

## Fit 4 Innovation

### Health Tech Market

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## Program presentation

# 1. Context and program presentation

## Context

**Medical devices** (MDs) and **in vitro diagnostic medical devices** (IVD-MDs), hereafter collectively referred to as MD/IVDs, are subjected to a strict regulatory framework. In particular, to access the European market, health technology (health tech) companies must comply with the European regulations EU 2017/745 (MDR) or EU 2017/746 (IVDR) that guarantee the performance and safety of their devices for patients and healthcare professionals.

In addition, for **digital medical devices**, horizontal regulations may also 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).

For commercialization within the EU market, these MD/IVDs are required to obtain CE certifications. However, laying the necessary corporate foundations (*e.g.* implementation of a quality management system) and assembling of the technical dossier for each medical product can be highly complex and turn into a big hurdle for start-ups and SMEs.

In this context, the Ministry of the Economy is sponsoring a new support program named “**Fit 4 Innovation – Health Tech Market (F4I – HT market)**”, to build up regulatory expertise in Luxembourg, to simplify access to such expertise for health tech companies and facilitate their regulatory strategic decision-making and their implementation, and thus accelerate commercialization of their 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.

## Program presentation

The **F4I – HT market** program consists of in-depth support for health tech companies, intended to help them (i) establish their regulatory roadmap for their innovative and new medical devices 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/IVDs.

According to the program rules, companies, *i.e.* start-ups and SMEs, 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](#)<sup>(1)</sup> from the Ministry of the Economy to support their CE marking project (referred to as the **company project**).

The program involves **external consultants**, assessed by Luxinnovation according to rules in force at the date of the application for the program, in charge of assisting the company through their project.

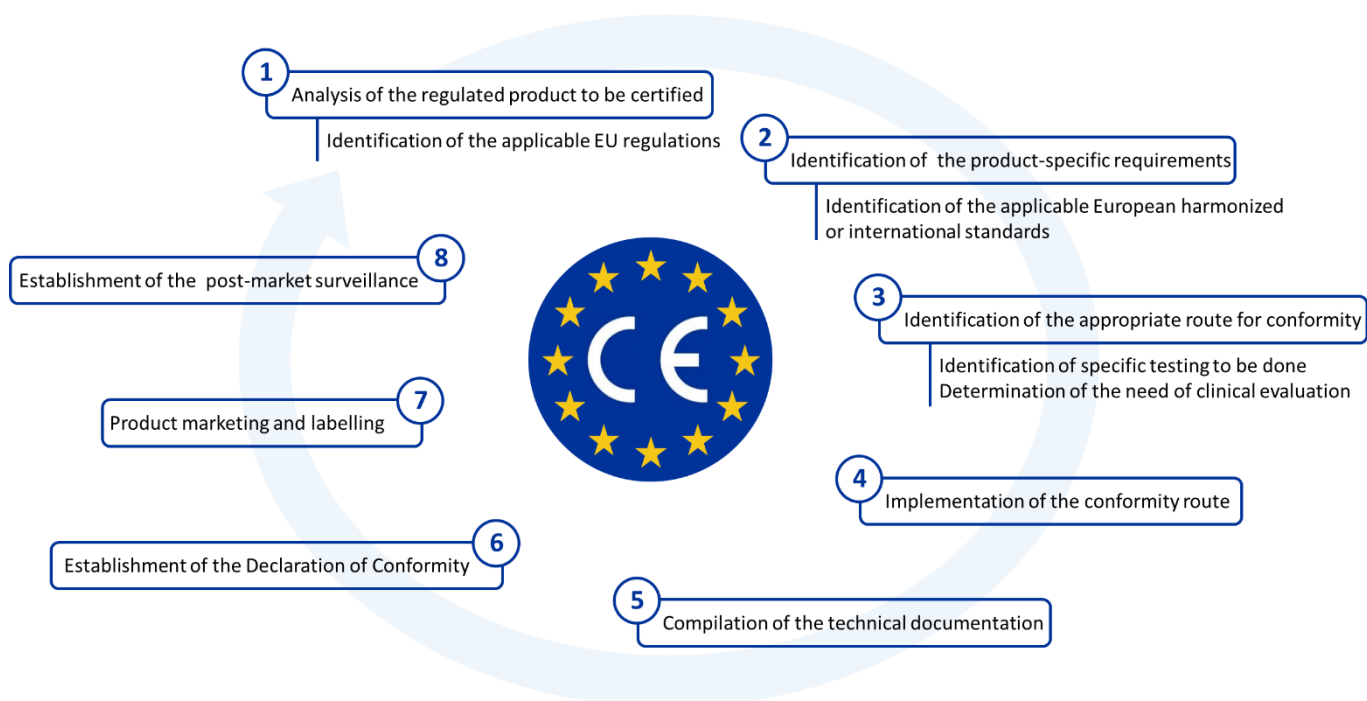
If the company project is approved, the Ministry of the Economy can co-finance the consultant fees for its mission (referred to as the **consultant mission**), provided the company and the mission fulfill all mandatory conditions (more details in the next sections).

### Company project

The company project aims to establish the 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, presented on figure 1. These eight steps are aligned with the scope and 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 include specific steps.

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 competitiveness 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 a typical CE marking process for MD/IVDs, described in eight steps

### **Consultant selection**

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*).

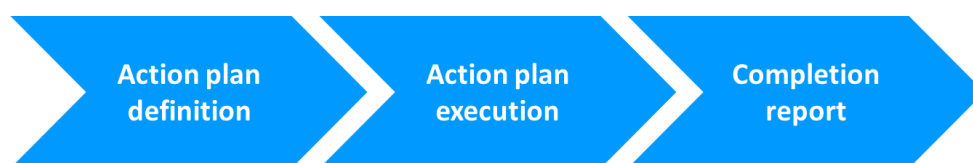
Please, note that it is mandatory for the company to provide a minimum of three consultant quotes as part of its application, as well as a justification of the ultimate consultant choice.

*Although consultants enrolled in the F4I – HT market program have signed a commitment charter undertaking to comply with the program methodology, it is the company’s responsibility to verify that the qualification of the consultant and of any service providers who could intervene during the company mission fits its needs. In addition, company should also ensure that the committed timeframe, the costs, deliverables and general terms regarding confidentiality are aligned with the program and the company project.*

### **Consultant mission**

The consultant mission aims at assisting the company in their project. Thus, based on the company needs, the consultant can either be involved in the overall CE marking process, from the identification of the applicable regulations (Step 1) to the establishment of the post-market surveillance (Step 8), or he can only assist the company during specific steps of the process.

The consultant mission proceeds as follow:



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

First, the consultant **defines a detailed action plan** that should specify the steps in which the 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 organized to facilitate the consultant analysis.

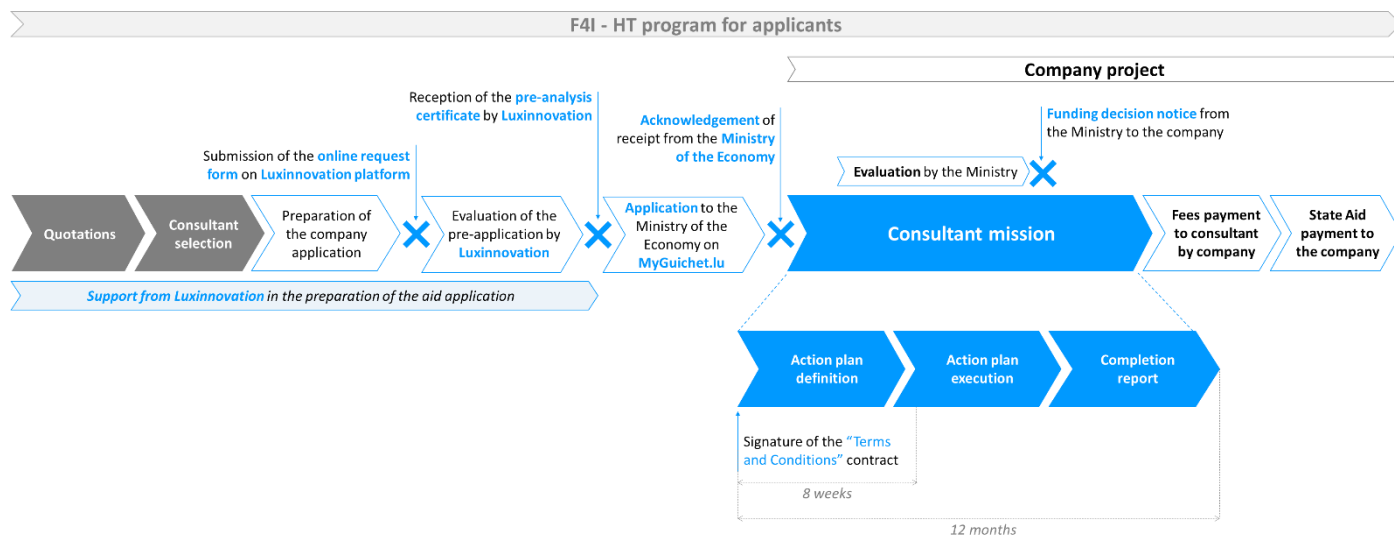
The proposed action plan is the subject of a feedback meeting in the presence of Luxinnovation. The consultant mission can stop at this step. However, if the action plan requires the consultant to continue his mission, a restitution meeting with the company, the consultant and Luxinnovation is to be 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 represent 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 under the conditions described in section 4. *Company obligations* of this document. 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.

### F4I – HT market program timeline for applicant companies

The overall timeline of the F4I – HT market program, including the consultant mission, is outlined on scheme 2. Please, note that the schematic and the hereinafter description present an overview of the main steps of the F4I – HT market program, their requirements and their specifications. Additional information can be found in the other sections of this document.



**Scheme 2.** Schematic representation of the F4I – HT market program timeline for applicant companies

- **Selection of the consultant.** Before submitting its application, the company must select the consultant with whom it will work within the framework of the F4I – HT market program from the list of approved experts.
- **Application to the F4I – HT market program.**
  - o With the consultant chosen, the company initiates its application by filling out the online form on Luxinnovation platform.
  - o Once validated, Luxinnovation reviews the request to ensure it is in line with the program rules, and then provide the company with a pre-analysis certificate.
  - o The company then prepares the full application file (including the pre-analysis certificate) and apply for financial aid to the Ministry of the Economy, under the SME innovation scheme, using the online assistant available on MyGuichet.lu.

Additional information on the application process is provided in section 3. *Company application*.

- **Acknowledgement of receipt by the Ministry of the Economy.** Once the company has submitted its demand for state aid, the applicant receives a confirmation from the Ministry of the Economy, by way of an acknowledgment of receipt of the financial aid application.

*Please note that the acknowledgment of receipt is not a funding decision. At this stage, the consultant can start its mission, with the company assuming the risk not to be funded by the expected state aid. Reasons of funding refusal include, but are not limited to, company ineligibility, mismatch of the scope of the company project and that of the F4I – HT market program or absence or invalidity of documents required within the application.*

- **Start of the consultant mission**, upon signature of the **Terms & conditions contract**. The consultant mission and timing are described earlier in this section. Meetings with Luxinnovation throughout the mission shall allow for directing the company to other appropriate aid schemes to pursue its project.
- After reception of application for financial aid for the F4I – HT market program, the **Ministry of the Economy evaluates the eligibility of the company and of the project**, and then sends the company a **funding decision notice**. If approved, the company will receive a positive funding decision notice from the Ministry, establishing the financing conditions of the project.
- After completing the consultant mission, the company **pays the consultant fees** according to the terms provided in the quote, and then sends a **request for reimbursement to the Ministry of the Economy** (section 6. *Grant of the aid*). Only eligible costs linked to the consultant mission can be considered, thus reimbursed for State aid.

## 2. Company eligibility

To be eligible for the F4I – HT market program, the company must fulfil the criteria set out in the Research, Development and innovation (RDI) aid schemes, in accordance to Article 7 of the amended Act of 17 May 2017 on the Promotion of Research, Development and Innovation.<sup>(1)</sup>

For information, this document summarizes the applicable legislation. For further information about the eligibility requirements, please see the General terms and conditions applicable to all financial aid for research, development and innovation and the legal texts to which this document refers (section 9. *Legal framework of the F4I – HT market program*).

In particular, the company must meet the following criteria:

- Have a registered office in Luxembourg
- Have a valid establishment permit issued by the General Directorate for Small and Medium-Sized Enterprises of the Ministry of the Economy
- Be classified as an SME according to the European Recommendation 2003/361/EC of 6 May 2003,<sup>(2)</sup> concerning the definition of micro, small and medium-sized enterprise (see below)
- Not be considered “undertaking in difficulty” (see below)
- Not carry out an activity that is excluded from state aid
- Have submitted the Aid Request application to the Ministry of the Economy prior to the commencement of work related to the F4I – HT market program.

### Analysis of the “SME” criterion

According to EU criteria,<sup>(2)</sup> a company is considered an SME if it employs **fewer than 250 employees** (full time equivalent) and has an **annual turnover not exceeding € 50 million**, and/or an **annual balance sheet total not exceeding € 43 million** (Article 2).

Both the number of staff and annual turnover/balance sheet of the company and that of any other company with which the applicant company forms a “single economic entity” should be taken into account. The notion of “single

economic entity” with regard to state aid refers to the business group to which the applying company belongs, *de jure* or *de facto*, and all other businesses with which it has a relationship of influence (Article 3).

### Analysis of the "Undertaking in difficulty" criterion

An undertaking that can be considered an undertaking in difficulty is not eligible under the financial aid schemes.<sup>(1)</sup> An "undertaking in difficulty" refers to any enterprise that fulfils at least one of the following conditions:

- in the case of a limited liability company (other than an SME that has existed for less than three years), where more than half of its subscribed share capital has disappeared as a result of accumulated losses. This is the case when deduction of accumulated losses from reserves (and all other elements generally considered as part of the own funds of the company) leads to a negative cumulative amount that exceeds half of the subscribed share capital;
- in the case of a company where at least some members have unlimited liability for the debt of the company (other than an SME that has existed for less than 3 years), where more than half of its capital as shown in the company accounts has disappeared as a result of accumulated losses;
- where the undertaking is subject to collective insolvency proceedings or fulfils the criteria under its domestic law for being placed in collective insolvency proceedings at the request of its creditors;
- when the undertaking has received rescue aid and has not yet reimbursed the loan or terminated the guarantee, or has received restructuring aid and is still subject to a restructuring plan;

## 3. Company application

As indicated before, the application must be submitted **before the commencement of the work**.

### Supporting documents

The application for state aid must not least include the following information and documents:

- A copy of the company's articles of association
- A copy of the business permit
- A copy of the CCSS certificate justifying the number of employees
- Bank details
- Account and balance sheet for the last two years for the applicant company and the group level
- At least three unbinding quotations (unsigned) from various consultants and a document explaining the final consultant choice.
- Each business, which was established less than 3 years ago, is required to provide a business plan.

Any other supporting documents deemed useful can be attached to the application.

## Application process

The preparation of the application, including the selection of the consultant as well as the preparation of the financial and project-related documents, can be done with the support from Luxinnovation.

Interested companies can apply for the F4I – HT market program **at any time**, following the two-step procedure below:

### (1) Introduction of the company application on Luxinnovation platform

- The company first fills out the online form on Luxinnovation platform: the company will be asked to provide information regarding its identification, the chosen consultant(s) as well as the description of the project to be carried out in the F4I – HT market program.
- Luxinnovation will review the information provided by the company and ensure that the project is in line with the program objectives and that the quote(s) comply with the program specifications.
- For positive evaluation, Luxinnovation will then issue (from the platform) a pre-analysis certificate, document attesting that Luxinnovation has successfully carried out the pre-check phase. This document must be attached to the application for financial aid to be submitted to the Ministry of the Economy (step 2).

### (2) Application for financial aid to the Ministry of the Economy on MyGuichet.lu

- The company prepares the full application file (including the pre-analysis certificate) and apply for financial aid to the Ministry of the Economy.
- Applications must be submitted using the online assistant available on **MyGuichet.lu**, under the **financial aid for SME innovation** scheme.
- The person submitting the application (the applicants themselves or their representatives) must have a LuxTrust product (*e.g.* Token, Smartcard or Signing Stick) or an electronic identity card.
- Once the application on MyGuichet.lu is finalized, the applicant companies will receive a notification, confirming that the Ministry of the Economy has received their application. From this acknowledgment of receipt, and upon signature of the present contract by the company, the project with the consultant can start and, eligible costs linked to the consultant mission can be considered for reimbursement.

## 4. Company obligations

### Collaboration

For the proper execution of the F4I – HT market program, the recipient company guarantees Luxinnovation and the consultant the necessary access to its premises and the relevant equipment or infrastructure. If deemed necessary, the company and the consultant will set up the necessary tools (communication and coordination tools) to allow remote collaboration with the consultant.

The company undertakes to be available for the smooth running of the project throughout the duration of the assignment of the approved consultant. At the outset of the mission, the company will designate a person responsible for the project, main contact point of the consultant and Luxinnovation.



## Access to information

The company guarantees the consultant access to all the information necessary for the smooth running of the mission, and in particular, access to the information and technical documentation related to the design, manufacturing, operation and performance of the MD/IVDs, over the entire duration of the F4I – HT market project.

If any information deemed confidential is essential for the smooth running of the project, the company commits to provide the information in another form (by opting for anonymization, for example) in order to guarantee secrecy. A specific non-disclosure agreement (NDA) can be signed independently of the program if needed.

The company undertakes to communicate to Luxinnovation relevant information, available at the end of the consultant mission, then along the whole device certification process, to allow for assessing the success of the company project.

By taking part in the F4I – HT market program, the company accepts that Luxinnovation, the Ministry of Economy and other public institutions, which commit to guarantee the anonymity of the data and of the company, will operate the statistical data of its project.

## Payment of the consultant fees

At the end of the consultant mission, upon reception of the consultant final report, the company undertakes to pay the consultant according to the terms provided in the quote.

## 5. Consultant obligations

Consultants enrolled in the F4I – HT market program have signed a commitment charter, agreeing to commit within the framework of the program. The template of the charter can be made available to the company.

The consultant undertakes to respect the clauses appearing in the specifications of the document *Call for consultants* (Annex 1) organized by Luxinnovation, in particular concerning:

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

Luxinnovation leaves it to the company to verify its agreement regarding data protection and confidentiality with the consultant to ensure compliance with the General Data Protection Regulation (GDPR, (EU) 2016/679).<sup>(3)</sup>

## Quotation

The selected consultant undertakes to provide the company, beforehand its application for the F4I – HT market program, with an unbinding quote, referring to the program, and including:

- 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.*

## 6. Grant of the aid

The Ministry of the Economy evaluates the application for state aid against the SME innovation scheme. The Ministry of Economy can award an eligible company with an eligible project a public aid up to a maximum of 50% of the total eligible fees. The company will receive a Decision document by the Ministry of Economy, detailing the terms to fulfill.

### Payment of the aid

After completion of the consultant mission, company requests the fees reimbursement from the Ministry of the Economy, including the final consultant report, the consultant invoice and proof of payment in the request.

The Ministry of the Economy evaluates the payment request against the terms of the grant awarded.

The company agrees to reimburse funds at the Ministry's first request if reported not being used for the purposes and conditions established with the State in the funding agreement.

## 7. Confidentiality & personal data

Luxinnovation will strictly consider confidential, and will refrain from disclosing, any information, document, data or concept of which they gained knowledge throughout the work carried out with the company within the framework of the F4I – HT market program, unless having received prior written consent from the company, and except to other employees of Luxinnovation, for carrying out the purposes of any agreements to which Luxinnovation and the company may hereafter agree on.

Notwithstanding the foregoing, the Luxinnovation may, at its own discretion, communicate in whole or in part Confidential Information to the Luxembourg Ministry of the Economy provided that such communication is needed for the assessment of the company eligibility or the evaluation of the company project submitted to the Ministry of the Economy for funding in the framework of the F4I – HT market program.

This confidentiality agreement will be effective upon signature of the present contract and will expire after five (5) years. Unless early termination, upon written notice, this agreement will remain effective thirty days after mailing said notice and the confidentiality obligations, described hereinabove, shall continue to apply for a period of five (5) years after the expiration of the agreement.

Personal Data will be processed by Luxinnovation as a data controller, in compliance with the applicable data protection legislation (*i.e.* the European regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation, GDPR)<sup>(3)</sup> which entered into force on 25 May 2018, replacing the Luxembourg Law of 2 August 2002, as well as any other subsequent regulation). For any further information, please contact our Data Protection Officer (dpo@luxinnovation.lu).

## 8. Jurisdiction

The F4I – HT market framework described in this document is subject to Luxembourg Law. In the event of a dispute relating to its existence, interpretation or execution, the courts of Luxembourg shall have sole jurisdiction.

## 9. Legal framework of the F4I – HT market program

(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>

(2) European Recommendation 2003/361/EC of 6 May 2003, concerning the definition of micro, small and medium-sized enterprise:

<http://data.europa.eu/eli/reco/2003/361/oj>

(3) Regulation (EU) 2016/679, and repealing Directive 95/46/EC (General Data Protection Regulation):

<http://data.europa.eu/eli/reg/2016/679/2016-05-04>