



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 Training/Education Workgroup Request for Proposals (RFPs)

The Medical Device Innovation Consortium (MDIC) and the Medical Extended Reality (MXR) Training/Education Working group request proposals for subject matter expert (SME) contracted services to support the evaluation of the draft working document “MXR Training/Education 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 training and education 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.

MXR Training/Education Background

The Medical Device Innovation Consortium (MDIC) has created a Medical Extended Reality (MXR) Training/Education Working Group comprised of medical device development, AR/VR experts, 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 training effectiveness metrics, and potential considerations for human factors and image quality testing of MXR surgical devices and systems.

The working group has completed a landscape analysis and preliminary gap analysis of the current state of medical device development with respect to MXR. The MDIC MXR Training/Education Working Group requests proposals for SME contracted services to support the evaluation and augmentation of the current landscape and gap analyses 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

The SME will provide an evaluation and augmentation of existing landscape and gap analyses, literature



review to support the gap analysis, interviews with SMEs for gaps and opportunities (as appropriate), summary of gaps and research, and recommendations for any follow-on work. Respondents are encouraged to consider responses to both the Human Factors and Training RFPs from the MDIC MXR Working Groups.

1 Subject Areas

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

1.1 Training Tools

- Expand upon the list of training tools in the MXR Training Working Group landscape report
- Identify any considerations that are unique to MXR for relevant training tools

1.2 Training Performance Criteria (Metrics)

- Identify methods and measurements that training is sufficient for required device proficiency
- Expand upon existing criteria identified in the Training Working Group landscape report

1.3 Team Training

- Identify any considerations that are unique to training a team that will be using devices in an operating room environment
- Identify any considerations that are unique to training a team with MXR devices

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(s) 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*
- Identification of any additional gaps
- Collaborate with Training/Education Working Group, attend meetings, perform follow-up actions
- Document summarizing literature review as it pertains to landscape and gaps, written according to best practice, including list of citations
- Recommendations for future work

**Framework document available upon request.*

MDIC MXR Training/Education 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 Training/Education 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

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_TE_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)
- Review of qualifications in relevant domain(s)
- Brief bio

Desired Qualifications

- Familiarity with training related to the use of medical devices in a surgical environment
- Expertise in medical extended reality (augmented and virtual reality)
- 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

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](#).