OPTOMICS - Combining optoacoustic imaging phenotypes and multi-omics to advance diabetes healthcare (Validation Study)

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# Administrative details

EU PAS number	
EUPAS1000000392	
Study ID	
100000392	
DADWIN EIL® study	
DARWIN EU® study	
No	
Study countries	
Estonia	

**Study description** 

Diabetes has emerged as a global pandemic affecting more than 420 million people worldwide, a number expected to further rise in the next decades.

The disease has very heterogeneous outcomes and accurate patient staging or prediction of subsets of individuals likely to develop disease and/or progress to disease complications are currently unmet clinical challenges in need of urgent attention.

OPTOMICS aims to research methodology that can deliver a paradigm shift in type 2 diabetes healthcare, by integrating:

- molecular phenotyping,
- a new generation of phenotypic measurements in humans, representative of diabetes onset and progression, allowed by novel portable and non-invasive optoacoustic technology, and
- cutting-edge computational approaches leveraging progress in Artificial Intelligence.

This research will develop and validate a digital twin model that catalyses a step change in shortening the path to translation, enabling applications in the entire spectrum from target identification & prevention/prognosis to patient stratification for type 2 diabetes and its complications.

In addition to the research and technology goals, OPTOMICS places special attention to the ethical needs and implications of the work performed and further aims at exemplary project management, human measurements, dissemination and communication activities and updating an adept exploitation plan for the digital twin developed.

### Study status

Ongoing

Research institutions and networks

Institutions

# University of Tartu Estonia First published: 01/02/2024 Last updated: 01/02/2024 Institution Educational Institution

# Contact details

### **Study institution contact**

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Study contact

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# **Primary lead investigator**

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Primary lead investigator

### **ORCID** number:

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# Study timelines

### Date when funding contract was signed

Actual: 01/01/2021

### Study start date

Actual: 09/10/2023

### **Date of final study report**

Planned: 31/12/2026

# Sources of funding

• EU institutional research programme

# More details on funding

Horizon 2020 Programme, Grant Agreement no 101017802.

# Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

# Methodological aspects

Study type

Study type list

# Study topic:

Disease /health condition

Medical device

### Study type:

Clinical trial

### **Data collection methods:**

Combined primary data collection and secondary use of data

# Study Design

### Clinical trial regulatory scope

Clinical trial not part of marketing authorisation application or subject to marketing authorisation approval

# Population studied

# **Age groups**

Adult and elderly population (≥18 years)

### **Estimated number of subjects**

500

# Data management

# **ENCePP Seal**

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

# Use of a Common Data Model (CDM)

## **CDM** mapping

No

# Data quality specifications

### **Check conformance**

Unknown

### **Check completeness**

Unknown

### **Check stability**

Unknown

# **Check logical consistency**

Unknown

# Data characterisation

### **Data characterisation conducted**

No