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Early screening for colorectal cancer via a simple blood sample

Submission date 31/08/2023	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 26/10/2023	**Overall study status** Ongoing	
Last Edited 08/08/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims

Colorectal cancer is the third most common cancer in men and the second in women, accounting for 10% of all cancers worldwide. It ranks second in terms of cancer-related deaths, just behind lung cancer. In certain European member states, a home-based screening test searching for occult blood in a stool sample has been in operation in recent years for people aged 50 years and over. Although this method is simple to perform, it only detects the already symptomatic stage of the disease. Therefore, although more invasive, colonoscopy remains the most reliable method of screening for colorectal cancer, as it enables polyps and other lesions to be visualized and removed using an endoscope with a camera. The risk of colorectal cancer following colonoscopy has been shown to be reduced by 70-90%. Early detection and removal of a pre-cancerous polyp prevents its progression to a tumor. In this way, colonoscopy saves many lives. Nevertheless, although colorectal cancer is now considered an easily preventable disease thanks to screening, long waiting and preparation times for colonoscopy prevent the implementation of large-scale screening for systematic surveillance and follow-up. Since the 1990s, there has been a gradual increase in the rate of colorectal cancer in adults under the age of 50. Although the reasons for this are still unknown, it has been suggested that environmental and behavioral changes influencing the microbiome (gut bacteria) are at the root of colorectal cancer in people under 50. The need to develop a large-scale, inexpensive, and non-invasive method of early detection of colorectal cancer is therefore urgent.

This study aims to develop a routine blood test accessible to all ages in order to identify people who would not otherwise be screened according to current European or national guidelines. The previous part of the DIOPTRA project would have identified in around 200 participants a protein group whose quantity varies during a precancerous stage of colon cancer. By quantifying this group of proteins, this blood test will be able to identify those citizens who absolutely should undergo further screening by colonoscopy. To validate this method, participants are invited to give a blood sample during their colonoscopy visit to the gastroenterology department. Once validated, this blood test has many advantages: it is almost non-invasive, inexpensive and could be well accepted by most of the population. As a result, DIOPTRA is positioning itself in the increasingly personalized medicine of the future, capable of adapting to the particularities of each individual.

Other aims:

1. In addition to an early detection method for colon cancer, numerous scientific studies have

identified parameters called risk factors which could be associated with the development of colorectal cancer, and their importance is not negligible. Suggestions for daily habits can be generated from these risk factors and may be very useful in the prevention of colorectal cancer.
2. Another aim of the study is to validate some of the risk factors identified in the previous part of the project. The DIOPTRA application would be created to help collect information, offer up-to-date personalized suggestions and raise awareness of early detection of colorectal cancer.
3. The findings and the final DIOPTRA solution will be the subject of a study of healthcare performance indicators in view of widening screening eligibility thanks to an effective, minimally invasive and financially affordable method.

Who can participate?
Individuals between 18 and 80 years old who visit the clinical sites for a colonoscopy

What does the study involve?
According to each clinical site's standards and pre-existing practice, enrolled individuals will undergo a screening colonoscopy, while blood will be collected via a minimally invasive method (before the colonoscopy) for the purposes of the study. All biological data will be used for protein-based analysis, allowing the construction of preliminary decision algorithms and AI analysis models. A sub-study with a one-year follow-up using a mobile application will also be conducted and a second blood sample will be collected after one-year period, with study feedback questionnaires.

What are the possible benefits and risks of participating?
There is no direct benefit from participating in this study. The donation of blood sample is free of charge. FIT test will be proposed in two clinical sites. However, in general, early detection of CRC can significantly enhance survival rates and treatment outcomes. Medical specialists could offer personalised prevention plans to reduce CRC risk. Participants will not experience any inconvenience during study. This study will not have any impact on the treatment participants have been offered or the diagnostic and monitoring procedures of the usual medical practice. Given that the collection of blood samples will be done with a minimally invasive method and the study does not pose any additional risks.

Where is the study run from?
From eight hospital sites and one biobank of the DIOPTRA project in eight countries: Austria, Belgium, Croatia, Cyprus, Denmark, Greece, Slovenia and Spain

When is the study starting and how long is it expected to run for?
January 2023 to December 2026

Who is funding the study?
European Health and Digital Executive Agency

Who is the main contact?
1. Mr Zheshen Jiang, Zheshen.jiang@chuliege.be
2. Mr Nicolas Gillain, nicolas.gillain@chuliege.be

Study website
https://www.dioptra-project.eu/

Contact information

Type(s)
Scientific

Contact name
Mr Zheshen Jiang

ORCID ID
https://orcid.org/0000-0002-4914-7041

Contact details
Domaine universitaire du Sart-Tilman B35
Avenue de l'hopital, 1
Liège
Belgium
4000
+32 (0)4323 3689
zheshen.jiang@chuliege.be

Type(s)
Principal Investigator

Contact name
Dr Catherine Loly

ORCID ID
https://orcid.org/0000-0002-6829-2324

Contact details
Domaine universitaire du Sart-Tilman B35
Avenue de l'hopital, 1
Liège
Belgium
4000
+32 (0)4323 7746
catherine.loly@chuliege.be

Type(s)
Scientific

Contact name
Mr Nicolas Gillain

Contact details
Domaine universitaire du Sart-Tilman B35
Avenue de l'hopital, 1
Liège
Belgium
4000
-
nicolas.gillain@chuliege.be

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
EU HORIZON project number: 101096649

Study information

Scientific Title
Early dynamic screening for colorectal cancer via novel protein biomarkers reflecting biological initiation mechanisms (DIOPTRA)

Acronym
DIOPTRA

Study objectives
Current study objectives as of 08/08/2025:

The main study hypothesis is that the DIOPTRA screening system has adequate clinical performance to diagnose CRC and advanced adenomas early. Moreover, the clinical performance is expected to surpass that of the FIT tests that are commercially available. An additional hypothesis is that the DIOPTRA system can accurately characterise an individual's risk of developing CRC. Finally, we hypothesise that the DIOPTRA behavioural suggestions, when applied, can significantly lower the behavioural risk of developing CRC. To evaluate these hypotheses, we will use multiplex protein biomarker measurements and demographic, behavioural, and clinical data from participants in the DIOPTRA study groups to test and refine the DIOPTRA AI models.

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Previous study objectives:

The main study hypothesis is that the DIOPTRA screening system has adequate clinical performance for the early diagnosis of colorectal cancer and advanced adenomas. An additional hypothesis is that the DIOPTRA system can accurately characterise the risk of an individual developing colorectal cancer. Finally, it is hypothesised that the DIOPTRA behavioural suggestions, when applied, can significantly lower the risk of developing colorectal cancer. To evaluate these hypotheses, the researchers will use multiplex protein biomarker measurements, along with demographic, behavioural, and clinical data from participants belonging to the DIOPTRA study groups to test and refine the DIOPTRA AI models.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 21/11/2023, Institutional Ethics Committee of CHU of Liege (Comité d'éthique Hospitalo-Facultaire Universitaire de Liège) (CHU de Liège ICAB (Institut Cancerologie Arsène Burny) Route 562, porte 166 Avenue de l'Hôpital,1, Liège, 4000, Belgium; +32 (0)4 323 2158; ethique@chuliege.be), ref: 2023/262

2. Approved 22/04/2024, The Regional Committees on Health Research Ethics for Southern Denmark (Damhaven 12, Vejle, 7100, Denmark; +45 (0)76638221; komite@rsyd.dk), ref: S-20240011

3. Approved 05/02/2024, Cyprus National Bioethics Committee (22 Laertou, Agios Dometios, Nicosia, 2365, Cyprus; +35 (0)722809039; cnbc@bioethics.gov.cy), ref: ΕΕΒΚ/ΕΠ/2023/73

4. Approved 05/09/2023, Scientific Board of GENIKO ANTIKARKINIKO OGKOLOGIKO NOSOKOMEIO ATHINON O AGIOS SAVVAS (171 Alexandras Ave, Athens , 11522, Greece; +30 (0) 2106409600-603; epistimoniko@agsavvas-hosp.gr), ref: 11566

5. Approved 07/02/2023, Scientific Board, Attikon Hospital (Rimini 1 City, Athens, 12462, Greece; +30 (0)210 58 31 000; greps@attikonhospital.gr), ref: Β'ΠΠΚ, ΕΒΔ62/01-02-2023

6. Approved 19/01/2024, Komisija Republike Slovenije za medicinsko etiko (Štefanova ulica 5 , Ljubljana, 1000, Slovenia; +386 (0)1 478 69 06; kme.mz@gov.si), ref: 0120-447/2023/12

7. Approved 22/10/2024, Etičko povjerenstvo Kliničke bolnice Dubrava (Avenija Gojka Šuška 6, Zagreb, 10000, Croatia; +385 (0)91/4112-397; povjerenstvo.eticko@kbd.hr), ref: 2024/1022-16

8. Approved 03/10/2023, Comité de Ética de la Investigación con medicamentos (CEIm) del Área de Salud de Burgos y Soria (Unidad de Investigación, Bloque F, Planta 0, Hospital Universitario de Burgos Avd Islas Baleares, 3, Burgos, 09006, Spain; +34 (0)947 256 533 ext 36078 ; r.alcaraz.ortega@gmail.com), ref: CEIm 2986

9. Approved 03/07/2023, Ethikkommission der Medizinischen Universität Graz (Neue Stiftingtalstraße 6 - West, P 08, Graz, 8010, Austria; +43 316 385 71400; ethikkommission@medunigraz.at), ref: 35-377 ex22/23

Study design
Prospective cohort multi-center study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Early screening of colorectal cancer from 18 to 80 years old

Interventions
Current interventions as of 08/08/2025:

The study will be a prospective, cohort, multi-centre study with a partial follow-up of one year. Changes to the recruitment process throughout the duration of the project are not envisaged. An equal sample size will be required for all 4 groups: healthy, non-advanced adenomas, advanced adenomas and CRC cases (subgroup definition details could be found in the protocol attached p15). Only the first two groups will be enrolled in the follow-up study. Initial data obtained will be used for the algorithm training, followed by pilot validation.

Biological samples will be collected via a minimally invasive method. According to each clinical site's standards and pre-existing practice, enrolled individuals will undergo a screening colonoscopy, while blood will be drawn (prior to the colonoscopy) for the purposes of the study. For the partial follow-up of one year, a second blood sample will be required one year after the initial blood sample and the DIOPTRA mobile application will be provided for one year of usage. All biological data will be used for in vitro protein-based analysis, allowing the construction of preliminary decision algorithms and AI analysis models.

Additionally, FIT (Fecal Immunochemical Test) will be organised in two of the centres (GOC and NKUA), with three centres (BURGOS, CHUL and RSYD) who could provide FIT test results in EHR.

Previous interventions as of 09/01/2025:

The study will be a prospective, cohort, multi-centre study with a partial follow-up of one year. Changes to the recruitment process throughout the duration of the project are not envisaged. An equal sample size will be required for all 4 groups: healthy, non-advanced adenomas, advanced adenomas and CRC cases. Only the first two groups will be enrolled in the follow-up study. Initial data obtained will be used for the algorithm training, followed by pilot validation.

Biological samples will be collected via a minimally invasive method. According to each clinical site's standards and pre-existing practice, enrolled individuals will undergo a screening colonoscopy, while blood will be drawn (prior to the colonoscopy) for the purposes of the study. For the partial follow-up of one year, a second blood sample will be required one year after the initial blood sample and the DIOPTRA mobile application will be provided for one year of usage. All biological data will be used for in vitro protein-based analysis, allowing the construction of preliminary decision algorithms and AI analysis models.

Previous interventions:

Prospective, cohort, multi-center study with a partial follow-up of 1 year. It is not envisaged to change the recruitment process throughout the duration of the project. An equal sample size will be required for all four groups: healthy, non-advanced adenomas, advanced adenomas and

colorectal cancer cases. For the follow-up study, only the first two groups will be enrolled. Initial data obtained will be used for the algorithm training followed by validation of the pilot.

Participants will be split into the following groups following the histopathological analysis of index lesions identified during colonoscopy:
1. Healthy: no neoplastic findings after a colonoscopy
2. Non-advanced adenomas
3. Advanced adenomas. Under the European Society of Gastrointestinal Endoscopy (ESGE) 2020 guidelines, the following adenoma should be classified as advanced adenomas as they follow the same follow-up guidelines: at least one adenoma ≥10 mm or with high-grade dysplasia or with a high % of villous growth pattern, or any serrated polyp ≥10 mm or with dysplasia
4. Colorectal cancer CRC stage I, II, and III

Biological samples will be collected via a minimally invasive method. According to each clinical site's standards and pre-existing practice, enrolled individuals will undergo a screening colonoscopy, while blood will be drawn (prior to the colonoscopy) for the purposes of the study. All biological data will be used for in vitro protein-based analysis, allowing the construction of preliminary decision algorithms and AI analysis models.

Intervention Type
Other

Primary outcome measure
Diagnostic sensitivity and specificity of DIOPTRA screening system in CRC detection measured using DIOPTRA variables with clinical diagnosis as reference (colonoscopy) at the end of the study

Secondary outcome measures
Current secondary outcome measures as of 08/08/2025:

1. Diagnostic sensitivity diagnostic sensitivity for the detection of advanced adenomas measured using DIOPTRA variables at the end of the study.
2. Diagnostic sensitivity of the DIOPTRA screening system for detecting CRC or advanced adenoma, and specificity for detecting healthy and non-advanced adenoma groups in the sub-population without a prior history of malignancy or concurrent malignancy* measured using DIOPTRA variables at the end of the study
3. Model performance metrics of the DIOPTRA screening system measured using the prospective data for refinement at the end of the study
4. Risk factor difference and protein biomarker concentration measured with or without behavioural suggestion using mobile questionnaires and protein concentration quantification over the follow-up one-year period
5. Estimated efficiency of resources allocation of DIOPTRA screening system costs compared to screening colonoscopy.
6. Sensitivity and specificity of the blood-based immunoassay compared to the FIT test for detecting colorectal cancer and advanced adenomas.
*Prior history of malignancy or concurrent malignancy:
Prior history of malignancy: other than CRC, if all treatment of that malignancy is completed at least 2 years before registration and the patient has no evidence of disease.
Concurrent malignancy: Concurrent, clinically stable malignancy, other than CRC, without previous treatment, that does not require tumor-directed treatment.

Previous secondary outcome measures:

1. Diagnostic sensitivity and specificity of the DIOPTRA screening system for detecting advanced adenomas measured using DIOPTRA variables at the end of the study
2. Diagnostic sensitivity and specificity of the DIOPTRA screening system for detecting CRC in the sub-population without a prior history of malignancy or concurrent malignancy* measured using DIOPTRA variables at the end of the study
3. Model performance metrics of the DIOPTRA screening system measured using DIOPTRA variables for refinement at the end of the study
4. Risk factor and protein biomarker concentration measured with or without behavioural suggestion using mobile questionnaires and protein concentration quantification over the follow-up one-year period
5. Cost-effectiveness parameters measured and compared with the DIOPTRA system with referential clinical pathway

*Prior history of malignancy or concurrent malignancy according to the inclusion criteria:
Prior history of malignancy: other than CRC, if all treatment of that malignancy is completed at least 2 years before registration and the patient has no evidence of disease.
Concurrent malignancy: Concurrent, clinically stable malignancy, other than CRC, without previous treatment, that does not require tumor-directed treatment.

Overall study start date
01/01/2023

Completion date
31/12/2026

Eligibility

Key inclusion criteria
Current inclusion criteria as of 08/08/2025:

Inclusion criteria for prospective data collection and pilot evaluation:
1. Any indication for total colonoscopy (including routine screening and presence of symptoms/ FIT positive)
2. Age between 18-80 years at the moment of recruitment (see above)
3. Absence of significant comorbidities (ASA IV)
4. Ability to provide valid (written informed) consent

Inclusion criteria for the follow-up study patients who will use the DIOPTRA mobile application:
1. Presenting the 4 inclusion criteria here above
2. Patients willing to use the DIOPTRA application regularly
3. Level of digital literacy allows managing mobile terminals (smartphones, smartphone apps, tablets)
4. Good internet connection coverage at home
5. Availability of a smartphone/ tablet (to use the app)
6. Belonging to the healthy or non-advanced adenoma groups

Previous participant inclusion criteria as of 09/01/2025:

Inclusion criteria for prospective data collection and pilot evaluation:
1. Any indication for total colonoscopy (including routine screening and presence of symptoms/ FIT positive)
2. Previously treated malignancy, other than CRC, if all treatment of that malignancy is completed at least 2 years before registration and the patient has no evidence of disease
3. Concurrent, clinically stable malignancy, other than CRC, without previous treatment, that does not require tumor-directed treatment
4. Age between 18-80 years at the moment of recruitment (see above)
5. Absence of significant comorbidities (ASA IV)
6. Ability to provide valid (written informed) consent
7. Boston-Bowel-Preparation-Scale (BBPS) left/transverse/right colon score ≥2, total score ≥6

Inclusion criteria for the follow-up study patients who will use the DIOPTRA mobile application:
1. Presenting the 4 inclusion criteria here above
2. Patients willing to use the DIOPTRA application regularly
3. Level of digital literacy allows managing mobile terminals (smartphones, smartphone apps, tablets)
4. Good internet connection coverage at home
5. Availability of a smartphone/ tablet (to use the app)
6. Belonging to the healthy or non-advanced adenoma groups

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Previous participant inclusion criteria:

Inclusion criteria for prospective data collection and pilot evaluation:
1. Any indication for total colonoscopy (including routine screening and presence of symptoms /FIT positive)
2. Age 18-80 years at the moment of recruitment (see above)
3. Absence of significant comorbidities (American Society of Anesthesiologists [ASA] IV)
4. Ability to provide valid (written informed) consent

Inclusion criteria for the follow-up study patients who will use the DIOPTRA mobile application:
1. Presenting the four inclusion criteria above
2. Patients willing to use the DIOPTRA application regularly
3. Level of digital literacy allowing to manage mobile terminals (smartphones, smartphone apps, tablets)
4. Good coverage of internet connection at home
5. Availability of a smartphone/tablet (in order to be able to use the app)
6. Belonging to the healthy or non-advanced adenoma groups

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
A minimum 1600 recruited across all 8 clinical sites (200/site), with estimated 416 recruited (52 /site) for follow-up study of one year (50% drop-out rate applied). For FIT test, 90 CRC, 54 AA and 125 healthy cases with both FIT and DIOPTRA test data

Key exclusion criteria
Current participant exclusion criteria as of 09/01/2025:
Persons belonging to the vulnerable group will not be included in the clinical study.

Other exclusion criteria for the prospective study:
1. Age under 18 y/o or above 80 y/o
2. Comorbidities ASA IV
3. Any condition (e.g. prior major abdominal surgery, prior abdominal or pelvic radiation therapy) that in the endoscopist's opinion could predispose to incomplete colonoscopy
4. History of colectomy for reasons other than CRC
5. Malignancy other than CRC, completely treated in the last 2 years prior to the registration or with clinical evidence of disease
6. Concurrent malignancy, other than CRC, clinically unstable or requiring tumor-directed treatment
7. Inflammatory bowel diseases
8. Polyposis syndrome
9. Pregnancy or suspicion of pregnancy
10. Colorectal cancer history
11. BBPS left/transverse/right colon score <2, total score <6
12. Not able to understand the study and provide valid consent

Exclusion criteria for the follow-up study:
1. Classification in the CRC or advanced adenoma groups
2. Non-availability of a smartphone/tablet or inability to use a mobile app (e.g., due to low digital literacy)

Previous participant exclusion criteria:
Persons belonging to the vulnerable group will not be included in the clinical study

Other exclusion criteria for the prospective study:
1. Age under 18 or above 80 years old
2. Comorbidities ASA IV
3. Recent major abdominal surgery (colectomy) or radiation prior to the recruitment
4. Inflammatory bowel diseases
5. Polyposis syndrome
6. Pregnancy or suspicion of pregnancy
7. Colorectal cancer history
8. Not able to understand the study and provide valid consent

Exclusion criteria for the follow-up study:
1. Classification in the CRC or advanced adenoma groups
2. Non-availability of a smartphone/tablet or inability to use a mobile app (e.g., due to low digital literacy)

Date of first enrolment
15/01/2024

Date of final enrolment
31/08/2026

Locations

Countries of recruitment
Austria

Belgium

Croatia

Cyprus

Denmark

Greece

Slovenia

Spain

Study participating centre
Centre Hospitalier Universitaire De Liege (CHUL)
Avenue De L Hopital 1
Liege
Belgium
4000

Study participating centre
Region Midtjylland (RSYD)
Skottenborg 26
Viborg
Denmark
8800

Study participating centre
Univerzitetni Klinicni Center Maribor (UKCM)
Ljubljanska Ulica 5
Maribor
Slovenia
2000

Study participating centre
Fundacion Burgos Por La Investigacion De La Salud (Burgos)
Calle Islas Baleares 3
Burgos
Spain
09006

Study participating centre
Ethniko Kai Kapodistriako Panepistimio Athinon (NKUA)
6 Christou Lada Str
Athina
Greece
10561

Study participating centre
Linac-Pet Scan Opco Limited (GOC)
Georgiou Karaiskaki 13
Limassol
Cyprus
50132

Study participating centre
Geniko Antikarkiniko Ogkologiko Nosokomeio Athinon O Agios Savvas (AGSAVVAS)
Leoforos Alexandras 171
Athina
Greece
11522

Study participating centre
Clinical Hospital Dubrava, Zagreb/Croatia, University of Zagreb Faculty of Pharmacy and Biochemistry (KBDZ)
Avenija Gojka Šuška 6

Zagreb
Croatia
10000

Study participating centre
Biobank GRAZ, of the Medical University of Graz, Austria
Neue Stiftingtalstraße 2 / Entrance B /Second floor
Graz
Austria
8010

Sponsor information

Organisation
Centre Hospitalier Universitaire de Liège

Sponsor details
Avenue De L'hopital 1
Liege
Belgium
4000
+32 (0)4323 0000
service.communication@chuliege.be

Sponsor type
Hospital/treatment centre

Website
https://www.chuliege.be

ROR
https://ror.org/044s61914

Organisation
Bloks Zdravni I Sotsialni Grizhi Eood (Blocks)

Sponsor details
Bul Aleksandar Malinov 85 Ofis 15
Sofia
Bulgaria
1715
+359 (0)89 220 2040
mc_mladost@blocks.care

Sponsor type
Hospital/treatment centre

Website
https://blocks.care/en/

Organisation
University Clinical Centre Maribor

Sponsor details
Ljubljanska Ulica 5
Maribor
Slovenia
2000
+386 (0)2 321 1000
gpisarna@ukc-mb.si

Sponsor type
Hospital/treatment centre

Website
https://www.ukc-mb.si/en/

ROR
https://ror.org/02rjj7s91

Organisation
Geniko Antikarkiniko Ogkologiko Nosokomeio Athinon O Agios Savvas (AGSAVVAS)

Sponsor details
Leoforos Alexandras 171
Athina
Greece
11522
+30 (0)210 64 09 000
info@agsavvas-hosp.gr

Sponsor type
Hospital/treatment centre

Website
https://agsavvas-hosp.gr/

Organisation

Region Midtjylland (RM-RRH)

Sponsor details
Skottenborg 26
Viborg
Denmark
8800
+45 (0)7841 0000
kontakt@rm.dk

Sponsor type
Hospital/treatment centre

Website
https://www.rm.dk/

Organisation
Linac-Pet Scan Opco Limited (GOC)

Sponsor details
Georgiou Karaiskaki 13
Limassol
Cyprus
50132
+357 (0)25208000
info@goc.com.cy

Sponsor type
Hospital/treatment centre

Website
https://www.goc.com.cy/en/

Organisation
Fundacion Burgos Por La Investigacion De La Salud (Burgos)

Sponsor details
Calle Islas Baleares 3
Burgos
Spain
09006
+34 (0)947 256 533
info@hubh.es

Sponsor type
Hospital/treatment centre

Website
http://hubu.es/

Organisation
Ethniko Kai Kapodistriako Panepistimio Athinon (NKUA)

Sponsor details
6 Christou Lada Str
Athina
Greece
10561
+30 (0)210 5831000
politis@attikonhospital.gr

Sponsor type
Hospital/treatment centre

Website
https://attikonhospital.gov.gr/

Funder(s)

Funder type
Government

Funder Name
European Health and Digital Executive Agency

Alternative Name(s)
Health and Digital Executive Agency, HaDEA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
During the project and for a period of 1 year after the end of the project, the dissemination of results by one or several parties including but not restricted to publications and presentations,

shall be governed by the procedure of Article 17.4 of the Grant Agreement and its Annex 5, Section Dissemination. All future documents in results and publications will be included on the DIOPTRA website: https://www.dioptra-project.eu/

Intention to publish date

01/07/2027

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository.
For data storage, the infrastructure of GRNET will be used by the project. GRNET S.A. is a public sector technology company in Greece that has been operating since 1998 providing networking, cloud computing, HPC, data management services, and e-Infrastructures to academic and research institutions, educational bodies, and public sector agencies operating under the auspices of the Ministry of Digital Governance. The retrospective and prospective data will be stored in the DIOPTRA centralised platform by utilising the ELK STACK. Elasticsearch comes up with Cross-cluster replication (CCR), a way to automatically synchronise indices from the primary cluster to a secondary remote cluster that can serve as backup. If the primary cluster fails, the secondary cluster can take over. Moreover, Elasticsearch provides snapshots as a backup of a running Elasticsearch cluster for data recovery stored in an off-cluster storage location called a snapshot repository
In addition to personal and familial history and symptoms, demographic, lifestyle, behavioral, and medical data will be collected. These data will be anonymized to provide an additional layer of privacy protection. The anonymized data that will be stored on the centralized DIOPTRA platform will be in a tabular form, where each variable is defined as numeric-integer, numeric-float, numeric-datetime, categorical-ordinal, categorical-nominal, categorical-binary and string. The data generated in this study will be only available for consortium partners of the DIOPTRA project and for future publication reviewing process.
Patients' consent will be obtained for the processing of their personal data in the study in compliance with the ethical principles for medical research involving human subjects set under the Helsinki Declaration and with the legal requirements set under the EU General Data Protection Regulation. The consent template is available in the annex of the protocol.
The primary objective of the present anonymization tool is to apply the k-anonymity method to the input data using the Mondrian algorithm. The following is required by the Mondrian algorithm:
1. A delimited file containing the data (currently the file types xlsx, xls are supported), the first row of which contains the attribute names.
2. The definition of the attribute subset that will be anonymized.
3. The declaration of the data type of each attribute of this subset, the data types being Numerical, Categorical, Address and Date. The address and date data types are distinguished from numerical and categorical because they involve a few extra steps of preprocessing.
4. The selection of a positive integer value for the k parameter.
The anonymization tool is available as an executable program that can be run on a Windows machine. Before uploading the data to the DIOPTRA platform, clinical partners will anonymize them using this tool.
As the data stored in the repository is anonymised data, it would not be subject to the GDPR restrictions. However, in case personal data is stored in the repository, the study makes sure that processing of personal data will be done in compliance with the data protection principles set under the GDPR and thus there might be some restrictions on further processing of that data. For example, transfer of the personal data to any party outside of the EEA requires that appropriate safeguards for the fundamental rights and the interests of the participants are in

place. Furthermore, it should be noted that the dissemination and exploitation of the study results including datasets created by the study regardless of whether they include anonymised or personal data, will be subject to the open science and open access requirements stipulated under the Grant Agreement No 101096649 as well as of the Horizon Europe Regulation 2021 /695 including complying with the “as open as possible, as closed as necessary” principle in the management of study data.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.0		16/10/2023	No	No
Protocol file	version 5.3	03/12/2024	09/01/2025	No	No
Protocol file	version 7	06/03/2025	08/08/2025	No	No