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Informational Packet

About the proposed PANCePP

The proposed PANCePP is a forward-looking initiative which aligns with African Union CDC's vision to create a "safer, healthier, integrated and prosperous Africa, in which Member States can efficiently prevent disease transmission, implement surveillance and detection, and always be prepared to respond effectively to health threats and outbreaks".

The value proposition for PANCePP include durable visionary benefits to the African continent such as:

- Strong Pan-African scientific network to support the evaluation of medicines
- Improve the health of communities across Africa by providing a reliable single source for up-to-date information on ongoing scientific research and findings across the continent.
- Bridge and enhance existing cross-continent knowledge and accessibility to health data sources and information
- Increase transparency for conducting clinical and health-related research studies
- Standardize and improve the methodologies for conducting health-related studies
- Improve governance for conducting research studies
- Improve cross-continent monitoring of the safe use of medicines and vaccines
- Create a Pan-African register for conducting post-authorization studies to enhance transparency of observational research and to provide evidence to support regulatory decision-making in the implementation of pharmacovigilance activities across the African continent
- Job creation, skills development, and scientific rigor that is comparable to standards found anywhere in the world.

We consider the PANCePP discussion a timely topic, given our theme for this year's conference, which is titled: **"Building Research Capacity in Pharmacoepidemiology for Healthcare Systems in Africa: Data Networks and Analytics to support Patient Care and Medical Products Policy"**.

Members of PANCePP would be public institutions and contract and research organizations (CROs) involved in research in pharmacoepidemiology and pharmacovigilance in Africa. Research interests would include the safety of medicines, disease epidemiology, drug utilization, as well as the benefits and risks of medicines. Participation would be voluntary.

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PANCePP would be modelled after the European Medicines Agency's Network of Centers for Pharmacoepidemiology and Pharmacovigilance, and would aim to strengthen the monitoring of the benefit-risk balance of medicinal products in Africa by:

- Facilitating the conduct of high quality, multi-center, independent post-authorization studies (PAS) with a focus on observational research;
- Bringing together expertise and resources in pharmacoepidemiology and pharmacovigilance across Africa and providing a platform for collaborations;
- Developing and maintaining methodological standards and governance principles for research in pharmacovigilance and pharmacoepidemiology.

Experts from the International Society for Pharmacoepidemiology (ISPE) were instrumental in the development of EMA's ENCePP, as well as similar organizations in Asia, and would be pleased to support the African Union in this regard.

About ISPE

ISPE is an international nonprofit organization dedicated to advancing the health of the public by providing a global forum for the open exchange of scientific information and for the development of policy, education, and advocacy for the field of pharmacoepidemiology, including such areas as pharmacovigilance, drug utilization research, comparative effectiveness review, and therapeutic risk management.

Pharmacoepidemiology is the science that applies epidemiologic approaches to studying the use, effectiveness, value and safety of pharmaceuticals. ISPE is firmly committed to providing an unbiased scientific forum to the views of all parties with interests in drug development, drug delivery, drug use, drug costs, and drug effects.

ISPE members represent the various scientific disciplines involved in studying drugs. Members are employed by the pharmaceutical industry, academic institutions, government agencies, non-profit and for-profit private organizations. Members have degrees in several fields, including epidemiology, biostatistics, medicine, nursing, pharmacology, pharmacy, law, health economics, and journalism. With members in 53 countries and regional and national chapters in Africa, Asia, Argentina, Belgium, Brazil, Denmark, and the Netherlands, ISPE truly provides an international forum for sharing knowledge and scientific approaches to foster the science of pharmacoepidemiology. ISPE sponsors conferences and seminars and an official journal — Pharmacoepidemiology and Drug Safety — published by Wiley.

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Since the formation of the ISPE African Regional Interest Group in 2018, we have grown rapidly from less than a dozen researchers to more than 370 members from over 20 countries within and outside Africa. Our members are active researchers with over 40 scientific publications in the last year alone (please see the attached).

Appendix 1

List of selected publications in the last year by members of the African Regional Interest Group and the Medicines Utilization Research in Africa (MURIA) Group

1. Olayinka O, Debashis B, Debjani M et al. Response to the Novel Corona Virus (COVID-19) Pandemic Across Africa: Successes, Challenges, and Implications for the Future. Front. Pharmacol., 11 September 2020 | https://doi.org/10.3389/fphar.2020.01205

2. Adenuga, B.A. & Rennie, T.W. A Profile of Adverse Drug Reactions of Atazanavir- and Lopinavir-Based Antiretroviral Regimens in Namibia. Drug Saf (2019) 42: 915. https://doi.org/10.1007/s40264-019-00832-3

3. Adenuga, Babafunso Aderemi, Dan Kibuule and Kayode Ds Bamitale. "An Interrupted Time Series Analysis of the Second line Antiretroviral Policy Change from Lopinavir Boosted with Ritonavir to Atazanavir Boosted with Ritonavir Based Regimens in Namibia." (2018). J Pharma Care Health Sys. 5(3)

4. Arana A, Margulis AV, McQuay LJ, Ziemiecki R, Bartsch JL, Rothman KJ, Franks B, D'Silva M, Appenteng K, Varas-Lorenzo C, Perez-Gutthann S. Variation in Cardiovascular Risk Related to Individual Antimuscarinic Drugs Used to Treat Overactive Bladder: A UK Cohort Study. Pharmacotherapy. 2018 Jun; 38(6):628-637. doi: 10.1002/phar.2121

5. Atieno OM, Opanga S, Martin AP, Kurdi A, Godman B. Pilot study assessing the direct medical cost of treating patients with cancer in Kenya; findings and implications for the future. Journal of Medical Economics. 2018; 21(9): 878-887; DOI: 10.1080/13696998.2018.1484372

6. Beyene, K., Aspden, T., McNeill, R., Sheridan, J. (2019) Modifiable risk factors for prescription medicine sharing behaviours. Research in Social and Administrative Pharmacy, 15(2):154-63.

7. Beyene, K., Aspden, T., Sheridan, J. (2019) Prevalence and predictors of medicine saving and future prescription medicine sharing: findings from a New Zealand online survey. The International journal of pharmacy practice, 27(2):166-174.

8. Beyene, K., Aspden, T., Sheridan, J. (2019) Using the behaviour change wheel to explore potential strategies for minimising harms from non-recreational prescription medicine sharing. Research in Social and Administrative Pharmacy, 15(2):130-44.

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9. Caleb Okoth, Sylvia Opanga, Faith Okalebo, Margaret Oluka, Amanj Baker Kurdi, Brian Godman. Point prevalence survey of antibiotic use and resistance at a referral hospital in Kenya. Hospital Practice 2018; DOI: 10.1080/21548331.2018.1464872

10. Canan, C., Alexander, G. C., Moore, R., Murimi, I., Chander, G., & Lau, B. (2019). Medicaid trends in prescription opioid and non-opioid use by HIV status. Drug and alcohol dependence, 197, 141-148.

11. Cohen, K., & Maartens, G. (2019). A safety evaluation of bedaquiline for the treatment of multi-drug resistant tuberculosis. Expert Opin Drug Saf. doi:10.1080/14740338.2019.1648429

12. Cohen, K., Stewart, A., Kengne, A. P., Leisegang, R., Coetsee, M., Maharaj, S., . . . Maartens, G. (2019). A Clinical Prediction Rule for Protease Inhibitor Resistance in Patients Failing Second-Line Antiretroviral Therapy. J Acquir Immune Defic Syndr, 80(3), 325-329. doi:10.1097/qai.0000000000001923

13. Cohen, K., Viljoen, C., Njuguna, C., & Maartens, G. (2019). Emtricitabine-associated red cell aplasia. AIDS. doi:10.1097/qad.0000000000002136

14. Dunia Alarkawi, M Sanni Ali, Dana Bliuc, Jacqueline R Center, Daniel Prieto-Alhambra. The Challenges and Opportunities of Pharmacoepidemiology in Bone Diseases. JBMR Plus (2018) 2: 187–194. doi: 10.1002/jbm4.10051

15. Enos M Rampamba, Johanna C Meyer, Brian Godman, Amanj Kurdi, Elvera Helberg. Evaluation of antihypertensive adherence and its determinants at primary health care facilities in rural South Africa. Journal of Comparative Effectiveness Research 2018; DOI:10.2217/cer-2018-0004

16. Eworuke E, Panucci G, Goulding M, Neuner R, Toh S. Use of tumor necrosis factor-alpha inhibitors during pregnancy among women who delivered live born infants. Pharmacoepidemiol Drug Saf. 2019;28(3):296-304.

17. Eworuke E, Welch EC, Tobenkin A, Maro JC. Use of FDA's Sentinel System to Quantify Seizure Risk Immediately Following New Ranolazine Exposure. Drug Saf. 2019 Jul;42(7):897-906. doi: 10.1007/s40264-019-00798-2.

18. Fadare, J. O., Obimakinde, A. M., Enwere, O., Desalu, O. O., & Ibidapo, R. O. (2019). Physician's Knowledge of Appropriate Prescribing for the Elderly–A survey among Family and Internal Medicine Physicians in Nigeria. Frontiers in Pharmacology, 10, 592.

19. Fadare, J. O., Ogunleye, O., Iliyasu, G., Adeoti, A., Schellack, N., Engler, D., ... & Godman, B. (2019). Status of antimicrobial stewardship programmes in Nigerian tertiary healthcare facilities: Findings and implications. Journal of global antimicrobial resistance, 17, 132-136.

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21. Fadare, J. O., Sunmonu, T. A., Bankole, I. A., Adekeye, K. A., & Abubakar, S. A. (2018). Medication adherence and adverse effect profile of antiepileptic drugs in Nigerian patients with epilepsy. Neurodegenerative disease management, 8(1), 25-36.

22. Frederick Morfaw, Mercy Fundoh, Christopher Pisoh, Bi Ayaba, Lawrence Mbuagbaw, Laura N. Anderson & Lehana Thabane. Misoprostol as an adjunct to oxytocin can reduce postpartum-haemorrhage: a propensity score–matched retrospective chart review in Bamenda-Cameroon, 2015–2016. BMC Pregnancy and Childbirth (2019) volume 19, Article number: 257 https://doi.org/10.1186/s12884-019-2407-3

23. Griesel, R., Cohen, K., Mendelson, M., & Maartens, G. (2019). Abdominal Ultrasound for the Diagnosis of Tuberculosis Among Human Immunodeficiency Virus-Positive Inpatients With World Health Organization Danger Signs. Open Forum Infect Dis, 6(4), ofz094. doi:10.1093/ofid/ofz094

24. Hallas J, Margulis AV, Pottegård A, Kristiansen NS, Atsma WJ, Appenteng K, de Vogel S, Kaye JA, Perez-Gutthann S, Arana A. Incidence of Common Cancers in Users of Antimuscarinic Medications for Overactive Bladder: A Danish Nationwide Cohort Study. Basic Clin Pharmacol Toxicol. 2018 Jun;122(6):612-619. doi: 10.1111/bcpt.12965. Epub 2018 Feb 22

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26. Jackson JW, VanderWeele TJ. Decomposition Analysis to Identify Intervention Targets for Reducing Disparities. Epidemiology. 2018 Nov;29(6):825-835. doi: 10.1097/EDE.0000000000000901. PubMed PMID 30063540; PubMed Central PMCID: PMC6218173.

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28. Jilian O. Etenyi, Faith A. Okalebo, Margaret Oluka, Kipruto A. Sinei, George O. Osanjo, Amanj Kurdi, Johanna C Meyer, Brian Godman, Sylvia A. Opanga. Comparison of zidovudine and tenofovir based regimens with regard to health-related quality of life and prevalence of symptoms in hiv patients in a kenyan referral hospital. Frontiers in Pharmacology 2018;9:984-998. doi: 10.3389/fphar.2018.00984

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30. Joseph Olusesan Fadare; Kazeem Oshikoya; Olayinka Ogunleye; Olufemi O Desalu; Alessandra Ferrario; Okezie Enwere; Adekunle Adeoti; Taofiki A Sunmonu; Amos Massele; Amanj Baker; Brian Godman. Drug promotional activities in Nigeria: Impact on the prescribing patterns and practices of medical practitioners and the implications. Hospital Practice 2018; 46 (2): 77-87

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31. Linda   Opanga, Mercy N Mulaku, Sylvia A Opanga, Brian Godman, Amanj Kurdi. Adverse effects of chemotherapy and their management in Paediatric patients with Non-Hodgkin's Lymphoma in Kenya: A descriptive, situation analysis study. Expert Review of Anticancer Therapy 2019;19:423-430. DOI: 10.1080/14737140.2019.1606717

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39. Nokuthula N Dlamini, Johanna C Meyer, Danie Kruger, Amanj Kurdi, Brian Godman, Natalie Schellack. Feasibility of using point prevalence surveys to assess antimicrobial utilisation in public hospitals in South Africa; a pilot study and implications. Hospital Practice 2019; 47:88-95

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