

**HelmholtzZentrum münchen**

German Research Center for Environmental Health

# KORA - Kooperative Gesundheitsforschung in der Region Augsburg in Data Sharing: Kulturwandel im Gesundheitswesen?

WORKSHOP DER MEDIZININFORMATIK-INITIATIVE

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**HELMHOLTZ** RESEARCH FOR  
GRAND CHALLENGES

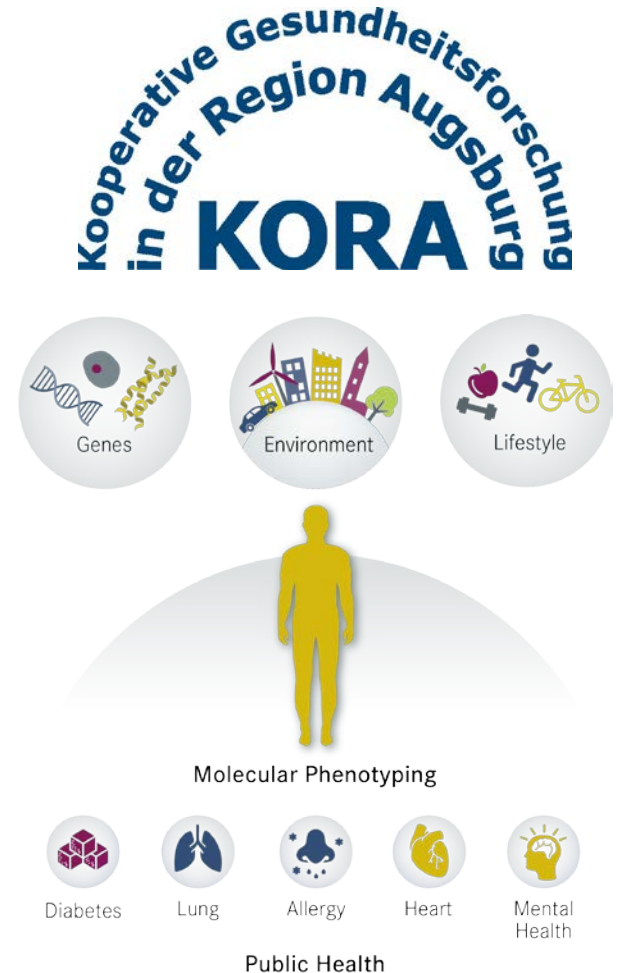
# KORA Platform

## KORA - population-based adult cohort

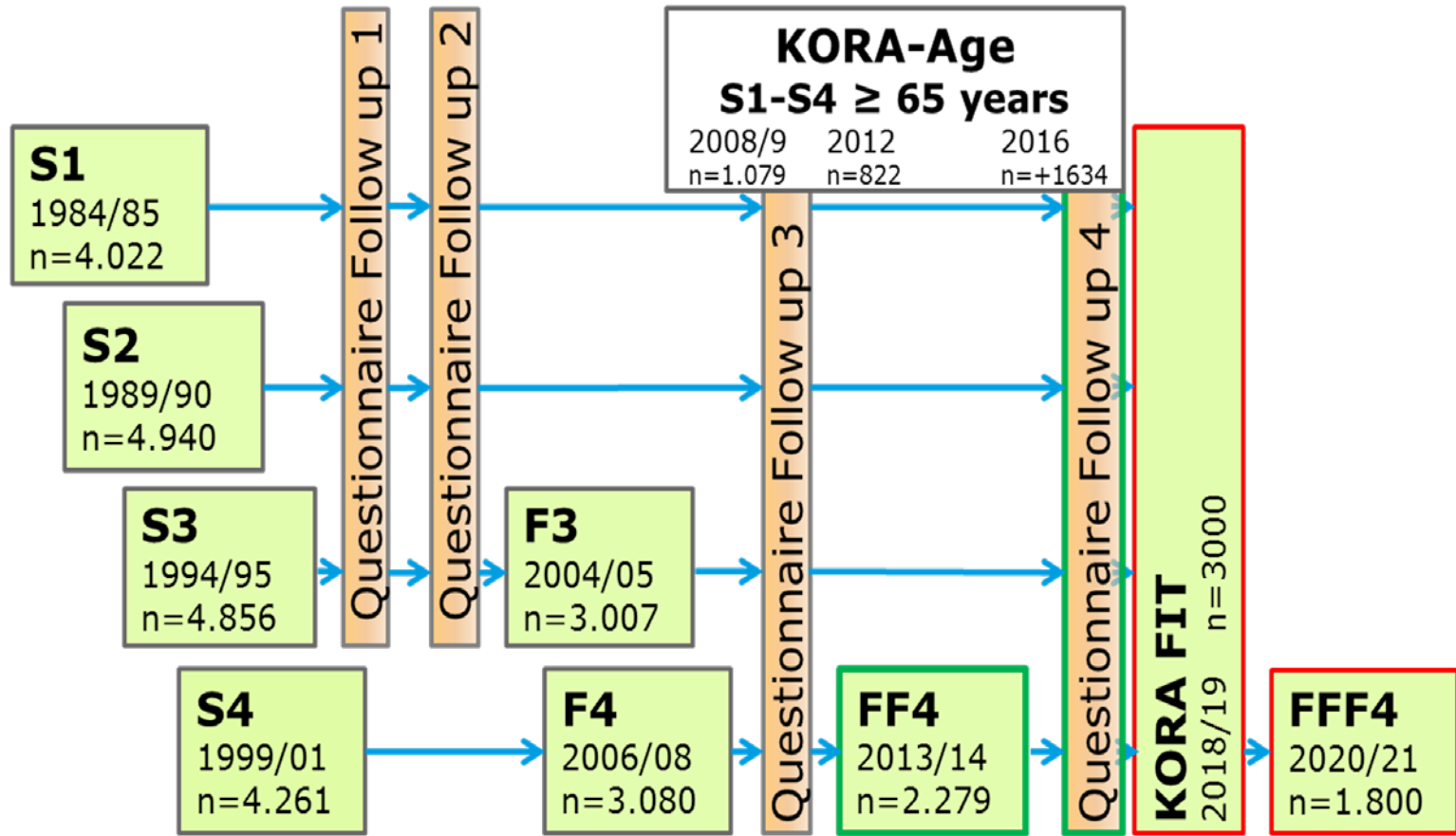
- Since 1984 in the Augsburg Region, Germany
- 18.000 adults in 4 baseline surveys
- Follow-ups and sub-studies for deep phenotyping

## Aims

- Promote health research
- Public health improvement
- Health care impact
- Policy support



# KORA Cohort



KORA cohort design: Survey (S) & Follow-up examinations (F), Questionnaire Follow-up.

- Easy **data and biosample access** with the electronic project application tool KORA.PASST

## KORA.PASST

- allows to register for KORA projects
- provides information on genotypic and phenotypic data
- helps to prepare a project agreement
- allows to check and approve projects by data owners and KORA board

# KORA Research Platform

- On average **300 publications per year** between 2014 and 2016. Most are collaborations with **data sharing**.
- **> 80 long-term cooperations** (HMGU, regional, national, and international)

	2015	2016	2017
Number of projects (biosamples and data) per year	164	170	160
Number of samples per year	26,871	19,391	22,102

# HMGU Biobank include KORA Biobank

- Helmholtz Zentrum Core Facility with approx. 1 million biosamples including DNA, serum, plasma, urine, saliva and stool.
- The Biobank works in close collaboration with other platforms at HMGU, especially the GAC, where large omics-datasets are generated.
- Coordination of the Joint Biobank Munich, a consortium of LMU, TUM and HMGU biobanks and partner in German Biobank Alliance and in European consortia (BioSHaRE and BBMRI-LPC).

# KORA Diabetes

S4-F4-FF4(-FFF4) focus on diabetes prevalence, disease development and complications, especially cardiovascular disease burden.

KORA contributes to

the German Center for Diabetes (DZD) and large diabetes consortia (e.g. GoT2D) and large collaboration with the pharmaceutical industry Innovative Medicines Initiative (e.g. EU DIRECT).

# KORA Heart Disease

S1-S3 focus on cardiovascular disease, as the WHO started the MONICA (MONItoring trends and determinants in Cardiovascular disease) project in the Augsburg region.

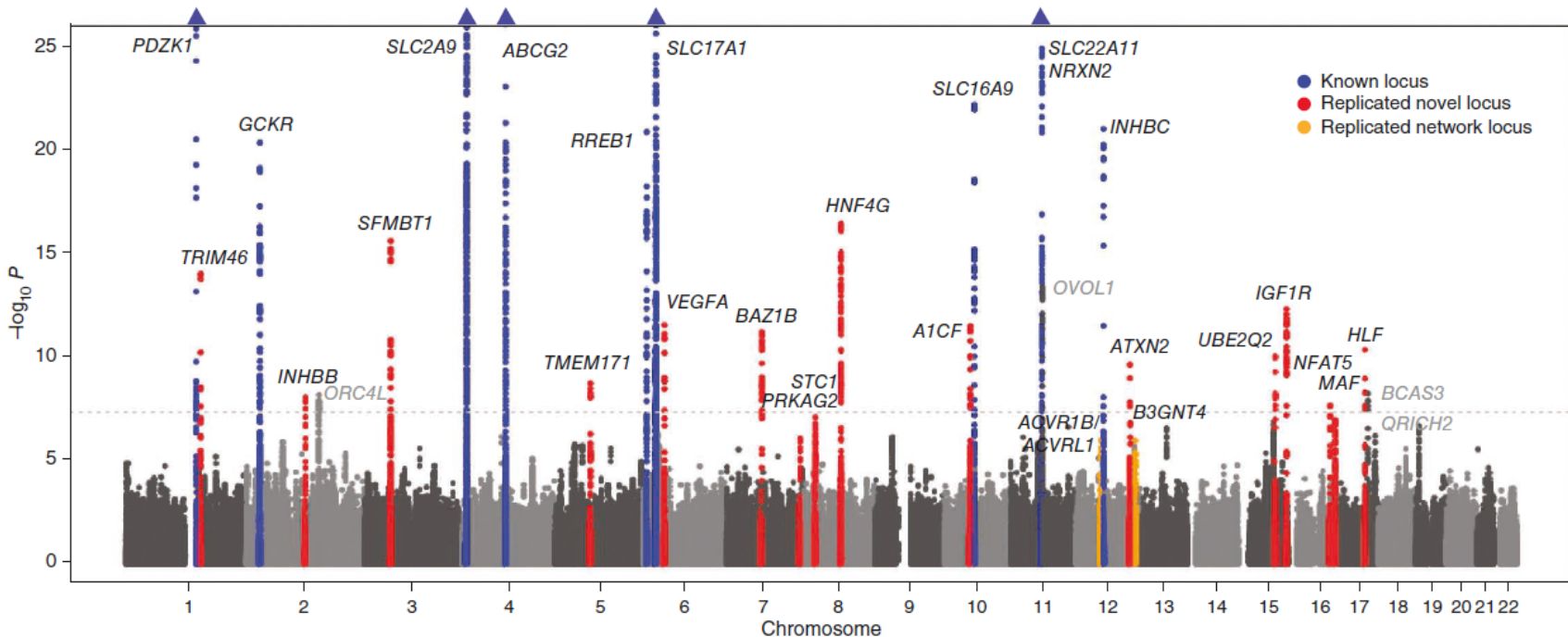
KORA contributes to

the German Center for Cardiovascular Disease (DZHK),  
the Munich Heart Alliance and  
international consortia (MORGAM, CHARGE, BiomarCaRE).



# GWAs - New loci associated with serum urate concentrations

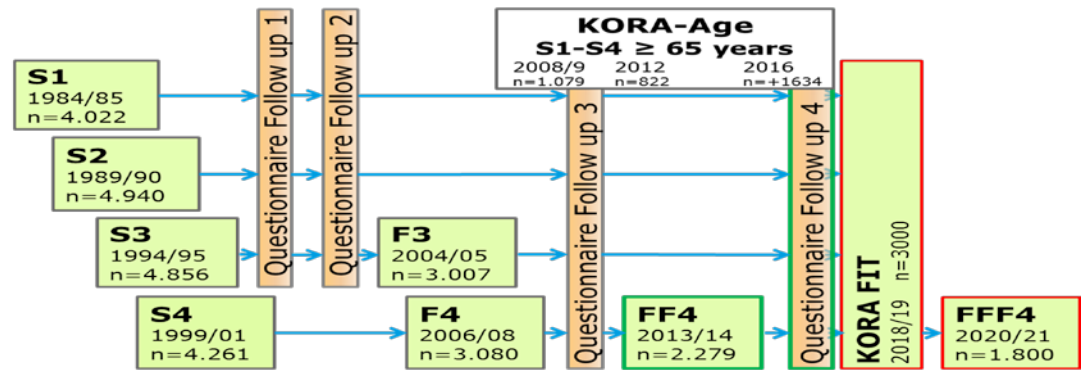
- 63 studies including 143,000 participants
- 28 genome-wide significant loci in uric acid
- 2 loci in gout GWAS
- Uric acid increasing alleles are increasing risk of gout
- Strongest loci harbor genes that code for renal transport proteins
- Other novel loci may be important in metabolic control of uric acid production and elimination



# Data Protection in Human Cohorts / Biobanking Research

- Human cohorts and biobanking faces the challenges of sustained follow-up of population-based study populations, collection of longitudinal samples and the sustainable storage.

- E.g. KORA Cohort established in 1984 latest follow up 2018/2019



➔ Ethical and data-protection considerations are regularly up-dated to meet current regulations.

# General Data Protection Regulation (GDPR) (Europäische Datenschutzgrundverordnung)

- Processing of special categories of personal data

Processing genetic data and biometric data is only allowed when the person has given explicit permission to process those personal data

- Improved right to withdraw

Data have to be deleted or destroyed immediately after the withdrawal of the consent form

It is enough to delete the connection or codification



Processes / Infrastructure need to be in place

- Data Protection Concept

- Separation of personal data and research data
- Double pseudonymous research data with unique identifiers

- Informed Consent Handling

- Up-to-date informed consent forms
- Process if informed consent is withdrawn

# Changes to KORA Informed Consent Form with the GDPR

- Data Sharing outside the European Union

Included in Informed Consent for KORA-Fit

- Informed Consent Withdrawal

Possibilities of withdrawal

- deletion of personal data (research data is then anonymous) and research data can still be used
- no further use of research data (for future research data only)

# Incentives of data sharing

- On authorship of data owners is agreed in the KORA project agreement
- Collaboration led often to participation in new national and international consortia
- Data gained by analyzing KORA samples are feed back into the KORA database. Data can be used for new projects

