

The French-speaking Diabetes Society is seeking the expertise of three leaders in the French biobanking ecosystem to accelerate the identification of new factors associated with major cardiovascular events (MACE*) in patients.

*(major adverse cardiovascular events)

Paris, 13th December, 2022

- Created in 2019 at the initiative of the Société Francophone du Diabète (SFD) and promoted by the Fondation Francophone pour la Recherche sur le Diabète (FFRD), the SFDT1 cohort aims to follow the health status of 15,000 people - adults or children over 6 years of age - living with type 1 diabetes, and to better understand this pathology in order to limit the burden of the disease. Currently, the cohort already includes nearly 1500 patients.
- SFDT1 collects a great deal of sources of information, including a biological bank that will contain biological samples from nearly 2000 patients. The SFD and the FFRD wish to develop the management of this biobank by setting up a collaboration with ADKINS BIOSCIENCES, an expert in networked biobanking and in the creation and management of biological resources collections in human health, Modul-Bio, an expert in innovative software solutions for the management of biospecimens, and CREAPHARM BIOSERVICES, a French private biobank offering highly secure storage of products of biological origin.
- This collaboration provides for more than 3,000 samples, of four different types (blood, urine, saliva, hair) to be taken at inclusion and then at 3, 6 and 9 years additional sample collections to be made available to researchers.
- Beyond this period, the SFD hopes to increase the total number of patients included - adults and children - in the SFDT1 study to 15,000, mobilising more than 70 clinical centres and CRBs throughout France.

The SFDT1 study: the disease, medical needs and means implemented

1) Background on type 1 diabetes, its main forms of complications and medical needs for better prevention of MACE

Cardiovascular disease is a common complication of type 1 diabetes (T1DM). Patients with T1DM have a doubled risk of cardiovascular (CV) mortality, even with good glycaemic control, compared to the general population. In addition, it has been shown that patients with T1DM without traditional CV risk factors have an approximately 80% higher risk of a CV event compared to individuals without diabetes. This indicates that other modifiable factors not related to CV mortality remain to be explored. Glycaemic variability, as assessed by continuous glucose monitoring (CGM), or hypoglycaemia, are candidates that may play a role in the increased CV mortality in T1DM patients.

2) The objectives of SFDT1: to facilitate access, optimised management and storage of biological resources tailored to the scientific community

The biobank built in the framework of SFDT1 will allow the identification and characterisation of new biomarkers and metabolic pathways associated with the health status and complications of people living with type 1 diabetes.

"Our objective is to identify new markers of cardiovascular risk from blood, saliva and urine samples, allowing in particular the identification of the role of genetic and epigenetic markers, and the exploration of the role of the environment, in particular endocrine disruptors in hair analysis." Jean-Pierre RIVELINE, co-coordinator of the SFDT1 cohort.

Relying on the synergies of 3 major players in biobanking in France

1) Coordination of the establishment of the SFDT-1 biospecimen collection

ADKINS BIOSCIENCES is committed to an optimization approach for an efficient and standardized management of all biobanking processes deployed during the constitution of the SFDT-1 biospecimen collection.

"With its expertise in networked biobanking, its privileged relationships with academic biological resource centres (BRCs), and its expertise in the management of data centralisation tools, ADKINS BIOSCIENCES intends to provide the SFD with tailor-made support to federate all those involved in the network, and to promote collection within optimised timeframes. »

Emilie ROBERT, Executive Director of ADKINS BIOSCIENCES.

Thanks to its knowledge of the field, ADKINS BIOSCIENCES will be in charge of the selection and affiliation of CRBs with clinical services to ensure the collection, processing and storage of samples in a certified environment (ISO 9001 and / or NF S 96 900 and/or ISO 20 387).

In addition to its consulting activity for the improvement and operation of the network (coordination of centres, harmonisation of practices, document management, etc.), ADKINS BIOSCIENCES will offer training services for the staff of the centres covering the operational details of collection as well as the use of a dedicated database developed by MODUL-BIO. Finally, ADKINS BIOSCIENCES will work in close

collaboration with CREAPHARM BIOSERVICES to manage the centralisation of samples from the different BRCs involved.

2) Implementation of MBioLIMS BioBanking®, a software dedicated to the management of biological data

MODUL-BIO will set up their product MBioLIMS BioBanking® software to manage and centralise information concerning the patients and samples of the SFDT1 cohort. All centres involved in sample collection will have access to the software. The system will be configured to automatically offer the expected samples at each patient visit. Users will be allowed to work only on data relevant to their centres. The SFD will have a supervisory role and will be able to view, manage and analyse data from all participating sites.

"The main interest of Modul-Bio's biobanking software is to centralise patient and biological information, in order to facilitate the analysis of the cohort data, and thus help the SFD to better understand type 1 diabetes in order to develop new therapies."

Laurent JACOTOT, CEO of MODUL-BIO.

MBioLIMS BioBanking® software will ensure the complete management of the life cycle of the samples and associated data of the cohort, in order to guarantee an excellent traceability and homogeneity of the collected data.

The SFDT1 patient data, including their biological data, will be stored in a secure manner. The system will be hosted in an HDS-certified datacenter to ensure compliance and protection of health data.

3) Secure storage of SFDT-1 biospecimens and management of collection kits

CREAPHARM BIOSERVICES manages the collection material, the logistics and the biobanking of the SFDT-1 study biological resources.

"As a specialist in the all-temperature storage of precious biological samples, CREAPHARM provides the SFD with its high-security biobank and its expertise to store both the existing collection and the samples of patients newly included in the cohort."

Frédéric MALBOZE, Director of CREAPHARM BIOSERVICES.

The entire collection will be repatriated to be preserved in the best conditions in the French biobank. Prospective samples will be regularly collected from the different BRCs mobilised by ADKINS BIOSCIENCES for the study and transported under suitable temperature conditions. Depending on their nature, they will be stored at -80°C or in a controlled environment. To optimise storage capacity, the collection will be reorganised within the biobank under a study.

In this study, the SFD also relies on CREAPHARM's experience in the design, constitution and distribution of kits for the collection of blood, urine, saliva and hair samples.

ABOUT ADKINS BIOSCIENCES

ADKINS BIOSCIENCES is a CRO specialising in biospecimen sourcing for Life Science companies, with recognised multidisciplinary expertise and know-how in the field of onco-haematology in Europe. The company provides customised collection building and management, identification and provision of existing samples, and advice on networked biobanking activities.

As a partner in the continuum of basic, translational and clinical research, ADKINS BIOSCIENCES accelerates the emergence of new therapies including biotherapies and advanced therapy drugs in numerous indications (oncology, immunology, virology, rare diseases, etc.), thus offering new perspectives for patients within the framework of predictive and personalized medicine protocols.

For more information: www.adkins-biosciences.com

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ABOUT MODUL-BIO

With more than 19 years of experience, MODUL-BIO, a privately held company with offices in France and Canada, is a leading publisher of biobanking software dedicated to the management of biological sample collection data for biological resource centres, national cohort projects, biotechnology and diagnostic companies.

For more information: www.modul-bio.com.

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ABOUT CREAPHARM BIOSERVICES

CREAPHARM BIOSERVICES is a French private biobank with a unique infrastructure, specialising in the storage and logistics of biological products at any temperature (from -196°C to room temperature). The guarantee of ultra-secure storage, in compliance with GMP requirements, for collections of biological samples, clinical samples, cell therapy products and bioproduction intermediates. Beyond operations, pharmaceutical laboratories, biotechnology companies and research centres benefit from consulting, auditing and training services provided by our cryopreservation experts.

CREAPHARM BIOSERVICES is an ISO 9001, ISO 20387 and NF S96-900 certified Biological Resource Centre (BRC). The storage of cell and tissue therapy products is governed by the authorisation granted by the ANSM according to article L.1243.2 of the Public Health Code.

For more information: <https://www.creapharm-pharma.com/biostorage/>