

## Forum for Collaborative HIV Research

### Global Surveillance of Antiretroviral Drug Safety Perspectives from Different Stakeholders

June 11, 2010  
Washington, DC

#### Meeting Recap

Steve had an important pearl:

**There is tremendous fragmentation despite a common purpose, a commonly understood need, passion for success and agreement on the how to succeed.**

The common agreement on how to succeed includes a role for:

- Innovator and generic companies
- In-country ministries of health
- Cohort and registries data to dig into drug safety issues
- Surveillance to identify new serious events
- Technical resources in the North
- Many tools in the tool kit
- Academia and research
- Regional collaboration
- Cooperation among funders and receptiveness to new paradigms
- Cost effectiveness and implementation research

Are these paradoxes or real contrasting values?

1. Role of confidentiality versus the need for public access.
2. Need for quality in data input versus time and resource constraints (e.g., user friendly).
3. Need for data sharing versus the importance in-country assessment and ownership.
4. Industry support and collaboration versus alignment of interests on drug quality and safety and pass-through of costs.
5. Expertise in funding and managing research and expertise in access, distribution and country-to-country relations versus the continuum of research to access to surveillance.
6. Northern technical resources (e.g., UMC, FDA, EMA, MCA) and building in-country infrastructure
7. Important institutional respect for government autonomy, national laws and differences among countries (e.g., OGAC, WHO, GF) and potential resource sharing and synergies of regional harmonization or collaboration on science, regulation and pharmacovigilance.
8. Innovator versus generic.
9. Reputation of pharmacovigilance as adverse event identification of low priority versus reality of drug safety being critical to effective use and clinical assessment of the risk/benefit ratio.
10. Cohort or sentinel investigations of suspected or attributive versus surveillance for signal detection and identification of unknown risks or counterfeiting.
11. Advantages of large international databases versus local needs.
12. Systems that use electronic systems versus "paper" systems.
13. Cost-effectiveness versus control of epidemic disease

However, there is consensus on the absence of resources.