

Post Marketing Surveillance (PMS)

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- 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 and Timelines:

Activity	Time	Milestones
1. Decide on priority diagnostics for PMS; 2. Identify 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
4. Conduct pilot PMS system in ? Countries	6 months (2 nd Forum: Jan/Feb 2014) -	PMS system piloted
5. Officially launch PMS system to ? countries in Africa	12 months (3 rd Forum: Jun/July 2014)	PMS system launched and expanded

PMS PLAN

- Identify who, what, where and why the plan
- Who to report to in the communication in the event of an adverse report.
- Monitoring laboratory results.