

# IHI JU INDEPENDENT OBSERVER'S REPORT

Call ID: HORIZON-JU-IHI-2023-04-  
two-stage

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Present at the evaluation: 11-14 December 2023

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# 1 Introduction and approach taken by the observer

This report describes the Independent Observer’s assessment of the evaluation process of the HORIZON-JU-IHI-2023-04-two-stage call, published on 27 July 2023 with submission deadline on 8 November 2023. 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.

The purpose of this report is to give an independent view on the evaluation process and provide recommendations for possible improvements.

The HORIZON-JU-IHI-2023-04-two-stage call included six topics with a total of 17 proposals split per topic as shown below:

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

All 17 proposals were admissible but only 15 were declared eligible.

The overall aim of **IHI-2023-04-01** topic was to develop non-animal approaches and generate evidence to support their use in situations where animal-based tests are used currently. This evidence will allow the industry and regulators to use these non-animal approaches in their work and decision-making processes.

In **IHI-2023-04-02** topic, the aim was to explore how the use of microsampling devices could be expanded to allow patients (or their caregivers) to collect a blood sample at home and send it for analysis.

In **IHI-2023-04-03** topic, the aim was to address the fact that many groups of people are not fully represented in clinical studies in Europe due for example to gender, ethnicity, or other diverse socio-economic, systemic, and cultural barriers.

In **IHI-2023-04-04** topic, the aim was to develop and test innovative trial designs and deliver methodological solutions that would speed up the development of treatments for rare/ultra-rare diseases.

In **IHI-2023-04-05** topic, the aim was to apply the ‘safe and sustainable by design’ (SSbD) principles to packaging and single-use devices, from the earliest design stages to the end of the product’s life. It will do

this for example by using alternative materials and facilitating the recycling of both packaging and devices. This will help the health sector to generate less waste and reduce its carbon footprint.

In **IHI-2023-04-06** topic, the aim was to develop novel manufacturing methods that would reduce the use of solvents, replace toxic 'substances of concern', and reduce water and energy use.

Only the applicant consortium whose proposal is ranked first per topic at the first stage is invited for the second stage.

A background briefing was organised for the Independent Observer ahead of the consensus meetings. The meeting took place via a WebEx conference call and was chaired by the Scientific Operations Coordinator. The website where all relevant information and supporting documents are included was provided shortly after the briefing. The Independent Observer also had access to the proposals and individual reports in SEP.

The consensus meetings were held fully remotely via WebEx and divided into three parts, as follows :

- for panels IHI-2023-04-03 and IHI-2023-04-06, the consensus meetings took place between 11-12 December 2023
- for panels IHI-2023-04-01 and IHI-2023-04-02, the consensus meetings took place between 12-13 December 2023
- for panels IHI-2023-04-04 and IHI-2023-04-05, the consensus meetings took place between 13-14 December 2023

The Independent Observer participated during the full five days of the consensus meetings.

## 2 Overall impression

The evaluation process was most professionally executed, in full coherence with the stipulated transparency and equal treatment regulations, hence the overall impression is excellent. The IHI JU evaluation team is highly professional, with an in-depth knowledge and experience both regarding how to conduct efficient and fair consensus meetings as well as knowledge about the topics concerned. The planned timing for the consensus meetings was very well respected and the supporting documents provided were comprehensive and appreciated by the experts.

- ***Scale of complexity of the evaluation task:***

The evaluation was the first stage of this two-stage call HORIZON-JU-IHI-2023-04, and was smoothly run in an excellent way, in full coherence with the guiding principles summarised in the guidelines set out for a IHI JU two-stage call. Hence, the evaluation was executed to a very high standard given the complexity of the process.

- ***Transparency of the procedures:***

The evaluation task followed the established rules for IHI JU The evaluation rules are available at the IHI website as well as at the EC Funding and Tenders portal. All experts involved in the evaluation are registered in the European Commission expert database, fully in line with the transparency requirements.

36<sup>1</sup> external experts (1 acting as dedicated rapporteur) were selected based on their expertise related to the topic they evaluated but also due to their significant capacity to evaluate a broad range of different health related areas as well as the potential impact of the proposals. The selection was done from the EC database where all potential experts must be registered and in full coherence with the rules. Out of the total number of experts, 67% were new, i.e. experts who have never participated in any EU evaluation before. The diversity among nationalities was well-maintained (30 expert from EU Member States, 5 experts from Associated Countries and 1 expert from a third country), and there was a balanced gender distribution among experts, comprising 44% women and 56% men.

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

Even though, the time allocated to finalise the Individual Evaluation Reports (IER) and draft the Consensus Report (CR) ahead of the consensus meetings was appropriate, some of the rapporteurs encountered some difficulties, due to the time pressure, to prepare a final draft CR prior to the panel meeting.

To achieve an efficient consensus meeting, it is essential to have well drafted CRs and moderators who can guide the discussion towards an agreement without steering the opinion of the experts. The quality of the CRs was high and the moderators of the different consensus meetings were highly professional with an impressive capacity to manage a well-balanced and dynamic discussion. One challenge when carrying out remote meetings is to manage to get all experts involved to an equal extent. The moderators during this evaluation had all an excellent ability to get everyone engaged, which is an important skill.

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

The implementation of the Horizon Europe guidelines, as well as the guidelines specific to IHI was excellent and efficient.

All moderators were very professional and highly experienced in how to run evaluations smoothly, while guiding the discussion in a transparent and efficient way. Furthermore, the moderators demonstrated an impressive knowledge about the topics discussed which ensured an efficient and reliable procedure.

The WebEx platform worked generally well and there were no major connection problems that negatively impacted the evaluation process.

- ***Impartiality, fairness and confidentiality:***

Ahead of the evaluation, the experts were well briefed about the importance of assessing each proposal on its own merits and base their judgement only on what was written in the proposal. At the start of the consensus meetings, moderators took the opportunity to once more highlight the importance that each proposal was handled in a fair and equal manner.

Additionally, it was emphasised to signal any potential conflicts of interest (CoI) at any time (experts' invitation, remote and central evaluation phases) of the evaluation, to keep confidentiality and never disclose any information about the proposals or results externally.

<sup>1</sup> 1 expert has participated only during the individual evaluation phase

To ensure a smoothly run evaluation, it is important to be well prepared. The IHI Evaluation Guidance documentation made available before the evaluation started, was much appreciated to allow experts to draft high quality Individual Evaluation Reports and Consensus Reports. Furthermore, the moderators were all very well prepared and paid much attention to that all criteria, as well as sub-criteria, were properly considered in a comprehensive and fair way. The text of each criterion was first agreed between the experts before the scoring to ensure full consistency between the text and scores.

Hence, the evaluation was very well managed in terms of preparation, organisation and timing.

- ***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:***

The IHI JU has established a high-quality evaluation system, emphasising the ongoing pursuit of improvement. The IHI JU staff, including call coordinator, moderators, and assistants, are all very professional, attentive to details and proactive, compared to other similar experiences at national or international level. The IHI JU evaluation procedures are transparent and ensure a high level of equal treatment and confidentiality to guarantee that the best proposals will be funded.

- ***Quality of the evaluation process overall:***

The overall assessment of the quality of the evaluation process is excellent. The experts engaged have all an impressive knowledge, the engagement is notable with a high level of professionalism. Moreover, the IHI JU staff is exceptionally competent and cautious to see to that the best proposals selected, based on a thorough assessment. The openness from the IHI JU Staff to receive ideas on how to improve the evaluation process should be noted.

### **3 Any other remarks**

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

- Despite attempts to improve SEP (Submission and Evaluation Platform), there is still more to do so that the tool is user-friendly and facilitates the evaluation. One such example is to make it possible to merge IERs per criterion whereas today the rapporteur must cut and paste the different sub-criterion per expert into one text which is time consuming.
- There are always pros and cons to run a fully remote evaluation. The pros are that it could be easier to find experts as they don't have to travel. The flipside of the coin is that it can be very challenging to keep up the concentration for many hours in an on-line meeting. However, the level of engagement from the experts should be noted.
- No conflict of interest was identified across the panels during the central evaluation.
- Experts have observed that the remuneration for their services remains similar from the previous Framework Programmes, highlighting the need for a revision in fees to align with current standards.
- A last but most important remark is that, despite long days and sometimes tricky discussions, the atmosphere was excellent, with a high level of engagement and openness. The group of experts stated that they very much enjoyed the exercise.

## 4 Summary of Recommendations

The overall quality of the first stage evaluation process of the HORIZON-JU-IHI-2023-04-two-stage call was excellent. The system that IHI JU has put in place to perform their evaluations is solid and guarantees a transparent process based on equal and fair assessment. The outstanding professionalism from the IHI JU Staff should be highlighted.

With such a solid process in place, there are only a few recommendations bring forward.

It is essential to continue to work on the running of remote evaluations. The days are intense, and it is easy to lose concentration so to plan for a few additional shorter breaks could be one way of maintaining the full attention. A Q&A for experts on how to run an efficient remote meeting could also be considered based on the experiences already gathered from previous evaluations.

The SEP tool could be further developed to become a real support in the evaluations.

It could be considered to review the time allocated to the experts to do their individual readings and assessment as the topic can be quite complex with several aspects to consider. Often the experts spend considerably more time per proposal than what is stipulated in their contracts.

To ensure to get the best experts also in the future, it's essential to align their compensation with current living standards.