

Post Marketing Surveillance (PMS)

POST MARKETING SURVEILLANCE (PMS)

- Collection of processes and activities to monitor the safety and effectiveness of devices once they are on the market.
- These activities are designed to generate information to quickly identify:
 - poorly performing devices and
 - other safety problems,

PROPOSED PAHWP WORKPLAN & TIMELINES

Activity	Time	Milestones
<ol style="list-style-type: none"> 1. Decide on priority diagnostics for PMS; 2. Identify of labs with expertise 3. Design pilot system: standardised protocols; communications platform; quality assurance materials 	3 Months (Oct 30 2013)	Directory of PAHWP PMS Lab Network and mechanism for PMS system
<ol style="list-style-type: none"> 4. Conduct pilot PMS system in ? Countries 	6 months (2 nd Forum: Jan/Feb 2014) -	PMS system piloted
<ol style="list-style-type: none"> 5. Officially launch PMS system to ? countries in Africa 	12 months (3 rd Forum: Jun/July 2014)	PMS system launched and expanded

DECIDE ON PRIORITY TEST

Short term - Rapid HIV test

Long Term (may change)

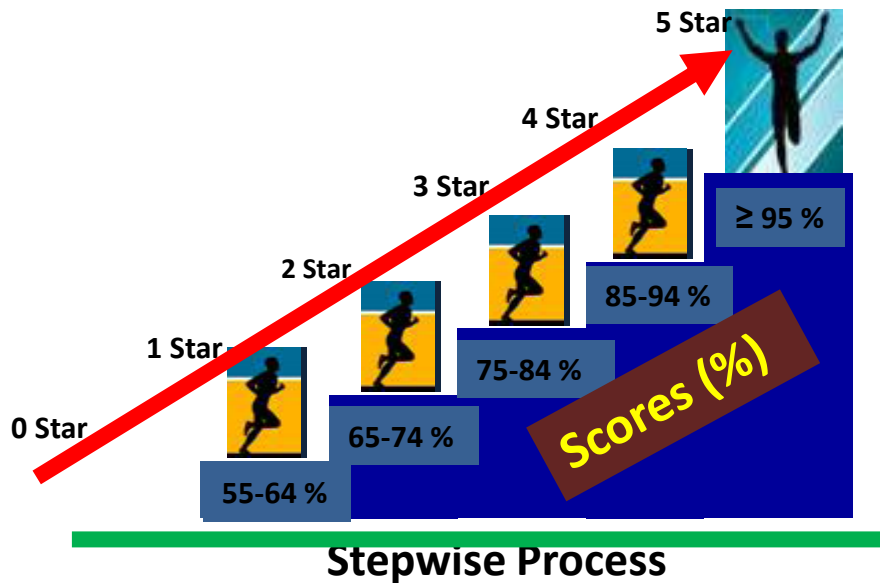
- CD4
- Viral Load
- EID
- ?? Malaria

SELECTION OF LABORATORIES

- Short term – Pilot
- Long term Consideration
- ?? Accreditation – not an option
- ?? SLIPTA
- Existing Laboratories in Countries – WHO list

No Stars (0 – 142 pts) < 55%	1 Star (143 – 165 pts) 55 – 64%	2 Stars (166 – 191 pts) 65 – 74%	3 Stars (192 – 217 pts) 75 – 84%	4 Stars (218 – 243 pts) 85 – 94%	5 Stars (244 – 258 pts) ≥95%
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End Point
National, Regional or International Accreditation Body



PILOTS

- Design protocols
- Conduct
- Launch

Timelines

PAHWP Technical working group for developing protocol for pilot post market surveillance of rapid tests to HIV.

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REPORTING AND MONITORING

- Who to report to in the communication in the event of an adverse report.
- Monitoring laboratory results.
- Start simple



Website link

SUMMARY

- Start somewhere
- Perform pilots
- Use existing laboratories in countries
- Use ASLM website

THE END

Thank you
Ke a Leboga
Ndo Livhuwa
Ndza Khensa
Asante Sana
Ngiyabonga
E Nkosi
Dankie
Merci beaucoup
Grazie

