# 4. REGISTRY OBJECTIVE AND PURPOSE

This observational, post-market registry aims to evaluate real-world safety, efficacy, and patient reported outcomes among participants receiving therapy with the Vanquish Water Vapor Ablation System (Vanquish Therapy). This includes longitudinal assessment of patients who have received or will receive the therapy one or multiple times as part of routine clinical care and encompasses those who completed a company-sponsored Vanquish therapy study (as applicable). By systematically collecting clinical, procedural, and participant experience data, the registry seeks to generate real-world evidence that:

- Supports clinical adoption
- Informs best practices
- Provides data to support regulatory and quality reporting
- Provides data to support health economics and reimbursement
- Enhances understanding of the device's performance in diverse patient populations.

Data collection is intended to form an evidence-base from which multiple research questions can be generated and conclusions can be drawn to help optimize outcomes to improve patient care and gain a better understanding of practice trends and therapy costs.

# 5. REGISTRY DESIGN

## 5.1. Registry Size and Duration

The global registry will enroll up to 2,500 participants from all geographies with regulatory approval and commercialization of the Vanquish System. The registry is estimated to remain active for up to 15 years.

## 5.2. Informed Consent

An informed consent form (ICF) is a legally effective, documented confirmation of a participant's voluntary agreement to participate in the registry. The Sponsor will provide a template ICF to each institution for Institutional Review Board/Ethics Committee (IRB/EC) submission. The template may be modified to suit the requirements of the individual institution. It is preferred that the Sponsor pre-approves changes to the ICF prior to initial submission to the IRB/EC. The ICF will be reviewed and approved by an IRB/EC prior to the commencement of the registry at each institution. Any changes to the ICF must be reviewed and approved by the IRB/EC before being used to consent a participant.

Each Investigator or assigned designee must administer the most current IRB/EC approved ICF to each participant and obtain a signature, or a legally authorized representative's signature, along with the date of consent prior to enrollment in the registry. The ICF must be obtained in accordance with the applicable guidelines on 21 CFR 50, 52, and 56, the Declaration of Helsinki, International Organization for Standardization (ISO) 14155 or local regulations and laws, whichever represents the greater protection of the individual.

# 6. PARTICIPANT SELECTION

## 6.1. Eligibility Criteria

Participants will be enrolled based on the inclusion/exclusion criteria listed below. The Investigator(s) are responsible for determining if a patient is a candidate for therapy with the Vanquish System.

### 6.1.1. Inclusion Criteria

1. Candidate for Vanquish therapy per physician discretion or participant has completed a company-sponsored Vanquish therapy study.
2. Participant is willing and able to provide written informed consent.

### 6.1.2. Exclusion Criteria

1. Contraindications per the Vanquish IFU.
2. Previously participated in VAPOR 2 study and is not planning to receive further Vanquish therapy.

# 7. INSTITUTION ORGANIZATION

## 7.1. Institution Selection

The clinical registry institutions must have adequate resources to support registry activities and be able to comply with applicable regulatory and local IRB/EC requirements.

## 7.2. Institution Principal Investigator

Each institution will have a Principal Investigator (PI) who is responsible for the conduct of the registry at the institution, including: protection of the rights, safety and welfare of the participants enrolled at their institution, the integrity of the registry data generated by their institution, and for ensuring the registry is conducted in accordance with the protocol, applicable US FDA regulations, the ethical principles outlined in ISO 14155, the Declaration of Helsinki, International Conference of Harmonization (ICH) Good Clinical Practice (GCP) guidelines, General Data Protection Regulation (GDPR) in the European Union (EU) as applicable for patient privacy, and local IRB/EC requirements.

## 7.3. Institution Activation

Institution activation is defined as the point in time when the Sponsor notifies the institution in writing that the registry may begin.

All local regulatory requirements must be fulfilled before the institution can be activated.