RFP Posting: Feb 1 2023
Submission Deadline: Feb 28 2023
Award Date: March 27, 2023
Performace of Work: April 1 - July 30 2023

Medical Device Innovation Consortium (MDIC)

MDIC MXR Human Factors Workgroup

Request for Proposals (RFPs)

The Medical Device Innovation Consortium (MDIC) and the Medical Extended Reality (MXR) Human Factors Working Group request proposals for subject matter expert (SME) contracted services to support the evaluation of the draft working document "MXR Human Factors Gap Analysis" and provide research content to address the identified gaps, where content is available.

The selected SME will evaluate the current gap analysis, review related literature, contribute relevant knowledge to fulfill relevant gaps, and identify additional clinical gaps and challenges in ensuring proper human factors evaluation and performance of MXR devices in the identified focus areas described within. As part of this activity, the SME is expected to provide additional summary and review of gaps that have already been identified for assessments of cognitive load, teamwork, use risk management, and heuristics.

The SME will prepare the document for final publication. The SME/vendor will also provide additional recommendations for potential follow-on field research or design of experiments, as appropriate/indicated.

MXR Human Factors Background

The Medical Device Innovation Consortium (MDIC) has created a Medical Extended Reality (MXR) Human Factors Working Group comprised of medical device development, human factors engineering, and AR/VR experts along with surgeons and regulatory professionals to develop a framework to support the safety and effectiveness of 3D-capable MXR Devices (virtual and augmented reality) for surgical planning and procedures, including open, minimally invasive, and robotic surgery. In collaboration with outputs from other MDIC MXR Working Groups, the framework will define terminology, identify safety and effectiveness metrics, and potential considerations for Human Factors development and testing of MXR surgical devices and systems.

The working group has completed a landscape analysis of the current state of Human Factors in medical device development and a preliminary gap analysis with respect to MXR. The MDIC MXR Human Factors Working Group requests proposals for SME contracted services to support the evaluation and augmentation of the current gap analysis and to contribute expertise and/or research in closing one or more of those gaps.

About MDIC

The Medical Device Innovation Consortium (MDIC) is the first public-private partnership created with the sole objective of advancing medical device regulatory science throughout the total product life cycle. MDIC's mission is to promote public health through science and technology and to enhance trust and confidence among stakeholders. We work in the pre-competitive space to facilitate development of methods, tools, and approaches that enhance understanding and improve evaluation of product safety, quality, and effectiveness. Tools and methods are made available to the public to benefit the broader medical device and healthcare ecosystem. Our initiatives improve product safety and patient access to cutting-edge medical technology while reducing cost and time to market.

More information on MDIC is available at: http://www.mdic.org

Project Concept and Overview

As part of this effort, the MDIC MXR Human Factors Working Group has identified key areas where gaps may exist with respect to Human Factors and Medical Extended Reality. In particular, it is uncertain whether current analysis methods and metrics used in non-medical domains are applicable to MXR in surgery and/or planning.

The proposed structure for this work is divided into two phases:

Phase 1 – Evaluation and augmentation of existing gap analysis, literature review to support the gap analysis, interviews with SMEs for gaps and opportunities (as appropriate), summary of gaps and research, recommendations for any follow-on work

Phase 2 – Follow-on field research, interviews and/or Design of Experiments (DOE), as indicated

This RFP is focused on deliverables for Phase 1. Respondents may respond to all or a subset of subject areas, per their expertise.

Subject Areas

The areas the working group has identified as potential gaps are as follows:

1.1 Cognitive Load Measurement/Testing

- Literature from the broader domain tends to separate AR and VR. Findings are generally mixed/inconclusive as to whether these modalities increase, decrease, or make no difference in cognitive load

    - Are there different considerations in MXR for AR and VR?
        - There is a likelihood of blurred lines between AR and VR in MXR (e.g., pass through visualization has similar capabilities as AR)
        - Do methods exist to focus on what the user experiences over the hardware/technology?
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- Literature on surgical cognitive load is largely based on simulation performance in XR, often with inexperienced (i.e., non-surgeon) subjects. Only one known study exists assessing cognitive load with respect to bariatric surgery outcomes and safety produced mixed results (Ruiz-Rabelo, Navarro-Rodriguez, Di-Stasi et al., 2015 Obes Surg).
    - Are there other studies/findings around cognitive load that can be applied to the surgical domain?
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- Self-report, NASA-TLX or SURG-TLX are the most common assessment methods in the surgical domain.
    - Are these methods sufficient or are there other assessment methods or questions that address the following issues with respect to surgical applications?
        - The ability of self-report to differentiate between actual cognitive load during the event and participants' inferred cognitive load following the event
        - Lack of definition or thresholds for what constitutes "too high" cognitive load or cognitive overload
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- The relationship between cognitive load elicited by XR and task performance is not well characterized, likely owing to design considerations, task requirements, etc. Frequently, the inconclusive outcome is, "it depends."
    - Is there any research with conclusive findings? How do they apply to the surgical domain?
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- Many efforts exist to use physiological metrics and/or task analysis to index cognitive load (e.g., heart rate variability, eye-tracking) but haven't been sufficiently validated for routine use and/or are not appropriate for application during actual surgery
    - Do any methods have promise in addressing the following issues with sensor-based measurements?
        - Potential for task interference in safety critical activities such as surgery
        - Influence of contextual, environmental, and personal variables on physiology and behavior have not been characterized and/or isolated

- How are interactions with or impacts to existing surgical tasks measured (e.g., monitoring vigilance/attention, decision making, task performance)?
    - Is there even a relevant baseline by which to compare?
    - How might a baseline be reliably established?

1.2 Teamwork

- What are the impacts of perceptual (e.g., auditory and visual capability) differences between team members?
- What are the impacts of MXR upon interpersonal communication within teams?
- How are mixed teams of remote and onsite individuals evaluated?
- What methods exist to manage scenarios in which the user/participant is the only one who can see what they are seeing (e.g., head mounted displays) and the researcher cannot faithfully reproduce or experience that?

1.3 Use Risk Management in MXR Applications

- There is a perception that VR sickness is well understood and can be referenced in the literature without specific application to the surgical domain but this may be erroneous
- There is an assumption that methods for risk management remain the same but the MDIC MXR HF working group is open to challenging that assumption
- Is likelihood for MXR-specific failure modes, use errors, hazardous situations and/or harms an appropriate metric? If so, how is likelihood estimated in the absence of historical data?
    - Is disorientation a harm or a hazardous situation?
    - Are unique assessment methods necessary for MXR?
- How to identify root causes of MXR-specific failure modes/use errors/hazardous situations?
- Are there duration of use considerations (longer duration > increased incidence of effects) (e.g., visual after-effects, neck strain w/HMDs, etc.)?

1.4 Heuristics for MXR Design

- AAMI HE75 defines heuristic reviews: In a heuristic review, clinical or HFE experts evaluate a device or system by assessing how it conforms to well-established user-interface design rules or heuristic guidelines… Sources for these heuristics include this recommended practice and its supplemental handbook (Gardner-Bonneau et al., 2009).
- Identify any relevant sources for heuristics relevant to MXR.
- Identify gaps in heuristics for MXR and opportunities for further development.

MDIC's Role

MDIC staff will oversee the management of this project and provide approval for any interim and final deliverables.

Details and Requirements

Selected SME will work remotely providing consultative support services for the following activities conducted under the guidance of the Client's Leadership Team:

- Review of existing framework*
- Validation of existing Gap Analysis and identification of any additional gaps
- Collaborate with Human Factors Working Group, attend meetings, perform follow-up actions
- Document summarizing literature review as it pertains to identified gaps, written according to best practice, including list of citations
- Recommendations for future work

**Framework document available upon request.*

Awarded Contract Duration and Timeline

It is anticipated the awarded contract can be completed within approximately 2-4 calendar months, with a desired end date prior to the close of Q2 2023. As it is possible that multiple SMEs may respond to this request and complete different portions of the research, responses to this request should provide an estimate of the hours to complete as well as the approximate duration.

Period of Performance/Contractor Need

1-3 Contractors
Approxiamately 4 Months

Timeline

Deadline for Proposal Submission: February 28th, 2023
Award Date: March 27th, 2023

Submission Components

To enable MDIC to evaluate the submission, the responding proposal must include the following into one single PDF document, not to exceed 10 pages with the following naming convention **lastname_firstname_MDIC_HF_RFP.pdf**

- Cover letter with Contractor's primary point of contact.
- Proposed approach

- Schedule for planned milestones and deliverables with an estimate of hours and calendar duration to complete
- Agreement that this work is being completed pro bono OR Estimated budget requirements
- Experience summary; what similar projects have you conducted (describe without disclosing confidential information)
- Brief bio

Desired Qualifications

- Familiarity with Human Factors Engineering
- Expertise in Extended Reality, cognition, human performance, and/or perception
- Ability to perform the services

Consideration

Selected SME(s) may opt to:

- Take opportunities to present their work in collaboration with MDIC
- Be listed as contributor(s) to MDIC's MXR body of work or remain anonymous.

Review Process

Responses to this RFP will be reviewed by MDIC staff. MDIC staff reserve the right to contact applicants with additional questions during the review period. MDIC staff reserve the right to consult any MDIC member organizations during the review and evaluation of RFP process. Responses will be reviewed for completeness and appropriateness of the responses as they pertain to the required submission components. MDIC will consider both the programmatic aspects of the proposal, as well as the anticipated cost with the programmatic elements of the proposal receiving greater weight. MDIC may, for example, choose a costlier proposal if its programmatic offering warrants the premium. However, as potential contractors' programmatic offerings move toward equivalency, cost will gain in importance.

Legal Disclaimer: The submission of a proposal in response to this RFP does not create a contractual relationship or obligation. MDIC's selection of a contractor will be contingent on the parties executing a mutually acceptable contract on or before **March 27, 2023**. MDIC reserves the right to terminate contract negotiations at any time and select another contractor if MDIC determines that it is unlikely that an agreement will be executed in a timely manner.

MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM

Contact for RFP

Please contact MDIC Team, **Jennifer R. Waters, Project Manager** or **Jithesh Veetil, Senior Program Director** at MXR@mdic.org with any questions or for arranging a teleconference to discuss potential submissions.

Proposal must be submitted by **February 28th, 2023**, using this online form.