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

**Submission date**
13/08/2025

**Registration date**
19/09/2025

**Last Edited**
19/09/2025

**Recruitment status**
No longer recruiting

**Overall study status**
Completed

**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
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)
Technology Strategy Board

## 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? |
|---|---|---|---|---|---|
| Protocol file | version 2.4 | | 21/08/2025 | No | No |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |