

Draft Questions for the Panel

1) Safety

The seven-day serious adverse event rate in the pivotal study was 6.25% with a 95% upper confidence bound of 11.19%. The pre-specified goal was 2.5% with an upper confidence bound of 7%.

Please discuss whether the safety results demonstrate that there is a reasonable assurance that the device is safe for the treatment of isthmus-dependent atrial flutter.

2) Chronic Effectiveness Results - Core Lab Determination

The blinded core lab adjudication of patient event recordings led to a chronic effectiveness result of 81.6% with a 95% lower confidence bound of 74.7%. The pre-specified chronic effectiveness goal was 90% with a lower confidence bound of 80%.

Please discuss whether the chronic effectiveness results based upon the core lab determination demonstrate that there is a reasonable assurance that the device is effective for the chronic treatment of isthmus-dependent atrial flutter.

3) Chronic Effectiveness Results – Clinical Determination

The Clinical Determination Analysis readjudicates some patients as chronic effectiveness successes who were adjudicated as chronic effectiveness failures by the blinded core lab. The readjudication is based on the investigator's assessment of whether or not an individual subject was a chronic success.

Please discuss the value of the chronic effectiveness results based upon the clinical determination.

4) Chronic Effectiveness Results –Additional Data

A retrospective analysis of 111 sequential OUS subjects with atrial flutter who were treated with the CryoCor Cardiac Cryoablation System was presented.

Please discuss the value of the OUS results in assessing the chronic effectiveness of the device.

5) Pain Study

A published study in 14 patients compared the perception of pain between RF ablation and cryoablation with the CryoCor Cryoablation System. All 7 of the patients treated with RF perceived pain with at least one application, and one of the 7 cryoablation patients perceived pain.

Please discuss the value of the pain study results.

6) Device Labeling

One aspect of the premarket evaluation of a new product is the review of its labeling. The labeling must indicate which patients are appropriate for treatment, identify the products potential adverse events, and explain how the product should be used to maximize benefits and minimize adverse effects.

Please comment on whether the Indications section identifies the appropriate patient population for treatment with the device.

Please comment on the remainder of the device labeling as to whether it adequately describes how the device should be used to maximize benefits and minimize adverse outcomes.

Please discuss any additional recommendations regarding the device labeling.

7) Risks and Benefits Assessment

Please provide your overall assessment of the risks and benefits of the CryoCor Cryoablation System for the treatment of isthmus-dependent atrial flutter as demonstrated in the premarket approval application.

8) Post-Approval Study

If you recommend approval, please discuss whether a post-approval study should be performed to address any issues that are unresolved but not essential to the approval of the device. If so, please comment on the major components of such a study including suggested endpoints and study duration.