PARTICIPANT INFORMATION SHEET/

INFORMED CONSENT FORM

Study Title: Comparative Observational Study to Evaluate the Agreement Between Acuvera Capture and Paper Records in the Collection of Best Corrected Visual Acuity (BCVA) Data in Ophthalmic Clinical Trials

PROTOCOL NO.:	**OE-VALi-2025-001**
ACRONYM:	**VALiCAPTURE**
ClinicalTrials.gov No.:	
PROMOTER:	OptymEdge
CLINICAL CENTER:	[see contact list]
PRINCIPAL INVESTIGATOR:	[see contact list]
ADDRESS:	[see contact list]
CONTACTS:	[see contact list]

We would like to invite you to voluntarily participate in a Clinical Study in which you will not receive any investigational medication. Before deciding whether to participate, you need to understand why this study is being carried out and what the study may involve. This document describes the purpose of the study, its procedures, and the potential associated benefits and risks. The investigator will accompany you throughout the study and will answer and follow up on any doubts and/or questions you may have.

Please allow as much time as you need to read this document carefully, and if necessary discuss it with a friend, family member or the investigator. Please ask him about any matter that is not clear, or if you need more information. You should only make a decision to participate in the study after you have understood it and when you have no further doubts about it.

If you decide to participate in this Clinical Study, you must sign and date the Informed Consent, which will also be signed by the Investigator, and you will receive a copy of this document. If you decide not to

participate, you are assured that there are no penalties in your health care. This clinical study is not a substitute for your usual medical care.

1. STUDY OVERVIEW

The goal of this study is to compare two methods of recording Best Corrected Visual Acuity (BCVA) scores — one using a traditional paper form and another using a digital application. No experimental treatments or medications are involved.

It will have a duration of 8 weeks and during this study, your eye examination results (including visual acuity and related eye health data) will be collected in a single visit and used for research purposes. Your data will be kept confidential to the extent permitted by law and will be identified by a study code instead of your name.

You will not receive direct medical benefit from taking part in this study; however, the information gained may help improve how vision tests are performed and recorded in future clinical trials. All procedures that are part of the study are non-invasive tests used in ophthalmological clinical practice. They have no risks or associated discomfort for participants.

You have the right to ask questions about the study at any time and to obtain answers before or during your participation. If you decide to withdraw, your decision will not affect your current or future medical care.

2. STUDY OBJECTIVES

Vision is one of the most important aspects of our quality of life. To assess how treatments can improve or stabilize vision in various eye diseases, a test called **Best Corrected Visual Acuity (BCVA) is used**. This test measures, with glasses or correction lenses, the best possible vision of each person.

Traditionally, the results of this test are written on paper. However, this method can lead to errors, such as mistakes in the transcription of numbers, missing data, calculations, or difficulties in reading the information. To reduce these problems, a digital application called **Acuvera Capture** was created, which allows results to be recorded directly in a software tool and with automatic checks and calculators to minimize errors.

This study aims to compare the paper record with the digital record created using the Acuvera Capture application. We intend to understand if the application is as accurate as the paper method, if it helps to reduce errors, and if it makes the process faster and easier for health professionals.

The results will contribute to improving the way this data is collected in clinical studies in the future, with benefits for the quality of research and, indirectly, for patient safety.

This Clinical Study was approved by the Ethics Committee for Health (CES) of the [clinical site name], which consists of an independent group of people, including individuals with medical training, who evaluate the legitimacy of the study and its scientific quality. They also review whether complete and adequate information is provided to the participants, to ensure the protection of the rights, safety and well-being of all participants, as well as to ensure public evidence of this protection.

This Clinical Study will involve approximately 90 volunteers. Your participation in the study includes only 1 planned visit to the clinical site.

When you participate in this Clinical Study, your data (also called "personal data") will be processed. What happens to your personal data, from its collection to its destruction, is called "personal data processing". The processing of personal data includes, for example, collection, recording, storage, structuring, transmission or transfer of data to the entities involved in the Clinical Study. You can find out more about what happens to your personal data in section 10 of this Participant Information Sheet.

This study will be carried out in two centers in Portugal, at the School of Health of the Polytechnic Institute of Porto (ESS-P.Porto), located in Porto, and at the Espaço Médico de Coimbra (EMC), located in Coimbra, according to the ethical principles and guidelines for Good Clinical Practice (according to what is defined in the Principles of Good Clinical Practice of the ICH-GCP and the ethical principles expressed in the Declaration of Helsinki), Law No. 21/2014 of 16 April (Clinical Research) amended by Law No. 73/2015 of 27 July and Law No. 49/2018 of 14 August and by the applicable legislation on the protection of personal data in force, namely Regulation (EU) 2016/679 of 27 April 2016 (GDPR) and National Law No. 58/2019 of 8 August.

This is an observational clinical study promoted by OptymEdge, the company that developed the Acuvera Capture digital application.

3. PROCEDURES AND CONDUCT OF THE CLINICAL STUDY

This is a study lasting 8 weeks and includes only one visit (V1).

Participants who sign the informed consent will complete the selection procedures and will be evaluated for their eligibility. If the participant's eligibility is confirmed, participants will be enrolled in the study and will perform the procedures planned for this single visit.

3.1. Procedures

If you agree to participate in this study, after signing the Informed Consent, you will be asked to perform several procedures, and you are already familiar with some of them.

Consultation with the doctor:

- The doctor will perform a general examination and you will be asked about previous and current illness.
- You will be asked about some personal data, such as age and gender.

Eye exam: Your eyes will be examined to assess your visual function, including:

- **Refraction**: Refraction is the measure of glasses you may need to see better. It will be done on each eye following a standardized procedure where several lenses will be tested and you will be asked which one helps you to see best. The exam is performed seated and 4 meters away from the vision chart (or 1 meter, if not possible at 4 meters). The final result will be recorded on paper or directly in the Acuvera Capture application, depending on the method assigned to the participant. This **refraction information** will then be used for the visual acuity test, ensuring that all results can be compared uniformly.
- **Best corrected visual acuity (BCVA):** You will be asked to read the letters on a board to measure your visual function. While refraction is going to be tested only once (and recorded either on paper or in Acuvera Capture), BCVA will be carried out 2 times: one to record your answers on paper and one through our digital application – Acuvera Capture. This will allow the examiner to compare the results using both methods

What kind of information will be collected?

When participating in and carrying out the procedures of this study, information from you (also called "personal data") will be collected solely for the purposes mentioned. This personal data includes, for example:

- Information that directly identifies you (such as your name and year of birth);
- Your gender and ethnicity;
- Information about your health and medical condition, including your medical history;

- Your treatments and response to them.

What happens to your personal data, from its collection to its destruction, is called "personal data processing". The processing of personal data includes, for example, the collection, recording, storage, structuring, transmission or transfer of data to the entities involved in the Clinical Study. You can find out more about what happens to your personal data below.

3.2. Timing of visits/Duration

This eight-week study has 1 visit. During this visit, you will go through the selection procedures and be evaluated for eligibility. If your eligibility is confirmed, you will be included in the study and the procedures described above will be carried out. Each visit is expected to last 1 hour. One or both of your eyes may be considered.

3.3. Treatment/ Randomization

No treatments will be performed in this study. However, if during the course of the event, you develop any changes that may threaten your vision, they will be treated immediately according to clinical practice.

4. POTENTIAL RISKS AND INCONVENIENCES TO THE PARTICIPANT

All the tests indicated and that are part of the study are non-invasive tests used in ophthalmological clinical practice. Most have no risks or associated discomfort for participants. If you have any ophthalmic symptoms, you should inform the investigator or a member of the team. The direct contact information of the investigator can be found in section 12 of this document.

5. BENEFITS

This study has the advantage of assessing your visual function with precise and rigorous methods. The information that will be collected will contribute to better information for doctors and investigators to improve the methods of assessing visual function and indirectly the clinical care to be provided in ophthalmology.

6. NEW INFORMATION

You will be informed of any new information that may be relevant to your medical condition or any new information we learn during this study that could affect your decision to participate.

7. ALTERNATIVE TREATMENTS

You will not receive any treatment in the context of this Clinical Study. However, if, during the Clinical Study, you develop any change in eye condition that may endanger your vision, you will be treated according to current best medical practice.

8. INSURANCE

Because all procedures to be performed in this study are non-invasive and part of current medical care/practice, no study-specific insurance is required.

In case you have a problem or any complaint about any aspect of this study, you should contact the investigator (contact information in section 12).

9. PARTICIPATION/WITHDRAWAL OF INFORMED CONSENT

Participation in this clinical study is completely voluntary. You are completely free to choose whether or not you want to participate in this clinical study. If you decide to participate in this study, you are also free to withdraw your consent at any time and without the need to explain why. This decision will not affect the health care you receive. We only ask you to inform the investigator or member of the research team as soon as possible if you decide to stop your participation in the study. If you choose to participate, you will receive a copy of this document.

The Investigator may also decide to withdraw you from the study if they think it is the best decision for your health. A premature termination of your participation in the study may also be decided by the Investigator if you are not following the study protocol, or by a decision of the study sponsor or the Regulatory Authorities. In any of these situations, you will be informed of the reasons.

10. Confidentiality AND PROTECTION OF PERSONAL DATA

10.1 What personal data about me will be collected?

If you join the study, your physician, health practitioner or other relevant investigator, and authorized persons will collect personal information about you in connection with the study as described in this Informed Consent Form, which include administrative information (e.g., name, address and emergency contact details), demographics (e.g., date of birth, age, language and gender), test results, study-related events and documentation, ethnicity and medical history and condition. The personal information will be collected directly from you, for example during exams, or as part of your medical history, and from your usual health practitioner. Some personal information may also be collected from publicly available databases, for example to re-establish contact with you in case of a safety issue. Note that the provision

and use of personal information under the study is required for you to participate in the study and that, absent such provision, you may not be able to participate in the study.

10.2 For what purposes is my personal data collected?

- To perform the study research as described in this Informed Consent Form (including assessing the effects of relevant products, publish study results and product commercialization), and for further research, to improve the design and outcomes of further studies and products. Further research helps contribute to fighting various conditions and delivering better standards of treatment for the population. The Study Team and the sponsor perform the above activities for scientific research purposes.
- To comply with legal duties including reliability and safety requirements, such as audit and monitor the study and adverse events, perform stability analysis, report to and communicate with competent authorities such as regulatory and inspections authorities and ethics committees that review the study to verify that it meets safety, reliability and ethical standards. The Study Team and sponsor perform the above activities to comply with legal obligations and public interest in the area of health.

10.3 How is my personal data protected?

Personal data collected at any time during the study will be kept strictly confidential. To ensure confidentiality, the data generated during the study is encoded with a number that will identify you in the study ("keycoded personal data"). Any information that leaves the clinical site will be keycoded and identified with your code instead of your name, unless otherwise noted in Section 11 below. Anyone who has access to your uncoded data (which is kept in the clinical center where you carry out the visits) is subject to professional secrecy and confidentiality agreements.

10.4 Who will have access to my personal data?

In addition to clinical center employees, who are subject to professional secrecy and confidentiality agreements, there are other entities that can access your personal data.

Occasionally, the Sponsor or his/her representative, the Ethics Committee of the Espaço Médico de Coimbra or another local and/or European Authority, under the supervision of the investigator, may have access to the uncoded medical records that identify you by name. In this way, it can be verified that the study is proceeding correctly, in order to ensure the accuracy of the information collected and recorded, and that your rights are being respected.

The keycode information collected during this study and the results of the study may be made available

to the national Competent Authority and the Ethics Committee, to the Health Authorities of other countries, in accordance with the national and international regulatory framework for clinical studies.

In addition, OptymEdge, which funds this Clinical Trial, will have access to your keycoded personal data (data that does not identify you).

The keycoded personal data may also be shared with partners such as pharmaceutical and/or medical device companies and other research institutions with which the Sponsor works, for the development and commercialization of medicines and/or diagnostic tests, or to support the Sponsor in conducting the Clinical Trial. Regulatory authorities will also receive encrypted information to carry out regulatory tasks.

All entities with whom your data is shared are duly instructed that they will have to protect your data as described in this Participant Information Sheet and specific contractual agreements will be drawn up, where necessary, to ensure the protection and security of the processing of your personal data.

The entity responsible for the processing of the study data (the "Data Controller") is the Study Sponsor, OptymEdge – 401 N Washington St, Suite 700, Rockville, MD 20850. Contact: {Insert Contact Email}. Do see also section 12 for other study contacts.

10.5 How long will my personal data be kept?

The personal data collected in the study will be kept for a minimum of 15 years after the end of the study. After this period, they may be stored for an additional period for the purposes mentioned above or due to legal reasons (e.g. review of retention obligations), or others, if required by law.

10.6 How will my personal data be used?

Signing the Informed Consent means that your personal data, namely clinical information, will be used for the following purposes:

- To assess the agreement between BCVA data collected on paper forms and in the Acuvera Capture application.
- Assess the frequency and nature of inconsistencies or entry errors identified during data collection and transcription
- Measure data entry time and overall efficiency.
- Collect feedback from certified examiners regarding usability and workflow.
- Scientific purposes and future research with strict respect for medical confidentiality and anonymity.

The personal data collected during this study and the result of the study may be presented for scientific purposes. However, you will never be individually identified in these presentations. Your identity will not be revealed in any report or publication.

The clinical site, the investigator and the members of the research team will use your personal data within the scope defined above.

We want to make sure that we learn as much as possible from this study, and we want to make the best use of the information you generously provide us (demographic information, information about your health status, your refraction, your visual acuity). Thus, for the purpose of conducting further clinical research in the area of visual function and for interaction with regulatory authorities, we may share your data not only with the VALiCAPTURE study research team, but also with third parties (e.g.: the funding entity (OptymEdge), other investigators outside the VALiCAPTURE study, and pharmaceutical companies) during and after the end of the study, with the aim of learning as much as possible about the Acuvera Capture application. The data will always be shared in an encrypted format so that your identity remains confidential and anonymous.

10.5 Can my Keycoded Personal data be identified?

For Keycoded Personal Data, the decoding key for your data will never leave your clinical center, and recipients of Keycoded Personal Data will not be provided the decoding key.

10.5 Will my personal data be transferred to other countries?

Your keycoded personal data may be transferred to countries around the world in connection with the study. Some countries may have data protection laws that are different from those in the country in which you are participating in the study. As regards personal data from the European Economic Area (“EEA” , i.e., the European Union’ s Member States plus Iceland, Liechtenstein and Norway), some non-EEA countries are recognized by the European Commission as providing an adequate level of data protection according to EEA standards (a list of which is available at https://commission.europa.eu/law/law-topic/data-protection/international-dimension-data-protection_en). For transfers from the EEA to other countries, including the U.S., adequate measures are sought to protect your personal information, such as identifying reasons of public interest or contracting measures, such as standard contractual clauses adopted by the European Commission and similar data transfer agreements. To know more about or obtain a copy of these measures where appropriate, please contact your Study Team.

10.6 What are my rights in relation to my personal data?

In accordance with applicable law, you can exercise the following rights in relation to your personal data:

- Access, correction, limit, transfer, or delete of your personal data, and to object to its use. However, some of these rights may be restricted if the data is being used for scientific research, as allowed by national or European Union law.
- Lodge a complaint with the competent supervisory authority for data protection. The national authority for data protection in Portugal is the National Data Protection Commission (CNPD).
- Withdraw your consent to data processing at any time, without having to give reasons, by informing the investigator and/or research team. This will not apply to the processing of your personal data prior to the date of withdrawal of consent. If you withdraw your consent to data processing, your participation in the study will end and no further data will be collected. The investigator and/or research team will discuss with you the choices you have regarding your personal data.
- If, for some reason, the investigator does not perform all necessary tests, the investigator may decide to withdraw you from the study. This does not affect the lawfulness of the processing of your data based on consent prior to the withdrawal of the study.

If you wish to exercise any of your rights in relation to your data, please address your request to the investigator (see contact in section 12) or to the data protection contact of study (see contact in section 12). If you are not able to resolve a problem directly with the data protection contact and wish to make a complaint, you can contact a data protection authority competent for your country (a list of European data protection authorities is available at https://edpb.europa.eu/about-edpb/board/members_en).

11. COMPENSATION

This is a validation clinical study that does not offer any financial compensation for your participation in this study.

12. CONTACTS

If you would like unbiased advice or additional information about participating in this clinical trial, you can contact the Independent Ethics Committee:

CES – Ethics Committee of the [clinical site name]

[see contact list]

Phone:

E-mail:

If during the study you have any questions about your participation or if you would like any specific information before making a decision, please contact the Principal Investigator:

Principal Investigator:

Clinical Centre:

If you have any questions about your personal data during the course of the study, please contact:

OptymEdge (part of the Emmes Group)

VALiCAPTURE Project Manager –

Email:

Emmes Data Protection Officer

Email: dpo@emmes.com

Thank you for taking the time to read this information sheet. If you wish to participate, you will receive a copy of this Information Sheet and the signed Informed Consent Form for safekeeping.

INFORMED CONSENT

1. I declare that I have read this form and voluntarily agree to participate in this clinical study.
2. I have been duly informed of the nature, objectives, risks and probable duration of the study, as well as what is expected of me.
3. I had the opportunity to ask questions about the clinical study and I understood the answers and information that were given to me.

   At any time I can ask the Investigator more questions. During the clinical study and whenever I want, I can receive information about the development of the study. The Investigator will provide any important information that arises during the clinical study that may alter my willingness to continue participating in the study.
4. I agree that you will use the information regarding my medical history and my treatments in compliance with applicable law and as described in this Informed Consent Form.
5. I authorize the consultation of my clinical file by the study team. I authorize the consultation of my data only by persons designated by the Promoter and by representatives of the Regulatory Authorities.
6. I agree to follow all instructions given to me during the clinical study. I agree to collaborate with the Investigator and inform him immediately of changes in my state of health and well-being and of any unexpected and unusual symptoms that occur.
7. I authorize the use of the results of the clinical study and, in particular, I accept that these results be disclosed to the health authorities. In addition, I agree that my information may be shared, only in encrypted form, with other research institutions and/or pharmaceutical and/or medical device companies with which the Sponsor works for the purpose of further clinical research in the area of visual function and for interaction with Regulatory Authorities.
8. I agree that the data generated during the clinical study may be computerized by the Sponsor or by someone designated by them, for this study or for future clinical research with strict respect for professional secrecy and anonymity.
9. I am aware of my rights related to personal data.
10. I know that I am free to withdraw from the clinical trial at any time, without having to justify my decision and without compromising the quality of my medical care. I am aware that the Investigator has the right to decide on my premature withdrawal from the study and that he will inform me of the cause of it.
11. I have been informed that the study may be stopped at the decision of the Investigator, the Sponsor or the Regulatory Authorities.

I understand my rights related to my personal data and consent to the processing of my personal data in the manner and for the purposes described in the Participant Information Sheet/Informed Consent.

I understand that I will receive a copy of the Participant Information Sheet/Informed Consent and I accept that the original remains at the clinical site.

Participant Name: _____

Signature: _____ ***Date:*** _____/_____/____
(YYYY/MM/DD)

I confirm that the information in the Participant Information/Informed Consent Sheet was explained accurately, and apparently understood by the study participant, and that consent was freely given by the study participant.

Name of Impartial Witness (if applicable): _____

Signature: _____ ***Date:***_____/_____/____
(YYYY/MM/DD)

I confirm that I have explained to the aforementioned participant the nature, purpose, potential risks and probable duration of the aforementioned Clinical Study.

Investigator Name:_____

Signature: _____ ***Date:***_____/_____/____
(YYYY/MM/DD)