Martini-Klinik
Prostatakrebszentrum

Patient survey and data collection

Help us in our research and teaching

Universitätsklinikum Hamburg-Eppendorf
UKE
HAMBURG

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Dear Patient,

We would like to know how you're doing. Not just before your stay with us, but also weeks, months and years afterwards. Did the treatment that you received help you, were there any complications and what is your quality of life like? Getting the answers to these questions is a key part of our patient aftercare at the Martini-Klinik, and also helps us to continually improve the quality of our treatments. In addition, by answering the questions you are making an important contribution to the scientific research into prostate cancer and the advancement of treatment. This enables us to give future patients even more precise information about possible treatments and the results that can be expected.
How you can help us?

When you give your consent and provide your email address, we will include you in our online patient survey. This survey is conducted using Philips Healthcare's VitalHealth QuestLink software. It goes without saying that we conduct our research in accordance with the strict regulations laid down in the advice on professional conduct issued by the Hamburg Ethics Committee and in line with data protection requirements. By giving your permission, you consent to your data being stored and used as described in detail below in this brochure.

If you support our research by participating in our patient survey, you will be emailed a questionnaire one month before your treatment, four weeks after your treatment, six months after your treatment, and then once a year at the time of the treatment. You can complete the questionnaires from the comfort of your own computer or mobile device.
We have been continuously building and expanding the Martini-Klinik database, which forms the basis of our scientific work, for over 20 years. Many of our research results have already led to a better understanding of prostate cancer and have helped to improve the diagnosis and treatment of this disease.

Despite all the progress made so far, further research is needed in order to be able to cure patients, including those with advanced prostate cancer, or even prevent prostate cancer from developing in future.

Thank you very much for your support.

With best wishes from the Martini-Klinik,

Prof. Markus Graefen

§§ Information on the use of patient data for medical research and teaching purposes

You are currently being treated at the Martini-Klinik. As part of your diagnosis and treatment, patient data is collected from you. This patient data can be of considerable value for medical research and advancement in teaching.

Medical research is necessary in order to continuously improve the early detection, treatment and prevention of diseases, and the insights we obtain from your patient data could play a major role in this research. We would therefore ask you to make your patient data and, where appropriate, information from our patient survey available to us for medical research purposes and also for the advancement of teaching. Your patient data will be stored in our research database.

Your consent is voluntary. If you choose not to take part or subsequently withdraw your consent, this will not result in any disadvantages for you.

If you do not fully agree with the type and long-term duration of use described below or your questions have not all been answered satisfactorily, you should not give your consent. You can give your consent in our Philips VitalHealth QuestLink software.

1 Collection of patient data

1.1 What are our objectives?

Your patient data will be made available for medical research and for teaching and training purposes related to prostate cancer.

> **The sole purpose of medical research is to improve the detection, treatment and prevention of diseases.**

Your patient data will not be used to develop biological weapons or for discriminatory research objectives. Nor is it the objective of this research to establish a diagnosis for you or to influence your actual treatment.

The aim is to use your patient data for a wide variety of medical research purposes and for teaching and training purposes for the broad benefit of the general public. At the present time, we cannot yet specify all the future medical research topics or teaching and training purposes; these may relate to entire disease areas (e.g. cancer) or to changes in genetic material that are currently still unknown. To this end, your patient data will be stored for 30 years from the date of your consent if you do not withdraw your consent before the end of this period. In specific cases, data may be of considerable importance to science even beyond this date. In these cases, we would consult the competent data protection authorities and an independent ethics committee to clarify whether it would be possible to use your data beyond this date.

Patient data

Patient data is all the information held about you that is used for your examination and treatment, including information from our patient survey. Examples of patient data include data from doctors' letters, your medical history, or results and data from diagnostic investigations and treatment, such as measurements and image/video materials. It also includes the results of laboratory tests, including examinations of your genetic material (e.g. to screen for congenital genetic disorders or acquired genetic changes, also including tumours).

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1.2 How is your patient data used scientifically?

Your patient data may be made available upon request to universities, research institutes, and medical research and development companies, as well as to companies that engage in medical teaching and training, for their own purposes. This data may only be used by the recipient for the specified and requested purpose and may not be passed on for other purposes. Your patient data is used solely for scientific purposes or for teaching and training purposes. The Martini-Klinik can charge users an appropriate fee for the provision of quality-controlled data. The ethical and legal validity of individual research projects or teaching and training purposes that include your patient data is reviewed beforehand by an independent ethics committee.
If required by the particular research project (e.g. further data after your treatment has been completed), your patient data is made available for the research in **pseudonymized** form only, which makes it impossible to directly identify you as an individual. The data is pseudonymized again before being passed on. If data does not need to be attributed for the particular research project, the data and materials are passed on without a pseudonym of this kind (**anonymized**).
Scientific results are only published in such a way that they do not contain any data that could identify you directly (name, date of birth, etc.). This also applies to genetic information in particular. However, your genetic data – including the complete set of genetic material (genome) – may be kept in specially protected scientific databases that cannot be accessed by the general public.

Your patient data may also be merged with your data from databases of other research or cooperation partners (e.g. other hospitals, institutes, companies in the healthcare industry or registers). This is subject to the prerequisite that you have also consented to this use with the relevant research partners or it is permitted by law. One example of this would be the Prostate Cancer Outcomes study, which is described in more detail from page 8 onwards.

Pseudonymization

When patient data is collected, information such as your name and date of birth is also recorded. You can easily be identified personally from information of this kind. This information is replaced by a combination of characters (the pseudonym). This prevents anyone from simply tracing the information back to you as an individual. The data is only traced back to you if your patient data needs to have additional information about you added to it or in order to contact you again.

Other than in cases permitted by you or regulated by law, data that identifies you as an individual is never passed on to researchers or any other third parties, in particular not to insurance companies or employers.

Anonymization

Anonymization alters your data in such a way that it can no longer be attributed to you as an individual, or doing so would require a disproportionate amount of technical effort.

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1.3 Who has access to your patient data and how is it protected?

Any data that can directly identify you as an individual (name, date of birth, address, etc.) is replaced by a pseudonym (pseudonymized). This ensures that your patient data can no longer be directly attributed to you as an individual. The pseudonym is managed by an independent body (data custodian). Without the involvement of this body, the patient data provided for medical research cannot be traced back to you, or doing so would require a disproportionate amount of technical effort.

Your consent also covers the possibility of your patient data being transmitted for the purposes mentioned to recipients in countries in the European Union or European Economic Area or other countries for which the European Commission has established an appropriate level of data protection.

Data can be transmitted to other countries in which no appropriate level of data protection has been established only if you give separate consent on the consent form (page 10, item 2.4). These countries may have a lower data protection level than the EU. In these cases, the Martini-Klinik ensures that the research partners are under a contractual obligation to comply with the EU data protection level as far as the law permits. Nevertheless, there is a risk that public or private bodies could access your patient data even though this is not permitted under European data protection law. In these countries you may also be entitled to fewer rights, or rights that are more difficult to enforce, and there may be no independent supervisory authority that could help you exercise your rights.

1.4 What risks are associated with the use of your patient data?

Whenever data is collected, stored and transmitted as part of research projects that include patient data, there is a residual risk of the data being traced back to you as a result of additional information being gathered, for example from the Internet or social networks. This is more likely if you yourself post genetic or other health data, e.g. for family history research, on the Internet.

1.5 How will you benefit personally?

Generally speaking, you cannot expect any personal benefit or direct advantage for your health from the scientific use of your patient data.

1.6 How will society benefit?

Medical research projects aim to improve our understanding of how diseases develop and their diagnosis, and to develop new and improved approaches to prevention, care and treatment on the basis of these findings. For more information about our activities, please visit www.martini-klinik.de.

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2. What does your right of withdrawal involve?

Your consent is voluntary!

You can at any time withdraw your consent, in full or in part, to the further collection or scientific use of your patient data without giving reasons and without suffering any negative consequences as a result.

You can withdraw your consent only to the future use of your patient data. Data from analyses that have already been carried out can no longer be removed retrospectively.

If you withdraw your consent, the patient data that is stored on the basis of this consent is anonymized by deleting the identification code assigned to you. However, anonymization of your patient data can never completely prevent genetic information, in particular, from subsequently being linked to you via other sources.

To withdraw your consent, please contact:

Anke Renter
Data custodian, Martini-Klinik am UKE GmbH
✆ +49 (0) 40 7410-53115
FAX +49 (0) 40 7410-43115
@ a.renter@uke.de

Further information and rights

The legal basis for data processing is your consent under the European General Data Protection Regulation (GDPR).

Person responsible for processing your patient data
Martini-Klinik am UKE GmbH
Prof. Dr. Markus Graefen
✆ +49 (0) 40 7410-51300
@ info@martini-klinik.de

Competent data protection officer
Matthias Jaster, University Hospital Hamburg-Eppendorf,
Martinistraße 52, 20246 Hamburg
✆ +49 (0) 40 7410-56890
FAX +49 (0) 40 7410-55015
@ dsb@uke.de

In addition, you have the option of making a complaint to a supervisory authority.

The jurisdiction of a supervisory authority depends, among other things, on the location of the responsible authority and on the federal state where you live, work or where the alleged breach of data protection took place. For a list of supervisory authorities and their addresses, please visit *www.bfdi.bund.de/DE/Infothek/Anschriften_Links/anschriften_links-node.html*.

The authority responsible for UKE is:
The Hamburg Commissioner for Data Protection and Freedom of Information, Ludwig-Erhard-Straße 22, 20459 Hamburg
✆ +49 (0) 40 42854-4040
FAX +49 (0) 40 42854-55015
@ mailbox@datenschutz.hamburg.de
🌐 www.datenschutz-hamburg.de

In addition, you have the right to obtain information about patient data relating to you (including, upon request, a copy provided free of charge) and, where appropriate, to request that this data be rectified or erased or its processing restricted. You also have the right to obtain your personal data in a standardized electronic format or to have this data transmitted to a body specified by you (right to data portability).

Information on the PCO Study

We would like to know how you're doing!

As part of an intensive collaboration between the International Consortium for Health Outcomes Measurement (ICHOM) and the Martini-Klinik, involving international representatives from urology, oncology and radiation therapy clinics, cancer registries and patient representatives, a recommendation was developed that enables both treatment results and clinics to be compared internationally.

The first project of this kind, the Prostate Cancer Outcomes (PCO) Study, has already started. As a prostate cancer centre certified by the German Cancer Society, we are taking part in the PCO study to improve the quality of outcomes in localized prostate cancer. Patient data is collected by questionnaire for an international comparison and evaluated without using personal details. The study investigates the quality of outcomes in the treatment of localized prostate cancer. Quality of outcomes includes survival after this disease, and also quality of life and side effects of treatment. We would be pleased if you could take part in this important study. Only you, as someone affected by this disease, can help us to find out more about the quality of outcomes after treatment of localized prostate cancer by answering our questions. The research project has received the approval of the ethics committees of the Berlin Chamber of Physicians and the Hamburg Chamber of Physicians. Taking part in the PCO Study involves participating in our continuous patient survey (see page 3) and giving us permission to use your patient data for scientific research purposes (see "Information on the use of patient data for medical research and teaching purposes" from page 4 onwards).

Why is this study being conducted?

Prostate cancer is the most common cancer among men in Germany, with around 60,000 patients being diagnosed with this type of cancer every year (Robert Koch Institute 2017). There can be significant differences in treatment and aftercare between hospitals within and outside Germany. In this study, the quality of outcomes for patients from your centre will be compared with that of patients from other centres in Germany and abroad. This will help doctors at the participating centres to find out even more about how the treatment and care of patients can be improved.

Who is responsible for this study?

The study is supported by a large number of committed partners: the German Association of Prostate Cancer Patient Support Groups (Bundesverband Prostatakrebs Selbsthilfe e.V.), the Help for Prostate Cancer Patients Association (Förderverein Hilfe bei Prostatakrebs e.V.), the German Cancer Society (DKG), the certification institute OnkoZert, the Movember Foundation and the participating prostate cancer centres. The study is funded by private donations, with no involvement by the manufacturers of medical equipment or drugs.

How will the study be carried out, what data is collected and what do I need to know about taking part?

If you take part in the study, the Martini-Klinik will ask you to fill in an online questionnaire at regular intervals. You will complete the first survey before you start your treatment, followed by further surveys after six and 12 months, and subsequently once a year. The results of your questionnaire will be linked to other relevant data on the disease and stored in the clinical database. The data will then be pseudonymized and evaluated by the German Cancer Society, OnkoZert and the international partners, led by Monash University in Melbourne, Australia and the University of California, Los Angeles (UCLA) in the USA. Pseudonymized means that the German Cancer Society, OnkoZert and the partners do not know which patient is linked to what data. Data cannot be traced back to individuals. Only the data custodian at the Martini-Klinik knows who is behind your pseudonym.

To participate in the study, you must give your consent via our QuestLink survey software (page 10, item 2.4). You will then be asked to complete the first questionnaire. Further invitations to take part in surveys will then be emailed to you.

The Martini-Klinik will merge your data with other information about you that is required in order to evaluate the data, such as the stage of your tumour, the size of your tumour or your age. This is important so that fair comparisons can be made between the prostate cancer centres. You do not need to do anything in this regard. The Martini-Klinik will pseudonymize your data and transfer the pseudonymized data to the German Cancer Society, OnkoZert and the international partners.

How will you benefit personally from participating in the study?

By taking part in this study, you can help improve the care of patients with prostate cancer in the medium and long term. There will be no direct personal benefit to you, for example in the form of financial advantages, if you take part. The study has been approved by the relevant ethics committee.

What risks are associated with participation in the study?

There are no risks associated with participation in the study. You simply have to fill in a questionnaire. Completing the questionnaire will take around 10 to 15 minutes of your time.

Are there any costs involved in participating in the study?

Apart from the time involved, there are no costs associated with participating in this survey.

Can I withdraw from the study at an early stage?

Participation in the study is voluntary. You can withdraw from the study at any time, without giving reasons and without suffering any negative consequences as a result.

Description of the data flow and data security:

Your name does not play a part in the scientific evaluation of the questionnaires. We only record your personal data so that we can contact you at a later date and attribute the data at the centre in our electronic research database. The server is located within the hospital in University Hospital Hamburg-Eppendorf's specially secured and restricted-access network. If you have consented to take part in the study, your data will be given a pseudonymization code that is documented in a separate list of codes held by the data custodian. This pseudonymization code is used for the questionnaires. Questionnaires that were sent out electronically and have been completed and returned are attributed in the research database using the pseudonymization code and saved. Data is encoded before it is exported for evaluation.

All information and personal or study-related documents are treated as confidential. To maintain confidentiality, all study records are stored in the research database in encoded form (pseudonymized) and neither your name nor address will be mentioned.

The pseudonymized data is evaluated by the German Cancer Society, OnkoZert and the international partners, who cannot link the data to you as an individual.

Once the study has ended, all data will be stored and archived in accordance with the applicable guidelines.

More information: http://www.ichom.org/ and https://www.pco-study.com/info

Sample copy of consent form for the use of patient data for medical research and teaching purposes

1. Possibility of being re-contacted (participation in the patient survey)

1.1 I consent to the Martini-Klinik re-contacting me by post, phone or email in order to send me questionnaires for in-house quality assurance where appropriate, to inform me about new research projects/studies or to obtain my consent to my patient data being linked to medical information from other databases.

yes ☐ no ☐

1.2 I consent to the Martini-Klinik contacting the general practitioner or private-practice urologist treating me in order to provide additional information, where appropriate, that is relevant for scientific questions.

yes ☐ no ☐

2. Collection, processing and scientific use of my patient data

This covers

2.1 the processing and use of my patient data for medical research and for teaching and training purposes in pseudonymized form only, as described in the patient information section.

2.2 the scientific analysis and use of my pseudonymized patient data by third parties, e.g. by other universities/ institutes/ research companies; this can also include my data being passed on for research projects abroad, but to certain countries only if I give my express consent. In addition, the data is pseudonymized again before being passed on to researchers outside the institution where I am being treated.

2.3 the option to merge my patient data with data in databases of other research partners. This is subject to the prerequisite that I have also consented to this use with the relevant research partners or it is permitted by law. I consent to the collection, processing, storage and scientific use of my patient data as described in items 2.1 to 2.3 of the consent form and item 1 of the patient information section.

yes ☐ no ☐

2.4 My consent also covers the transmission of my patient data to countries in which no appropriate level of data protection has been established by the European Commission. The possible risks of my data being passed on in this way have been explained to me (item 1.3 in the patient information section). This consent is required in order to participate in the PCO Study.

yes ☐ no ☐

3. Dates and signatures

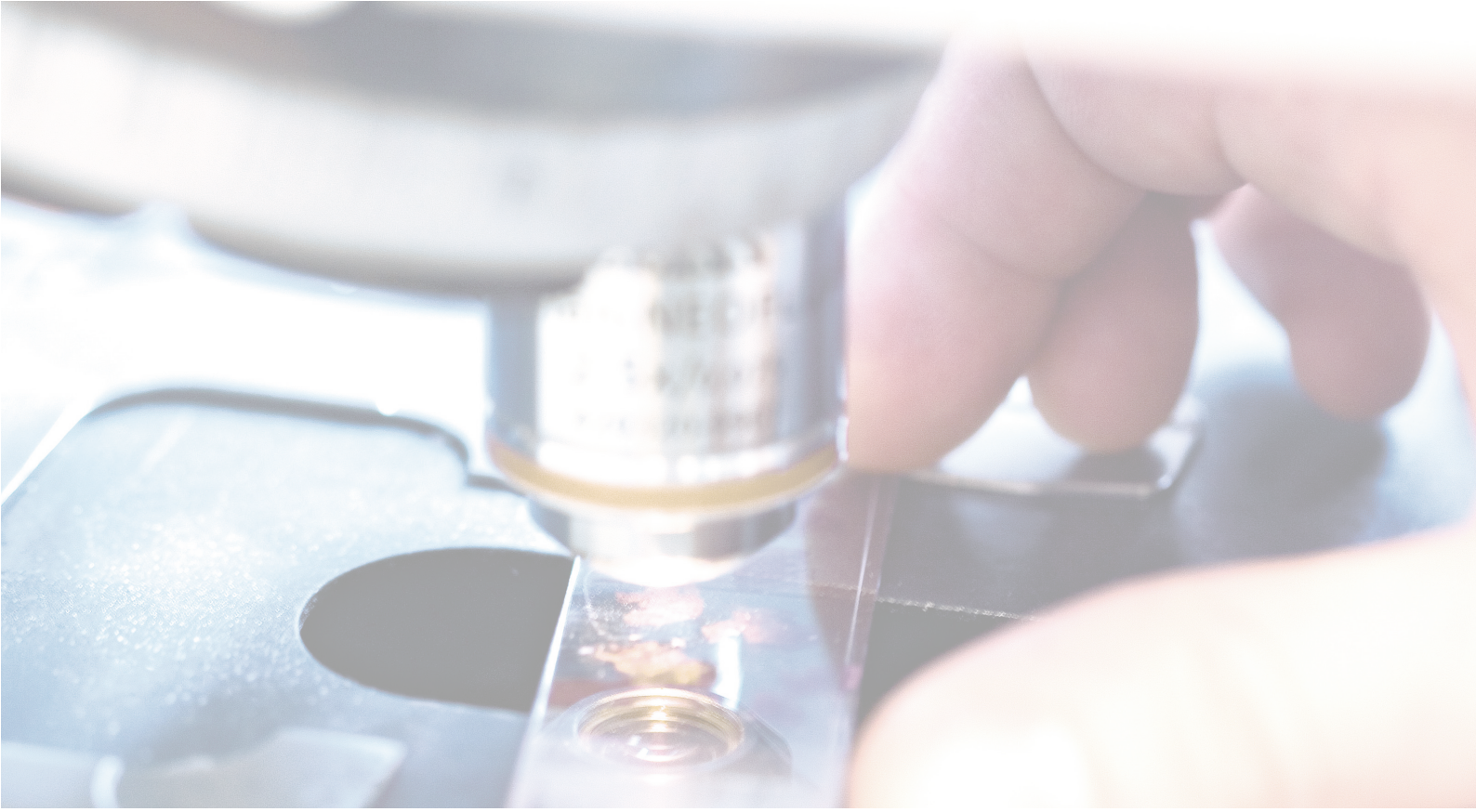
First name and surname of member of the treatment team | Signature of member of the treatment team

Patient's first name and surname | Patient's signature | Place, date

4. Right of withdrawal

Meine My consent is voluntary!

I can withdraw my consent, in full or in part, at any time without giving reasons, and without suffering any negative consequences as a result, by contacting the data custodian Anke Renter. ✆ +49 (0) 40 7410-53115 FAX +49 (0) 40 7410-43115 @ a.renter@uke.de If consent is withdrawn, the data that is stored on the basis of this consent will be destroyed/deleted or anonymized where this is permitted by law. Data from analyses that have already been carried out can no longer be removed (item 2 in the patient information section). I have been informed about the use of my patient data and the associated risks, and give my consent in the above-mentioned context. I have had sufficient time to consider my decision and all my questions have been answered satisfactorily.



Supporting research

Heinrich Warner Foundation

If you would like to support prostate cancer research financially, the Heinrich Warner Foundation offers you the opportunity to donate to uro-oncological research in North Germany. You can state that you would like your donation to be used for this purpose (by indicating “Für die uro-onkologische Forschung in Norddeutschland”) or donate without specifying a particular cause.

Account holder: Heinrich Warner Stiftung
IBAN: DE88 2007 0024 0040 0242 00
BIC: DEUTDEDBHAM
Bank: Deutsche Bank AG, Hamburg

Heinrich Warner was a Hamburg businessman who died of prostate cancer in 1977. In his will he established the Heinrich Warner Foundation, through which he wanted to help people suffering from urological tumours. The Heinrich Warner Foundation fulfils this mission by funding research work and scientific communication in this field.

You can find further information on the website: www.heinrich-warner-stiftung.de

As at: August 2021

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European
Prostate Epicenter
For Robot-assisted Radical Prostatectomy

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DKG
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Prostatakrebs
Zentrum