APPENDIX 1

Data Sharing Information for Participants in the Clinical Investigation

ESSENCE Study: E-health Self Symptom assEssmeNt as a front door and facilitator of CarE

Please read through the privacy policy at the end of this document for more information about the processing and your respective rights.

What is the purpose of the study?

This Quality Improvement (QI) study is being conducted to evaluate the accuracy of the symptom assessment as well as the value it provides to CUF patients when making informed decisions about when and where to seek healthcare and to improve their understanding of what may have caused their symptoms. This study also plans to assess the value the symptom report provides to the physician and the effect it has on the consultation. Therefore we plan to enroll at least 209 CUF patients who either have a CUF Digital teleconsultation or visit the emergency department (ED) in-person. It is also anticipated that not all participating patients will schedule an appointment with a participating CUF physician and therefore for those participants, we will not be able to evaluate the effect the report has on their medical consultation.

How will my data be processed when I participate in the study?

If you agree to participate in the study, your Ada assessment report will be shared with CUF to be used to identify appropriate treatment options for you. You will be assigned a study participation number and the routinely collected information of the symptom assessment flow *(sex, age, medical consultation booked), symptom assessment information (Risk factors, symptoms confirmed and denied, condition suggestions, advice level, care navigation options, pre- and post assessment questions)* will be stored in a dedicated study electronic data capturing system together with your CUF identification number. To understand if you sought care after using the symptom checker, we will look into your electronic health record and see if you had a consultation with a physician at CUF following your symptom assessment. This will help us better understand how the symptom assessment may have influenced your healthcare journey. In case you schedule a consultation with a CUF physician who also participates in the study, your physician will fill out a survey evaluating the accuracy of your specific symptom report and the value it may have provided to your specific consultation. This survey alongside information about your medical consultation from the electronic health record such as the condition identified, the symptoms you presented with etc. will be stored in the same file in the electronic data capturing system.

In case you did not book a consultation with CUF after checking your symptoms or we have specific enquiries about your healthcare journey, we might reach out to you again to ask you some questions. However, there is no obligation to respond to this message.

To further deepen the understanding of the effect the symptom assessment has on patient outcomes, we may compare the insights from this study with the patient journeys of CUF patients who did not use the symptom checker.

It might also be useful to analyse your data using a so-called AI-based large language model (LLM's). When possible, your data will be anonymized before being used in such a LLM. Where full anonymisation is not possible, we will reach out to you to provide more information on the planned processing of your data and ask for your specific consent. For more information on how your data is processed, please also see the *privacy policy* at the end of this study information.

Your Ada assessment will be processed by CUF not strictly for the purposes and the duration of this study but generally for services provided through its MyCUF-App. For more information, please see the privacy policy of CUF.

Will there be any change in my treatment if I consent to the use of my data in the study?

No, reading through this study information is the only additional work that we ask from you. If you agree to participate in the study, you consent to the use of your health information in the study as described above and you allow your doctor to complete a questionnaire after your medical consultation. You can ask your doctor about the study when you have your consultation. You can withdraw your permission for the use of your data in the study at any time, without any change to your treatment.

Will anyone else have access to my health information?

Apart from Ada and CUF, monitors, auditors, regulatory authorities, and the CUF Academic center research team can have access to the source data to ensure the study is conducted correctly and ethically. These parties will be granted direct access to participants' medical records for verification of the study procedure to the extent that is permitted under Portuguese laws and regulations, without violating confidentiality. By consenting to participation, you authorize this access.

What are the potential benefits of agreeing to participate through having my health information used in this study?

There is no change to your treatment or diagnosis as a result of participation. Although there is no individual benefit from participation, this study will benefit the CUF healthcare system, the Ada symptom assessment tool, and the experience of future users.

Are there any risks or expenses associated with entering this study?

As the study is purely observational with no intervention for you as a patient and no change in diagnosis or care, and there is no risk or expense associated with participation.

This post-market, quality improvement study is intended to benefit the CUF hospital system, future CUF patients, and the development of the platform associated with research participation.

By choosing to participate in this clinical trial, it is important to acknowledge that your personal information, including sensitive health data, may be collected, used, and disclosed. While we make every effort to prioritize your privacy, it is crucial to recognize that there is a potential risk of privacy loss throughout the trial process.

There is insurance coverage in place for the study for costs associated with liability from medical device failure or clinical investigation-related injuries.

How do I obtain information about the results of the study?

The insights derived from the study will be published in scientific journals and presented at conferences. A simple language summary of the findings will be published in CUF's news system and on a national level in select newspapers or magazines. Individual patients' names or medical details will not be included in any of these reports. Any possible information for publication will be released in such a way as to protect an individual's identity.

What will happen if I don't want to carry on with the study?

Participation in this research study is completely voluntary, and you are entitled to withdraw at any point without explanation. If you decide to leave the study, any data (whether it is a partial or complete collection of data) that refers specifically to you will be destroyed, and the researchers will not be allowed to use it for this study or future studies. If you voluntarily withdraw or decline to participate, neither the care that you receive nor your treatment will be affected. You have several options to withdraw:

1. You tell your treating doctor that you would like to withdraw.
2. You message Ada Health (essence-study@ada.com) and let them know you want to withdraw from the study.

3. You message the Principle Investigator of this study, Dr. Pedro Flores (pedro.v.silva@cuf.pt), and let them know you would like to withdraw from the study.

Who is responsible for the study, and how can I get more information about it?

The overall person responsible for this study is the Principal Investigator: Dr. Pedro Flores, CUF Hospital Descobertas, Lisbon, Portugal [pedro.v.silva@cuf.pt]. You can also contact the study coordinator at your CUF Hospital from the list below for further information:

- **Hospital CUF Descobertas**
  - Coordinating investigator: Anabela Marques [anabela.marques@cuf.pt]
  - Coordinating investigator: Hugo Faria [hugo.faria@cuf.pt]
- **Hospital CUF Tejo**
  - Coordinating investigator: Ana Boquinhas [ana.boquinhas@cuf.pt]
- **CUF Digital (Teleconsultations)**
  - Coordinating investigator: Filipa Lourenço [filipa.lourenco@cuf.pt]
  - Coordinating investigator: Pedro Flores [pedro.v.silva@cuf.pt]

We prioritize your privacy and adhere to the relevant legal frameworks in Portugal. We ensure compliance with the notification, communication and information duties provided for in Law No. 21/2014 of 16 April, which regulates clinical research, as well as the Portuguese Data Protection Law, which guarantees that personal data, including health data, is processed and protected. Our commitment extends to upholding Medical Confidentiality and Professional Secrecy principles, which obligate our healthcare professionals and researchers to maintain the confidentiality of your personal information. Additionally, we strictly follow the Ethical Guidelines for Clinical Research.

Ada Health GmbH Privacy Information for the ESSENCE Study

PLEASE READ THIS POLICY CAREFULLY BEFORE AGREEING TO PARTICIPATE IN THE STUDY SPONSORED BY ADA HEALTH GMBH.

This study is sponsored by Ada Health GmbH (HRB 189710), Karl- Liebknecht-Straße 1, 10178 Berlin, Germany ("Ada Health") and conducted by José de Mello Group's CUF Hospital Network, R. Mário Botas, 1998-018 Lisbon, Portugal ("CUF"). Ada Health and CUF are acting as the joint controllers (as defined under Article 4 (2) GDPR = RGPD) for processing activities in connection with the study.

Questions, comments, and requests regarding this Privacy Policy can be addressed in Portuguese to Dr. Pedro Flores [+351 210 116 607, pedro.v.silva@cuf.pt] or in English to Ada Health's data protection officer [dpo@ada.com].

This privacy information only covers the study after you have completed your symptom assessment. The assessment itself is subject to Ada Health's general privacy policy

[https://ada.com/privacy-policy/], which is accessible in the app and amends the following information.

How is your data being processed?

- To understand which data is being processed and how, please see the description above.
- *Use justification:* Your consent (Article 6(1)(a) and Article 9 (2)(a) GDPR/RGPD). When you agree to take part in the study, you give us consent to process your personal data including your health data for the study. You can revoke your consent at any time. However, this means that you can no longer take part in the study. Regarding the further use of your Ada assessment data by CUF, the applicable use justification for CUF is Art. 9 (2)(i) GDPR.
- *Duration of storage:* Your data and all study materials will be stored for ten (10) years after the end of the Clinical Investigation, always in accordance with the principle of data minimisation.

Where is the data stored?

The personal data that we collect for this study is stored in the European Union in an Electronic Data Capturing (EDC). We do not share your personal data with anyone outside the EU. When your data is shared with CUF to administer your further treatment, the data will be stored as explained in CUF's privacy policy.

What are your rights as a data subject?

Under GDPR/RGPD you have various rights in relation to your personal data according to Art. 12 and following GDPR/RGPD. This includes your right

- to request information and a copy of your personal data, Art. 15,
- To correct inaccurate data, Art. 16
- to delete your data, Art. 17
- To restrict the use of your data, Art. 18 or
- to receive it in a structured, commonly used and machine-readable format, Art. 20.

You can exercise your rights by contacting CUF's Dr. Pedro Flores [+351 210 116 607, pedro.v.silva@cuf.pt] or Ada Health's Data Protection Officer [dpo@ada.com]. You also have the right to file a complaint with the competent data protection authority.

For CUF, the competent authority is:

CUF DPO (Data Protection Officer)

Tel..: +351 962 103 334

E-Mail: dpo@cuf.pt

For Ada Health, the competent authority is:

Berliner Beauftragte für Datenschutz und Informationsfreiheit,

Friedrichstr. 219, 10969 Berlin

Tel.: 030 13889-0 | E-Mail: mailbox@datenschutz-berlin.de

You are not subject to any automated decision making when taking part in the study.

Joint Controllership Agreement

As required by GDPR/RGPD Article 26, a Joint Controllership Agreement (JCA) has been signed between CUF and Ada Health GmbH to outline which party is responsible for processing different types of data. ESSENCE Study participants can request to see the JCA by contacting either party with the contact details above.