STUDY TITLE:	A multi-center cohort study for conventional ultrasound image set collection to create a training data set for research purposes (image processing and analysis, AI training).
SHORT TITLE:	ThrombUS+ Study A
SPONSOR:	ThrombUS + EU Horizon Project Consortium represented by Consortium Coordinator "ATHENA". ThrombUS+ is an Innovation Action Project co-funded by the European Union, under HORIZON-HLTH-2023-TOOL-05-05 "Harnessing the potential of real-time data analysis and secure Point-of-Care computing for the benefit of person-centred health and care delivery". Views and opinions expressed are those of the author(s) only and do not necessarily reflect those of the European Union or HADEA. Neither the European Union nor the granting authority HADEA can be held responsible for them.
STUDY SITE:	The study is conducted in different Hospitals. These Hospitals are called study sites in this document. Your study site is [insert name]
PRINCIPAL INVESTIGATOR:	Principal investigator is the doctor who is responsible for this study at each participating Hospital. The principal investigator at your Hospital is [insert name]
LOCAL CONTACT INFORMATION (emergency contact number):	
STUDY PARTICIPANT No.:	

INFORMATION AND CONSENT FORM FOR STUDY SUBJECTS

Dear Patient,

You are being asked to participate in this study because you are suspected with Deep Vein Thrombosis (DVT) and you are referred for a standard ultrasound scan.

Please read the following information carefully. It contains important information to help you decide whether to participate in this study or not. The study staff will have a detailed interview with you to inform you about the study and the possible pros and cons of your participation. Ask questions about anything that is not clear at any time. You may take home an unsigned copy of this information to think about and discuss with your family, friends or personal doctor before you decide whether to participate or not.

Your participation in this study is voluntary. If you join this study, you can still stop at any time. You have the right not to sign this consent form. There will be no judgment or penalty or loss to the benefits you are entitled if you choose to not participate. If you decide to participate, you will be asked to sign and date at the end of this form.

Your signature confirms that you agree and accept to take part in this study and to the handling of your data as described in this form.

The following sections will discuss the requirements of this study and the details of your role as a participant.

What is the purpose and the background of the study?

Deep vein thrombosis and its fatal complication pulmonary embolism (PE) afflict millions of people worldwide and are responsible for a large percentage of acute hospitalizations.

Early diagnosis of DVT is crucial and has been proven to prevent life-threatening complications, minimize the risk of long-term disability, improve treatment outcomes and reduce healthcare costs. Despite the progress made with current techniques, there is a need for new methods to enable continuous monitoring DVT diagnosis.

For this reason, ThrombUS+ EU Horizon project brings together an interdisciplinary team to develop a novel wearable device that is expected to achieve automated early DVT detection, provide a continuous assessment of DVT risk and support DVT prevention.

This study aims to collect and create a labelled ultrasound image data set containing ultrasound images series of patients that undergo routine ultrasound scans on lower limbs, because of suspected deep vein thrombosis.

The data will be anonymized and then the data will be used to train an artificial intelligence model within ThrombUS+ project to achieve automated detection of deep vein thrombosis on conventional ultrasound scans.

Finally, the anonymized data will be used to develop an open access database to be used freely for research and innovation purposes by other researchers, supporting open science and innovation.

This study needs approximately 3.000 participants/scans from approximately five (5) countries. In [insert your country], it is expected that [insert your target] participants will participate.

This study has been approved by [insert your local Authorities].

What happens during the study?

ThrombUS+ Clinical Study A is a one visit, non-interventional (a type of study in which all participants receive routine clinical care and are not assigned per protocol to a specific treatment or health intervention), multicentre (more than one sites participate), diagnostic image data collection study.

Your participation in the study will last approximately 30 minutes for being informed about the study and signing the Informed Consent Form (ICF) and the allotted typical time for the conventional DVT scan as planned. Your participation does not require you to do any additional visits at the site or other procedures than the standard clinical practice.

The visit will include:

- Signing of Informed Consent Form
- Collection of data on demography, medical history and pharmaceutical treatments
- Body Composition Information
- DVT ultrasound scan, as originally planned by your provider

What are your responsibilities during the study?

As study follows the routine clinical practice, you have no additional responsibilities during the study other than that required during your already planned appointment. Please tell your study doctor if you have previously participated in this study.

Can you withdraw your participation from the study? When does the study end?

You may choose to leave the study at any time. You do not have to explain why you want to stop. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled. Leaving the study will not affect your future medical care. The investigators use the data that have been collected up to the moment that you decide to stop participating in the study.

In these situations, the study may stop:

- The end of the whole study has been reached.
- Your doctor thinks it is better for you to stop.
- One of the following authorities decides that the study should stop:
    - Sponsor
    - the Ethics Review Committee assessing the study

What happens after the study has ended?

When the results of the study are available, you will be able to get the most important information by asking the investigator at your hospital.

What are the pros and cons if you participate in the study?

There are no guaranteed direct medical benefits to you from participating in this study. However, you may benefit by assisting the study research team to understand better your condition. You may contribute as well new information that may benefit other patients and provide the medical and scientific community with information about DVT diagnosis.

The procedures that will be done in this study, the ultrasound scan, are as per standard clinical practice, hence there are no additional risks.

What will be done with your personal data?

Are you participating in the study? Then you also give your consent to collect, use and store your personal data.

What personal data do we store?

The personal data that we store could be:

- demographic data
- medical/pharmaceutical information
- images that we collect during the study

How do we protect your privacy?

To protect your privacy, when you join the study we give you a code, and only the authorised study personnel could match that code with your identity. This code is only for you. We keep the key to the code in a safe place in the hospital. When we process your data, we always use only that code. Even in reports and publications about the study, nobody will be able to understand that it is you behind this code.

Who can see your data?

Some people can see your name and other personal information without a code. This could include data specifically collected for this study, but also data from your medical file. These are people checking whether the investigators are carrying out the study properly and reliably. These persons can access your data:

- Sponsor, or the Sponsor's representatives (including monitors that keeps an eye on the safety and well conduct of the study).
- An auditor who is hired by the sponsor.
- National and international supervisory authorities.

These people will keep your information confidential. We ask you to give permission for this access.

Your personal data are protected by EU regulation 2016/679 GDPR. What does this mean?

- The sponsor (ThrombUS + EU Horizon Project Consortium represented by Consortium Coordinator "ATHENA") is controller of your data.
- If you wish to make a question regarding your data, please contact the Data Protection Officer (DPO) of the Sponsor's representative: Email: dpo@athena-innovation.gr, address: Artemidos 6 & Epidavrou, 15125, Marousi, Greece
- Data (information) derived from this study will be used for research purposes specifically in the context of the ThrombUS research project. Your personal data and data about your health will be collected, used, and stored for this study. The collection, use and storage of your data is required to answer the questions asked in this study and to publish the results.
- All information related to this study will remain confidential and to the extent permitted by the applicable laws and/or regulations will not be made publicly available.
- You are not legally, contractually, or otherwise obligated to provide your personal data, however if you do not do so, you will not be able to participate in this study.
- The lawful basis for the processing of the personal data involved in the project is your explicit consent, in accordance with Article 6(1)(a) and Article 9(2)(a) of the General Data Protection Regulation (GDPR).
- Recipients or categories of recipients of your personal data are the Sponsor, its research partners and service providers, Regulatory Authorities such as medicines regulators and ethics review councils.
- The coded data may be transferred within your country or to other countries for analysis. Where the data protection rules in other countries are not as strict as the rules in your country, the sponsor will adopt appropriate measures to provide an adequate level of protection according to EU law.
- Your personal data will be stored for at least 25 years at the site. Only your study doctor will be able to link your unique code number to you.

- Your rights regarding your personal data are clearly defined in the GDPR legislation as per which you have the right to access, correct, erase, restrict or object to data processing, and the right to data portability. You can seek more information on said rights or exercise any of them by contacting the DPO.
- You have the right to withdraw your consent at any time in relation to the data processing based on consent. The withdrawal of consent shall not affect the lawfulness of processing based on consent before its withdrawal. You can do so by contacting the DPO, the details of whom can be found above in this information sheet.
- You also have the right to file a complaint with the Data Protection Authority. For (please insert your country) the relevant Data Protection Authority is (please insert local info address, mail, telephone).
- The data subject shall have the right not to be subjected to a decision based solely on automated processing, including profiling, which produces legal effects concerning him or her or similarly significantly affects him or her. As part of the ThrombUS research program, you will not be subjected to any such decision.

Will you receive compensation or are there any associated costs in your participation in the study?

This study is funded by the Sponsor. The Sponsor will pay the study doctor and/or institution for his/her expenses, time, and effort to conduct this study. The study doctor and the institution/Hospital have no other financial ties to Sponsor which impact your personal treatment.

There will not be any monetary payment to you for participating in this study. There will be no additional costs to you for your participation in this study.

Are you insured during the study?

You are not additionally insured for this study. Because if you participate in the study, you run the same risks as with the standard clinical practise.

Do you have any questions?

You can ask questions about the study of the investigator/research team.

Do you have a complaint? Discuss it with the investigator or the doctor who is treating you.

Do you have any question about your rights? Please contact your personal doctor, lawyer, or write to the committee that reviewed the ethical aspects of this study at: <insert ethics committee name and contact here>.

Thank you for your attention!

Informed consent form

STUDY PARTICIPANT No.: _____

I understand that participation in this study will involve the collection and processing of my personal information (including coded health information) as described in this patient information form. By signing below, I am confirming that I have read this patient information form and understand it.

I declare the following:

- I have read the information sheet. I was able to ask questions. My questions have been answered well enough. I had enough time to decide if I wanted to participate.
- I know that participation is voluntary. I also know that at any time I can decide not to participate in the study or to stop participating. I do not have to explain why.
- I agree to comply with the instructions that were given to me in this informed consent document.
- I understand that I will not lose any of my legal rights by signing this informed consent document.
- I give consent to collect and use my data. The investigators only do this to answer the question of this study.
- I give free access to my medical records to authorized representatives of the sponsor or please insert local Authorities or International Health Authorities (i. e. European Medicines Agency).

By signing this informed consent document consent to:

- The processing of my personal information to conduct the study as described in this informed consent document.
- The inclusion of my anonymised imaging data in an open access database to be used for research and innovation purposes by other researchers, thus promoting open science and innovation.
- The processing of my personal information for scientific meetings, presentations and/or publications about the study.
- The processing of my personal information to make submissions to regulatory agencies and other health authorities

By signing below, I agree that I would like to participate in the study.

Printed name of study participant_____

Signature of study participant _____ Date of signature _____

"Statement by an impartial witness"

If written informed consent is not possible and it is provided orally, it must be completed by two impartial witnesses. Signature of an impartial witness is required if the subject or subject's legal representative cannot hear/speak/read/or write.

I confirm that the information in the Information and Consent Form has been accurately explained and clearly understood by the participating patient in the study, as well as that consent has been given freely by her/him.

Printed name of impartial witness (1) _____

Signature of impartial witness _____ Date of signature _____

Printed name of impartial witness (2) _____

Signature of impartial witness _____ Date of signature _____

"Statement from the patient's legal representative"

…….. is not able to give himself/herself (name of study patient) his/her consent because ……(reason the study patient is unable to sign).

I assure you that I have received the Information and Consent Form and I allow the participation of the patient in the study, as I believe that this would also be the desire or will of the patient. I understand that if the patient expresses a different opinion, he will leave the study without any negative consequences for himself.

Printed name of the legal representative_____

Statement of Investigator RECEIVING THE CONSENT

I hereby assure that I have explained to the person(s) mentioned above the nature and purpose of the study and the potential benefits and risks associated with participation. I have answered the questions posed and the potential participant in the study has received a copy of the signed consent document. I acknowledge my commitment to the care and well-being of the aforementioned participant, respect for the rights and wishes of the participant(s), and conduct the study in accordance with current guidelines and regulations of Good Clinical Practice).

Printed name of the Investigator _____

Signature of the Investigator _____

Date of signature _____

*Consent may be obtained by the Principal Investigator or by the Sub-investigator(s) of the ThrombUS+ Study A, who (or whom) have been authorized by the Principal Investigator to do so.