Gemeinsam forschen für eine gesündere Zukunft

NATIONALE KOHORTE

The German National Cohort (GNC)

Gefördert vom Bund, den Ländern und der Helmholtz-Gemeinschaft

Aims of the German National Cohort

- To address research questions concerning a wide range of possible causes for major chronic diseases
- Extensive collection of health-related data
- Relevant issues
  - Disease pathogenesis
  - Promotive factors
  - Role of genes, environmental effects and psychosocial stress
  - Possibilities to protect ourselves
  - Earlier diagnosis

Focus on major diseases

- Cardiovascular disease
- Diabetes mellitus
- Cancer
- Neurologic and psychiatric disorders
- Respiratory disease
- Infectious disease

Definition German National Cohort

- Large-scale, nationwide, long-term population study
- Cohort (in demographics) = a group of individuals, whose health development is monitored over a long timespan
- German contribution to international epidemiologic research

Funding

- The GNC is funded by
  - German Federal Ministry for Education and Research (BMBF)
  - Participating Federal States
  - Helmholtz Association
  - Leibniz Association
  - Participating research institutions

Bundesministerium für Bildung und Forschung

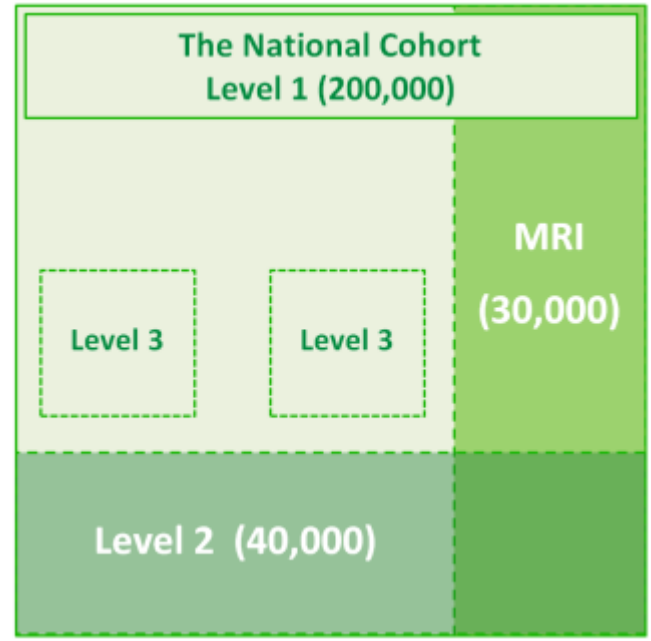
HELMHOLTZ | GEMEINSCHAFT

Leibniz-Gemeinschaft

Gefördert vom Bund, den Ländern und der Helmholtz-Gemeinschaft

Study design

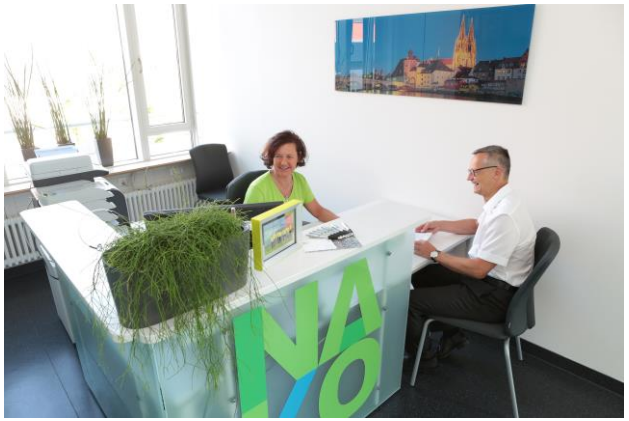
- Prospective population-based cohort study
- 18 study centers
- Participants between 20-69 years old
- Random samples in defined regions
- **Level 1** n=200.000 duration: 2,5 h
- **Level 2** n=40.000 duration 4 h
- **Level 3** n=variable (additional research projects, external funding)
- **MRI** program, n=30.000, at 5 sites



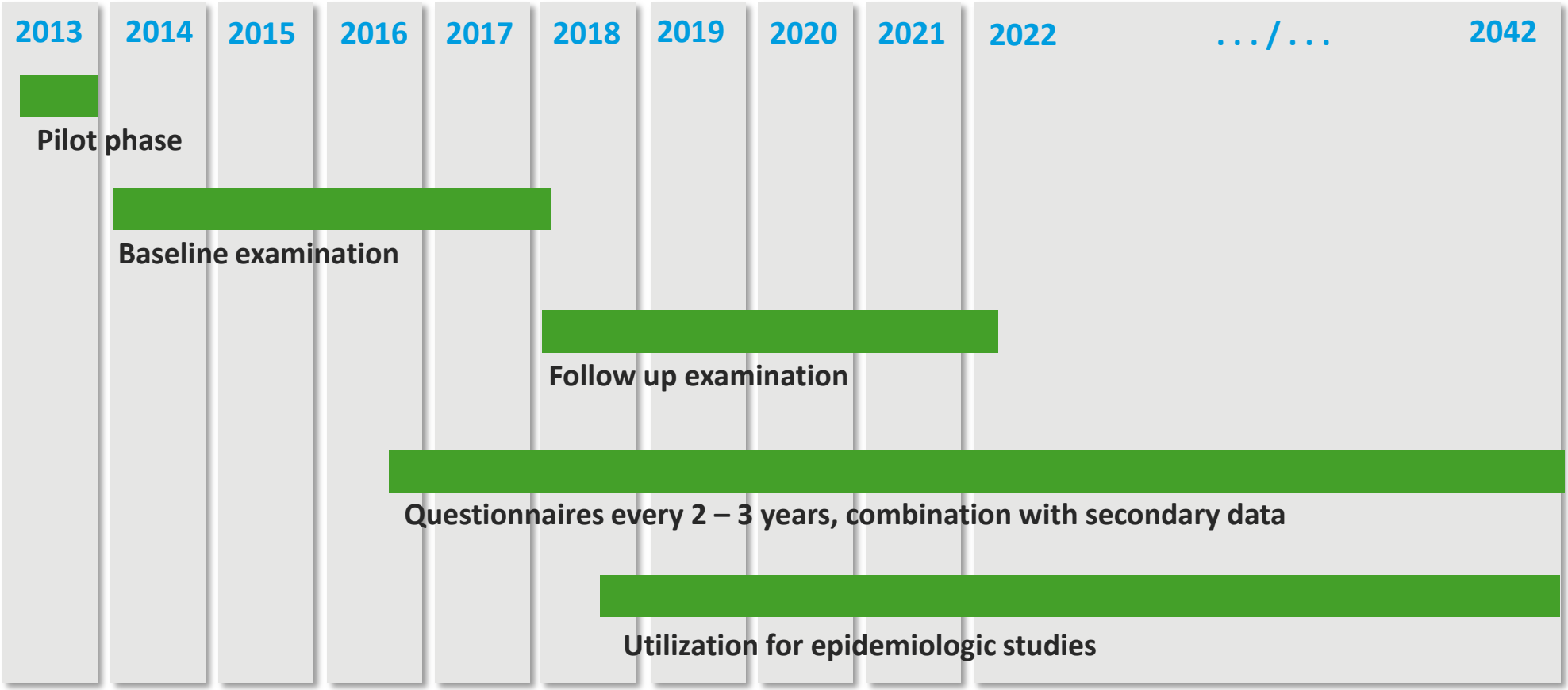
18 Study centers

Study procedure

- Random sample of the population is drawn from the population registries
- Informing the participant about the study
- Informed consent
- Baseline examination (1 - 4 years)
  - Interviews, questionnaires, physical measurements, collection of biosamples
- Follow up examination (4 years)
- Follow up
  - Questionnaires every 2-3 years
  - Combination with secondary data

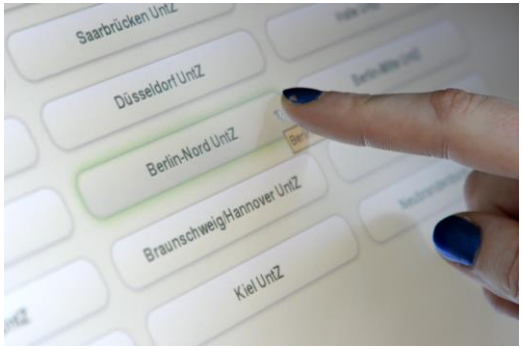


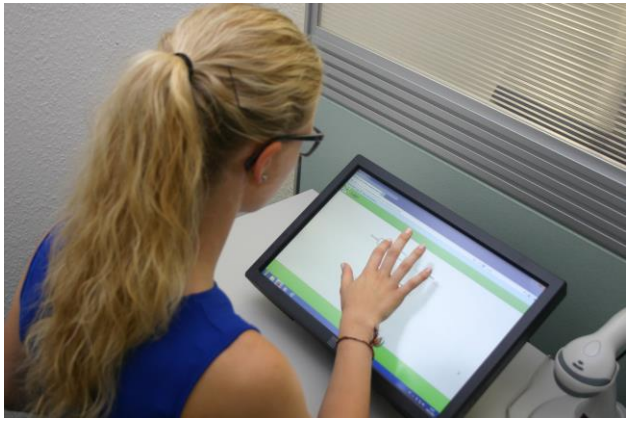
Time schedule



Part 1: Questionnaires and Touchscreen

- Sociodemographic information
- Medical history, medication
- Lifestyle
  - Diet
  - Physical activity
  - Sleep
- Additional health-related factors
  - Psychosocial factors (socioeconomic status, occupation, work-related stress)
  - Environmental factors





Part 2: Examinations

Cardiovascular system
- Blood pressure and heart rate
- ECG, Electrocardiography
- Vascular Explorer (pulse wave)

Diabetes
- OGTT
- AGE Reader

Cognitive functions test
- Memory, attention/ executive, motor coordination

Pulmonary function
- Spirometry

Musculoskeletal system
- Knee, hip, hand joints

Oral health
- dental chart

Sensory organs
- Ophthalmological measurements, hearing test, olfactory test

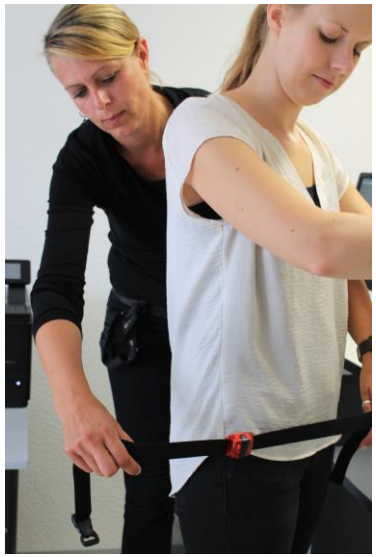
Physical activity and fitness
- 7-day accelerometry
- Ergometric test, hand grip strength

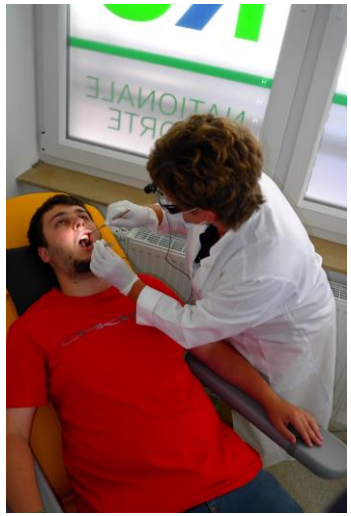
Anthropometry
- weight, body height, BIA, ultrasound, waist and hip circumferences

Collection of biosamples
(blood, urine, nasal swabs, saliva, stool)

Extract from Level 1

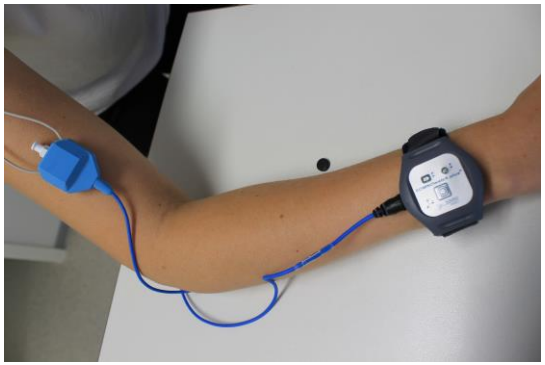
- Physical activity (7-day accelerometry)
- Hand grip strength
- Pulmonary function: spirometry
- Oral health (tooth count, …)
- Olfactory tests (sniffing sticks)
- BIA

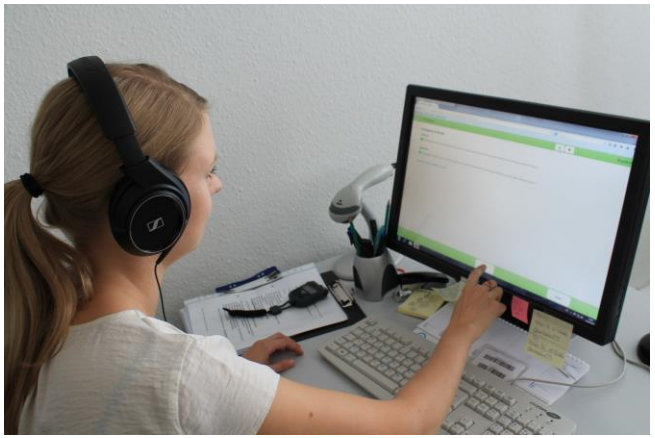




Extract from Level 2

- Examination of sleep behavior (Somnowatch), incl. long-term ECG
- Ophthalmologic test
- Aural examination (incl. touchscreen and headset)
- Ergometry test (bicycle)
- Medical examination of hip, knee and hand joints (arthrosis and rheumatoid arthritis)



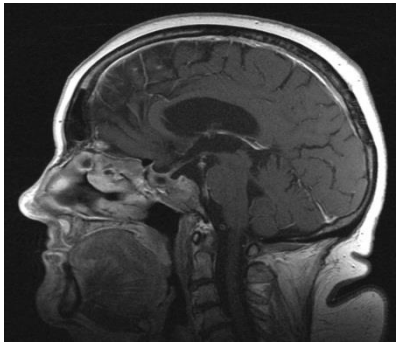


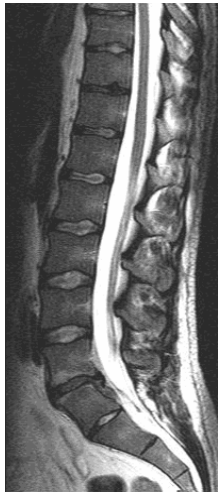
Magnetic resonance imaging (MRI)

- Research topics
  - Neurodegenerative disease
  - Cardiovascular disease
  - Diabetes mellitus and other metabolic diseases
  - Musculo-skeletal disease
  - Cancer

Whole-body- MRI
Heart-MRI
Brain-MRI

→ duration < 60 min





Whole-body-MRI

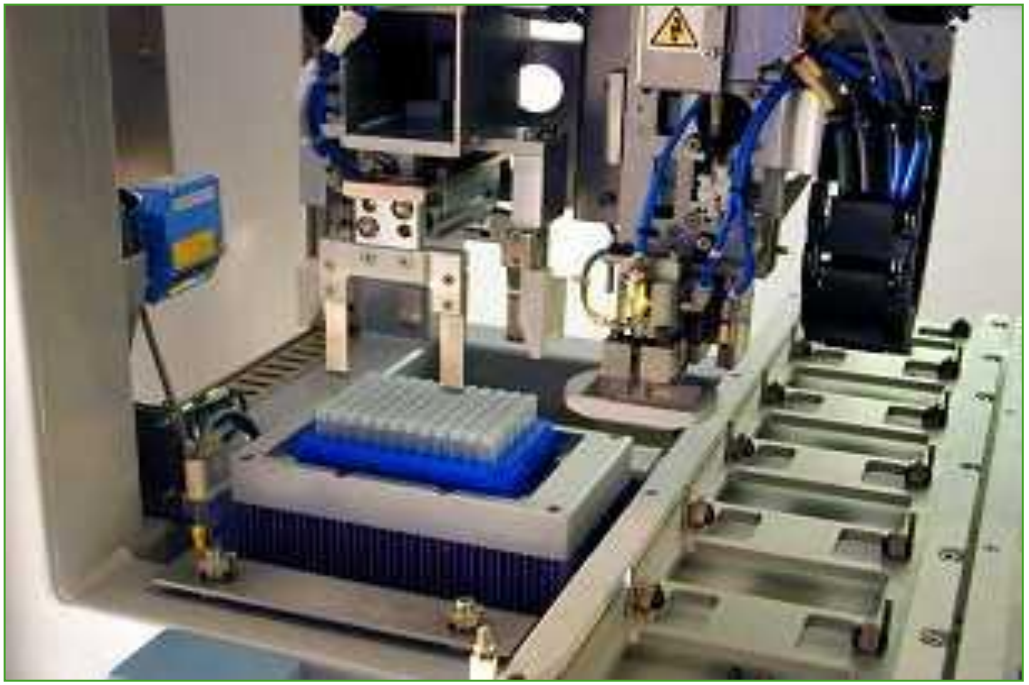
Biorepository

- For safety reasons there will be several storages
  - Central biobanking (2/3 of the biosamples)
  - storage at the study sites
- Overall ~ 20 Mio. samples

Source: UK Biobank

Fully automated sample processing at -20°C

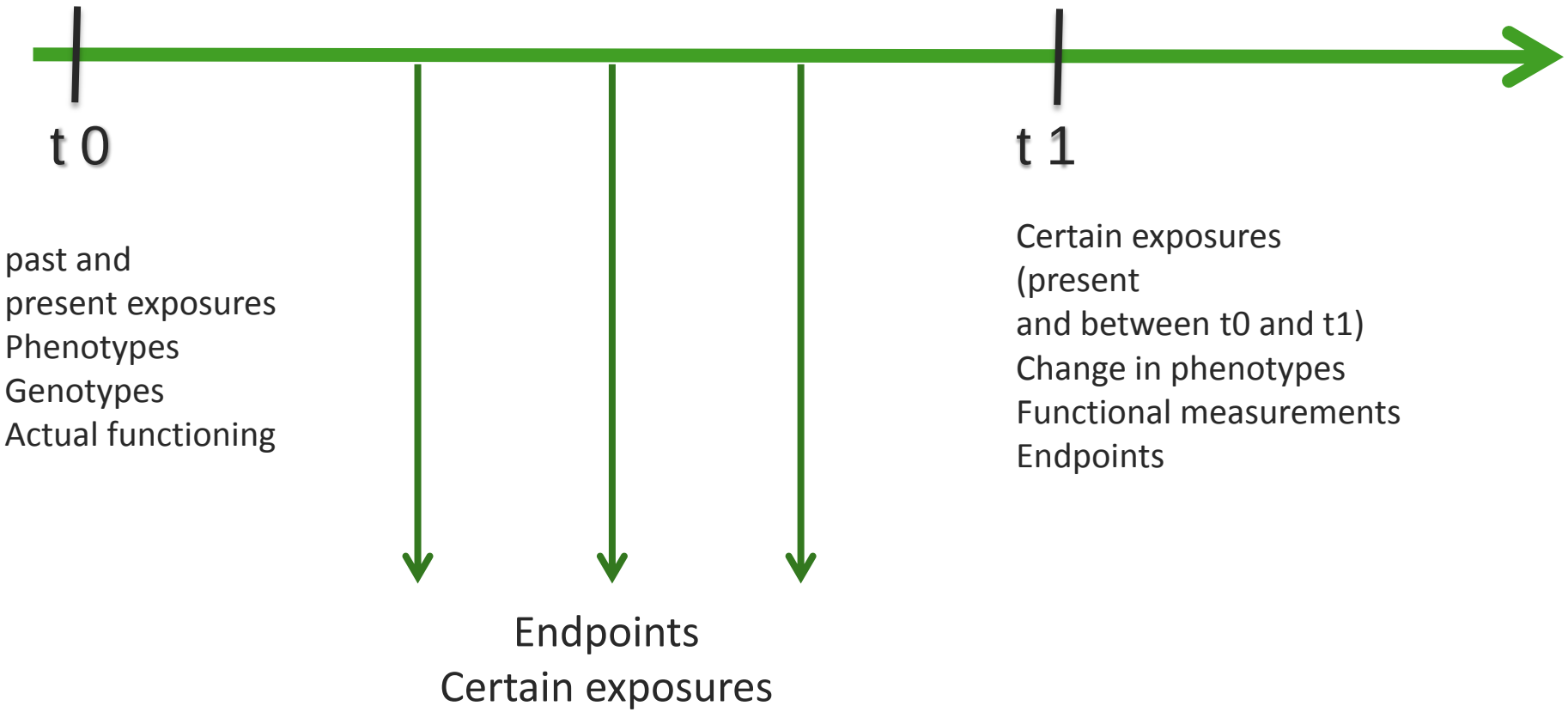
Allocation in controlled surrounding



Identity check of allocated tubes

Source: UK Biobank

The strength of the cohort design



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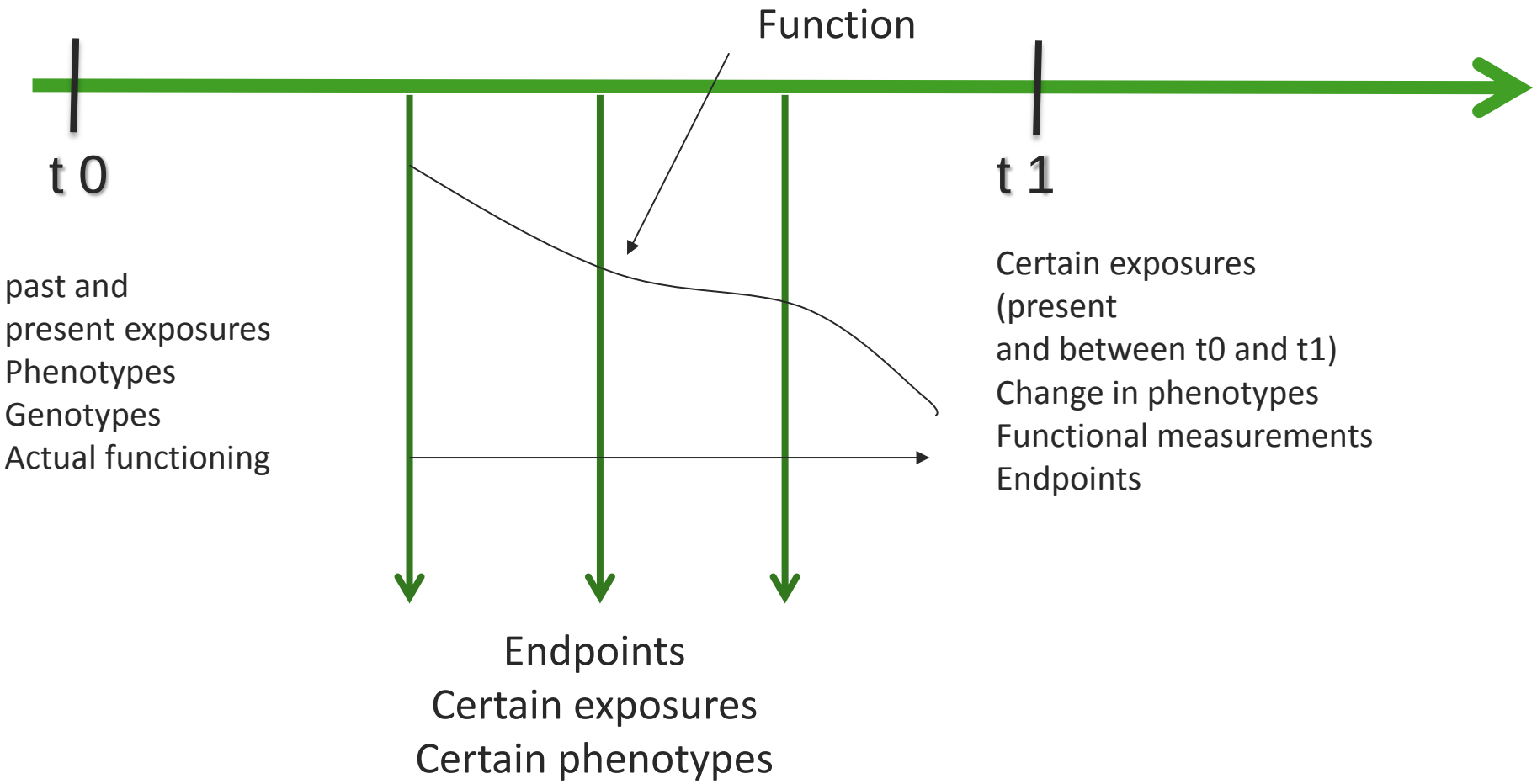

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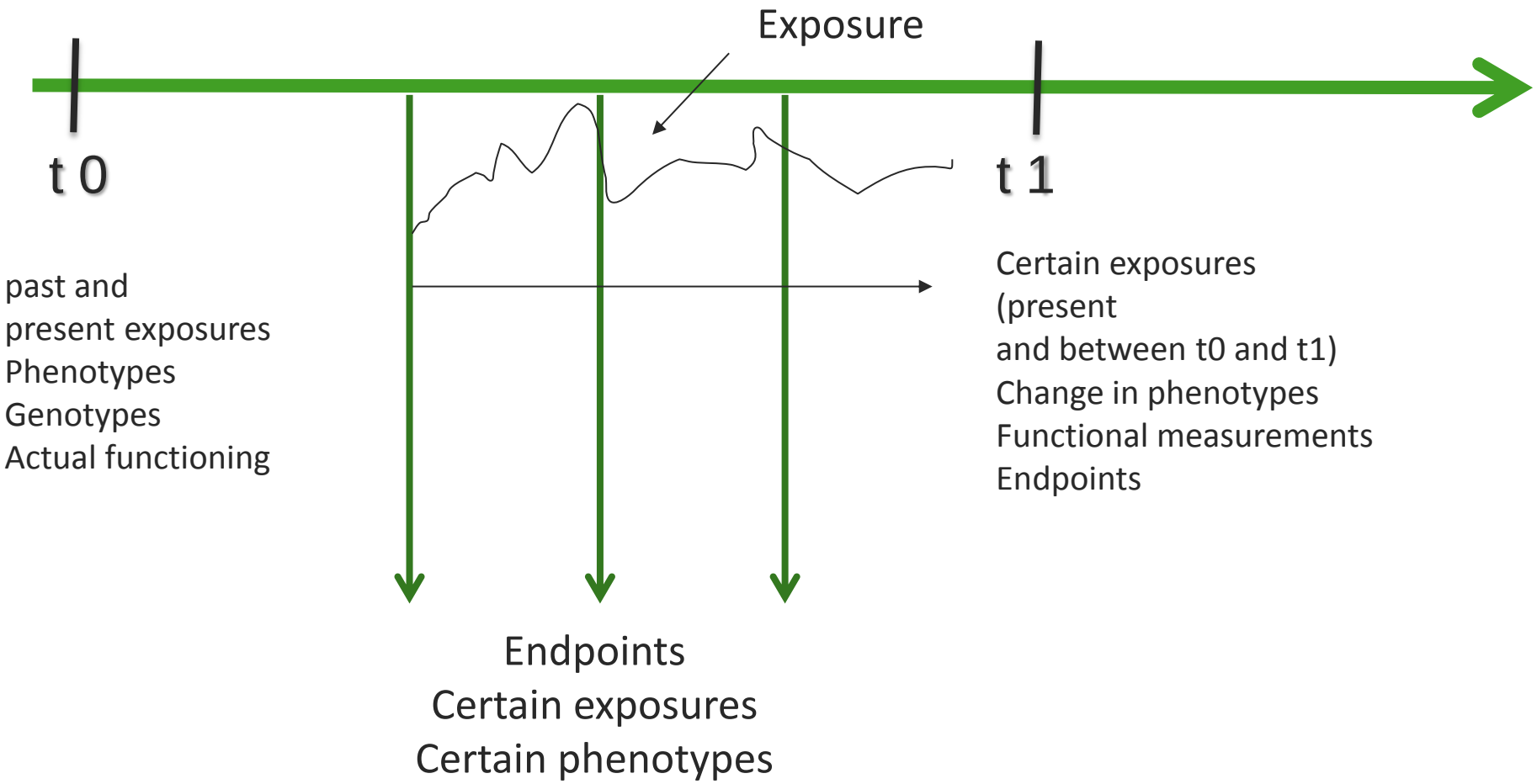

Secondary and register data

- Why is the linkage to secondary data important?
  - Supplement/ validation of self-reported information of participants
  - Support of follow up
- Data from statutory (and if necessary private) health insurance
  - Information on the use of health services and medications
- Data from other social insurance carrier
  - Employment history, status of pension , rehabilitation treatments
- Mortality registers
  - Vital status, causes of death
- Data from epidemiological and clinical cancer registry
  - Stage distribution, survival analyses, therapeutic method

Quelle: Wiss. Konzept der Nationalen Kohorte, S. 135f

Access to data and biosamples

- Data and samples are restricted for scientific use
- The association Nationale Kohorte e.V is the owner of data and samples
- Access to data an samples is regulated by Use & Access Committee
- No access for insurances and employers
- Use for primary commercial purpose excluded

Ethics and data protection 1

- Modular set up of consent form
  - Information and transparency
  - Participant can withdraw his/her approval at any time, also for single parts of study protocol
- Warranty
  - Ethical regulations and data protection law are respected
  - Respecting the right to privacy
  - Confidentiality of data

Ethics and data protection 2

- All persons actively engaged are obligated to follow the data protections provisions and also the medical secrecy.
- The underlying procedures were introduced to the Germany Commissioner for Data Protection and the competent Ethics Committee.
- Results are pseudonomized and can be analyzed exclusively for scientific purpose.

What´s unique?

- Homogeneous study protocol for a great number of participants (200.000)
- Young age groups (20% 20-39 years old)
- Reassessment of all 200.000 participants after 4 years
- Implementation of imaging methods (magnetic resonance imaging, MRI)
- Compatibility of study protocol with other European studies (data pooling)
- Generation of a exceptional standardized data pool

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NEW STUDY

The German National Cohort: aims, study design and organization

German National Cohort (GNC) Consortium

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Abstract The German National Cohort (GNC) is a joint interdisciplinary endeavour of scientists from the Helmholtz and the Leibniz Association, universities, and other research institutes. Its aim is to investigate the causes for the development of major chronic diseases, i.e. cardiovascular diseases, cancer, diabetes, neurodegenerative/-psychiatric diseases, musculoskeletal diseases, respiratory and infectious diseases, and their pre-clinical stages or functional health impairments. Across Germany, a random sample of the general population will be drawn by 18 regional study centres, including a total of 100,000 women 2–3 years) and record linkages. The GNC is planned for an overall duration of 25–30 years. It will provide a major, central resource for population-based epidemiology in Germany, and will help to identify new and tailored strategies for early detection, prediction, and primary prevention of major diseases.

Keywords Population-based cohort · Non-communicable diseases · Chronic infections · Life-style and socio-economic factors · Magnetic resonance imaging · Pre-clinical disease · Functional impairments

Summary

- The National Cohort demonstrates an ideal research resource for national and international purpose
- Availability of a well phenotyped population-based sample including secondary data from diverse sources
- This sample is examined again in 4 years
- In the meantime further information can be collected on the basis of secondary data and also by questionnnaires

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NAKO
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Many thanks for your attention!

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