Fit 4 Innovation

Health Tech Market

Call for consultants

1. Introduction

This document sets out the Luxinnovation's expectations of consultants interested to enroll in the **Fit 4 Innovation – Health Tech Market (F4I – HT market)** program and it describes the consultant enrollment procedure.

The **F4I – HT market** program supports the competitiveness, sustainability and development of small and medium-sized enterprises (SMEs) in the health technology (health tech) sector in Luxembourg, facilitating access to **knowledge and expertise in the European regulatory framework for medical devices**.

The F4I – HT market program, organized by Luxinnovation and supported by the Ministry of the Economy, draws on the experience of consultants, experts in regulatory affairs of medical devices and *in vitro* diagnostic medical devices, and specialized in supporting the process for obtaining **CE marking** for MD/IVDs.

In line with the government priorities, defined in the *Data Driven Innovation Strategy* highlighting a keen interest in supporting competitiveness of digital health companies, the program was designed to cover the needs of all health tech companies, with a specific attention to those developing **digital technologies** such as medical software, artificial intelligence or data security algorithms.

2. Concept of the Fit 4 Innovation – Health Tech Market program

2.1. Context

Medical devices (MDs) and ***in vitro* diagnostic medical devices** (IVD-MDs), hereafter collectively referred to as MD/IVDs, are tools whose intended use has a medical purpose. They assist in diagnosis, prognosis, prevention, monitoring, treatment or alleviating of diseases, or in disability prevention. In addition to benefits for patients, the development and commercialization of new medical technologies contributes to the quality of healthcare systems.

In order to adapt with the technological progress of the past twenty years in health tech and to ensure better protection of public health and patient safety, the European Union recently replaced the existing directives with **two new regulations**:

- Regulation EU 2017/745 (or MDR), in force since May 2021
- Regulation EU 2017/746 (or IVDR), in force since May 2022

The European regulatory framework requires companies to guarantee the performance and safety of their MD/IVDs for patients and healthcare professionals. The up-front work to lay the necessary corporate foundations (*e.g.* implementation of a quality management system) and the assembly of the technical dossier for each product can be complex, especially for devices that recently have been up-classified to need clinical validation and implementation of quality management systems.

In addition, for **digital medical devices**, horizontal regulations also may apply to guarantee the protection, security of medical data (General Data Protection Regulation, GDPR: EU 2016/679, Cybersecurity Act: EU 2019/881) and, eventually, to guaranty the safety and respect of fundamental rights, in particular in case of Artificial Intelligence-based technologies (AI Act proposal: COM(2021)206).

Today, the Luxembourg health tech ecosystem is young, with ~ 50% of its companies created less than 10 years ago, and characterized by a high number of small companies. Remarkably, ~ 80% of the health tech workforce is active in companies with less than 10 employees. As MD/IVD certification requires multiple interlocking evaluations to successfully come together, without existing in-house skills and experience, it turns into a big hurdle for start-ups and SMEs, costing time and money.

The ambition of the Ministry of the Economy is to create a favorable environment, offering health tech companies the conditions needed to accelerate commercialization of their MD/IVDs in the European Single Market. To address the current market gap, the Ministry of the Economy is sponsoring this new support program to build up regulatory expertise in Luxembourg and to simplify access to regulatory expertise for health tech companies to enable them accelerate their regulatory strategic decision-making and roll out the implementation steps.

The **F4I – HT market** program targets health tech companies looking to (i) establish their regulatory roadmap for their innovative or new MD/IVDs on the European market, and (ii) identify and implement the necessary corporate procedures and documentation that are prerequisites to obtain **CE marking** for new MD/IVD.

2.2. Concept

The **F4I – HT market** program, funded by Ministry of the Economy and coordinated by Luxinnovation, is aimed at **SMEs** in the health tech sector intending to launch a specific, innovative and new **regulated MD/IVD** on the European market.

As part of the program, Luxinnovation facilitates the access of SMEs to the specific expertise needed to obtain CE marking through the selection and enrollment of **consultants**. Luxinnovation provides overall supervision of the program, facilitates its administrative management, assesses, in close collaboration with the competent authority for health and the Ministry of the Economy, the qualification of enrolled consultants and assures the sustainability of the program.

Company projects are carried out directly by the consultants, while Luxinnovation monitors the progress of the projects. The company selects the consultant with whom it will work from the list of consultants enrolled in the F4I – HT market program. The project can address one or multiple steps of the CE marking process, depending on the needs of the company, as justified by a sound regulatory roadmap highlighting those needs and challenges to be met.

2.3. Methodology of the program

Consultant choice by companies

As a first step, it is recommended that the company discusses its regulatory needs with Luxinnovation in order to outline a project that can address them. Following this initial meeting, Luxinnovation will suggest a few external experts among the consultants enrolled in the program, appropriate for the project scope. The company is expected to obtain unbinding quotes from several potential experts. Each consultant quote must describe the potential consulting project with sufficient information in order for the company to thoughtfully select the consultant with whom it will work within the framework of the F4I – HT market program (the details about the quote requirements are provided in section *5. Consultant obligations*).

Please, note that it is mandatory for the company to provide a minimum of three consultant quotes as part of its application, as well as a justification of the ultimate consultant choice.

Company application

Companies can request a Financial Aid under the Article 7 of the amended Act of 17 May 2017 on the Promotion of Research, Development and Innovation[1] for F4I – HT market from the Ministry of the Economy.

Companies can prepare their application for the **F4I – HT market** program with the support from Luxinnovation, and then apply for financial aid under the **SME innovation scheme** using the online assistant available on **MyGuichet.lu**.

*It is important to note that the company must submit its application to the Ministry of the Economy prior to the commencement of work with the consultant as any costs incurred before application are not eligible to the financial aid. The acknowledgment of receipt of the application submission from the Ministry of the Economy does not guarantee the co-funding of the company project (i.e. the project will be evaluated by the Ministry of the Economy, which will then send the company a **funding decision notice**.). The consultant can start its mission from reception of the acknowledgment of receipt, if the company assumes the risk not to be funded by the expected state aid.*

The procedure for company application is presented in details in the document *Terms and Conditions*.

Company project

The ***company project*** aims to establish their roadmap to CE marking for a specific, innovative and new MD/IVD. New products are defined as goods or services that have never been commercialized by the company or that significantly differ in their intended use from existing products, thus that are to be launched on a new market (here, in the medical market). As previously mentioned, of particular interest are projects that focus on **digital technologies** (*e.g.* Artificial Intelligence, mobile health, telemedicine, Big Data analytics...).

A typical CE marking process can be schematically broken down into eight steps (Figure 1). These eight steps are aligned with the scope and thus, eligible for funding in the context of the F4I – HT market program. Based on the internal expertise of the company and on the maturity of the regulated product to be certified, the company project can cover the whole process or only includes specific steps.

[1] Law of 17 May 2017 on the promotion of Research, Development and Innovation: https://legilux.public.lu/eli/etat/leg/loi/2017/05/17/a544/jo

Accepted projects must demonstrate how they will help the company unlock a strategic regulatory bottleneck at company level or product level that is preventing them achieving their competiveness in the market. In other words, it is essential to anticipate and highlight the projected economic impact of the project on the company.

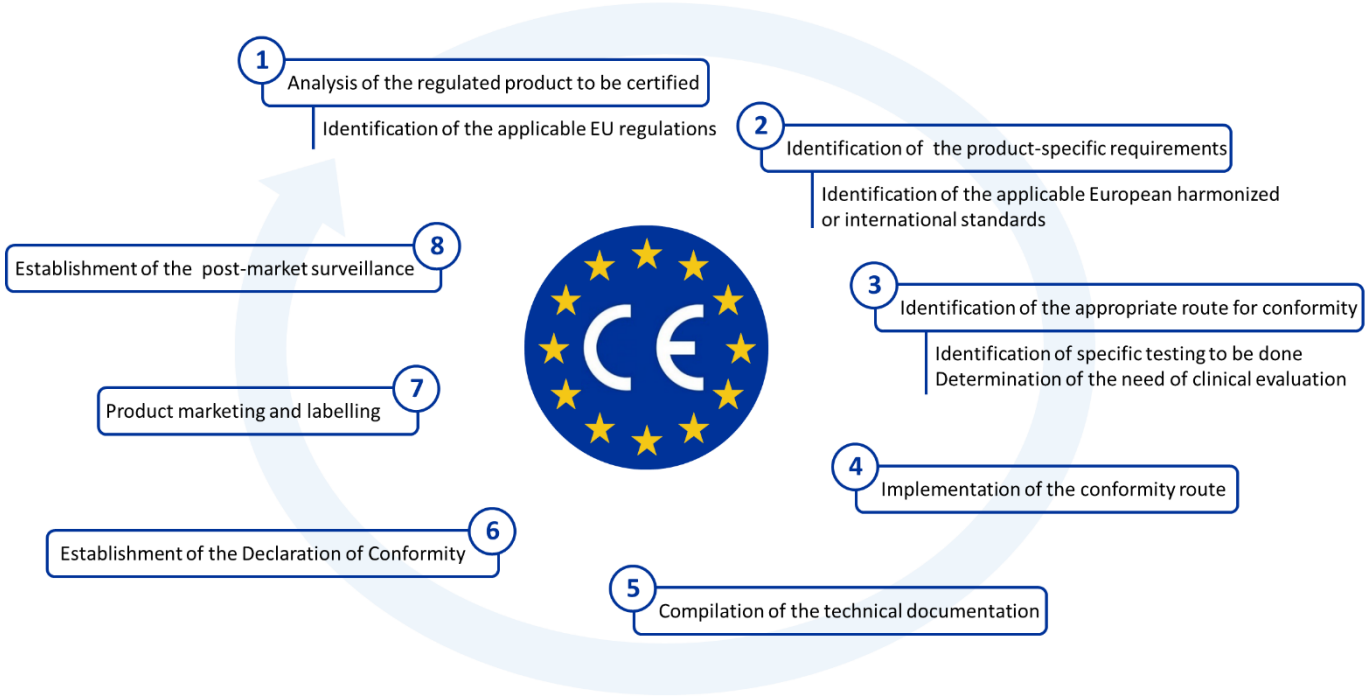
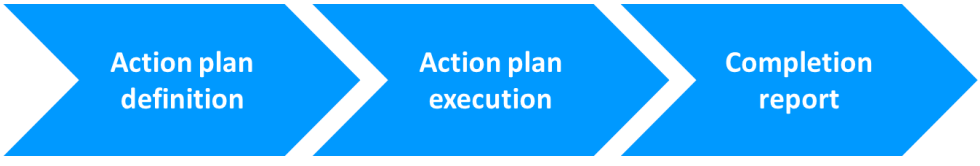


Figure 1: Schematic view of the CE marking process of MD/IVDs, described in eight steps

Consultant mission

The role of the consultants, referred to as the ***consultant mission***, is to help companies to establish their roadmap to CE marking. Thus, consultants can be involved in the overall process, from the identification of the applicable regulations (Step 1) to the establishment of the post-market surveillance (Step 8).[2] However, based on the needs and internal expertise of the company, consultant mission can only focus on specific steps of the process.

The consultant mission proceeds as follow:



Scheme 1. Schematic representation of the steps of the consultant mission

[2] With the implementation of MDR and IVDR, the establishment of Post-Market Surveillance (PMS) procedures is an integral part of the product marketing approval process. Without PMS, initial commercialisation is blocked.

First, the consultant **defines a detailed action plan** that should specify the steps in which he will be involved, and include a description of the main milestones to achieve through the program. Then, the consultant **executes the action plan**, by supporting the company in the actions to be undertaken and/or by producing the deliverables identified in the action plan. Finally, the consultant provides a **completion report** to the company, describing the outcome of its mission and the potential next steps for the company to obtain certification for their MD/IVDs.

Deliverables. At the beginning of the project, the consultant must provide an action plan to the company (see above). If the action plan requires the consultant to be further involved in the CE marking process, the consultant continues his mission with the company. After completing his mission (*i.e.* after completing the tasks assigned to the consultant in the action plan), the consultant must send the company and Luxinnovation a written report including:

- the action plan proposed at the beginning of the project,
- completed by any documents attesting for the achieved milestones (*e.g.* listing of the applicable standards, of the required testing, of the compiled technical documents…).

Methodology. The consultant support takes place in form of workshops, face-to-face when possible (respecting the health precautions in force), and/or remotely. If possible, visit(s) of the company premises and product demonstration should be organize to facilitate the consultant analysis.

The proposed action plan is the subject of a feedback meeting in the presence of Luxinnovation. The consultant mission can stop at this step. However, if the action plan requires the consultant to continue his mission, a restitution meeting with the company, the consultant and Luxinnovation is to be organized after completing the project.

Mission timing. The consultant mission shall not start before the submission of the company project to the Ministry of the Economy and can start upon acknowledgment of receipt by the Ministry of the Economy of the demand for state aid. The action plan must be established during the first eight (8) weeks of the project, starting from the signature of the present contract. Overall, the F4I – HT market program should not represents more than twenty-five (25) days of work by the consultant (including report writing and telephone interviews, in addition to the workshops indicated above), and the consultant mission shall be realized within a period of twelve (12) months.

Fees and costs. The consultant's fees are calculated based on the daily rate, fixed by the consultant in the quotation, and that does not exceed € 2,000.00 excluding VAT; thus, maximum budget of the consultant mission shall not exceed € 50,000.00 excluding VAT. In addition to the meetings and workshops indicated above, it should include reports preparation and phone calls. Fees will be paid by the company according to the terms provided in the quote. Travel costs and specific costs (*e.g.* software licenses fees or costs related to patents) are not eligible. Luxinnovation can support companies to check the eligibility of these specific costs to state aids.

3. Enrollment process for consultants

3.1. Timeline of the call for consultants

The overall timeline of the call for consultants is outlined on scheme 2.

The call for consultant applications for enrollment in the F4I – HT market program is open from **September 22, 2022 to November 15, 2022, 6pm**. From November 15, 2022 to December 15, 2022, consultant applications will be evaluated, and provisional enrollment will be announced from **December 15, 2022**.

Scheme 2: Timeline of the call for consultants for the F4I – HT market program

3.2. Consultant application

The Call for consultants is open to independent contractors as well as to consulting firms. Individual and firms interested in the call can send their application to Luxinnovation at the following email address: fit4innovationhealthtech@luxinnovation.lu.

Applications must include the following documents:

- A copy of the articles of association of the consulting firm or proof of the legal status of the independent consultant
- Bank details
- Balance sheet and profit and loss accounts for the last financial year
- A Curriculum Vitae of the independent consultant or of all consultants of the firm likely to work in the framework of the F4I – HT market program
- A presentation of the skills and experience of the consultant(s) (see section *4. Consultant eligibility*, for extensive information regarding the sought consultant profiles)

This presentation must include detailed examples of projects carried out by the consultant(s) on behalf of SMEs (initial situation, analysis of the needs, proposed strategy, project implementation, results), thus allowing Luxinnovation to assess the relevance of the application.

- A track record of consulting and earnings of the last 3 years
- A cover letter explaining the consultant's or the firm's interest in the program as well as information related to the consultant(s)'s availability for the program, mobility and spoken languages.

Please, note that in case of firm applications, the expertise of each individual consultant will evaluated independently. Thus, the selection process may result in the enrollment of only some of the proposed consultants.

Uncompleted applications or received after the deadline will not be considered.

3.3. Evaluation process of consultants applications

Evaluation of consultants' applications will be carried out in two steps.

- **File-based evaluation**

Luxinnovation will first review all the complete application files received and select the applicants invited for the second phase of evaluation based on their eligibility, as well as their expertise and experience presented in their application.

- **Interview-based evaluation**

The consultants invited to the second step of the evaluation process will discuss their application with an evaluation committee. The committee panel will include members of **Luxinnovation** and of the **Ministry of the Economy** (Directorate General Industry, New Technologies and Research), who reserve the right to make use of external experts. Provisional enrollment results will be announced from December 15, 2022.

4. Consultant eligibility

4.1. Required qualifications

In order to be able to apply for the **Call for consultants**, the candidate consultant must have strong expertise in all or some of the following areas:

- **Medical device regulation**

Mastery of applicable European regulations related to medical devices (EU 2017/745) and/or *In-Vitro* Diagnostic medical devices (EU 2017/746) or the prior directives are **mandatory** for applying.

As the F4I – HT market program specifically aims at fostering digital technologies, experience of the impact of General Data Protection Regulation (EU 2016/679) and / or the Cybersecurity Act (EU 2019/881) on the design, development, risk management etc. will be **a real asset** for the application to the F4I – HT market program, and **mandatory for work involving digital medical devices.**

In addition, knowledge and ability to identify specific harmonized technical standards required for MD/IVDs certification will **strengthen** the consultant application. To cite only a few indicative standards:

- Comprehensive Quality Management System for the design and manufacture of medical devices (ISO 13485)
- Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155)
- Medical device software – software life cycle processes (IEC 62304)
- Medical electrical equipment (IEC 60601 series)
- Labelling and packaging (ISO 11607 series)
- Biocompatibility (ISO 10993 series)
- …

Clinical study implementation

Knowledge of the international ethical and scientific quality standards applying to clinical studies involving human subjects in a European context would be an **advantage** in the selection.

- A bonus if knowledge of the procedure for setting a clinical trial in Luxembourg or neighboring countries
- Guidance and support for clinical study design
- Preparation of the documentation for ethics application
- …

4.2. Track-record of supporting CE marking process for MD/IVDs

To apply for the F4I – HT market enrollment call, the candidate consultant **must** also have a strong track-record in the CE marking certification process, as a consultant, auditor or responsible person in a health tech company, including experience in some but not necessarily all following activities:

Conformity establishment

- Establishing conformity assessment route
- QMS establishment for MD/IVDs
- Labelling requirements
- Post market surveillance
- Vigilance System
- …

Preparation of technical documentation

- Device Specification
- Design & Manufacturing Information
- Risk Analysis
- Safety and Performance Requirements
- Instructions for Use (IFU)
- Declaration of conformity
- …

4.3. Additional selection criteria

In addition, the following criteria will also influence the selection of candidates:

- **Consulting skills:**
- Proven ability to communicate highly technical details to non-experts
- Demonstrated experience of constructing compelling arguments in favor of a given option over an alternative

- **Background in training**: experience and track-record in upskilling client company staff through formal and informal training sessions in various formats.

- **Availability:** Consultants must be able to fulfil the mission defined with the company in the application to the Ministry of the Economy within maximum twelve (12) months.

- **Mobility:** Candidates must be available to travel to Luxembourg for short periods.

- **Language:** Applicants must speak at least one of the following language: English, French, Luxembourgish or German. Any other language will constitute an advantage in the selection process.

5. Consultant obligations

Quotation

The selected consultant undertakes to provide the company, beforehand its application for the F4I – HT market program, with an unbinding quote, mandatory for company applications to the Ministry of the Economy.

The quote must refer to the F4I – HT market program and include:

- A methodological note covering the essential elements of the mission (objectives, methodology, deliverables…);
- The details of work packages (content, deadlines, costs) aligned with the methodology and approach described above;
- The name of all consultants and service providers who will be involved in the company project;
- The daily rate (maximum of € 2.000,00 excluding VAT);
- The total cost of the mission (maximum of twenty-five (25) work days by the consultant);
- The payment terms.

It is important to note that no firm agreement (i.e. signed quote) between the company and the consultant should have been set before the company application, as the costs of any items described in such agreement will not be eligible to the financial aid.

Commitments

Consultants enrolled in the F4I – HT market program undertakes to comply with the clauses described in this document, in particular concerning:

- The approach and methodology;
- The deliverables (action plan, milestones listed in the action plan & final report);
- The amount of remuneration.

Consultants who has successfully passed the selection process will sign a **commitment charter**, confirming their agreement to the following conditions:

- The consultant must respect the methodology described in section *2.3. Methodology of the program* of this document. Any adaptation of the program will not affect ongoing projects.
- The consultant is subjected to an obligation of means, by virtue of which he/she must deploy his/her best efforts to achieve the objectives of the mission defined with the company in the committed time frame.
- The consultant must establish the action plan for the company with the first eight (8) weeks of the project, starting from the signature of the Terms and Conditions contract by the company. The F4I – HT market program should not represents more than twenty-five (25) days of work by the consultant, and the consultant must realize his/her mission within a period of twelve (12) months.
- The consultant will refrain from any commercial canvassing, and will ensure that the program is promoted in accordance with the rules of conduct established by Luxinnovation.
- The consultant must not exceed € 2,000.00 excluding VAT as daily consultancy rate.
- The consultant must be fully transparent with the company regarding any service providers who will possibly intervene during the company project.
- In case of sub-contracting, the consultant will be in charge of coordinating the mission with all stakeholders;
- The consultant's definitive enrollment will only be effective after finalization of a first project. Enrollment will last until the duration of any ongoing projects or be renewed annually.