EUROSTARS Project Evaluation

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Agenda

- Brief introduction
- Evaluation process
- Guideline
- Example – ‚Best practise‘

Overall

We pay particular attention to the application of technology to produce marketable products, processes and services. The applied marketing strategy of projects is considered as important as the degree of innovation and the technical merits. It is therefore vital that you, the expert, have an excellent understanding of dissemination strategies, appropriate market areas and routes to that market.

Experts can only form opinions based on the content you provide

You may have the best idea in the world, but if you:

- are not clear
- lack detail
- fail to be convincing
- fail to be concise (to the point)

you will lose your reader and you will not be successful.

Innovators have ideas. Innovative entrepreneurs can explain and sell their ideas to others.

Evaluation process

Two-step evaluation process

1. Three independent technical experts per project
   I. Quality and efficiency of the implementation – Project planning and consortium quality
   II. Impact - Market and Commercialisation
   III. Excellence - Innovation and R&D

   Written report plus scoring on scale 1-6 (6 = best)

2. Independent evaluation panel (IEP)

Primary and secondary evaluator for each project

- Based on the reports from technical experts
- Outcome: Ranking of all projects (above and below a threshold)

EUROSTARS PROPOSAL

E! -

Expert Assessment Form

EXPERTISE REF

Assessment Date

TITLE

QUALITY AND EFFICIENCY OF THE IMPLEMENTATION	RATE

1. Quality of the consortium

(1000 character limit)

2. Added value through co-operation

(1000 character limit)

Example – IEP Briefing report

Project pitch

We'll do an improved version of our advanced time-lapse cells incubat[redacted] solution to try different component setups, to find the best method for[redacted] determination, to find most cost effective solution, to develop own smart software allowing automated analysis and sampling. We will deliver a fully working technical prototype allowing us to prepare for mass production and thus offering a competitive product without outside components.

Expert ID number	Basic Assessment	Market and Commercialization	Innovation and R&D
7,060	4	4	4
1,278,000	2	4	3
1,643,031	6	6	6

[redacted] - R and D Performing SME (Main partner)

Is this partner eligible to receive national funding?	***Answer: Yes***
Does this partner have the financial capacity to undertake their part in the project'	***Yes***

[redacted] LTD - SME

Is this partner eligible to receive national funding?	***Answer: Yes***
Does this partner have the financial capacity to undertake their part in the project'	***No***

No annual acount or business plan was uploaded before cut off.

Evaluation process – outcome May 2016

Mitterlehner: Heimische KMU belegen Spitzenplätze in Europa-Ranking

Erfolgreich im Wettbewerb: 13 Forschungsprojekte mit österreichischer Beteiligung werden mit 3,1 Millionen Euro aus Förderprogramm Eurostars-2 unterstützt

Wirtschaftsminister Reinhold Mitterlehner zieht eine positive Bilanz über die jüngste Ausschreibungsrunde des transnationalen Förderprogramms Eurostars-2. "Noch nie waren so viele Projekte mit österreichischer Beteiligung erfolgreich. Dadurch können wir 13 innovative Vorhaben mit rund 3,1 Millionen Euro unterstützen", sagt Mitterlehner. Im internationalen Eurostars-Ranking platzieren sich mehrere Projekte mit österreichischen Akteuren im Spitzenfeld: auf dem ersten, zweiten und fünften Platz unter insgesamt 130 geförderten Projekten. Für die Reihung haben unabhängige Experten den technologischen Innovationsgrad sowie die Marktchancen bewertet. "Das Ergebnis zeigt die hohe Innovationskraft unserer Klein- und Mittelbetriebe. Sie sind das Rückgrat der heimischen Wirtschaft und bringen das Land nach vorne", so Mitterlehner.

Numbers from May 2016:

- Phase I: Evaluation by technical experts
  - 299 project applications
  - 195 projects with sufficient quality; 75 projects weak/poor
- Phase II: Evaluation by IEP jury
  - 130 projects were placed above threshold
  - 103 projects received funding also from national resources

- This makes a funding success rate of 79% and an overall success rate of 34%.

Evaluation sheet from IEP, example below threshold

Quality and efficiency of the implementation	**108**	/200 - threshold set at 120 points (60 %)
Comments	The consortium lacks some key expertise. Synergy is not clear. Project plan is not well presented with vaguely defined milestones and deliverables. Subcontracting costs seem poorly justified.	
Result	**Below threshold**	
Impact	**122**	/200 - threshold set at 120 points (60 %)
Comments	The size of the market is well described. Market entry is presented but barriers to entry might be severely underestimated. Competitive advantage is not convincing.	
Result	**Above threshold**	
Excellence	**90**	/200 - threshold set at 120 points (60 %)
Comments	The concept seems innovative but the technical aspects are not well presented. Technical challenges and the associated risks are not clearly defined. Technical feasibility is unconvincing.	
Result	**Below threshold**	
Total Score	**320**	/600 - threshold set at 402 points (67 %)
Result	**Below threshold**	
Overall result	**Below threshold**	

Evaluation sheet from IEP, example above threshold

Quality and efficiency of the implementation	**171**	/200 - threshold set at 120 points (60 %)
Comments	The consortium is complementary and qualified. Project plan is clear and well defined. The project budget and cost breakdown is well structured/justified. Further arrangements in the division of management duties and ownership may be obtained during negotiation. Expected subcontractor costs are specified and justified.	
Result	**Above threshold**	
Impact	**172**	/200 - threshold set at 120 points (60 %)
Comments	Realistically quantified market size. The product has high potential on a global scale. The potential competitors are identified. Market entry strategy has been well described. Projected revenues seem to be realistic considering already signed contracts with end users.	
Result	**Above threshold**	
Excellence	**150**	/200 - threshold set at 120 points (60 %)
Comments	The product demonstrates an incremental improvement over their own existing solution. It potentially delivers a cost effective, value-added product to the market. The risks have been clearly identified and properly discussed with sufficient detail.	
Result	**Above threshold**	
Total Score	**493**	/600 - threshold set at 402 points (67 %)
Result	**Above threshold**	
Overall result	**Above threshold**	

Example

Selected questions taken from the Epithydia project, ranked 1st in the cut-off 5 competition (May 2016 evaluation)

Example

03 WHAT DO YOU WANT TO DO?

The consortium will develop an innovative epigenetic-based diagnostic kit for the detection [redacted] The kit will be based on a promising set of DNA methylation markers. In this project, these biomarkers will be developed into an actual IVD kit that will be analytically and technically validated, and subsequently tested in a proof-of principle study. Directly after this project, the consortium will perform larger scale validation studies.

05 HOW WILL YOU MAKE MONEY?

By selling the CE-IVD certified EPITHYDIA kit supported by a validated software solution to hospitals and clinics the partners will generate money through distribution agreements with international companies. The consortium has already strong collaborations with key companies and distributors in the molecular diagnostics field. The output of this project will be marketed taking advantage of this existing network for a potentially global product commercialisation.

Example

09 WHAT ARE YOU GOING TO SELL? TO WHOM AND HOW?

TARGET MARKET – In Europe, 4% of the population are diagnosed wi annually [3, 4]. 10-20% of these patients are diagnosed as "s cancer" as there is no clear, specific analysis to classify them. There is a high unmet medical need for a sensitive and specific diagnostic assay since currently all these patients undergo surgery, including all associated risks and side effects and costs for the healthcare system. This is a substantial target market for the EPITHYDIA kit. The main end-users will be diagnostic laboratories and hospitals. However, oncologists, surgeons and radiologist are important stakeholders as well, as they prescribe patients' treatment plan. The consortium expects to generate sales of €59.1 million by the year 2025, based on a 5% market share in the target market.

COMMERCIAL STRATEGIES – The technology used in EPITHYDIA assay is described in a patent application submitted in 2014 by AIT. The preferred strategy of the consortium is to use the generated data package within EPITHYDIA to obtain regulatory approval for CE-marking. Diagenode's experience and know-how will ensure the product manufacturing throughout the product lifecycle, and in compliance with ISO 13485 certification. Diagenode will actively pursue the most effective commercialization channels for the EPITHYDIA kit and it is expected that it will enter into a distribution agreement with a large diagnostic company specialized in IVD products and/or the oncology diagnostic market, and a strong presence among of clinical laboratories (end-users of the product). During the project, candidates will be actively approached. Diagenode has recently successfully established similar distribution agreements. Diagenode will exploit the EPITHYDIA kit as part of their current contract diagnostic portfolio in Europe. This will eventually generate early upfront milestone payments and/or royalties for the consortium as agreed in the CA.

Example

11 EUROSTARS FUNDING DOES NOT COVER ALL OF THE ELEMENTS IN THE PRODUCT DEVELOPMENT CYCLE. WITH REFERENCE TO YOUR BUSINESS PLAN, QUANTIFY THE FINANCES INVESTED TO DATE, THE PROJECT COSTS, AND THE FUTURE INVESTMENTS (YOUR OWN/OTHER RESOURCES) THAT WILL BE NECESSARY/REQUIRED FOR COMMERCIALIZATION.

FINANCES INVESTED TO DATE – All consortium partners have invested extensively in the technologies and expertise that will be combined in this project. DIAGENODE is a leading global provider of complete solutions for epigenetics and molecular diagnostics. Whereas epigenetic assays, compliance with ISO 13485 and CE IVD products development are complex, the company facilitates the production of the necessary high-quality reagents, robust protocols and analytical/clinical validation expertise. Over the last 5 years the company has invested an average of €1 million/year in R&D activities. AIT has been involved in the early biomarker discovery and method development studies for the [redacted] the past, AIT has successfully cooperated with many clinical facilities and has vast expertise in molecular diagnostic methods for conducting genome wide screening, targeted multiplex assay development, discovery and validation of biomarkers. Over the last 10 years the research organization has invested €500.000 in the research of potential biomark[redacted]. PLATOMICS a SME bioinformatics company is specialized in big data IT solutions for Life Sciences and will be involved in developing appropriate validated software application to perform bioinformatical and biostatistical analyses for the EPITHYDIA test as well as a companion clinical analysis support tool. The company has invested in the existing infrastructure of the platform with €700.000 so far.

INVESTMENTS DURING THIS PROJECT – The financial need for the EPITHYDIA project equals around €1.47 million, of which around €883.439,70 is requested from the Eurostar's program and the remainder will be co-financed by the consortium. The SME companies play a key role in the EPITHYDIA (86% of the overall budget). With this budget the consortium will be able to develop and validate the EPITHYDIA diagnostic assay in comparison to existing clinical diagnostic methods. This will provide the data package necessary to make the assay available as valuable tool for the diagnosis and monitoring of patients with [redacted]

FUTURE INVESTMENTS – Prior to this project, all partners have already invested significantly into the shared strategy and vision of the EPITHYDIA project. All partners are dedicated to develop and commercialize the envisaged product. The strategy of the consortium aims to obtaining CE-IVD marking of EPITHYDIA during the

Question 12

DESCRIBE THE STEPS AND TIMELINE TOWARDS COMMERCIALIZATION AND BEYOND.

THIS EUROSTARS PROJECT (2016-2019)

During this project, the consortium will develop the prototype IVD test and perform full preclinical program, including reagent development, assay production, stability testing, analytical validation and software development. Subsequently, the IVD will be tested in a Proof-of-Concept (PoC) study using patient samples to accomplish validation on patients' cytology slides. The analytical, technical and PoC data package will provide all data needed for registration and CE-IVD marking.

2018-2019: Final phase of EPITHYDIA project (Figure 3)

Towards the end of this project, the consortium will register the product as an IVD and obtain CE-IVD marking. Furthermore, the consortium will initiate partnerships and/or distribution deals with leading international diagnostic companies with existing presence and network in the end-user market (diagnostic labs and hospitals) to introduce the product at a larger scale on the market. Under the terms of such distribution deals, the consortium will receive royalties over sales. Furthermore, Platomics will apply for Quality and CE certification of their new developed software processes.

BEYOND THIS PROJECT

2019-2020: European market introduction

Market introduction is expected 12 months after the end of this project. An additional study will be performed with patient material (approx. 2000) in a prospective multi-center study to generate additional results to meet 510(k) requirements and further support the kit claims.

Diagenode has all the required production facilities to up-scale the EPITHYDIA manufacturing process and will bring the EPITHYDIA kit to the diagnostic market. The CA defines the future benefits for AIT and Platomics from sales/royalties obtained by Diagenode. The rights to exploit this product by respective partners have been defined and will be included in the consortium agreement. The data generated in this project and potential co-development with other partners can significantly reduce the time-to-market for envisaged spin-off markets.

2022: Expansion to broader market commercialization

Further market reaching out will be sought by the consortium leader Diagenode as defined in the CA, with a focus on the US territory. Compliance with US 510(k) will already be integrated as much as possible during the primary development phase of the EPITHYDIA product to ensure an efficient commercial expansion of the product availability and additional linked revenues.

SPIN-OFF POTENTIAL

All partners can use this project as a showcase for turning scientific discoveries into valuable business propositions. DIAGENODE will strengthen their market position as expert company in molecular diagnostics assay development. AIT will be able to further develop the potential of PCR-based epigenetic biomarker diagnostic technology as a ground-breaking technology and molecular approach. Given the wide-range of possible biomarkers for this new biomarker assay technology, it is expected it will generate substantial revenues for all parties. Spin-off applications may include different biomarkers for screening populations at risk (e.g. smokers, persons with occupational exposure to carcinogenic agents or radiation). PLATOMICS will be able to further develop the new developed software processes to generate different software spin-off applications.

COST AND REVENUE SHARE

All participants within the consortium shall invest their own share in the project costs. The details on revenue sharing will be outlined in the Consortium agreement (CA). Such a CA will be signed prior to the start of the project and negotiated in good faith. The CA will take into consideration background/foreground IP, investments made by each partner and the phase in which such investment was made. The CA will accommodate that the partners will share the revenues from this project accordingly their relative investment, background IP and specific tasks in this

Example

17 IDENTIFY THE POTENTIAL BARRIERS TO MARKET ENTRY AND DESCRIBE HOW EACH WILL BE OVERCOME.

COMPETITION – A thorough market analysis revealed that there is presently no DNA methylation diagnostic kit for [redacted]he market, but several companies have products under development (Table 1). EPITHYDIA has significant advantages over these competitors in terms of costs, minimally-invasive nature of the test by using already obtained cytology slides and ease of use and implementation since the test can be performed using standard laboratory equipment. Diagenode is a leading global provider of complete solutions (kits) for epigenetics research and CE-IVD molecular diagnostics assays development, manufacture and commercialization. Therefore, at this time this risk is considered to be low.

REGULATORY – EPITHYDIA will be marketed in Europe as an IVD medical device, which requires CE marking under directive 98/79/EC. Diagenode will perform all the validation work and the conformity checks. The EMA offers scientific advice, which will be requested by Diagenode in order to ensure that the design of the clinical study meets all current regulatory requirements and that the agency supports the use of the epigenetic biomarkers for the indicated purpose.

MARKET ACCEPTANCE – It is evident that EPITHYDIA will serve an unmet need for accurate and minimally invasive det[redacted]The test will not onl[redacted] will also lower treatment costs as currently the patients diagnosed with suspici[redacted] RECEIVE SURGER[redacted] costs varies $11.500-$25.000)[17]. By using EPITHYDIA, a large number of unnecessary surgeries can be prevented. Therefore, Diagenode expects that patients, physicians, hospitals and healthcare payers will rapidly accept the diagnostic test, as the EPITHYDIA product starting price will be competitive. After successful validation and in combination with the post-project prospective clinical validation to support market claims, the risk in market acceptance is thus considered to be low

COMMERCIALIZATION COSTS – Another barrier to market entry is the high cost of development and commercialization. The financial constraints associated with marketing and distributing of the EPITHYDIA are considerable and have been forecasted with great diligence in this project. The best approach for the consortium is to partner with international leading molecular diagnostic companies that offer a strong existing distribution network and have all the required resources for a strong marketing effort. This approach has already been successfully used by Diagenode for other molecular diagnostic kits. By using such approach/business model the risk is low.

MANUFACTURING AND DISTRIBUTION CAPABILITIES – Diagenode will use its existing extensive network of partners for marketing and distribution of the EPITHYDIA, and will pursue distribution agreements with relevant leading molecular diagnostic partners. Diagenode has capacities to manufacture the kit on a larger scale and to sustain the kit commercialization throughout the product lifecycle, and has been certified for IVD assay development activities (ISO13485) and for quality management (ISO9001). Long term marketing and sales, and

Example

25 WHAT ARE THE RISKS OF THIS APPROACH? HOW WILL YOU REDUCE THESE RISKS?

This project is associated with technological risks. This project is designed in a way to limit risks and increase the chances of success as much as possible. Nevertheless, using expert judgement as risk analysis methodology, the following technological risks were identified with related strategies for risk minimization.

– The test has not the anticipated performance.
The consortium is continuously identifying new predictive (epigenetic) markers as part of its R&D programs. These may be included in a next version of the assay to improve performance. Furthermore, the design of the EPITHYDIA kit will take into account measures to minimize potential variability. Previous studies have shown that the technical variability is sufficiently low to support the diagnostic use claims.

– Handling biobank and retrospective data.
Biobanks face a number of challenges when handling a large volume of diverse samples. These challenges include keeping patient data secure and accessible only to those authorized and accurately and efficiently handling manual data input to minimize inaccuracies and duplication of work. State-of-the-art software solutions are equipped with several security features that are designed to keep the data secure and available to those who are authorized. These security features include stored and transmitted data encryption as well as support for security compliance organizations such as HIPAA and FDA 21 CFR Part 11.

– Not enough material material in cytology plate.
In some cases it might be possible that there are not enough cells in on the cytology plate when taken from a

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