

IHI JU INDEPENDENT OBSERVER'S REPORT

Call ID: HORIZON-JU-IHI-2024- 07-single-stage

Date of evaluation: From 24 to 26 June 2024

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Present at the evaluation: From 24 to 26 June 2024

Signature and date

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1 Introduction and approach taken by the Observer

My role for this report was to independently observe the evaluation process of the IHI Joint Undertaking (JU) call HORIZON-JU-IHI-2024-07-single-stage, which consisted of three RIA topics:

1. **HORIZON-JU-IHI-2024-07-01**: Improving clinical management of heart disease from early detection to treatment
2. **HORIZON-JU-IHI-2024-07-02**: User-centric technologies and optimized hospital workflows for a sustainable healthcare workforce
3. **HORIZON-JU-IHI-2024-07-03**: Clinical validation of biomarkers for diagnosis, monitoring disease progression and treatment response.

A total of 28 full proposals were submitted for all three topics, of which 5 were declared ineligible and 1 inadmissible. The number of eligible full proposals submitted for topic 1, 2 and 3 were 5, 7 and 10, respectively.

In order to successfully complete the task of 'Independent Observer', I carried out the following activities:

- Review of the following documents:
 - Independent observer's contract CT-EX2022D618571-101 issued by the contracting authority.
 - The Horizon Europe programme and rules of participation¹
 - The Horizon Europe Programme guide²
 - IHI Call 7 topic text for all three topics mentioned above including expected outcomes, scope and expected impact and applicable call conditions³
 - Legislation creating IHI⁴
 - IHI Strategic Research and Innovation Agenda⁵
 - IHI guide for applicants⁶
 - IHI guide for contributing partners⁷
 - Frequently asked questions⁸
 - IHI guidelines for in-kind contributions to additional activities (IKAA)⁹
 - Guide for applicants and project consortia on regulatory considerations for IMI and IHI projects¹⁰
 - Checklist for assessing IHI JU eligibility for funding of companies having an annual turnover of less than EUR 500 million¹¹
 - Section 3.2 (Selection - From evaluation to grant signature) of EU Funding & Tenders online Manual¹²
 - IHI evaluation form¹³
 - The standard observer report template to prepare the present document
- Attended a specific Independent Observer (I.O.) briefing delivered by the IHI Call coordinator on 13 June 2024.
- Attended the remote consensus and ranking meetings held between 24 and 26 June 2024. As meetings for all three topics ran in parallel, I rotated between the meetings with the aim of observing

¹ <https://eur-lex.europa.eu/eli/reg/2021/695/oj>

² https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/programme-guide_horizon_en.pdf

³ <https://www.ih.europa.eu/apply-funding/ih-call-7>

⁴ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2021.427.01.0017.01.ENG

⁵ https://www.ih.europa.eu/sites/default/files/Imnqr/IHI_Strategic_Research_and_Innovation_Agenda_3.pdf

⁶ https://www.ih.europa.eu/sites/default/files/IHI_Guide_for_Applicants.pdf

⁷ https://www.ih.europa.eu/sites/default/files/uploads/Documents/ShapelHI/Guide_IHI_Contributing_Partners.pdf

⁸ https://www.ih.europa.eu/sites/default/files/uploads/Documents/Calls/Call_FAQs.pdf

⁹ https://www.ih.europa.eu/sites/default/files/IHI_Guidelines_in_kind_contribution_additional_activities.pdf

¹⁰ https://www.ih.europa.eu/sites/default/files/uploads/Documents/ProjectResources/Guide_RegulatoryConsiderationsIMI_IHI_Projects_final.pdf

¹¹ https://www.ih.europa.eu/sites/default/files/uploads/Documents/ProjectResources/IHI_JU_CHECKLIST_turnover_less_than_EUR_500M_AV.docx

¹² https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/om_en.pdf

¹³ https://www.ih.europa.eu/sites/default/files/IHI_Evaluation_form_RIA.pdf

at least 1 complete proposal evaluation (leading to the preparation of the final consensus report) per call topic (during the first two days), and 1 complete ranking list preparation. By the end of the evaluation phase, I was able to observe two full proposal evaluation per call topic and two final ranking list preparations for the topics 2 and 3. During the second and third days I also reviewed randomly selected IERs, CRs, ESR on SEP to evaluate their quality and compliance with the standard format.

- Throughout the evaluation period I had several exchanges with the moderators to ask questions, seek clarification and get clear and prompt answers. I also contacted the moderators and call coordinator a few days after the end of the evaluation period to obtain further information to prepare this report.
- Towards the end of the evaluation period, I also contacted several expert evaluators to get their impressions of the evaluation process and their ideas for improving the overall process.

2 Overall impression

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

With a total of 22 eligible proposals evaluated by 25 experts, I found the overall workload to be well balanced within the range of standard Horizon Europe RIA proposals. Nevertheless, the present call had some specific requirements and a few extra annexes that demanded extra attention from the experts:

- Aim of the funding call: demanded a thorough understanding of the specific objectives and expected impacts of the IHI initiative along with the specific call text. This required evaluators to have a clear understanding of the strategic goals and how each proposal aligned with these goals, adding a layer of complexity to the evaluation process.
- In-kind contribution and types of participants: were essential components that necessitated careful examination. Evaluators needed to assess not only the financial contributions but also the nature and value of the in-kind contributions provided by the members of the industry associations. This aspect was crucial for determining the feasibility and sustainability of the proposed projects.
- Annex to the Budget table: required meticulous scrutiny, especially for assessing the 45% eligibility criterion. More specifically, according to the call requirements, applicants must ensure that at least 45% of the sum of total project eligible costs plus costs of any related In-kind contributions to additional activities is provided by IHI JU private members and IHI JU Contributing Partners, their constituent entities and affiliated entities. If the 45% Industry contribution is not secured collectively by the industry consortium participants, the proposal is declared ineligible and therefore is not evaluated. Experts had to ensure that the budget allocations were appropriate, justified and aligned with the proposed activities and expected outcomes.

Furthermore, the page limit for the present call was increased to 50 pages compared to the standard 45 pages for Horizon Europe RIA proposals. This extension meant that there was more content to review, increasing the overall complexity and requiring additional effort and detailed attention from the expert evaluators. For first-time expert evaluators, this presented a significant challenge, requiring extra diligence and a comprehensive approach to ensure a thorough and accurate evaluation. First-time experts appreciated the guidelines and details given in the briefings and also the support they received by the moderators that facilitated their work.

- **Transparency of the procedures:**

The evaluation procedures were transparent to all participants, including evaluators, moderators and myself as the independent observer. All of us had access to publicly available information, primarily found on the EU Funding and Tenders (FT) Portal and the IHI's website.

Each participant type (expert evaluators, moderators and myself) received specific briefings in a timely manner for the evaluation. Additionally, a comprehensive consensus briefing was provided on the first day of the consensus phase. These briefings included general information about the call and its content, as well as all relevant details for the evaluation process. This encompassed the planning of all phases (individual evaluation, consensus and panel ranking), evaluation criteria and sub-criteria, scoring system, score interpretation table and tips for writing high-quality reports (IERs and CRs).

Participants were contacted for their specific roles, they were made aware of the transparency requirements and the necessity to disclose any potential Conflict of Interest (COI) in order to take necessary measures,

during evaluation. The absence of Col was ensured through specific clauses in each individual's contract. By signing their contracts and the annex regarding the code of conduct, participants acknowledged these requirements and confirmed, to the best of their knowledge, that they had no conflicts of interest. In addition, preliminary COI check were performed using the tool available in SEP.

My presence as an independent observer, with the freedom to raise any questions to the evaluation staff (expert evaluators, moderators and the call coordinator), is a clear indication of the commitment to full transparency in the evaluation exercise. All questions I raised were promptly and clearly answered without any restrictions. For transparency and openness, experts were also informed that they could raise any concerns with me if they wished.

I am fully convinced that all applicable procedures and rules, whether general Horizon Europe rules or those specific to this IHI call, were clear and transparent to all experts and myself. The evaluation process was conducted to high standards of diligence, fairness, and transparency throughout the entire evaluation exercise.

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

The overall evaluation process spanned from 24 May 2024 to 26 June 2024, with the period from 24 May 2024 to 13 June 2024 dedicated to individual remote evaluation and IER preparation. The consensus phase took place from 24 to 26 June 2024. This timeframe was sufficient to cover all phases of the evaluation process, including IER preparation, CR drafting, consensus meetings, quality of CR by the IHI legal officers and panel meetings for the 22 proposals being evaluated, allowing experts to complete their work efficiently.

Each expert evaluator was assigned either 5 or 6 proposals to review during the individual evaluation phase, which lasted about 2.5 weeks. This is generally a reasonable timeframe. However, one first-time expert evaluator noted that the time required for each proposal was 50% more than anticipated. In my view, first-time evaluators are often over-cautious, dedicating more time than necessary to each proposal.

The consensus phase meetings for topics 1 and 2 were completed well within the assigned daily schedules. In fact, the final day meetings for both topics finished slightly ahead of schedule, indicating that the throughput time was adequate. However, the meetings for topic 3, which had the highest number of submitted proposals, extended beyond the scheduled timings. Although topic 3 was assigned the most expert evaluators, which was beneficial during the individual evaluation phase, this did not alleviate the workload during the consensus phase. The topic 3 moderator invited only the expert evaluators involved in evaluating each specific proposal to the consensus meetings, providing other evaluators with breaks. Despite that the workload on both moderators was very high, as they had to start their work before and continue after each day's meetings, yet the moderation proved to be effective.

The workload and the provided time for the Quality Control, by IHI legal officers, of the CRs appeared to be appropriate, as indicated by the limited number of suggested changes. Overall, the efficiency of the procedures was maintained, ensuring a thorough and fair evaluation process.

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

The SEP system was utilized as the primary document repository for IERs, CRs, ranking lists, and all steps required for the evaluation process e.g. submissions and approvals. This system operated smoothly and reliably, with experts finding it intuitive and easy to use, seldom requiring assistance from the moderators.

For the remote evaluation phase, the Webex tool was employed. It was familiar to all participants and functioned without major technical issues. Occasionally, there were minor connection problems on the participant's end, but these did not adversely impact the evaluation process. Most participants turned off their microphones (while mostly keeping their cameras on) when they were not speaking to maintain the quality of the exchanges.

Overall, I believe the procedures, including the IT tools used in the present IHI evaluation, were reliable and robust. The implementation of these procedures was efficient and effective, contributing to a smooth evaluation process.

- **Impartiality, fairness and confidentiality:**

I am fully convinced that the evaluation process was impartial, fair and conducted in full compliance with all general Horizon Europe rules while also taking into account the specificities of the IHI call (e.g., 20% non-EU IKOP, 45% eligibility criteria).

The early detection and treatment of potential conflicts of interest were key to achieving impartial and fair evaluations. All experts, along with myself, signed a declaration of the absence of conflict of interest (COI) as part of our contracts. The importance of avoiding conflicts of interest was also reiterated to experts during briefings. Conflicts of interest are generally detected before the start of the evaluation but could also be uncovered during the evaluation.

The overall evaluation process was fully compliant with the principles of independence, impartiality, objectivity, accuracy and consistency.

The involvement of multiple panel members in the evaluation process for each proposal, with well-defined roles (5 or 6 expert evaluators, 1 independent observer, and 2 moderators), significantly contributed to achieving impartial and fair evaluations.

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

The evaluation process adhered closely to the rules and criteria specified in the Horizon Europe Grants Manual for assessing project proposals. This included rigorous evaluation based on specific criteria of each sections i.e. excellence, impact and quality and efficiency of the implementation.

A notable aspect of the process was the moderators commitment to ensuring that expert evaluators assessed each proposal section independently and objectively, without veering into broad interpretations or extrapolations. This approach maintained consistency and fairness across all evaluations.

In addition to these general procedures, the IHI evaluation team provided comprehensive briefing materials to the experts which offered detailed context and content specific to the call and its three distinct topics, ensuring that evaluators had a clear understanding of what was expected to be delivered.

One particular observation during the consensus phase was the occurrence of disagreements among evaluators regarding the interpretation of a specific sub-criteria. The moderator swiftly addressed this by referencing the exact text related to the evaluation criteria, utilizing screen sharing to clarify and resolve the issue efficiently. This proactive measure prevented prolonged discussions and ensured that consensus could be reached promptly.

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

Having participated in evaluation processes for several national calls in Ireland and Germany, I can confidently say that the IHI evaluation process is as robust and of high quality, if not better, than other national and international research funding schemes. Many countries are known to be inspired by the EU evaluation methodology to enhance their own national processes.

The main evaluation principles include objectivity and impartiality, independence of evaluators, participation of all parties concerned in the entire process, transparency and focus, reliability, consistency, completeness and clarity of reports, fairness, and protection of the interests of the parties involved. I believe that all these principles are well embedded and efficiently implemented in the EU evaluation process including the present IHI evaluation. This ensures that the evaluation is conducted to the highest standards, maintaining fairness and protecting the interests of all parties involved.

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

I believe the evaluation was conducted in a transparent and open manner, with all proposals receiving detailed attention and fair treatment in compliance with the applicable rules and procedures. This conclusion is based on discussions and email exchanges with some expert evaluators and moderators, attendance at briefings, reading of relevant documentation, review of randomly selected IERs, CRs, and ESRs and full-time observation of the entire consensus phase meetings.

Throughout the entire process, the IHI evaluation staff demonstrated their commitment to transparency and adherence to all applicable rules and procedures. The moderators consistently facilitated the evaluation process within their panels, maintained impartiality and urge their experts to actively participate during the discussions by providing their assessment/view and ensured equal treatments for all proposals The

professionalism and availability of all participants greatly contributed to the smooth and efficient running of the evaluation process.

I consider that the entire evaluation process conducted by the expert evaluators and IHI staff was of the highest professional and quality standards, in accordance with the rules and guidelines for the Horizon Europe programme, as well as specific IHI rules whenever applicable.

3 Any other remarks

- **Quality of the documentation provided to experts beforehand**

All experts and the observer had access to all of the relevant documents, needed to conduct a high quality evaluation process, which were provided during multiple different specific briefings along with the usual documents that applicants had been using to prepare their proposals, available on the “Funding and Tender portal” (such as the IHI work programme and the relevant annexes, the IHI application forms, the evaluation forms, usable for both IERs and CRs).

Furthermore, I contacted several expert evaluators and all of them were highly satisfied with the quality of the provided documents therefore I am convinced that all relevant information was made available to all those who “need to know” and that the information was clear, comprehensive and of high quality.

- **Quality of the on-site briefing sessions:**

I received my briefing on 13 June 2024 and all evaluators, along with myself, received the consensus phase briefing on 24 June 2024, the first day of the consensus phase. Furthermore, at the beginning of each day during the consensus phase, the moderator conducted a quick meeting summarizing the current status and the day's agenda. These high-quality and comprehensive briefings covered the relevant topics thoroughly, while providing expert evaluators and myself the opportunity to ask any remaining questions before starting the consensus phase.

- **The understanding by experts of the call (context, topics), of the evaluation process and their role and of the award criteria and scoring scheme:**

All experts were well-informed about the call and the specific topics they were evaluating. They understood the significance of their role in determining the funding decisions for the proposed projects. The instruction to evaluate the proposals as written and to refrain from recommending substantial changes or improvements was clearly comprehended by the evaluators.

Most expert evaluators demonstrated a good understanding of the award criteria and scoring scheme. However, on the first day of the consensus phase, some evaluators expressed misunderstanding about aspects of the scoring scheme, such as distinguishing between multiple minor shortcomings and weaknesses. Moderators promptly clarified these concerns by referring to the scoring scheme through on-screen sharing. Throughout my observation, moderators consistently referenced the scoring scheme before finalizing the consensus and awarding scores, which enhanced the integrity of the evaluation process.

Some experts felt less comfortable assessing the budget table, noting that financial experts might be better suited for this task.

Other important aspects well understood by evaluators included the requirement to provide comments before assigning scores, avoiding double penalization or reward for the same reason under different criteria, emphasizing the quality of the consensus report for clear feedback to applicants and to prevent potential disputes, and maintaining consistency between comments and scores.

Overall, the experts demonstrated a solid understanding of their roles, the evaluation criteria, and the importance of maintaining fairness and consistency throughout the evaluation process.

- **The allocation of experts to proposals: balance (gender, geographic, sector), relevance and balance of expertise:**

For the evaluation of the 22 proposals in this call, 25 expert evaluators were selected based primarily on their expertise and coverage of the various facets of the call. Efforts were made to maintain a balanced gender representation, geographic diversity and diversity in the types of organizations represented.

- **Gender Balance:** 44% of the experts were women, indicating a significant effort towards gender balance in the evaluation panel.
- **Expertise and Experience:** Among the experts, 12% were first-time experts for Horizon Europe, while 36% were new to evaluating IHI calls. This mix ensured a blend of experienced evaluators and fresh perspectives.
- **Geographical Coverage:** Experts were recruited from 12 different EU countries, aiming to provide diverse perspectives and ensure regional representation. Importantly, 16% of these experts were from widening or low R&I performing countries, contributing to geographic diversity.
- **Sector Representation:** Roughly one-quarter of the experts came from private for-profit organizations, highlighting the involvement of industry perspectives. The remaining experts were from higher or secondary education organizations, research institutions, or other public bodies such as hospitals or government-funded agencies.

Overall, the allocation of experts aimed to ensure a comprehensive evaluation process that considered the broad spectrum of expertise needed for the diverse criteria and sub-criteria of the call. The balanced representation across gender, geographic origin and sectors helped in providing fair and informed evaluations of the proposals under consideration.

- **The process of the individual evaluations and the actors involved:**

The individual evaluation process was conducted from 24 May 2024 to 13 June 2024 in a fully remote manner with no interaction between myself and the evaluators. Therefore, the quality of the process and the experts evaluators involved can only be judged by the review of IER. I reviewed a few randomly selected IERs and found all of them to be of good quality. Another opportunity to assess the expert evaluators was during the consensus meeting, where overall, they demonstrated high competence in their respective fields and maintained a professional conduct.

- **The process of the consensus meetings and the actors involved:**

I attended the consensus meetings scheduled from 24 to 26 June 2024 for the evaluation of Horizon Europe projects under the Innovative Health Initiative (IHI). The final day meetings for topics 1 and 2 concluded a few hours ahead of schedule, whereas discussions for topic 3, which had the highest number of submitted proposals, extended beyond the planned timeframe.

On the first day, significant time was dedicated to discussing the initial proposal across all panels. This initial discussion period is typical, allowing expert evaluators to seek clarifications and establish a common understanding of the consensus process for subsequent evaluations. Moderators played a crucial role by providing necessary clarifications and fostering an inclusive environment where experts felt comfortable raising concerns.

Although the consensus meetings for topic 3 exceeded their allocated time, I believe this was reasonable given the volume of proposals to review. However, it also placed a considerable workload on the moderators responsible for this topic.

- **Criteria and scoring scheme: appropriateness, completeness, relevance, clarity, consistency in application:**

The three main criteria and their sub-criteria applicable to the evaluation process were thoroughly explained to all experts, who demonstrated a strong understanding of these criteria. Additionally, all evaluators were well-versed in the scoring system and understood the significance of score thresholds. Throughout the evaluation, the score interpretation table served as a useful reference to ensure consistency and clarity in scoring against agreed-upon comments for each criterion.

While negative comments often included qualifiers such as "minor shortcoming" or "shortcoming" to indicate severity, there was some variability in the application of these terms among the expert panels in their IERs. However, during the CR preparation, moderators ensured that scores were consistently applied across all evaluations. Their vigilance and guidance contributed significantly to maintaining uniformity in scoring throughout the entire process.

Overall, the criteria and scoring scheme were appropriately understood and consistently applied by evaluators during the CR phase, highlighting the effectiveness of the moderators in ensuring fairness and accuracy in the evaluation process.

- **The process of the final panel meeting and the actors involved:**

The final panel meeting, which culminated in the preparation of the final ranking list, was conducted efficiently and smoothly. This efficiency was facilitated by the fact that the top proposals did not have identical scores, which streamlined the decision-making process.

Before finalizing the ranking list, all experts formally expressed their agreement with the consensus reports and the final ranking list, thereby endorsing the evaluation results. This consensus ensured that the evaluation process concluded with a unified decision supported by all participating experts.

Overall, the final panel meeting served as a critical step in solidifying the evaluation outcomes, marking the conclusion of a thorough and well-coordinated evaluation process

- **The process of the hearings (if any) and the actors involved:** *Not applicable*

- **The occurrence and handling of specific issues (if any) such as conflicts of interest:** *Not applicable*

- **The quality of evaluation summary reports:**

The importance of providing high-quality ESRs was clearly emphasized to all experts, considering that these reports represent the sole feedback received by applicants after extensive effort and dedication. Throughout the evaluation process, all involved parties diligently adhered to this directive.

My independent review of randomly selected ESRs confirmed that they consistently delivered fair, clear, and valuable feedback to the applicants. Constructive comments were present where warranted, aiming to guide applicants in refining their future proposals.

The presence of constructive feedback is particularly beneficial as it encourages applicants to enhance their submissions for future opportunities. This approach not only supports the continuous improvement of proposal quality but also reflects the commitment to fostering a supportive and developmental environment within the evaluation process.

Overall, the quality of the ESRs underscored the dedication to providing meaningful feedback, thereby contributing to the enhancement of future applications and the overall effectiveness of the evaluation process.

- **Overall conduct of staff: responsiveness, hospitality, competence:**

Throughout all phases of the evaluation process, I was consistently impressed by the professionalism and support demonstrated by all IHI staff involved in the evaluation. Their high degree of responsiveness and competence significantly contributed to the smooth operation of the evaluation.

I observed that all questions, whether from expert evaluators or myself as an independent observer, were addressed promptly and efficiently. This responsiveness ensured that any queries or concerns were resolved in a timely manner, thereby facilitating the continuity and efficiency of the evaluation process.

- **Infrastructure and working conditions for evaluators:**

The complete evaluation process, including both the individual assessment and consensus phases, was conducted remotely. From my personal observation, all experts and moderators appeared to have access to good working conditions and the necessary infrastructure to perform their roles effectively and process was conducted without significant technical or logistical hindrances.

- **Workload and time given to evaluators for their work, (remotely and/or on-site, as applicable):**

As already mentioned above the overall time allocated the complete evaluation process (individual and consensus) was adequate. However, the consensus meetings of topic 3, which has the highest number of submitted proposals (10 in total), exceeded the planned duration.

- **Remuneration of evaluators (in relation to workload):**

Based on my inquiries with expert evaluators, the feedback regarding remuneration in relation to workload was generally positive. Nearly all evaluators expressed satisfaction or did not comment on the remuneration issue. Only one expert strongly suggested that the remuneration was inadequate.

4 Summary of Recommendations

After observing the complete evaluation process and gathering feedback from expert evaluators, I have identified several recommendations for consideration by IHI in future evaluations:

- While variations in moderation styles were within acceptable limits during the present evaluation, moderators should consider assertively playing the role of 'Time Keeper' to manage lengthy discussions effectively. This may involve course corrections, including terminating extended discussions when necessary. It is crucial for expert evaluators to accept these interventions professionally and not take them personally.
- Virtual meeting platforms offer various productivity-enhancing features such as voting mechanisms. These tools should be explored for potential implementation in future evaluations to improve efficiency. Prior to implementation, conducting test runs is essential to ensure all participants are comfortable and proficient with using these tools.
- Some experts have strongly suggested replacing long lunch breaks with multiple short breaks during the consensus phase meetings. Moderators should discuss and explore this option with all experts during the initial briefing on the first day of the consensus phase.
- Considering the emerging use of generative AI in fields such as health, it may be advantageous to enhance the AI expertise within the evaluation process in order to ensure specialised insights of proposals involving AI technologies.

I would like to emphasize once more that despite the intensive nature of the evaluation process, it was thoroughly enjoyable and conducted with the utmost professionalism. This was evident from the expressed desire of several expert evaluators to collaborate again in future IHI evaluations, a sentiment I wholeheartedly share.

Additionally, I extend my sincere thanks and gratitude to all the staff from IHI involved in this evaluation, their support and facilitation were invaluable, enabling me to fulfil my role without any hindrance.