AVEA HAUTWERK

Inquiry for Participation in the research project:

Reverse the clock: A research project on the effects of a collagen activator on biological age and skin quality.

Dear Madam, dear Sir,

We hereby inquire whether you would be willing to participate in our research project. Your participation is voluntary. All data collected within the scope of this research project are subject to strict data protection regulations.

The research project is conducted by Avea Life AG in collaboration with the dermatology clinic Hautwerk, Zurich. If you are interested, we would be happy to inform you about the results of this research project.

To give you an initial overview, here are the most important details. Further, detailed information will follow. For remaining questions we are always available.

Why are we conducting this research project?

- The goal of the research project is to demonstrate, within the framework of an observational study, the influence of the Collagen Activator supplement from Avea Life AG on biological age and skin quality.

What do I need to participate? – What happens to me if I participate?

- If you have already made the decision to take Avea's Collagen Activator for the next 6 months, you can contribute to this study and learn more about your skin health and biological age.
- We will analyze your biological age at two time points through saliva samples and assess your skin quality at three time points through skin analyses conducted at a dermatology clinic in Zurich. All measurements are unintrusive tot he body.
- Data collection involves three in-person visits, during which a skin analysis will be performed at Hautwerk dermatology clinic in Zurich. The subsequent visits will take place one month and three months after the first visit. During the first visit, you will also provide the first saliva sample. Each visit should not exceed a time commitment of half an hour to one hour.
- In addition to the on-site visits, you will receive a monthly questionnaire (total of 6 questionnaires) that should take no longer than 15 minutes to complete.
- After 6 months, you will independently provide the second saliva sample and send it to the study team (saliva is given onto a piece of paper and dried).
- Please start taking the Collagen Activator only after the first appointment.

What are the benefits and risks associated with the project?

Benefits

- The collagen activator is freely available on the market, and there are no known risks associated with its consumption.As part of the study, you will have the opportunity to closely monitor the effects of the Collagen Activator on your body.
- Additionally, by participating, you contribute to the field of clinical research, specifically in the area of skin aging and the influences on aging processes.

Risks and burden

- As all examinations are unintrusive to the body, the burden from the investigations is minimal.
- The data will be used solely for the evaluation of the study and will not be disclosed to third parties.
- Considering that recruitment takes place in the Zurich area, the travel time and effort are minimal.

By signing at the end of the document, you confirm that you voluntarily participate in the study and that you have understood the contents of the entire document.

Detailed Information

1. **Objective and selection**

In this informational document, we refer to our research endeavor as a research project. If you choose to participate in this research project, you will be a participant.

The aim of this research project is to investigate the effects of Avea's Collagen activator product on the skin, specifically on skin aging processes and whether they can be influenced by the product. If you have already bought the Collagen activator, are in good health and belong to the age group of 35 years and above, you may qualify to participate in the study.

2. **General information**

- There are numerous products available on the market that claim to have an effect on skin aging. We aim to directly demonstrate this effect on individuals through our study. By participating, you will contribute to further research on the effects of orally consumed dietary supplements on the skin.
- The project will span approximately 6-9 months and will be conducted at the main site, the dermatological clinic Hautwerk in Zurich. The goal is to recruit around 60 individuals who meet the inclusion criteria and are willing to test the product.
- The research project will be conducted in compliance with Swiss laws and adheres to all internationally recognized guidelines. The competent ethics committee has reviewed and approved the research project.

3. **Procedure**

	>-1 day	**-1**	**0**	**Month 1**	**Month 2**	**Month 3**	**Month 4 + 5**	**Month 6**
Visit	*Information*	*Screening (online)*	*1st visit*	*2nd visit*	*Online check-in*	*3nd visit*	*Online check-in*	*Online check-in*
Information	+							
check inclusion-/ exclusion		+	+					
Participant characteristics		+						
Written consent			+					
Skin Tests			+	+		+		
Questionnaire			+	+	+	+	+	+
Saliva sample			+					+

It is possible that we may have to exclude you from the research project prematurely. This happens in cases where you do not adhere to the agreed-upon appointments, do not consistently fill out the questionnaires, or if we suspect that the product is not being taken or not being taken correctly. The correct intake refers to taking one portion of the Collagen Activator daily. One portion is packed in a sachet containing 11.5 grams of powder. The powder from the sachet should be dissolved in a glass of water (at least 200ml) and then consumed by drinking it. The intake should take place in the morning.

4. **Benefits**

If you participate in this research project, you have the chance to learn more about your skin quality and biological age.

5. **Voluntary participation and Responsibilities**

Your participation is voluntary. During the study, you have the right to refuse the skin analyses and saliva sample collection without providing a reason and without any consequences. If you choose not to participate in this research project or wish to withdraw your participation later, you are not required to provide a justification. Your treatment and care are independent of your decision.
If you choose to participate in this research project, you will be asked to:

- Adhere to the requirements and demands of the research project as specified in the study protocol.
- Inform your study personnel about any complaints or changes in your well-being.
- Refrain from consuming any similar products during the study that could directly affect the results.

6. Risks and Burdens

Through the research project, you will be exposed to minimal risks during the measurements, such as providing a saliva sample and undergoing unintrusive skin analyses.

The collagen activator is freely available for you on the market. It has undergone the necessary testing phases and so far there are non known risks or side effects.

The collection of biological material in the form of a saliva sample poses minimal risks. There are usually no significant risks associated with saliva sample collection. Self-collection of saliva samples is typically easy, painless, and does not require any medical expertise or experience. The saliva sample collection is considered unintrusive to the body, as it involves spitting saliva onto a clean spoon and transferring the saliva to a piece of paper.
To determine biological age, 9 short DNA sequences will be analyzed. The sequence data will be deleted once the biological age analysis is completed. No additional information will be derived from these data, and there is no risk of extracting health-related information.

The skin analyses will involve the use of measurement devices such as a Skin Moisture Measurement Device (corneometer), a Skin Elasticity Measurement Device (cutometer), a Skin Thickness Scanner (ultrasound scan (22 MHz)), and a Skin Texture Scanner (Visia scan). These tests are generally safe and unintrusive to the body but can, in rare cases, cause skin irritation or damage, especially if performed too frequently or with excessive pressure. The Skin Moisture Measurement Device measures moisture in the outermost layer of the skin, while the Skin Elasticity Measurement Device evaluates skin elasticity and firmness. The Skin Thickness Scanner is used to measure skin thickness and the depth of wrinkles and lines. Although this test is considered safe, patients with open wounds or skin infections should avoid it. The Skin Texture Scanner is another test used to assess various aspects of the skin, including pigmentation, redness, and texture. This test is also safe and unintrusive to the body. It is important to note that these tests are performed by trained personnel, and during the study, all necessary precautions will be taken to minimize any potential risks.

The data will be encrypted for evaluation purposes. Information that allows for identification of individuals will be treated as strictly confidential and will be subject to medical confidentiality.

For women who could become pregnant:
If you become pregnant during the research project, you must inform your study personnel. The study personnel will discuss the further course of action with you. If you are currently breastfeeding, you are excluded from participating.

7. Alternatives

If you do not wish to participate in this research project but are open to the possibility of participating in other research projects, please speak to your study personnel.

8. Results

There are

1. Individual results that directly concern you
2. Individual results of the research project that arise incidentally (known as incidental findings)
3. Objective final results of the entire research project.

About 1: Individual results that directly concern you: After the completion of the research project, you will receive your individual results. If you do not wish to be informed about these results, please inform your study personnel. If an unknown medical condition is discovered during the study, you will be informed about it. If you do not wish to be informed (known as the right not to know), please discuss this with your study personnel. Individual results will be communicated to you in writing.

About 2: Incidental findings: These are unexpected findings that were not specifically sought but are discovered incidentally. If any incidental findings are relevant to your health, you will be informed about them. This means that if an unknown medical condition is accidentally discovered or a potential future condition can be prevented, you will be notified. If you do not wish to be informed (known as the right not to know), please discuss this with your study personnel.

About 3: The objective final results of the entire research project are the conclusions drawn from the comprehensive analysis of all collected data. These results are not individual findings but rather represent the overall outcome of the study. They will be published in the form of a scientific publication to provide insights into the gained knowledge to the scientific community and the public. As a participant in the study, you can access the publication as it will be freely available to the public. However, the publication will be written in a way that preserves the anonymity of the participants and does not disclose personal identifiers. Thus, your individual information will be protected and treated confidentially.

9. Confidentiality of data and samples

a. Data processing and encryption

For this research project, data and biological material related to your personal and health information will be collected and processed. During data collection, your data and biological material will be encrypted. Encryption means that all identifying information that could identify you (such as your name, date of birth, etc.) will be deleted and replaced with a code. Individuals who do not have access to this key list cannot draw any conclusions about your identity. The key list will always remain with the institution conducting the study and will be treated with strict confidentiality.
Only a very few specialized individuals will have access to your unencrypted data, and only for the purpose of fulfilling tasks within the research project. These individuals are bound by confidentiality. As a participating individual, you have the right to access your data.

b. Data protection and protection of samples

All data protection regulations are strictly adhered to. It is possible that your data may need to be transmitted in encrypted form, for example, for publication, and made available to other researchers. If health-related data/samples are stored on-site, it constitutes a database/ biobank for research purposes.
The collection and storage of saliva samples are carried out with appropriate measures to prevent unauthorized or accidental disclosure and to prevent alteration, destruction, or theft of biological material. The saliva samples are stored in secure facilities with controlled access and under appropriate environmental conditions to preserve sample quality. Access to the material is only granted to authorized personnel. After the saliva samples have been analyzed, all biological material and DNA sequence data are destroyed and deleted.

c. Data protection for Reuse

Your data may be important for answering other research questions at a later date. This other database must adhere to the same standards as the database for this project.
For this reuse, we ask you to sign another consent form at the very end of this document. This second consent is independent of participation in this project.
Your saliva samples and DNA sequence data will be destroyed and not reused for other research questions after analysis.

d. Data protection for Genetic Testing

There are confidentiality risks (e.g., the possibility of identifying you) associated with the collection, storage, and transmission of data from your saliva samples in the context of genetic research, especially regarding information about your genetic material. These risks cannot be completely eliminated and increase as more data can be linked, especially if you yourself publish genetic data on the Internet (e.g., for genealogy purposes). The project management takes all measures to minimize these confidentiality risks for you. The saliva samples are destroyed after analysis. Only very short DNA sequences are analyzed, and the data are deleted after analysis. The saliva samples are analyzed by our partner, TruMe Laboratories, located in the US. They comply with all the standards required in Switzerland, ensuring adherence to our quality requirements. We also ensure that the data protection regulations of Switzerland are complied with. Your data will only be transmitted in encrypted form for analysis. Therefore, TruMe Laboratories will at no time be able to identify you.

e. Access rights during Audits

This research project may be reviewed by the relevant ethics committee and the project management. In such audits, the study participant must disclose their data. All parties involved must maintain absolute confidentiality.

10. Withdrawal

You can withdraw from the research project at any time. However, the data and samples collected until that point will still be analyzed in encrypted form.
In the event of withdrawal, your data and saliva samples will remain encrypted in the project documents. This is for your medical safety. Please consider whether you agree to this before participating in the project.

11. Compensation

If you participate in this research project, you will not receive direct compensation. However, you have the opportunity to receive all your test results upon completion of the study and gain important insights into your health (value approximately 1000 CHF).

There are no costs incurred by you or your health insurance through participation.
The results of this research project may potentially contribute to the development of commercial products. By participating, you do not have any entitlement to claim for commercial developments (e.g., patents).

12. Liability

If you suffer any harm as a result of the research project (through examinations), Avea Life AG, which initiated and is responsible for the project's implementation, shall be liable. The conditions and procedures are legally regulated. If you have suffered harm, please contact the study participant.

13. Funding

The research project is fully funded by Avea Life AG.

14. Contact person

You may ask questions regarding participation in the project at any time. If you have any uncertainties that arise during or after the research project, please contact:
Dr. med. C. Bettina Rümmelein, +41 43 343 93 01, ruemmelein@hautwerk.ch

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Consent Form

Written Consent Form for Participation in a Research Project
Please read this form carefully. If there is anything you do not understand or would like to know, please ask. Your written consent is necessary for participation.

BASEC-number:	2023-00953
Title of the research project:	Reverse the clock: Ein Forschungsprojekt zu den Effekten eines Kollagen Aktivators auf biologisches Alter und Hautqualität.
Responsible Institution (Project Lead with address):	Dr. med. C. Bettina Rümmelein, Hautwerk, Maneggstr. 17, 8041 Zürich
Location of Conduct:	Zurich
Head of Research Project at Study Site: Name and Surname in Block Letters:	Dr. med. C. Bettina Rümmelein
Participant: Name and Surname in Print Letters: Date of Birth:	

- I have been orally and in writing informed by the undersigned investigator about the purpose, process of the research project, potential advantages and disadvantages, as well as possible risks.
- I voluntarily participate in this research project and accept the content of the written information provided for the aforementioned research project. I have had enough time to make my decision.
- My questions regarding participation in this research project have been answered. I will keep the written information and receive a copy of my written consent form.
- I agree that the competent experts of the project management and the ethics committee responsible for this research project may have access to my unencrypted data for the purpose of examination and control, but with strict adherence to confidentiality.
- I will be informed about results and/or incidental findings directly related to my health. If I do not wish to be informed, I will inform the investigator.
- I can withdraw from participation at any time and without stating reasons. My further treatment is independent of participation in the research project. The data and samples collected up to that point will still be used for the evaluation of the research project.
- The institution Avea is liable for any potential damages.

- I am aware that the obligations mentioned in the information leaflet must be adhered to. In the interest of my health, the investigator may exclude me at any time.

Place, Date	Participant signature

Confirmation from the investigator: I hereby confirm that I have explained to this participant the nature, significance, and scope of the research project. I assure that I will fulfill all obligations related to this research project in accordance with the applicable laws in Switzerland. If I become aware of any aspects during the course of the research project that could affect the participant's willingness to participate, I will promptly inform them.

Place, Date	Investigator/Physician/Person in Charge in Print Letters Signature of the Investigator/Physician/ Person in Charge

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Consent Declaration for the Further Use of Data in Encrypted Form

BASEC-number:	2023-00953
Title of the research project:	Reverse the clock: A research project on the effects of a collagen activator on biological age and skin quality.
Participant: Name and Surname in Print Letters: Date of Birth:	

I allow my encrypted data from this research project to be further used for medical research.

I understand that the data is encrypted and the key is securely stored. The data may be sent to other locations, both domestically and internationally, for analysis if they adhere to the same standards as in Switzerland. All legal requirements regarding data protection will be followed.

I make this decision voluntarily and can revoke it at any time. If I withdraw, my data will be anonymized, and my samples and genetic data will be destroyed. I only need to inform the project management without providing a reason for my decision.

Normally, all data and samples are analyzed as a whole, and the results are summarized for publication. If there is a result that is important for my health, it is possible that I may be contacted. If I do not wish to be informed, I will communicate this to my investigator.

I do not have any claim to a share in the commercial use of the results derived from the data and samples.

Place, Date	Participant signature

Confirmation by the investigator: I hereby confirm that I have explained to this participant the nature, significance, and scope of the further use of data.

Place, Date	Investigator/Physician/Person in Charge in Print Letters Signature of the Investigator/Physician/ Person in Charge