Clinical evidence

- Clinical evidence for IVD medical devices consists of scientific validity, analytical performance and clinical performance.
- Premarket registration of IVD Medical Devices classed as high risk, where an incorrect result can endanger individual or public health, requires evidence that the probable benefits of using the test outweigh the risks.
- Manufacturers are required to supply evidence from prospective studies to establish clinical performance and operational characteristics of the device.
- If a device is to be used at the point of care (POC) then the study must be performed at the point of care.

- Clinical studies are expensive and may take years to plan and execute.
- Currently there is large scale duplication of studies in Africa with some devices delayed market entry in some countries for years.
- Costs to the manufacturer are substantial and are a disincentive to registering products in small countries where financial returns are limited.
- To reduce unnecessary costs and delays there should be mutual recognition of clinical evidence generated by studies undertaken in accredited laboratories/clinics when using approved protocols. Joint review of data should be undertaken.

Pilot project is to be undertaken using new POC tests for people living with HIV (CD4, viral load and early infant diagnosis)

Regulatory Oversight: Better, Safer, Faster & Cheaper

	Harmonization Activities	Results	Impact
Pre-market Controls			
Submission Dossier	❖ Consensus on essential data for review ❖ Adoption of a common dossier ❖ Training on Good Review Practice	A common submission template	Companies saves time, effort and money
Clinical trials	❖ Development of common protocol ❖ Establishment of trial ready sites ❖ Joint review of trial data	More country approvals for fewer trials	More affordable IVDs Faster access of quality-assured diagnostics
Manufacturing site audits	❖ Convergence of standards ❖ Mutual or 3rd party recognition of audit results	Reduce duplication of audits	Better patient outcomes
Marketing Controls			
Post-marketing Surveillance	• Establish regional lab network to monitor POCTs • Develop system for reporting product failures • Mechanism for corrective action/recalls	Ongoing assurance of quality of POCTs	More public confidence in diagnosis