

Pharmacovigilance and post-registration studies capacity

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&

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EDCTP Stakeholder Meeting on Capacity Development

Berlin, Germany, 3rd July 2014



Overview

- Capacity for PV and post-registration studies
- Current initiatives
- Building upon existing activities and structure
- Way forward and conclusions

Capacity for Pharmacovigilance

WHO definition for pharmacovigilance:
The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or **any** other possible **drug-related problems**

The importance of pharmacovigilance, WHO, 2002

Drug = medicines, vaccines, herbals etc.

“Drug-related problems” include SSFFCs (spurious, sub-standard, fake, falsified and counterfeit medicines), rumour-induced problems, problems during mass treatment programmes



Capacity for PV

- No objective measure currently exists for measuring capacity for PV in member states
- WHO PV Indicator has been recently launched but it is yet to be fully validated
- Indicator-based Pharmacovigilance Assessment Tool (IPAT) from MSH/SIAPS has also been developed but not yet validated
- WHO's concept of “minimal capacity is thus mostly used”
- Or the number of ADR reports (Individual Case Safety Reports – ICSRs) submitted annually by the country to the WHO ICSR database – Vigibase –per million inhabitants



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Minimal Capacity

- According to WHO, a country is considered to have “minimal capacity” for PV if it has the following:
 1. A National PV Centre with at least one full-time dedicated staff and in membership of the WHO Programme for International Drug Monitoring
 2. A national spontaneous reporting system
 3. A database for adverse drug reactions
 4. A Pharmacovigilance Advisory Committee
 5. A Communication Strategy

The African Situation

- Regardless of what measure is used, PV and post-registration studies (PRS) capacity in Africa is weak
- The situation is improving thanks to dedicated and continuous efforts by WHO and the WHO-CC in Accra, Morocco together with other partners
- But support is needed to ensure sustainability of the gains made so far

The WHO PV Programme

(as at 30th June 2014)

Official Member
Associate Member



Official Members (dark blue): 118
Associate Members (light blue): 29

The status of Africa within the WHO PV Programme (as at 30th June 2014)



Official Members (dark blue): 32
Associate Members (light blue): 5

Ass. Members

1. Algeria
2. Burundi
3. Gambia
4. Guinea-Bissau
5. Zanzibar

However....

- Most of the countries only joined the WHO Programme recently
 - 2009-2014: 17 members out of 32
 - 2000-2009: 10 members
 - 1992 (South Africa; Morocco) – 1999: 5
- Number of ICSRs submitted very very low
 - Less than 1% of the 9million ICSRs in Vigibase come from Africa
- WHO-CC in collaboration with WHO and UMC have been investigating and supporting.....

Reporting In Africa

Total number of ICSRs from African countries (cumulative)

	African countries
2004	6,424
2005	7,246
2006	8,401
2007	10,786
2008	11,319
2009	16,638
2010	20,895
2011	26,650
2012	41,133
2012.5	49,387
2013	55,192
2013.5	62,967
2013.667	67,710

African members of the WHO Programme

2004	8
2005	9
2007	11
2008	15
2009	18
2010	24
2011	26
2012	29
2013	31

WHO Collaborating Centre for Advocacy and Training in PV, Accra, Ghana and Capacity Development for PV in Africa



WHO-CC Terms of Reference - I

- The terms of reference of the WHO-CC
 - Training in pharmacovigilance in African countries for building and strengthening of spontaneous adverse drug reaction reporting systems
 - Advocacy for pharmacovigilance across Africa either alone or in collaboration with WHO
 - Promoting the integration of pharmacovigilance into public health programmes
 - Technical support to national pharmacovigilance centres

Terms of Reference - II

- Support in communication and crisis management to national pharmacovigilance centres
- Acquisition (from WHO, UMC) and distribution of needed literature and technical tools to national pharmacovigilance centres and governments
- Research in pharmacovigilance including cohort event monitoring of specified medicines
- Assistance in the development and maintenance of pregnancy registers



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RCORE designation – May 2014



Ref: RCORE/01/2014

Date: 02 May 2014

Prof Alex Dodoo
Director, Centre for Tropical Clinical Pharmacology & Therapeutics
Director, WHO Collab. Centre for Advocacy and Training in Pharmacovigilance
University of Ghana Medical School
P. O. Box 4236, Accra, Ghana: Tel/Fax: +233-302-668219

Dear Prof. Dodoo,

Re: **Application for designation as a Regional Centre of Regulatory Excellence**

Following review of your application, I am happy to inform you that your institution has been approved for designation as a ***Regional Centre of Regulatory Excellence (RCORE) in Pharmacovigilance.***



2013/2014 Activities-I

Country Visits

The following countries were visited for strengthening in PV and Regulatory Activities

- 2013
 - Eritrea, Liberia; Rwanda; Kenya, Guinea; Uganda, Angola; South Africa, Togo
- 2014
 - Mauritius, Namibia, Mauritania, Burundi, Tanzania and counting....
 - Scheduled: Zanzibar(Jul26-Aug 1), Djibouti (September)



Our Flagship 4 week Pharmacovigilance Fellowship Course

Pharmacovigilance Fellowship

- 4-week training in the theory and practice in PV
- Includes hands-on sessions on tools used in PV
- Field trips to the Ghana National PV centre, hospitals, research institutions and rural field stations

4 courses so far:

17th June – 12th July, 2013

16th September – 11th October, 2013

2nd June – 28th June 2014

14 July- 8th August 2014

31 participants from 24 African countries

Modules include but not limited to;

- Developing an ADR reporting culture
- PV methods
- Regulatory aspects of PV
- Mechanism of ADRs
- Causality Assessment
- Research in PV
- Statistics and bioinformatics
- Data management



WHO Collaborating Centre for Advocacy & Training In Pharmacovigilance
Accra, Ghana

Aims:
The Fellowship is aimed at providing the following:

- The theory and practice of Pharmacovigilance (PV).
- Practical hands-on training in PV.
- Training on the use of PV associated softwares.
- Field visits to introduce participants to the real life practice of PV in hospitals, regulatory and industrial settings.

Duration & Dates:
Four (4) weeks

First offering: 2nd - 27th June, 2014
Application Deadline: 20th May, 2014

Second offering: 15th September - 10th October, 2014
Application Deadline: 1st September, 2014

Registration:
Participation will cost **USD 3,300.00** and includes course materials, lunch and two coffee breaks, field trips and visit to tourist sites in and around the capital.

Sponsorship may be available for those who qualify.

The WHO Collaborating Centre

Pharmacovigilance Fellowship

Application forms & detailed training brochure can be downloaded via the following links:
<http://www.who-pvafrika.org>
<http://www.who-umcafrica.org>

Contact: training@who-pvafrika.org or call +233 289 014 000

Deliverables:
Certificates of competence will be issued to each participant who successfully completes the program.

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 **WHO Collaborating Centre for Advocacy & Training in Pharmacovigilance**

 **SANTÉ-AFRIQUE INTERNATIONAL LIMITED (SAI)**
www.santehq.com.gh

This fellowship is being organised in collaboration with Santé-Afrique International Ltd, the leading African organization providing solutions in patient safety, drug safety, vaccine safety, IT solutions for longitudinal data management, electronic data capture systems and patient management systems.

Visiting Address: 18 Mango Tree Avenue, Asylum Down, Accra, Ghana
Mailing Address: P. O. Box LT 282 Lartebikorshie, Accra, Ghana

Our Yearly Data Management Course

WHO Collaborating Centre for Advocacy & Training In Pharmacovigilance
Accra, Ghana

Data Management for Regulatory Affairs and Public Health

Aims:

To equip healthcare professionals with skills and tools needed to effectively manage data in their field of work.

Duration & Dates:

Five (5) days; 24th - 28th March, 2014.

Cost: \$1950

Application forms & Detailed Training brochure can be downloaded via the following link:

<http://www.who-pvafrica.org>
<http://www.who-umcafrica.org>

Contact: training@who-pvafrica.org or
call +233 289 014 000

Modules:

- Design and Development of Data Collection Instruments
- Data Validation Specification (Error/Edit Checks)
- Data Entry Processes
- Data Management Plan (DMP)
- Patient Reported Outcomes
- Introduction to Statistics and Data Management in Public Health
- Local National and International ICSR Databases
- Database Support
- Database Transmission
- Collection of Longitudinal Safety Data - MEDSPINA



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WHO Collaborating Centre for Advocacy
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2013 Activities-II

- **Communication and Crisis Management**
 - Providing support to countries in effective Communication & Crisis Management
 - Support to Ghana (Ministry of Health) in developing a manual for Communication and Crisis Management for Public Health Programs in collaboration with the WHO Ghana Country Office

2013 Activities-III

Support in Risk Management Plans

- Support to the National Drug Authority (Uganda) in the development of an enterprise risk management plan.
- Assistance in providing framework for developing risk management plans
- Support in providing tools for data collection for a risk register

2013 Activities - IV

Toolkits

- Pharmacovigilance toolkit (www.pvtoolkit.org)
- Vaccine Pharmacovigilance Toolkit (under development – www.vaccinepvtoolkit.org)
- Malaria Pharmacovigilance Toolkit (<http://pvtoolkit.org/malaria-pv-toolkit/>)
 - under revision with new sections and areas

EHR for Patient Care and PV (V)

■ MedSpina

- EHR incorporating PV features
- HL-7 framework
- Longitudinal data collection

■ Developed and being deployed in Ghana (now) and Uganda (later this year)



The image shows a screenshot of the MedSpina website. The background is dark blue with a large, faint image of a stethoscope. The website content is organized into several sections:

- BEST TRAINING & SUPPORT**: A list of services including a Dedicated Account Manager, Live Expert Training, Priority Phone Support, Easy Remote Connect, Customer Portal, and Video Tutorials & Help Manual.
- Product Tiers**: Three product options are shown with icons of software boxes and CD-ROMs:
 - Professional**: Single User Version suited for an individual Doctor / Receptionist.
 - Premium**: Multi-User LAN Version suited for a Clinic with Reception, Lab and/or Pharmacy.
 - Enterprise**: Multi-Location Version suited for companies/clinics with multiple sites/branches or need to multi-site hospitals.
- Quality Indicators**: A box containing five red stars for each of the following categories: Software Quality, Expert Training, After Sales Support, and Value for Money. Below this is the text "(Based on survey October 2012)".
- Contact Us**: A box with the following information:
 - Address: 18 Mango Tree Avenue, Asylum Down, Accra, Ghana.
 - Email: info@medspina.com
 - Phone: +233 289 014 000 / +233 302 268 746
 - Website: www.medspina.com
- MedSpina Logo**: A green cross with a white stethoscope inside, with the text "MedSpina" below it.
- Tagline**: "Africa's **No.1** Doctor Friendly Software". A small Ghanaian flag is visible in the top right corner of the logo area.
- Feature Icons**: A row of six green square icons with white symbols:
 - EASY TO USE (person with magnifying glass)
 - BEST SUPPORT (hand holding a tool)
 - BEST TRAINING (computer monitor)
 - FOR AFRICA BY AFRICA (globe)
 - FREE DEMO (video camera)

Meetings-ASoP Dec 3-5 2014, Host-WHO-CC, Accra (VI)

- ASoP is the African Society of Pharmacovigilance
- Formed in 2010 and accepted as a Chapter of the International Society of Pharmacovigilance (ISoP) in 2010
- A key activity is to bring ALL stakeholders in PV in Africa once a year – to meet, network, share ideas and improve PV in Africa

ACCRA2014
AFRICA SOCIETY OF PHARMACOVIGILANCE CONFERENCE

2ND AFRICAN SOCIETY OF PHARMACOVIGILANCE (ASoP) CONFERENCE

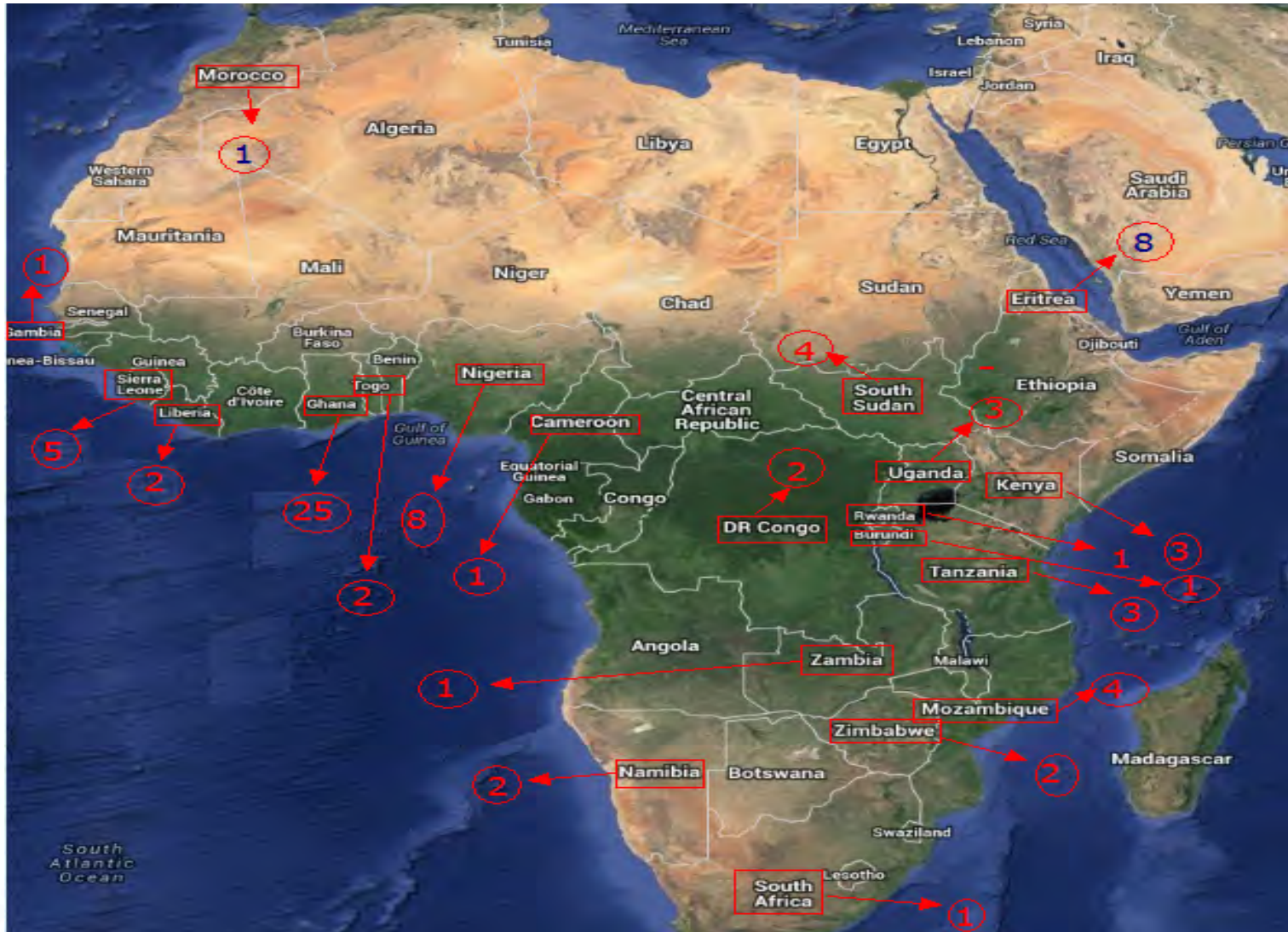
THEME
Pharmacovigilance In Africa : New Methods, New Opportunities, New Challenges

3rd-5th DECEMBER, 2014
La-Palm Royal Beach Hotel
8am-5pm

www.asop2014.com
African Society of Pharmacovigilance
ASoP 2014

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Number of People Trained at WHO-CC, Accra since 2013....80!!!!



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Way Forward - I

- Pharmacovigilance in Africa has improved tremendously over the past 5 years in terms of NUMBERS
 - However, nearly a third of African countries still have no pharmacovigilance capacity at all
- Where PV and PRS capacity exists, the QUALITY is variable; usually very weak
- The focus now is improving quality and not just quantity

Way Forward - II

- Countries with PV activities do not want to be just data collectors
 - They now want support and training to ANALYSE their data and MAKE DECISIONS based on their data
 - Data analysis; data management skills now deemed essential
 - This calls for broader thinking into DATA CAPTURING approaches – from paper to electronic across the entire spectrum



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Way Forward - III

- There is therefore the need for
 - Training of data management
 - Development of African-specific tools for data capture
 - Electronic health records should now be seriously considered for appropriate sites in Africa
 - Pharmaco-epidemiological studies need to be conceived and undertaken
 - The harmonisation efforts across the continent should consider PV as an essential component of regulatory capacity building



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Way Forward - IV

- The WHO-CC in collaboration with WHO (HQ; AFRO) and partners (AMRH; AU/NEPAD; WAHO; INDEPTH; INESS) have led development of PV across Africa
- There is the need for DEDICATED support for the WHO-CC to continue this important work
- Building parallel structures etc. will not inure to the benefit of anyone
- WHO-CC is ALREADY providing the leadership and advocacy and welcomes ALL partners including the EDCTP.....

Thank you!!!

