

## **General Description of Codex4SMEs**

The Interreg project Codex4SMEs (Companion diagnostics expedited for small and medium-sized enterprises) plans to improve healthcare by enhanced adoption of Personalized Medicine in North-West Europe. The objective is to establish a network, which supports SMEs along the value chain of Companion diagnostics (Cdx) development.

Companion diagnostics (Cdx) are an indispensable tool for optimum application of Personalized Medicine: they allow tests to determine the molecular causes of a disease before treatment has started. However, thus far the development of companion diagnostics has been highly time-consuming and costly, so at present it is only used in the context of very few treatments.

Codex4SMEs is establishing a transnational network of nine partners and two sub-partners from seven countries (DE, FR, NL, UK, IE, LU and AT) and expedite the development of the SMEs' products in the field of Cdx. There is a need to improve SMEs' innovative capabilities and raise both international competitiveness and the impact of North-West Europe SMEs in this global market as the USA are far ahead - Codex4SMEs will directly address this challenge.

### **Biobank Graz (BBG): Lead partner for Knowledge Transfer Service within the Codex4SMEs network**

Biobank Graz (BBG) of the Medical University Graz is the largest academic and clinical biobank in Europe and member of the European biobanking network BBRMI-ERIC and the Austrian network BBRMI.at. Biobank Graz offers its services not only to scientists at Medical University of Graz, but also to scientists from academia and industry worldwide. Due to its leading position in automation of collection and storage of samples, the maintenance of highest sample quality is one of the key features of Biobank Graz.

Biobank Graz has been specifically designed to support the needs of biomedical research in the fields of human diseases, drug discovery and public health. Advanced modern biomedical research that aims at improved therapeutic and diagnostic methods and strategies eventually culminates in personalized medicine and requires an integrated infrastructure which links biobanks with the required IT-infrastructure, analysis platforms, systems biology and other biological resources.

Biobank Graz currently contains approx. 20 million samples from approx. 1.2 million donors representing a non-selected patient group characteristic of Central Europe from patients treated at the LKH University Hospital Graz during the last 30 years. Biobank Graz comprises both population-based and disease-focused collections of human biological material. Samples include a large number of FFPE blocks stored at room temperature, fresh frozen cryo samples stored in the vapour phase of liquid nitrogen as well as a large variety of body fluids (e.g. serum, plasma, whole blood, buffy coat, urine and liquor) stored at minus 80°C. Collection of fluid samples as well as all storage facilities are based on innovative automated or semi-automated systems. Biobank Graz is serving approximately 300 projects requests each year.

## Contact information

Regional partners for application related questions:

- University of Leicester (and subpartner),UK
- BOM Holding BV, NL
- WestBIC, IE
- Innovation Quarter (and subpartner),NL
- Medicen Paris Region, FR
- BioRegio STERN Management GmbH, DE
- CÙRAM, IE
- Integrated Biobank of Luxembourg, LU

Point of contact for Knowledge Transfer Service related questions:

Biobank Graz:

E: [codex4smes@medunigraz.at](mailto:codex4smes@medunigraz.at)

## General Workflow of Codex4SMEs

### Application requirements:

**European** SMEs in the field of (Companion) Diagnostics for Personalized Medicine may apply to participate in the project via the regional partner network of the Interreg NWE Codex4SMEs project. They are welcome to submit an application.

As a **North-West-Europe (NWE) approach**, SMEs from all over NWE and especially from one of the **participating partner regions** (see table of partners below) will receive preferential treatment for the offered biobank services.

Region/Country	Partner	Contact email address
Regions of Stuttgart, Tübingen, Reutlingen, Neckar Alb   Germany	BioRegio STERN	codex4smes@bioregio-stern.de
North Brabant   The Netherlands	BOM Business development & foreign investment BV	codex4smes@bom.nl
Zuid-Holland   The Netherlands	InnovationQuarter	codex4smes@innovationquarter.nl
France	MEDICEN Paris Region	codex4smes@medicen.org
Ireland	WestBIC	codex4smes@westbic.ie
Ireland	CÚRAM Centre for research in Medical Devices	codex4smes@curamdevices.ie
United Kingdom	University of Leicester/Medilink	
Luxembourg	Integrated Biobank of Luxembourg	codex4smes@ibbl.lu
Austria	Biobank Graz at the Medical University of Graz	codex4smes@medunigraz.at

SMEs can't apply for the same support scheme twice if they received access to the relevant service already. However, they can apply for different services and combine them.

### Knowledge Transfer Service:

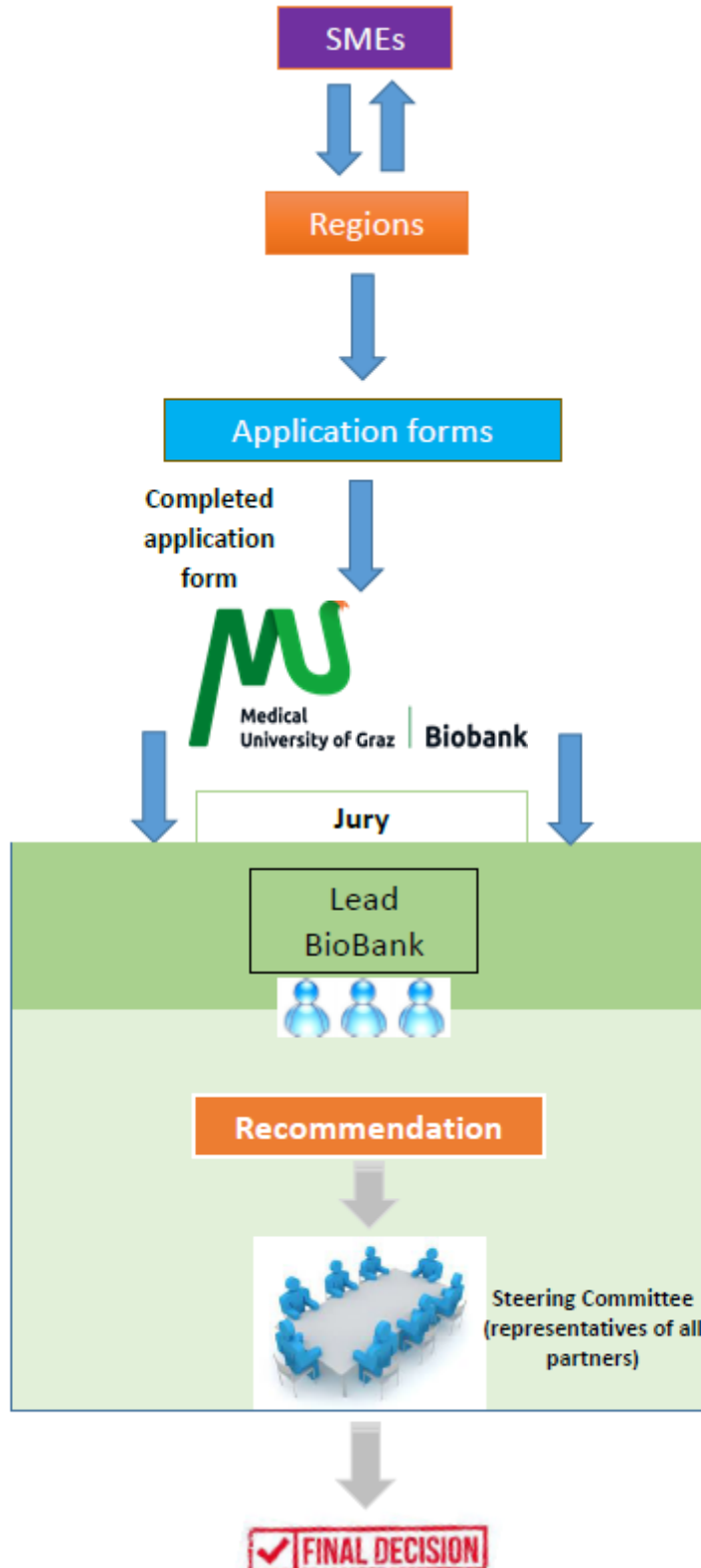
If access to a Knowledge Transfer Service is required for the applicants project the respective documents and application forms described later in this guideline have to be submitted to either of the regional partners or directly to Biobank Graz (BBG) which is the responsible partner for the Knowledge Transfer Service within the Codex4SMEs network.

- The feasibility of the requested Knowledge Transfer Service is reviewed by Biobank Graz.
- If the requested Knowledge Transfer Service is available from Biobank Graz the submitted project applications are reviewed on a weekly base.
- The applications will be submitted to the Codex4SMEs Jury consisting of three staff members of BBG and of the members of the Steering Committee, composed of representatives of each partner institution of the Codex4SMEs project.
- The Codex4SMEs Jury will review the applications and will finally decide if an applicant will be granted access to the Knowledge Transfer Service through the framework of Codex4SMEs.

### Data Protection Regulation

All data submitted to a respective project partner of the Codex4SMEs consortium will be treated according to the EU General Data Protection Regulation (GDPR).

## General Workflow Overview



### Service Portfolio Knowledge Transfer

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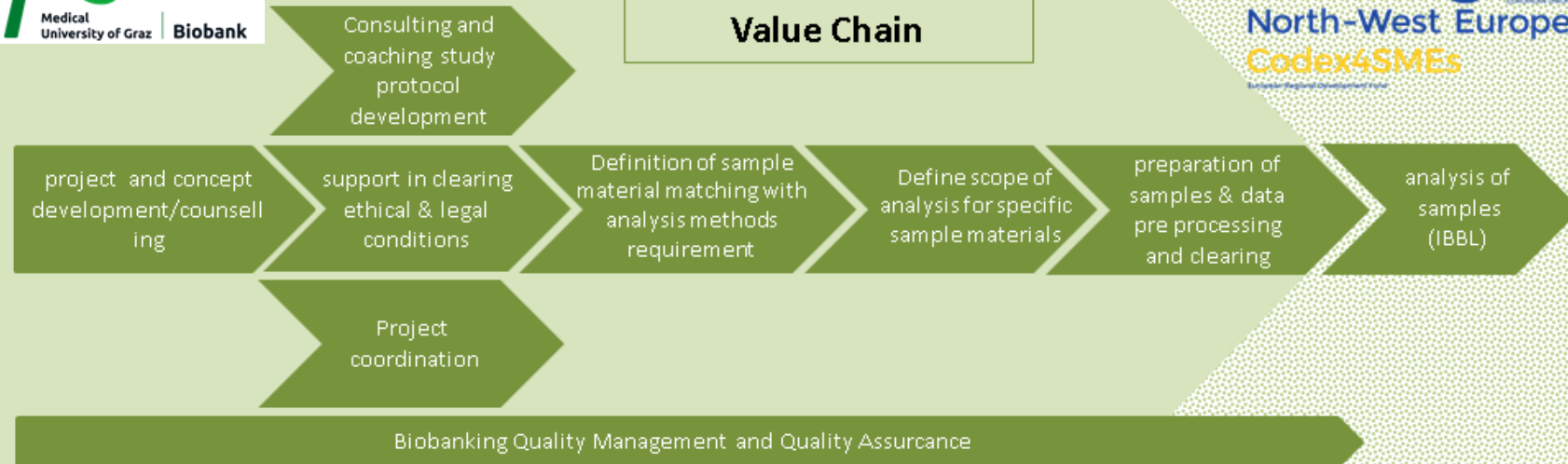
- ❖ Development of project ideas and concept development/counselling
- ❖ Project coordination
- ❖ Consulting and coaching - study protocol development
- ❖ Support in clearing ethical & legal conditions
- ❖ Definition of sample material matching with analysis methods requirement
- ❖ Define scope of analysis for specific sample materials
- ❖ Preparation of samples & Data pre-processing and clearing
- ❖ Biobanking quality management and quality assurance

### Overview Educational and Networking Activities of a Biobank

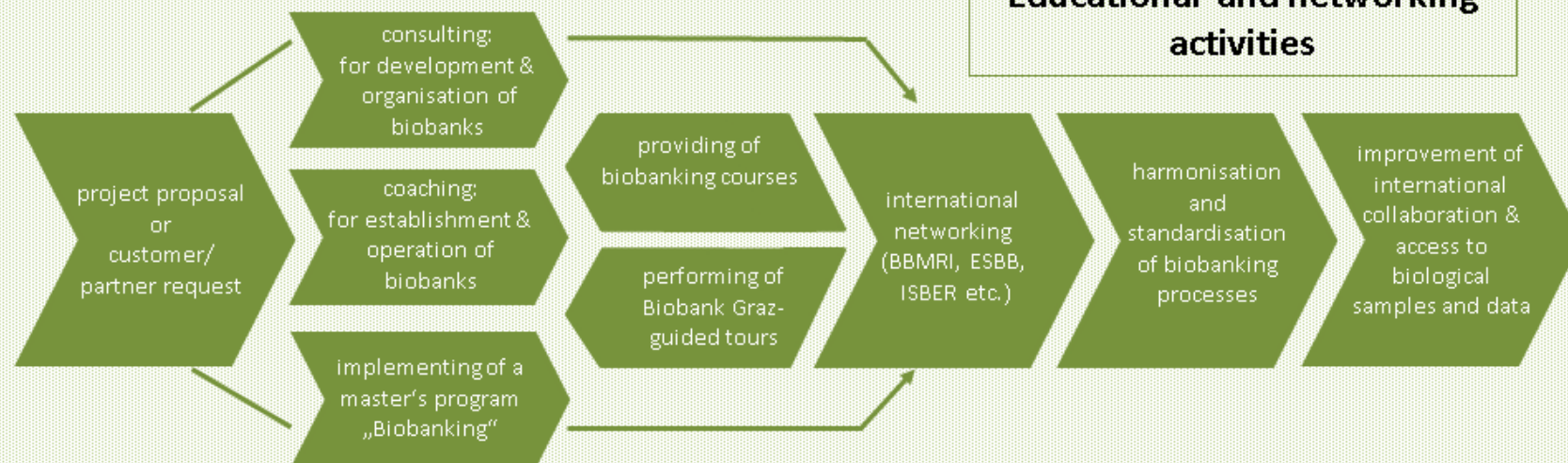
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- ❖ Development of projects with educational contents and biobanking trainings
- ❖ Consulting and coaching:
  - In organisation of a biobank (e.g. prospective sample collection; planning and realization of prospective study cohorts, legal, ethical, technical and organizational aspects of Biobanking)
  - Support at the installation of new biobanks
  - Protection of sample quality and prevention of sample loss
  - Minimal sample consumption
  - Comparability and standardization of analyses
  - Use of analysis data in different studies
  - Cost minimization
- ❖ Guided tour through the Biobank Graz
- ❖ Biobanking courses
- ❖ Master of Science in Biobanking
- ❖ Contact to and networking with other biobanks

### Service Portfolio – Value Chain



### Educational and networking activities



## Knowledge Transfer Service Access

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1. Codex4SMEs – Homepage: [www.nweurope.eu/codex4smes](http://www.nweurope.eu/codex4smes)
2. Regional Partner's Network Homepage
3. Webinars
  - 3.1. on general topics (dates to be announced on the Codex4SMEs homepage)
  - 3.2. on specific topics on demand (request during roadshows or through application)
4. On-site visit
  - 4.1. Biobanking course
  - 4.2. Guided tours
  - 4.3. Booking single modules of master course "MSc Biobanking"
5. Direct consulting and counselling on requested topics of our service catalogue

## Important Links

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BIOBANK GRAZ:

<http://biobank.medunigraz.at/en/>

ZMF - Center for Medical Research – Core Facility:

<http://zmf.medunigraz.at/en/core-facilities/>

BBMRI CATALOG:

[http://catalog.bbmri.at/biobank.html?\\_cachebust=2.6.2&bbid=MUG](http://catalog.bbmri.at/biobank.html?_cachebust=2.6.2&bbid=MUG)

MASTER Program:

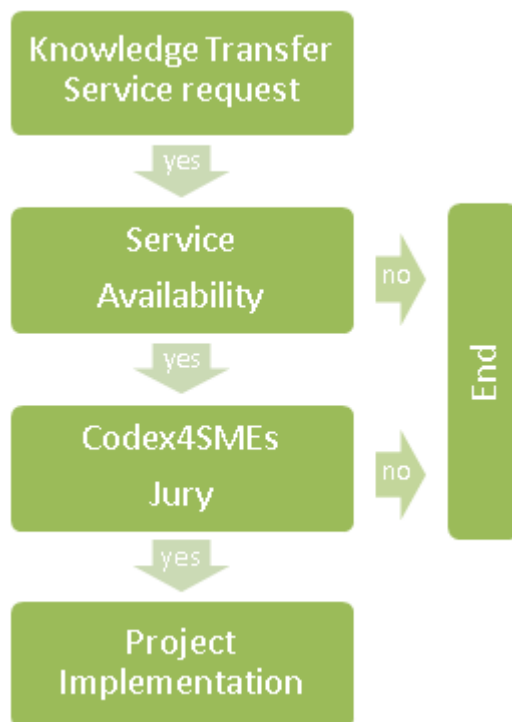
[www.medunigraz.at/mscbiobanking](http://www.medunigraz.at/mscbiobanking)

BIOBANKING COURSE:

<http://biobank.medunigraz.at/education/biobanking-course/>



## Knowledge Transfer Service Workflow



## Post Project “De Minimis” Processing

After the service has been finalized the beneficiary SME will receive a notification letter by its regional contact person of the project. Additional information regarding De Minimis Regulation can be found in the next section.

## Additional information on De Minimis regulation

### 1 De minimis<sup>[1]</sup>

The *de minimis* rule allows for State aid relevant activities, but only those that are of minimum financial importance, up to a threshold in a rolling three year period, subject to certain administrative steps being taken. The amounts of *de minimis* aid granted to a single undertaking within the last 3 financial years cannot exceed €200,000<sup>[2]</sup>.

#### 1.1 Single undertaking

Single undertaking means all enterprises having at least one of the following relationships with each other:

- (a) one enterprise has a majority of the shareholders' or members' voting rights in another enterprise;
- (b) one enterprise has the right to appoint or remove a majority of the members of the administrative, management or supervisory body of another enterprise;
- (c) one enterprise has the right to exercise a dominant influence over another enterprise pursuant to a contract entered into with that enterprise or to a provision in its memorandum or articles of association;
- (d) one enterprise, which is a shareholder in or member of another enterprise, controls alone, pursuant to an agreement with other shareholders in or members of that enterprise, a majority of shareholders' or members' voting rights in that enterprise.

Enterprises having any of the relationships referred to in points (a) to (d) through one or more other enterprises shall also be considered to be a single undertaking.

Please note that enterprise means here any undertaking performing economic activity.

#### 1.2 Exclusions

*De minimis* granted by NWE Programme (both direct and downstream) does not apply to:

- (a) aid granted to undertakings active in the fishery and aquaculture sector,
- (b) aid granted to undertakings active in the primary production of agricultural products;
- (c) aid granted to undertakings active in the sector of processing and marketing of agricultural products, in the following cases:
  - i. where the amount of the aid is fixed on the basis of the price or quantity of such products purchased from primary producers or put on the market by the undertakings concerned;
  - ii. where the aid is conditional on being partly or entirely passed on to primary producers;
- (d) aid to export-related activities towards third countries or Member States, namely aid directly linked to the quantities exported, to the establishment and operation of a distribution network or to other current expenditure linked to the export activity;
- (e) aid contingent upon the use of domestic over imported goods.

<sup>[1]</sup> Commission Regulation (EU) No 1407/2013 of 18 December 2013 on the application of Articles 107 and 108 of the Treaty on the Functioning of the European Union to *de minimis* aid Text with EEA relevance, <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1458746162354&uri=CELEX:32013R1407>

<sup>[2]</sup> In the road freight transport sector this threshold is decreased to €100,000 and will not apply for acquisition of road freight transport vehicles.