|  |  |  |
| --- | --- | --- |
| Logo, company name  Description automatically generated | **Application Form** | A picture containing text  Description automatically generated |
| * This application form must be completed and sent to IBBL [Codex4SMEs@ibbl.lu](mailto:Codex4SMEs@ibbl.lu) between:   + **December 1st, 2022 and February 28th, 2023.** * Please complete the application form as exhaustively and accurately as possible. * For questions related to completing this form, please contact: [Codex4SMEs@ibbl.lu](mailto:Codex4SMEs@ibbl.lu) | | |

|  |  |
| --- | --- |
| **Submitted by (Name):** | Name & Surname (*this is the person who will receive all the official communications about the programme)*:  Title:  E-Mail:  Telephone Number:  Co-applicant(s) (if applicable): |
| **Organisation and Address:** | Name of Organisation:  Department:  Address:  Country: |

|  |  |
| --- | --- |
| **Personal data processing** | *Codex4SMEs is an Interreg NWE project, which will support European SMEs in the growth area of Personalised Medicine. The aim of this project is to build a transnational network to accelerate the development of (companion) diagnostics throughout the whole value chain for SMEs in your country and in other European countries.*  *All information will be treated with the utmost confidentiality. The Codex4SMEs expert group will sign a contract (rules of procedure), protecting information and data gained from the applicants during the application and evaluation processes. Please check the consent box below according to your preferences.*  **I confirm that the company named above meets the** [**SME definition**](https://ec.europa.eu/growth/smes/sme-definition_en) **of** **the EU Commission.**  **I have the right to give out information regarding this/these biomarker/s candidate(s)**  **I am authorized to submit this application on behalf of my institution/company**  **I hereby consent to the completeness and accuracy of information given in this application as well as all documents**  **I approve the storage and processing of transmitted personal information and data in accordance with the EU General Data Protection Regulation**  **I agree to provide the Codex4SMEs partner with a short report about the results of the Action within one month after the end of the Action (The recipient will use and fill in a dedicated reporting template provided by the Codex4SMEs partner).** |
| **Name, date and signature** |  |

## Codex4SMEs Services- Modular biomarker validation services

|  |  |
| --- | --- |
| **Biomarker candidate**  **Mandatory requirement:** The SME must provide the sample to work on (in-house) or must have already made arrangements with CROs or sample providers for the LIH-IBBL Translational Biomarker Group to acquire biospecimens within a reasonable time. | |
| **I hereby confirm that appropriate samples are available, and can be transferred to LIH-IBBL following the signature of a Material Transfer Agreement (MTA)** | |
| **Select one or more biomarker validation service** | **BM pre-analytical validation**: to assess the pre-analytical variables dealing with BM robustness (ex.: collection tube, sample processing delays, sample freeze/thaw cycles, ischemia and fixation time, etc.)  **BM analytical validation**: to assess the characteristic of the method of choice (ex: mass-spec versus ELISA, qPCR vs ddPRC, etc.) and its performance (ex: LOD/LOQ, linearity, trueness, etc.)  **BM** **clinical verification**: this step is meant as a small scale testing (max 50 samples per each clinical case and appropriate control/s, if needed) to offer an overview of a potential clinical validation outcome, thus decreasing the chances of future cross-validation failures |
| **Biomarker candidate** | |
| **Disease Area (human only):** | *(Provide information on disease area of your biomarker candidate):* |
| **Type of Biomarker** | *(Please tick as appropriate)*  diagnostic  prognostic  predictive  other, please specify: |
| **Class of Biomarker** | *(Please tick as appropriate)*  protein  DNA (human  RNA/miRNA  other, please specify: |
| **Analytical Method** | *(Please tick as appropriate)*  immunoenzymatic  qPCR  RT-qPCR  flow cytometry  other, please specify: |
| **Biospecimen Type** | *(Please tick as appropriate)*  whole blood  serum  plasma  peripheral blood mononuclear cells  cerebrospinal fluid  other, please specify: |
| **Describe scientific excellence and innovation potential of biomarker** | |
| **Description of Biomarker case** | *(Please describe: (1) The nature, use and clinical need for your biomarker (2) Your preliminary results/statistical analysis to show the potential of your biomarker. Max. 3000 characters)* |
| **Preliminary results/statistical analysis** | *(Status of biomarker proof-of-concept – to what extent has the biomarker been verified so far)*  Biomarker proof-of-concept done so far, on:  cases (with formal diagnosis)  controls  independent cohorts  independent laboratories  Proof-of-concept results published? Yes No  Reference to published results (Maximum 3 references) and patent number (if applicable): |
| **Clinical need for biomarker & Innovation potential** | *Is there already a (Companion) diagnostics product available using this biomarker?*  No  Yes  *If yes, please indicate the advantage of your method and/or the clinical area where this biomarker is being used (max. 500 characters):* |
| **Commercialisation & innovation potential** | *Is there already a Companion diagnostics product available on the market, and approved for clinical use for the same medical condition, based on this biomarker?*  No  Yes  *If yes, please indicate the advantages of your method, compared to the one already in use (max. 800 characters):* |
| **I agree to the following in case my application is approved** | Sign a Non-Disclosure Agreement (NDA) with IBBL  Sign a Material Transfer Agreement (MTA) with IBBL for the transfer of the required samples  Provide all information and documentation required to implement the biomarker validation plan, in particular full details of the materials and methods to allow IBBL to establish the method in its own laboratory  Acknowledge IBBL, and the Codex4SMEs partners in scientific publications and commercial brochures  Allow Codex4SMEs consortium to use the name of the winners for communication purposes |

## De-Minimis self-declaration

Please complete this declaration of previous State aid received under the [de-minimis rule](https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=LEGISSUM:l26121&from=EN). Using this information we will assess your eligibility to receive assistance. Please note that having received previous aid under the de-minimis Regulation does not automatically disqualify you from receiving further de-minimis aid from the North West Europe Programme. Please include any aid received, from national or EU sources, in this declaration.

Declaration

I, the undersigned, representing [enter organization name] and receiving aid within the framework of the project Codex4SMEs declare that:

the institution I represent and all other entities belonging to the same company group as my institution have not received any contribution falling under the de-minimis Regulation during the previous three fiscal years (this being the current fiscal year and the previous two fiscal years)

the institution I represent and all other entities belonging to the same company group as my institution have received the following contribution(s) falling under the de-minimis Regulation during the previous three fiscal years (this being the current fiscal year and the previous two fiscal years):

|  |  |  |  |
| --- | --- | --- | --- |
| Beneficiary, project name and programme | Country granting the de minimis aid | Amount granted, in EUR | Date of granting |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  | **Total:** |

I acknowledge that untruthful/false declarations, in addition to the administrative sanctions and the request for refunding unduly received contribution charged with the interests, can also be prosecuted by the penal code.

