Practical realization of Data Security and Genome Database

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Biobanks

- Biobank
  - An organized collection of human biological material and associated information stored for one or more research purposes
- Population biobank
  - The collection has a population basis
  - To supply biological materials or data derived therefrom for multiple future research projects
  - It contains biological materials and associated personal data

Background of the Estonian Biobank

- Research institute of the University of Tartu
- Longitudinal, prospective, population based biobank, established in 2000
- 52,000 gene donors recruited
- 5% of the adult population
  - 18 years and older
- Supported directly by the government
- The project is conducted according to the Estonian Human Genes Research Act

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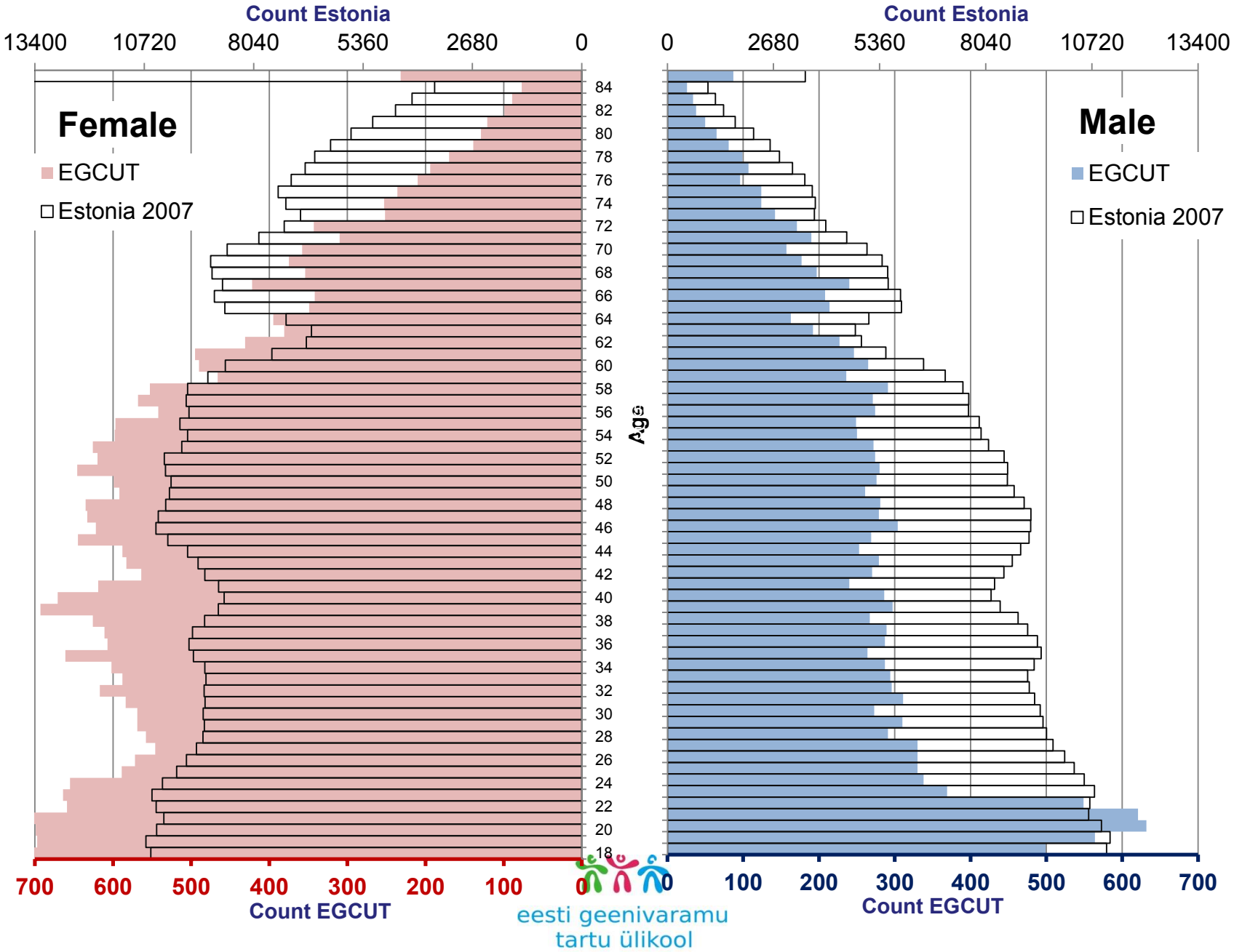
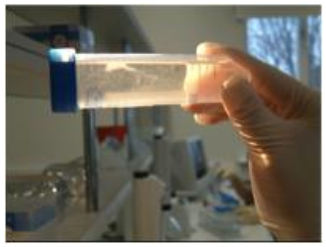
Population pyramid (50155 participants)



Data “infrastructure” for research

- Good quality data collection
  - Biomedical data (DNA, plasma, WBC)
  - Phenotype
  - Genealogy
  - Epidemiology data
  - Genotypes



- Open to various research projects
- Well defined procedures for data release
- Usable next 30 years

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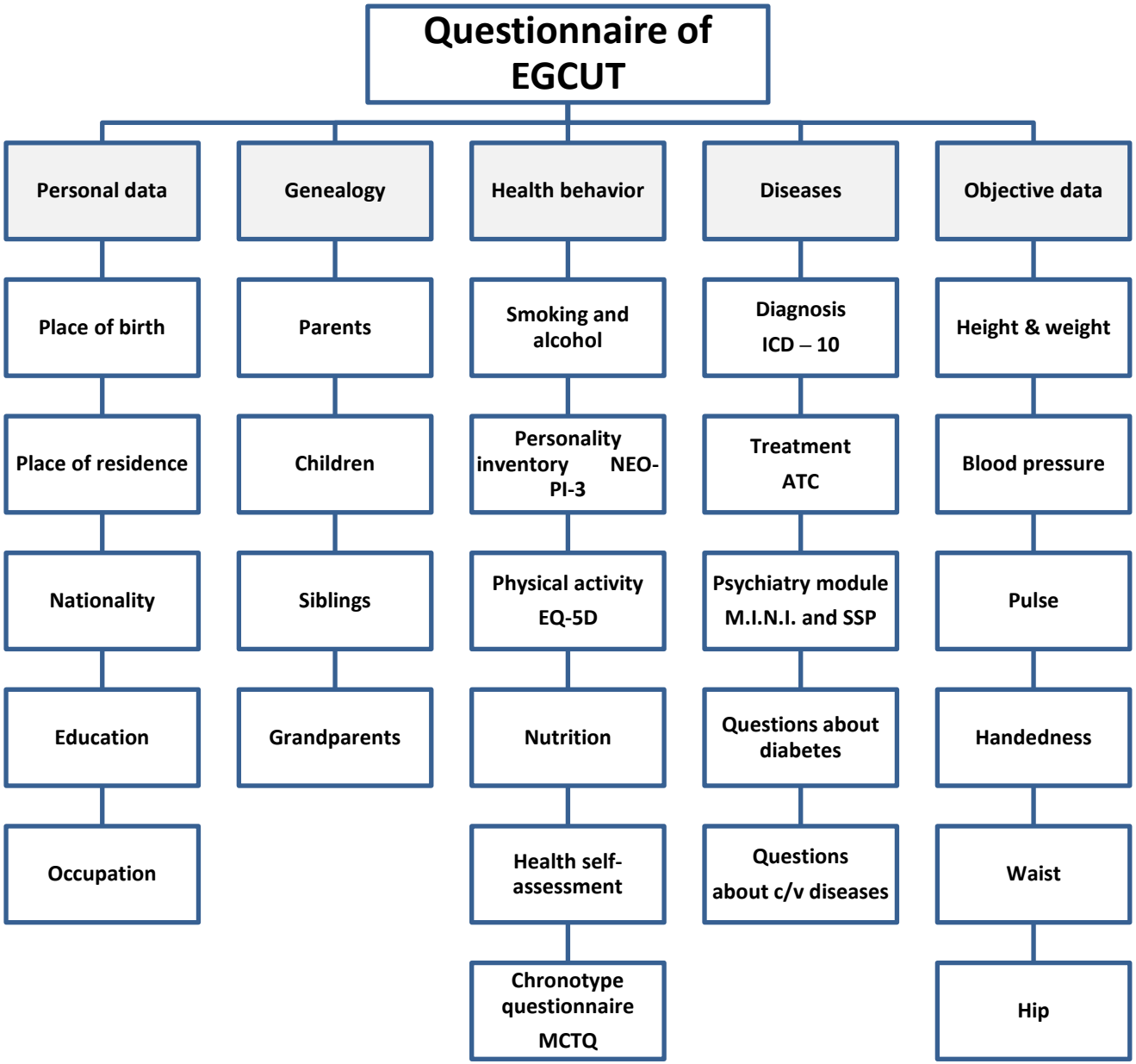

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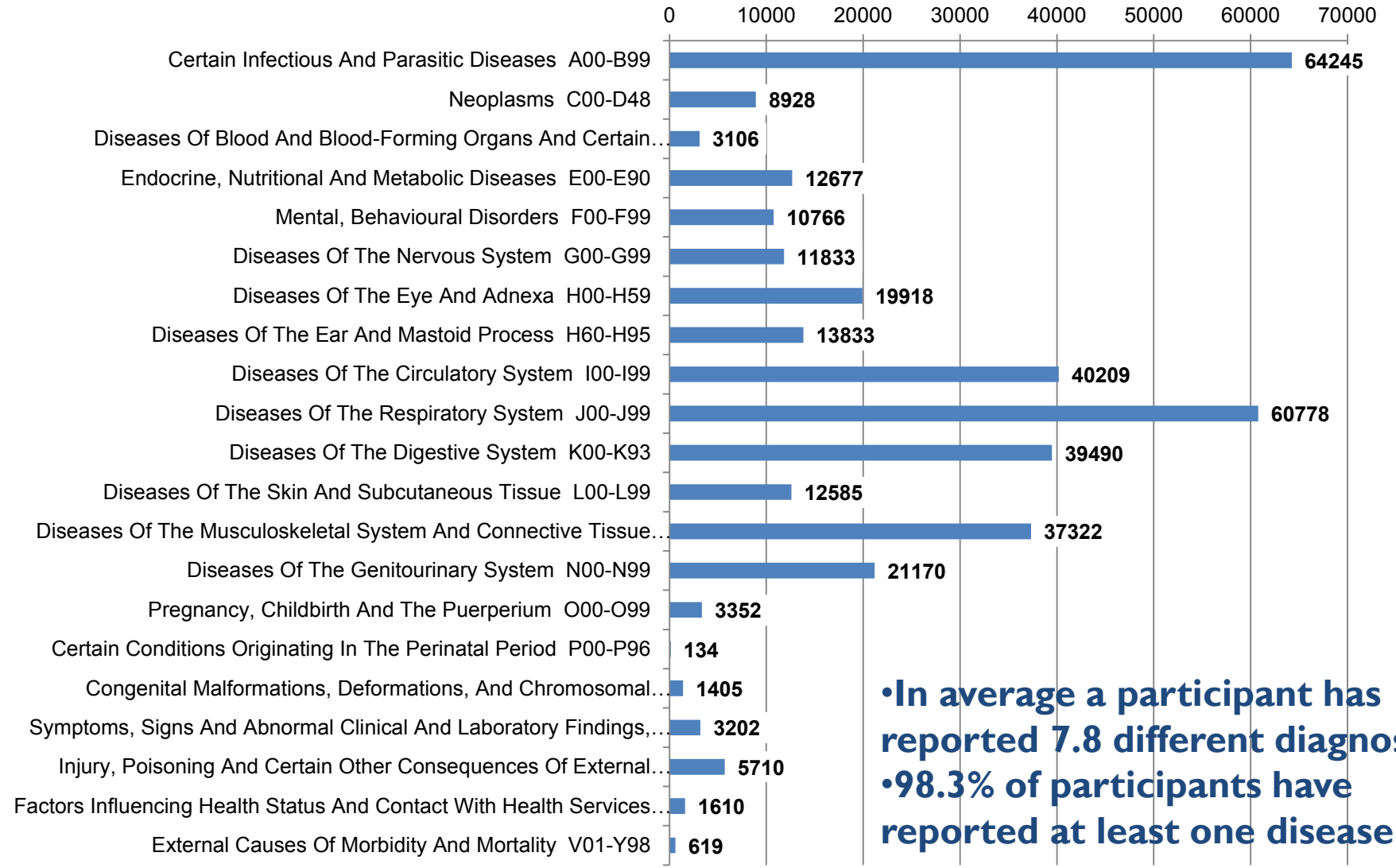
Diagnoses in the database

(50155 participants)



- **In average a participant has reported 7.8 different diagnoses**
- **98.3% of participants have reported at least one disease**

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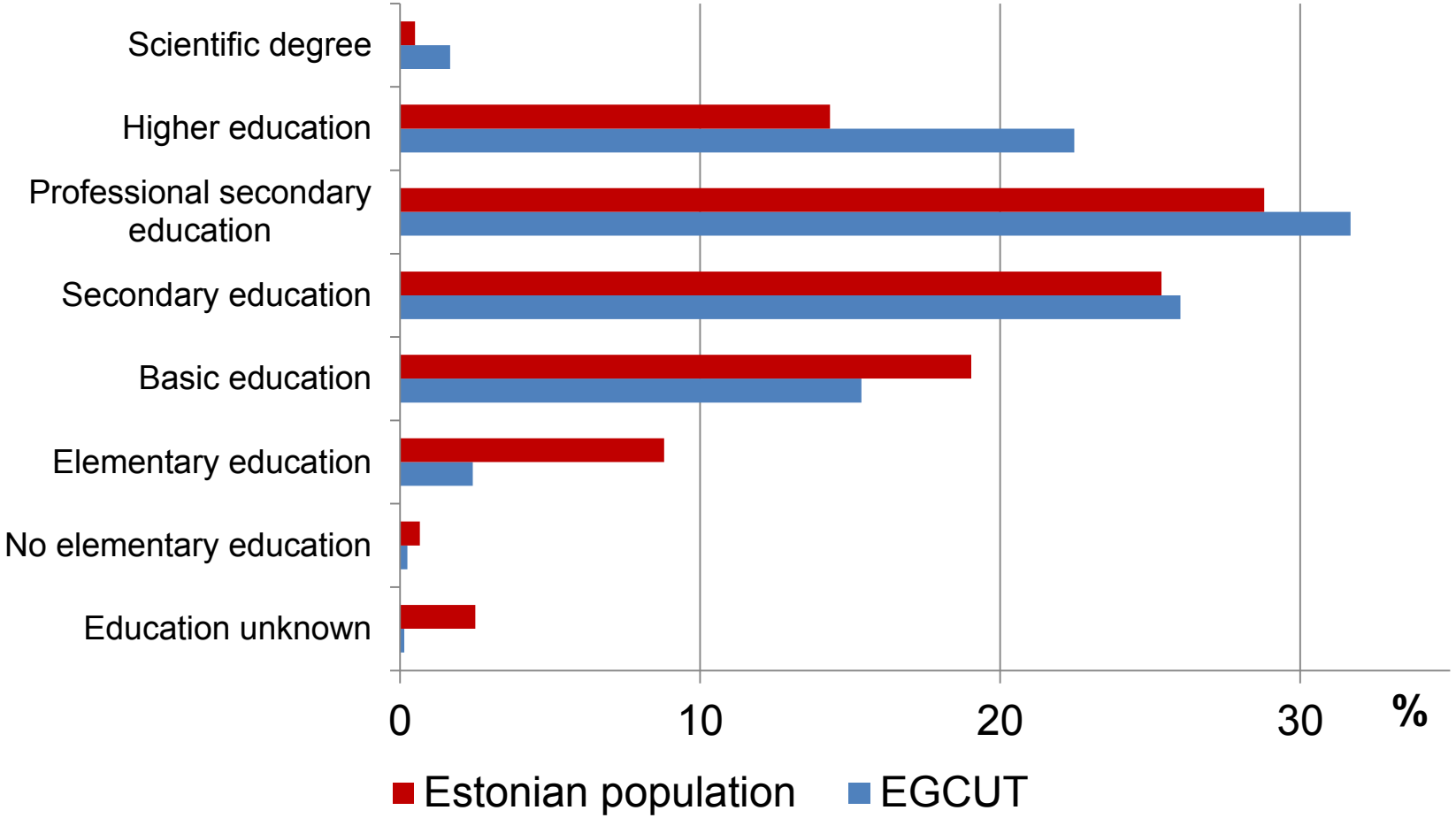
Education: the Estonian population vs. EGCUT

(50155 participants)



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Realization and data security

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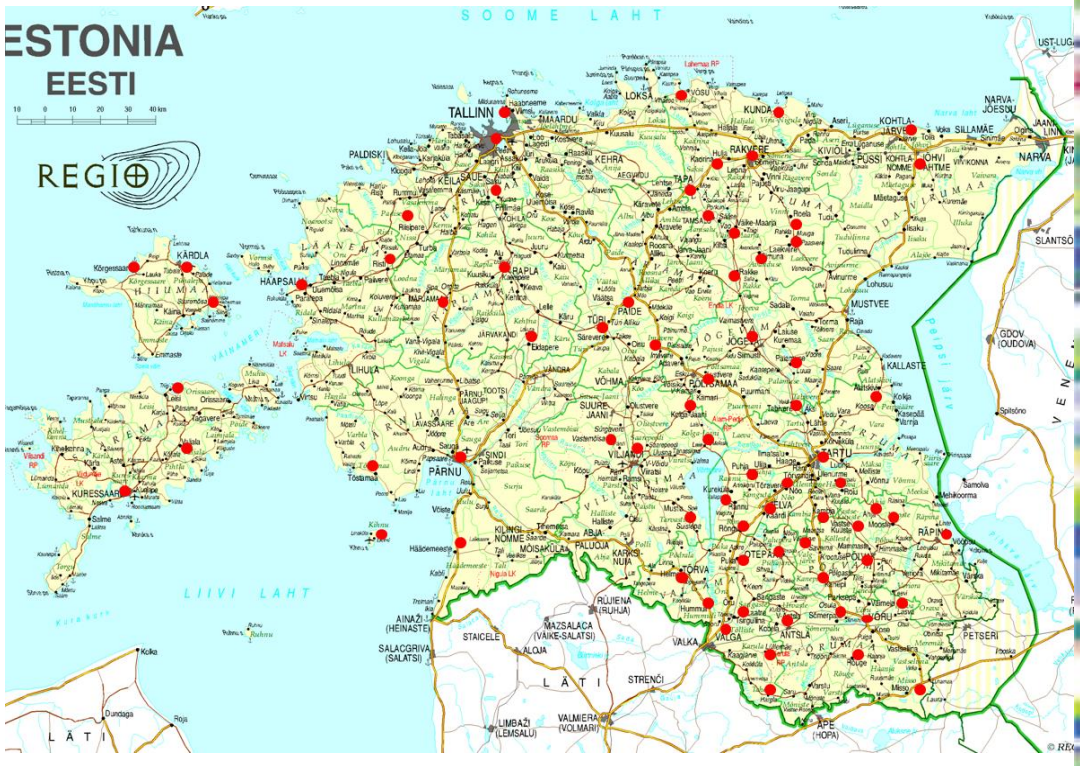
Network of recruiters

- Primary care providers (PCPs)
- Network of 640 recruiters
  - 454 GPs (56% of all GPs in Estonia)
  - 186 senior nurses and nurses
- 30h training
  - genetics, biobanking, data protection, ethics & law



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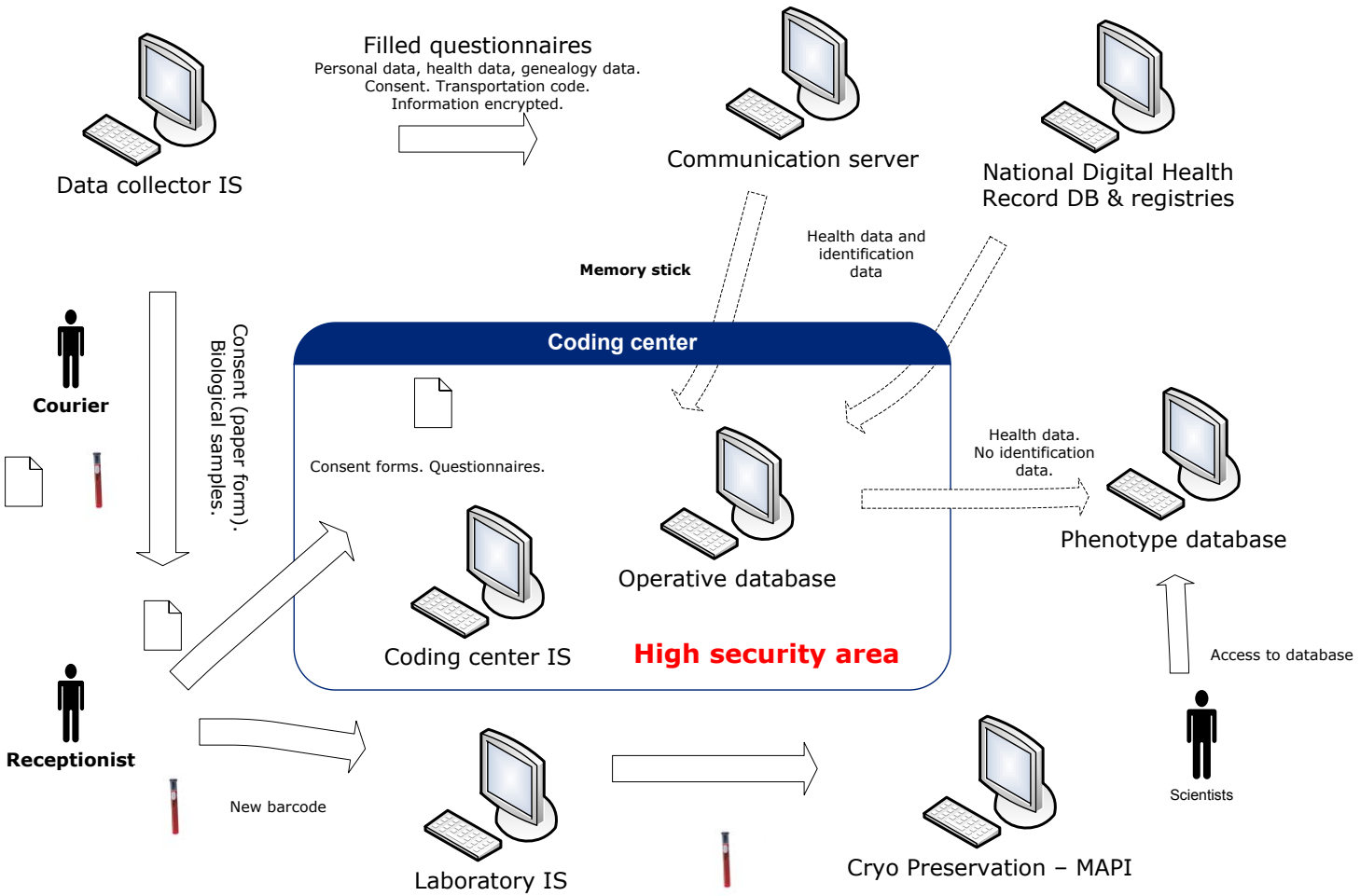
Data and sample collection



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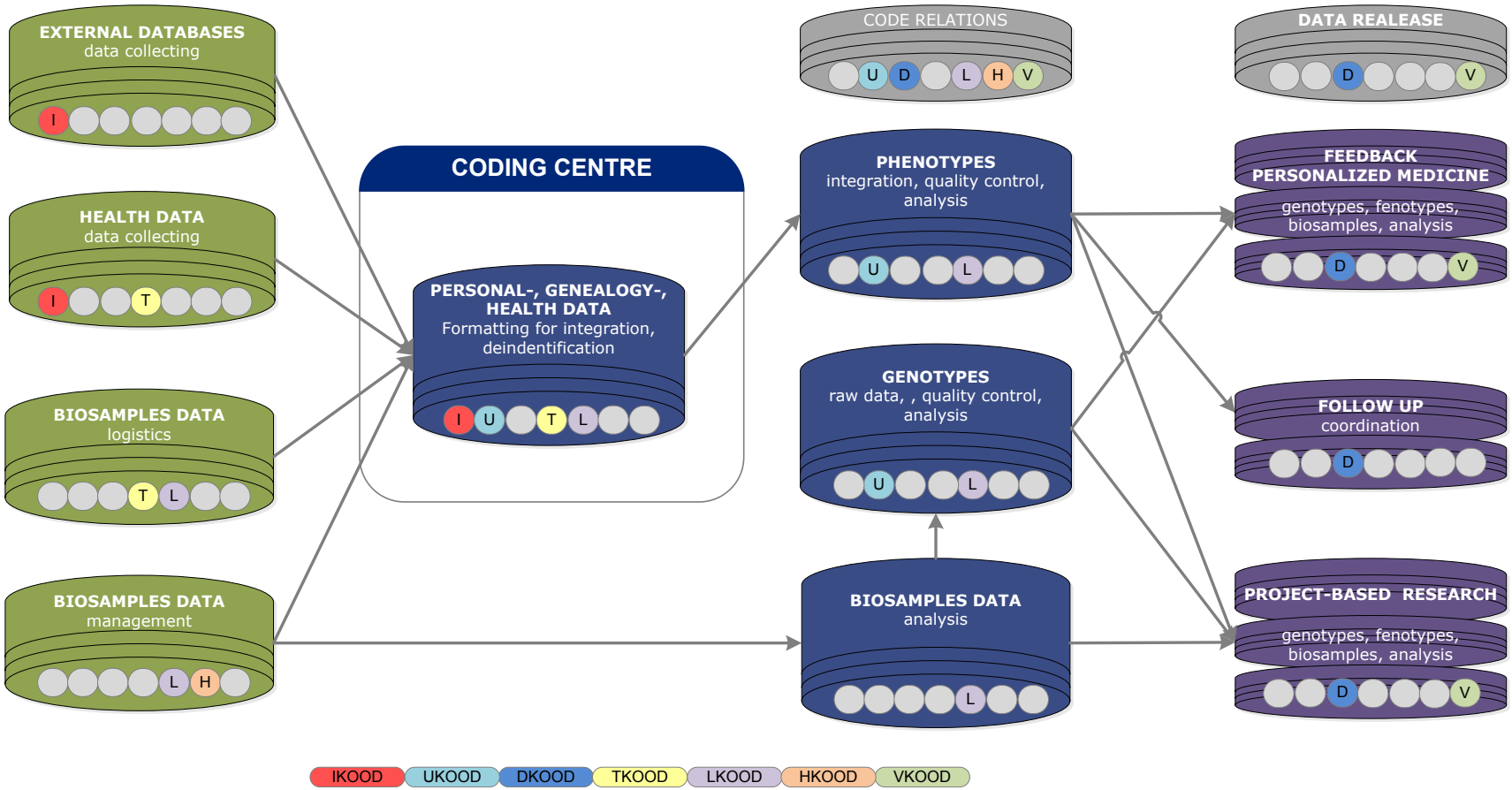
Coding challenges



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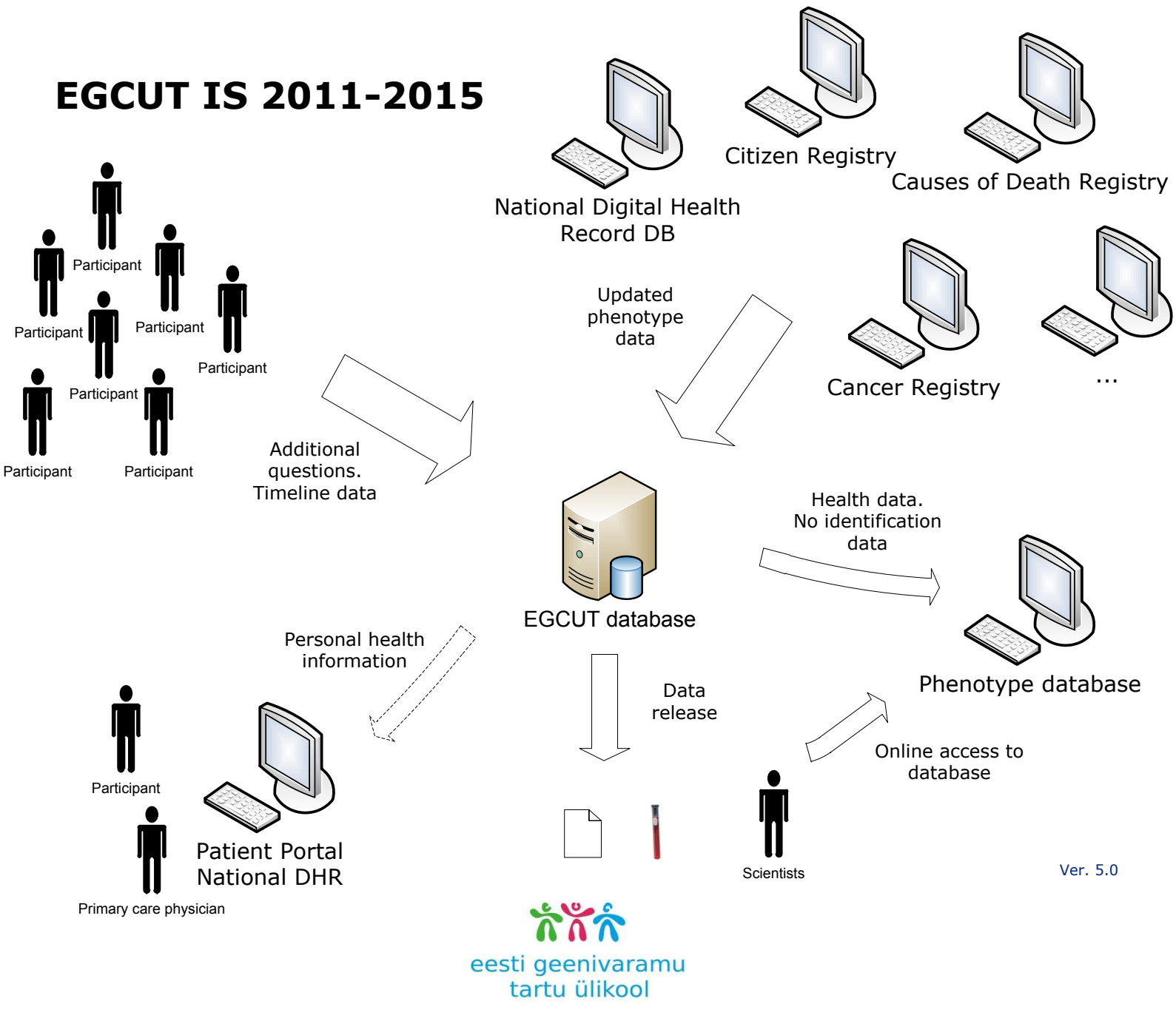
Data updates

- Follow-up and re-examining participant
- National registries
  - Citizen Registry
  - Estonian Causes of Death Registry
  - Estonian Cancer Registry
  - Estonian Tuberculosis Registry
- Hospitals
- National Health Insurance Fund
- Estonian National Health Information System

EGCUT IS 2011-2015

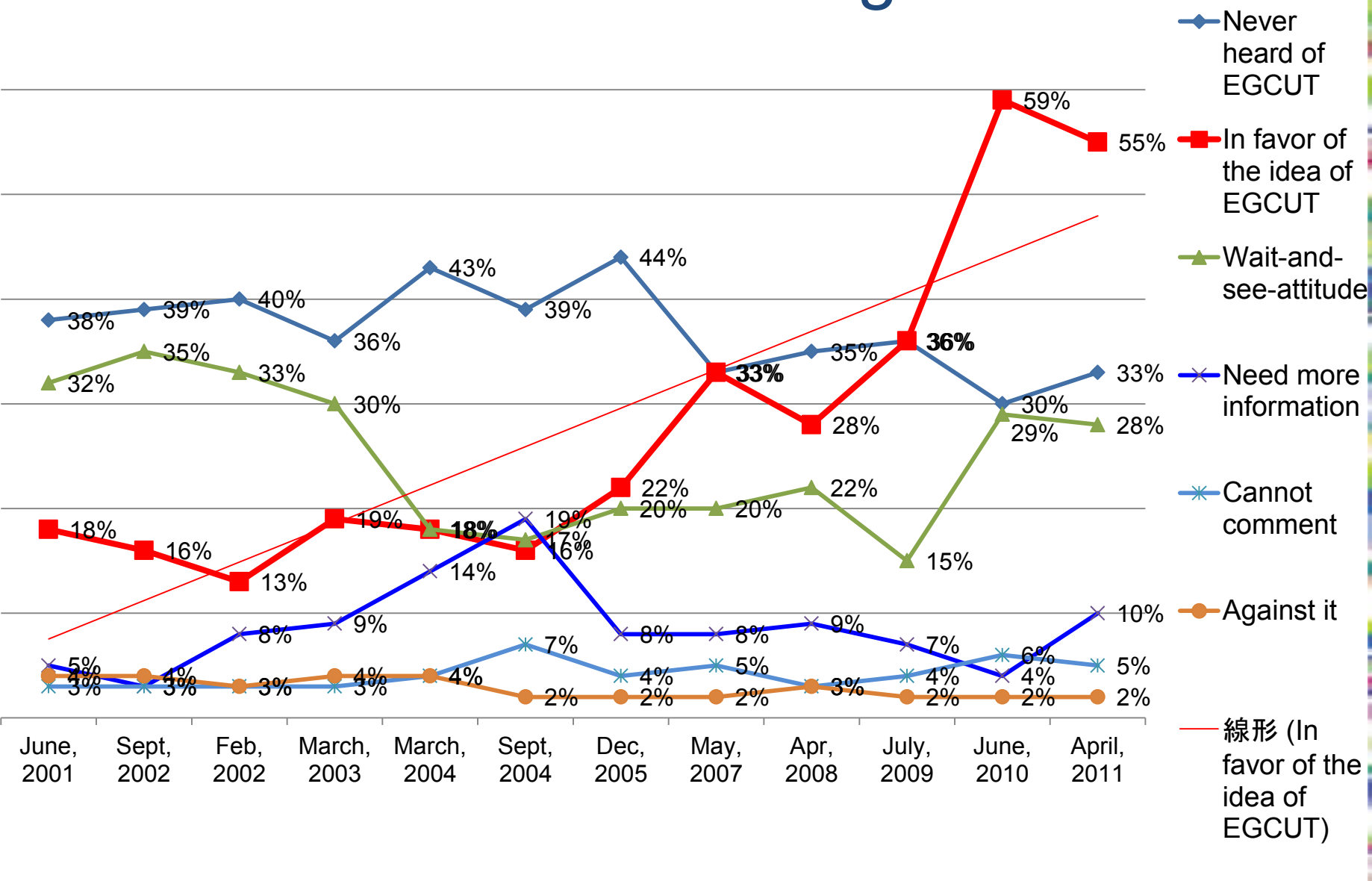


Human Genes Research Act

Enforced 08.01.2001

- HGRA regulates
  - scientific research on human genetics
  - establishment and maintenance of the biobank
  - use of genetic information (informed consent)
  - legislation is forbidding third party access to the database (police, employers, insurance companies etc.)
- HGRA protects
  - confidentiality of the gene donor
  - public from the misuse of the genetic information
  - gene donor from the genetic discrimination
- **HGRA allows re-contacting and collection of health data from other registries**
- Gene donors have the right to get feedback on their genetic information
    - feedback should be accompanied by clinical counseling

Public opinion very positive and awareness high

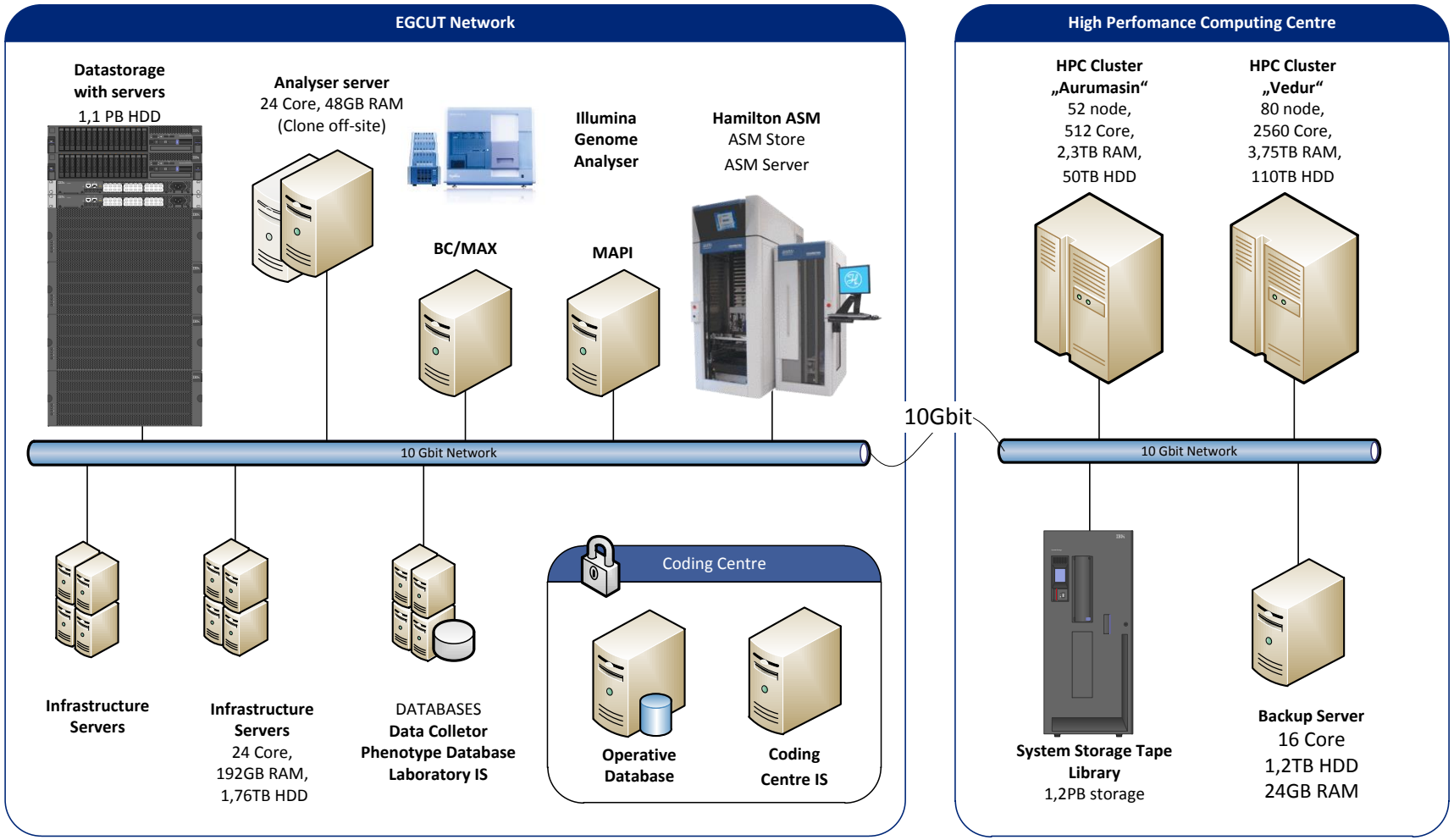


EGCUT servers and storage
June 2012

- **15** servers
- Datastorage **1,1 PB** harddrives
- **1,2 PB** system storage tape library

Computing power

- **3100 processor core**
- **6,2 TB RAM**



Serverite ülevaade 2012-05-30a RHansson

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Tools and enablers of information exchange

- One universal national identification code
  - Registries and databases use to uniquely identify persons
- National PKI infrastructure
- The Estonian ID card
  - Smartcard with two digital certificates
- National Data Exchange Layer X-Road
- Obligatory national data security framework
- High public acceptance and trust
  - No public incidents or misuses (10 years)

The Estonian ID card

- The ID card is a **mandatory** ID document for all Estonian residents from the age of 15
- Enables secure digital authentication and signing
- A digital signature has the same legal consequences as a hand-written signature
- Does not have any additional information
  - No bank account, no health information etc.
- Active cards: **1 192 102** (08.02.2013)
  - Estonian Population 1 286 540 (01.01.2013)
  - Estonia has been issuing ID cards from January 1st 2002

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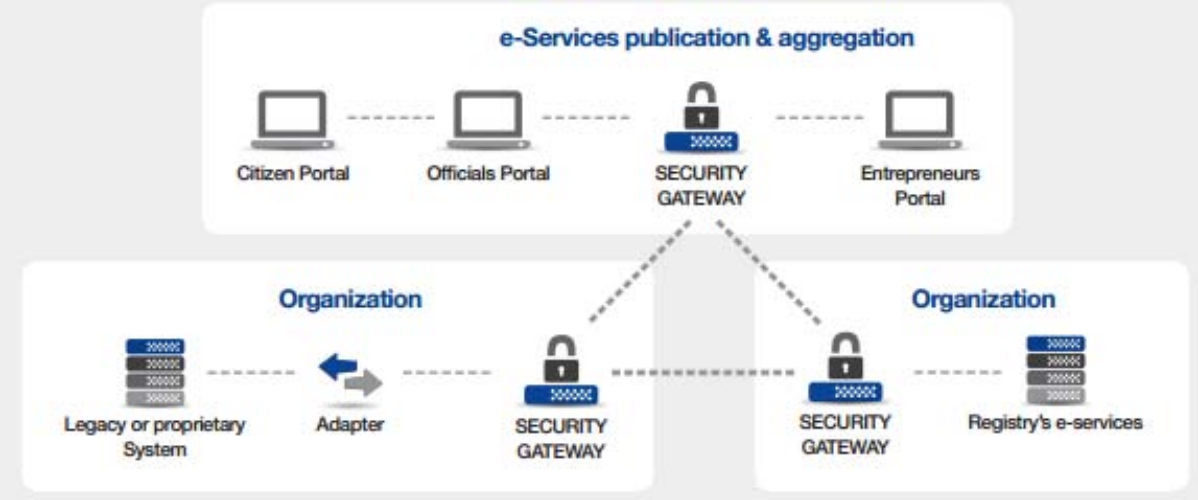
Public Key Infrastructure PKI

- PKI or the public key infrastructure enables secure digital authentication and signing
- The infrastructure also allows forwarding data by using an encrypting key pair: a public encryption key and a private decryption key
- In Estonia, this technology is used in relation with electronic identity (ID card, mobile ID, digital ID)
- Certification Service and Time-stamping Service provider is non-governmetal

Data Exchange Layer X-Road

- Technical and organisational environment, which enables secure Internet-based data exchange between the state's information systems



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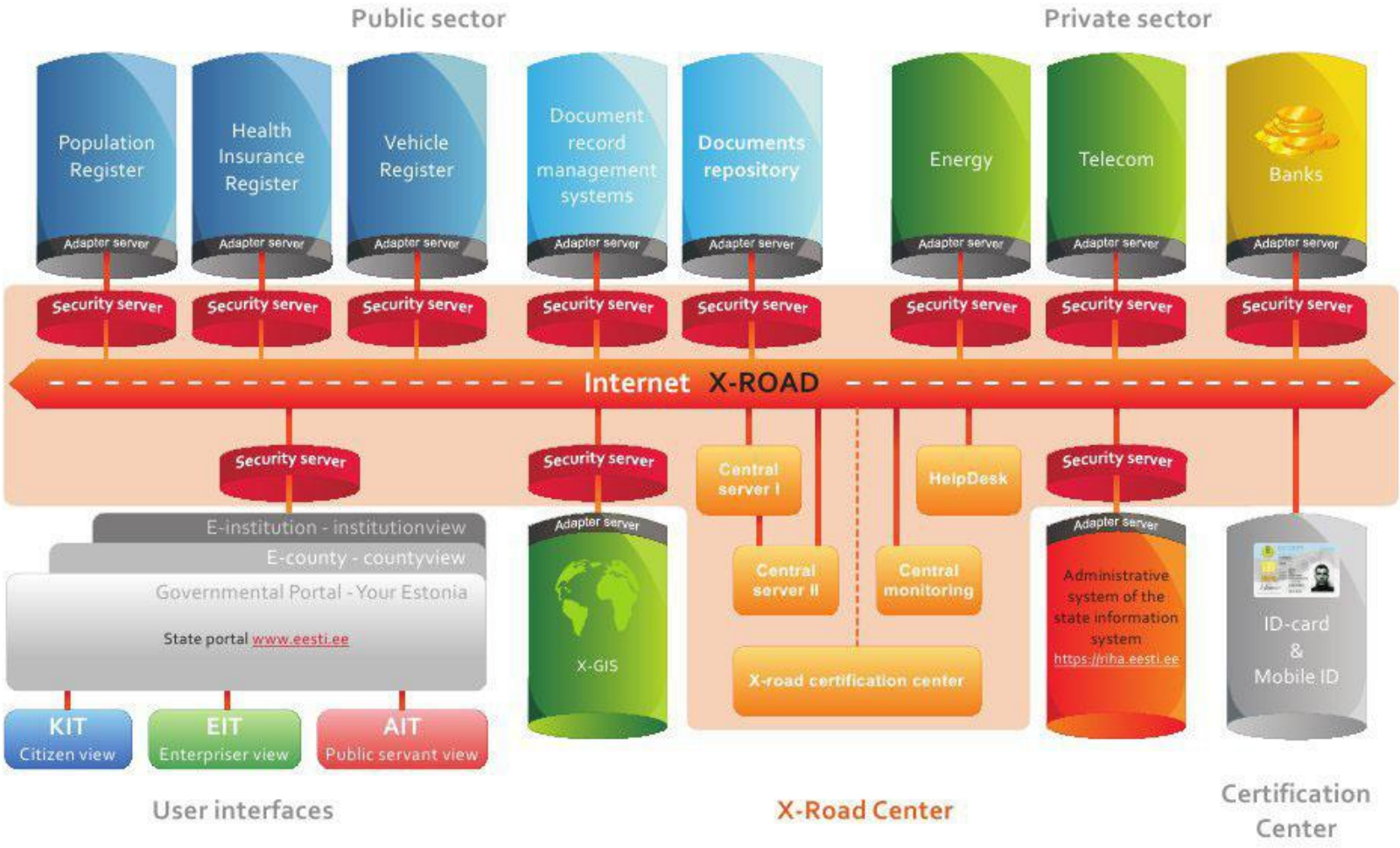
Estonian Information System's Authority

Estonian information system



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5 main principles of security of Estonian E-health system

1. A secure authentication of all users (ID-card)
2. A maximum accountability (transparency)
   - All action will leave an unchangeable (and unremovable) secure trail
3. Coding of personal data
   - Separating of personal data from medical data
4. Encrypted database
   - Allows to remove the confidentiality risk from the technical administrators
5. Effective monitoring tool
   - All actions are monitored and corresponding counter-measures are applied

Personal control as security measure

- People have easy and universal access with ID-card
  - No need for usernames or other access methods
- People can see what data is available about them
- People can see who has been accessing their data
- People can give legal commands online (ID-card)
  - For example: Person can close doctors access to his/hers EHR data in Patient Portal

National data security framework

- Legislation
  - Public Information Act
  - Personal Data Protection Act
  - Electronic Communication Act
- Three-level IT baseline security framework ISKE
  - Government Regulation, obligatory for Public sector
- Supervision
  - **Data Protection Inspectorate** defends citizens constitutional rights
  - **Estonian Information Systems's Authority** inspects the security of the information systems of state and local government agencies and providers of vital services
  - **Computer Emergency Response Team** (CERT) **Estonia**

Conclusions

- Estonia has great potential to implement state level personalized medicine solutions
  - Genetic research with 5% of population genetic and continuously updated phenotype information
  - Nation wide Health Information Exchange platform
  - 10 years of experience of national level e-services (PKI, X-Road, ID-card, security framework)
  - High level public trust and acceptance

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Thank you!

- Additional information:
  - Erkki Leego, erkki.leego@ut.ee
  - http://www.geenivaramu.ee/en/ (Estonian Genome Center, University of Tartu)
  - https://www.ria.ee/en/ (State Information System)
  - http://www.e-tervis.ee/ (Estonian E-Health Foundation)

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