Bio- and Genome Bank Denmark

RBGB

A8_en. Guiding Principles, PIXI

RBGB
REGIONERNES BIO- OG GENOMBANK

Table of Contents

1. Vision

Bio- and Genome Bank Denmark (RBGB) is a health service that primarily functions as part of the Danish Healthcare System by providing materials for diagnostics and in particular, support for research and development of targeted and individual courses of treatment. This allows for an expeditious diagnosis and timely intervention in the patient's course of treatment.

1.1 Background

In 2009 the Danish Ministry of the Interior and Health provided funding to establish an infrastructure for Danish cancer research and the Danish Cancer Biobank (DCB).

In April 2014 the Danish Regions established the Danish Rheumatologic Biobank (DRB). Later that year on the 12th of September the Danish Regions founded two national secretariats, one for RBGB and the other for Patobank (anno 1999). By using Patobank's model as an inspiration, the Danish Regions decided to expand RBGB's scope to all pre-existing and future biobanks. The infrastructure is national regarding registration in RBGB and the collection of biological materials.

In 2020 the Danish Regions decided to expand the scope of Patobank to include genetic data in their pathological databank. And today, the RBGB infrastructure is used by multiple national biobanks.

Denmark is a leading country in creating national biobanks with uniform guidelines and registration practices.

2. Organization

The Regional Directors of Health is the principal governing body of the organization. They elect the members of RBGB's Steering Committee and the members of the Scientific Advisory Boards, as well as approving the overall budget.

The main task of the Steering Committee is to assist the Regional Directors of Health in an advisory role. Furthermore, the committee is responsible for developing the organizational structure, submitting interregional policy proposals for approval by the Regional Directors of Health, and notifying the RBGB Secretariat of relevant published documents.

The RBGB Secretariat is subordinate to the Steering Committee. The secretariat along with the Biobank Center Managers are responsible for the day-to-day administration, development, and assistance of researchers and clinicians. The secretariat is located at the department of pathology in Herlev Hospital.

The Scientific Chairman Board consists of the Chairmen of the Scientific Advisory Boards and their relevant healthcare partners[1], who contribute to compatibility and conformity across the various biobanks. The board of chairmen raises subjects to the Steering Committee and contribute with their experiences from national and international undertakings.

[1]The Chairman of Patobank, the Director of the Danish Clinical Quality Program (RKKP), a representative of the Danish Regions, and the Director of the RBGB.

Each Biobank has a Scientific Advisory Board attached to ensure the clinical perspective is always being considered.

The biobank centers are the backbone of RBGB and placed in all Danish regions. Their clinical, biochemical, pathological, and hematological departments collect, handle, and store the biological material for clinical use. This ensures that the material is stored close to the patient by the corresponding region meanwhile the data registration and time logging is done in the national RBGB database.

For more information and guidelines on a specific biobank go to https://www.rbgb.dk/

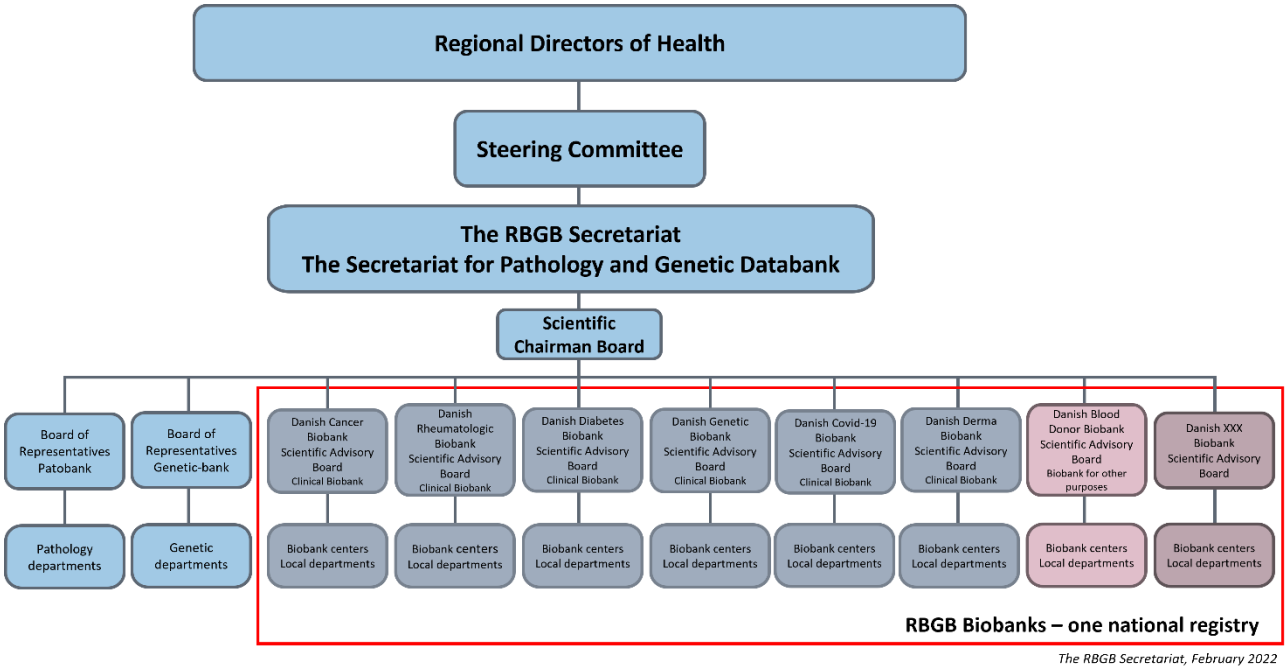

Figure 1. Organization of RBGB. The figure shows how RBGB is organized with a Steering Committee, a national secretariat, and Scientific Advisory Boards for current and future biobanks.

3. Collection and Data Storage

When biobanks collect a sample, a distinction is made between the biological material, termed "the wet data", and the metadata, termed "the dry data".

"The wet data" is biological material: such as blood, bone marrow, tissue, or urine. The respective local department uses the biological material in diagnosing or treating the patient. The local departments pseudonymize the stored biological material and store it for 10 years after the patient is deceased.

"The dry data" is the specific information connected to the biological material. When biological material arrives at the biobank, the biobank center registers the material's metadata in RBGB's national database. Examples of metadata can be diagnosis codes, age, or the collection date of the sample. The biobanks prioritize exact time logging to ensure high quality and continuity in the stored data.

The quality of materials and metadata in RBGB are presented yearly as indicators in the RBGB Annual Report[2].

[2] https://www.rbgb.dk/

4. Use and Transfer of Personal Data to other entities in the Danish Healthcare System

Information security is an integral part of administrating health data concerning a patient's diagnosis and treatment. RBGB makes sure to verify and document that the use and transfer of health data are authorized and lawful. All data in the custody of RBGB is subject to confidentiality.

When a piece of biological and clinical material is transferred to research, it is done in accordance with an approved application from the Danish National Medical Research Ethics Committee (VEK). Additionally, RBGB searches the National Database of Non-Consent to the Use of Tissue Samples for Scientific Purposes before the transfer. If the patient is not in the database, the transfer of biological material and the corresponding metadata is completed. It is always a matter of specific assessment: how much biological material can be transferred to research and how much is needed for diagnosis and treatment. In each case RBGB carefully considers present and future needs[3].

5. Collaboration with Private Companies

In 2016 new guidelines were developed for RBGB's collaboration with various members of MedTech Denmark. The guidelines state that any collaboration agreement must at a minimum live up to the standards for public research agreed upon by RBGB and the Danish Regions and the data protection laws.

RBGB will only transfer anonymized metadata and pseudonymized biological material to private actors when applications have been approved with the relevant public authorities and in accordance with current legislation.

Under the secretariat's supervision and responsibility, it is possible for companies to have the biological material linked to additional health data.

By default, the cost of handling is presented in "*Outline of Estimated Handling Costs*", but it is possible to come to a separate agreement with the Danish Regions.

6. Ethics

All stored data is pseudonymized in secure servers. Every employee with access to the RBGB database has a duty of confidentiality and their own personal user and password, which logs activity in the database.

7. Financing

RBGB is an operational task that is shared between the Danish regions. It is the responsibility of each region to ensure that sampling and registration of the biospecimens are carried out. The distribution of funds to the biobank centers is based on key indicators, such as the number of diagnoses or the base population in the region.

It is always free to request and receive metadata regarding biological material. A prospective project is always entitled to one free transfer per collected biospecimen in RBGB. In other instances, it is the applicant who incurs the expenses related to data retrieval, handling, packaging, and shipping of the biospecimens unless agreed upon otherwise.

[3] More can be found in "Principper for Regionernes Bio- og GenomBank", p. 10 (Danish version)

[4] See Section 3

8. Legislation

In Denmark, biobanks are regulated by the Danish Health Care Act, the Scientific Ethical Committees Act[5], the Danish Data Protection Act, and the General Data Protection Law.

9. Future Biobanks

Since it is impossible to know what questions will be posed by future diagnostics and research, there is a demand for a national infrastructure and continual creation of new biobanks, that store current and future health data for the good of the patients and their need for personalized medicine.

10. Biobanks with Different Health and Medical Scientific Purposes

RBGB can supply its infrastructure to biobanks with different health and medical scientific purposes, which include more general research. A current example from RBGB is the Danish Blood Biobank. It collects blood samples and corresponding data for the Danish Blood Donor Study.

[5] "LBK nr. 1338 af 01/09/2020", "Bekendtgørelse af lov om videnskabsetisk behandling af sundhedsvidenskabelige forskningsprojekter og sundheds-datavidenskabelige forskningsprojekter".

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