

Medical Device Approval for HPV Testing

Difficulties

- Cost Prohibited
 - Tens of thousands of samples needed
 - Time consuming
 - Willing clinical trial sites



Why ?

Heterogenous Sample Collection and Result Comparison to traditional methodology

Goal-Simplify Approval of more Effective/Economic Tests.

- How?
 - Accept Approved Tests as Standards of Comparison
 - Establish same or equivalent sample
 - Number of cells collected
 - Number of Infected Cells (Degree of infection or disease)
 - Virus Copies per cell
 - Simple Kappa Statistical Analysis (>0.8 for non inferiority)

Proposed Solution

Traditional

- Heterogenous comparison using 2 sample collection
- Apples to Oranges
- Prolonged longitudinal study with required biopsy comparisons.

Proposed

- Dividing one homogeneous sample into 2
- Apples to Apples
- Eliminates Cost
- Reduce costs by leveraging the use of already approved technology as basis of new technology comparisons.

Proven successful in Europe

- Kappa value of 1.000 (perfect agreement) (38% positive population 90 samples)
- Kappa Value of 0.905 (strong agreement) (42% positive population 90 samples)