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

Submission date
13/08/2025

Recruitment status
No longer recruiting

Registration date
19/09/2025

Overall study status
Ongoing

Last Edited
19/09/2025

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

Study website
https://histofy.ai

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Prof David Snead

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
342246

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Laboratory

Study type(s)
Diagnostic

Participant information sheet
Not applicable

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

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

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

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

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

Overall study start date
20/02/2025

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

Age group
Mixed

Lower age limit
1 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
500

Key exclusion criteria
Haematoxylin and eosin-stained tissue section slides are unavailable

Date of first enrolment
13/08/2025

Date of final enrolment
20/09/2025

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor details
The Venture Centre
Sir William Lyons Road
Coventry

England
United Kingdom
CV4 7EZ

Sponsor type
Industry

Website
https://histofy.ai/

Funder(s)

Funder type
Government

Funder Name
Innovate UK

Alternative Name(s)
innovateuk

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
31/10/2025

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