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.