Panel Questions

Panel Question 1

Would the panel recommend one or a combination of the following three proposals to increase the number of women positive for CIN3+ and/or HR HPV in clinical studies:

1. Supplementing from referral clinics

2. Utilizing archived specimens

3. Capping the vaccinated population

Panel Questions

Panel Question 2

Regarding the NILM/HR HPV double negative and ASC-US/HR HPV double negative populations in clinical studies supporting HPV device approval:

Do the benefits of colposcopy referral for the assessment of verification bias outweigh the risks associated with the procedure and potential overtreatment?

Please discuss for each of the two populations separately.

Panel Questions

Panel Question 3

Regarding the indications for use (IFU), do the benefits outweigh the risks for:

A. Consolidating the indications to encompass one general screening population
B. Removing references to specific triage tests and clinical actions?

Please discuss any potential risk mitigation measures if a new IFU statement were to be used.

Panel Questions

Panel Question 4

Please discuss whether the following types of data evaluations are acceptable for the assessment of safety and effectiveness for new HR HPV devices:

A. Adoption of a molecular composite comparator method
B. Evaluation of relative performance against a clinical endpoint comparator

Please discuss minimum acceptable performance criteria.

Panel Questions

Panel Question 5

If the panel recommends assessing HR HPV device performance against a clinical endpoint comparator:

A. Is utilizing a mixed histological/molecular comparator acceptable?

B. If so, how should the combination of HPV result and histological diagnosis factor in when assigning "comparator positive" and "comparator negative" results?

Histology Diagnosis	**HPV typing result using molecular comparator**				
	High Risk HPV positive			Low Risk HPV positive	HPV Neg
	16, 18, 45, 31, 33, 52, 58	35, 39, 51, 56, 59, 68	66*		
NEG				NEG	NEG
CIN1				NEG	NEG
CIN2					
CIN3	POS	POS			
CIN3+	POS	POS			