

Rapid Parmacovigilance Implementation in Developing Countries

SHORT OVERVIEW AND EFFORTS OF RAPID PHARMACOVIGILANCE

The overall goal of the RaPID Pharmacovigilance Program is to provide a ***RAPID ‘turn-key’ outsourced solution for gathering and assessing safety data*** on drugs used in public health programs in the pediatric and adult population.

This RaPID approach aims to establish the pharmacovigilance processes and systems ***within 100 days, for any health program in any country:***

The support RaPID provides includes:

1. gathering of pharmacovigilance data/ADR reports
2. data entry of ADR reports into Vigiflow and other related software
3. assessment of findings, causality assessment and signal detection
4. recommendations for strengthening public health programs with respect to safe drugs
5. support for strengthening pharmacovigilance in-country and in health programs

In addition, the RaPID approach will initiate the process of ***long-term capacity building*** of the ART centers to manage this capacity in-house.

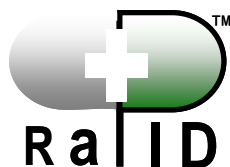
Methodology:

We work with ‘gold-standard’ protocols and manuals established by WHO¹ and other leading institutes and then customize them to the needs of the country and the public health programs. The customization is done by global pharmacovigilance experts in collaboration with the Ministry of Health and National Drug Regulatory Authority of the country.

We then work with the NDRA and local partners to hire nurses and pharmacists from the private sector and deploy a RaPID ‘pharmacovigilance force’ (akin to a ‘sales force’) to gather pharmacovigilance data in ART centers, TB centers, public and private sector clinics and pharmacies.

After checking the data for completeness and quality, again in coordination with the NDRA, the data is uploaded onto the RaPID website (www.rapidpharmacovigilance.org). The data is downloaded and entered into Vigiflow by specially trained and ‘validated’ staff. After global experts provide support for causality assessment and signal detection, the final report and findings are prepared and sent back to the national NDRA and public health program. This whole cycle should be conducted every 30 days to provide on-going information for the health program and the Ministry of Health. For serious adverse events, the plan is to speed up the cycle to 7-15 days.

¹ For example: A practical handbook on the pharmacovigilance of antimalarials medicines; WHO (Authored by David Coulter)



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Current Ongoing Pharmacovigilance Efforts by RaPID

1. *Pharmacovigilance Capacity Assessment:*
 - Completed assessment of pharmacovigilance capacity in various countries, including Kenya, Tanzania, Uganda. In discussions with additional countries.
2. *Development of Protocol for Assessing ACTs:*
 - With support from the Roll Back Malaria Partnership, and technical collaboration of our partners, we are in process of developing a protocol for assessment of use of ACTs in public and private sector.
3. *Assessment of ADR/AE Reports*
 - Discussing with various countries to provide them support for data entry (into Vigiflow) and assessment of data. Preliminary and detailed discussions have been held with countries in Latin America, Asia and Africa.
 - Have started to conduct this assessment on a pilot basis.
4. *Development of Software for Cohort Event Monitoring (CEM)*
 - To date, there is no appropriate software for capturing and assessing CEM data for public health that meet the needs of developing countries
 - RaPID is in the process of funding and catalyzing the customization of a software that can be used in public health programs for capturing CEM data (Vigiflow is good for ADR data only)
 - The interim solution would be applied until the CEM Flow (Vigiflow's version adapted for CEM) software by Uppsala is ready
5. *Data Gathering and Assessment of Pharmacovigilance data in ART Centers:*
 - In discussions with the National AIDS Control Organization for providing assistance in gathering data (very little data is gathered today) and assessing the findings.

Partnerships:

By working with a group of leading academic, government and private NGOs in US, Europe, Africa and India, we apply the strengths of these organizations to achieve our goals in a very short time. Our technical supporters include:

- Uppsala Monitoring Centre, a WHO Collaborating Center for Pharmacovigilance (Sweden)
- Swissmedic, the Swiss National Drug Regulatory Authority (for support related to Vigiflow)
- O3i, Inc (a non profit NGO based in New York, hosting the RaPID pharmacovigilance program)
- Ecumenical Pharmaceutical Network, present in more than 30 countries in Africa
- Indian Institute of Health Management Research (IIHMR), an academic training institute and also a WHO Collaborating Center.