MARTINI-KLINIK
PROSTATE-CANCER-CENTER

Biomaterials and patient data

Help us with research and teaching

Information to support research and teaching

Universitätsklinikum Hamburg-Eppendorf

Our analyses and results are already part of important research collaborations with leading international cancer centers and have contributed to improving patients' quality of life.

Information

Patient Survey 4

Photographs and video recordings 4

The biobank (blood and urine samples) 5

Tissue sample storage 5

Use of patient data, and biological materials for medical research purposes 6

Withdrawel 11

Consent

Consent to the use of patient data and biological materials for medical research and teaching purposes 14

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Dear patient,

You are currently receiving treatment at the Martin-Klinik. As part of your diagnosis, therapy and post-treatment interviews, patient data is collected from you and biomaterials (tissue and body fluids) are obtained. Both are of great value for medical research and further development in teaching.

For more than 30 years, we have been continuously expanding data, serum, and tissue banks at the Martini-Klinik and the University Medical Center Hamburg-Eppendorf, which form the basis of our scientific work. Many research results have already led to a better understanding of prostate cancer and have contributed to improve diagnosis and treatment of this disease.

Our goal is to be able to prevent the development of prostate cancer in the future, improve your quality of life, and cure patients with advanced prostate cancer.

It goes without saying that we conduct our research activities in accordance to the strict guidelines of the Hamburg Ethics Commission and data protection requirements.

The results of our research projects have already led to innovative diagnostic procedures and therapies. We ask for your continued support in the future so that we can further improve the quality of life and chances of recovery for prostate cancer patients.

The Martini-Klinik team

Prof. Markus Graefen

Patient Survey

Value-based Healthcare

Usually, surgeons do not learn anything about the further course of treatment, as their patients are cared for by specialists in private practice.

We have therefore been regularly surveying our patients since 1992. We are interested in what is important to you: quality of life, healing rate, continence and potency.

By answering the questions you are making a major contribution to improving our treatment and to scientific research and further development of prostate cancer therapy. This helps us to provide future patients with even more precise information about possible therapies.

How can you support us?

With your consent and by providing your email address, we will add you to our online patient survey platform. On this platform you will give your consent to participate in research.

You will receive an invitation link to the questionnaire by email 30 days before your therapy, four weeks after your treatment, after 6 months, and then annually at the time of therapy. Completing the questionnaires takes approximately 30 to 60 minutes.

Thank you for participating in the survey!

Photographs and video recordings

Photographs or video recording is essential for quality assurance, training and continuing education, as well as for the further development of methods within surgical procedures. The image or video recording taken during treatment (diagnosis, surgery) is stored in the patient file or in a separate video archive.

Photographs or video recordings may be published by the clinic in printed material (books, magazines) or in electronic media, e.g., in case reports. In this case, all personal details will be anonymized in accordance with the provisions of the General Data Protection Regulation and the material will be protected by copyright. Nevertheless, the material may be copied by third parties, e.g., by photographing it or taking a screenshot. Therefore, further distribution cannot be completely ruled out. There are no claims for remuneration or compensation in connection with the creation, archiving, and publication. The consent is valid without any restrictions in terms of time or location. It can be revoked at any time without affecting medical treatment. However, this has no effect on processing or publication that has already taken place.

Biobank

(blood and urine samples)

On the trail of potential tumor markers

Your treating physicians are committed to continuously improving the current diagnosis and treatment of prostate cancer. The insights we gain from your patient data and biomaterials can help us better understand the development and treatment of prostate cancer.

We would therefore like to ask you to make your patient data and biomaterials available to us for medical research purposes, but also for the further development of teaching. Your patient data will be collected in our research database. The biomaterials you provide will be stored in a quality-controlled manner in the Martini-Klinik biobank or in the UKE tissue bank.

Biological materials

Biological materials are tissue samples and/or body fluids that are taken from you for diagnostic or therapeutic purposes and are no longer required after the investigations have been completed (residual materials). They can include blood, urine, stool, saliva, cerebral fluid or tissue taken, for example, during an operation or biopsy. These residual materials can be useful for medical research and to this end are stored in the Martini-Klinik biobank or the UKE tissue bank. In addition, you can also donate additional samples (e.g. a limited additional amount of blood) for medical research purposes during a routine blood test or scheduled puncture.

tissue sample storage

From molecular change to customized treatment

Research into diseases is never complete – prostate cancer, too, frequently exhibits unknown mechanisms. Alongside the biobank, the tissue bank at the University Hospital Hamburg-Eppendorf is a key resource for research into prostate cancer. More than 18,000 samples of prostate cancer tissue form the basis of numerous research projects aiming to identify currently unknown genetic mechanisms of prostate cancer.

Changes in the cells that are responsible for the development and aggressiveness of prostate cancer tumours can be analysed at molecular level and are at the same time starting points for new treatments. For example, a genetic mechanism for the early development of prostate cancer in young men was identified in an international research project in which the Martini-Klinik and the UKE pathology department played a major role.

A new technology known as tissue microarrays (TMAs) is an especially important feature of the tissue bank. These tissue chips were developed by a working group at the Martini-Klinik and the Institute of Pathology at the University Hospital Hamburg-Eppendorf (UKE) in order to predict longterm outcomes for patients with prostate cancer. Tiny tissue samples from thousands of prostate tumours can be stored on these chips. This enables a large number of tumours to be screened quickly and accurately for genetic changes. We are using the results of these evaluations in our research to help us develop new prostate cancer drugs for the future.

New findings will contribute to the development of new strategies for diagnosis and personalized treatment. For example, the blood of patients at risk can be screened for these specific genetic changes. Relevant tumours could then be diagnosed at an even earlier stage than they are now and treated more quickly.

The doctors and researchers at the Martini-Klinik are confident that the new understanding of the causes of prostate cancer will now provide the opportunity for effective preventive measures to be developed that will prevent the disease from occurring in the first place.

Use of patient data and biological materials

for medical research purposes

1 Collection of patient data and biological materials

1.1 What are our objectives?

Your patient data and your biological materials will be made available for medical research as well as for teaching and training purposes on prostate cancer.

Your patient data will neither be used to develop biological weapons, advertisement 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.

Medical research serves exclusively to improve the detection, treatment, and prevention of diseases.

At the present time, we cannot yet specify all the future medical research topics as well as teaching and training purposes on prostate cancer; 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 and biomaterials **will be stored and retained for 30 years from the date of your consent, even after your death**, if you do not withdraw your consent before the end of this period.

In special cases, data and biomaterials may be of considerable importance to science even beyond this point in time. In such cases, we would consult with the relevant data protection supervisory authorities and an independent ethics committee to clarify whether it would be possible to use your data and biological materials beyond this date.

Patient data

1. Personal data: Information that identifies you/your person (name, address, email address, insurance number, etc.).

2. Clinical data: Information used in connection with your stay at our clinic (clinical parameters from doctor's letters, medical history, the results of laboratory tests, measurements, image/video material, etc.). Laboratory tests may involve your genetic material being examined (e.g. to screen for congenital genetic disorders or acquired genetic changes, including tumours).

3. Research data: additional information collected for research purposes or as part of studies, e.g., from questionnaires.

1.2 How is your patient data used scientifically?

Your patient data may be made available upon request to universities, research institutes and research companies for medical research purposes as well as companies that pursue medical teaching and training.

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 and donated biological materials will be used solely for scientific or teaching and training purposes. The Martini-Klinik can charge users a fee to cover the expense of providing quality-controlled data.

The ethical and legal validity of individual research projects, teaching and training purposes that include your patient data and biological materials is reviewed beforehand by an independent ethics committee.

If required by the particular research project (e.g. if follow-up data needs to be attributed), your patient data and biological materials are made available for the research in pseudonymized form only, which makes it impossible to directly identify you as an individual.

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 can only be 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.

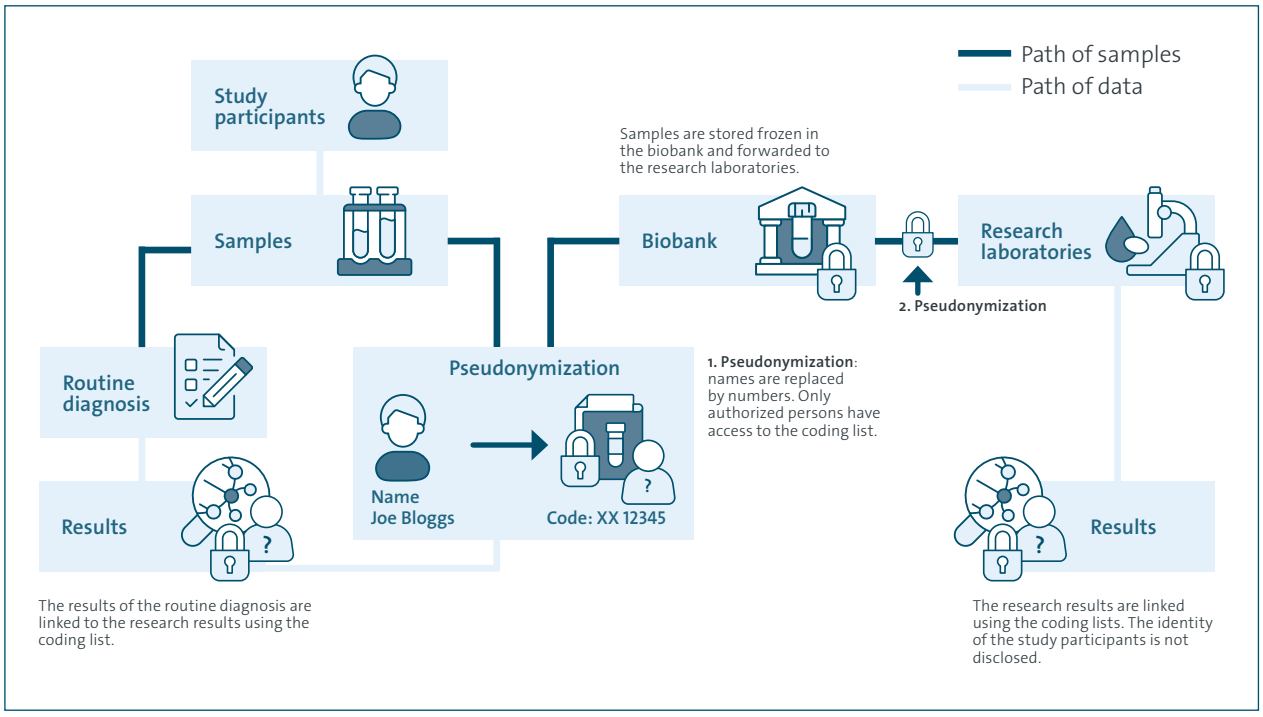
The data and biological materials are further **pseudonymized** before being passed on. If data does not need to be attributed for the particular research project, the data and materials are passed on without a pseudonym of this kind **(anonymized)**.

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.

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.

Biobank for research into prostate cancer



Your patient data and data from the analysis of your biological materials may also be merged with your data from databases of other research partners or cooperation partners (e.g. other hospitals, institutes, healthcare companies 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.

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

All 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 person (data custodian). Without the involvement of this person, 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 and biological materials 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. 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 and biological materials 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 does participation involve?

Your participation in the Martini-Klinik biobank requires your consent to the following four items (A-D):

A. Consent to take a blood sample:
By giving your consent, you allow us to take approx. 25 ml of blood from you in addition to the blood samples that are medically necessary and to use this blood for research purposes. The blood samples are pseudonymized and stored for the Martini-Klinik's research purposes.

B. Access to your disease-specific data:
By giving your consent, you grant us permission to access relevant information relating to your health. This is solely information that is contained in your medical record and information from the questionnaires that are sent or handed to you by the Martini-Klinik during your medical treatment.

C. Storage of samples:
By giving your consent, you agree to your biological materials (urine, blood, possibly prostate secretions) being stored in the Martini-Klinik biobank.

D. Communication of results:
You will **not** be informed about the results of the investigation of your samples for research purposes. If you do not agree with this policy, you cannot take part in this study.

1.5 How are the data and samples stored and secured?

In order to maintain confidentiality, the samples, data resulting from the analyses and personal medical information are pseudonymized. Pseudonymized data can only be reattributed to the specific study participant by certain authorized persons using a list of codes that is only available to these persons. The authorized person is the data custodian at the Martini-Klinik. Anonymous data can no longer be linked by anyone to a specific individual. The aim of the planned studies is to research a possible connection between molecular changes in the cells from your body fluids and your individual disease progression. Only this correlation will enable us to discover whether specific molecular information is also of clinical relevance, i.e. whether it is

a potential new marker for diagnosis, prognosis or treatment. As a result, we cannot anonymize your data since this would make it impossible for us to establish this important link with the data on disease progression.

The samples you provide (blood, urine, possibly prostate secretions) will be put in special containers for cryopreservation (freezing) in the research laboratory and labeled with a sticker, which is identified by a unique code (biobank number). This biobank number is generated automatically by the database and saved in an archive database, to which the data custodians have access. This archive database only contains data on the type of sample material, the date on which the sample was taken and the internal Martini-Klinik patient number.

Samples and information are only passed on to scientific partners in pseudonymized form. If it is necessary for reidentification to be carried out in order to link current progression data to the molecular data, this can only be done by the data custodians (also see figure on page 7).

Specific measures

- We do not save personal details in the archive database
- We have strict security measures in place to prevent unauthorized people from accessing the data
- We employ strict access controls, security precautions on the computer and the use of data encoding methods as well as confidentiality agreements and staff training
- Samples and data are pseudonymized again before being passed on (double encoding)

1.6 What are the benefits for you personally?

Personally, you cannot generally expect any immediate advantage or benefit for your health from the scientific use of your patient data and biomaterials.

1.7 How does this benefit our society?

The greatest health benefits from the planned analyses of the samples in the Martini-Klinik biobank are not expected for several years. Scientific research projects aim to improve our understanding of the development of diseases and their diagnosis, and on this basis to develop new and improved approaches to prevention, care, and treatment. Further information about our activities can be found at www.martini-klinik.de.

1.8 What risks are associated with the use of your patient data/biomaterials?

Privacy and data protection:
Whenever data is collected, stored and transmitted as part of research projects that include your patient data and data from the analysis of your biological materials, there is a residual risk of the data being traced back to you as a result of additional information retrieved, for example, from the Internet or social networks.

It is theoretically possible, but very unlikely, that security measures relating to the computer systems used to store patient-related data could be breached. If this were to happen, you could potentially be identified, which in turn could lead to a breach of privacy. However, we will do everything in our power to protect the confidentiality of your information (see Figure S.7). Of course, employers, insurance companies, and other unauthorized family members will not have access to this data.

The risk of traceability is generally higher for genetic parameters, as a person's genetic information is usually unique to that individual.

This is more likely if you yourself publish genetic or other health data, e.g. for family history research, on the Internet. You can also protect yourself from the risk of identification based on stored genetic data by participating in only one such study.

Physical risks:
Apart from the additional approx. 25 ml of blood taken during a routine blood test, there are no other physical risks. Blood tests are associated with a rare

risk of nerve damage. In very rare cases, this can lead to chronic pain and a possible negative impact on quality of life. We would like to assure you that these examinations are carried out by qualified staff and that your wellbeing is our top priority.

1.9 What happens if something is found in your samples?

The additional samples taken for research purposes are not used to confirm the diagnosis or as a basis for cancer treatment, and so you will not be sent any individual results. In addition, you will not be informed of any incidental findings or other medical conditions that are not connected to your medical treatment at our clinic.

1.10 Will this data be used commercially?

Analysis of the data and samples may one day lead to the commercial use of a medical or genetic test or product, e.g. by a university clinic, private company or in the form of a partnership between the two. This means that both research teams and private companies could potentially benefit financially.

With your consent, ownership of the biomaterials is also transferred to the Martini-Klinik. If the research results in commercial benefits, e.g., through the development of new drugs or diagnostic procedures, you will not receive any share of the profits.

1.11. Will you be paid for taking part?

Your participation is voluntary and you will not receive any payment for taking part.

1.12. How can you withdraw your consent to participate in the study?

You can withdraw your consent to participate in the establishment of a biomaterial bank at the Martini-Klinik at any time without giving reasons and you will then receive confirmation of this. If you withdraw your consent, the remaining samples and the material isolated from them will be destroyed and the data generated and personal information will not be used in further studies.

If the coded data has already led to scientific results that have been published, the information linking you to the database (key list) will be destroyed.

Right of withdrawal

2 Right of withdrawal

2.1 What does your right of withdrawal involve?

Your consent is voluntary.

You can withdraw your consent at any time, in full or in part, to the further collection or scientific use of your patient data or the biological materials that you have provided 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 and biological materials. Data from analyses that have already been carried out can no longer be removed retrospectively.

If you withdraw your consent, the biological materials that you have provided for the research are destroyed and your 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:

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

2.2 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:

Prof. Dr. Markus Graefen
Martini-Klinik am UKE GmbH
+49 (0) 40 7410-51300
info@martini-klinik.de

Relevant data protection officer:

Matthias Jaster
Universitätsklinikum 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 reponsible 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/Service/Anschriften/anschriften_node.html

The authority responsible for the UKE is:

The Hamburg Commissioner for Data Protection and Freedom of Information,
Ludwig-Erhard-Straße 22, 20459 Hamburg
+49 (0) 40 42854-4040
mailbox@datenschutz.hamburg.de
www.datenschutz-hamburg.de (in German)

2.3 Rights of affected persons

You are entitled to all rights of data subjects under Art. 15 ff. GDPR. You have the right to obtain information about the patient data concerning you and, if necessary, to request its correction, deletion, or restriction of processing. You also have the right to receive data provided by you in a standardized electronic format or to have it transferred to a location specified by you (right to data portability).

Right of withdrawal

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 biological materials remaining for the research and 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 4 in the patient information section).

I have been informed about the use of my patient data and biological materials 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

If you would like to financially support prostate cancer research, the Heinrich Warner Foundation offers the opportunity to support uro-oncological research in Northern Germany. You can make a donation earmarked for "uro-oncological research in Northern Germany" or a non-earmarked donation.

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

The founder of the foundation, Heinrich Warner, born on September 16, 1892, was a successful Hamburg merchant who died of prostate cancer in 1977. In his will, he bequeathed his entire estate to the Heinrich Warner Foundation. By establishing the foundation in his will, he wanted to help all people suffering from urological tumors. The Heinrich Warner Foundation began its work with assets of, 250,000 German Mark and a piece of agricultural land. The foundation's board of directors succeeded in developing the land for construction and selling it to an investor, thereby increasing the foundation's assets to over 2 million German Mark. It is the founder's wish that the income from the assets he has accumulated be used to promote outstanding scientific achievements in the field of urological cancer research.

More information: www.heinrich-warner-stiftung.de

Other foundations

www.krebshilfe.de

Cancer Aid throughout Germany

With well over 100 million Euros in donations, German Cancer Aid is the most important private donor in the field of cancer research in Germany. It makes a significant contribution to improving care for cancer patients nationwide and raising awareness of the concerns of cancer patients.

www.ucch.de

Leading oncology medicine in Northern Germany

Leading oncology centers in Germany are regularly assessed by an international commission of experts according to strict quality criteria set by German Cancer Aid. In Northern Germany, the UKE with the UCC Hamburg is the leading oncology center. The Hubertus Wald Tumor Center is committed to the same goals in the Hamburg metropolitan region as German Cancer Aid as a whole.

Martini-Klinik
Prostate-Cancer-Center
Universitätsklinikum Hamburg-Eppendorf

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20246 Hamburg

Stand: September 2025

www.martini-klinik.de

DKG KREBSGESELLSCHAFT
Zertifiziertes Uroonkologisches Zentrum für
Prostatakrebs
Harnblasenkrebs
Nierenkrebs

European Prostate Epicenter
For Robot-assisted Radical Prostatectomy

LGA InterCert
Zertifiziertes QM-System
DIN EN ISO 9001:2015