SDNTT" - Swiss Dermatology Network for Targeted Therapies

Dear Lady, Dear Sir,

we are asking you here if you would be willing to participate in our research project.

Your participation is voluntary. All data collected in this research project is subject to strict data protection regulations.

The research project is conducted by the Swiss Society of Dermatology and Venereology (SGDV).

In a consultation, your dermatologist will explain the most important points and answer your questions. So that you can already get an idea, you will find the most important information here. Further detailed information will follow.

By signing at the end of the document, you attest that you are participating voluntarily and that you understand the contents of the entire document.

Detailed information

1. Aim and selection

We refer to our research project as a research project in this handout. If you participate in this research project, you are a participant.

In this research project we want to investigate the efficacy of modern psoriasis therapies under everyday conditions, the benefit for patients and the safety of the therapies. We ask you to participate in this research project if you have been diagnosed with psoriasis, are over 18 years old, and are new to drug treatment with a biologic or one of the conventional systemic (internal use) agents.

2. General information

- We currently know little about long-term outcomes, optimal treatment, and efficacy in real-world conditions when treating psoriasis in dermatology practices.
- As a result, the Swiss Dermatology Network for Targeted Therapies (SDNTT) is documenting for the first time the long-term course of patients receiving a defined biological or conventional systemic drug in dermatology practices in Switzerland.
- Data on your course of treatment, the success of treatment and any side effects that may occur are to be collected and evaluated centrally for Switzerland.
- The research project does not affect the nature of your treatment. Therefore, you will not be subjected to additional examinations, nor will you receive any treatment other than that intended for you by your dermatologist.
- We conduct this research project as required by the laws in Switzerland. Furthermore, we observe all internationally recognized guidelines. The responsible ethics committee has reviewed and approved the research project.

3. Procedure

- Participation means that you will fill out questionnaires today, in three and six months, and subsequently at six-month intervals about your current state of disease, your condition, and any side effects of the medication (see Fig. 1). You can obtain the questionnaires from your dermatologist.

- Standardized questionnaires are thus presented to you and the dermatologist:s 44 times. The 44 visits will be within the scope of your normal treatment visits and no examinations beyond the clinical routine will be performed.
- It takes about 10-15 minutes to fill out a questionnaire.
- Information collected includes treatment characteristics, potential side effects and treatment efficacy, clinical parameters, current health status, and data on patient-defined benefits and your quality of life.

Your participation in the registry is limited to 20 years. To exclude multiple participation in the registry, your name and date of birth are stored separately and encrypted. Pseudonymization[1] ensures that your health data is processed strictly separately from your personal identifying data.

24 patient visits (20 years)	**44 Doctor questionnaires**
1 inclusion visit (E) **41 follow-up visits (F)**	**1 Inclusion questionnaire** **41 Follow up questionnaires**

10 – 15 min
Per questionnaire

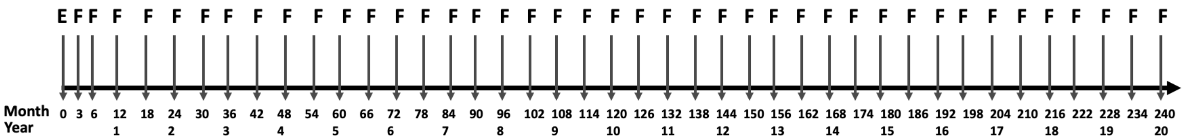

Figure 1: Inclusion questionnaire (E) and follow-up questionnaires (F) over a 20-year period.

4. Benefit

You will not personally benefit from participating.

Further information on the efficacy, patient benefit and safety of the drugs is needed. This can only be obtained through long-term observations in cooperation between dermatologists and patients. Therefore, your dermatologist is participating in this research project, which is being conducted by the *Swiss Society of Dermatology and Venereology (SGDV)* together with the *Competence Center for Health Services Research in Dermatology* (CVderm) at the University Hospital Hamburg, Germany.

5. Voluntariness and duties

You are participating voluntarily. If you do not wish to participate in this research project or later withdraw your participation, you do not have to justify this. Your treatment/care is guaranteed regardless of your decision.

If you participate, we will ask you to fill out several questionnaires.

[1] In the case of pseudonymization, an identification feature (e.g. the name) is replaced by a code (consisting of a sequence of letters and numbers) in order to exclude or make it significantly more difficult to establish the identity of the person concerned.

6. Risks and burdens

Your treatment will not be affected by participation in this research project. Only you and your treating dermatologist decide about your treatment. Therefore, no risks arise for you through participation.

7. Results

Your dermatologist will inform you of any new findings that affect the benefit or safety of the therapy you are receiving. Your dermatologist may provide you with a summary of the overall results at the end of the research project.

8. Data confidentiality

8.1 Data processing and encryption

For this research project, data about you (name and date of birth) and your health will be collected and processed. During data collection, your data will be encrypted. Encryption means that all reference data that could identify you will be deleted and replaced by a code. People who do not have access to this key list cannot draw any conclusions about you. The key list is stored in a password-protected database using cryptological encryption methods. Only very few professionals (dermatologist and data protection coordinators of the research project in Switzerland and Germany) will see your unencrypted data, and only to perform tasks within the research project. These persons are subject to the obligation of confidentiality. You as a participating person have the right to see your data.

8.2 Data processing and encryption

For this research project, data about your person and health will be collected and processed, partly in automated form. During data collection, your data will be encrypted. Encryption means that all reference data that could identify you (name, date of birth, etc.) are deleted and replaced by a code. People who do not have access to this key list cannot draw any conclusions about you. The key list always remains in the institution/hospital.
Only very few professionals will see your unencrypted data, and only to perform tasks within the research project. These persons are subject to the duty of confidentiality. You as a participating person have the right to see your data.

8.3 Data protection

All data protection specifications are strictly adhered to. It is possible that your data may need to be transmitted in encrypted form, for example for publication, and may be made available to other researchers. If health-related data is stored on-site, it is a database for research purposes. The sponsor is responsible for ensuring that the same standards are maintained abroad as in Switzerland. Physicians who are responsible for the follow-up treatment can provide information about your health status.

8.4 Data protection in case of further use

Your data could be important for answering other questions at a later time and could later be sent to and used in another database in Switzerland or abroad for investigations not yet defined in detail. This other database must comply with the same standards as the database for this project. For this further use, 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.

9. Inspection rights during inspections

This research project may be reviewed by the responsible ethics committee, and by the project management. Your treating dermatologist must then disclose your data for such inspections. All participants are bound to absolute confidentiality.

10. Resignation

You can withdraw from participation in this research project at any time. In this case, the data collected up to that point will be evaluated anonymously.

In the event of withdrawal, your data will therefore continue to be stored in encrypted form in the registry database. Any link between your personal identifying data and your health data will be deleted at your request.

11. Compensation

If you participate in this research project, you will not be compensated for it.

12. Liability

If you suffer any damage as a result of the research project, the *Swiss Society of Dermatology and Venereology (SGDV)*, which initiated the research project and is responsible for its implementation, is liable. The conditions and the procedure are regulated by law. If you have suffered damage, please contact your dermatologist.

13. Funding

The research project is funded by the *Swiss Society of Dermatology and Venereology (SGDV).* SDNTT receives financial support from pharmaceutical companies.

14. Contact

You may ask questions about participation in the research project at any time. Also, if you have any uncertainties that arise during the research project or afterwards, please contact:

Prof. Dr. Nikhil Yawalkar
Universitätsklinik für Dermatologie
Inselspital
Freiburgstrasse 34
CH-3010 Bern
Tel. 076 433 76 40

Declaration of consent

Written informed consent to participate in a research project

Please read this form carefully. Please ask if there is anything you do not understand or would like to know. Your written consent is required for participation.

BASEC number (after submission):	**PB_2023-01170**
Title of the research project (scientific and lay language):	"SDNTT"- Swiss Dermatology Network for Targeted Therapies
Responsible institution (project management with address):	Schweizerische Gesellschaft für Dermatologie und Venerologie (SGDV)
Place of implementation:	Universitätsklinik für Dermatologie Inselspital Freiburgstrasse 34, 3010 Bern
Head of the research project at the study site: **Surname and first name in block capitals:**	Prof. Dr. Nikhil Yawalkar Universitätsklinik für Dermatologie Inselspital Freiburgstrasse 34, 3010 Bern
Participant: **Name and first name in block letters:** **Date of birth:**	

- I have been informed verbally and in writing by the undersigned dermatologist:in about the purpose, procedure, possible advantages and disadvantages as well as possible risks of the research project.
- I am voluntarily participating in this research project and accept the content of the information on the above research project. I have had sufficient time to make my decision.
- My questions related to participation in this research project have been answered. I will keep the written information and receive a copy of my written informed consent.
- I agree that the responsible experts of the project management and the ethics committee in charge of this research project may inspect my unencrypted data at my dermatologist's office for testing and control purposes, but under strict observance of confidentiality.
- I will be informed of results that directly affect my health. If I do not wish to be informed, I will inform my dermatologist.
- I understand that my health-related and personal data will only be processed in encrypted form for research purposes for this research project by SDNTT and the *Competenzzentrum Versorgungsforschung in der Dermatologie* (CVderm) Hamburg, Germany. I may withdraw from participation at any time and without giving reasons. My continued treatment is guaranteed regardless of my participation in the research project.
- SDNTT and CVderm guarantee the protection of my personal and health-related data and keep the name and date of birth password-protected and separate from the health data. The employees of SDNTT and CVderm have committed themselves to silence in a written declaration. They are also bound to secrecy according to the legal regulations of data protection. If I revoke my declaration of consent, my health data will only be processed anonymously. I consent to the anonymized use of my health-related data collected during the long-term follow-up for the purpose of scientific evaluation in the European network of psoriasis registries (Psonet).

Place, date	Signature participant

Confirmation of the informing dermatologist: I hereby confirm that I have explained the nature, significance and scope of the research project to this participant. I assure that I will fulfill all obligations in connection with this research project in accordance with the laws in force in Switzerland. If, in the course of the research project, I learn of any aspects that could influence the participant's willingness to participate in the research project, I will inform him/her immediately.

Place, date	Signature of dermatologist

Declaration of consent for further use of data in encrypted form
(for the further use of data of this research project)

BASEC number (after submission):	**PB_2023-01170**
Title of the research project (scientific and lay language):	"SDNTT"- Swiss Dermatology Network for Targeted Therapies
Participant: Last name and first name in block letters: Date of birth:	

I give permission for my encrypted data from this research project to be reused for medical research.

The data can be sent to other data for analysis at home and abroad if they comply with the same standards as in Switzerland. All legal requirements for data protection are complied with.

I decide voluntarily and can withdraw this decision at any time. If I withdraw, my data will be anonymized. I only inform my investigator/the project management and do not have to justify this decision.

Normally, all data are evaluated as a whole and the results are published in summary form. If there is a result that is important for my health, it is possible that I will be contacted. If I do not wish this, I will inform my investigator.

I give permission for my data to be anonymized and understand that in this case I cannot be informed of random results or withdraw from the research project.

If results from the data are commercialized, I have no right to share in the commercial use.

Place, date	Signature Participant

Investigator's Acknowledgement: I hereby acknowledge that I have explained to this participant the nature, significance and implications of the further use of samples and/or genetic data.

Place, date	Surname and first name of the investigator in block capitals Signature of the investigator