

# Cancer diagnostics using artificial intelligence

<b>Submission date</b> 13/09/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 16/09/2022	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/03/2025	<b>Condition category</b> Cancer	<input checked="" type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The exact location, size and activity level of malignant tumors in the head and neck region can be difficult to determine accurately. A correct assessment these tumors on PET-CT images is essential in order to secure successful treatment. The aim of this study is to investigate whether or not artificial intelligence tools can assist in the assessment of head and neck tumors.

### Who can participate?

Patients of all ages who were treated for head and neck cancer with radiotherapy at Rigshospitalet between 01/01/2014 and 01/01/2020, who were also scanned with PET-CT for treatment planning purposes

### What does the study involve?

The study does not have an effect on patient treatment. Tumor delineations are used to train and validate artificial intelligence algorithms in order to determine if the quality of these is sufficient to be used in a clinical setting.

### What are the possible benefits and risks of participating?

Participation involves no risks or benefits.

### Where is the study run from?

Rigshospitalet (Denmark)

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

January 2020 to June 2022

### Who is funding the study?

1. Louis-Hansen Fonden (Denmark)
2. Capital Region of Denmark (Denmark)
3. Hartmann Fonden (Denmark)

### Who is the main contact?

David Gergely Kovacs Petersen, david.gergely.kovacs.petersen@regionh.dk

## Contact information

**Type(s)**

Principal investigator

**Contact name**

Mrs Barbara Malene Fischer

**ORCID ID**

<https://orcid.org/0000-0002-6065-3375>

**Contact details**

Blegdamsvej 9  
Copenhagen  
Denmark  
2100  
+45 (0)35459824  
[barbara.malene.fischer@regionh.dk](mailto:barbara.malene.fischer@regionh.dk)

**Type(s)**

Scientific

**Contact name**

Mr David Gergely Kovacs Petersen

**ORCID ID**

<https://orcid.org/0000-0002-0383-1446>

**Contact details**

Blegdamsvej 9  
Copenhagen  
Denmark  
2100  
+45 (0)30470433  
[david.gergely.kovacs.petersen@regionh.dk](mailto:david.gergely.kovacs.petersen@regionh.dk)

## Additional identifiers

**Protocol serial number**

480\_21

## Study information

**Scientific Title**

Clinical comparison and validation of openly available deep learning methods for automated metabolic tumor volume delineation on PET-CT of head and neck cancer

**Study objectives**

Artificial intelligence can be used for automated tumor delineation of head and neck cancer in quality matching that of a nuclear medicine specialist.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 18/06/2020, Danish Patient Safety Authority (Islands Brygge 67, 2300 København S, Denmark; +45 (0)7228 6600; stps@stps.dk), case no. 31-1521-340, ref: SMMO.

## Study design

Single-centre observational study

## Primary study design

Observational

## Study type(s)

Diagnostic

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

Head and neck cancer

## Interventions

A single-centre study of automated tumor delineation accuracy with retrospectively registered head and neck cancer patients scanned with PET-CT for radiotherapy treatment planning between 01/01/2014 and 01/01/2020. Patients are not exposed to any new interventions as a part of this study. The researchers study PET-CT scans that were acquired as a part of routine clinical radiotherapy treatment.

## Intervention Type

Device

## Phase

Not Applicable

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

Automated metabolic tumor volume delineation

## Primary outcome(s)

Tumor delineation accuracy measured using the dice coefficient at a single timepoint

## Key secondary outcome(s)

1. Tumor delineation accuracy measured using Hausdorff distance at a single timepoint
2. Lesion-level detection accuracy measured using f1 score (harmonic mean of positive predictive value and sensitivity) at a single timepoint

## Completion date

06/06/2022

## Eligibility

### Key inclusion criteria

Patients treated with radiotherapy for cancer of the head and neck who received a PET-CT scan for treatment planning purposes as a part of clinical routine

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Total final enrolment**

1184

**Key exclusion criteria**

1. Patient PET or CT image not acquired according to required protocol
2. Clinical metabolic tumor volume delineation incomplete

**Date of first enrolment**

21/03/2021

**Date of final enrolment**

15/10/2021

**Locations****Countries of recruitment**

Denmark

**Study participating centre**

**Rigshospitalet**

Blegdamsvej 9

Copenhagen

Denmark

2100

**Sponsor information****Organisation**

Rigshospitalet

**ROR**

<https://ror.org/03mchdq19>

## **Funder(s)**

### **Funder type**

Charity

### **Funder Name**

Aage og Johanne Louis-Hansens Fond

### **Alternative Name(s)**

Aage and Johanne Louis-Hansen's Foundation, Aage og Johanne Louis-Hansen ApS, Louis-Hansen Fonden, Aage and Johanne Louis-Hansen Foundation

### **Funding Body Type**

Private sector organisation

### **Funding Body Subtype**

Trusts, charities, foundations (both public and private)

### **Location**

Denmark

### **Funder Name**

Region Hovedstaden

### **Alternative Name(s)**

Capital Region of Denmark

### **Funding Body Type**

Government organisation

### **Funding Body Subtype**

Local government

### **Location**

Denmark

### **Funder Name**

Hartmann Fonden

### **Alternative Name(s)**

Hartmann Foundation, The Hartmann Foundation, The Hartmann Brothers Foundation, Brødrene Hartmanns Fond

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Trusts, charities, foundations (both public and private)

### Location

Denmark

## Results and Publications

### Individual participant data (IPD) sharing plan

The researchers intend to publish the datasets generated and analysed at either <https://www.cancerimagingarchive.net/> or using an in-house server. The data sharing is pending legal approval, and the platform used for sharing depends on this approval. The type of data shared will be PET images, CT images and tumor volumes delineated by nuclear medicine physicians. The data is expected to become available indefinitely for researchers upon publication at the end of 2022. The data will be accessible upon legal approval for healthcare researchers in an anonymized form without prior participant consent.

Updated 13/03/2025:

The data is shared and available at the website <https://rigshospitalet-tumour-segmentation.regionh.dk/>

### IPD sharing plan summary

Stored in publicly available repository

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		22/02/2024	23/02/2024	Yes	No
<a href="#">Dataset</a>			13/03/2025	No	No
<a href="#">Protocol file</a>	version 11	16/09/2021	16/09/2022	No	No
<a href="#">Statistical Analysis Plan</a>	version 1		16/09/2022	No	No