Bio- and Genome Bank Denmark

RBGB

Principals, PIXI

RBGB
BIO- AND GENOME BANK DENMARK

Tabel of Contents

1. Vision and Background

Bio- and Genome Bank Denmark (RBGB) is established to support personalized treatment for patients in the Danish health care system. The transparency of RBGB makes diagnostics and research easier by:

1. Securing of high quality of the biomaterial based on national guidelines for handling, storage and registration,
2. Supporting joint collaborations both nationally and internationally.

In 2009 The Danish Ministry of Health released funding to establish an infrastructure for Danish cancer research and Danish Cancer Biobank (DCB). In this process DCB contributed, as the first biobank, to the establishment of the nationwide infrastructure later known as RBGB, including several biobanks.

In April 2014 Danish Regions decided to establish Danish Rheumatologic Biobank (DRB). On the 12th of September the same year Danish Regions established two national secretariats in the structure: a RBGB secretariat and a Patobank secretariat. Subsequently, Danish Regions decided to expand RBGB to include both existing- and future biobanks. The infrastructure of biobanks in RBGB is nation-wide with national collection of biological materials and registration in the RBGB register.

In 2020 Danish Regions expanded the infrastructure to include Genetic databank under the same governing organ as RBGB and Patobank. Today several nationwide biobanks have been constituted under the administration of RBGB.

Within the area of establishing nationwide biobanks, with national registrations of both clinical information as well as protocols for the handling, storage etc. of biological material, all following national guidelines, Denmark is pioneering.

2. Organization

The Regional Directors of Health are the highest decision-making authority in the organization structure of RBGB. They approve the annual budget as well as designating the members of the National Steering Committee and some of the members of the Scientific Advisory Board ensuring geographical representation from all Danish regions.

The National Steering Committee provides information on the development of the organization's structure, which may be relevant to pass on to the Regional Directors of Health. In addition, guidelines are set for political approval under the auspices of the Regional Directors of Health.

Below the National Steering Committee is the National RBGB Secretariat who, together with the center project managers, are responsible of the daily operation, development, as well as servicing researchers and clinics. The National RBGB Secretariat is situated at the Department of Pathology, Herlev Hospital.

The Scientific Chairman Board consists of the chairmen of the Scientific Advisory Board in addition with relevant partners within the health area to ensure harmonization across the biobanks. The Scientific Chairman

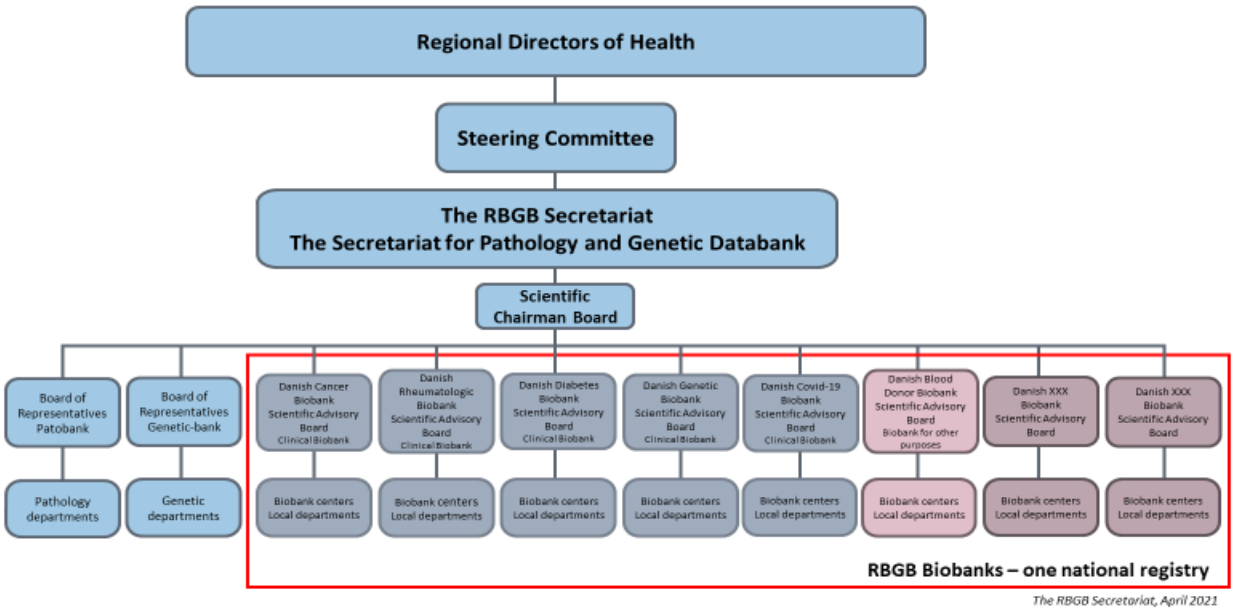
Board recommends topics to be discussed in the National Steering Committee and contributes with its knowledge of national and international experiences.

For each biobank a Scientific Advisory Board has been established to secure the clinical anchoring.

The biobank centers are a subsidiary part of RBGB which are situated in the five regions. As part of the biobank centers, the clinical biochemical, pathological, and hematological departments are collecting, handling, and storing material with the purpose of diagnostics/treatment and/or research. Biological material from patients is stored where the patient is treated but registered nationally in the RBGB register.

For more information and guidance on the biobanks included in RBGB, see www.regioner.dk/rbgben

Organization chart for RBGB



3. Collecting and storage of data

The biomaterial and information connected with the biomaterial, collected by biobanks, is distinguished as wet data and metadata.

Wet data is defined as biological material e.g. blood, bone marrow, tissue, ascites and urine. The respective departments use the biological material in treatment/diagnosis of the patient. Biological material is only allowed to be used in research studies if the patient has given their fully informed consent unless the National Committee on Health Research Ethics has provided a dispensation. The biomaterial is stored pseudonymized in the biobanks. This means that there is no accessible information accompanying the biological samples which can directly identify the patient.

Metadata is the existing information connected with the biological material. When the department receives the biomaterial, metadata on the sample is registered in the national RBGB register. Examples of metadata may be patient identification, diagnosis code, age, and the date of sampling/surgery. It is high priority to ensure real-time registration to ensure continuity and high quality of the data.

The quality of materials and their metadata is presented through several indicators announced in RBGB's annual report.

4. The use and retriveal of data in public context

Information security is an important aspect of health data. The use and retrieval of health data is subject to confidentiality, integrity and accessibility.

Approval from the National Committee on Health Research Ethics is required before retrieval of biomaterial for research studies. Prior to retrieval of material from RBGB, a search in the Danish register 'Vævsanvendelsesregistret' (VAR) is made. Material from patients who have actively signed up to VAR cannot be retrieved for research projects. The amount of biomaterial retrieved from the biobank is based on the analyses to be performed in addition with ensuring that sufficient material remains in the biobank for the patient's own diagnosis and treatment.

5. RBGBs collaboration with the private industry

In 2016 guidelines for the collaboration between RBGB and medico companies were set. The guidelines state that the collaboration must meet the minimum standards of public research that RBGB has with Danish Regions. For private actors RBGB only provides anonymized analysis data and pseudonymized biomaterial. The retrieval is not done until all the necessary applications have been approved by the relevant public authorities.

Under the national RBGB Secretariat's management, the private companies have the possibility to connect the biomaterial and analysis data to other health data.

The cost for handling biomaterials and analysis data follows the existing pricelist "Oversigt over vejledende håndteringsomkostninger". Agreement on other finance models can be reached with Danish Regions.

6. Ethics

All data is stored pseudonymized on secure servers. All employees with access to the servers and the registration system are under duty of confidentiality and have personalized access codes, which are logged when using the register. The registered citizen with material in the biobank always retains the legal position to withdraw their given consent of the use and storage of their health data.

7. Economy

RBGB is a joint regional operational task, which is to ensure sampling and registration of biomaterial. Funding for the center project managements is dispensed based on key figures which can be number of diagnoses or the population base.

The retrieval of metadata describing the biomaterial is free of charge. Prospective research projects always have one free retrieval of biomaterial from RBGB. In other research situations the applicant must pay all expenses for retrieval including selection, packaging, as well as shipping cost for the biomaterial, unless another agreement has been made.

8. Law

In Denmark the biobanks are regulated by, amongst other things, the Healthcare Law, The law on Ethical Research[1] and the Data Protection Law.

9. Up-coming Biobanks

As it is impossible to know which questions the diagnostics and research will be rising in the future, there is continuously a need for expanding existing infrastructure with new biobanks, which can store both present and future health data beneficial for both the patients' own personalized treatment and the continuous development of the research within personalized medicine.

10. Biobanks for other health science purposes

RBGB can contribute with its biobank infrastructure for other purposes within health science comprehending more general investigations. An example of this within RBGB is the Danish Blood Donor Biobank, which collects blood samples and accompanying metadata for the Danish Blood Donor study.

[1] LBK nr. 1338 af 01/09/2020, Bekendtgørelse af lov om videnskabsetisk behandling af sundhedsvidenskabelige forskningsprojekter og sundhedsdatavidenskabelige forskningsprojekter.