Master's thesis

Máster Universitari en Enginyeria Industrial (MUEI)

Exploitation plan for the market launch of a new on line computational application for occupational dosimetry in radiology

REPORT

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Author: Jordi Martínez Robles

Director: Mercè Ginjaume Egido

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ETSEIB
Escola Tècnica Superior
d'Enginyeria Industrial de Barcelona

UPC

Summary

This thesis is about the best strategy to get public funding in European calls for highly innovative projects. Using the example of a project application which takes part in the Fast Track to Innovation (FTI) call of the European Commission's H2020 framework program, a series of improvements based on success stories and on the criteria of the evaluators are proposed to have more possibilities of obtaining funding. The project wants to bring the product PODSTAR to the market, which is an online dosimetry platform for medical staff during interventional radiology. At the beginning of the project, the product is in TRL 6, wanting to fund its jump to the market through this call.

In the final section, national level financing alternatives are sought and the usefulness of these tax incentives is reflected in addition to highlighting the most important points when writing an application of this type.

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1 Glossary

For the correct understanding of some concepts included in the report, a list is provided with the meaning of some acronyms and abbreviations that will be used frequently.

- PODIUM: Personal Online DosImetry Using computational Methods
- PODSTAR: Personalized Online Dosimetry monitoring for Staff in Radiology
- FTI: Fast Track to Innovation
- ESR: Evaluation Summary Report
- CAGR: Compound Annual Growth Rate
- ERCP: Endoscopic Retrograde Cholangio-Pancreatography
- SAM: Serviceable Available Market
- TAM: Total Available Market
- SOM: Serviceable Obtainable Market
- WP: Work Package
- PID: Proyecto I + D
- LDI: Linea Directa de Innovación

2 Introduction

During the 2018-2019 period, the UPC, together with other research centers and hospitals, carried out a feasibility study on how to solve the problem of occupational dosimetry in medical staff working with interventional radiology. Currently, improvements have been implemented for patient dosimetry, but this is not the case for staff dosimetry, a very wide field opens up for workers after the new restrictions approved in the European directive 2013/59 / EURATOM. This is how PODIUM kicked off. During this study, the 3D tracking technique and dose analysis were developed and satisfactory tests were performed in two hospitals.

Once it was seen that the project could end up being a marketable and competitive product and that it covered an orphan need until now, it was decided to look for an industrial partner to finalize, finance and introduce the final product to the market.

This is how a new consortium of companies was created, whose objective was to launch a marketable product based on the feasibility study done in 2018, this time called PODSTAR. It was decided that a mixed (public - private) funding strategy was the most appropriate and funding was sought in a call for the EU H2020 framework, the Fast Track to Innovation (FTI). The FTI call accelerates the market uptake of ground-breaking innovations by providing funding in an open, accessible scheme that nurtures ideas from consortia of innovators of all types and sizes from across Europe.

The application was launched to the call but this was rejected by the evaluators of the European Commission. The rejection report focused on the absence of justification for the demand for the product (PODSTAR) and a more detailed business plan. This is where this Master's thesis begins, whose objective is to analyze the weak points of the application sent and to improve it so that it can be approved by the evaluators and thus obtain public funding and be able to launch PODSTAR to the market.

2.1 Objectives

the general objective of this thesis is to prepare a proposal that can meet the SMART (specific, measurable, achievable, realistic and time-based) criteria and obtain funding for the PODSTAR project. They are as follows:

- To analyze the types of grants within the framework of the European Union's H2020 and find alternatives for funding the PODSTAR project.
- To redo and reframe the application for the FTI call to get the necessary score and access the competitive tendering ranking.

As for the specific objectives of the project, they cover areas such as project financing, management, knowledge of the European tax framework, and technical knowledge of medical radiology. They are presented below:

- To know and analyze the European public financing framework for R and D projects.
- To establish and present a preliminary and sustainable business plan of the project
- To know and analyze the radiation protection market in medical interventions.

- To analyze and study the European Fast Track to Innovation (FTI) program to fit the PODSTAR project to the required standards.

2.2 Scope

The objective of this master's thesis is to prepare the basis to obtain public investment. In this project, changes will be suggested and solutions will be proposed both in the technical area and in the economic area of the project and of the consortium formed by the 5 entities that develop PODSTAR. Of course, the changes suggested at the company and project level will not be mandatory for the consortium, but will be part of the technical assessment that will add the experience in the R and D financing consultancy and the engineering knowledge. Thus, it will be a decision of the consortium if it includes the suggested changes in its business model and if it again submits PODSTAR to the competition to receive European funding.

Monitoring of suggested changes, as well as a possible new call for FTI grant, is outside the scope of the project.

2.3 Motivation

The motivation for carrying out this project has come to me from my work experience in an R and D project funding consultancy. I have worked with companies seeking mixed funding, obtaining funding from public entities related to R and D. However, being able to participate in a European project was a challenge that I wanted to accept, being useful my specialization in the biomedical branch of industrial engineering to reach better results.

3 Planning

To structure the planning of the master's thesis, the execution time has been divided into weeks. Taking into account that the semester starts on February 17 and the submission date is June 22, there is a total of 18 weeks to develop the project.

The thesis has been divided into 4 different tasks, or stages, and the necessary resources and time devoted to each have been captured. The deep yellow boxes mean weeks of intense dedication to that task. The light yellow ones are those weeks of much less dedication, with tasks of reviewing or correction of mistakes. The white boxes are those weeks without dedication to the given task.

Task	*Resources*	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	*12*	*13*	*14*	*15*	*16*	*17*	*18*
Senior Revision	Videoconferences																		
Preliminary analysis of the original application and the ESR	Original application and ESR																		
Detection of weak points	Original application, H2020 regulations and success cases																		
Improvement proposal	Granters Review of successful proposals																		
Documentation and analysis of national alternatives	Documentation and legislation on grants																		
Thesis Report and Defense preparation	Digital text editing tools																		

Figure 1: Master's thesis planning

4 PODSTAR description

Based on new epidemiological evidence of the effects of ionizing radiation, ICRP [9] recommended changes in the dose limits for workers that use ionizing radiation. These changes have been included in the the European Directive 2013/59 EURATOM [6] on the basic safety standards for protection against the dangers arising from exposure to ionizing radiation. One of the most important changes is the reduction of the dose limit of the lens of the eye from 150 mSv to 20 mSv per year. This reduction has significant implications for the dose monitoring of workers, in particular for interventional radiology (including cardiology) and other image-guided procedures, where the staff is close to the radiation source. The Directive also establishes new requirements for continuing education and training in the field of medical exposure.

Due to the restrictions imposed by the Directive at the European level, a need has been created for monitoring the dose of medical staff and a need for training for exposed workers to improve awareness and promote good practices. PODIUM was a feasibility study to find a marketable solution to this new problem.

Nowadays, measurement of occupational radiation doses using physical dosimeters is standard practice. Primary dosimeters (worn at the chest of the personnel) give a first general indication of the cumulative radiation dose that the worker received during a specified time period and are mandatory by law. In some countries **double dosimeter (a secondary dosimeter) is mandatory to consider the effect of protective aprons** as well. However, dosimeters lack accuracy, give no information on the cause of high doses or the time of the exposure, give no information on radiation doses to particular body parts or organs and they are difficult to use for training or position optimization. Other dosimeters (e.g. ring, eye lens) also exist and can overcome some of the limitations mentioned above. In some countries, these other dosimeters are mandatory but they are too uncomfotable.

Figure 2: Current personal dosimeters worn by medical staff

However, they are often not worn by the medical staff for practical reasons. In fact, interventional staff are often reluctant to wear dosimeters, and prone to misuse or loss of them. A completely automated monitoring system for occupational dosimetry that provides information on actual radiation doses over the whole body without hindering the movements during the treatment of the patient, will dramatically change healthcare workers' vision and daily-life practice.

Currently, personal dosimetry is typically performed by issuing staff with physical dosimeters. However, this practice has many limitations both technically and in use. First, the results from passive dosimeters are usually known only after a month of delay. Secondly, performing precise and reliable personal dose measurements in all types of workplaces is often difficult or it

can return inaccurate results. **Achieving a factor 2 of uncertainty is the common routine in personal dosimetry.** Uncertainty factor 2 is accepted according to ICRP publication 75 [10].

The recent trend of dosimetry is moving towards active personal dosimeters (APDs) and active systems that can transfer the dose data to online applications (smartphones, servers). However, APD technology is not more accurate than passive dosimeters, and it is not working properly in some fields such as pulsed radiation fields [22]. However, it is not a very exploited field and there are no APDs for eye lenses or extremities.

Figure 3: Current APD developed by RaySafe

The APDs that currently exist, like the one shown in the image, act more like an alarm than an accurate measurement. Its function is more qualitative than quantitative. Current personal active dosimeters warn medical personnel when the received dose exceeds certain limits, allowing the worker to correct his position and avoid dangerous exposures. However, it is not an accurate measurement system, it is only point measurament and it does not provide a systematic analysis by zones or by time. This problem without solution is where PODSTAR comes in.

With increasing computational power, computer simulations can be performed faster and faster. In the framework of the PODIUM project, SCK-CEN and UPC developed an online application to calculate workers' doses. In the proposed methodology, instead of measuring individual doses with physical dosimeters, doses are calculated by **monitoring, on one hand, the position of the personnel in the interventional room and, on the other hand, the spatial radiation field** (including its energy and angular distribution).

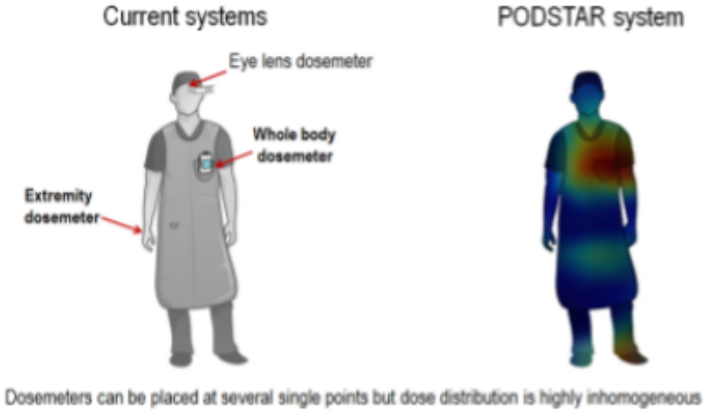

Figure 4: Comparison between the PODSTAR system and a physical dosimeter [5]

Using the 3D tracking technology incorporated and the information on the dose emitted by the radiation source (RDSR data format), the online dose analysis service of PODSTAR will be able to measure, once the intervention is over, the dose at which Every worker has been exposed at every moment and in every area of his body. These data will be used by the virtual training service to provide continuous training to workers and improve good practices during interventions. The following is an outline of the procedure that PODSTAR follows to analyze the data.

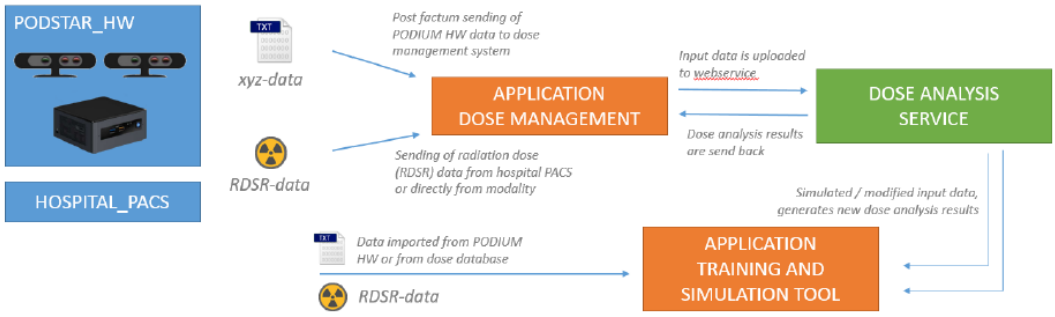

Figure 5: PODSTAR data flow [5]

As you can see, the data is processed on a server external to the hospital and the results are sent back to the analysis service installed on the hospital computers. The client must not have dedicated servers or computing power, this is subcontracted, which makes it a more accessible product for more medical centers.

In a nutshell, PODSTAR start from the know-how of PODIUM and transfer the virtualized methodology of the prototype into a commercially mature product. Through the use of a 3D tracking with cameras and the information of the radiation emitted in the intervention room, it is possible to monitor and map the dose received by the medical staff. The information from cameras and radiation sources is sent by the dose analysis system to an external server where results are processed and returned back. These results will be available in the dose analysis service installed in each medical center once the intervention has finished. The dose received by each worker, in each area of the body, can be checked at any time.

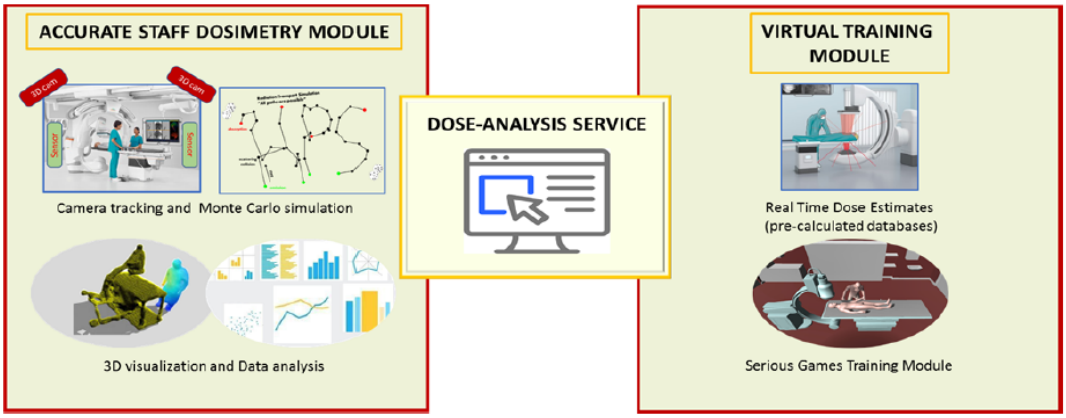

Figure 6: Summary of the PODSTAR product [5]

Moreover, these results are sent as feedback to the PODSTAR virtual training service. These data will be used for continuous training of workers, improving their practices during interventions, evaluating their actions and optimizing them. As you can see, PODSTAR is a complete product that meets the demands of the market both at the legislative and user levels, offering a comfortable, precise, fast and useful service.

5 H2020: Fast Track to Innovation

Within the motto of the European Union "Union for Innovation", the European Commission approved in 2014 a framework within which RD by community companies would be promoted. The objective of the program, through the implementation of three pillars, was to contribute to tackling the main social challenges, promote industrial leadership in Europe and reinforce the excellence of its scientific base in the 2014-2020 period [1]. H2020 finances projects, generally through transnational collaboration, that can be framed in any of the phases that go from research to market, such as: research activities; technological development, demonstration and innovation, as well as other horizontal activities to support research and innovation.

Figure 7: H2020 framework logo

To get an idea of the impact of the H2020 framework at a national level, we are going to analyze the data, all referring to the European Union of 28 member countries, which come from the official information on the results of the evaluation of competitive calls provided by the services. from the European Commission to the Program Committees of each of the H2020 programs / areas.

Firstly, Spain's involvement in the innovation framework program is being very high. In data collected in the 2014-2019 period, Spain obtained a return of 10 %, being the fourth country at community level. In global terms, the Spanish entities obtained an aggregate grant of 4,630 million euros in all the calls awarded in this period, placing Spain in fourth position in the ranking for subsidy received, after Germany, the United Kingdom and France [2] .

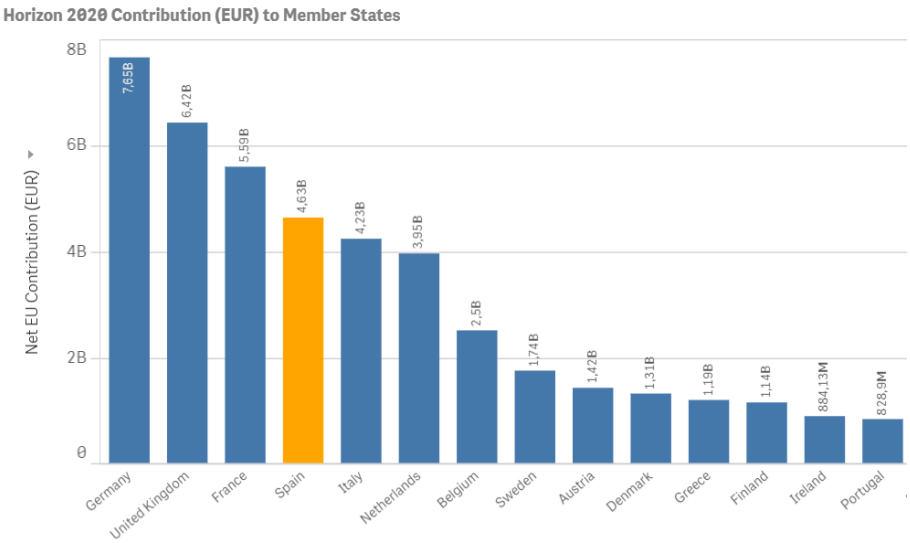

Figure 8: Return obtained in H2020 by countries

Adapted from *H2020 Spanish Participation Results* [3]

Spanish entities are showing great interest in Horizon2020 and are present in more than 40.579 proposals submitted to the calls. During the first five years of H2020, Spain has coordinated 699 projects developed in collaboration with other EU-28 States, becoming the first country with the largest number of led projects, with 15.8 pct. of the total. This consolidates the technological positioning of Spanish entities in the international arena (period 2018-2019 [3])

Among Spanish beneficiaries, companies are the organizations that have most contributed to the return, with 37 % of the financing obtained by our country. The rest of the subsidies have been distributed mainly between universities, public research centers, research associations, technology centers, Public administrations and associations. The UPC stands out in the ranking of participations in the program, being the fifth public entity in number of participations. With these data on the table, an upward trend of the public financing strategy in projects with high technological risk can be observed, being especially successful.

As for the success rate, Spain is around 13.1 %, one point above the community average of 12 %. Specifically for the area in question, that of the FTI, is part of the call for the SME instrument. In this case, Spain stands out as the first country with the highest return with 17.6 %. of the EU-28.

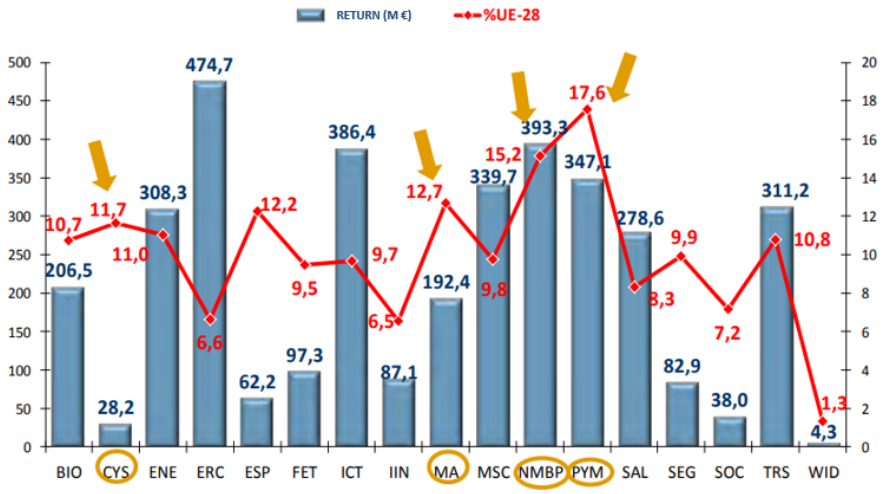

Figure 9: Return obtained in H2020 by call area

Adapted from *H2020 Spanish Participation Results* [3]

This graph represents the return obtained by Spanish companies (milion euro) and the percentage they occupy within the EU-28 by subject area. Axis X represents the thematic areas as the European Commission divides the participations to its grants. The initials PYM stand for innovation in SMEs; the results of *access to risk financing, SME Instrument and FTI - Fast Track to innovation* are accounted for. Other acronyms like ESP (space) and FET (Future and Emerging Technologies) are other examples.

Thus, within the H2020 framework there are calls for all kinds of challenges or needs to be financed. Moreover, there are specific calls for certain areas of the technique, mostly being the most competitive. Specifically, there are two types of calls for financing the landing on the

market of products that use cutting-edge and highly innovative technologies; These are the SME Instrument and Fast Track to Innovation (FTI).

In order for a product to fit with an SME Instrument (recently called EIC Accelerator) or FTI, it is important to analyze the technology (market disruptive innovation) and the multi-level business it generates. They are very competitive calls. There are different conditions that characterize each of them, but what makes the difference between the two in this case is the consortium. If you want to develop the technology without partners and being a small company, the right one is EIC Accelerator. If it is with international partners or in a consortium, the option to choose is the FTI.

In the case of PODSTAR, the requirements are fulfilled to fit perfectly with the call of the FTI, seeking financing to achieve a jump in the TRL of PODSTAR from 6 to 9 and be fully marketable. Therefore, the FTI call and its conditions must be analyzed in depth, bearing in mind its requirements and its selection and evaluation criteria.

FTI accelerates the market uptake of ground-breaking innovations by providing funding in an open, accessible scheme that nurtures ideas from consortia of innovators of all types and sizes from across Europe. It **supports actions undertaking innovation from the demonstration stage through to market uptake**, including activities such as piloting, test-beds, systems validation in real-world working conditions, validation of business models, pre-normative research, and standard-setting. Next, a table is attached that extracts the main information of the call to highlight its potential.

Table 1: FTI call analysis

BENEFICIARIES	Participation of **three to no more than five** different legal entities, independent of each other, in a **consortium**.
	Allocation of at least 60 % of the overall budget to consortium partner(s) from industry; or a minimum of 2 industry partners out of a consortium of 3 or 4; or a minimum of 3 industry partners out of a consortium of 5.
	All consortium members established in EU Member States or in countries associated or in countries associated to Horizon2020.
DEADLINE	19/02/2020
	09/06/2020
	27/10/2020
BUDGET	2018: 100.000.000 €
	2019: 100.000.000 €
	2020: 100.000.000 €
MODALITY	Non-repayable grant and competitive concurrence
FUNDING RATE	The maximum EU contribution per action is €3 million (funding rate: 70% for for-profit entities; 100% for not-for-profit entities).
ELEGIBLES PROJECTS	Proposals must relate to any field of H2020 under the specific objective **"Leadership in enabling and industrial technologies"** and/or to any of the specific objectives under the priority "Societal challenge".
	FTI targets relatively mature, ground-breaking new technologies, concepts, processes and business models that need final development to be able to shape a new market and achieve wider deployment.
	If the proposal involves technological innovation, the consortium should declare that the technology or the technologies concerned are at least at **Technology Readiness Level (TRL) 6**. The intention will be to bring the TRL up to 8 for technological innovations and to an analogous level of maturity for non-technological innovations during the lifetime of the FTI action.
	FTI actions are encouraged to be interdisciplinary, cutting across different sector and technologies. Actions supporting innovative concepts that have the potential to disrupt or to create new markets are particularly welcome.
	Duration: 12-36 months (around 2 years). Marketing of the project object before 36 months from the start of the project. The proposal must implicitly include the pre-existing business plan showing the market launch within that term.
ELEGIBLES COSTS	**Fundable activities:** validation of the system in real work environments, testing, piloting, validation of business models, establishment of standards, pre-normative research, obtaining European quality seals.
	Financing expenses: personnel, subcontracting, other costs (depreciation, consumables, travel and subsistence allowance), direct costs of providing financial support to third parties, indirect costs (25% of direct costs excluding subcontracting).

Table 2: FTI call evaluation procedure

EVALUATION PROCEDURE	**Impact (50% weighting):** The objectives of the submitted proposal are in line with the expected impacts of the FTI, notably fast development, commercial take-up and/or wide deployment of innovative solutions, time to initial market take-up, leveraging of private investment in research and/or innovation. In addition, in line with the objectives of the European Innovation Council Pilot, proposals that can create a new market are particularly sought after. The proposed innovation is expected to generate a positive impact at the European level other than economic (societal, environmental, scientific, etc). Wherever appropriate, the minimisation of impacts on climate and the environment is taken into account.
	Excellence (25% weighting): The objectives of the proposal are defined in a clear and pertinent way, support Horizon 2020 objectives, and directed towards fast, wide market uptake. The proposed activities to be executed will contribute to a credible, realistic and optimal development of the innovation to the level of market uptake. The underlying, jointly developed business innovation concept of the proposed innovation is sound, and has already been tested in an operational/production environment. It has a potential to bring important progress to or revolutionise an existing industrial sector, business practice and/or societal challeng
	Quality and efficiency of implementation (25% weighting): The proposal demonstrates that the partners of the consortium are complementary, and together have what it takes (personnel, facilities, skills, networks, access to markets...) to deliver on groundbreaking innovation and fast, wide market uptake. Implementation risks and threats are well identified; the proposal contains a risk mitigation plan, with detailed actions.

As it has been shown, the main characteristic of the FTI is to be a non-reimbursable financing. For companies, being able to be 70 % of the total cost of the project fully financed. If to this, we add the opportunity cost of the interest that we would stop paying in a credit-based financing strategy, the cost of the project (for a company) is reduced by 75 %, being able to undertake a project with much more risk than with other strategies. The economic risk is not assumed by the non for-profit entities that form the consortium and that makes it much more attractive to commercialize ideas that, at first, could remain in a laboratory and remain unexploited.

However, given its clear advantages, it is a call where the competition is very high and where you must not only meet the requirements, but be a more interesting project than the rest to obtain financing. Each project obtains a specific score for each module and, according to the weight of each one, a final grade up to 15 can be obtained. To obtain financing, the grade must exceed the limit of 13. If it exceeds it, the projects are ordered. from highest to lowest score, granting funding to the first of the ranking and continuing with the following until the budget is over. It could be the case of exceeding the limit of 13 and not obtaining financing.

If we rely on the data provided by the EASME agency of the European Commission, the success rate in the FTI calls is 7 %. This gives us an idea of how difficult it is that, not only is our project eligible, but it can be financed. However, another relevant fact is the real success rate. This rate is calculated based on the financed projects / projects that have passed the cut-off. This

rate is much higher, at 59%, Which indicates that 6 out of 10 projects that pass the cut-off would obtain funding. Calculating the success rates based on the number of above-threshold proposals would better reflect the chances of high quality and well formulated proposals. The conclusion that we can draw is that, even though it is very difficult to finance a project with the FTI, if we make a proper application which exceeds the cut-off stage, we have great possibilities of obtaining financing for the project.

Looking at the evaluation criteria, special attention is paid to the *impact* module. This module evaluates the business plan developed, the existence of a target business segment and the implementation strategy in the target segment. Special attention should be paid to the weaknesses [4] presented in this module to improve the application.

6 Starting situation and methodology to apply

As already mentioned in the introduction, the Consortium of 5 organizations, companies and research centers, among them the UPC, looked for public funding for market entry through the FTI call in the H2020 program. The consortium, now called C5, participated in the call on 10/22/2019 with a request developed by C5 members and complying with the formal requirements of FTI (Table 1)

Once the application was submitted, a team of experts from the H2020 program and the European Commission evaluated the application, giving a score to each of the 3 modules already explained in point 5. These expert evaluators have a general knowledge but never evaluate a application from their field of knowledge, but always the applications are evaluated by experts with general knowledge of the sector, never specific. The reason for this peculiarity is that the European Commission wants applicants to be able to explain their activities and innovative technologies to all audiences and not only to someone skilled in the art. For this reason, **the application must be concrete and detailed enough to underpin each module and each activity, but general enough so that it can be understood by any reader**. During the cut-off of 2015-2016 and 2018, about 75% of evaluators were from the business sector, where 25% where affiliated with the academic/research world. The FTI Evaluators divide almost equally with regard to gender, about 45% were females.

When the application has been evaluated, the European Commission publishes an Evaluation Summary Report (ESR) where it specifies the score given to each module and the main weaknesses that the experts have detected in each one.

PODSTAR received an overall score of 9.95 far below from the cut-off located at 13 points. The criteria that penalized the most was the low score in the IMPACT module (3 out of 5), since it is the module with the highest weight in the overall mark. This makes us think that the demand approach, the justification of the project and the future plan were not well thought out. A summary table with the main weaknesses detected by the experts in the ESR is attached below.

Table 3: Main weaknesses detected in PODSTAR ESR

Criterion	Weakness
EXCELLENCE	· The innovation is considered not to have been sufficiently tested with a considerable number of tests. · Market entry barriers have not been taken into account. · Does not compare to the competition
IMPACT	· Evidence of the demand for a new radiation protection product on the market is not provided
	· A long-term implementation strategy is not provided
	· Lack of detailed competition analysis
IMPLEMENTATION	· Risk analysis is short and incomplete
	· "Best value for money"
	· Clinical tests in the WP

Adapted from *ESR* [4]

As we can see, the majority of negative points that the application has are located around the non-justification of the market demand to be addressed and a poorly detailed future business plan. Barriers to entry to the market and analysis of the competition little detailed, future strategy and a risk plan are elements that experts want to find in applications.

Furthermore, a guiding principle of the H2020 program is "best value for money". The goal is to make sure that the consortiums and / or companies that participate in the program, in case they have to hire external collaborators, make sure that this collaboration is the best in relation to quality / price, that different options are compared and the best is chosen with objective, functional and organizational criteria of the project. They want to avoid hiring by subjective criteria and / or by partiality and that the money from the grant goes exclusively for the technical and economic achievement of the project.

In order to improve the submitted proposal, the detected main weaknesses are very important. For each one, a reformulation of the module and / or section should be found based on past experiences and success stories.

The healthcare sector is a very competitive area within the calls of the H2020 program. Normally, the applications that participate in the calls have an extremely high level of innovation, around 50 % [1]of the projects funded by the FTI in the last calls have been projects of the healthcare or biotech sector, occupying the highest positions and scores. Thus, these cases are a good example where to look at and base the application remodeling on cases in the same sector that have already worked well in the FTI calls.

Thus, the methodology that will be applied for the improvement and restructuring of the application will be that of, for each detected weak point to be improved, **propose a series of improvements based on a sum of the experience in the drafting of national and European applications and in specific success stories of the sector**, looking for different projects that best suit PODSTAR's needs and that help improve the ESR score.

Below is presented a table with specific proposals, based on the writing of grants applications. Afterwards, each proposal will be undertaken separately, searching the bibliography and databases for successful cases to support the proposal and adapyo t it to the case of PODSTAR. To give an example, in the case of planning the validation of clinical tests, funded projects related to the clinical testing of drugs, their phases and their approval by the medical authorities should be analyzed. However, in the case of looking for a successful business plan, one should turn to hardware-based funded healthcare projects. This is how each proposal will take shape throughout this master's thesis, specifying in each case why each change is undertaken.

Table 4: Proposals

Weakness	Proposal
The innovation is considered not to have been sufficiently tested with a considerable number of tests. Market entry barriers have not been taken into account. Does not compare to the competition	A specific description of TRL is missing, the level of maturity of the technology. The proposal should graphically represent how TRL has evolved over time, and for each level is important to say what actions were taken and what results were achieved. The objectives section should be developed differently: Mention in a table the objectives of the project and for each of them, the KPIs that are needed. In the state of the art section, compare in a table the characteristics offered by the project and the technologies already on the market to demonstrate how PODSTAR is better.
Evidence of the demand for a new radiation protection product on the market is not provided	Is important to emphasize in data, references and charts that show the needs of the market, the size, the segments and how it is growing. The part about market barriers has to be more schematic. For each barrier, propose a solution on how to overcome it
A long-term implementation strategy is not provided	The long-term market-up-take strategy must be specified. More explanation of to whom it is sold and the countries of destination, from the year of entry to the market until 2030.
Lack of detailed competition analysis	Analysis of competition also considering sales prices.
Risk analysis is short and incomplete	From the ESR, much emphasis is placed on a mitigation plan for possible risks. Detail and expand the project risks (validation and implementation risks).
"Best value for money"	Justify why it has been decided to subcontract entity X for that price.
Clinical tests in the WP	It is a very technical aspect, but due to the details they ask, probably it should restructure the WPs according to success stories in the HealthCare sector: - Management - Requirements - Replication, scale-up, simulation - Use case demonstration - Dissemination

From here, the proposals will be analyzed in detail, proposing an alternative text and the chosen improvements will be applied. The ideas presented as proposals above are subject to change when analyzed in detail; these are guidelines to follow, but not definitive proposals.

Thus, to outline how the application improvements will be applied, the procedure will follow the following 4 phases:

- Pay attention to the critical points indicated by the ESR. Each and every one of the main weaknesses will be analyzed and addressed to try to restructure its explanation, adding more data and arguments if necessary.

- Search for new ways to structure the weakest points of the application. The H2020 framework's calls have very clear and established criteria, seeking detailed, specific, business-oriented explanations with a future plan. Through the experience obtained in the drafting of national grants, propose improvements to the detected weaknesses, among them, those mentioned in the ESR report [4], following the criteria sought by the FTI evaluators.

- Once the new orientation has been decided, success cases from previous FTI calls that can be adapted to the PODSTAR situation will be looked for. Projects in the Healthcare sector have a high success rate in this type of call; Looking at how they detail your application will help make your PODSTAR application better.

- Finally, the improvement will be proposed, giving a determined approach and trying to fit perfectly with the evaluation criteria of the European Commission.

In addition to a better writting and description of the FTI proposal, the study will be oriented towards the search for an alternative financing strategy at a national level. It has been deemed necessary to include this study as a contingency measure to a possible second rejection of European public financing and thus, have other alternatives that ensure the continuity of the project.

7 Application improvements

To analyze each improvement that will take place, the order of criteria followed by the ESR will be followed. Therefore, they will start with the improvements related to the **IMPACT** criterion, followed by those of **EXCELLENCE** and ending with those of **IMPLEMENTATION**.

7.1 The demand and the market

The weakness detected by the evaluators has been the lack of a detailed justification of why the development of a solution for radiological protection in interventional radiology is necessary. In summary, what it should be tried to achieve is that the project does not seem a research programme; make sure that the proposal is business oriented and focuses on the market potential of PODSTAR innovation.

From the standardized criteria of the FTI calls, a clear description of the demand is sought, why this demand is created, how the demand will grow and how the product will cover this demand. Convincing description of targeted users or customers of the innovation, how their needs have been addressed, why the users or customers identified will want to use or buy the product, service or business model, including compared to what is currently available if anything at all. This, linked to the analysis of competitors that will be discussed later, should give the reader a precise idea of how necessary the solution is in the market.

On the other hand, the analysis of the market in which the proposed solution would enter is also important. The description of the market, its size, the growth rate and the stakeholders are considered essential to complement the first part. An expected market size is requested. Above all, much emphasis is placed on analyzing the market, not only at the national or European level, but at the global level. Convincing specification of the potential to create new markets or create market disruption together with a convincing specification of the substantial demand (including willingness to pay) for the innovation.

By carefully analyzing the *Market analysis* section of the FTI proposal [5], one can find successes and errors. Starting with the hits, the Kotler's 7-Os model is a good approach. It is a systematic model used to analyze and understand the behavior of buyers in a certain market. It is a good way to understand where the product plays on, who it is for and what the buyer is looking for. However, PODSTAR is a product that creates a new market, one that is very little exploited and emerging, where a need is found and there is still no solution to fill it. This is where the failure of the market analysis is considered to be.

In the last proposal [5], the justification of the project focuses on the advantages the product brings or the novelty of its characteristics; everything that makes PODSTAR good and innovative. However, the growing (and imperious) need for such a product and the real justification for why it has been carried out are not delimited. **A product is developed because of a need to be met is detected and, from there, you try to innovate within the possibilities, but the process is never the reverse.**

The PODSTAR features that are highlighted are the ability to expose a whole-body dose map, the ability to gradually replace the necessary secondary dosimeter, the possibility of not carrying dosimeters on the medical staff, the virtual training platform (VTP) and the instantaneous return of dose results once the procedure is complete. However, it is not explained why medical centers need PODSTAR or why PODSTAR fills a gap in a very new market. This explanation is

needed for the evaluators.

The proposed market description is based on two pillars: **the need created by the European council directive 2013/59 / EURATOM** [6] and the lack of solutions that meet the demand created and the **growth of the popularity of the interventions with "image-guided procedures"**.

The approved European directive affects the workers in a great extent, as explained in 4, since it will be necessary to have an exact control of their exposure, not only in a specific point of the body, but in different points or areas, with the permitted limits being different according to the area of the body that is studied. Moreover, this need opens up to another future one: possible changes in the limits of radiation by areas of the body or inclusion of new areas. **It will be necessary to have an adaptable product** that has a measurement system that analyzes the whole body of the worker and not singular points.

Once the need has been argued by the legislative part, the justification must be addressed explaining the growth of interventions where radiation exposure exist. **The number of workers exposed to radiation increases every year in Europe and the use of non-invasive techniques such as image-guided procedures are increasingly common in European hospitals.** Therefore, with the created and growing need, and the lack of a solution in the market, the justification of the demand for the PODSTAR project will be explained.

Exploring applications of the healthcare sector from past years, the conclusion drawn is that the description of the market they make and how the product meets the need can be summarized in 3 phases:

- The product must work for what is required
- The product must work in the customer environment
- The client must trust that he will be able to make the most of the product.

As we see, the first two points are easily demonstrable with descriptions, tests and even videos. However, the third point is the hardest. We must specify because the product is the one that best fits the customer's need. This and everything described above is what we will try to explain in the market analysis. Thus, taking everything into account, a market description, a market impact and an identification of target users is proposed.

Market description

In December 2013, the European Council approved a new directive on radiation protection in workplaces, making all the previous directives obsolete and mandatory for the member states in their national legislation. This directive emphasizes the importance of individual monitoring, and even reduces the dose limit for the eye lens, based on the new ICRP recommendations [9]*. This reduction has significant implications for the dose monitoring of workers, in particular for interventional radiology (including cardiology) and other image-guided procedures, where the staff is close to the radiation source. The Directive also establishes new requirements for continuing education and training in the field of medical exposure.It is stipulated that in EUROPE there are 1M* [8] *of workers who work with radiation, a number that is growing year by year given current market trends. The impact of the solution in the market would be great and with enormous potential, having a long history of the number of potential users it would have.*

Secondly, another trigger that increases the demand for a solution to measure occupational exposure is the rapid growth of the image-guided intervention or interventional radiology imaging market. The interventional radiology market, globally, is expected to grow at a very interesting rate in the next 10 years [7]. *If we look back, this market was valued at US$ 16,367.0 Mn in 2018 and is projected to expand at a CAGR of 5.2% from 2019 to 2027. Interventional radiology emerges as one of the preferred diagnostic and therapeutic procedures due to its advantages as a minimally invasive, precision and lesser hospital stay. Furthermore, the current trend of awareness of early diagnosis and demand for non-surgical treatments is driving the rapid growth of the market.*

Thus, this growing demand for minimally invasive procedures that require interventional radiology and the obligation to increase dosimetry and radiology protection measures in the workplace, create the perfect market gap to provide a solution that meets this demand and that, in addition , give extra value as a product so that, in the future, customers will follow trusting PODSTAR. The market where PODSTAR wants to enter is brand-new and high innovative, created for the aforementioned reasons, and without a competitor or direct substitute. Being the first product in a new market gives you unique advantages that PODSTAR wants to take advantage of.

Focusing specifically on Spain, where the interventional radiology procedures performed are collected in the Health Center Statistics, it can be seen a trend of great growth in this type of procedure. Regarding hemodynamic tests, in 2016 231,513 were registered, increasing by 6,141 tests ($Delta$ 2.7%) compared to the year previous. 37,281 ERCP were also performed, 8,493 more than the previous year ($Delta$ 29.5%). Finally highlight 347,652 interventional radiology procedures ($Delta$ 2%). As we can see, the trend of this type of procedure is one of sustained growth, a trend that can be extrapolated to other community countries.

	Públicos-SNS		Privados		Total		Diferencia	
	2015	2016	2015	2016	2015	2016	SNS	Privados
Pruebas de TAC	3.927.942	4.086.514	758.969	834.338	**4.686.911**	**4.920.852**	4,04%	9,93%
Pruebas de RM	1.800.861	1.913.445	1.145.302	1.242.696	**2.946.163**	**3.156.141**	6,25%	8,50%
Pruebas de PET	96.868	109.122	25.739	29.182	**122.607**	**138.304**	12,65%	13,38%
Broncoscopias	71.567	94.321	6.427	8.090	**77.994**	**102.411**	31,79%	25,88%
Colonoscopias	575.272	763.713	192.551	279.603	**767.823**	**1.043.316**	32,76%	45,21%
ERCP	26.866	34.445	1.922	2.836	**28.788**	**37.281**	28,21%	47,55%
Pruebas de hemodinámica	190.078	193.841	35.294	37.672	**225.372**	**231.513**	1,98%	6,74%
Radiología intervencionista	295.109	299.136	45.906	48.516	**341.015**	**347.652**	1,36%	5,69%

Figure 10: Diagnostic and therapeutic activity according to functional dependence. Years 2015-2016

Target user and market impact

Once the demand / market created has been explained, it will be detailed how PODSTAR is the product that best fits this demand and its impact on the market is absolutely positive for radiation safety.

First, PODSTAR offers an occupational dosimetry system with a reduced number of personal dosemeters, out the need for active personal dosimeters (APD). Through 3D tracking with cameras, computational algorithms and RDSR-data, it is able to map the whole-body dose of the medical staff simultaneously and determine the dose to part of the body. This method implies 3 main advantages:

- *It is able to calculate the exposure of a whole-body model, being able to determine the exposure at any organ of interest, in particular, in the extremities and the eye (ensure that the requirements*

of the European directive are fulfilled), collect feedback and, through the virtual training platform, train which movements or areas are of greater exposure.

- *It has the ability to progressively and through approvals from regulatory agencies, to replace physical dosimeter with its mapping of whole-body exposure, obtaining results from all areas of the body and not only from singular points. The results would be obtained once the intervention was finished, not like now.*

- *It has a great modular and adaptive capacity. The current directive and legislation introduce exposure limits in certain body areas, however, the tendency is that new restrictions might come into place, in particular, there are studies hihglighting the importance to monitor the brain dose. The accumulated radiation to which medical personnel who practice interventional radiology are exposed will grow, (due to the growth trend of image-guided interventions discussed in 7.1) and with it the regulation on radiation protection. For this reason, the PODSTAR concept is the most appropriate for this situation. Its mapping of whole-body doses makes it possible to adapt limits to new areas of the body and to new restrictions.*

Thus, it is shown that PODSTAR is a product that fits perfectly into the market gap and that creates a positive impact. In addition, its didactic approach with the virtual training platform (also required by the European directive) makes it more attractive to medical personnel, since they do not only see it as a protection measure, but as a product of continuous training on their own mistakes .

To sum up, the growth of the market is due to the fact that the drivers surpass the restraints. PODSTAR is designed to completely neutralize one of the restraints on the market: the cumulative exposure to radiation by the medical staff. This creates a positive impact on the market and places PODSTAR as a driving force and key player in it.

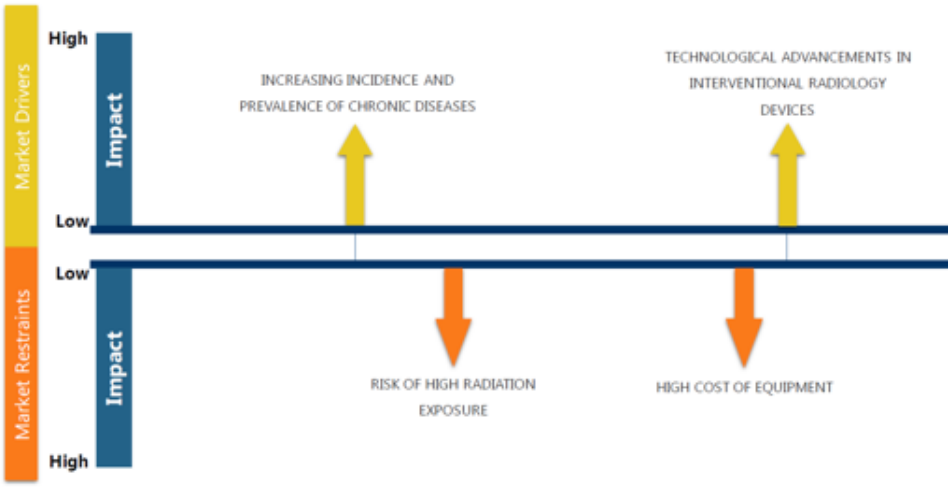

Figure 11: Market drivers and restraints

7.2 Market Barriers

To complement the improvements introduced in the description of the market, it has been necessary to organize and represent the most characteristic barriers to market entry. This type of analysis is essential in any market study and, although it is not expressly requested in the ESR, it is an important study to be carried out.

To carry out the analysis, for each detected market barrier, a measure has been proposed to overcome it. This exercise is very well seen by the evaluators of the European Commission, taking the initiative to overcome the possible problems that may arise.

Table 5: Measures to overcome Market Barriers

Barrier	Measure to overcome challenge
Reluctance of doing staff dosimetry without physical dosimeters	This barrier to public perception is one of the most difficult to overcome. Breaking old habits is complicated and more when it comes to the health of the medical staff. Thus, this barrier will be overcome over time and with the client's perception that PODSTAR is a product that works and meets expectations. In addition, in parallel, results, tests and demonstrations to regulatory bodies must convince that this product is a reliable substitute for APD so that its approval leads to greater customer confidence.
Problems with staff being filmed	For medical staff, and for workers in general, their privacy is important. It is necessary to raise awareness, explain and demonstrate that the 3D tracking of the PODSTAR cameras is used to recognize objects and staff and that these models are used for the calculation of doses, at no time will they be recorded in a conventional way.
Changes in regulatory and policy frameworks	This is an ever-present barrier or problem and it is that a change in the regulation or protection policies that frontally attack the PODSTAR technology could be a serious problem. However, the homologation of the technology by the regulatory entities and the ability of PODSTAR to adapt to changes in the restrictions, could significantly minimize this barrier.
Need of resellers	Due to the need to obtain data from the radiation emitting devices to make the calculation, the agreements with the companies of these devices will be very necessary. The joint sale of the device and the protection method (PODSTAR) can strengthen sales and be a very beneficial synergy. For this, agreements must be established with companies present in the market of medical devices emitting radiation for a cross-sale of the devices.
Need of Radiation Dose Structured Report (RDSR) format.	Currently, not all devices support this standard. Legislation on patient dose monitoring however is pushing the upgrade or replacement of these older devices. It is expected that by the time of the go-to-market, the vast majority of the v-devices will adhere to this standard.

7.3 Market up-take strategy and sales projection

One of the biggest weaknesses of the original proposal pointed out in the ESR is the lack of a long-term market strategy. The long-term market-up-take strategy must be specified. It should be explained to whom PODSTAR is sold, the number of expected products sold and the countries of destination, from the year of entry to the market until 2030. To design the most suitable market up-take strategy, disruptive software products have been studied in the market, which were developed to meet specific demand but which created a market segment where there was none before. Thus, a general description of the market up-take to be carried out and will be

made. Then, linked to point 7.1, a market quantification will be made, reaching a sales projection.

Market up-take

As can be seen in the sales forecast in the original proposal, revenue follows a mixed strategy. During the first years, the increase in new installed equipment is very high year by year, the implantation in the market is constant and fast and follows the growth patterns of the market. Then, in the medium term, the strategy is reversed and the number of new installations year after year is reduced in favor of subscription revenues, being a much more sustainable business model and being consistent with the S curve model of a new technology.

The current market situation is very well described with the S curve model attached below. In a growing market where there is a predominant and mature technology, it may be shaken by the emergence of a new technology that replaces the previous one, and that also meets the expectations of users beyond satisfying their needs 13. The current situation in the occupational exposure protection market is the one marked with the indicator in red 12. However, this behavior is cyclical; once the technology proposed by POD-STAR renders the previous one (APD) obsolete, its impact and market penetration will grow very fast, driven by the growth of the market where it is located (almost 6% CAGR in 5 years) until it must fight for the niche market with the competitors that emerge in the year 2-3 of world class, threatening their dominance in the market.

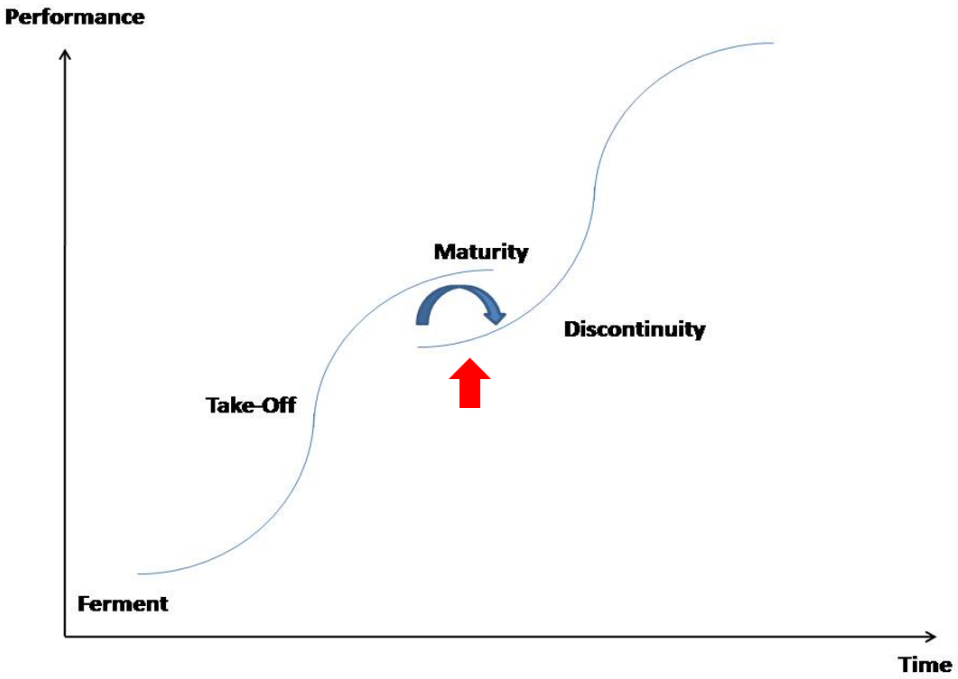

Figure 12: S curve model of new technologies entering the market

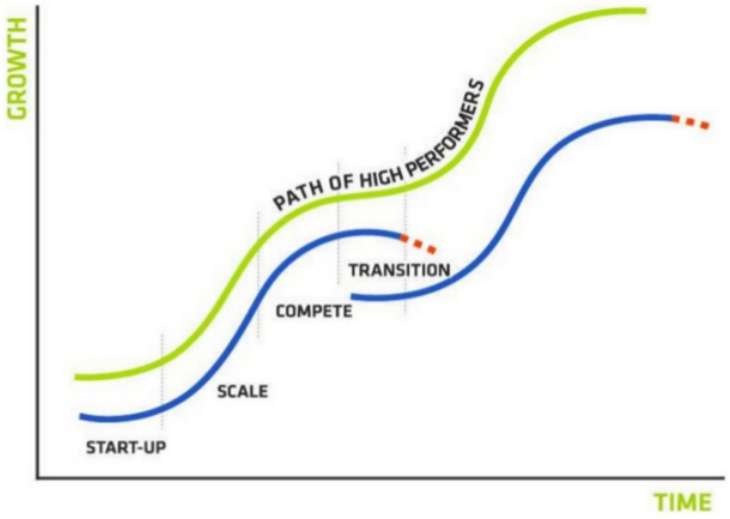

Figure 13: S curve model representing the customer's expectations in the technology performance

To avoid this situation, PODSTAR has two bargaining chip. Its ability to adapt to changing market behaviors is one of its main strengths. Its modular and digital structure means that, subject to different changes in legislation, new restrictions or even customer requests and customization, PODSTAR is ready to deal with these changes quickly and at no cost to the customer. On the other hand, the mixed revenue model, based on long-term service subscriptions (software as a service (SaaS) model) makes the engagement that is created between customers and PODSTAR play in their favor; If customers trust PODSTAR and find that it works, it will be much more difficult for them to bet on changing the complete installation. If PODSTAR's business model were to sell equipment from year to year, each time at a higher rate, it would be easily substitutable by a competitor that would render it obsolete. However, due to its subscription model, clients having made an investment in PODSTAR, knowing how it works and checking its educational capabilities on the virtual platform makes its replacement much more difficult.

Sales Projection

In order to make a sales projection as accurate as possible, the potential market must first be quantified. To carry out this market study, 3 market components are identified when performing a top-down analysis. TAM is the Total Addressable Market. How big is my market universe? SAM is the Available Market. How many can I reach with our sales channel? How many can we serve? And the SOM is the Final Target Market. Who are my buyers now? Who will be the most likely buyers?

Figure 14: Market components

The market component that are the most interesting in studying is SAM. Quantifying it and studying its evolution will be crucial to make an accurate quantification. There are multiple models that could be applied to solve this problem, taking into account the accumulated dose per worker, the number of interventions, the number of exposed medical personnel, ... However, it has been considered that the most appropriate is to focus on PODSTAR buyers. As explained above, PODSTAR is complemented by interventional radiology units to provide hospitals with the dose information to which their workers have been exposed. For this reason, the buyers of PODSTAR will be hospitals where interventional radiology procedures are carried out.

The number of interventional radiology units per country has been considered to be the most accurate way of quantifying the market that PODSTAR can access, regardless of its market share. In order to have data as close to reality as possible and, taking into account that the countries do not provide exact information on their interventional radiology units, it has been considered to correct the data of the angiography units. **These units are the most used in interventional radiology but not the only ones, therefore, applying a factor x1.5 allows us to obtain a close idea to the interventional radiology units by country**. The countries of the analysis have been chosen based on the presence criteria of the main company of the consortium, Qaelum, purchasing power and importance within the EU.

Country	Number of Hospital Facilities	Total Adressable Market (TAM)	Number of Interventional Radiology Units	Interventional Radiology Units per Hospital	Serviceable Available Market (SAM) *Units*	Market Share *Penetration (%) SAM*	Serviceable Obtainable Market (SOM) *Units*
Spain	764	764	401	0,5	401	8,0%	32
Germany	3.183	3.183	1.314	0,4	1.314	2,6%	34
France	3.382	3.382	695	0,2	695	2,9%	20
United Kingdom*	1.257	1.257	111	0,1	111	1,8%	2
Austria*	270	270	110	0,4	110	7,0%	8
Belgium	187	187	191	1,0	191	15,0%	29
Sub-Total		9.043			2.820		124

Figure 15: Target market quantification

Data extracted from [11], [13], [12]. The complete sales projection is in Appendix I.
(*) The data for these countries has been extrapolated based on published data from 2007, following the growth trend of CT scanners.

Once the potential market has been quantified, a market evolution over the next few years must be stipulated and projected in order to project sales. The growth of the market is modifiable and adjustable according to the trend of the market in which the solution is included. However, in general, the market profiles of applicants for FTI funding are often highly disruptive and have great potential. For this reason, they tend to follow a trend of (1) strong initial growth, (2) stabilization in the medium term and (3) slight decrease in the long term. For this, growth percentages similar to other FTI candidate solutions in the biomedical sector that fit the PODSTAR market have been used.

Country	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Spain	401	421	449	488	542	621	703	785	869	943	999
Germany	1314	1381	1473	1599	1779	2038	2305	2577	2851	3093	3277
France	695	730	778	845	940	1077	1218	1362	1507	1635	1732
United Kingdom	111	117	124	135	150	172	195	218	241	261	277
Austria	110	115	123	133	148	170	192	215	238	258	273
Belgium	191	200	213	232	258	295	334	374	413	448	475
Sub-Total (1)	2820	2964	3160	3433	3817	4373	4947	5530	6118	6637	7032
Year-over-Year Growth	-	*5,10%*	*6,63%*	*8,62%*	*11,20%*	*14,57%*	*13,11%*	*11,80%*	*10,62%*	*8,49%*	*5,95%*

Figure 16: Market evolution (SAM) I

Country	2031	2032	2033	2034	2035	2036	2037	2038	2039	2040
Spain	1040	1071	1089	1084	1078	1072	1064	1055	1045	1034
Germany	3413	3512	3574	3557	3538	3516	3490	3462	3429	3391
France	1804	1856	1889	1880	1870	1858	1845	1830	1812	1792
United Kingdom	288	297	302	300	299	297	295	292	290	286
Austria	284	293	298	296	295	293	291	288	286	283
Belgium	495	509	518	516	513	510	506	502	497	492
Sub-Total (1)	7325	7538	7670	7634	7592	7545	7491	7429	7358	7278
Year-over-Year Growth	*4,16%*	*2,91%*	*1,75%*	*-0,47%*	*-0,54%*	*-0,62%*	*-0,72%*	*-0,83%*	*-0,95%*	*-1,09%*

Figure 17: Market evolution (SAM) II

Thus, once the evolution of the market is projected, it will be necessary to stipulate how PODSTAR's market share will grow over the years since its introduction on the market. Starting the market share according to the presence of Qaelum in the hospitals of the different countries, and following a growth trend similar to that discussed before, looking at other disruptive products in similar markets, the evolution of the market share and sales can be projected.

Market Share (%)	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Spain	8,00%	8,24%	8,98%	10,19%	11,57%	12,44%	12,62%	12,62%	12,62%	12,62%	12,62%
Germany	2,56%	2,64%	2,80%	3,05%	3,32%	3,49%	3,52%	3,52%	3,52%	3,52%	3,52%
France	2,89%	2,98%	3,16%	3,44%	3,75%	3,94%	3,98%	3,98%	3,98%	3,98%	3,98%
United Kingdom	1,78%	1,83%	1,94%	2,12%	2,31%	2,42%	2,45%	2,45%	2,45%	2,45%	2,45%
Austria	7,00%	7,21%	7,86%	8,92%	10,12%	10,88%	11,05%	11,05%	11,05%	11,05%	11,05%
Belgium	15,00%	15,45%	16,84%	19,37%	22,27%	23,94%	24,30%	24,30%	24,30%	24,30%	24,30%
Average share (%)	6,21%	6,39%	6,93%	7,85%	8,89%	9,52%	9,65%	9,65%	9,65%	9,65%	9,65%

Figure 18: Market share evolution (estimation)

Units	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Spain	34	37	44	55	72	87	99	110	119	126	131
Germany	35	39	45	54	68	80	91	100	109	115	120
France	21	23	27	32	40	48	54	60	65	69	72
United Kingdom	2	2	3	3	4	5	5	6	6	7	7
Austria	8	9	10	13	17	21	24	26	28	30	31
Belgium	30	33	39	50	66	80	91	100	109	115	120
Units	130	143	167	208	267	321	364	403	437	463	482

Figure 19: Sales projection (estimation)

As we can see, looking this projection, selling 130 units in the first year and growing around 270% in 10 years, the return on investment would be totally satisfactory.

7.4 Business plan

This point is not explicitly mentioned in the ESR, but studying different successful proposals, it has been observed that the evaluators of the European Commission welcome the proposals that are absolutely aimed at entering the market in the short term. For this reason, the definition of a preliminary business plan, with clear lines of action, is positively valued. This business plan will be defined in table format and will have the following elements: *Product Differentiation, Target Market Perception, Product Positioning, Market Segmentation, Distribution Channel, Cost and Pricing*. The business plan is agreed with the company of the consortium in charge of commercial affairs, Qaelum. Along with it, this plan has been drawn up, with a special emphasis on pricing and costs, a section entirely prepared by them.

<table>
<tr><th colspan="2">Preliminary Business Plan for PODSTAR</th></tr>
<tr><th colspan="2">Product Differentiation</th></tr>
<tr><td colspan="2">PODSTAR will demonstrate that it is a product capable of monitoring the occupational dosimetry of medical staff during an intervention without the need for uncomfortable physical meters. The differentiation of the product lies in its focus on the target: the comfort and safety of medical staff. Using 3D tracking through cameras, offers the ability to monitor and map specific areas or organs without the need to carry dosimeters in each of them, improving the comfort of staff during the intervention. Moreover, offering a virtual training platform offers to the staff the ability to improve best practices and analize in which positions or movements they would be safer.</td></tr>
<tr><th>Target Market Perception</th><th>Product Positioning</th></tr>
<tr><td>· PODSTAR works properly, is effective and easy to use.

· PODSTAR accurately monitors organ radiation without the need of uncomfortable physical supplements.

· PODSTAR is a unique product designed by and for medical personnel. There is currently no substitute product.</td><td>PODSTAR will be positioned as first-line occupational dosimetry platform for medical staff in interventional radiology, and the only application proven to be functional, comfortable and easy to use in this area in well-designed clinical trials.

The product will be installed and standardized for use in specialized radiology centers with experience in interventional radiology and occupational dosimetry. The medical liaison staff will interact with the medical personnel in charge of the interventions, in the centers where PODSTAR is installed, and will establish a social media strategy taking into account the regulatory limitations to do so.</td></tr>
<tr><th>Market Segmentation</th><th>Distribution Channel</th></tr>
<tr><td>No market segmentation is planned. The interventional medical radiology community is small and well-informed through a high-quality scientific meeting program, scientific literature, and social media. If PODSTAR is proven to be a functional and effective application, it is likely to quickly become the product of choice in countries where the product is approved. Access to the product will depend on the ability to pay a subscription to the dose-map calculation service and virtual training platform and to have a means of payment; consequently, there may be a bias towards centers or hospitals in developed countries that have a reimbursement system. The first wave of registrations is intended to be in clients that already have the QAELUM dose management system for patients and that its introduction and installation is simpler.</td><td>· QAELUM will establish and / or strengthen relationships with radiologists and specialized centers as advocates of PODSTAR

· Communications with radiologist and medical physicists using PODSTAR will be managed by a QAELUM medical liaison officer.

· The distribution of PODSTAR will be carried out through the QAELUM logistics system, taking care of the installation and set up directly in the specialized centers.

· It is estimated that there are 1 million radiation workers in Europe and legislation on its protection increasingly restrictive, demanding, currently scarce, measurement products. It is estimated that on the European and USA market, about 12,000 devices would be suitable to be equipped with PODSTAR.</td></tr>
<tr><th>Cost of PODSTAR driven by:</th><th>Pricing</th></tr>
<tr><td>· COGS (Cost of Goods Sold): hardware cost and operational cost.

· Royalties fees QAELUM will pay to academic partners

· Personnel cost: skilled pre-sales engineers for train and support sales people. Digital marketing roles.

· SG&A and marketing cost.</td><td>Price will be in the range of € 42K for 5 years use, but may vary between the US, the EU and the rest of the world as is common with medical products due to different restrictions on payers.</td></tr>
</table>

Figure 20: PODSTAR early Business Plan

7.5 Measures to maximize impact

Focusing on the strategy to maximize the impact of the solution in the market, the ESR report does not specifically mention it as a weak point. However, this type of call, so focused on market entry, values this type of explanation very positively. Having a detailed business plan, a clear projection of the evolution of the market and sales and a strategy of dissemination and exploitation are considered fundamental pillars of the application.

The strategy outlined in the application is very complete and detailed, in such a way that only one addition will be added where the dissemination strategy will be divided into 3 phases, following a model commonly used in the Healthcare sector for SaaS products, which truly fits PODSTAR.

As it can be seen, PODSTAR will adopt a multi-channel dissemination strategy, given the wide spectrum of entities to make an impact on (private and public healthcare institutions, healthcare network entities, suppliers, etc.). With that in mind, the dissemination actions for delivering innovation to market will be implemented in a path of three phases

- ***Awareness:*** *It is essential to raise awareness of the increasing challenges of radiation protection during interventions that the health system faces at all levels due to new community legislation, showing the motivation and reasoning behind the project. To that end, PODSTAR will provide solutions to overcome these challenges (at the technological, organizational and training levels).*
- ***Understanding and participation:*** *PODSTAR will create a brand-new technological solutions. Their understanding will be increased by active participation of the stakeholders. Moreover, taking into consideration the expected changes in EU regulations, these solutions will address compliance-related problems.*
- ***Action (target audience engagement and influence):*** *by demonstrating the solution to end-users (events, demos, presentations), a pro-active cooperation can begin, by using their received feedback to think of alternative approaches or implementations.*

Figure 21: Dissemination strategy

7.6 The competition analysis

This point is one of the most important in an FTI call request along with the justification of the market demand. The ESR evaluation highlights that the comparison with the competition has only been made with a single competitor, demanding a more exhaustive and extensive analysis of the competition.

The most common and detailed way of doing the competition analysis is to make a comparative table. In this way, the different products of the radiological protection market in interventional radiology will be compared by using relevant indicators and product functionalities. In this way, a global vision of the members of the market and the functionalities that each one has will

be given.

	Aimed at medical staff?	Calculation or measurement by zones or per organ	Possibility of working with more than one person simultaneously	Need to carry a physical dosimeter	Virtual training or education platform	Adapted dose analysis service or platform
GENEAL ELECTRIC: DoseManagement and DoseWatch	✗	✓	✗	✗	✓	✓
Toshiba/Canon: Dose Tracking System (DTS)	✗	✓	✗	✗	✗	✓
Bayer / Radimetrics: eXposure	✗	✗	✗	✗	✓	✓
Qaelum: Dose	✗	✓	✗	✗	✓	✓
Siemens: Teamplay	✗	✗	✗	✗	✗	✓
Philips: DoseWise Portals	✗	✗	✗	✗	✗	✓
RaySafe i3	✓	✗	✓	✓	✗	✓
PODSTAR	✓	✓	✓	✗	✓	✓

Figure 22: The competition analysis

Extracted from [14], [15], [16], [17], [18], [19], [20]

The biggest difference between these products and PODSTAR lies in their scope. While most of these products focus on the calculation and management of the doses received by the patient, PODSTAR focuses on the medical staff. These products were developed based on the EURATOM 2013/59 Directive, which strengthened the requirements concerning the dose information provided to patients undergoing medical procedures using ionizing radiation. However, the Directive also refers to new scientific information on tissue reactions which has implied a more strict control of the exposure of the lens of the eye of workers, in particular of interventional radiologists. It also establishes requirements related to training of exposure workers to reduce their exposure.

This difference makes PODSTAR a differentiating product in terms of interventional radiology, where medical staff must be close to the radiation source. Moreover, its virtual training platform, its capacity for calculating organ doses, its ability to work with more than one person at a time and its comfort (it does not need to carry a physical dosimeter) make it a truly disruptive product. Measurements in real time which increases awareness. Among the main advantages of PODSTAR, we can highlight that workers don't need to carry physical meters, which translates into much more comfort for medical staff. Moreover, PODSTAR provides information on doses not only at the thorax, but also and the ability to monitor entire areas or organs. Herein lies the main difference between the two products.

However, when we compare PODSTAR with RaySafe i3, we are talking about products with the same focus/scope; we could say that it is the direct competitor. Both focus on the protection of medical staff, whereas none of the aforementioned products does. However, both have different approaches. RaySafe i3 is based on electronic physical dosimeters, which are meant to be placed on the thorax. Compared to traditional passive staff monitoring dosemeters (not included in this comparison because they do not offer any of the advantages of PODSTAR) they provide measurements in real time, which increases awareness. However, since they are worn above the protecton means, the dosemeter reading has to be corrected to assess worker's effective dose. PODSTAR calculates doses without the need to carry physical meters, which

translates into much more comfort for medical staff. PODSTAR also provides the ability to calculate not only the effective dose but also organ doses. In addition to the Directive requirements about assessing the extremity doses and eye lens doses it also calculates doses in other organs of interest such as the brain or the heart. At present, PODSTAR cannot give real time reading, but the doses are available just after the procedure has finished which is much earlier than the standard passive dosimetry. Herein lies the main difference between the two products. Qaelum's experience in patient dose management and the results of the UPC and SCK research project, MEDIRAD [21], will allow in a second phase that PODSTAR will allow the calculation of doses of workers and patients together. Workers dose calculation has been prioritized because it is unique and there is no competition.

As it has been observed, the price has not been included as a comparison indicator. This is because, being a really brand-new market segment, the majority of companies that are identified in the comparison neither offer the same service as PODSTAR or directly compete with it, at least at the beginning of the market entry. However, RaySafe i3 is the product that could compete directly with PODSTAR if it adapted its functionalities. For this reason, in the original request, the price of RaySafe i3 is compared with PODSTAR, since today, it is the most real comparison that buyers will be able to make when they decide to contract a radiation protection service.

7.7 Evolution of TRL

Continuing with the "EXCELLENCE" criterion, the following three points, including this one, will try to improve, as far as possible, the explanation given in the original proposal. The score obtained in the ESR report (3.88 / 5) in this criterion is the highest among the three, having few weak points regarding nuances in the explanations. Thus, the improvements to be proposed below are based on complements to the original explanation, especially taking into account the indications of the European Union and the positive impressions of the evaluators to other successful proposals.

As for the evolution of the TRL, from the European Commission they value very positively to see an evolution of the TRL of the candidate projects to be financed. Therefore, it is proposed to outline the TRL jump that the project will make from its inception to its entry into the market. It will be linked to the project's objectives, which will be redefined adapting them to the evaluation criteria of the CE.

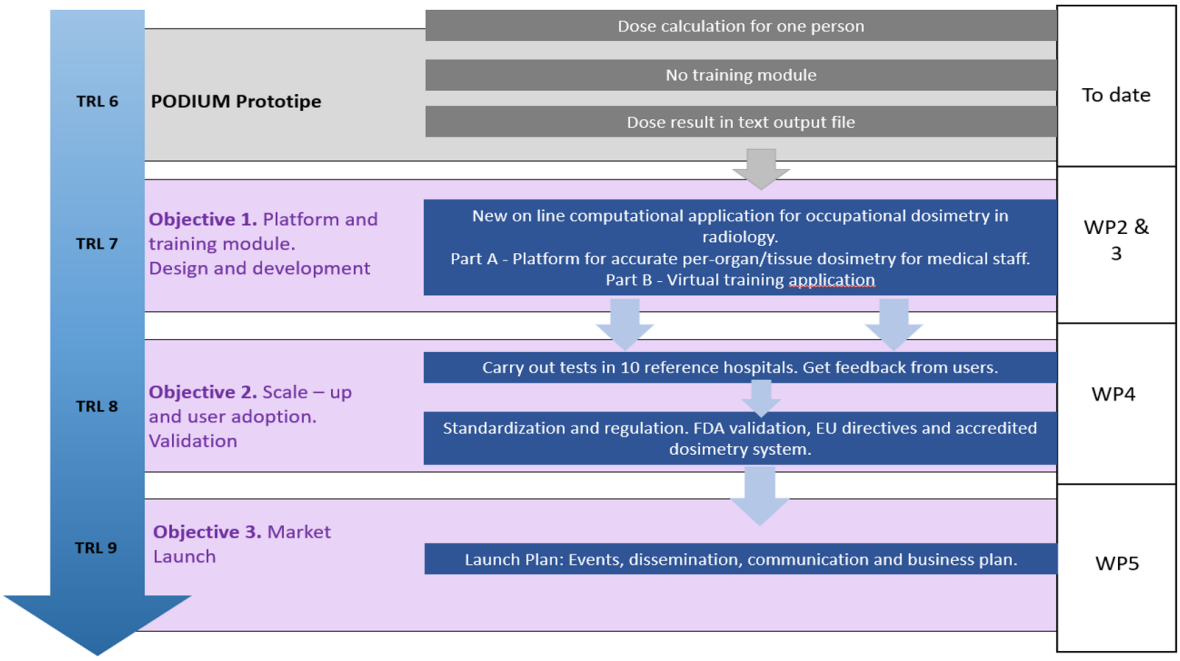

Figure 23: PODSTAR TRL evolution

7.8 Objectives

Linking with the previous section on the evolution of the TRL throughout the project, the objectives of the project are redefined to fit the criteria of the European calls. To do this, the objectives are grouped into 3 groups, representing the TRL jump. Each objective must have its title, its description, its association to a corresponding WP and its KPIs for its measurement. Goals must meet the SMART rule, and therefore must be measurable. The following objectives are defined, being a general goal and three specific goals:

General goal: *The end result of the PODIUM H2020 project is a working staff dosimetry prototype that has been successfully tested in different hospitals. Therefore, current technology level reaches the Technology Reference Level (TRL) 6. The PODSTAR project aims at technically optimising this prototype towards a more advanced (well-performing under real-life conditions), professional and regulatory-proof software system (i.e. complete and qualified system) returning TRL 8. Specifically, starting from PODIUM's tracking technology, PODSTAR will integrate a volumetric capture system that will allow for easy multi-sensor integration, calibration and synchronization. Explorations of the market, validation of the business model and having the product evaluated by the end-user at regular time intervals further explains the precise fit of PODSTAR in this FTI call. It is our goal to be ready for commercial roll-out of the product at the end of the project.*

Objective 1. Technical Excelence	
Description	The main goal is to build a market-ready platform for accurate per-organ/tissue dosimetry for medical staff in fluoroscopically guided procedures, including a virtual training application for an improved understanding and optimisation of the radiation received by the staff. The team wants to focus in improving the occupational dosimetry, increasing its accuracy. (from up to 100% uncertainty levels towards 20% for the dosimetry module, from no estimation towards estimations within 20% for organ doses). On the other hand, the training module main goal is to give to medical staff or end users a good understanding of ionising radiation in an operating theater and protective measures in less than 3 hours using serious game principles, thus reducing the radiation exposure of the staff.
Addressed in	WP2 & 3
KPIs	Platform design (beta, final), End-user evaluation (beta, final), 3D tracking module (beta, final), Accurate dosimetry calculation module (beta final), Real-time organ dose prediction module (beta final).

Figure 24: Objective 1 definition

Objective 2. Scale-up and user adoption	
Description	Once the preliminary design and development have been completed, the prototype should be validated through clinical tests in hospitals or reference centers. It is really important to get feedback from users, reaching an acceptance level of 85%. To obtain the largest number of end users for these tests, hospitals and centers will be contacted and events will be organized to promote the prototype. The final objective is to achieve the installation of 5 PODSTAR equipment in reference institutions in order to start entering the market through the academic and professional world. Through tests with end users, the necessary feedback will be obtained to reach the final versions, both of the measurement platform and the virtual training, being able to deliver a definitive integrated product.
Addressed in	WP4
KPIs	Cloud-based platform(beta,final), Virtual Training Module (beta, final), PODSTAR integrated product (beta, final). Data reports from tests. Final integrated product.

Figure 25: Objective 2 definition

Objective 3. Market launch	
Description	Once the final prototype has been developed, a product launch plan should be made. The search for investors is an important aspect, which implies the obligation to have a specific business plan. All scenarios must be considered and planned for market entry, dissemination, communication, pricing or monetization elements must be taken into account. At the same time, certification, validation and standardization must be obtained from the regulatory institutions.
Addressed in	WP5
KPIs	PODSTAR Business Model, PODSTAR Promotional and Branding Material, Standardisation, Regulation & Compliance Reports, Communication, Dissemination, and Advertising Reports

Figure 26: Objective 3 definition

7.9 State of the art

The scope of the state of the art is closely linked to point 7.6 of the competition analysis. At a general level, by doing a market analysis we can get an idea of the technologies developed in the field of radiological protection during interventional radiology. Even so, different projects or technologies in progress that may be related to PODSTAR have been explored and are presented in a table form. The projects, methods or technologies that has been found similar to PODSTAR are based on three fundamental points; 3D tracking of one or more simultaneous people, dosimetry staff and virtual training in healthcare. In this way, the "EXCELLENCE" criterion section would be completed.

NAME	LONG NAME	DESCRIPTION	EAR OF INTRODUCTIO	IMILARITY TO PROJEC	FIELD OF STUDY	SIMILARITY KEYWORDS
SIMPL	Automatic Estimation of 3D Human Pose and Shape from a Single Image	Method to automatically estimate the 3D pose of the human body as well as its 3D shape from a single unconstrained image	2016	Medium - Low	3D tracking	3D body shape, human pose, 2D to 3D, CNN.
LapSim	Laparoscopic Simulator	Give the students the opportunity to improve their psychomotor performance through standardized and measurable training, provided only by virtual reality simulators	2018	Medium	Virtual Training	Basic skills, tasks training and imaging
Eyesi VR Magic	Eyesi Cataract and vitroretinal	Cataract and vitreoretinal surgery training	2017	Medium	Virtual Training	Basic skills, tasks training, imaging, surgery training
RaySafe	RaySafe i3	Active dosimetry system that provides real-time insights about radiation exposure, helping medical staff and physicians evaluate and directly adjust their behaviors and more effectively use all the radiation reduction solutions provided in the room.	2018	Medium - High	Staff dosimetry	Staff dosimetry, real time measurement
Teamplay Dose	Teamplay Dose from Siemens	Radiation dose management solution providing easy access to dose data, supporting the quality assurance process for monitoring imaging radiation dosage. teamplay Dose displays data for continuous dose performance evaluation.	2019	Medium - High	Patient dosimetry	Monitoring, display and management

Figure 27: State of the art overview

7.10 Clinical test in the WP

Lastly, the "IMPLEMENTATION" criterion will be worked on. This criterion has as its central pillar the project plan and its organization; You must detail the activities to be carried out, how long they will last and the necessary resources, to achieve the objectives proposed in EXCELLENCE.

The ESR makes an express mention of the lack of a product testing and validation plan that could ensure precision in the calculation and measurement of doses. To achieve a better score in this criterion and to improve this weak point, it has been decided to restructure the WP in such a way that, having the same number of WP as the original proposal, a new WP is created dedicated exclusively to PODSTAR clinical trials and check its effectiveness, precision and safety.

The WPs that undergo the main changes are WP 3 and 4. The WP 1 remains as the activity focused on project management. In the same way, WP 2 remains the WP in charge of the design and analysis of product requirements at a high level. However, the WP 3 has undergone modifications. Initially, WP 3 had the specific objective of developing improvements to 3D tracking and online dosimetry algorithms. Now the development of the PODSTAR training module is added, initially located in WP 4 but moved to it to make room in 4 and dedicate it only to the testing phase. Thus, WP 3 will be in charge of developing the product improvements and WP 4 will be in charge of the testing phase. To carry out this workload change, 10 person - month per participants are reduced in WP 4 corresponding to DXT and added to WP 3 by the same company, as it will be in charge of developing the training module. WP 5 remains in charge of Marketing, Advertising and Early Adoption. The changes in the WP summaries and objectives are shown below. Goals written in italics mark new goals in the corresponding WP. Those without italics are the objectives that were already part of the WP previously.

WP3	Lead beneficiary		UPC		
	Up-scaling/Productization				
Participant number	1	2	3	4	5
Short name of participant	QM	DXT	UPC	SCK	CERTH
Person-months per participant	4	16	32	32	34
Start month	M1	**End**	M27		

Figure 28: New WP 3

Objectives WP3

- To iteratively develop the core components of the PODSTAR platform for people and equipment 3D tracking, accurate dose calculation, and real-time dose estimation through two major releases
- To optimise and up-scale the Online dosimetry algorithms developed in the recent PODIUM H2020 Project to go from the demonstration stage to market uptake and increase the number of people monitored, to improve the tracking system and to optimize the hardware cost versus accuracy.
- *To develop the PODSTAR training module by integrating the latest virtual training technologies with dosimetry simulation.*

In this way, activity 4.2 of the original proposal will become activity 3.4 in the new proposal.

WP4	Lead beneficiary		QM		
	Demonstration				
Participant number	1	2	3	4	5
Short name of participant	QM	DXT	UPC	SCK	CERTH
Person-months per participant	45	28	9	6	4
Start month	M3	**End**	M29		

Figure 29: New WP 4

Objectives WP4

- Iteratively develop the PODSTAR platform including cloud-based framework and virtual training system through two major releases
- *Test the preliminar release of the core components delivered by WP3 in a group of selected hospitals and integrate the results to the PODSTAR productised platform.*
- *Demonstrate the functionality and advantages of the new release of the PODSTAR platform in at least 5 hospitals of 3 countries*
- Deliver two major releases of the complete platform, tested and documented

Therefore, this new WP 4 - Demonstration must incorporate the following deriverables as a

KPI: Testing of the beta product release in at least 2 hospitals (different European countries), evaluating the final product release by at least 5 hospitals, spread over 3 countries at minimum.

7.11 Risk Management

As a last point, the ESR evaluation highlights a more precise and detailed Risk Management. As part of the project organization, carrying out adequate risk control is essential for achieving the main goals. To propose a redesign of this section, different successful proposals have been consulted. The most common way to approach risk analysis is by posing the potential problem and a measure to mitigate it. The mitigation approach is very important for evaluators as it gives a sense of larger project planning.

DESCRIPTION OF RISK	LEVEL OF THE RISK	WP INVOLVED	MEASURE TO OVERCOME RISK
Key staff leave the team (leave employment, ill health, retirement etc.)	LOW	WP 1-5	The Project Manager will ensure good project management and communication chain to enable efficient information sharing and personnel planning across the project team. In the work teams there will always be the figure of the second on board, who will share competences with the team leader and who can take over if the situation occurs that the boss is missing. The loss of the team leader is considered more sensitive than that of another member
The actual costs and person months of the project exceed those estimated within the project application	LOW/MEDIUM	WP 1-5	The figures in the project proposal are estimates and any shortfall on costs or person time will be answered as soon as possible. A periodic Reports delivery strategy is adopted to quickly identify delays and take action.
Clinical trials are expensive and time-consuming and the outcome of the trials is uncertain both with respect to safety and efficacy results. Study delays may also occur	MEDIUM	WP 4	This risk is one of the most worrisome in the development of such a project. To try to mitigate it, it is considered that an adequate follow-up and a good design of the clinical tests will be sufficient for a good development of the testing phase.
Potential technical issues around development	LOW	WP 3	Expectations for development problems are low, as the teams in charge have experience in their fields and will use technologies with which they are familiar. Iterative processes and continued monitoring by the project management will be key to detect problems in time.
Introduction of new legislation that affects current regulations	LOW	WP 1-5	It is unlikely that in the short-medium term the European Commission will launch new regulations on radiation protection, taking into account that there are still many countries that have not adopted the previous directive into their national legislation. However, PODSTAR is prepared to update its software if new changes appear on the scene.

Figure 30: Risk Management

7.12 Best value for money

The importance of this point to discuss lies in the great attention given by the European Union to the inappropriate use of its funds destined to finance projects. The objective is that the money planned to be used to contract the services of external collaborators is justified. Normally a justification is required as to why it is chosen to hire X collaborator. This justification can be developed in multiple ways, such as justifying a relationship of trust and knowledge of the project for having participated in other phases of the same project or as being the partner that best meets the needs.

In the particular case of PODSTAR, it is contemplated in the budget to contract an external collaboration solely to carry out the certification of the product. When the time comes to hire these services, it is recommended to request 3 different quotes from 3 different collaborators. In this way, justify that the chosen one meets the best ratio of services provided - cost.

8 National funding alternatives

From the management of the consortium in charge of submitting the application for the POD-STAR project to the FTI call, they are aware of the great difficulty in obtaining financing for this type of call. Being of competitive competition and of a high innovative level, the projects presented are of great technological risk with innovations in leading fields such as the biomedical, pharmaceutical or chemical sector. Therefore, it is aware that public financing alternatives should be studied in case the application to the FTI is not granted to the project.

At a national level, there is a reference entity in terms of public financing in RD, the Center for Industrial Technological Development (CDTI [3]). There are other entities that finance RD projects such as Red.es, however CDTI is the benchmark entity, aligned with the H2020 framework of the European Union, comparable criteria and a greater variety and quantity of calls. Thus, the most profitable and those that offer the most resources calls proposed by CDTI will be reviewed. To schematize the content, a table format will be used.

	PID	CERVERA	LDI	LIC-A	CIEN	NEOTEC
TERM	Open	Open	Open	Open	Open	01/07/2020
LOAN	Loan with non-refundable tranche	Loan with non-refundable tranche	Refundable loan	Partial refundable grant	Partial refundable grant	Full non-refundable grant
NON - REFUNDABLE TRANCHE	Up to 85%of the bankable budget	Up to 85% of the total approved budget	up to 85% of the bankable budget if it is co-financed with FEDER	Up to 75% of the total approved budget	Up to 85% of the bankable budget	Up to 70% (max. 250K)
TYPOLOGY	R+D	R+D	Innovation, investment	Investment	R+D consortium	Recently created / business plan
SME / LARGE COMPANY	All	SME and MID-Cap	All	SME and LC (in some CCAA)	All	Small companies
BUDGET MIN/MAX	175K €< x < €	175K €< x < €	175K €< x < 2M€ / 2,5M€	175K€ <x < 30M€	5M € < x < 20M€	175K €< x < €
SOLVENCY	Not in crisis	Not in crisis	Not in crisis and Credit condition greater than B -	Not in crisis	Not in crisis	-

Figure 31: CDTI Calls comparison

Data extracted from [3]

At first glance, the most profitable call seems to be NEOTEC. This call is designed for start-up companies with a large technological base; whose core business is directly related to the RD project to be financed. It is the call that offers the best conditions since it is based on non-reimbursable grants of up to 70% of the project budget (with a maximum of 250K).

Taking into account that RD could be accredited without any problem, since it really is a truly innovative project and the evaluators of the European Commission accredited its qualification in the first proposal, there would be no problem in presenting the project to this call.

As only Spanish companies can present themselves, the strategy to follow would be to present the UPC individually (or form a spin-off) and present the services of the other members of the consortium as expenses of external collaborators. Now, seeing the budget limitation presented by the call, the project should be raised again and some activities should be cut. The central activity of the project could be carried out by the UPC in the consortium, with the support of other collaborators, but leaving the other activities outside the project. In this way, a project according to the regulatory bases would be achieved.

However, the proposed strategy does not fit with the regulatory bases to participate in this call. In the regulatory bases it is stated that the applicant companies must be constituted in a maximum of three years prior to the closing date of the period for submitting aid applications. Thus, being a strategy for creating a new company, the NEOTEC call would not be valid.

Thus, in the first instance, the NEOTEC call would be the most financially interesting due to the fact of not having a loan. However, due to the type of company that must be an applicant, it does not work in the case at hand.

If another type of strategy is wanted, there are international calls called Bilateral. This type of call promotes a collaboration between two companies from two community countries to achieve a common scientific-technological objective. In this case, since there is a much more open collaboration than just two companies and a much more distributed workload, these calls would not be entirely adequate.

Thus, if we look again at the comparative table, after the NEOTEC calls, the PID call is the most profitable in terms of net grant (if we are looking for a large non-repayable tranche as in the case of the FTI). This call (PID) is one of the calls that are most requested by innovative companies in Spain. This is because its non-refundable tranche is considerably high compared to other calls and is very open to many types of topics, as long as they are unequivocally classified as RD. This call is in accordance with the strategy that has been defined in the NEOTEC call and new companies could participate.

In the face of this type of call, you can always ask yourself whether or not to take out a CDTI loan or go to the banking channel. In many cases, companies with a heavily loaded balance of financing may find it more interesting to finance a project through the CDTI so as not to further increase their risk statistics at the Bank of Spain, since these types of calls do not count in CIRBE (public loan).

Thus, having chosen the path of the CDTI public loan and choosing the PID call, it remains to study the conditions it offers. These conditions are very advantageous, however, they are far from what an FTI can offer at European level.

First, CDTI tests the company. Check that is not in crisis to proceed to deliver the grant. This test is not public but, from the experience obtained, they usually examine the consolidated accounts and whether the losses exceed half of the own funds. Once the solvency of the company has been verified, CDTI can request more or less guarantees or a capital increase, depending on the status of the accounts.

Once this step has been carried out, the application is technically evaluated and, if it is positively resolved, the grant is awarded. The % of the budget that gets subsidized depends on what the evaluator considers, being able to reach a maximum of 85% of the project budget. The non-refundable tranche it offers can range from 20% to 30%, depending on the evaluator's criteria and the type of the applicant company. In case of being a small company, just the case in hand, the NRT could reach 30%.

Thus, with the strategy mentioned in the NEOTEC call, the PID call from CDTI could be considered as an alternative to the FTI. Not having a maximum bankable project budget leaves the door open to include the entire original project in this call and not have to cut it, as if it would happen with NEOTEC. However, the higher the project budget, the more accredited its inno-

vation must be for CDTI to agree to funding the project. Even so, having participated in a more complicated call such as the FTI and RD being accredited without any doubt, it is considered that CDTI would have no problem financing a large part of the project budget.

The cons appear in the financial part of the project. As it is not a full non-repayable grant, but a public loan with a non-repayable tranche, the company must have its own resources to face the project. CDTI does not confer the grant at once, but rather an advance (about 35%) and the rest once the completion of the project is justified. Moreover, studying it from the field of financial solvency, it should be shown that the applicant company (or consortium) has sufficient own funds and is not at risk of crisis, something that is difficult to demonstrate in newly created companies that need very large subsidies to carry out their projects.

To sum up, national alternatives cannot compete in terms of economic advantages with European grants and calls. These, even though they are much more complicated to obtain, are still the best alternative for a company or consortium that wants to carry out a truly innovative project. However, if there was no alternative but to resort to the national market, the PID call is the one that best suits the PODSTAR project, although the form of the consortium should be restructured, directing it towards a company with demonstrable solvency.

9 Budget

To make a budget as close to reality as possible, the planning made at the beginning of the document has been taken into account, since the actual dedication has really been very similar.

An average dedication of 15 hours per week has been taken. Thus, knowing the weeks dedicated, the total hours dedicated to each task will be obtained. The price / hour reflected is the market average in RD financing consulting where the person in charge of carrying out the project is a junior consultant with little experience.

In this way, a total of 6,600 euros is obtained as a budget for the report of proposals for improvements for the application of the FTI call. The sum of hours of total dedication falls within the range of 12 ECTS (dedication to MUEI's Master's thesis) since an ECTS reflects a dedication of between 25 and 30 hours.

Budget of the development of the Master's thesis			
Task description	***Hours spent***	***Price/Hour***	***Cost***
Senior Revision	24	30 €	720 €
Preliminary analysis of the original application and the ESR	60	30 €	1.800 €
Detection of weak points	60	30 €	1.800 €
Improvement proposal	180	30 €	5.400 €
Documentation and analysis of national alternatives	30	30 €	900 €
Thesis Report and Defense preparation	5	30 €	150 €
TOTAL	**359**	-	**10.770 €**

Figure 32: Master's thesis budget

10 Environmental impact

The environmental impact assessment is the set of technical studies and analyzes that make it possible to assess the effects that the execution of a certain project may have on the environment. This analysis constitutes the most appropriate instrument to preserve natural resources and the environment. Thus, the environmental variable is introduced in decision-making about projects, which will provide greater reliability and confidence in the decisions to be taken. Furthermore, the environmental impact analysis of public and private projects in Catalonia is regulated by the legal framework 21/2013, which obliges projects to evaluate the environmental impacts of their activities.

In the case of the PODSTAR project, environmental impact is not a main aspect. The use of X-rays does not generate environmental contamination. In addition, the proposed solution reduces the transport of dosimeters from hospitals to dosimetry laboratories. In this way, the use of the platform in the cloud is promoted, which allows a great availability of information to various people without generating waste paper or transport impact.

Specifically in the writing and execution of this thesis, it has been carried out using telematic tools, remote meetings, PDF documents and minimizing transport. This has been enhanced by the pandemic situation that has been experienced in recent months but which exemplifies the little impact that both the thesis and PODSTAR have on the environment.

Conclusions

In this section, an attempt will be made to synthesize and highlight the most relevant conclusions that have been obtained from carrying out this project to improve an application for public funding of an RD project.

First, the great incentive potential of public grants in terms of RD project development should be highlighted. Many times, both large, mid-cap and small companies do not develop projects with a high technological and economic risk due to the possible loss of the resources invested and the low probability that they will be successful. Only large companies with financial support resources can afford to take big risks by developing innovative projects. Thus, by incentivizing public grants, smaller companies can carry out their innovative projects by externalizing economic risk.

Calls like the FTI, focused on market entry, help and incentivize the technological leap from TRL 6 to 9. However, this is just one example, and there are many European calls more focused on research and less mature technologies that support technological leaps in lower TRL. In this way, as a first conclusion, the incentive effect of public grants, whether European or national, is really positive in the field of innovation and helps the growth of the common market.

Focusing reflection on the strategy and approach of the projects eligible for an FTI, two essential factors have been found for any candidate project:

- **A clear orientation of the product towards the market is necessary.** The FTI call is oriented to products in the prototype phase and to incentivize their scale-up for their market launch. Therefore, the evaluation criteria in this area are very demanding. A business plan, justification of the demand, knowledge of the market, sales projections and a very worked and concrete future plan are requested. In other calls this aspect is not emphasized too much, however, in this call it is the most important. The request should not leave doubts about the business plan that the product will follow once it reaches the market.

- **RD must be accredited with a TRL 6 rating**. As has already been mentioned on many occasions in this thesis, the FTI call funds the arrival on the market of highly innovative products in its sector. For this reason, it is essential to know how to prove the value contributed to the market, if it exists, or how it creates a new one. Only the most disruptive projects will be funded, so it will be essential to know how to explain why the prototype developed is innovative in the market in question.

As another remarkable aspect, it would be the need for good planning and implementation of the project. However, this aspect is highly subordinate to the other two so it would be directly affected.

Another important aspect that should be highlighted in these global conclusions is the impact of COVID19 with respect to PODSTAR. Due to the impact that the virus has had and will have in the world, it is necessary to comment at what level this situation impacts in terms of the benefits of PODSTAR and how it can gain value.

Firstly, due to the effects of the virus on the respiratory system, the number of ICUs available in hospitals has had to be increased, thus acquiring many more X-ray devices. This causes the number of health workers exposed to radiation to highly increase. Although it is not specifically

interventional radiology, where PODSTAR focuses on because is the practice that receives the highest doses, it can be seen how the trend in demand for dosimetry continues to increase with health emergencies and how PODSTAR can positively respond.

On the other hand, COVID19 has turned out to be a highly contagious virus. This aspect causes the in-out of material, what means an additional risk in any workplace, especially in hospitals. Therefore, the number of dosimetric readings had to be reduced due to the use of physical dosimeters; the period has been extended from one month to 2-3 months. This problem would not exist using the technology proposed by PODSTAR. The non-existence of physical dosimeters would not entail any problem in this type of situation and the readings could continue to be carried out with the usual frequency without problem.

In this way, it can be seen that the solutions provided by PODSTAR are very positive and far superior to those that currently exist, using an example that has affected all sectors, such as the COVID19 pandemic.

To sum up, as the final conclusion of the master's thesis that the incentive effect created by public subsidies in the field of RD is really positive for companies or consortiums with a large technological base, where their core business is related to the development of disruptive projects. In this way, public organizations assume the economic risk of the project and allow the growth of companies that, due to their own resources, could not finance this type of project with such a high technological risk.

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