

# THE BIOBANK OF THE DIABETES RESEARCH INSTITUTE (BIODRI), SILVIA PELLEGRINI AND FABIO MANENTI

State-of-art and future development/perspectives of the research area at international level (max 2000 characters):

BioDRI is a non-profit service unit aimed at the collection, processing, storage and distribution of human biological samples and related data, that arises from the scientific need to have access to biological samples from healthy subjects and patients with pancreatic diseases. The intrinsic usefulness of a biobank derives from the strong standardization of processes, a fundamental point to ensure the repeatability and validity of the scientific research.

In the absence of a Biobank, each research unit must independently implement a bureaucratic and procedural system to acquire biological material from patients for a specific study. This process also has the strong limitation of not allowing long-term storage of any biological samples not used in the specific study; in fact, unused samples must necessarily be destroyed, leading to a waste of material that could be of interest in other studies.

BioDRI offers itself as a solution to these limitations, dealing with the long-term collection and storage of biological samples without limiting their use to a specific study and allowing individual research units to use the collected material. Moreover, since BioDRI is present within a European node of biobanks (BBMRI-ERIC), the samples collected by BioDRI can be shared with all the biobanks of the consortium, and vice versa. Currently in Europe, there are more than 600 biobanks with more than 3000 collections of biological samples; the presence of BioDRI on this platform guarantees and will guarantee access to any category of biological samples from all over Europe to all research groups of the DRI. In the next few years BioDRI aims to become a national and international reference center for the collection of biological samples from patients suffering from pancreatic diseases, and this will allow DRI researchers and clinicians to establish worldwide fruitful scientific collaborations to allow the advancement of knowledge in the field of diabetes and pancreatic diseases.

Actual lines of research (as is) of the Diabetes Research Institute (max 2000 characters):

Currently BioDRI is involved in the collection of biological samples for 24 different clinical studies of the DRI. BioDRI mainly deals with the storage of biological samples necessary for carrying out already ongoing clinical studies, however, thanks to its existence, it has been and will be possible to start new ones as well. To date, the biological materials collected by BioDRI and made available for research are: peripheral, portal and cord blood and their derivatives (serum, plasma, PBMC, whole blood), urine, faeces and pancreatic cystic fluid. These biological materials were collected from healthy controls, from patients with type 1 and 2 diabetes, patients with monogenic diabetes, patients with pancreatic diseases and from patients who have undergone a transplant of pancreatic islet, pancreas or kidney.

Since its creation on 07/11/2019, BioDRI has collected more than 24.500 aliquots of biological samples (data updated to 31/12/2021) with an economic effort of about € 40.000 only for the purchase of the consumables necessary for storage and the hardware for barcode reading.

At present more than 1400 of these aliquots of biological samples have been distributed to internal and external collaborators for the development of research projects, one of which has already led to a publication (Doi: 10.3390/biology10121349).

Strengths of the research area (as is) of the Diabetes Research Institute (max 2000 characters):

BioDRI was founded as a biobank oriented to the collection of samples of patients suffering from T1D, T2D, monogenic diabetes and other metabolic and pancreatic diseases. The strength of this strategy lies in the small number of existing biobanks with the same purpose; for example, throughout Europe only 3 official Biobanks (located in Brussel-Belgium, West-Friesland-Netherlands, and in Riga-Latvia) have a collection of samples derived from patients with type 1 diabetes, the main category of interest of BioDRI.

Another big plus is that BioDRI is composed by highly qualified personnel and experts in diabetes and pancreas-related diseases; thanks to the experience of the staff and the standardization of processes, the quality of the biological samples collected is high. Moreover, BioDRI is classified as a satellite biobank of the Biological Resources Center (CRB) of OSR and consequently follows all the quality and standardization rules of the ISO9001 standard for which the CRB is accredited.

BioDRI is located within the DRI, which relies on BioDRI for the storage of biological samples taken for most of the clinical trials currently ongoing and for any future ones. This strong connection between BioDRI and DRI represents a further bilateral strength for the development of scientific collaborations internal and external to DRI.

Weaknesses of the research area (as is) of the Diabetes Research Institute (max 2000 characters):

As anticipated, BioDRI was born in 2019 and actively began recruiting in mid-2020. At present there are still numerous weaknesses, which undermine the achievement of the goal that BioDRI has set itself. Below is a list of the current main issues:

- limited staff, none of which 100% dedicated to BioDRI processes (BioDRI staff is often involved in one or more research projects);
- currently, an inadequate software is dedicated to BioDRI for the management of bio-banked biological samples. The software, while allowing the complete cycle of BioDRI processes, is not free from errors and malfunctions that slow down the work activity;
- an electronic spreadsheet is currently used for the collection of patient clinical data. This system must certainly be replaced with specialized software for the collection and management of clinical data to allow BioDRI to fully exploit the potential of collecting the medical history of biobanked patients;
- the lack of medical / nursing staff dedicated exclusively to the recruitment of patients and collection of biological samples;
- currently BioDRI shares spaces and instrumentation with the DRI. The acquisition of spaces and dedicated equipment is essential for achieving the short term goals;
- the management of sample collection is not 100% optimized for all the protocols followed by BioDRI. An adjustment of the global organization level is required;
- BioDRI does not follow 100% of the clinical protocols of the DRI. In order to expand the types of collected biological samples, BioDRI should proceed with the complete management of all clinical protocols.

Short-medium term OSR/UniSR goals (0-18 months): milestones and deliverables (max 1000 characters):

M1: BioDRI acquisition of ISO 20387 certification.

D1: adaptation of all sample collection and processing procedures to the new standards of ISO 20387.

D2: transition to CRB's IT biobank system, replacing the software currently used by BioDRI.

D3: integration in the new IT biobank system of a module for the management of clinical data of patients.

D4: training of patient recruiters and BioDRI staff to use the new software.

M2: Advertising of BioDRI outside the DRI.

D1: creation of a BioDRI presentation page on the DRI website, complete with current development, objectives and contacts.

D2: publishing and sharing of an article on DRI website to bring BioDRI to the attention of the public.

D3: update of BioDRI data on BBMRI-It and BBMRI-Eric platforms.

## Medium term OSR/UniSR goals (18-36 months): milestones and deliverables (max 1000 characters):

M1: Acquisition of a dedicated system for the collection and management of clinical data.

D1: Transition of data and procedures to the new system for data collection.

D2: Training of patient recruiters and BioDRI staff to use the new software.

M2: Active recruitment of OSR patients with T1D (onset and long-standing), T2D and monogenic diabetes.

D1: Participation in grants dedicated to biobanks to support this investment.

D2: Assignment of staff exclusively dedicated to BioDRI.

D3: Advertising of BioDRI at social events and among patient associations.

D4: Creation of a website dedicated exclusively to BioDRI, both for patients and for potential new collaborators interested in the samples collected by BioDRI.

D5: Creation of a booking system for patients to independently book date and time of donation of their biological samples to BioDRI.

D6: Identification of spaces and personnel dedicated to the collection of biological samples from patients and their clinical data.

## Long term OSR/UniSR goals (36-60 months): milestones and deliverables (max 1000 characters):

M1: Recognition of BioDRI as a reference biobank for the study pancreatic and metabolic diseases at national and international level.

D1: Establishment of fruitful collaborations with research groups inside and outside DRI.

D2: Active recruitment of patients with T1D (onset and long-standing), T2D and monogenic diabetes (OSR and outside the hospital).

M2: Generation of a biobank of human induced pluripotent stem cells (iPSC) lines derived from patients with T1D and monogenic diabetes for disease modeling studies.

D1: activation of a collaboration with the new facility for iPSC lines generation present in OSR within CRB.

D2: generation of iPSC lines from patients with monogenic diabetes and from a selection of patients with T1D.

## Investments of the Diabetes Research Institute (e.g. personnel, space, technology) to achieve the short-medium-long term goals (max 2000 characters):

Personnel: recruitment of 2 technicians, 1 data manager, 1 nurse, 1 medical doctor, all exclusively dedicated to BioDRI.

Space:

- identification of a space for the collection of biological materials from patients;

- 1 sterile hood, 2 centrifuges and 2 PC stations for the exclusive use of BioDRI.

Technologies: software for clinical data management, web space for hosting a dedicated website.

Consumables: materials for the processing of biological samples.