

Questions for the Panel to consider: Devices for treatment of Emphysema

1. What is the appropriate control group for a clinical evaluation of these devices? For example, for which patients would LVRS be an appropriate control group, and for which patients would medical management be an appropriate control group?
2. Clinical trials for these devices will be required to demonstrate safety. Please comment on what you believe to be the most important safety parameters to be evaluated in clinical trials of these devices (e.g., rehospitalization, COPD exacerbation, air leak, pneumonia, infection, hemoptysis, respiratory failure, death).
3. Clinical trials for these devices will also be required to demonstrate effectiveness. Please discuss the merits of each of the parameters below as well as any other parameters that you believe to be important to demonstrating device effectiveness. When possible, please discuss the degree of improvement or decline that would be clinically significant for these or other parameters (e.g., an increase in how many feet in the 6MWT is a significant improvement).
 - a. Pulmonary function (FEV_1)
 - b. 6 minute walk test
 - c. Maximum exercise capacity
 - d. Quality of Life (SF-36)
 - e. Dyspnea questionnaires
 - f. Length of hospital stay
4. The duration of follow-up should allow FDA to adequately assess the safety and effectiveness of these permanently implanted devices in a chronically ill population. Please comment on what you believe to be the appropriate duration of follow-up for a pivotal clinical study for these devices.