Summary Report

Joint Kick-Off meeting and Baseline Assessment

PAVIA and PROFORMA

Addis Ababa, Ethiopia

27th August-31st August 2018

The EDCTP2 Programme is supported under Horizon 2020, the European Union's work Programme for research and Innovation.

Report summary

The PAVIA (Pharmacovigilance Africa) and PROFORMA are Projects funded by European-Developing Countries Clinical Trials Platform (EDCTP), a funding mechanism under the EU's Horizon 2020 research program. Both consortia focus on strengthening the coordination and support mechanisms for responsible uptake of new drugs and vaccines in sub-Saharan Africa and aim to strengthen local capacity for pharmacovigilance. The projects activities overlap in Tanzania and Ethiopia.

A joint kick-off meeting and baseline Assessment was conducted starting 27th August to 31st August, 2018 in Addis Ababa, Ethiopia.

The Kick-off meeting was held on August 27, 2018 at Elilly International Hotel, Addis Ababa. A total of 59 participants attended the meeting. These were representatives from the National Pharmacovigilance Center, Armauer Hansen Research Institute, the Regional Health Bureau, selected Health facilities, Universities, Education Bureau, Market Authorization Holders, Partners/ non-governmental Organizations that support the national TB program, National Public Health Institute, members and work package leads from both Projects.

Mr. Abdella Kasso, Medicine Registration and Licensing Directorate Director welcomed the participants to the meeting and introduced the objectives of the meeting. He stated that the meeting was intended to introduce the objectives of the PAVIA and PROFORMA projects to the relevant stakeholders and partners.

This was followed by a key note Address made by Ms. Heran Gerba, Deputy Director General of the Ethiopian, Food, Medicine and Healthcare Administration and Control Authority (EFMHACA).On her speech, Ms. Heran mentioned that the regulatory Authority is strengthening the pre-marketing and post-marketing activities in the country. She thanked EDCTP and the partners in the consortia for the support they provided to strengthen the national Pharmacovigilance center starting March 2018. She declared the official opening of the meeting and passed her good will for the success of the program.

Day One- August 27/2018

Morning:

On the morning session of the day, Presentation was given on the available legal frameworks and tools at the national Pharmacovigilance Center, the initiatives planned to be taken by the Center were also introduced. The objectives of the meeting; which were to Conduct a joint kick off meeting and introduce the objectives of the PAVIA and PROFORMA projects and to conduct a baseline assessment on the overall pharmacovigilance system of the country there by to construct a roadmap for strengthening the national pharmacovigilance system were also mentioned in the presentation.

This was followed by presentations on Overview of the PROFORMA project, Overview of the PAVIA project and the areas of overlap between the two.

Preceding this, a general introduction on the baseline assessment process and the indicators to be used were presented.

Presentation 1
Title: Objective and Overview of the meeting
Presenter: Mrs. Tigist Dires, Clinical Trail and Pharmacovigilance team coordinator, EFMHACA

Presentation 2
Title: PROFORMA- Project Overview
Presenter: Eleni Aklillu, PhD, PROFORMA coordinator

Presentation 3
Title: PAVIA Project Overview
Presenter: Linda Härmark, PharmD, PhD, Netherlands Pharmacovigilance Centre, Lareb

Presentation 4
Title: Areas of Overlap & timelines for joint activities
Presenter: Eleni Aklillu, PhD, PROFORMA coordinator

Presentation 5
Title: Baseline Pharmacovigilance Assessment
Presenter: Jessica Maltha, MD, PhD, PAVIA Project

Afternoon:

The Afternoon session was organized for data collectors and implementers only.

The Joint baseline assessment schedule was announced. Healthcare Professionals from four selected health facilities (St. Peter TB specialized Hospital, ALERT Hospital, Bishoftu Hospital and Geda Health center) discussed the data collection tool. And, Clarification was given on the type of data required from the informants at the data collection sites.

The day's program was finalized by a closing remark from Mr. AbdellaKasso, Medicine Registration and Licensing Directorate Director, he thanked all for being present at the meeting and requested the informants to facilitate the data collection process when the data collectors visit their respective working health facilities.

Day Two- August 28/2018

Morning:

Data Collection Site:

Ethiopian Food, Medicine and Healthcare Administration and Control Authority

Key Informants:

Clinical Trial and Pharmacovigilance Team members

Afternoon:

Data Collection Site:

Ethiopian Food, Medicine and Healthcare Administration and Control Authority

Key Informants: Market Authorization Holders (MAHs).

This was done by categorizing the MAHs in to three groups.

a) Local Pharmaceutical Manufacturers

   Addis Pharmaceutical Factory (APF), Ethiopian Pharmaceutical Manufacturing Company (EPHARM), Julphar Ethiopia.

b) Muti- national Companies
   Roche, Sanofi

c) Pharmaceutical Importers and Distributors
   Eyasu Drugs and Medical Supplies importer and Distributor, DAT international PLC, ZAF pharmaceuticals PLC

Assessment at EFMHACA

Day Three – August 29/2018

Morning:

The team was divided into three groups.

One group continued the assessment at the Pharmacovigilance center at FMHACA. While the other two teams visited St. Peter TB Specialized Hospital and ALERT Hospital. The overall pharmacovigilance system in each of the hospitals including TB specific pharmacovigilance reporting was assessed as per the prepared tools.

One team visited and conducted the assessment at the Addis Ababa University.

Afternoon:

The assessment was done by three teams.

One team collected information from the National TB program. Another team conducted the assessment on the Neglected Tropical Diseases (NTD) and national Immunization (EPI) Programs.

The second team visited the Policy, Planning, monitoring and Evaluation Directorate at the Federal Ministry of Health.

Day Four – August 30/2018

The team was divided in to two groups. The Visit and assessment was conducted at Bishoftu Hospital and Geda Health center. The overall pharmacovigilance system in each of the hospitals including TB specific pharmacovigilance reporting was assessed as per the prepared tools.

Assessment at Bishoftu Hospital.

Day Five- August 31/2018

The Final day of the program was scheduled for sharing the findings of the assessment among data collectors and EFMHACA. It was a half-day session held at Elilly International Hotel.

The deputy Director General of EFMHACA, welcomed Paul Tanui, Representative from NEPAD to the session. She thanked him for joining and that the initiative could use his expertise on how to create a structured system in general.

Findings from assessing the different departments in the University, the national Medicines Regulatory Authority, the Market Authorization Holders, the National TB Program and Health facilities were presented to the plenary. This gave a wider picture as of what the pharmacovigilance situation in the country looked like.

A general recommendation was given regarding bringing together the fragmented sections of Pharmacovigilance which are found in the different available legal documents.

NEPAD representative appreciated the fact that EFMHACA is collaborating with regional countries on areas of medicines registration, which could also be extended to pharmacovigilance activities. He also mentioned since these projects are working in other countries with different Pharmacovigilance maturity levels, lessons learned can be shared. And, NEPAD will continue to support both projects.

The final closing remark was given by Deputy Director General of EFMHACA, she thanked all participants from both projects for their participation. She also stated that the findings from the assessment showed what the pharmacovigilance system looks like as a country. And, the team should take the assignment to come up with a good road map within a short period of time. She also stated that EFMHACA is ready to work towards improving the pharmacovigilance system.

Way Forward:

1. The assessing team to submit the findings report to FMHACA .
2. FMHACA to prepare a road map based on the findings.

Annex 1:

Joint Kick- off meeting Schedule

Final Schedule kick off.docx

Annex 2:

List of participants

Kick-off meeting.pdf

MAHs.pdf

Wrap-up session.pdf

Annex 3:

BLA schedule and team composition, Eth