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| Logo, company name  Description automatically generated | **Application Form** | A picture containing text  Description automatically generated |
| * This application form must be completed and sent to EATRIS [codex4smes@eatris.eu](mailto:codex4smes@eatris.eu) between:   + **March 1st and August 31st, 2023.** * Please complete the application form as exhaustively and accurately as possible. * For questions related to completing this form, please contact: [codex4smes@eatris.eu](mailto:codex4smes@eatris.eu) | | |

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| **Submitted by (Name):** | Name / Surname / Title / Position:  Co-applicant(s) (if applicable): |
| **Organisation and Address:** |  |
| **Type of organisation** |  |

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| **Personal data processing** | *Personal data means any information relating to an identified or identifiable natural person (‘data subject’). Certain information you provide with this Research Proposal Form includes personal data such as name, position, title, e-mail or phone number of an applicant or co-applicant/s.*  *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 accept my personal data to be processed only for the purpose of EATRIS providing assistance or service according to this Research Proposal Form  I agree to my personal data being shared with the Codex4SMEs project in order to evaluate the submitted "Research Service" application, knowing that EU data protection rules will be strictly respected.  I accept that my personal data may be recorded in EATRIS database and processed by EATRIS for the purpose of future project/collaboration opportunities  I accept to receive electronic communications on EATRIS news, events and activities  *Personal data will be processed according to EATRIS* [*Privacy Policy*](https://eatris.eu/privacy-policy/) *and in compliance with the General Data Protection Regulation (GDPR). You can change your mind at any time or modify, restrict or withdraw above stated preferences upon request to: personaldata@eatris.eu or by post to EATRIS ERIC, De Boelelaan 1118, 1081 HZ Amsterdam, Netherlands*  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** |  |

## Project details

|  |  |
| --- | --- |
| **Project title** |  |
| **Management team and their expertise** | *Provide the list of project partners and their expertise* |
| **Project summary** | *Provide the summary of the project (max 300 words)* |

## Codex4SMEs Regulatory Assessment Service

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| --- | --- |
| **Product description** | *Provide details on the product* |
| **The product is under jurisdiction of *in vitro* diagnostic regulation (IVDR)?** | Yes  No  tbc |
| **Development stage** | *Provide details on the stage of development (preclinical lead finding – preclinical lead optimisation - pharmaceutical, pharmacotoxicological – clinical Phase I, II, III, dossier in preparation)*  *Has early/informal scientific advice been provided before?* |
| **Outline of work plan, brief description of (anticipated) steps/activities and how these are interlinked/planned during the project** | *Describe next steps in the project (planned and considered) and provide context on research objectives and working hypothesis where needed.* |
| **Unmet medical needs** | *Provide details on the indication, available treatment options (therapeutic or intervention)* |
| **Has a registration procedure been considered?** | *Centralised (EU), decentralised, mutual recognition, national, tbc.* |
| **What (formal) documentation is available for review by a regulatory expert?** | Investigator’s brochure  Briefing document  Business plan  Project plan / report  Patent publication  Scientific publication (peer reviewed)  Other, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **What are specific questions that need to be addressed by the regulatory expert?** | *If already known, phrase as questions and detail the specific regulatory guidance expected from a regulatory expert, in view of the (possible) anticipated end product(s) and the regulatory compliant development path(s) foreseen/ to be defined.* |

## 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):

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

