Clinical Protocol Form		
Document Title	Document Description	Version No.
TP-172	**Clinical Evaluation of an Intra-procedural 3D Needle Guidance Platform for Soft Tissue Tumors or Organs Requiring Percutaneous Biopsy as an Adjunct to Standard Image Guidance**	**3**

Study Title: Clinical Evaluation of an Intra-procedural 3D Needle Guidance Platform for Soft Tissue Tumors or Organs Requiring Percutaneous Biopsy as an Adjunct to Standard Image Guidance

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Protocol Signature Page

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Protocol Number: TP-172

Protocol Version and Date: Version 3; 02May2025

SPONSOR

I agree to the terms of the protocol.

Sponsor Representative Name	Signature	Date

SITE

I will conduct the study in accordance with the provisions of this protocol. I agree to conduct this study in compliance with United States (US) Health and Human Service regulations (45 CFR 46); applicable U.S. Food and Drug Administration regulations; standards of the International Conference on Harmonization Guideline for Good Clinical Practice (E6); Institutional Review Board/Ethics Committee determinations; all other applicable country, state, and local laws, and regulations.

I have read and understand all sections of the protocol.

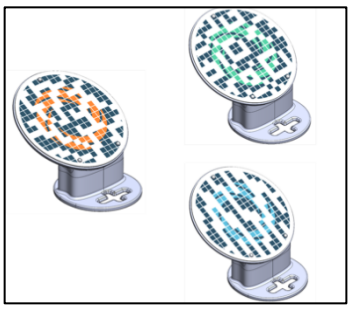
Principal Investigator Name	Signature	Date

Summary

Protocol Title	Clinical Evaluation of an Intra-procedural 3D Needle Guidance Platform for Soft Tissue Tumors or Organs Requiring Percutaneous Biopsy as an Adjunct to Standard Image Guidance
Brief Background/Rationale	This clinical feasibility evaluation is intended to further characterize and quantify the potential benefits of the FDA cleared XR90 AR imaging and guidance platform utilization in percutaneous soft tissue biopsy. This study will seek to build on the findings of safety, procedural benefits, and overall clinical feasibility shown in previous bench, cadaveric, and single-site clinical evaluations.
Primary Objectives and Variables	The primary objective of this study is to compare procedural efficiency (time of tumor localization, time from skin to target) of the XR90 system when used in adjunct to standard-of-care imaging to standard-of-care imaging alone (ultrasound/CT) for clinical percutaneous biopsy procedures.
Secondary Objective(s)	Secondary objectives of this study include evaluating safety, system utility, and system efficacy.
Study Population	- Consentable adults - Patients in need of standard of care (SOC) soft-tissue tumor biopsy where the target is visible and targetable on ultrasound; ~102 patients total (51 per arm) across all sites. 34 patients per study location (17 patients in Arm A and 17 patients in Arm B)
Disease sites/Conditions	Soft tissue tumors requiring biopsy with ultrasound as part of standard of care guidance
Study Workflow	- Pre-initiation bench top education of all potential operators and assistants (trainees, technologists, nurses) - Patient consent - Pre-procedural cone beam CT (rotational fluoroscopy) with spot markers - Segmentation of CT data (can be anonymized) - Pre-procedural equipment setup - Pre-procedural registration - Pre-procedural tumor and trajectory localization and timing - Procedure using XR90 + standard of care guidance or standard of care guidance per randomization

	- Procedural accuracy metrics - Post-procedural operator survey
Duration	The study is expected to last for 2 years
Equipment	- MediView to provide XR90 system and compatible components to enable proper functionality and data collection, including: o Fiducial markers (CT-Spot Markers) o Integrated ultrasound o HoloLens headset and storage o EM Navigation System o Triangle Template o Sterile ACM (i.e., Registration) Markers o Disposable EM Probe Bracket o Sterile CIVCO eTRAX needles o Laptop with HIVE - Equipment from clinical site: o Biopsy needle o Fluoroscopy and/or CT imaging system

Definitions and Acronyms (alphabetical)

Term	Definition
ACM	ACM Registration markers used with the MediView XR90 System. A sterile component of the XR90 system that is placed on the patient's skin at CT spot marker locations in order to register different types of holograms. Three Registration Markers corresponding point locations in CT, EM, and Head-mounted Display (HMD) coordinate systems. The Registration Markers provide the transformations for EM-to-HMD and CT-to-HMD coordinate system. 
Adjustment Function	After an anatomy landmark (point marked on the CT-based holograms) and an ultrasound landmark (point marked on the HUD in HMD coordinates) have been set, the words, "Adjust Anatomy" will translate the CT-based holograms from the anatomy landmark position to the ultrasound landmark position.
CT	X-ray Multi-detector row Computed Tomography
EM	Electromagnetic (EM) tracking of sensor-equipped tools and interventional instruments. Also used for fiducial locations on the patient skin.
Flashlight Projection	Live streamed ultrasound image projected on the head mounted display relative to and extending from the physical ultrasound probe toward the phantom or patient. Image matches the image on the ultrasound scanner and HUD. 
HLR	Holographic Light Ray. A holographic representation of the tracked physical instrument including a representation of the tip.
HMD	Head-Mounted-Display (i.e., Microsoft HoloLens)
HUD	Heads-Up Display. A virtual interactable user interface panel that also displays live streamed ultrasound through the HMD. The HUD is used for selection and loading of Holographic Anatomy, setting a virtual target and Needle Guide on the virtual ultrasound image, manipulating the Needle Guide handle, and interacting with general UI buttons through near or far interaction.

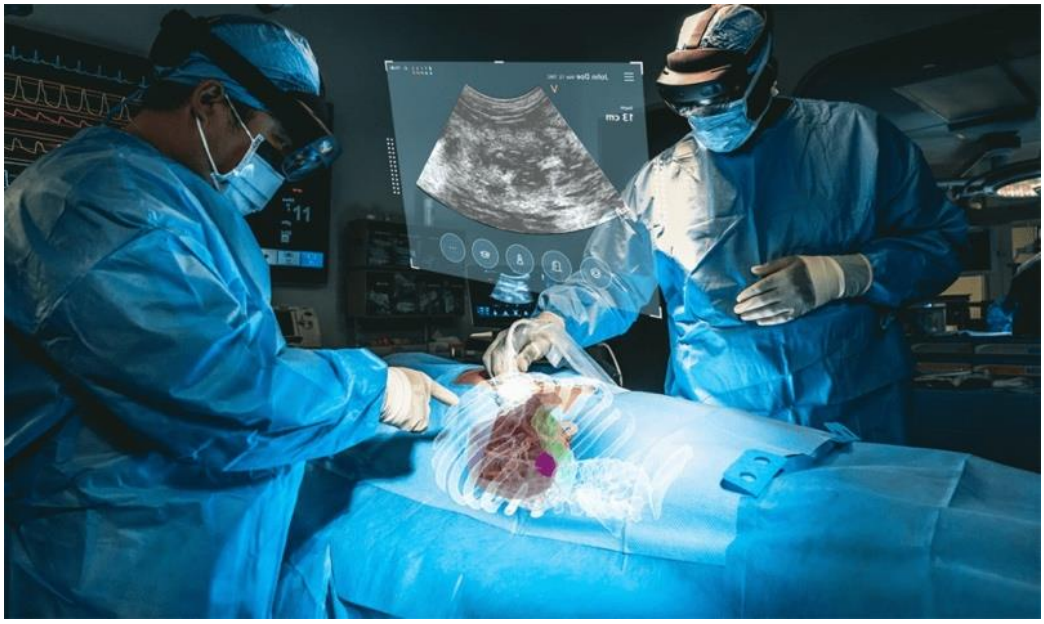
Needle Depth	Distance between skin insertion (percutaneous access) point and the (center of the) target tissue along the needle path.
System Registration	System registration is defined as the estimation of a geometric transformation aligning objects such that the distance between corresponding points on these objects is minimized, bringing the objects into alignment. Objects can include a virtual / holographic representation of (physical) surgical instruments, virtual representations of (physical) anatomical structures, and virtual representations based on real-time imaging of anatomical structures.
US	Ultrasound
XR-90 (“system”)	MediView proprietary AR platform incorporating head-mounted display of holographic anatomy from preprocedural CT, fiducial-based intraoperative registration, holographic display of real-time streaming ultrasound, and EM tracking of ultrasound probe and sensorized needle/trocar

Introduction

Percutaneous procedures (thermal ablation, biopsy, etc.)) is a leading diagnostic and treatment mode in the growing field of image-guided "interventional oncology [1, 2]. One drawback is that images are displayed table-side on conventional 2D flat-screen monitors, and some including CT utilize radiation [3].

Percutaneous biopsy is an ideal, minimally invasive way to obtain tissue to make a pathological diagnosis and is standard of care for many cancers. Biopsies are often sampled from tumors in difficult-to-access or otherwise sensitive locations, and current image guidance is often not ideal due to the same issues with two-dimensionality which often leads to increased procedure and examination time often resulting in increased radiation exposure

Instead of using such flat screen displays, this pilot evaluation will provide 3D holographic visualization of target tumors and augment the navigation of tracked instruments directly to the biopsy target.



MediView XR90 Holographic Surgical Navigation System

Background/Rationale

Augmented Reality (AR) places digital content into the real world through a display device such as the Microsoft HoloLens. The user can visualize both the real world and digital content at the same time. In healthcare, the use of AR to deploy 2D and 3D objects has been shown to improve ergonomics, patient monitoring, and workflow [4]. AR

may provide enhanced tumor visualization and location, leading to increased, and more efficacious, percutaneous procedures AR may help to facilitate ideal probe/needle planning and trajectory by allowing providers to visualize their intended target in a 3D space [5].

Percutaneous biopsy is an ideal, minimally invasive way to obtain tissue to make a pathological diagnosis, stage or monitor disease progression or response to treatment. Biopsies are often sampled from tumors in difficult to access or otherwise sensitive locations. Sub-centimeter accuracy is required for these minimally invasive percutaneous procedures to have clinical benefits for patients [6-9]. Near perfect accuracy is required to prevent injury and enhance the success of obtaining an adequate tissue specimen. A primary factor limiting percutaneous therapies is the quality and nature of image guidance currently available to operators, making the required accuracy challenging to achieve [10].

Surgical navigation systems aim to improve image guidance and have been shown to improve percutaneous needle-based procedures by improving targeting accuracy and decreasing the number of intraprocedural CT scans required to achieve correct placement [11, 12]. The standard of care image guidance utilized for these procedures, primarily US and CT, are limited by two-dimensional projections of inherently complex 3D anatomy, and, for the latter, the need for ionizing radiation. Multimodal image fusion platforms can help improve depth perception and spatial anatomic understanding [13, 14]. Head-mounted-display-based multimodal image fusion AR platforms such as XR90 provide improved depth perception and spatial understanding, while also allowing true three-dimensional and even interactive projections [15, 16]. The use of AR for surgical navigation may potentially improve operator confidence and facilitate percutaneous procedures on more challenging targets that would not be appreciable with only standard-of-care guidance. Furthermore, the use of AR for percutaneous procedures can reduce the risk of injury by enhancing the accuracy of needle placement and providing visualization to avoid critical structures [4, 5, 16, 17].

Studies have demonstrated the XR90 system's efficacy and accuracy in both benchtop and cadaveric environments (within 5mm). Early in-human clinical usability evaluations of the XR90 platform were performed as an adjunct to standard-of-care imaging in 12 patients for percutaneous thermal ablation of abdominal soft tissue tumors, predominantly of the liver and kidney. The results of the study demonstrated early clinical feasibility and potential benefits of the system. [16]

This clinical evaluation is needed to further characterize and quantify the potential benefits of percutaneous biopsy, assisted with the XR90 3D surgical imaging system. This continued innovative implementation of the platform as a medical device to assist in percutaneous targeted biopsy of soft tissue tumors will allow for further assessment of device functionality, operator acceptability, and additional data collection to help quantify the potential benefits of this platform.

Potential benefits to the patient, to be formally proven in future studies: decreased procedure time, decreased of complications (e.g., critical structure avoidance), and ultimately, improved patient outcomes.

To date, few studies have evaluated the performance of the XR90 guidance system in a clinical setting. Comparing percutaneous needle placement for biopsies of a soft tissue target with the assistance of XR90 compared to under only standard-of-care guidance will allow for the evaluation of procedure success rate, , overall procedure time, and complications. This multicenter prospective randomized control trial is designed to compare the efficacy and utility of the XR90 guidance platform used adjunct to standard of care guidance to standard of care guidance (2D) only for percutaneous needle-based procedures.

Investigational Device Description

The MediView™ XR90 system is an augmented reality-based medical device to be used adjunctively to clinical ultrasound (US) systems, with the ability to holographically display and fuse standard-of-care US with digital anatomical models based on computed tomography (CT) imaging. The XR90 system provides navigational guidance and remote collaboration features. The system is comprised of a commercial, off-the-shelf augmented reality head-mounted display, wirelessly connected to a streamer that interfaces with commercially available ultrasound system and an electromagnetic (EM) field generator. The US signal is transmitted from the streamer to the head-mounted display, where a holographic display of the US image is stereoscopically projected into the user's field of view. A proprietary algorithm for EM and optical tracking registers the CT holograms to the operative site and is fused with the live US projection. The XR90 system provides unconstrained orientation (position, scale, and rotation) of the US image to the proceduralist in a convenient and contextual location by viewing the US image, physical US probe, interventional instrument, and hands all within the operator's field of view via two modes of viewing. First, the virtual heads-up display (HUD) streams the ultrasonic image from a local compatible US system, provides access to system information and status, and enables users to set a Holographic Needle Guide. Second, the Flashlight mode enables a proceduralist to holographically project the same streamed ultrasonic image coaxially from the ultrasound transducer in real-time using an EM-tracked probe bracket, which provides additional context to the proceduralist. Users may choose a point of interest on the HUD and instantiate a virtual needle trajectory ("Holographic Needle Guide") both on the HUD and in relation to the Flashlight. XR90 is intended to be used adjunctively to diagnostic imaging per standard of care and provides navigational guidance to the user. Always refer to standard of care and prioritize clinical experience or judgment when using the XR90 system. XR90 is not intended to be the sole guidance for any procedure.

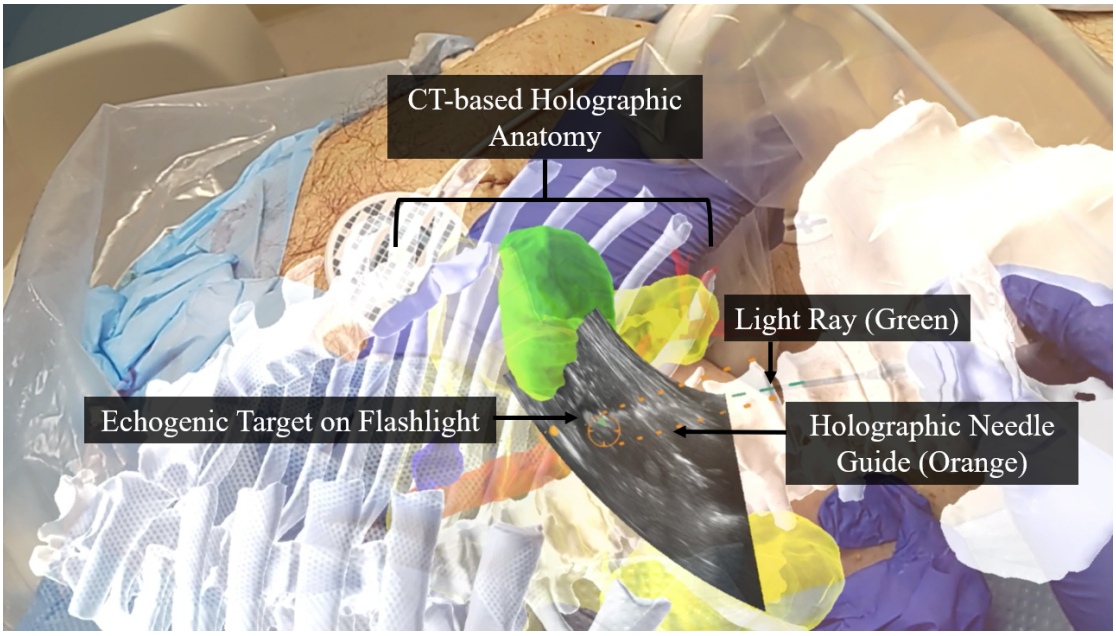


Figure 1: Depiction of three main registered projections visible to the operator when using the AR platform. 1 3D anatomical models, such as bone (white, liver (green) and kidney (yellow). 2 Ultrasound Flashlight: projected coaxially with echogenic target. 3 Holographic Light Ray in dark green. An additional needle guide feature is displayed in orange.

XR90 is a 510K cleared device (K223125). The system has been cleared for use as an adjunct to the standard of care in needle-based, ultrasound-guided procedures. Additional features have been added to the system to assess their usability in a clinical setting that the FDA has not evaluated, including the ability to utilize voice commands to record metrics such as needle depth and procedure time and the ability of the provider to upload images directly onto the system.

A list of the voice commands is listed below:

- Log Procedure Start- creates a timestamp of the procedure start time.
- Log localization start- creates a timestamp of the time localization is started.
- Log localization end- creates a timestamp of the localization ending.
- Log targeting start- creates a timestamp at the start of targeting.
- Log targeting end- creates a timestamp of the end of targeting. Also records the EM vector position of the needle tip for needle depth.
- Log Needle Redirect- creates a tally log of the number of needle redirects required during the procedure.
- Log Attempt- creates a tally of log of the number of attempts needed during the procedure.

Voice commands were verified during the design control process of the XR90 system via TR-105 and demonstrated that when a voice command was used, the system performed as intended.

In addition to voice commands for research software has been included to allow for the investigator to directly upload segmentation files without interacting with the noncustomer-facing portal which is required under the current workflow. This will decrease the time spent waiting on staff to upload segmented Cone beam CT files during the procedure.

Intended Use

The XR90 (XR90-SYS) is a medical display workstation intended for 3D image visualization and image interaction in conjunction with traditional imaging and monitors. The virtual images are generated from tracked Ultrasound, tracked interventional device, and 3D volumetric data acquired from CT sources and stereoscopically projected such that the proximity of the virtual interventional device is displayed relative to live ultrasound and 3D models from previously acquired CT. The device is intended to provide visual information and reference to be used by the health care professionals for analysis of surgical options during pre-operative planning, and the heads-up, intra-operative display of the images during ultrasound-guided needle-based procedures. Virtual images on the heads-up display should always be used in conjunction with traditional monitors.

The XR90 (XR90-SYS) system is intended to be used as an adjunct to the interpretation of images performed using diagnostic imaging systems and is not intended for primary diagnosis.

The XR90 (XR90-SYS) system is intended to be used as a reference display for consultation and guidance to assist the clinician who is responsible for making all final patient management decisions.

During system use, the position and orientation tracking of the interventional instruments should always be available to the clinician on traditional imaging and monitors.

Cohort of Users and Population Description

This is intended to be a multi-site prospective randomized control trial. This device evaluation will include participants undergoing a diagnostic US-guided percutaneous soft tissue biopsy as a part of their standard of care.

Population

All qualified adults referred to IR for needle-based, percutaneous soft tissue tumors requiring biopsy with ultrasound as part of standard of care.

Sample Size and Justification

The enrollment goal of this study 34 participants per study site (17 patients in Arm A and 17 patients in Arm B) for a total of 102 participants.

This study is designed to compare the procedural efficiency of the XR90 system with standard-of-care (SOC) imaging in percutaneous biopsy procedures. We focused on detecting clinically meaningful differences for the primary endpoints of: time of tumor localization, and skin to target time.

1. **Primary Endpoints: Time of Tumor Localization and Time from Skin to Target**

The time from initiation of localization to planned trajectory and skin to target will be measured as described in the Endpoints and Study Design section of this protocol. To ensure the study is adequately powered for a continuous outcome, a two-sample t-test was used to determine the required sample size. Given the presence of two primary endpoints, a Bonferroni correction was applied to control for the overall Type I error rate. The total two-sided alpha of 0.05 was split evenly between the two endpoints, resulting in a significance level of 0.025 for each primary comparison.

For time of tumor localization, we assumed a SOC mean of 15 minutes with a standard deviation (SD) of 3 minutes, targeting a 2-minute difference. These estimates were based on current literature and preliminary data comparing Arm A (XR90) to Arm B (SOC)in porcine models [18, 19]. Under these assumptions and using a two-sided alpha of 0.025, a total of 89 participants (approximately 45 per group) are required to achieve 80% power to detect this difference.

Similarly, for time from needle placement into the skin to entry into the target, we assumed an SD of 4 minutes and a clinically meaningful difference of 3 minutes. Using the Bonferroni-adjusted alpha of 0.025 and targeting 80% power, the required total sample size is 71 participants (approximately 36 per group).

The planned enrollment of approximately 102 participants exceeds the minimum required sample sizes for both primary endpoints after adjustment for multiple comparisons, ensuring the study remains adequately powered to detect the targeted effects while controlling the overall Type I error rate at 5%.

This protocol specifies an enrollment goal of 102 subjects. This study is adequately powered to evaluate the utility of the investigational device and detect a meaningful difference between XR90 and SOC.

Participant Inclusion Criteria

Participants will be considered suitable if they fulfill all the Inclusion Criteria. General inclusion criteria will be assessed during the initial patient evaluation by conducting a history and physical examination.

General Inclusion Criteria:

1. At least 18 years of age.

2. Willing and able to give informed consent prior to enrollment.
3. Subjects in need of a diagnostic soft-tissue tumor biopsy which is the primary target for needle placement as a part of their standard of care. .
4. Has met all criteria to undergo percutaneous biopsy with ultrasound.
5. Subjects with soft-tissue lesions ≥1 cm or ≤8 cm in depth
6. BMI of ≤40

1. General Exclusion Criteria

1. Children under the age of 18.
   Currently pregnant at the time of the procedure
2. Not willing or able to give informed consent.
3. Subjects with pacemakers or AICDs.

Site and Provider Inclusion:

1. Three sites who routinely perform percutaneous needle-based procedures as a part of their practice.
2. Attending providers who specialize in interventional radiology and who perform ≥10 needle-based procedures every 12 months will be recruited for the study.
3. Physician Assistants who specialize in interventional radiology and who perform ≥10 needle-based procedures every 12 months will be recruited for the study
4. PGY5-7 interventional radiology residents may also participate in the procedure when under the supervision of a qualified attending.

Center and Provider Exclusion Criteria:

1. Medical Attendings who do not specialize in interventional radiology.
2. Medical Attendings who have not performed ≥10 needle-based procedures in the past 12 months.
3. PGY4 or less residents
4. Physician Assistants who do not specialize in interventional radiology or have not performed ≥10 needle-based procedures in the past 12 months

Ethical Considerations

This study will be conducted in accordance with the submitted protocol, GCP (good clinical practice) guidelines, and all applicable government regulations and policies and procedures. This protocol and any amendments will be submitted and approved by the Institutional Review Board (IRB) to conduct the study.

Inclusion of Women and Minorities

Adult men, adult women**,** and members of all races, ethnic groups, and genders are eligible for this trial.

Informed Consent

The formal consent of each subject, using the IRB-approved consent form, will be obtained before that subject is submitted to any study procedure. All subjects for this study will be provided a consent describing this study and providing sufficient information in language suitable for subjects to make an informed decision about their

participation in this study. The person obtaining consent will thoroughly explain each element of the document and outline the risks and benefits, alternate treatment(s), and requirements of the study. The consent process will take place in a quiet and private room, and subjects may take as much time as needed to make a decision about their participation. Participation privacy will be maintained and questions regarding participation will be answered. No coercion or undue influence will be used in the consent process. This consent form must be signed by the subject, and the person obtaining the consent. A copy of the signed consent will be given to the participant, and the informed consent process will be documented in the research record.

Imaging

Various videos and photographs will be taken during the procedure for the purpose of documentation and record keeping. Media will be collected by dedicated MediView support personnel or dedicated research support staff unless collected from the first-person viewpoint of the operator wearing the HoloLens2. Media collection will not be allowed to interfere with the efficiency of the procedure.

Study Objectives

Primary Objective

The primary objective of this study is to compare procedural efficiency (time of tumor localization, time from skin to target) of the XR90 system when used in adjunct to standard-of-care imaging to standard-of-care imaging alone (ultrasound/CT) for clinical percutaneous biopsy procedures.

Secondary Objectives

Secondary objectives of this study include evaluating safety, system utility, and system efficacy.

Study Design

1. Design

Patients scheduled to undergo a biopsy as part of their standard of care treatment by a participating provider will be assessed for eligibility and if interested, consented for the study. The trial will be structured as a standard two-arm, parallel design, individually randomized prospective trial. Patients will be randomly assigned to either Arm A or Arm B for the study. . This trial is open label for the provider but closed for the subject.

> **Arm A (XR90 Experimental Group):** Participants randomly assigned to this arm will undergo percutaneous biopsy procedures using the assistance of XR90 guidance system in adjunct to standard of care guidance. XR90 is not intended to be used as sole standard of care for needle guidance. The XR90 system and GE ultrasound, and all disposables needed will be provided by the study sponsor.

Arm B (Standard of Care Group): Participants randomly assigned to this arm will undergo percutaneous biopsy with standard of care CT and ultrasound needle guidance only.

2. Randomization

After patients have been screened and enrolled in the study, research staff will create the subject in the EDC and they will be automatically randomized to either arm A or B in the EDC. Patients will have an equal chance of being assigned to either group. Randomization will be blinded to subjects but open to providers.

Study Endpoints

Primary Endpoints

1. **Time of Tumor Localization:**
   - **a.** Arm B (Standard of Care Arm): The time from initiation of localization of standard imaging (defined by when the ultrasound probe is put into operator's hand) until operator has planned a trajectory and point of entry (by placing a finger or trocar on the skin entry site and verbalizing completion of localization) will be measured and recorded.
   - **b.** Arm A (XR90 Guided): The time it takes from initiation of localization using the platform (defined by when the sensorized instruments are first put in the operator's hand) until the operator has planned a trajectory and point of entry (by placing finger or trocar on the skin entry site and verbalizing completion of localization) will be measured and recorded.
2. **Time From Skin to Target**
   - a. Arm B (Standard of Care Arm): The elapsed time from when the proceduralist inserts their trocar or biopsy needle through the skin (excluding skin knicks) and when the provider verbalizes they have reached their intended target in order to collect a biopsy under ultrasound guidance.
   - b. Arm A (XR90 Guided): The elapsed time from when the proceduralist inserts their trocar or biopsy needle through the skin (excluding skin knicks) and when the provider verbalizes they have reached their intended target in order to collect a biopsy using XR90 as an adjunct to ultrasound guidance.

Secondary Endpoints

1. **System Utility**
   - **a. Procedure technical success-** the completion of biopsy procedure. Procedures will be determined to be complete once the provider has verified (via ultrasound or CT) the trocar has reached the intended target, as if the proceduralist were to ablate or biopsy.
   - **b. Assessment of biopsy difficulty and sample adequacy**
     - i. Biopsy difficulty will be evaluated objectively according to the depth of lesion and subjectively on a scale of 1-10 (10 being most difficult) by the operating provider after the procedure.

ii. Sample adequacy will be evaluated by measuring diagnostic yield as a binary outcome (Yes/No): Whether the biopsy led to a definitive pathological diagnosis

c. **Needle attempts**: An attempt shall be defined as the entrance of the needle into the skin with the planned advancement of the needle toward the targeted lesion. An attempt will be counted at the beginning of targeting and each time an operator removes their needle from the skin and restarts localization. We anticipate no significant difference between the number of needle attempts performed with 2D standard of care modalities as compared to those performed using the XR90 guidance system in adjunct to standard of care.

d. **First attempt success**: Was the proceduralist able to successfully obtain a specimen without having to remove a needle from the skin and re-inserted with a different trajectory. Yes or No. We anticipate no significant difference of First Attempt Success rate for procedures performed with 2D standard of care modalities as compared to those performed using the XR90 guidance system in adjunct to standard of care.

e. **Post procedure user usability survey**

2. **System Efficacy**: We anticipate the system will perform according to the intended use statement.
   - **a.** Error messages displayed by the device will be recorded.
   - **b.** Records will be kept of any adverse events related to the medical device.
   - **c.** Operators will participate in a survey subjectively evaluating the efficacy of the system.
3. **Safety:**
   - **a.** **Procedural complications:** Complications such as prolonged bleeding requiring escalation of the case (transfusion, admission, etc.), bile duct injury, vascular injury, urinary tract injury burns that occur during the procedure will be recorded. We anticipate that there will not be a significant difference in the rate of complications that occurs in the procedure performed with XR90 guidance when compared to procedures performed under only 2D standard-of-care.
   - **b.** **Critical structure avoidance**: The inadvertent puncture of a critical structure which would routinely be avoided during a biopsy procedure will be noted. Critical structures will be defined as any anatomical structures with the potential to cause escalation of the case or long-term complications such as prolonged hospital stay.

Benefit/Risk Assessment

This study will be used to support the following benefits/claims of the XR90 system:

- XR90 can assist a proceduralist in gross localization of tumors imaged under ultrasound using the combination of ultrasound Flashlight and CT-based Holographic Anatomy.

- The registered images in XR90 enables intra-operative display of the virtual instrument location in relation to the virtual anatomy and ultrasound to assist in spatial understanding, visualization, and trajectory planning.
- XR90 provides in-plane or out-of-plane needle guidance to navigate a virtual representation of an interventional instrument to a desired virtual target location.
- XR90 will not increase the amount of complications that occur during percutaneous needle base procedures. Complications after percutaneous procedures vary widely and can occur in up to 10% of patients. Complication that occur after percutaneous procedures often include bleeding, infection, bile duct injury, burns hepatic vasculature damage, pulmonary complications, and liver failure. [24-27] Complications that occur during the simulated procedure will be recorded. We anticipate that there will not be a significant difference in the rate of complications that occurs in the procedure performed with XR90 guidance when compared to procedures performed under only 2D standard-of-care.

Risks have been identified through the MediView Risk Management process in accordance with ISO 14971:2019 "Medical devices – Application of risk management to medical devices," and residual Medium or High-level risks will be evaluated throughout the course of this study to support a conclusion that the benefits of the XR90 system outweigh the risks during a procedure.

Harm is defined as physical injury or damage to the health of people, damage to property or the environment. The Risk Management File identified thirty-seven (37) types of harms that have a post-risk mitigation risk level of Medium or High, which are known as potential adverse events (AEs) associated with the XR90 system. Of these thirty-seven (37) types of harms identified, 35 of them cause damage to the patient's anatomy due to the needle taking the wrong trajectory. The remaining two harms are a burn due to fire and risk of explosion. The details of each harm, including sources and controls, are in the Risk Management File and PDPROJ-4.0 BRA, Benefit/Risk Analysis, XR90.

Training

1. Provider Training:

1. Providers will undergo benchtop training with the XR90 system prior to performing clinical cases. Training includes: 1) positioning and adjustment of the headset, 2) use of the sensor-equipped ACMs, 3) placement of sensor-equipped fiducial markers, 4) localization of a tracked device relative to anatomical holograms as an adjunct to standard flat panel monitors for ultrasound and fluoroscopic imaging per standard of care, 5) use of HoloLens 2 voice commands and holographic dashboard, 6) use of projected sonography, 7) measurement of relevant intraprocedural metrics
2. A bench set-up will enable training for use of the HoloLens 2 HMD. This is based on Computerized Imaging Reference Systems (CIRS) models including, but not limited to, Model 071 and Model 057A. The bench set-up will be used to align a needle and sensor-equipped co-axial stylet with tumor targets within the phantoms.
3. Training Target Criterion: The proceduralist must accurately place the needle in 10 targets ranging in depth from 3 to 10 centimeters at site initiation visit or early on-site training.

2. Lab Technologist Training:

1. The support staff will be trained on positioning the mobile console and the EM generator in the interventional suite prior to clinical use.
2. The technologist will also be trained in appropriate and sterile handling of all intraprocedural equipment.

Study Procedures

Screening and Enrollment

1. Subjects will be screened as they are scheduled for biopsy procedures.
2. Subjects will be invited to participate in the study and must sign an informed consent before initiating any study procedures.

Randomization:

After the subjects have signed the consent, subjects will be randomized to either Arm A (XR90 experimental group) or Arm B (standard of care). Randomization will occur in the EDC.

Arm A (XR90 Experimental Group) Pre and Intraoperative Steps:

1. System Setup (10-15 minutes)

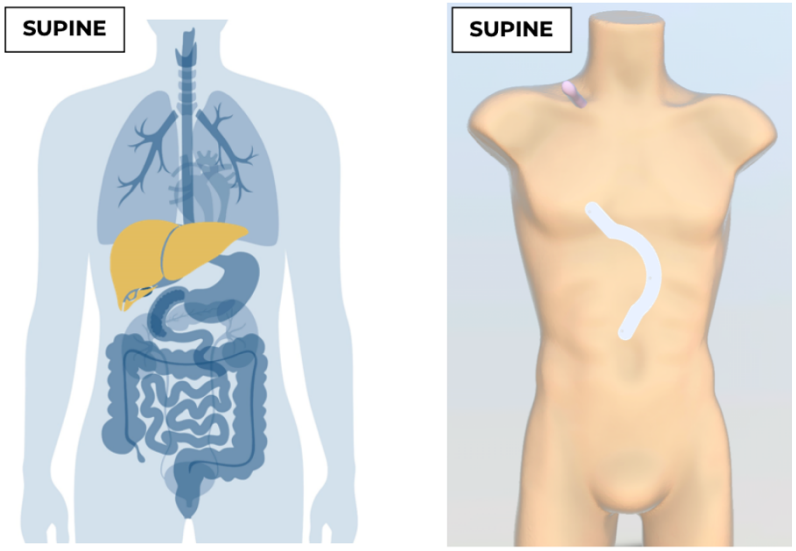
1. Position the ultrasound cart equipped with MediView XR90 components at tableside to enable viewing of the commercially available ultrasound system ultrasound monitor and connection of EM tracking cables while maintaining a minimum distance of 1 meter between the EM Field Generator and the ultrasound cart. Confirm there is at least a 1-meter separation between the ultrasound cart and procedure table.
2. Install the EM Field Generator on the underside of the patient table using brackets that attach to the tabletop edges (see figure below). Connect the EM Field Generator cable to the SCU.

2. Preoperative Steps

All procedures for this study will take place in an IR CT Angio Suite equipped with a C-Arm, carbon fiber table and an ultrasound system.

Pre-Procedure Cone Beam CT or CT Acquisition

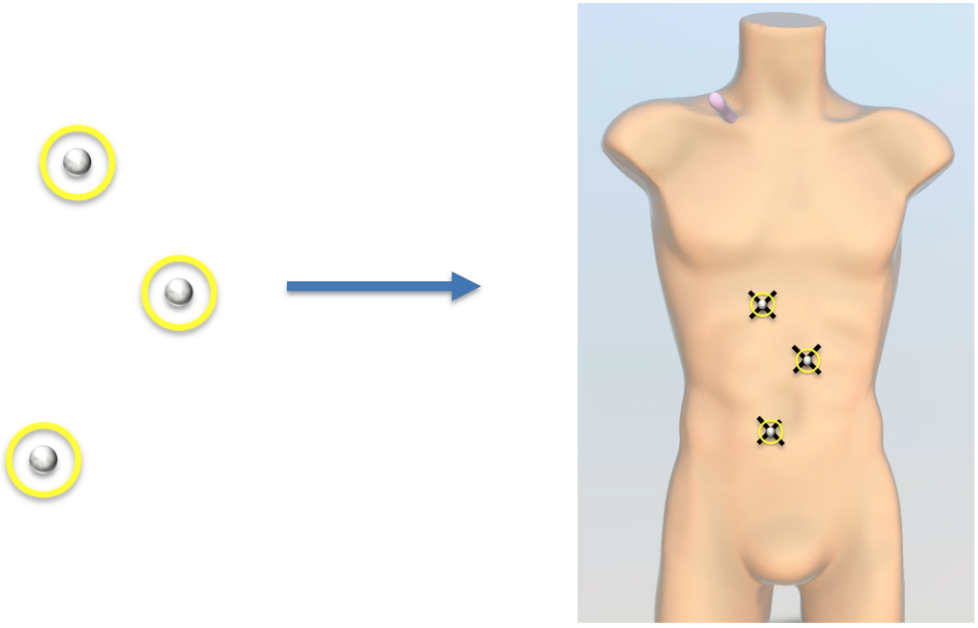
1. Cone Beam CT or CT scans will be acquired the day of the procedure per data acquisition protocol for the specified indication.
2. Position the subject on the Angio table same way they will be positioned for the procedure (Ex: supine).
3. Place the Triangle Template with respect to the expected needle entry point, such that three points are not interfering with the proceduralist's working space. As much as possible, center the triangle template around the area of interest.



Depiction of triangle template placement with liver as primary area of interest.

4. Mark three holes with ink in the Triangle Template.

5. Cover the marks with radiopaque CT markers (Beekly spot marker).



Depiction of Spot Marker placement for pre-procedure CT with Live as primary area of interest.

Reconstruction

Apply noise reduction algorithm during reconstruction with a medium level of noise reduction, (scanner specific, ex: Canon – AIDR, GE – ASiR, Philips – iDOSE, Siemens – SAFIRE).

1. Perform reconstruction to thin slices as follows:
   - 1.0 mm thickness
   - 0.8 mm increments

   Note: Raw data should be stored per institutional protocol to allow for later reconstructions, if necessary.
2. Expiratory breath hold as per provider preference.
3. In the event that the 3 CT markers are unable to be seen on the scan (due to limitations of the field of view of the CBCT scanner), the participant will be transitioned to Arm B and the procedure completed as per SOC.
4. Remove radiopaque CT markers and cover ink marks with adhesive covers (point guards).
5. Inform the subject, that the point guards must be worn between the CT scan and the procedure. Patients can shower normally. Bathing, hot tubs, swimming, and vigorous scrubbing over the covers should be avoided. Note: Pre-operative CT scans are routine and clinically indicated and do not represent additional radiologic imaging or patient radiation dose

4. Operating provider will provide the research personnel or MediView staff with a description of the target (location and dimensions), a list of desired anatomy for segmentation, and any specific phases that should be included for segmentation. No identifiable patient information should be included on this form.

Post-processing CT Data Set

1. The tumor, target organ (liver, abdomen/peritoneum, kidney, bone, or other soft tissue area), surrounding organs (e.g. gallbladder/bile ducts, spleen, pancreas, bowel), other surrounding soft tissue, skin, arteries, veins, and nearby bone surfaces (as well as fiducial marker locations) are segmented from pre-operative CT using an AI algorithm designed by the investigator team at Weill Cornell Medicine.
2. Region growing, contouring, and semi-automated organ segmentation will be performed by experienced research personnel with supervision of the operator.
3. Segmentation results will then be uploaded into XR90 for intra-procedural use.
4. These segmentation results will be represented in the 3D surface models and imported to HoloLens.
5. Anatomical 3D surface models will include:
6. Skin, individual fiducial markers, bone, organ of interest (kidney for a kidney biopsy, or liver for liver biopsy, etc.) tumor(s) for target, surrounding vasculature, and critical structures near the organ of interest as identified by the provider (e.g., portal vein, renal collecting duct, etc.)
7. Optional anatomical features include: lungs, specified retroperitoneal organs (liver, kidney, gallbladder, etc.), specific veins, arteries, may be segmented at an operator's request.
8. The time it takes for the pre-procedural process for each case, including segmentation time, and any quantifiable resources/cost, can be measured and recorded as needed for future evaluation.

3. Intraoperative Steps

Tumor Localization with XR90 Guidance

1. Subjects will undergo standard surgical preparation and induction of anesthesia/sedation.
2. Position the subject on the table with the region of interest/abdomen approximately centered in the EM measurement volume above the generator.
3. While subject is undergoing anesthesia induction operator dons the HMD and initiates the XR90 application.
4. Attach the EM Probe Bracket to the C1-5 ultrasound probe and connect its EM sensor cable to the SCU.
5. Place three Registration Markers (Orange, Green, and Blue) at the skin ink mark locations. For each Registration Marker, the alignment cross is centered on the skin mark. Each Registration Marker cable is connected to the SIU. Follow the process defined in LBL-0033. Use additional adhesive (such as Steri Strips or Tegaderm) if needed.
6. Use a near or far interaction to open the Patient Selection Menu on the HUD if not open. Select the subject's name to load the CT-based Holographic Anatomy.
7. Verify system readiness with EM tracking status indicator on the HUD according to LBL-0033. All tracked devices should display a green checkmark status indicator in the upper right corner of the HUD. If tracked devices are in the measurement volume and status indicators are red, check for metal in proximity with the EM generator (be sure the C-arm is parked in the home position).

8. Adjust the HUD to the preferred position and scale using near or far interactions.
9. Perform system registration by selecting the "Start Registration" button on the HUD or saying the voice command "Start Registration." Gaze at each of the three Registration Markers one at a time until the MediView logo appears over each.
10. Activate the ultrasound Flashlight view (by pushing the button on the HUD or by saying the voice command, "Flashlight On" aloud). At this point, start the localization timer.
11. If desired a holographic needle guide (pictured below) may be placed and used to trajectory planning in order to assist with the avoidance of critical structures and minimize new attempts and redirects.

   a. If desired, instantiate a Needle Guide, tap a target within the ultrasound cone on the HUD using a near or far interaction. The Needle Guide will instantiate both on the HUD and with respect to the Flashlight projection and will be synchronized, providing pre-operative planning and intra-operative visualization to the user. Only one Needle Guide may be instantiated at a time. XR90 can switch between in-plane and out-of-plane approaches using the "Lock In- Plane" or "Lock Out-of-Plane" voice commands.
   b. Once the Needle Guide instantiates, you have the option to hide it. This button will appear when you focus on the Needle Guide handle via near or far interaction. Focusing with eye gaze is not supported with the Needle Guide.
   c. A user may grab the green handle of the needle, otherwise known as the Needle Guide handle, to change the orientation of the Needle Guide. The Needle Guide may only be adjusted on the HUD. Any changes to the Needle Guide on the HUD will be simultaneously changed on the Needle Guide with respect to the Flashlight.
12. The tracked interventional instrument (e.g., a sensor-equipped trocar) will be positioned prior to percutaneous access in accordance with the treatment plan using standard ultrasound, fluoroscopy, and cone-beam CT guidance as needed. The XR90 platform alone will not be used for the final position of the

trocar prior to percutaneous access. Standard of care US will be used for all diagnostic purposes during the procedure. Images and videos will be recorded from the HoloLens.

13. Video and images may be captured from the HoloLens. Ultrasound and fluoroscopy screen captures will be acquired.
14. After positioning the interventional instrument (e.g., a sensor-equipped trocar) for percutaneous access, the trocar will be advanced using XR90 in adjunct to standard image guidance. Patients will receive standard of care with primary guidance for placement of probe/biopsy needle under ultrasound, CBCT, and (including the use of additional FDA cleared needle guidance or image fusion systems that may be available and normally used as standard of care).
15. The trocar and/ or biopsy needle placed with standard image guidance is then advanced according to standard of care.

Arm B Standard of Care Simulated Needle Placement

1. For patients randomized into the standard arm (B) the same protocol will be followed as described above except for the absence of the XR90 system including the EM generator, HMD, and registration markers.
2. Percutaneous biopsies will be performed with 2D CT and ultrasound guidance.
    a. Needle gauge selection will be provider preference.
    b. Must be commercially available ultrasound system.
3. The operator uses standard of care 2D imaging to guide the needle to the target.
4. Record the localization time using standard of care imaging.

Collection of Data:

Study coordinators will be responsible for the collection of data and entry in Greenlight Guru Clinical for both Group A and Group B. MediView support staff provide training to study personnel for the collection of data and study management. Providers will be responsible for performing the procedure, noting attempts, and any critical structures if unintentionally encountered. The study coordinator will record all metrics in a designated data collection sheet via electronic study management system.

1. **Time of Tumor Localization:**
    a. Arm B (Standard of Care Arm): The time from initiation of localization of standard imaging (defined by when the ultrasound probe is put into operator's hand) until operator has planned a trajectory and point of entry (by placing a finger or trocar on the skin entry site and verbalizing completion of localization) will be measured and recorded.
    b. Arm A (XR90 Guided): The time it takes from initiation of localization using the platform (defined by when the sensorized instruments are first put in the operator's hand) until the operator has planned a trajectory and point of entry (by placing finger or trocar on the skin entry site and verbalizing completion of localization) will be measured and recorded.
2. **Time From Skin to Target**

a. Arm B (Standard of Care Arm): The elapsed time from when the proceduralist inserts their trocar or biopsy needle through the skin (excluding skin knicks) and when the provider verbalizes they have reached their intended target in order to collect a biopsy under ultrasound guidance.
b. Arm A (XR90 Guided): The elapsed time from when the proceduralist inserts their trocar or biopsy needle through the skin (excluding skin knicks) and when the provider verbalizes they have reached their intended target in order to collect a biopsy using XR90 as an adjunct to ultrasound guidance

3. **Assessment of biopsy difficulty and sample adequacy**
    a. Biopsy difficulty will be evaluated objectively according to the depth of lesion and subjectively on a scale of 1-10 (10 being most difficult) by the operating provider after the procedure.
    b. Sample adequacy will be evaluated by measuring diagnostic yield as a binary outcome (Yes/No): Whether the biopsy led to a definitive pathological diagnosis
4. **Needle attempts**: An attempt shall be defined as the entrance of the needle into the skin with the planned advancement of the needle toward the targeted lesion. An attempt will be counted at the beginning of targeting and each time an operator removes their needle from the skin and restarts localization.
5. **First attempt success**: Was the proceduralist able to successfully obtain a specimen without having to remove a needle from the skin and re-inserted with a different trajectory. Yes or No. .
6. **Procedure Technical Success:** Procedures will be determined to be complete once the provider has verified (via ultrasound or CT) that an adequate biopsy specimen has been obtained per standard of care. Categorical Y/N value
7. **Needle placement depth** Distance between skin insertion (percutaneous access) point and the (center of the) target tissue along the needle path. Before removing the etrax needle from the subject, the provider will place their hand at the tip of the skin and hold their hand in place as they remove the needle. Calibrated calipers will be used to measure the distance from the providers hand to the depth of the needle.
8. **Complications-** participants will be monitored for at least 2 hours after the procedure. Any complications noted to occur before discharge or during the procedure will be recorded. Possible complications include but are not limited to the following:
    a. Prolonged bleeding requiring escalation (transfusion, admission, or prolonged monitoring)
    b. Bile duct injury
    c. Vascular injury
    d. Urinary tract injury
    e. Prolonged hemodynamic instability requiring intervention (unplanned fluid bolus, medication administration, unplanned admission, etc.)
9. **Total in-room time of participant:** the elapsed time between when the participant enters the rooms and when the participant exits the room after completion of the procedure.
10. **Critical Structures encountered**: Critical structures unintentionally encountered by a provider will be noted by the operator and recorded by a research coordinator or MediView staff present at the procedure. A critical structure to be avoided include:
    a. Central Biliary tree including Gallbladder
    b. Portal Vein
    c. Inferior Vena Cava
    d. Aorta
    e. Spleen
    f. Bowel

g. Renal collecting duct (unless targeted for biopsy)
h. Pleura/lungs

11. Operator Survey

a. Likert based survey questionnaire given to the primary operator prior to and following the procedure, evaluating:
    i. Ergonomics/comfort
    ii. Distraction introduced by the HMD
    iii. Operator confidence (esp. in terms of anatomic complexity)
    iv. Potential benefits in terms of case planning, speed, , complexity, safety
    v. Overall usability

12. **Error Messages**: Error messages displayed on the HUD of XR90 will be recorded. Error messages will be recorded in the procedural logs of the XR90 system or may be read out loud by the proceduralist wearing the device. The research coordinator will be provided an unaltered copy of the procedural log following the completion of each case.

Safety Monitoring

Overview

The safety of participants enrolled in this clinical investigation will be continuously monitored throughout the study. This includes the systematic collection, documentation, and evaluation of all adverse events (AEs), serious adverse events (SAEs), device deficiencies, and any unanticipated adverse device effects (UADEs). The primary objective is to identify any safety issues related to the investigational device and take appropriate action to mitigate risks

Monitoring Procedures

1) All study sites will be monitored regularly by a Clinical Research Associate (CRA) to ensure protocol compliance and accurate data collection. Safety data will be collected at each study visit through:

    a) Procedural Data Collection, including any procedural complications both related and unrelated to the device
    b) Device error messages
    c) Device performance assessments

All safety events will be recorded in the case report form (CRF), including the severity, relationship to the device, action taken, and outcome.

Reporting Requirements

Investigators must report all SAEs to the sponsor within 24 hours of awareness.
UADEs must be reported to the appropriate regulatory authority (e.g., FDA) and Institutional Review Board within 10 working days of sponsor notification.

Data Safety Monitoring Board (DSMB)

An independent DSMB will review cumulative safety data at a quarterly interval. The DSMB is authorized to recommend protocol modifications, temporary suspension, or early termination of the study in the event of significant safety concerns.

Stopping Requirements

Study-Wide Stopping Criteria

The sponsor, DSMB, or regulatory authorities may suspend or terminate the study under any of the following conditions:

1. **Unacceptable Risk to Participants:**
    a. Two or more serious adverse events (SAEs) are determined to be directly related to device.
    b. A pattern of moderate or severe AEs suggests a safety risk associated with the device's functionality or its use in the target population.
2. **High Rate of Device Malfunction:**
    a. If ≥12% of enrolled participants experience device malfunctions that could reasonably lead to diagnostic or therapeutic error, the study will be paused pending investigation and corrective action.
3. **Security or Privacy Breach:**
    a. Discovery of a cybersecurity vulnerability or data breach involving personal health information (PHI) that poses a risk to participants.
4. **Regulatory Concerns**
    a. Any notice from regulatory bodies (e.g., FDA, EU Notified Body) recommending suspension or withdrawal based on emerging safety data.
5. **Individual Participant Stopping Criteria**
    a. A participant may be withdrawn from the study under the following conditions:
        i. The participant experiences a serious adverse event that is possibly or definitely related to the device.
        ii. The investigator determines that continued participation poses a risk to the participant's health or well-being

6. **Actions Upon Suspension or Termination**
    a. The cause will be fully investigated by the sponsor and/or DSMB.
    b. No additional participants will be enrolled until the investigation is complete.
    c. A corrective and preventive action (CAPA) plan will be initiated.
    d. If the issue cannot be resolved or is deemed unresolvable, the study may be terminated permanently.

Statistical Analysis Plan

Descriptive statistics will be used to assess the demographic variables of patients undergoing percutaneous ultrasound guided biopsy procedures. A combination of Chi-square analysis and Two Sample test will be used to determine if there is an association between the XR90 needle guidance platform and the safety and utility of biopsy procedures compared to the standard of care group. A stratified comparative sub-analysis may be performed if there are quantifiable differences in the demographic makeup of each group. Statistical tests yielding p-values of $\leq .05$ will be considered significant.

The statistical analysis for the number of needle attempts follows a percentile bootstrap method because the data is discrete, and a normal distribution cannot be assumed. This method is a non-parametric approach that does not assume any specific distribution for the data to construct a 95% confidence interval. Minitab 21 will be used for resampling and construction of a confidence interval. Further, a randomization test will be used to determine if there is a significant difference between the two means.

For categorical variables, such as first attempt success rate, a Chi Square Test and Fisher's Exact Test will be used, since there are two groups (Arm A (XR90), Arm B (SOC)).

Data Handling and Record Keeping

The Principal Investigator and the sponsor will carefully monitor study procedures to protect the safety of research subjects, the quality of the data and the integrity of the study. All data will be securely maintained by within the eCRF an electronic data capture and clinical data management tool. Only investigators and the sponsor who have access to the database will access data relevant to the study. All data will be completely de-identified and will not include any direct identifiers. A separate key code will be generated in order to allow investigators to go back into the source data and extract further information or run down outliers in their analysis to make sure they are not transcription errors. Once analysis is completed, the key code will be destroyed.

At the study's conclusion, the data will be stored in a repository for future use, retained and later destroyed per institutional policy. All relevant research data will be archived for two years after final reporting, publication of the project, or post market approval. Research data will be stored on MediView maintained servers longer if required by a sponsor or regulation.

Greenlight Guru Clinical

Greenlight Guru Clinical (https://www.greenlight.guru/) will be used as the primary Electronic Data Capture and clinical data management tool in this study.

Greenlight Guru Clinical is designed and developed in compliance with the PIC/S Guidance, PI-011-3 Good Practices for Computerized Systems in Regulated "GxP" Environments, with software validation based on medical device software standards.

Greenlight Guru Clinical is designed to enable MediView XR Inc, and its users to comply with Good Clinical Practice (such as the ISO 14155:2020 standard), ICH GCP, and other industry requirements, such as FDA 21 CFR Part 11, HIPAA and the EU GDPR. For more information see https://www.greenlight.guru/gcp-fda-21-cfr-part-11-and-hipaa-compliance-facilitation-statement.

All data in Greenlight Guru Clinical is collected, transferred, and stored encrypted in databases, which are hosted on ISO certified servers that are managed by Greenlight Guru Clinical within the European Union (Ireland and the Netherlands). Backups are performed continuously throughout the day. For more details on the security, backups, and encryption standards of Greenlight Guru Clinical, see https://www.greenlight.guru/clinical-security-and-service-level-statement.

MediView XR, Inc. has entered a contractual agreement with Greenlight Guru Clinical which clarifies how Greenlight Guru Clinical complies with regulatory requirements for processing of personal identifiable information according to applicable regulations, such as the EU GDPR.

The focus of the data collection includes:

- Age
- Gender
- Height
- Weight
- BMI
- Cancer type
- Cancer location (including depth)
- Video and images captured from the HoloLens without patient identifiers. Ultrasound, CT, and fluoroscopy screen captures will be acquired without patient identifiers.
- Procedure Technical Success
- Specimen adequate for pathological diagnosis
- Needle Depth
- Complications
- Critical Structures avoided
- Total time of participant in room
- Time required for localization to target
- CT to Registration time
- Number of registration attempts
- Time for localization
- Skin to target time
- Number of attempts
- Adverse Events

Record Keeping

Investigator Records

The investigator(s) will maintain accurate, complete, and current records relating to the investigator's participation in the study in compliance with 812.140(c) including:

1. All correspondence with another investigator, an IRB, the sponsor, a monitor, or the FDA
2. Records of receipt, use or disposition of a device.
3. Records of each subject's case history and exposure to the device.

Investigator Reports

The investigator will prepare and submit complete, accurate, and timely reports in compliance with 812.150(c) of the following:

1. Unanticipated adverse device effects
2. Withdrawal of IRB approval shall be reported to the sponsor within 5 working days
3. Progress reports will be submitted to the sponsor, the monitor and the reviewing IRB at regular intervals at least yearly.
4. The investigator will notify the sponsor and IRB of deviation from the investigational plan in order to protect the life or physical well-being of a subject in an emergency. Notification will occur as soon as possible but no later than 5 working days. Prior approval by the sponsor is required for changes or deviations from the plan unless in the event of the described emergency.
5. The investigator will notify the IRB and sponsor if a device is used without obtaining informed consent within 5 working days after the use occurs.
6. The investigator will submit a final report of the study within 3 months of the conclusion of the study to the sponsor and the IRB.

Sponsor Records

The Sponsor will maintain accurate, complete, and current records relating to the study in compliance with 812.140 (c) including:

1. All correspondence with another investigator, an IRB, the sponsor, a monitor, or the FDA.
2. Records of shipment and disposition. Records will include the name and address of the co-signee, type, and quantity of device, date of shipment, and batch number.
3. Signed investigator agreements including the financial disclosure information required to be collected under 812.42 (c)
4. Records concerning adverse device effects (both anticipated and unanticipated) and complaints.
5. Any other records that the FDA or IRB requires to be maintained by regulation or specific requirements for this particular study.

Sponsor Reports

The sponsor will prepare and submit complete, accurate, and timely reports in compliance with 812.150(c) of the following:

1. The sponsor will report unanticipated adverse device effects to the FDA and all reviewing IRB's and participating investigators within 10 working days after the sponsor receives notice or becomes aware of the effect.
2. The sponsor will notify the FDA and all reviewing IRB's and participating investigators of any withdrawal of approval of the study or a part of the study by a reviewing IRB within 5 working days after receiving notification of the withdrawal of approval.
3. The sponsor will notify the IRB and all investigators of any withdrawal of the FDA approval of the study within 5 days of receiving notification of the withdrawal of approval.
4. The sponsor will supply a current investigator list including names and addresses of all participating investigators to the FDA 6 months after receiving FDA approval.
5. The sponsor will submit progress reports to the IRB and FDA at regular intervals at least semi-annually.
6. The sponsor will report any request that an investigator return, repair, or otherwise dispose of any units of a device to the IRB and FDA. Notices will be made within 30 working days after the request is made.
7. The sponsor will notify the FDA of the completion or termination of the study within 30 working days of the completion or termination of the study. A final report will be submitted to the FDA and IRB within 6 months of completion or termination of the study.
8. The sponsor will copy FDA of any report by an investigator disclosing the use of an investigational device without informed consent within 5 working days of receiving notice of such use.
9. The sponsor will upon request by the reviewing IRB or FDA provide accurate complete and current information about any aspect of the investigation.

Determination of Unanticipated Adverse Events

Determination of Unanticipated Adverse Events(UAE) is listed below:

1. The primary investigator or MediView staff is responsible for reporting a UAE once they become have acquired information that reasonably suggest an UAE has occurred.
2. An Adverse Event form should be completed in the EDC once the primary investigator or study coordinator becomes aware that a possible UAE has occurred.
3. A UAE is defined as: A death or serious injury was or may have been attributed to a medical device, or that medical device was or may have been a factor in a death or serious injury, including events occurring as a result of:
4. Failure Malfunction- the failure of a device to meet its performance specifications or otherwise perform as intended. Performance specification include all claims made in the labeling for the device.
5. Improper or inadequate design
6. Manufacture Labeling or Use error

Dissemination of Data

The results of this study may be used for presentations, posters, publications, and post-market approval regulatory claims made by the sponsor. The publications will not contain any identifiable information that could be linked to a participant. Publications, poster presentations, oral presentations, abstracts, or any other forms of publication by study participants will be reviewed and approved by the sponsor before submission. Publications should follow the cadence outlined in the clinical trial agreement. Publication or presentations by investigators or staff without sponsor approval is prohibited.

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Appendices

To be attached as separate documents

LBL-0022	MediView XR90 User Manual
LBL-0026	XR90 HFV Needle Based Proceduralist Powerpoint
LBL-0028	CT Acquisition Protocol & MediView Triangle Template Instructions for Use
LBL-0031	XR90 EM Probe Bracket Instructions for Use
LBL-0032	XR90 Field Generator Brackets Instructions for Use
LBL-0033	XR90 Registration Markers Instructions for Use
MKT-0012	XR90 Training Video
REC-XXX	XR90 Post Procedure Operator Survey
PDPROJ-4.0 BRA	Benefit/Risk Analysis, XR90

Versions

Version 0	Initial Release
Version 1	Updates to expected study duration, TRE calculations, added power analysis for sample size justification and other minor updates
Version 2	Endpoints and eligibility criteria updated. Power analysis and sample size adjusted. Minor formatting and grammar changes.
Version 3	Justification for power analysis and sample calculations added. Stratification criteria removed. Language added to clarify device additions, data collection and randomization procedures. Inclusion and exclusion criteria updated. Title updated to reflect new inclusion criteria. Grammar and formatting updated throughout the document.