



Budgeting and Timeline for Establishing Pharmacovigilance Capacity		
Steps and Activity	Estimated Cost	Timeline
1. Assess country's overall pharmacovigilance capacity, and specifically assess the pharmacovigilance capacity in <i>Public Health</i> programs of HIV, TB and Malaria	€ 10,000 (includes in-country visit)	1 month
2. Assess and develop policies, framework, strategy and approach for establishing/strengthening pharmacovigilance in the country (developed jointly with country and global experts)	€50,000 to 75,000 (includes in-country visit by consultants)	2-3 months
3. Assess human resource capacity and conduct workshops in strengthening pharmacovigilance capacity	€30,000 to 50,000 per workshop; normally require 2-4 different workshops per year	Each workshop is 7-10 days
4. Post-workshop, continue off-site and on-going technical support for duration of grant period	€50,000- 75,000	Conducted over 2 years
5. Establish new systems and/or support the strengthening of existing systems for passive pharmacovigilance (spontaneous reporting). Hiring of staff should be budgeted separately.	€75,000 to €100,000	Over 2 years
6. Develop protocols for conducting drug specific active pharmacovigilance in country. Conducted jointly with other stakeholders in the country and internationally.	€20,000 to 25,000 (includes in-country visit by experts and formal acceptance of protocol by NDRA)	2-3 months
7. Conduct product specific active surveillance of key first line drugs (phase 1)	€ 350,000-500,000 (per drug or FDC [fixed dose combination] assessed).	Year 1
8. Conduct product specific active surveillance of key first line drugs (phase 2)	€350,000-500,000 (per drug FDC assessed)	Year 2

**For additional information, please contact:
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