

Questions for the Panel to Consider: Devices for Ablation of Lung Tumors :

1. Please discuss where you believe that ablation as a means of local control may fit into the current armamentarium of treatments for lung cancer. Local control may mean reduction, stabilization or a decrease in the growth of tumor size. Please describe the specific patients for which this treatment may be appropriate, in terms of extent of disease, size of the tumor(s), and evidence of failure of other treatments.
2. Please discuss what you believe to be the appropriate endpoints for a study to demonstrate the effectiveness of ablation devices for the treatment of primary and secondary lung malignancies, e.g., increase in survival, reduction in tumor size, improvement in symptoms, improvement in quality of life.
3. Please discuss the imaging modalities that you believe would be appropriate to assess tumor size during these studies.
4. The duration of follow-up should allow FDA to adequately assess the safety and effectiveness of treatment with these devices. Please comment on what you believe to be the appropriate duration of follow-up for a pivotal clinical study for these devices.

Please describe the appropriate control group, endpoints and duration of follow-up for a clinical study of an ablation device that is to be used in place of surgical resection of lung tumors for patients who would be considered operable.