

The PopGen 2.0-Network

Ute Nöthlings, Epidemiology, Christian Albrechts University of Kiel

Ingolf Cascorbi, Pharmacology

Holger Kalthoff, Comprehensive Cancer
Center

Michael Krawczak, Medical Informatics and
Statistics

Maximilian Mehdorn, Neurosurgery

Christoph Röcken, Pathology

Stefan Schreiber, 1st Medical Department

Ulrich Stephani, Neuropediatrics

Peter Zabel, University Lung Center



**UK
SH**

Major goals

1. Quality assurance for samples and data
2. Promotion and simplification of scientific collaborations through an integrated probe data management connected to the national P2B2 platform
3. Harmonization of all ethical, legal and social issues arising from the use of human samples



General concept

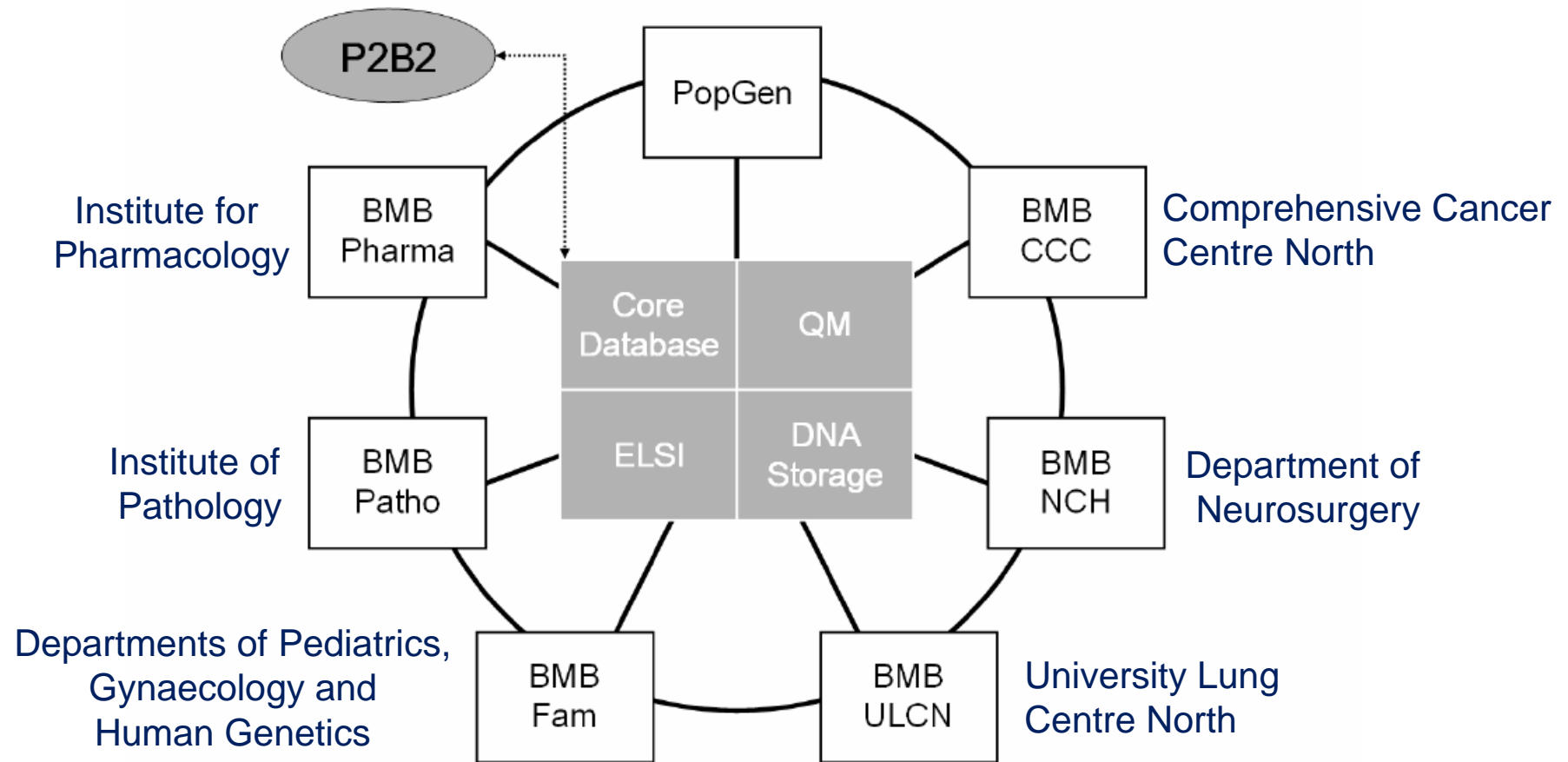


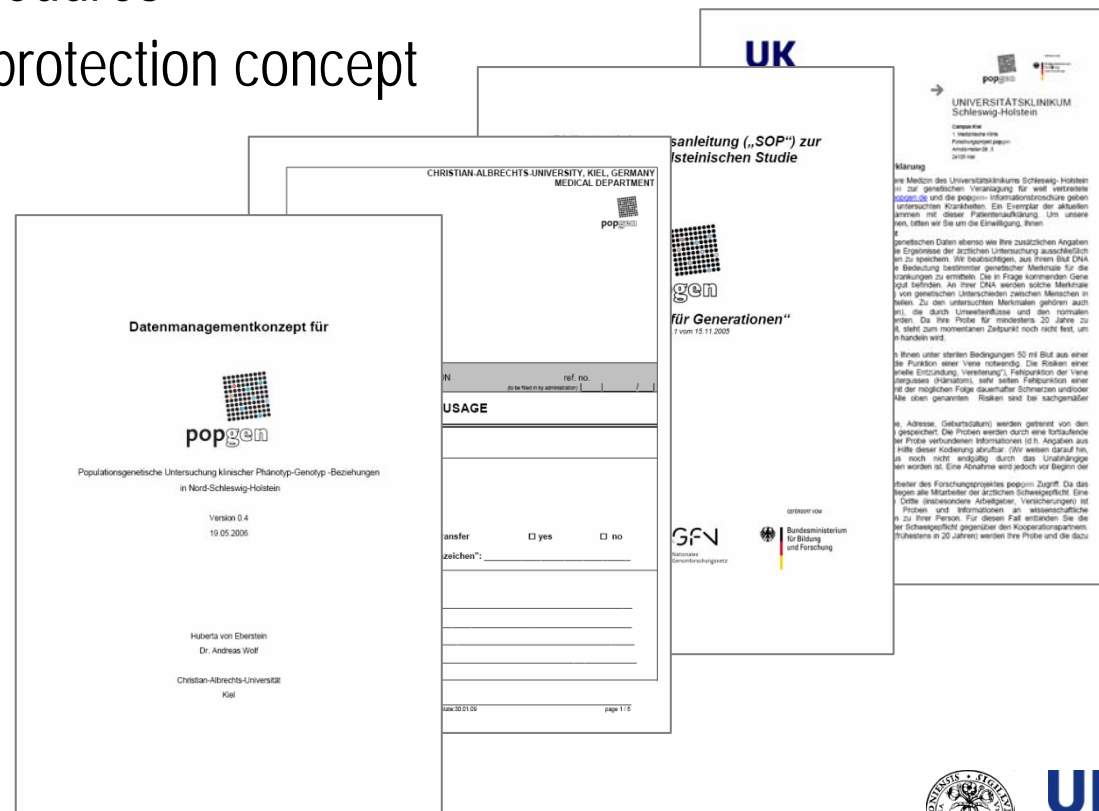
Fig. 1: Organisational structure of the PopGen 2.0 Network (P2N)



Rules and Standards

- standard operating procedures
- data management and protection concept
- consent forms
- patient information
- transfer agreements

in collaboration with



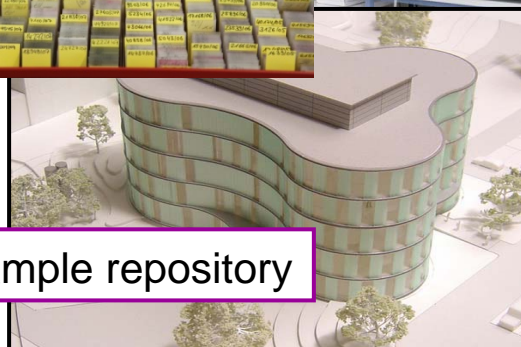
The partners

Acronym	P2N-Partner	Populations	Biomaterial	Size (N)
popgen	Biobank popgen	32 sub projects: inflammation, oncolog., neurolog. diseases, populationbased controls	DNA, RNA, blood, serum, plasma, erythrocyten, urin, stuhl	>75.000
BMB-CCC	Comprehensive Cancer Center	div. cancer sites	Tumor tissue, serum, plasma, blood, RNA, DNA, Lavagen	2400-4000
BMB-NCH	Neurosurgery	Brain tumors	Tumor tissue	2700
BMB-ULCN	„Airway Center North“	div. Lung diseases	Tissue, serum, sputum, Lavagen	200-20.000
BMB-Fam	Pediatrics/ Gynaecology/ Human genetics	inflammation, onkolog., neurolog. diseases	DNA, RNA, blood, tissue	200-6000
BMB-Patho	Pathology	div. Cancer sites, Amyloid-, Lymphnode- and child tumor registry	FFPE- and cryo-tissue	>700.000
BMB-Pharma	Pharmacology	neurolog., onkolog. diseases	DNA	100-2000

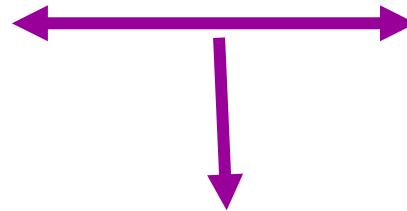
Infrastructure



Sample repository



Standardized storage
(-20°C, -80°C)
SOPs



Study centers



phenotype database
genotype database
clinic registries

Comprehensive Centers



Patient recruitment, examination



Workpackages

I Core database

II Ethical, legal, social issues

III Quality management

IV DNA storage



I Core database

- to develop, implement and maintain a **central repository for all probe-related data** and a sensible core set of data
- Proposed elements:
 - Identity of host biobank(s)
 - Unique sample identifier, host-biobank sample identifier(s)
 - Age, sex of donor
 - Type and amount of sample
 - Type and availability of IC
 - Key indicators of sample and data quality
 - ICD-code(s), MeSH-term(s), MIM number(s)
- Connection to **P2B2**-platform



II Ethical, legal, social issues

- Adoption of the **PopGen data protection concept**
- to set up a **centralized informed consent (IC) management** that includes not only the evaluation of existing IC, but also the provision of guidelines for the future design, collection and storage of IC
- Collaboration with the **Ethics Committee** of the Medical Faculty of Christian-Albrechts-University Kiel
- to streamline and intensify the **public relations** of P2N biobanks
- Status symposia



III Quality management

- to **provide** and **monitor** approved **SOPs** for probe and data handling
- to organize and promote quality-related **training** for all staff in the P2N component biobanks
- to obtain **accreditation** for P2N
- to establish and maintain cross-links with **electronic patient** records
- to establish and maintain cross-links between all tumor-related biobanks in P2N and local **cancer registries**
- to implement a system of **external evaluation** by the Independent Centre for Privacy Protection Schleswig-Holstein (ULD) and by experts from an external biobank (Jena University Clinic)



IV DNA storage

- to operate an **automated DNA storage facility** at -20°C and -80°C
- Central storage of DNA optional
- Service:
 - BMB-CCC – extraction of RNA and DNA from solid tissues
 - BMB-Patho – micro-dissection, immunohistochemistry, microarrays
 - BMB-ULCN – HOPE fixation technique

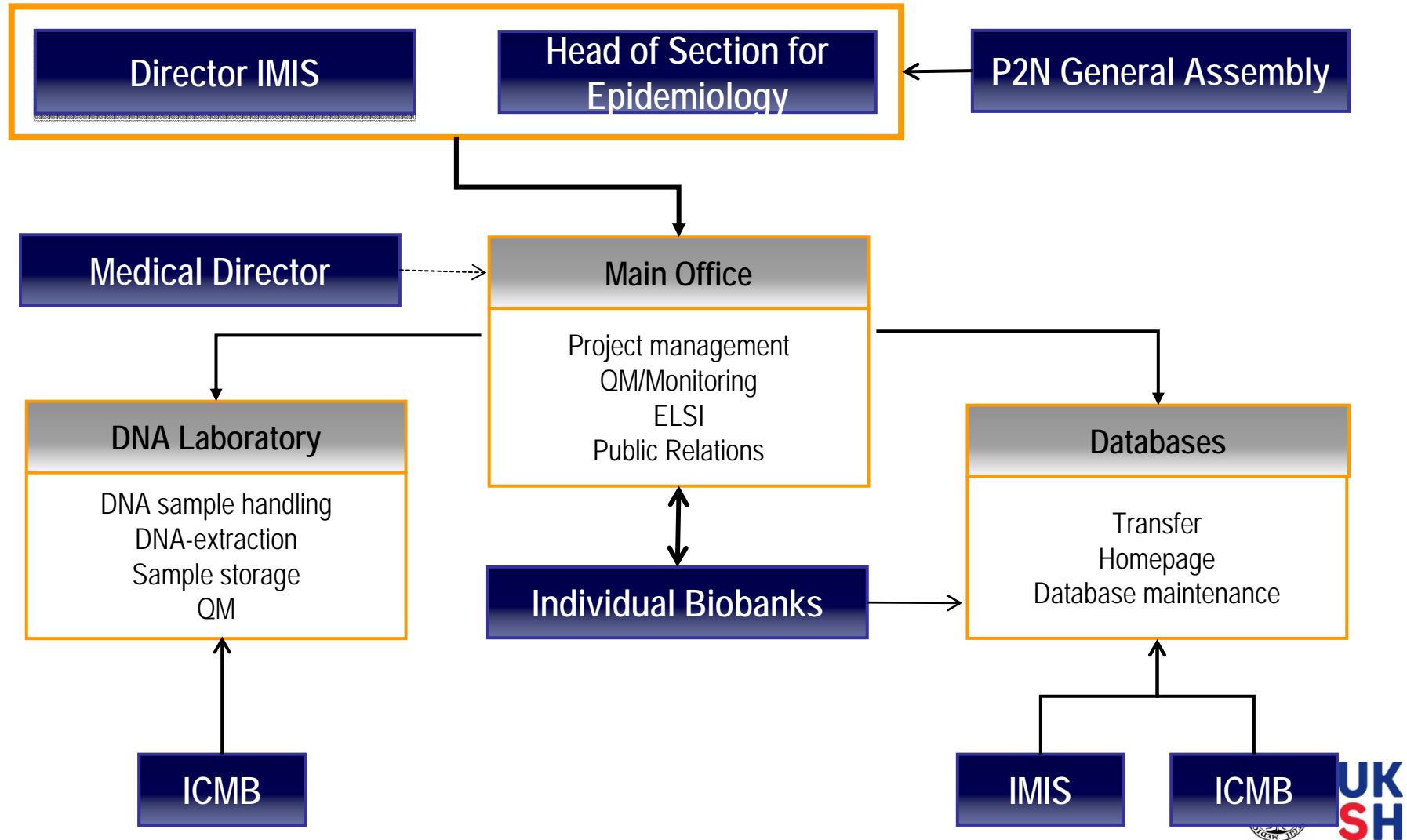


Use & access

- P2B2-platform to initiate and streamline requests
- P2N-**board** („P2N Kuratorium“) to decide; 3 members, rotating
- **Preparation** of the decision by **partner biobank**
- **Evaluation sheet**: Harmonized reviewing criteria
- Full **transparency** of decision process
- **Ethics comittee** moderates in case of conflict
- Administrative handling by **popgen 2.0 management**



Governance & maintenance

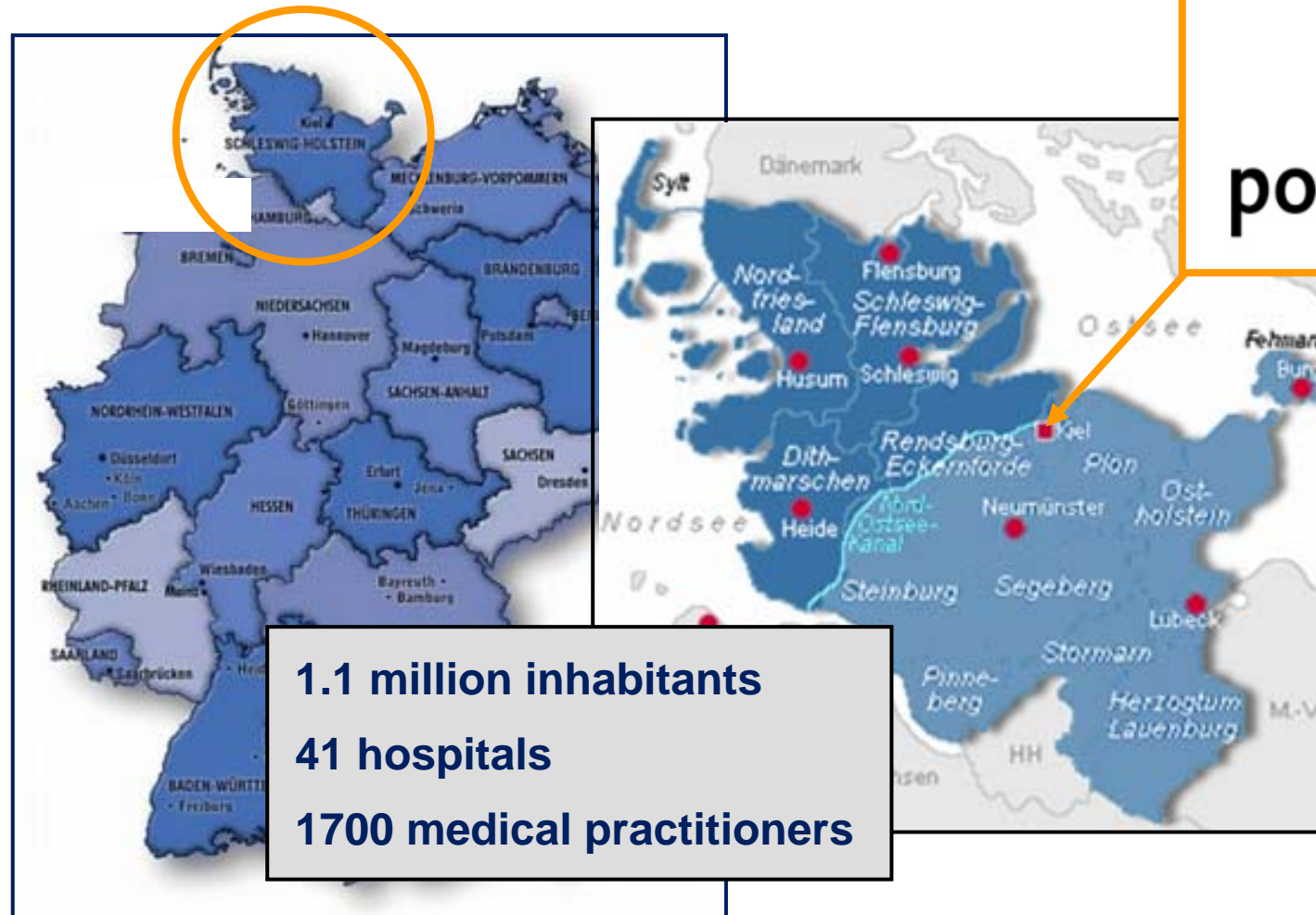




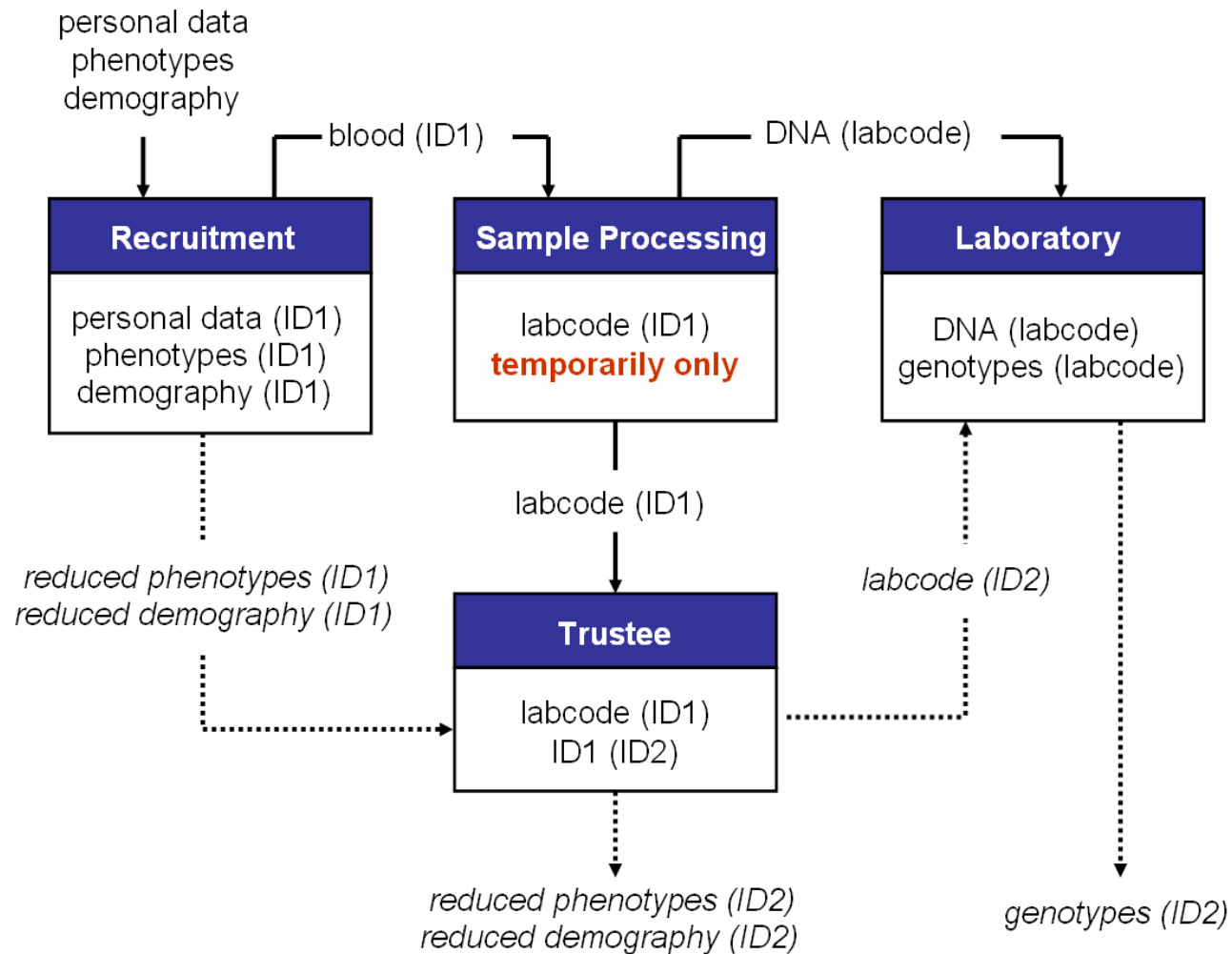


**UK
SH**

The PopGen Biobank



popgen Data Management



developed
in collaboration with



ULD S-H Kiel



UK
SH

The popgen Biobank



Disease-Specific Populations

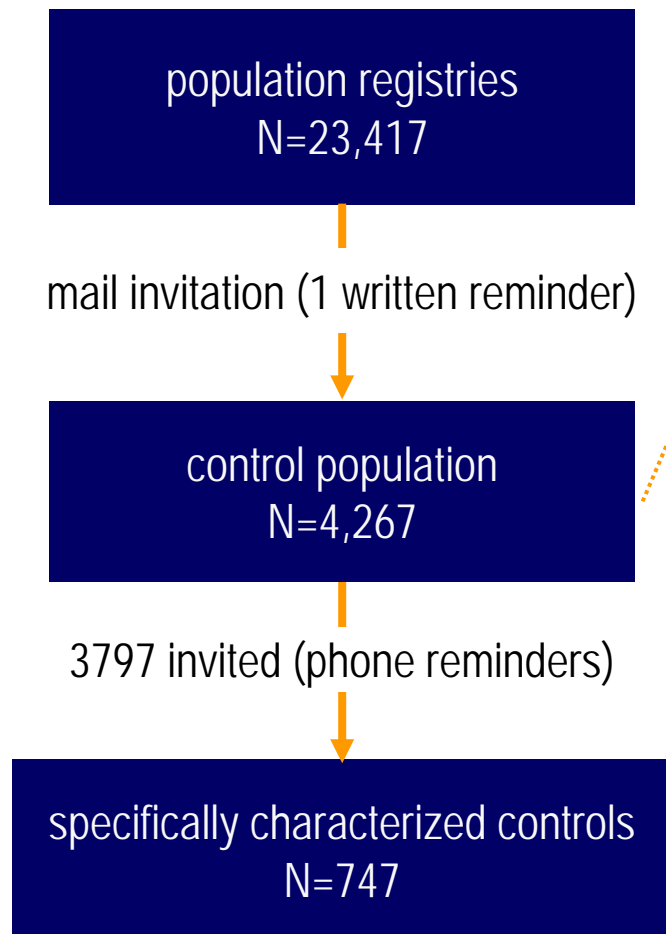
coronary heart disease
colorectal cancer
inflammatory bowel disease
gallstones
non-alcoholic steatohepatitis
psoriasis
etc.

Control Populations

general population controls
specifically characterized controls
blood donors



popgen Controls



Biomaterial

- EDTA blood, DNA

Standardized Questionnaires

- health status, ethnicity, anthropometry

In addition:

- serum
- biomarkers
- socio-demographic variables
- family history
- selected lifestyle variables (alcohol, smoking)

Physical and Medical Examinations

- weight, height, waist, hip
- physical strength
- blood pressure
- ultrasonography



popgen