

Paper Ballot

TransMedics Organ Care System™ (OCS) Lung System

The sponsor has proposed the following Indications for Use:

The TransMedics® Organ Care System™ (OCS) Lung System is a portable organ perfusion, ventilation, and monitoring medical device intended to preserve donor lungs in a near physiologic, ventilated, and perfused state for transplantation.

The following questions relate to the approvability of the TransMedics Organ Care System™ (OCS) Lung System. Please answer them based on your expertise, the information you reviewed in preparation for this meeting, and the information presented at the panel meeting.

Panelist Name: _____

Please place an “X” next to your vote for each question.

Voting Question 1:

Is there reasonable assurance that the TransMedics Organ Care System™ (OCS) Lung System is safe for use in patients who meet the criteria specified in the proposed indication?

YES _____

NO _____

ABSTAIN _____

Voting Question 2:

Is there reasonable assurance that the TransMedics Organ Care System™ (OCS) Lung System is effective for use in patients who meet the criteria specified in the proposed indication?

YES _____

NO _____

ABSTAIN _____

Voting Question 3:

Do the benefits of the TransMedics Organ Care System™ (OCS) Lung System for use in patients who meet the criteria specified in the proposed indication outweigh the risks for use in patients who meet the criteria specified in the proposed indication?

YES _____

NO _____

ABSTAIN _____