



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

Medical Device Innovation Consortium (MDIC)

MDIC MXR Image Quality Workgroup Request for Proposals (RFPs)

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

The selected SME(s) 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 image quality evaluation and performance of MXR devices in the identified focus areas described within.

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.

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

The MDIC MXR Image Quality Workgroup is developing a framework to support the safety and effectiveness of 3D-capable MXR Devices (virtual and augmented reality head-mounted displays) for surgical planning and procedures, including open and minimally invasive surgery.

The framework will define terminology, identify safety and effectiveness, potential considerations and testing approached or evaluation gaps for MXR Image Quality.

Phase 1: Focus on drafting of Image Quality Landscape for FDA initial reviews and comments.

Phase 2: The subgroup is now preparing additional written chapters related to gaps and challenges in focus areas. MDIC is requesting bids related to these Phase 2 activities.

As part of this effort and as a working group, we looked at other display systems (e.g., monitors/displays), KPI (Key performance indicators) to understand the following:

- Are they relevant to AR systems – is the parameter transferrable to AR device
- can the parameter be used "as is"
- If not, what kind of change (if at all possible) needs to be made for AR devices (depending on AR technology).



- Is the testing method for such parameter applicable to AR devices
- If not, what kind of change is needed for AR devices (depending on AR technology)
- What parameters and testing methods are specific to AR devices

Additionally, our group reviewed existing quantitative vs qualitative test methods and their application in assessing AR devices for image quality. The overall scope of work is framed around interoperable applications only – limit the scope to surgery and surgery planning with optical see-thru Augmented and Mixed Reality devices. VR & video see-thru are partly covered.

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 vendor SME(s) will work remotely providing consultative support services for the following activities conducted under the guidance of MDIC Leadership team.

MDIC MXR Image Quality Phase 2 Deliverables

- Review of existing Literature and Framework document
- Validation of existing Gap Analysis and identification of any additional gaps
- Editorial Services
- Collaborate with Image Quality Subgroup, attend meetings, perform requested actions
- Document/chapters summarizing literature review as it pertains to identified gaps, written according to best practice, including list of citations
- Recommendations for future work

The selected vendor is expected to leverage subject matter expertise to support Image Quality deliverables and maintain Best Practices for documentation of FDA-regulated medical devices.

**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_IQ_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 Image Quality
- 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.

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](#).