of sarcoma or a mimic of sarcoma and whose tissue has been processed as part of their clinical care. The study is fully inclusive of all genders, age ranges, ethnicities and members of all socio-economic groups.

**Participant type(s)**

Patient

**Age group**

All

**Lower age limit**

1 Days

**Upper age limit**

100 Years

**Sex**

Both

**Target number of participants**

50000

**Total final enrolment**

50000

**Key exclusion criteria**

Does not meet the inclusion criteria

**Date of first enrolment**

01/10/2023

**Date of final enrolment**

31/12/2029

## Locations

**Countries of recruitment**

England

United Kingdom

Wales

**Study participating centre**  
**Royal National Orthopaedic Hospital NHS Trust**  
Brockley Hill  
Stanmore  
United Kingdom  
HA7 4LP

**Study participating centre**  
**Manchester University NHS Foundation Trust**  
Cobbett House  
Oxford Road  
Manchester  
United Kingdom  
M13 9WL

**Study participating centre**  
**The Newcastle upon Tyne Hospitals NHS Foundation Trust**  
Freeman Hospital  
Freeman Road  
High Heaton  
Newcastle upon Tyne  
United Kingdom  
NE7 7DN

**Study participating centre**  
**The Royal Marsden NHS Foundation Trust**  
Fulham Road  
London  
United Kingdom  
SW3 6JJ

**Study participating centre**  
**Nottingham University Hospitals NHS Trust - Queen's Medical Centre Campus**  
Nottingham University Hospital  
Derby Road  
Nottingham  
United Kingdom  
NG7 2UH

**Study participating centre**

**Oxford University Hospitals NHS Foundation Trust**

John Radcliffe Hospital  
Headley Way  
Headington  
Oxford  
United Kingdom  
OX3 9DU

**Study participating centre**

**Great Ormond Street Hospital Central London Site**

Great Ormond Street  
London  
United Kingdom  
WC1N 3JH

**Study participating centre**

**Swansea Bay University Local Health Board**

One Talbot Gateway  
Seaway Drive  
Seaway Parade Industrial Estate  
Baglan Port Talbot  
West Glamorgan  
United Kingdom  
SA12 7BR

**Study participating centre**

**University College London Hospitals NHS Foundation Trust**

250 Euston Road  
London  
United Kingdom  
NW1 2PG

**Study participating centre**

**The Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust**

Gobowen  
Oswestry  
United Kingdom  
SY10 7AG

**Study participating centre**

**Sheffield Teaching Hospitals NHS Foundation Trust**

Northern General Hospital  
Herries Road  
Sheffield  
United Kingdom  
S5 7AU

**Study participating centre****Cambridge University Hospitals NHS Foundation Trust**

Cambridge Biomedical Campus  
Hills Road  
Cambridge  
United Kingdom  
CB2 0QQ

## **Sponsor information**

**Organisation**

University College London

**Sponsor details**

4th Floor, West  
250 Euston Road  
London  
England  
United Kingdom  
NW1 2PG  
+44 (0)20 3447 9928  
uclh.randd@nhs.net

**Sponsor type**

University/education

**Website**

<http://www.ucl.ac.uk/>

**ROR**

<https://ror.org/02jx3x895>

## **Funder(s)**

**Funder type**

Government



**Funder Name**

UK Research and Innovation

**Alternative Name(s)**

UKRI

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

**Funder Name**

Tom Prince Cancer Trust

**Alternative Name(s)**

UKRI

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

**Funder Name**

Skeletal Cancer Trust

**Funder Name**

Sarcoma UK

**Alternative Name(s)**

SUK

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United Kingdom

**Funder Name**

Chordoma UK

**Funder Name**

Bone Cancer Research Trust

**Alternative Name(s)**

The Bone Cancer Research Trust, BCRT

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

Planned publication in a peer-reviewed journal, internal report, conference presentation and publication on website.

**Intention to publish date**

31/12/2025

**Individual participant data (IPD) sharing plan**

The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

**IPD sharing plan summary**

Published as a supplement to the results publication