Interreg
North-West Europe
Codex4SMEs
European Regional Development Fund

Codex 4SMEs Service Catalogue

Codex4SMEs Fast-Track-Programme for Dx Manufacturers

With the mission of "**the right drug, at the right dose, at the right time, to the right patient**," the Interreg Nord-West Europe Codex4SMEs project funds the development of innovative diagnostics for improved personalized healthcare in Europe. The funding is targeted at small and medium-sized companies (SME) in the life sciences and medical technology sectors engaged in the development of diagnostics. For the development of improved diagnostics, nine partners from six EU countries have launched a strong Fast Track programme offering SMEs a wide range of services along the entire value chain.

Applicants' requirements

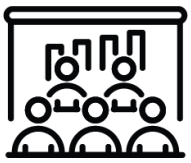
European **SMEs** in the Diagnostics area may apply to participate in the Codex4SMEs project via the regional partner network of the Interreg NWE Codex4SMEs project. Please check if your company meets the SME definition of the EU (more details via SME self-assessment). The services received through the Codex project will be deemed as state aid relevant. Therefore, SMEs are required to submit an application together with a self-declaration of the state aid received by the company under the *de-minimis* rule.

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 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
Luxembourg	Integrated BioBank of Luxembourg	codex4smes@ibbl.lu
Rhine-Neckar Metropolitan Region	Health Innovation Hub & Holding GmbH	Bojana.trajkovska@innovationinhealth.eu
Groot-Amsterdam	European Research Infrastructure for Translational Medicine	codex4smes@eatris.eu
Flanders	FlandersBio	willem.dhooge@flanders.bio

Service Overview

Note: Clicking on a service will direct you to a detailed description:



Interactive online seminars on biomarker validation

Tailored consultancy services on specific biomarker topics

Modular biomarker validation services

Meet & Match.Dx

Translational assessment

COVID-19 research services

Research services

Partner search

Full regulatory assessment

Business Growth programme

How to apply for services?

- ✓ Check your eligibility:
  - Does your company meets the SME definition of the EU?
  - Did your SME receive more than a total of €200.000 of De Minimis state aid between 2020 and 2022? For more information about *de-minimis* aid, please click here.
- ✓ Browse the service catalogue
- ✓ Select a service you want to apply for (Note: An SME can apply for several different services, however cannot apply for the same service more than once.)
- ✓ Complete application form
- ✓ Submit your application and your *de minimis* self-declaration

Rules of procedure and Data Protection Regulation

Rules of procedure
The Codex4SMEs Service Provider will sign a Letter of Engagement or Non-disclosure Agreement depending on the services for which the SME is applying, protecting information and data gained from the applicants during the application and evaluation processes.

Applicants have to agree to this procedure during the application process. Agreement to this procedure is given through the respective application form.

The applicants agree to complete the application form, including the self-declaration of the State aids received by the company under the *de-minimis* rule accurately and truthfully.

Data Protection Regulation
Data submitted via application form to partners of the Codex4SMEs consortium will be treated according to the EU Regulation 2016/679 (General Data Protection Regulation - "GDPR").

Service providers

IBBL - Integrated BioBank of Luxembourg

IBBL (Integrated BioBank of Luxembourg) is the lead Biobank for the Biomarker validation Services within the Codex4SMEs project. IBBL is an autonomous not-for-profit institute dedicated to helping researchers bridge the gap between bench and bedside. To accelerate the translation of biomarkers into the clinic, IBBL has developed a biomarker validation service that takes biomarker candidates through the early stages of validation from discovery right up to clinical validation. IBBL's scientific leaders have many years of experience in biomarker validation and a track record of bringing products to market. Its team of experts ensures that the design and execution of biomarker validation studies is done to the highest standards. IBBL can carry out all the steps of pre-clinical validation including, pre-analytical and analytical validation, a clinical verification pilot study and a comparison to gold standards/reference methods.

Health Innovation Hub & Holding GmbH

The Health Innovation Hub & Holding GmbH thrives to connect industry, science, entrepreneurship, society and politics within Health Care in Germany. We aim to facilitate, verify and apply innovative concepts to enrich the public with new scientific findings in Health Care such as in healthy ageing and other appliances. IN this, we help transfer innovation into tangible prodicts and services and strenghthen Health Care. The Health Innovation Hub & Holding supports companies, institutes and organizations with their service portfolio to get health innovation started in Digital health, Health Tech, Biotech and MedTech.

EATRIS - European infrastructure for translational medicine

EATRIS is the European infrastructure for translational medicine. We bring together resources and services for research communities to translate scientific discoveries into benefits for patients.
We provide access to a vast array of pre-clinical and clinical expertise and facilities that are available within 115+ top-tier academic centres across Europe. We focus on improving and optimising preclinical and early clinical development of drugs, vaccines and diagnostics. Solutions are developed in the fields of advanced therapy medicinal products, imaging and tracing, small molecules, vaccines and biomarkers.
Our research infrastructure offers a broad range of research services for both academia and industry across various research fields. In addition, we work with public funding agencies, charities and policy makers with tailored actions to help improve the translational research and innovation ecosystem. We also provide regulatory services, training and education and mentoring.

Services provided by IBBL

Interactive online seminars on biomarker validation topics - IBBL

IBBL provides detailed insights within various fields of biomarker topics such as regarding the importance of pre-analytics in biomarker discovery, the advantages of Biomarker Validation or sharing insights on concrete use cases. These insights will be provided within the format of an interactive online seminar tailored to the needs of interested SMEs.

What you get

Meet expert in the field

Insights on biomarker validation topics

Up to max. € 3.000

How it works

Interested SMEs will have to register for these online seminars and have the opportunity to provide information regarding their needs by answering a short questionnaire, as well as choosing between different provided appointments (where the seminars will be held) during the registration process. The SMEs will receive detailed information about date, time and title of the online seminar. The number of participants will be limited to max. 10 attendants.

Examples of topics:

- Importance of pre-analytics in biomarker discovery
- The advantages of Biomarker Validation
- Sharing insights on concrete use cases

Who should apply	Small and medium sized companies and Start-ups from the in vitro diagnostics area
Number of available online seminars	3 – each seminar will address a different topic
Application/Participation	The deadline for submitting the application is published on the project website: see Overview
Programme dates	The date for each online seminar is set in advance. An SME may attend only one of the three seminars.
Programme location	Online via Teams
Programme cost	Free of charge
Partners	IBBL and further specific experts in the field on demand
Contact	codex4smes@ibbl.lu
Find out more and apply	Applicants apply for services by submitting the application form and the *de-minimis* self-declaration to Codex4SMEs partner codex4smes@ibbl.lu before the closing date (see above).
Contractual obligation	None

Tailored consultancy services on specific biomarker topics - IBBL

Consultancy services are meant to increase the chances, for the SME's BM, to be successfully validated and subsequently translated into a diagnostic product, a drug or even be part of an algorithm with diagnostic, prognostic or predictive value.

IBBL provides coaching for a strategic biomarker development.

Since the creation of a dedicated platform, back in 2016, IBBL has provided to its clients a fee-for-service-based technical biomarker validation. Later on, the LIH-IBBL Translational Biomarker Validation Group has been involved in EU-funded projects aimed at translating newly discovered BM into diagnostic kits, personalized drugs, or key components in the AI-driven pipeline for personalized medicine.

Thanks to the expertise, and the variety of projects in which IBBL has been a key partner, the LIH-IBBL Translational Biomarker Group can now offer consultancy services to SMEs willing to exploit the translation of their BM further down the proof-of-concept phase.

What you get

Meet expert in the field

Tailored consultancy services on biomarker development

€ 3.000 voucher for consultancy services

How it works

Interested SMEs will have to fill in an application form detailing their needs for the consultancy service.

Some examples supporting the SME during the study design phase, the initial discovery stages, or right after proof-of-concept patent registration below include, but are not limited to, the proposed IBBL consultancy services:

- Circulating BM: choice of the most appropriate collection tube for downstream analysis, including sample handling, processing and storage conditions
- Tissue BM: tissue handling (ex.: warm and cold ischemia time) and processing (ex.: fixation time) for FFPE (formalin-fixed, paraffin-embedded) and FF (fresh-frozen) biospecimens
- Discovery technology platform: evaluation of its fitness-for-purpose in relation with the BM under study and considering its potential future translation (ex.: potential for platform bridging)

Who should apply	Small and medium sized companies and Start-ups from the in vitro diagnostics area
Number of available services	12 tailored consultancy services
How applicants are selected	Application will be evaluated by IBBL and the SMEs will receive an official confirmation of the whole Codex4SMEs consortium.
Application open	Continuously open call until September 2023
Programme dates	Dates will be arranged individually
Programme location	Online
Programme cost	Free of charge
Partners	IBBL
Contact	codex4smes@ibbl.lu
Find out more and apply	Applicants apply for services by submitting the application form and the *de-minimis* self-declaration to Codex4SMEs partner codex4smes@ibbl.lu before the closing date (see above).
Contractual obligation	The successful applicants agree to • Sign a Non-Disclosure Agreement (NDA) with IBBL • 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

Modular biomarker validation services - IBBL

IBBL provides research support on modular biomarker validation services.

The LIH-IBBL Translational Biomarker Group will offer to participating SMEs the following BM validation services:

- **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

Each SME can choose to request a full-fledged (all bullet-points above) service, in the order they wish.

Each SME can also select one or more validation item, again in the order they wish.

What you get

Meet expert in the field

Modular biomarker validation services

Up to a max. of € 30.000 voucher

How it works

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.

Who should apply	Small and medium sized enterprises (SME) and Start-ups from the in vitro diagnostics area
Number of available services	1
How applicants are selected	Evaluation by IBBL and confirmed by Codex4SMEs consortium as a whole, evaluation criteria
Evaluation criteria	1) Scientific excellence and innovation potential a. Soundness of preliminary results/statistical analysis b. Status of biomarker proof-of-concept – to what extent has the biomarker been verified so far c. Clinical need for biomarker d. Commercialisation potential e. Innovation potential 2) Technical feasibility a. Assay feasibility b. Access to biospecimens c. Is optimisation required? d. Homebrew or commercial assay e. Complexity of the biomarker/assay Similar weight will be given to scientific excellence and innovation potential, and to technical feasibility.
Application open	The deadline for submitting the application is published on the project website: see Overview This service is granted only to **one** SMEs
Programme dates	Dates will be arranged individually
Programme location	IBBL
Programme cost	Free of charge
Partners	IBBL
Contact	codex4smes@ibbl.lu
Find out more and apply	Applicants apply for services by submitting the application form and the *de-minimis* self-declaration to Codex4SMEs partner codex4smes@ibbl.lu before the closing date (see above).
Contractual obligation	The successful applicants agree to • Sign a Non-Disclosure Agreement (NDA) with IBBL • 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

Services provided by Health Innovation Hub & Holding GmbH

Meet & Match.Dx – Health Innovation Hub & Holding GmbH

The quest for better solutions to healthcare's greatest challenges starts with and depends on diagnostics. The advancement in diagnostic technologies and techniques is a driving force for many European companies to change the pace of healthcare service delivery.

If you are interested in working with them to change the way diseases are detected and diagnosed, join Meet & Match.Dx, a challenge-based acceleration programme that connects SMEs developing breakthrough diagnostic solutions with major pharmaceutical and medical technology companies in Europe through tailored workshops and one-to-one pitch sessions, with the aim to explore partnership opportunities. Check out the challenges in specific areas posed by our Pharma and MedTech partner companies and apply today!

What you get

One-on-one access to Pharma & MedTech decision-makers

Training and workshop with Pharma & MedTech partners and renowned experts

Demo Day to pitch your diagnostics solution to external Pharma & MedTech companies

How it works

The programme will consist of a set of pre-definited challenges by the Pharma & MedTech companies and SMEs are invited to apply to the challenges with an operational product/technology. Once the call is closed, the Pharma & MedTech companies will select the SMEs with whom they would explore partnership opportunities within the programme. Selected SMEs will be invited to participate in 4 programme modules, including a week-long training, pitch session with the challenge owner and a Demo day to showcase their solution to external Pharma & MedTech companies.

Module 1 - Training	Module 2 – Individual meetings	Module 3 Deepening contacts	Module 4 – Final Demo Day
Aim: provide the tools to SMEs to better tailor & present their proposal to the challenge owners	Aim: get to know each other through individual meetings in which the SMEs present their tailored solution to company representatives	Aim: selected SMEs have meetings at the corporates location to go into details of a possible collaboration	Aim: enhance SMEs visibility letting them present their solution & the developments accomplished during the programme to other corporates

• Training in different skills
• Workshops offered by the Pharmas & MedTech explaining in deep their challenge
	• 1:1 with all the SMEs enrolled in the programme in individual meetings divided in two parts:
	  • Pitch
	  • Q&A
		• SMEs will pitch at the Pharma & MedTech companies premises
		• 1:1 of SMEs with relevant people inside the company
			• SMEs pitch in front of Pharma & MedTech company representatives, Health Innovation Hub partner & stakeholders

May 2023 / Online	**Jun 2023 / Online**	**Jul 2023 / companies' premises**	**Sep 2023 / Online**

Challenges for 2023

1. **Integration of a cuffless blood pressure monitoring technology into the Beurer product portfolio** in collaboration with Beurer
2. **Simplified nucleic acid extraction and/or sample preparation** in collaboration with Aidian
3. **Improving healthcare access in low and middle-income countries** in collaboration with Siemens Healthineers
4. **Digital technologies to improve antibiotic prescription practices** in collaboration with Qiagen

Full description of the challenges is available here.

Programme dates

Module 1 – Training: May 2023
Module 2 – Pitching sessions: June 2023
Module 3 – Roadshow: July 2023
Module 4 – Demo Day: September 2023

Eligibility criteria

Small and medium-sized companies with a product/technology that addresses one of the challenges released by Pharma & MedTech companies.

How applicants are selected

Applications are selected based on the quality of the business idea, fit for the programme challenges, and team's motivation and level of commitment.

How to apply

Submit your application via the application portal until 23 April 2023, 23:59 CET.

Deadline to apply

23 April 2023, 23:59 CEST

Webinars

Get more info about the programme and the application process:

- 3 March, 2023, 11 am CET – Register here
- 28 March, 2023, 11 am CET – Register here

Programme location

Online/hybrid

Programme cost

Free of charge

Partners

Health Innovation Hub & Holding GmbH

Contact

Bojana Trajkovska (bojana.trajkovska@innovationinhealth.eu) and Ares Albà Roselló (ares.alba-rosello@innovationinhealth.eu)

Services provided by EATRIS

Translational assessment – EATRIS

Advancing promising diagnostics towards clinical application is a complex undertaking. Often translational challenges lead to projects high failure rates.

The objective of the present call is to **offer an additional valuable support to SMEs in assessing and optimising the translational feasibility and potential of the projects that your SME is interested in funding.**

In the context of Codex4SMEs project, EATRIS will perform a translational assessment of the project and will provide you with a feedback on issues such as medical need, market and pipeline overview, regulatory pathway, intellectual property and translational tools. The output of this assessment will support SMEs in gaining more confidence in selecting high potential projects, and its investigators can optimise their plans according the realities of the development pipeline.

What you get

Insight in health economics, IP and regulatory pathways

Full assessment of your translational research projects

Up to a €4000 voucher to use with experts in EATRIS network.

How it works

Who should apply	Small and medium sized enterprises (SMEs) and Start-ups from the diagnostics area (*in vitro* diagnostics, imaging, spectroscopy, electrophysiological techniques, etc.)
Number of available services	2
How applicants are selected	The *Translational assessment application* submitted by the SME, is evaluated by the Scientific team at EATRIS C&S according the following criteria: • The project is translational • Impact of the project for the diagnostics in health sector • Unmet medical need • Clinical feasibility • Development phase The final decision is given within 2 weeks.
Application open	Continuous open call until end of project in September 2023
Programme dates	Individual appointments between client and experts
Programme location	Online
Programme cost	Free of charge
Partners	EATRIS | European infrastructure for translational medicine
Contact	Emanuela Oldoni, PhD codex4smes@eatris.eu Scientific Programme Manager EATRIS | European infrastructure for translational medicine
Find out more and apply	Applicants apply for services by submitting the online application form and the *de-minimis* self-declaration to Codex4SMEs partners before the closing date (see above).

General Workflow for winners

Once approved, the SMEs is required to provide EATRIS with additional information in the format of business plan, flyer, leaflet or any document available at the company:

- Project research topic, background, objectives and hypothesis
- Outline of work plan, brief description of (anticipated) steps/activities and how these are interlinked/planned during the project
- Unmet medical need that the intended product meets
- Intellectual property (IP) strategy and the list of patents
- Regulatory strategy and the product classification

The translational feasibility of the project will be evaluated by experts at EATRIS. This will help you to identify potential gaps and bottlenecks that may be experienced during the execution of the project.

The translational assessment report is put together and provided by EATRIS to the service user within one month and comprises:

- Assessment of translational strategy, to ascertain whether the study goals defined in the proposal can be achieved in the most optimal way and to identify potential future technical or operational hurdles;
- Preliminary analysis of the intellectual property status, to detect potential issues in relation to protection of the invention;
- Assessment of medical need and clarity of end-product definition, to ascertain that the proposal has a clear clinical end-goal in mind, serving a defined patient population with unmet medical need;
- Preliminary analysis of regulatory pathway, to identify obvious potential conflicts with regulatory requirements towards authorisation of a new product.

During the translational assessment individual appointments (online) between client and experts might be organised.

Please note that the assessment will be based on the limited information provided in the proposal or business plan, and as such cannot be understood as a complete and/or authoritative advice, but as an opinion only. The information as part of the advice will be compiled to the best efforts of EATRIS.


1. Application submitted
Confidentiality
4. Report delivery
2. Application review
Eligibility criteria
EATRIS Evaluation
3. Translational assessment
Experts' consultation

COVID-19 research services - EATRIS

An effective response to the COVID-19 pandemic requires a robust surveillance strategy, for which virus testing will be central. Diagnostic screening should be performed at a mass scale, extended to the asymptomatic population, and repeated over time. Different types of diagnostic tests are now available with alternative methods and benefits. As monitoring capacity is limited, there is a strong necessity for new strategies that could massively increase laboratory efficiency while maintaining the benefit of time- and cost-effectiveness.

The objective of the present call is to offer an additional valuable support to SMEs in their efforts in moving towards better diagnostics solutions for COVID-19, though Codex4SMEs project. **The selected SMEs will be provided with the latest COVID-19 related technologies and core facilities in the field from 115+ biomedical research institutes in 14 EU countries** belonging to the EATRIS.

In fact, EATRIS brings together resources and services to facilitate academic collaborations with industry. The infrastructure's resources are highly relevant for SMEs in the context of the COVID-19 pandemic caused by the SARS-CoV-2 virus and include, among others, the following expertise and services:

- Extensive expertise in the Biomarkers of dysregulated and protective immune response in COVID-19 patients.
- Possibility to single- and multiplex technology on patient plasma (pre-and post- treatment if any)
- Plasma and cell isolation and Olink technology for ongoing mechanisms determination
- Molecular biology quantifications (from qPCR to ddPCR)
- SARS-COV-2 models
- Samples access
- Large stocks of validated and infective SARS-COV-2 for in vitro and in vivo assays
- In vivo studies of viral pathogenesis and antiviral drug safety/efficacy.

EATRIS serves as a single point of contact, provide (legal) support and act as a negotiator to facilitate project initiation and monitor project execution when needed.

What you get

Face-to-face time with European pre-clinical and clinical experts in COVID-19

Access to COVID-19 bio-samples and technologies from European research infrastructure

Up to a €25000 voucher to use for wet lab research services from EATRIS network.

How it works

Who should apply	Small and medium sized companies and Start-ups from the diagnostics area (in vitro diagnostics, imaging, spectroscopy, electrophysiological techniques, etc.)
Number of available services	2
How applicants are selected	The *Research service application* submitted by the SME, is evaluated by the Scientific team at EATRIS C&S according the following criteria: • The project is translational • Impact of the project for the diagnostics in COVID-19 sector • Unmet medical need and clinical feasibility • Phase of development (TRL2-4) • Good match and technical scope The final decision is given one month after the call closure.
Application open	The deadline for submitting the application is published on the project website: see Overview The final decision will be given 1 month after the closure date.
Programme location	Online
Programme cost	Free of charge
Partners	EATRIS | European infrastructure for translational medicine
Contact	Emanuela Oldoni, PhD codex4smes@eatris.eu Scientific Programme Manager EATRIS | European infrastructure for translational medicine
Find out more and apply	A precise and detailed request would lead to a more fruitful response from the network and better inventory for the proposal as well as a fruitful match. Some of the COVID-19 research services available from EATRIS are listed in the EATRIS Portfolio. Applicants apply for services by submitting the online application form and the *de-minimis* self-declaration to Codex4SMEs partners before the closing date (see above).

General Workflow for winners

Upon approval, EATRIS will disseminate the service request to the institutes belonging to the infrastructure to identify interest and confirm capacity with(in) the expert centres.

After two weeks a report with at least three options will be presented to the client, who is in charge of selecting the scientific groups they would like to explore potential collaboration with. EATRIS will facilitate the initiation of the project by scheduling meetings with the chosen group as well as negotiating project agreements.

Research services - EATRIS

Are you developing diagnostics and need help with access to bio-samples (from the emergency department, recovered patients and radiology), validation of diagnostic tests (in terms of sensitivity or specificity) and contacts with relevant clinical trial sites?

The objective of the present call is to offer customised research services for SME's specific needs including access to bio-samples and bioreagents, technology platforms and diagnostic testing as well as support for the initiation of clinical trials. **The selected SMEs will be provided with the latest technologies and core facilities in the field from 115+ biomedical research institutes in 14 EU countries** belonging to the European infrastructure for Translational Medicine's (EATRIS).

EATRIS serves as a single point of contact, provide (legal) support and act as a negotiator to facilitate project initiation and monitor project execution when needed.

What you get

Face-to-face time with European pre-clinical and clinical experts

Access to bio-samples and Technologies from European research infrastructure

Up to a €25000 voucher to use for wet lab research services from EATRIS network.

How it works

Who should apply	Small and medium sized companies and Start-ups from the diagnostics area (in vitro diagnostics, imaging, spectroscopy, electrophysiological techniques, etc.)
Number of available services	2
How applicants are selected	The *Research service application* submitted by the SME, is evaluated by the Scientific team at EATRIS C&S according the following criteria: • The project is translational • Impact of the project for the diagnostics in health sector • Unmet medical need and clinical feasibility • Phase of development (TRL2-4) • Good match and technical scope The final decision is given one month after the call closure.
Application open	The deadline for submitting the application is published on the project website: see Overview The final decision will be given 1 month after the closure date.
Programme location	Online
Programme cost	Free of charge
Partners	EATRIS | European infrastructure for translational medicine
Contact	Emanuela Oldoni, PhD codex4smes@eatris.eu Scientific Programme Manager EATRIS | European infrastructure for translational medicine
Find out more and apply	A precise and detailed request would lead to a more fruitful response from the network and better inventory for the proposal as well as a fruitful match. Applicants apply for services by submitting the online application form and the *de-minimis* self-declaration to Codex4SMEs partners before the closing date (see above).

General Workflow for winners

Upon approval, EATRIS will disseminate the service request to the institutes belonging to the infrastructure to identify interest and confirm capacity with(in) the expert centres.

After two weeks a report with at least three options will be presented to the client, who is in charge of selecting the scientific groups they would like to explore potential collaboration with. EATRIS will facilitate the initiation of the project by scheduling meetings with the chosen group as well as negotiating project agreements.

Partner search - EATRIS

Do you need scientific support for the development your diagnostics?

The objective of the present call is to help you **find the right European academic partner** thanks to a comprehensive database of high-end capabilities and expertise of 115+ top-tier institutions.

The service is delivered by EATRIS and the team will provide you with a report listing the potential matches among EATRIS members within a few business days.

What you get

Matchmaking of scientists from high-ranking academic centres across Europe

Access to cutting-edge technologies and core facilities

Up to a €1000 voucher to use for partner search in our network.

How it works

Who should apply	Small and medium sized companies and Start-ups from the diagnostics area (in vitro diagnostics, imaging, spectroscopy, electrophysiological techniques, etc.)
Number of available services	6
How applicants are selected	The SME, is evaluated by the Codex4SMEs partners based on different criteria: • are you an SME, • is your company eligible for de minimis support, • willingness to participate
Application open	Continuous open call until end of project in September 2023. The final decision will be given within a week.
Programme dates	Individual appointments between client and experts
Programme location	Online
Programme cost	Free of charge
Partners	EATRIS | European infrastructure for translational medicine
Contact	Emanuela Oldoni, PhD codex4smes@eatris.eu Scientific Programme Manager EATRIS | European infrastructure for translational medicine
Find out more and apply	For accessing the research services the applicant has to fill and submit the *Partner search application.* Applicants apply for services by submitting the online application form and the *de-minimis* self-declaration to Codex4SMEs partners before the closing date (see above).

General Workflow for winners

Once approved, EATRIS team will provide you with a report listing the potential matches among EATRIS members within a few business days. It will then be the client responsibility to choose with whom explore a collaboration. Individual appointments between the SMEs and the best match identified might follow.

Full regulatory assessment - EATRIS

Addressing regulatory issues is an integral part of diagnostics development, and their importance will only continue to increase for the foreseeable future.

The objective of the present call is to **offer an additional valuable support to SMEs in assessing and optimising the regulatory strategy of the projects that your SME is interested in funding.**

In the context of Codex4SMEs project, EATRIS regulatory service and support centre is available to help guide SMEs through the regulatory complex world, especially for complex and hybrid products for which clear regulatory guidance may not be available. Early assessment of the potential requirements may prevent unnecessary project delays, reduce extra costs and most importantly prevent penalties resulting from non-adherence to legal requirements.

Through a combination of in-house and external partnerships with a range of regulatory experts and groups, EATRIS can provide regulatory support for diagnostics. Our range of services include:

- Expert opinion
- Guidance for the development of (in vitro) diagnostics related to conformity assessment in the EU
- Pre-clinical and clinical plan development
- Informal scientific advice with selected national competent authorities, for highly complex projects

Access to EATRIS Regulatory Database (free of charge) that contains information about the regulatory requirements, guidelines and legislations from 27 EU countries (as well as Norway, Switzerland, Turkey and Israel) regarding drug and medical device development derived from the application of European legislation.

What you get

Full expert advice on the regulatory requirements for your diagnostics

Access to EATRIS Regulatory Database

Up to a €6000 voucher for regulatory assessment

How it works

Who should apply	Small and medium sized companies and Start-ups from the diagnostics area (in vitro diagnostics, imaging, spectroscopy, electrophysiological techniques, etc.)
Number of available services	3
How applicants are selected	The *Regulatory assessment application* submitted by the SME, is evaluated by the Scientific team at EATRIS C&S according the following criteria: • The project is translational • Impact of the project for the diagnostics in health sector • Unmet medical need • Clinical feasibility • Development phase The final decision is given 1 month after the closure date of the call.
Application open	The deadline for submitting the application is published on the project website: see Overview The final decision will be given 1 month after the closure date.
Programme dates	Individual appointments between client and experts
Programme location	Online
Programme cost	Free of charge
Partners	EATRIS | European infrastructure for translational medicine
Contact	Emanuela Oldoni, PhD codex4smes@eatris.eu Scientific Programme Manager EATRIS | European infrastructure for translational medicine
Find out more and apply	For accessing the research services the applicant has to fill and submit the *Regulatory assessment application.* Applicants apply for services by submitting the online application form and the *de-minimis* self-declaration to Codex4SMEs partners before the closing date (see above).

General Workflow for winners

Once approved, the SMEs is required to provide EATRIS with additional information:

- Product description and its relationship with the in vitro diagnostic regulation (IVDR)
- Development stage
- Outline of work plan, brief description of (anticipated) steps/activities and how these are interlinked/planned during the project
- Details on the indication
- Registration
- Documentation available

The regulatory strategy of the project will be evaluated by experts at EATRIS. A report is put together and provided by EATRIS to the service user within one month.

Please note that this assessment is based on the limited information provided in the proposal or business plan, and as such cannot be understood as a complete and/or authoritative advice, but as an opinion only. The information as part of the advice will be compiled to the best efforts of EATRIS.

Other services

Business Growth Programme

The Business Growth Programme will offer expertise within various fields relevant for SMEs' market and business growth.

Examples of topics which could be covered in the programme:

- Regulatory issues
- Reimbursement issues
- Market analysis issues
- Investor readiness issues

The Business Growth Programme will be provided by the engagement of suitable experts from the different partner regions within the format of online training.

What you get

Meet experts in the field

Tailored consultancy service in the different business growth fields

Up to a €2000 voucher

How it works

Codex4SMEs will organise closed dedicated training with topics of most interest to small groups of SMEs (max. 3 SMEs per workshop).

Who should apply	Small and medium sized companies and Start-ups from diagnostics area (in vitro diagnostics, imaging, spectroscopy, electrophysiological techniques, etc.)
Number of available services	15
Application open	Please find the deadlines for workshop sign-up in the application form. The final decision will be given within a week.
Programme dates	The date for each online training is set in advance. An SME may attend only one of the provided seminars.
Programme location	Online
Programme cost	Free of charge
Partners	Innovation and Management Centre Limited T/A WestBIC
Contact	Eunan Cunningham, codex4smes@westbic.ie
Find out more and apply	Applicants apply for services by submitting the online application form and the *de-minimis* self-declaration to the regional Codex4SMEs partner codex4smes@westbic.ie.