

Healthcare industry BW

The German National Cohort: collecting data for a healthier future

A large-scale long-term cohort study will be carried out to explain the causes of widespread diseases, in particular cancer, coronary heart disease, stroke and diabetes, and to identify the risk factors that lead to or favour the development of a certain disease. The principal objective of the German National Cohort (GNC) is to create the conditions that enable the development of new strategies for the prevention, risk assessment and early detection of chronic diseases.



Cities where the German National Cohort study centres are located.

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Numerous epidemiological studies have provided evidence over the years that factors such as nutrition, lifestyle habits and the environment have a huge impact on the development of major chronic diseases and the number of deaths resulting from them. Most of these studies are case-control studies, in which subjects are questioned about their past conduct at the time of diagnosis or therapy. However, the subjects might not recall everything or knowingly hide something, which is why such studies can lead to the collection of inaccurate and even incorrect information. Such problems can be reduced considerably with so-called prospective cohort studies. In studies of this kind, a specific group of people – a cohort – is monitored and observed over a long period of time, and information is recorded about whether and when disease occurs. Information is collected and

measurements are made at the start of the study and continue throughout the entire observation period. The more data that are recorded the better – the subjects are asked questions, undergo medical examinations and measurements are taken. Data of sick and healthy people are compared, enabling the investigators to pinpoint which factors contribute to the risk of developing a disease and to what extent they do so.



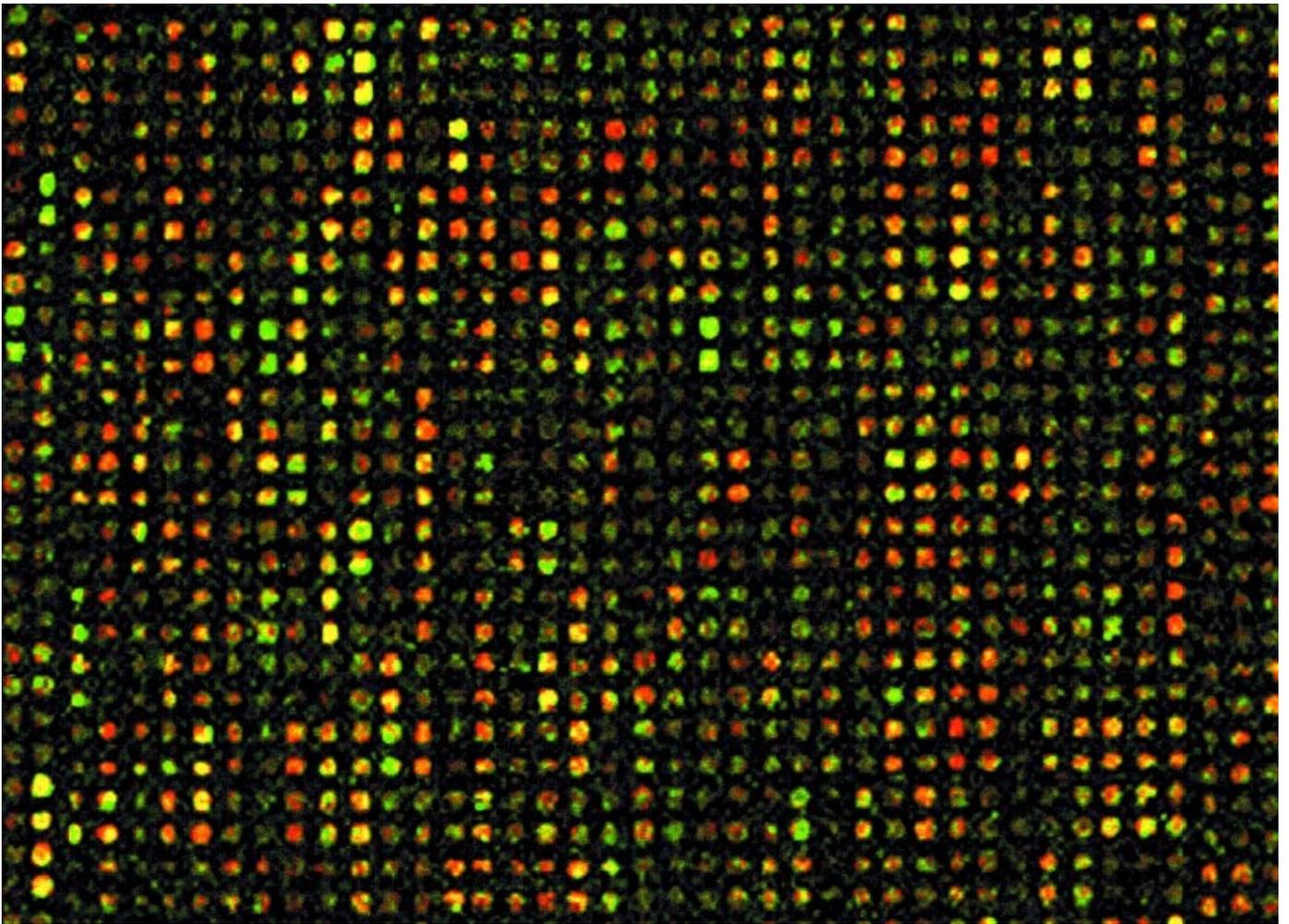
Prof. Dr. Rudolf Kaaks
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After several years of planning and preparation and a one-year pilot study, the largest, most time-consuming and most expensive epidemiological study ever was commenced in Germany in spring 2014. The German National Cohort (GNC) is a prospective population study involving 200,000 people aged between 20 and 69 from across Germany. The study has the potential to pinpoint the causes of the development of widespread diseases, along with their early detection and prevention. The huge cooperative study is being carried out by four Helmholtz Centres, four Leibniz Institutes and fourteen universities, which together have established a total of eighteen study centres across Germany where the examinations will be carried out, analysed and followed up. Over the next 10 years, the German federal and state governments and the Helmholtz Association will provide funding for the study totalling 210 million euros. The study itself, including patient follow-up, will run until 2042. Scientific coordination of the study is in the hands of a four-member board, including Prof. Dr. Rudolf Kaaks, head of the Department of Cancer Epidemiology at the German Cancer Research Center (DKFZ) in Heidelberg. Administrative coordination and project management are also located at the DKFZ.

Do we need this large-scale study?

More than two thirds of all deaths in Germany are attributable to cancer, coronary heart disease (myocardial infarction), stroke and diabetes-related complications. There is growing evidence that in addition to genetic factors, certain lifestyle and environmental factors such as nutrition, physical activity, alcohol consumption, smoking, psychosocial stress, viral and bacterial infections and chronic inflammatory processes play an important role in the development of each of these chronic diseases. These factors are most likely also involved in the development of neurodegenerative and neuropsychiatric diseases such as dementia and depression, respiratory diseases such as COPD and asthma as well as infectious diseases.

Little is however known about the significance of these factors. "In order to be able to answer such issues, we first have to acquire a better understanding of how these aforementioned diseases develop and how we can better protect ourselves against them," says Rudolf Kaaks. "For many years, debates have revolved around whether it is best to reduce the quantity of red meat consumed or whether it is important to be physically active, eat a lot of fruit and vegetables, etc." The GNC will study a random sample of the German population who will be medically examined and questioned on lifestyle habits. In addition, biological samples will be stored in a central databank for future



Biomarker analysis using microarrays
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research. As some of the subjects develop diseases, the epidemiologists will be able to correlate the diseases with the data collected and find out who develops a certain disease and who does not. The comparison of data of those who become ill while under observation with healthy subjects will enable the epidemiologists to pinpoint the factors that influence the risk of developing a particular disease.

Although some large-scale cohort studies are already being conducted in Germany, they only involve patients in specific individual regions, have been planned independently of one another and are often related to a particular disease. Only part of the data collected can therefore be merged for further analysis to answer specific questions. In addition, most prospective studies are conducted with subjects aged over 50 and therefore cannot be used to examine the development of disease in younger people. In the case of the long-term European Prospective Investigation into Cancer and Nutrition (EPIC) study, which also involves the Department of Epidemiology at the DKFZ in Heidelberg, the average of the subjects is over 60.

The study programme

Large-scale cohort studies have already been carried out in the USA, Sweden, Great Britain and other countries. The design of the GNC will be similar to that of international cohort studies, but is aimed at providing even more information. To recruit the required number of study participants, 400,000 people will be contacted and 100,000 women and 100,000 men will be enrolled in the 18 regional study centres. All subjects will be medically examined and questioned, and their cognitive functions assessed. Each participant will also provide biological samples of which 100 aliquots (from serum,

blood, plasma, erythrocytes, DNA, RNA, living cells, urine, saliva, nasal smears and stool) will be stored in a central biorepository for later research. A total of 20 million aliquots will thus be stored here, and a backup of these aliquots will be stored at the recruitment clusters involved. A systematic collection of tumour tissue will be stored in a central tumour bank at the DKFZ for research into cancer. After five years, all participants will undergo follow-up investigations at their local study centre. Follow-up observation of the participants will involve the use of questionnaires and the data will be linked up with other registries.



Follow-up of the study subjects using questionnaires.
© EPIC study

40,000 study participants will take part in MRI (magnetic resonance imaging) examinations of the heart, brain and whole body. "This depth of investigation in such a large-scale study is unique worldwide," says Kaaks, explaining that the biological samples as well as the images can at a later stage be used to compare the data in an as yet unforeseen manner. The biobank will contain as many different biological samples and images as possible in order to make it suitable for providing answers to a wide range of different questions in the future. "The collection of data is only the first step. This is then followed by data analysis and use of the information obtained for a wide range of investigations," explains Prof. Dr. Karl-Heinz Jöckel from Essen University Hospital where a complex new medical research infrastructure is being established.

The study is aimed at identifying the causes of chronic diseases and the factors that contribute to the risk of developing a disease. In addition to identifying the causes of chronic diseases and disease risk factors, the GNC is also aimed at evaluating biomarkers for the early detection of disease and subclinical phenotypes. Kaaks and his colleagues also plan to develop models that enable the risk of developing chronic diseases to be predicted. These models have the potential to be used for developing personalized prevention strategies, for example to find out which people need to undergo frequent screenings and which do not.

Unjustified fear about the collection of big data

The collection of such huge amounts of data as the GNC is intending to collect, has also fired criticism and mistrust issues, especially as the recent NSA scandal has raised public awareness of the use and misuse of personal data. The acquisition of extensive patient-related data, their linkage with other files and their storage on servers that might be open to abuse by hackers, raises fears of 'transparent human beings', state and societal control of individual lifestyles and the misuse of data for commercial purposes.

Prof. Dr. Iris Pigeot, director of the Leibniz Institute of Prevention Research and Epidemiology in Bremen and instrumental in the planning and conduct of the GNC, vehemently contradicts the view that the data to be collected are similar to the gigantic big data repositories Facebook, Google, Twitter and similar social media websites are creating through the acquisition and storage of

personal data without the users being aware of this. Social media users are equally unaware of what happens to these data and what they are used for (advertising, sales, etc.). The statistical scientific analysis of data in studies like the GNC is a far cry from such commercial exploitation.

As far as the GNC is concerned, each study participant has given his or her explicit consent to the collection of his or her data. It should also be stated that GNC has no links whatsoever with medical companies. The study participants know exactly what happens with the data and what they are used for. The collected data are also linked with other data, but only in those cases when the study participants have been informed comprehensively about the use of their data and only when they have given their explicit consent. All GNC data are collected from individual subjects, but are allocated a pseudonym and personal identification details are not stored on the servers. The key to the identification of the subjects is in the hands of an independent trustee. The coordinators of the study also pointed out that all investigations associated with the GNC have been approved by the ethics commissions of the federal German and state governments and are carried out in cooperation with data protection officers. Prior to enrolment in the study, each participant must indicate whether he or she wants to be informed in cases when the investigations lead to results of clinical relevance. In order to be enrolled in the study, study participants must give their consent for cases in which the investigations lead to the accidental identification of a life-threatening condition that the doctor is obliged to report.

Prior to enrolment, all participants will be made aware of the fact that the GNC is not a medical treatment study that assesses potential therapy options and that no diagnoses are made. The GNC, which is the largest ever prospective cohort study carried out in Germany, is an investment in the future; it will provide important findings about factors that lead to the development of widespread diseases, thereby facilitating the development of more effective prevention and early detection strategies for the most widespread diseases, and thus create the basis for a healthier future.

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