

IHI JU INDEPENDENT OBSERVER'S REPORT

Call ID: HORIZON-JU-IHI-
2023-04-two-stage (2nd stage)

Date of evaluation: From 27 to 29 May 2024

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Present at the evaluation: From 27 to 29 May 2024

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1 Introduction and approach taken by the observer

This report presents the Independent Observer’s assessment of the second stage evaluation of the HORIZON-JU-IHI-2023-04-two-stage call. The purpose of this report is to give an independent view on the evaluation process and where it is possible and relevant, provide recommendations for improvements.

The Independent Observer followed the evaluation with the aim to observe and report on the practical workings of the evaluation process. This includes the conduct and fairness of the evaluation sessions, on the application of the award criteria and on the procedures and their implementation, including IT tools.

The call was published on 27 July 2023 with short proposal submission deadline on 8 November 2023 and included six topics.

The first stage evaluation took place between 11-14 December and 17 short proposals were submitted, in total. Two proposals were declared ineligible; therefore 15 proposals were assessed by external experts. Details are shown in the table below:

Topic	Proposals
Topic 1: IHI-2023-04-01 – Expanding translational knowledge in minipigs: a path to reduce and replace non-human primates in non-clinical safety assessment.	3
Topic 2 : IHI-2023-04-02 – Patient-centric blood sample collection to enable decentralised clinical trials and improve access to healthcare	4
Topic 3 : IHI-2023-04-03 – Inclusive clinical studies for equitable access to clinical research in Europe	2
Topic 4 : IHI-2023-04-04 – Establishing novel approaches to improve clinical trials for rare and ultra-rare diseases	5
Topic 5 : IHI-2023-04-05 – Safe & sustainable by design (SSbD) packaging and single use device solutions for healthcare products	1
Topic 6 : IHI-2023-04-06 – Sustainable circular development and manufacturing of healthcare products and their quantitative environmental impact assessment	2
Total	17

The maximum financial contribution from IHI JU for the six topics is EUR 83 350 000 and the indicative in-kind (and financial) contribution from industry partners and contributing partners is EUR 85 076 000.

Applicants were informed about the results of the first stage evaluation on 24 January 2024 and were invited to submit a full proposal by the second stage submission deadline which was 23 April 2024. Only the applicants' consortium whose proposal was ranked first per topic at the first stage were invited for the second stage, hence only six proposals were evaluated during the second phase of the evaluation.

Ahead of the consensus meeting, the Independent Observer was invited to attend a background briefing via a WebEx conference call. The briefing included a comprehensive overview of the evaluation process, and the Independent Observer was provided with all the relevant supporting documents. The Independent Observer also had access to the proposals and individual reports in SEP.

The six consensus meetings were carried out, fully remotely via WebEx and between 27th and 29th May 2024.

The Independent Observer participated during the three days of the consensus meetings, including the panel briefing and the proposal review meetings and had the opportunity to discuss with the IHI scientific officers/moderators and experts, aspects related to the evaluation process. All experts received the email address of the Independent Observer and were encouraged to provide comments/feedback both during and after the evaluation process.

2 Overall impression

The evaluation process was run in a highly professional manner, fully in line with the guidelines regarding transparency and equal treatment of each of the six proposals. The instructions and supporting documents were ample and of high quality and well received by all experts.

The time schedule was very well respected and the IHI JU Staff has a notable knowledge and extensive experience both in how to run consensus meeting as well as content wise resulting in a most professional evaluation process.

- Scale of complexity of the evaluation task:

The evaluation of HORIZON-JU-IHI-2023-04-two-stage call was run in full coherence with the guiding principles outlined in the documentation. Each proposal was assessed based on the three evaluation criteria outlined in the Work Programme, i.e. excellence, impact and implementation. The evaluation was most professionally executed, given the complexity of the process, following the standard procedure for IHI JU two-stage call.

- Transparency of the procedures:

Overall, the evaluation process was fully in line with the IHI JU established rules which and can easily be found at the IHI website and the EC Funding and Tenders portal. All the 28 experts involved are registered in the European Commission expert database, in line with the transparency requirements,

The 28 experts were selected based on their expertise related to the topic and also due to their significant capacity to evaluate a broad range of different health related areas.

In addition, in order to provide a continuum some of the experts were the experts were employed in both stages of the evaluation. In order to comply with the rotation rules for Horizon Europe, new experts were also added. The balance between different nationalities was good and the gender balance was acceptable with seventeen male and eleven female experts.

- Throughput time of the process and the efficiency of the procedures

The allocated time to draft and finalise each of the Individual Evaluation Reports (IER) was considered as sufficient, as well as the time given to draft the Consensus Reports. It should be recognised that the proposals are quite complex and requires a notable capacity from experts to assess and formulate high quality IERs, therefore the experts were very professional showing a high capacity to perform a very good assessment. To achieve an efficient procedure and keep the quite tight timetable, the moderator played a significant role. Each consensus meeting was chaired by two scientific officers from IHI JU, with one as the principal moderator and the other to support. The two scientific officers complemented each other in a good way. All the scientific officers were very professional, with a high capacity to manage a well-balanced and dynamic discussion. A special attention was paid to get an equal involvement of all experts and to ensure that all views were considered in a transparent way, which can be more challenging when the consensus meeting is held remotely than if this was done at an on-site meeting.

- Efficiency, reliability and usability of the implementation of the procedures, including the IT-tools:

The evaluation procedures were implemented in full coherence with the guidelines of Horizon Europe and the specific IHI guidelines.

All the moderators showed great experience in handling the discussions in a consistent and efficient manner and showed extensive knowledge about the topics discussed.

The procedures for on-line consensus meetings are now well-established and the WebEx platform worked overall well with no incidents that had an impact on the evaluation process. Both experts and moderators are used to handle minor delays efficiently and compared to a few years ago, the WebEx format works well.

- Impartiality, fairness and confidentiality:

Ahead of each of the six consensus meetings, the experts were thoroughly briefed by the scientific officers about the procedures including the interpretation of the scores. An introductory welcoming video by the Executive Director of IHI was also displayed to set the scene and give all the experts a level playing field. It was duly underlined that each proposal should be evaluated on its own merit and to only take into account what was written in the proposal to make sure that every proposal is treated in a fair and equal way.

Each expert had to declare any potential Conflict of Interest ahead (CoI) when selected as expert for this call. The importance of assessing any potential CoI at any moment during the evaluation was repeated ahead of the consensus meeting. The experts were also clearly instructed to never reveal any information about the proposals or results externally and to respect confidentiality also once the evaluation was accomplished.

The preparations and organisation of the evaluation were excellent. The moderators including the supporting scientific officer were all very well prepared. The experts were provided with comprehensive background information to perform their tasks with confidence to insure a fair treatment of each proposal.

The documentation provided ahead of the evaluation was sufficiently detailed to allow the experts to draft high quality Individual Evaluation Reports and Consensus Reports.

During the consensus meetings, the moderators of the six panels paid attention to that all criteria, including the sub-criteria were thoroughly addressed in a coherent and impartial manner. The final text per criterion was first agreed among the experts before the scoring, to make sure that there was consistency between the text and the scores,

- Conformity of the evaluation process witnessed with the evaluation procedures published in the HE Grants Manual:

The evaluation process was fully in-line with the evaluation procedures published in the Horizon Europe Grants Manual

- Quality of the EU evaluation process in comparison with the evaluation procedures of national and/or other international research funding schemes:

Compared to similar experiences with national evaluation procedures, the quality of the IHI evaluation process is outperforming many others in terms of quality and professionalism. The level of consciousness about the importance of fairness, transparency and confidentiality throughout the whole evaluation process among the IHI JU Staff is excellent, comparing to similar experiences with national procedures.

- Quality of the evaluation process overall:

The evaluation was of very high quality in all steps, from the documentation provided, to the experts with overall quality of the evaluation process was excellent, from experts with notable knowledge and experiences to the engagement and professionalism of the IHI JU Staff. This excellent evaluation process guarantees that each proposal is correctly assessed and hence ensuring that the best proposals are selected. The IHI JU Staff was also accommodating any suggestion on how to improve the evaluation process.

3 Any other remarks

The Independent Observer has the following addition remarks, not already covered:

- The engagement and knowledge among the experts was impressive. There was a clear mutual respect and generosity for each other's views between the experts which resulted in well performed and high-quality consensus discussion. The professionalism of the IHI JU Staff should once more be underlined.
- Overall, the feedback from the experts was very good and that the IHI evaluations work was performed in a very good atmosphere. Experts noted the high engagement and team spirit from the IHI JU team and that they very much enjoyed the exercise.
- The remote evaluation has the main advantages of less travels and efficiency in time, nevertheless, some of the experts expressed that in-person meetings could be an alternative from time to time as this would allow for exchange of knowledge and experiences beyond the actual consensus meetings.
- While the on-line concept and the WebEx platform has improved, the SEP tool would need to be further adapted to further facilitate the process.
- No conflict of interest was identified

4 Summary of Recommendations

The overall impression of the second stage evaluation process of the HORIZON-JU-IHI-2023-04-two-stage call was excellent. The procedure is solid, yet pragmatic and, together with the engagement and professionalism of the IHI JU Staff (i.e. scientific officers and call coordination team), form an evaluation system that vouches for impartiality, fairness and that the proposals selected will bring impact.

The only few recommendations that could be re-iterated would be to insist on the need to further develop the SEP tool to be a real support in the remote evaluation process.

Based on the feedback from some of the experts, it could be considered to re-introduce the stage 2 hearing of the consortium. To have the opportunity to ask questions directly to the consortium was perceived as a way to bring a further understanding of the potential of the proposal.