# Testing the MitProfiler tool for detecting and counting dividing cells in stained tissue samples

Submission date	Recruitment status  No longer recruiting	Prospectively registered		
13/08/2025		[X] Protocol		
<b>Registration date</b> 19/09/2025	Overall study status Completed	Statistical analysis plan		
		Results		
Last Edited	Condition category Cancer	Individual participant data		
19/09/2025		[X] Record updated in last year		

### Plain English summary of protocol

Background and study aims

MitProfiler is a computer algorithm which uses machine learning, a form of artificial intelligence, to train computers to recognise mitotic figures in pathology samples (that is, samples of human or animal tissue prepared for microscopic examination). Mitotic figures are seen in cells which are dividing. They are the chromosomes in the cells which can be seen preparing to divide and separating into the daughter cells as the cells divide. They are an important feature of normal tissue biology (e.g. in growing regenerating tissue) and diseases such as cancer (where cells grow and divide in an uncontrolled manner). Pathologists see and count mitotic figures routinely in their work. Having the computer do this task saves time, reduces fatigue in pathologists and should deliver more consistent results as observations between individual human pathologists vary to some extent. By getting human pathologists and the MitProfiler algorithm to count mitoses in the same samples, this study aims to measure how the MitProfiler algorithm performs in comparison to human pathologists.

### Who can participate?

Patients with haematoxylin and eosin-stained tissue sections from various tumour types

### What does the study involve?

This study involves comparing the human pathologists' counts of mitotic figures in stained tissue sections with an automated mitotic counting algorithm.

What are the possible benefits and risks of participating?

If the results are as good or better than human pathologists, the data derived will be used to support the regulatory approval of the device through the Medicines and Healthcare Regulatory Authority.

Where is the study run from? Histofy Ltd (UK)

When is the study starting and how long is it expected to run for? February 2025 to September 2025

Who is funding the study? Innovate UK

Who is the main contact?
Prof. David Snead, david.snead@uhcw.nhs.uk

# Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

**Prof David Snead** 

#### **ORCID ID**

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### Contact details

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# Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

# Integrated Research Application System (IRAS)

342246

# ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

MitPro Study Protocol 2.4

# Study information

### Scientific Title

Validation of the MitProfiler algorithm for the detection and quantification of mitotic figures in haematoxylin and eosin-stained tissue sections

### Acronym

MitPro validation study

### **Study objectives**

MitProfiler is a computer algorithm which uses machine learning, a form of artificial intelligence, to train computers to recognise mitotic figures in pathology samples (that is, samples of human or animal tissue prepared for microscopic examination). Mitotic figures are seen in cells which are dividing. They are the chromosomes in the cells which can be seen preparing to divide and separating into the daughter cells as the cells actually divide. They are an important feature of normal tissue biology (e.g. in growing regenerating tissue) and diseases such as cancer (where cells grow and divide in an uncontrolled manner). Pathologists see and count mitotic figures routinely in their work. Having the computer do this task saves time, reduces fatigue in pathologists and should deliver more consistent results as observations between individual human pathologists vary to some extent. By getting human pathologists and the MitProfiler algorithm to count mitoses in the same samples, this study aims to measure how closely the MitProfiler algorithm performs in comparison to human pathologists. If the results are as good or better than human pathologists, the data derived will be used to support the regulatory approval of the device through the Medicines and Healthcare Regulatory Authority.

### Ethics approval required

Ethics approval required

### Ethics approval(s)

approved 20/02/2025, London - Fulham Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8084, (0)207 104 8286, (0)207 104 8109; fulham.rec@hra.nhs.uk), ref: 25/LO/0158

### Study design

Observational cohort study

### Primary study design

Observational

### Study type(s)

Diagnostic

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

Sarcoma, melanoma, carcinoma, carcinoid

#### **Interventions**

This observational study involves comparing the blinded counts of mitotic figures in archived hematoxylin and eosin (H&E) sections with an automated mitotic counting algorithm.

### Intervention Type

Device

### Phase

Not Applicable

### Drug/device/biological/vaccine name(s)

MitPro

### Primary outcome(s)

Interobserver variation of mitotic counts measured using data generated by the MitProfiler algorithm and human pathologists at one timepoint

# Key secondary outcome(s))

Time taken to produce mitotic counts measured using data generated by the MitProfiler algorithm and human pathologists at one timepoint

### Completion date

30/09/2025

# **Eligibility**

### Key inclusion criteria

Patients with haematoxylin and eosin-stained tissue sections from tumour types:

- 1. Breast cancer
- 2. Neuroendocrine tumour
- 3. Melanoma (including uveal melanoma)
- 4. Soft tissue sarcoma
- 5. Leiomyoma
- 6. Lung cancer
- 7. Glioblastoma
- 8. Meningioma
- 9. Thyroid cancer
- 10. Retinoblastoma

### Participant type(s)

**Patient** 

# Healthy volunteers allowed

No

### Age group

Mixed

### Lower age limit

1 years

### Upper age limit

100 years

#### Sex

All

### Key exclusion criteria

Haematoxylin and eosin-stained tissue section slides are unavailable

#### Date of first enrolment

13/08/2025

### Date of final enrolment

# Locations

### Countries of recruitment

**United Kingdom** 

England

# Study participating centre North Tees and Hartlepool NHS Foundation Trust

University Hospital of Hartlepool Holdforth Road Hartlepool United Kingdom TS24 9AH

# Sponsor information

### Organisation

Histofy Ltd

# Funder(s)

# Funder type

Government

### **Funder Name**

Innovate UK

### Alternative Name(s)

UK Research and Innovation Innovate UK, innovateuk

### **Funding Body Type**

Government organisation

## **Funding Body Subtype**

National government

### Location

**United Kingdom** 

# **Results and Publications**

# Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date

# IPD sharing plan summary

Data sharing statement to be made available at a later date

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 2.4		21/08/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes