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Proposal Evaluation Form

EUROPEAN COMMISSION

Horizon 2020 - Research and Innovation Framework Programme

Evaluation Summary Report - Research and innovation actions

Call: H2020-FETOPEN-1-2016-2017
Funding scheme: RIA
Proposal number: 737178
Proposal acronym: SmarTooth
Duration (months): 36
Proposal title: A Bionic Implant to Restore Dental Sensitivity
Activity: FETOPEN-RIA-2016

N.	Proposer name	Country	Total Cost	%	Grant Requested	%
1	UNIVERSIDADE DO PORTO	PT	427,420	10.89%	427,420	10.89%
2	TECHNISCHE UNIVERSITEIT DELFT	NL	1,105,019	28.15%	1,105,019	28.15%
3	FONDAZIONE BRUNO KESSLER	IT	636,091	16.20%	636,091	16.20%
4	FRAUNHOFER GESELLSCHAFT ZUR FOERDERUNG DER ANGEWANDTEN FORSCHUNG E.V.	DE	816,750	20.80%	816,750	20.80%
5	GADGETWHISPER UNIPESSOAL LDA	PT	174,284	4.44%	174,284	4.44%
6	Triteq Ltd	UK	449,545	11.45%	449,545	11.45%
7	Saliwell Ltd.	IL	316,754	8.07%	316,754	8.07%
	Total:		3,925,862		3,925,862	

Abstract:
SmarTooth is a beyond state of the art bionic device aiming at restoring dental sensitivity resorting to an implant that transforms occlusion mechanical forces into electrical impulses to be delivered to the trigeminal nerve endings. SmartTooth is a new and patented concept which has never been implemented before. It consists of an implantable class 2b medical device, comprising two wirelessly interconnected electronic modules; one in the implanted tooth with force sensing ability and the other interface the trigeminal nerve. Its design and implementation involve state of the art technologies and critical issues that will require developing new solutions at different levels. Furthermore, the project will develop a comprehensive technology platform for miniaturized medical electronics, comprising all aspects: sensing, data and energy transfer, and biocompatible 3D micro packaging. It should be noticed that these developments are reusable for a number of other medical applications like medical dosing, salivation stimulation and other sensory functions. SmarTooth transforms dental implants into active prosthesis, restoring dental sensitivity. It is meant for people who need or already have dental implants, to prevent dental overload, mastication motor function impairment, and improving body balance and posture. Six to 10% of the world population have no teeth. In the developed world 130 million teeth are lost each year. In 2014 33 million implants were done worldwide and the market is growing at 6% a year. According to MarketsandMarkets, by 2020 the implant market will represent 46 million units, i. e., an addressable market of €10000 million. The consortium involves research institutions and staff with long experience in biomedical electronics, sensors and instrumentation, structural mechanics, neurophysiology, oral surgery and dentistry.

Evaluation Summary Report

Evaluation Result

Total score: 4.00 (Threshold: 0)

Form information

SCORING

Scores must be in the range 0-5.

Interpretation of the score:

0 *The* ***proposal fails to address the criterion*** *or cannot be assessed due to missing or incomplete information.*

1 Poor. *The criterion is inadequately addressed, or there are serious inherent weaknesses.*

2 Fair. *The proposal broadly addresses the criterion, but there are significant weaknesses.*

3 Good. *The proposal addresses the criterion well, but a number of shortcomings are present.*

4 Very good. *The proposal addresses the criterion very well, but a small number of shortcomings are present.*

5 Excellent. *The proposal successfully addresses all relevant aspects of the criterion.Any shortcomings are minor.*

*** The asterisk means mandatory field**

Criterion 1 - Excellence

Score: **4.00** (Threshold: 4/5.00 , Weight: 60.00%)

Note: The following aspects will be taken into account, to the extent that the proposed work corresponds to the topic description in the work programme. If a proposal is partly out of scope, this must be reflected in the scoring, and explained in the comments.
Compliance with the FET-gatekeepers as described in the call:

Clarity and novelty of long-term vision, and ambition and concreteness of the targeted breakthrough towards that vision.

1---------
The proposal envisages a device embedded in a dental implant abutment which provides pressure sensing capabilities. The listed breakthroughs are concise and well defined, and the specific contributions to science and technology - improved piezoelectric force sensors, miniaturised ultra-low power circuitry and new nerve stimulating microelectrodes - are clear.

2---------
The project is sound and with described social impact in the field of oral implantology, proposing an electronic implant device which aims at restoring dental sensitivity around natural teeth for a better control of the masticatory forces at the jaw. This will have consequences in terms of posture and balance control. This long-term vision, is well-described. However its competitiveness towards the traditional low cost oral implants' market is not fully elucidated. The gains with this device might not be strong enough to justify its added value for the patient.

The research concept is clearly targeting a concrete goal since it is supported by already consolidated technology to develop the proposed ideas.

3---------
SmarTooth targeted breakthrough is the restoration of sensory motor regulation of biting and chewing in dental implants. To this end, the project presents a clear and credible technology contribution. The scientific contribution, when it comes to the biological and clinical relevance of the designed system, is not developed enough in the proposal. The long term vision in terms of added value for the patient is not really discussed, while the long term vision and benefit in terms of technological innovation (batteries, system-in-package) is precisely defined.

4---------
The proposal well define the long term vision of the proposed approach through the development of a bionic device for the restoration of dental sensitivity through the transformation of occlusion mechanical forces into electrical impulses.
The proposal clearly describes the proposed breakthrough, thus detailing the limits of the existing solutions that mainly consists in removable or fixed prostheses in which the bone sensitivity is vague and imprecise.
The innovations comprise the incorporation of biomedical electronics and sensing technologies directly impacting in the involved scientific and technical domains, such as the definition of the forces and power/batteries applied, miniaturization strategies and packaging requirements.
The long term vision of the proposed approach is well defined and will provide breakthroughs which will go beyond the development of this specific bionic device. It will represent a new step in the growth of the overlap between biology and technology.

Novelty, non-incrementality and plausibility of the proposed research for achieving the targeted breakthrough and its foundational character

1---------
The proposal presents a potential revolution in dental implantology. In particular, it promises not only functional restoration but also sensitive one which is crucial to avoid bruxism and, therefore, early implant failure. However, there are doubts about the commercial viability of the concept because the typical implantologist (a dentist or oral surgeon) avoid dealing with nerves altogether. It is not credible dental clinics will employ neurosurgeons to attach the microelectrodes into the trigeminal nerve.

Besides the aforementioned caveat, the project would be able to train a new generation of researchers specialised in this device and its techniques which could become employed by the SMEs that pretend to commercialise the product (as well as, presumably, develop improved versions).

2---------
The concept of creating a bionic implant device at the oral cavity is novel and ambitious, building on sustained knowledge by the consortium. As presented, the research proposed is relies on previous know-how within the consortium which detains IP for developing such a bionic implantable device. Therefore it is not clearly demonstrated that the present proposal constitutes a new line of investigation, rather than an incremental path already being followed.

3---------
SmarTooth innovation lies in the design of a bioelectronic system, based on a force transducer interfaced with the trigeminal nerve, responsible for motor functions related to the jaw. There is no equivalent system in the literature. The project outcome is ambitious but feasible, as it is based on improvements from previous designs either from the partners either from the literature. If the project is successful, the designed system would be foundational in the sense that it would be the first operational application of the bionic transducer patented by one of the partners.

4---------
The proposed research is novel and ambitious, in particular in technological terms it is an early stage, high risk visionary technology since never before such an ultra-dense electronic package has been developed which includes energy conversion and storage, sensing and communication functions all together.
The main novelty consists in the wireless data transfer capability to the brain for the generation of an adequate motor response, thus clearly reflecting the ambitious and far-reaching approach of the proposal.
The proposal is far reaching, indeed the currently, electronic implants that address oral and maxillofacial pathologies are mostly at an incipient stage.
The proposal only marginally explain how the project results will open new lines of investigation for the use and implementation of the studied technologies, thus limiting the research approach to the specific field identified in the proposal, without the opening of completely new technologies.

Appropriateness of the research methodology and its suitability to address high scientific and technological risks.

1---------
The proposal clearly outlines a suitable development plan with specific, measurable, attainable, relevant and time-bound objectives. In particular, it proposes a parallel development of all the subsystems (piezoelectric sensors, electrodes, ASIC, antenna & microbattery) before integrating them for its demonstration in a clinical study.

2---------
The ideas in the proposal are well justified against the state of the art regarding electronic implants being proposed to address oral and maxillofacial pathologies, and would not be achievable individually by the partners. The proposal describes measurable objectives, starting by

an initial validation of the concept towards the miniaturization of already existing larger prototype. Therefore, the proposed methodology describes more of a technological adaptation of an existing technology rather that the creation of radically, early-stage technology.
The overall objectives are attainable within the proposed consortium.

3---------
Research methods on the technological developments are fully appropriate. Parallel streams of research will be conducted to validate separate elements of the targeted system, to be integrated in the second half of the project. As a whole, the proposed research can not address optimally the technology development as it does not investigate the needs and effects of neurostimulation in that context.

4---------
The analysis of the state of the art is clearly defined, highlighting the relevance of the considered pathology, indeed the jaw is a strategic point of the human body in terms of posture and balance control.
The existing gaps are well described and clearly explain how the restoration of dental sensitivity and muscular control have not yet been addressed.
The proposal clearly describes the research methods and the work plan strategy that promotes a close interaction among experts in the involved scientific and technical domains. The specific objects are sufficiently described but only marginally identified however they are clearly interconnected with the general research methods, in a time relevant and attainable structure, dedicating the first half of the project to the medical device design and development and focusing the second part on its validation.
The chosen research methods is appropriate with the project goals and fully correspond to each planned activity.

Range and added value from interdisciplinarity, including measures for exchange, cross-fertilisation and synergy.

1---------
The proposal combines a range of fields, most notably related to dentistry and neuroscience but also engineering (e.g. signal processing and transmission, embedded circuit design).

2---------
The proposal is highly inter- and multidisciplinary, ranging from mechanics, microelectronics, biophysiscists, neurophysiologists, medical dentists, etc. The consortium is highly qualified and combines well these distinct disciplines into the development of the new electronic implant device, demonstrating a high degree of complementarity. High synergy between partners is therefore expected. The participation of three SMEs adding critical knowledge (ex: a specific component of the devices) increases the degree of feasibility of the proposal.

3---------
SmartTooth is without any doubt interdisciplinary in the engineering disciplines range : mechanics, microelectronics, micro-technologies, instrumentation. Yet SmartTooth proposal does not demonstrate integrated research all along the project life with researchers in biology/neurosciences ; the industrial expert partner in dentistry and neurosciences is essentially present in the final validation process (clinical trial).

4---------
The project ideas fully reflects in the interdisciplinary of the consortium, that implies a close unconventional collaboration among engineers (electronic and mechanical), biophysicists, neurophysiologists, oral medicine, and system integration specialists. This interdisciplinary approach is essential for the project positive outcome and involves knowledge acquired by all partners in domains such as mechanics, microelectronics, micro-technologies and advanced manufacturing.
The strict cooperation between the actors involved will support the scientific breakthrough and the high quality development of project idea towards the implementation of a new implantable medical bionic device into the market.

Criterion 2 - Impact

Score: **4.00** (Threshold: 3.5/5.00 , Weight: 20.00%)

Note: The following aspects will be taken into account, to the extent to which the outputs of the project should contribute at the European and/or International level:
Contributions to the impacts listed under this topic in the workprograme:

Importance of the new technological outcome with regards to its transformational impact on technology and/or society.

1---------
The main technological outcome is the actual purpose of the proposal: the creation of a dental implant capable of conveying pressure signals to patient's trigeminal nerve. Besides that, none of the technological developments are actual breakthroughs for the consortium members. At most, incremental steps.

However, it is very unclear how the availability of such an improved dental implant could become widely used by current or future implantologists as it requires neurosurgery (a discipline they are not trained into).

2---------
The long-term technological outcome of the proposal is clearly defined. The transformational impact of the present project on society is presented, as to improve life quality of patients that need oral implants, contributing to increase sensitivity at the oral cavity. However, the gains of this technology with respect to the cost implications and logistics for the patient (it is a re-chargeable device) should be better argued, since this would impact on the commercial potential of the technology.

3---------
The SmarTooth technology can have an important societal impact for patients with dental prostheses: overall health and comfort improvement with a limited cost (as the technology is compatible with any existing dental implant). Technological impact is also clearly identified; its most transformational aspect lies in the design of rechargeable microbatteries, suitable for many bio-electronic applications beyond SmarTooth.

4---------
The proposal clearly define the reference target and the market size, through the classification of patients. Furthermore it describes the development of new knowledge and competencies, for example as concerning biomechanics, pressure measurements, electroneurophysiology and neurostimulation, enlarging the capability to develop novel intelligent nanomaterials, bioelectronics components

and neuroscience applications, however it only partially details the long-term technological outcome and impact.
The proposal address the transformational impact on society and technology, such as the decrease of the patient's visits to the dental clinic, the contribute to satisfaction and pleasure and the gain in motion and balance, thus improving the quality of life and consequently reducing health related costs.
The transformational impact in technology is mainly focused in the development of miniaturized sensors, subcutaneous wireless communication and implantable microelectrodes power supply.

Impact on future European scientific and industrial leadership, notably from involvement of new and high potential actors

1---------
An pressure-sensitive dental implant is revolutionary and would certainly spur European industrial leadership in the market provided there is no need for a neurosurgeon to place electrodes into the trigeminal nerve. Unfortunately, the current design needs the presence of such neurosurgeon.

2---------
The consortium includes young researches who are likely to keep up the research in a long run. Gender balance as also been properly achieved in the project. It is composed of researchers coming from well-recognized universities/institutes in the field of the proposal. The consortium encloses SMEs which are expected to bring additional knowledge in terms of industrialization of the device and eventually carry it to market realization.

3---------
The consortium is committed to promote gender parity for young researchers. If the project is successful, academic partners will be essentials in the electroceutics technology community for their contribution on micropower sources. Regarding industrial leadership, the consortium has a coherent valorization strategy. One of the industrial partners aims at exploiting the future introduction of the SmarTooth medical device in the market. Again, the lack of neuroscience academic contributors will prevent them from impacting research on the fundamentals of neurostimulation.

4---------
The proposal describes how the developments and competences achieved during the project will promote the training of students, contributing to better qualified professionals for the development of other devices using similar technology.
The project is committed to creating equal opportunities for women and men with an established policy of equal opportunities, thus to give the same job opportunities for men and women, based only on merit, competencies and skills. The consortium is committed to contribute to a fair gender parity of young researchers choosing a career in science by implementing a policy of working time flexibility in order to better balance the demands of work with other needs of the researchers (e.g., regarding family responsibilities such as child-care, children schools, and healthcare).
The involvement of SMEs in the consortium strengthen the industrial interconnection with the research activities, thus defining the market needs.

Quality of methods and measures for achieving impact beyond the research world and for establishing European though leadership, as perceived by industry and society.

1---------
The proposal clearly details the IPR and Communication & Dissemination strategies which are deemed adequate.

2---------
The project describes convincingly the main actions regarding dissemination of results towards the scientific community and to a broader audience and measures to maximise it. The dissemination of scientific knowledge includes patents, publications, attendance to conferences in the several areas, a project a website, etc. Exploitation of results has also been provided, including IPR protection. The participation in international fairs, etc, has promotional actions and marketing of the technologies have been described.

3---------
The consortium proposes a standard but fully relevant set of measures to disseminate and promote the project outcomes (academic and industrial).

4---------
The proposal sufficiently describes the standard measures for communication and exploitation, through the participation to fairs, publication in scientific papers, marketing activities and demo realization. Furthermore the project will generate data from a pre-clinical tests that will require results protections. A proper Intellectual Property management plan is detailed in the proposal, thus guaranteeing the correct exploitation of project results and confidentiality measures.
The proposal also plan additional measures based on new media such as Facebook and LinkedIn.
All these activities will raise awareness with public engagement, influencing the attitudes of decision-makers and enabling the sector to take future actions.
However the proposal only partially describes how the dissemination measures will support achieving the expected impact.

Criterion 3 - Quality and efficiency of the implementation

Score: **4.00** (Threshold: 3/5.00 , Weight: 20.00%)

Note: The following aspects will be taken into account:
Soundness of the workplan and clarity of intermediate targets.

1---------
Workplan is sound and includes clear and realistic target. The workplan covers, in a credible schedule, the parallel development of the required technologies (e.g. piezoelectric sensors, micro power supply, microelectrodes, etc) before integrating them for a later phase which consists on a pre-clinical trial.

2---------
The project's workplan is presented in very good detail and well-organized into tasks and specific deliverables which allow for assessing its feasibility. The work load is properly distributed during the timeframe of the project. The workpackages reveal an already considerable degree of maturity of the proposed technology. The most critical risks of the proposal are identified, and measures to overcome them are plausible

and seem feasible.

3---------
The workplan is clear and includes a precise description of the hardware development phases. Most WPs are dedicated to hardware developments. There is no time for improving the devices after the clinical trials, due the the length of the development phases and the 36-month duration of the project. Intermediate technological targets are well defined.

4---------
The proposal clearly describes the planned activities, starting from the study of the biomechanics phenomena, through the capture, modulation and transmission of the signal, to the pre-clinical study.
Milestones are clearly defined and relevant for the proposed research approach high quality development.
The defined work packages and related activities and deliverables are fully described and well interconnected in an appropriate research structure that fully reflects the proposed approach, with proper deliverables and precise tasks description.
Research activities are well balanced with the specific objectives identified and the transversal activities are well interconnected for the achievement of the project results.
Furthermore the proposal clearly describe the critical risks for implementation and the relative recovery plan.

Relevant expertise in the consortium.

1---------
The interdisciplinary consortium conform a well-balanced team of relevant fields experts and infrastructures with no obvious redundancies.

2---------
The consortium expertise is highly interdisciplinary and matches very well with the project needs going from microelectronics to dentistry. The capability and expertise of the consortium is excellent and well demonstrated along each of the proposed tasks. Each partner has a clear defined goal and good synergies are foreseen sustained on previous and on-going collaboration. The companies in the consortium will add important expertise, for instances in WP3 for the development of the new rechargeable micro-batteries. As described, the consortium is well-balanced, no extensive overlapping of competences are detectable in the description of the consortium.

3---------
The consortium gathers experienced researchers in biomedical electronics, sensors and instrumentation, structural mechanics. For instrumentation, technology transfer and certification purposes, it also includes companies with good track records in their respective fields. As mentioned earlier, the consortium lacks a neuroscience academic partner in charge of optimizing the stimulation functionalities and parameters.

4---------
The expertise in the consortium fully reflects the project ideas and are high qualified in order to achieve the project results. Indeed the consortium involves research institutions and staff with long experience in biomedical electronics, sensors and instrumentation, structural mechanics, neurophysiology, oral surgery and dentistry, a company with in-house design, manufacturing, research and development capabilities, a company with experience on developing intra-oral
devices, and a start-up company that will target future phases of medical certification and commercial exploitation.
The consortium is well balanced, without redundancies, including research centers and universities and industrial actors able to define the industrial requirements, the market needs and to support the preliminary marketing activities.

Appropriate allocation and justification of resources (person-months, equipment, budget).

1---------
The budget is reasonable and allocation of human and equipment resources is appropriate and well allocated.
UPorto has the knowledge in mechanical, VLSI design and simulation, as well as experience with piezoelectric materials and facilities for delivering WP1. TUD has contributed to embedded medical products which shows their credibility for leading WP2. FHG is a strong global player in microelectronics and integration of lithium ion batteries which makes them a key partner for WP3. GW is an SME with limited experience but with competences on medical devices business and IPR management which is enough for leading WP6. Triteq is a product design company with in-house research, design, engineering, software and manufacturing capabilities which makes them a credible system integrator (WP4). Finally, SW experience include the development of intelligent intra-oral devices based on electrostimulation of nerves that control salivary secretion which allows them to actively contribute to WP5.

2---------
The budget description is very clearly detailed. The person-months are allocated to each workpackage are representative of the specificities of the research work in each step of the project.
A good level of detail of the consumables and equipment is provided as to assess the requested budget by partner. The overall budget is comprehensive and there is good balance between personnel and other costs, considering the degree of advancement of some of the technologies that will be combined in the present project.

3---------
The person-month effort is distributed proportionally to the WP workload. A very important budget is allocated to the company in charge of the system manufacturing and integration, which burdens the project global cost and somehow limits the potential budget for research. It feels little appropriate that the start-up company, targeted for future production of the Smartooth device, is almost not involved in the development and integration phases of the devices .

4---------
The allocation of person months reflects to the activities to be performed and the proposal describes and justifies the presence of anomalies, however in some cases the unbalance is very high; for example work package 2 requires more than 35% of the total person months.
The necessary equipment is present and properly described, indeed all partners hold already the main equipment needed to develop the respectively assigned tasks. The equipment to be acquired are properly described and justified and mainly consists in laptops for the researchers, specific data acquisition boards for the pre-clinical trials, and devices for the biomechanical structure.
The overall budget is comprehensive and adequate to the project activities, however it is unbalanced towards partner 2 that alone requires more than 28% of the total budget, thus reflecting the unbalance of WP 2 person months allocation.

Scope of the proposal

Status: **Yes**

Comments (in case the proposal is out of scope)

Not provided

Operational Capacity

Status: **Operational Capacity: Yes**

If No, please list the concerned partner(s), the reasons for the rejection, and the requested amount.

Not provided

Exceptional funding of third country participants/international organisations

A third country participant/international organisation not listed in General Annex A to the Main Work Programme may exceptionally receive funding if their participation is essential for carrying out the project (for instance due to outstanding expertise, access to unique know-how, access to research infrastructure, access to particular geographical environments, possibility to involve key partners in emerging markets, access to data, etc.). (For more information, see the Online Manual)

Based on the information provided in the proposal, I consider that the following participant(s)/international organisation(s) that requested funding should exceptionally be funded:
(Please list the Name and acronym of the applicant, Reasons for exceptional funding and the Requested grant amount.)

Not provided

Based on the information provided in the proposal, I consider that the following participant(s)/international organisation(s) that requested funding should NOT be funded:
(Please list the Name and acronym of the applicant, Reasons for exceptional funding and the Requested grant amount.)

Not provided

Use of human embryonic stem cells (hESC)

Does this proposal involve the use of hESC?

No

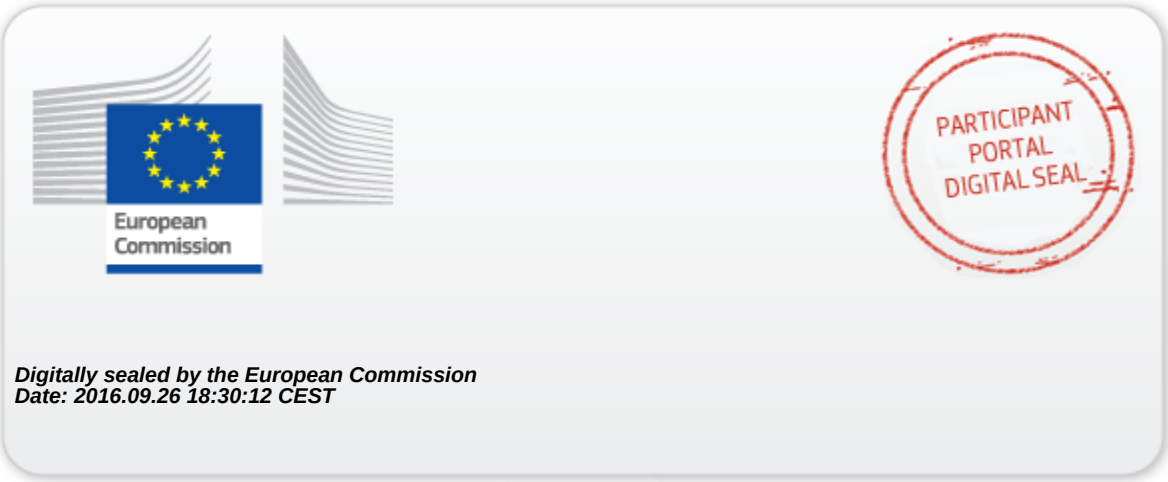
If yes, please state whether the use of hESC is, or is not, in your opinion, necessary to achieve the scientific objectives of the proposal and the reasons why. Alternatively, please also state if it cannot be assessed whether the use of hESC is necessary or not because of a lack of information.

Not provided

Panel comments on proposal

This evaluation summary report contains the final marks endorsed by the final review panel. The panel based its appraisal on prior individual reviews conducted by four independent experts. The comments of the individual evaluators, or extracts from them, are included in this report. While not necessarily subscribing to each and every opinion expressed, the panel found that to a big extent they provide a fair overall assessment, indicating both essential strengths and weaknesses identified in the proposal.

The panel was made aware of the previous ESR linked to this proposal as indicated by the applicants. In the light of the requirements of FET Open, the panel endorsed the comments of the current evaluators and the final score.



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