



Food and Drugs Authority Safety Monitoring Department/National Pharmacovigilance Center

Adverse Reaction Reporting Scoreboard

Outlook of Regional Performance

The Safety Monitoring Department of the FDA publishes the Adverse Reaction Reporting Scoreboard bi-monthly to provide quantitative information on training programs and individual case safety reports (ICSRs) from the sixteen regions. The objective of this publication is to compare trends in reporting adverse reactions to drugs and vaccines and other health-related products at the regional level to enhance the diagnosis, management, and reporting of safety issues. It is expected that, the publication will help improve reporting of adverse reactions and detection of new safety signals for vaccines, medicines and other healthcare products. This edition highlights PV activities between July and August 2024.

Pharmacovigilance Training Programs

The FDA had 143 pharmacovigilance (PV) training programs between July to August 2024 in the 16 regions with a total of 3,253 participants consisting of practicing and student healthcare professionals. Figure 1 shows the performance of the regions in terms of the number of PV training programs.

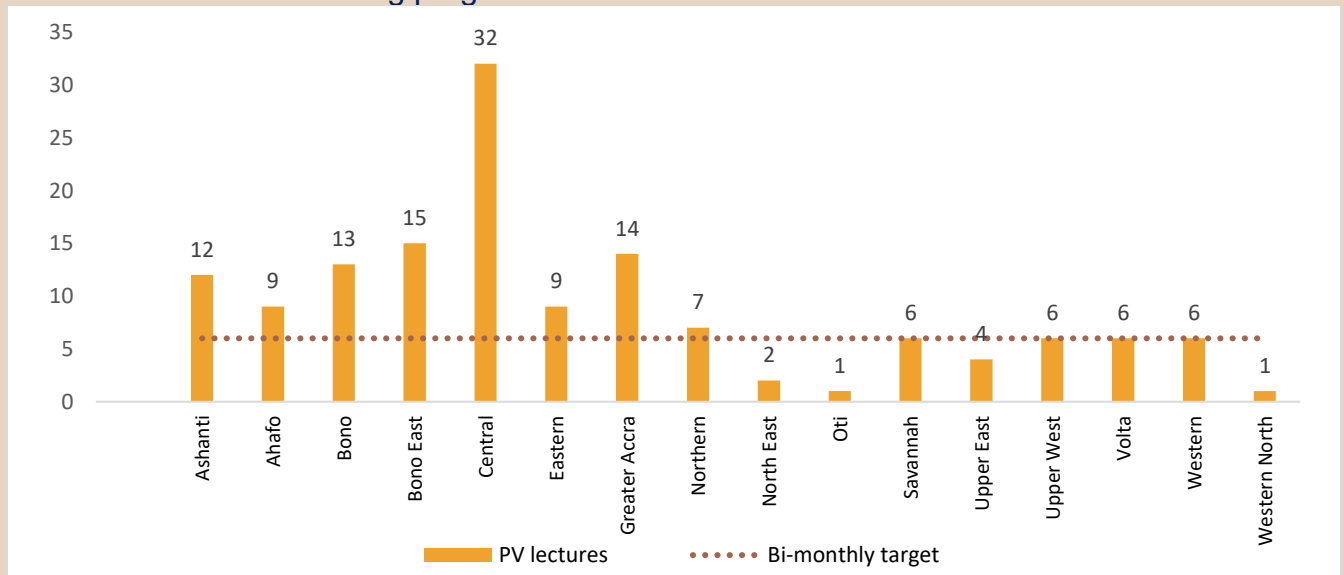


Fig. 1: The number of PV training programs organized in the regions.



Figure 2 shows the percentage of the professional backgrounds of the participants trained during the PV training programs.

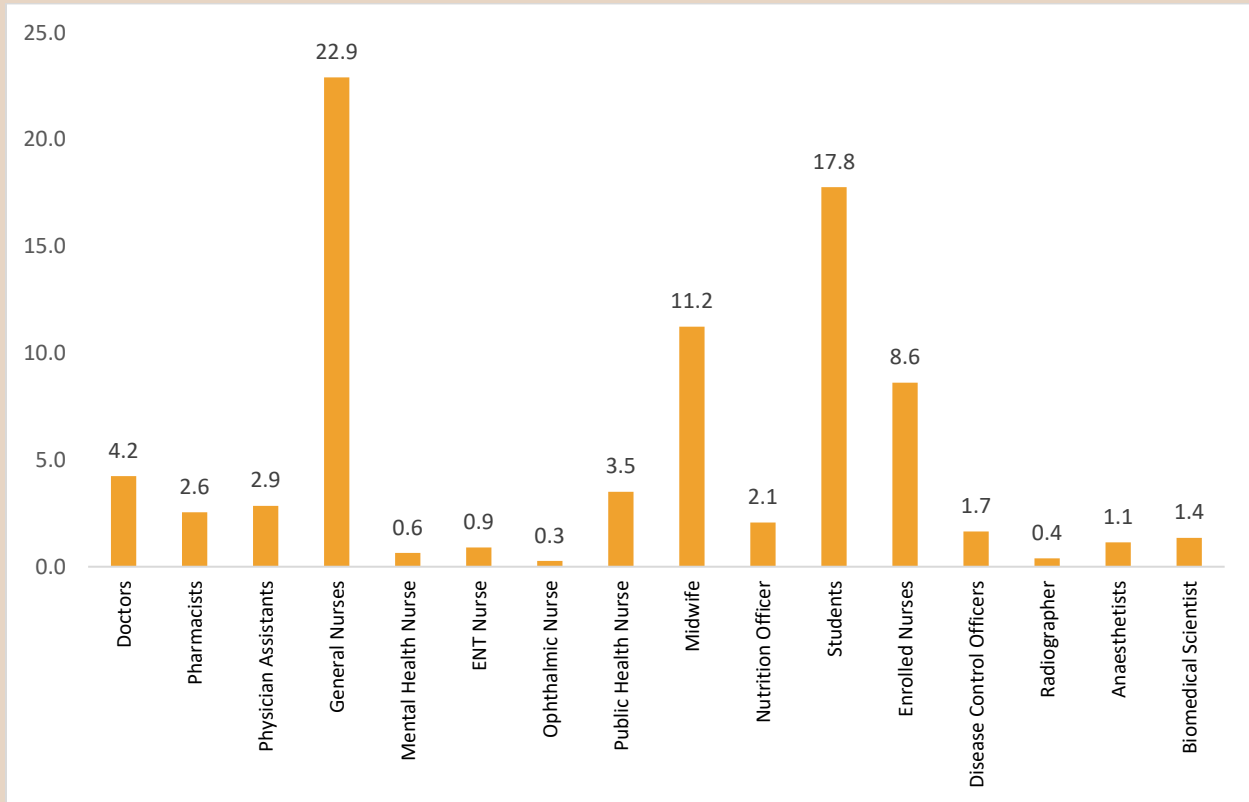


Fig. 2: Professional background of participants for the PV training programs in percentage.

Adverse Reactions Reported

Seven hundred and thirty-two (732) Individual Case Safety Reports were received for medicines, vaccines and other health products; this comprises 326 adverse events following immunization (AEFI), 6 product quality issues and 400 adverse drug reactions. The Bono East region recorded the highest absolute number of reports and a reporting rate of reports per 100,000 population as seen in figure 3 and 4 respectively.

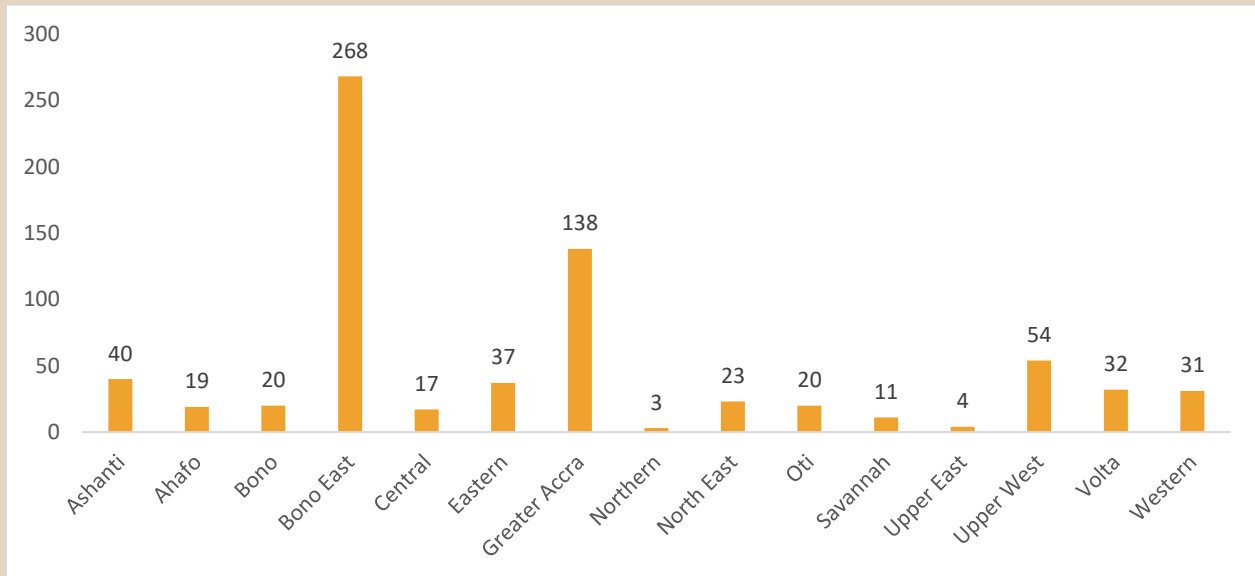


Fig. 3. Number of adverse reaction reports received in the region.

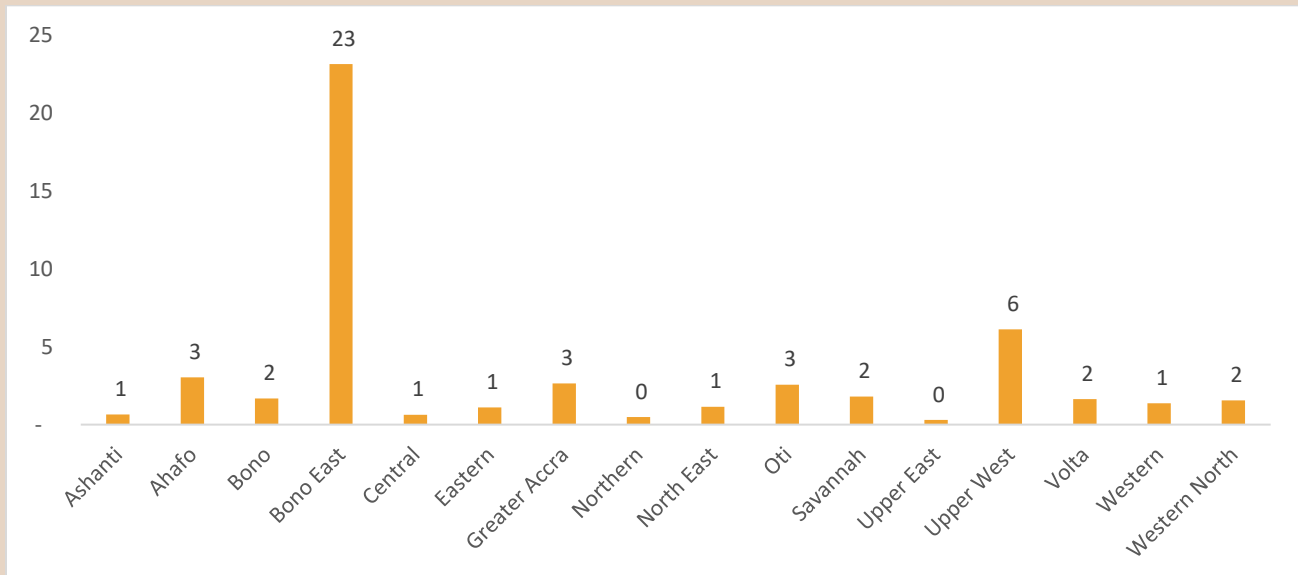


Fig. 4: Regional reporting rate per 100,000 population (2021 Population and Housing Census).

Entry of Data into the SafetyWatch System (SWS)

Figure 5 shows the total ICSRs entered into the SWS by the regional offices excluding the Greater Accra region. Central region entered the highest number of ICSRs into the system during the period under review. Regions not presented on the graph did not enter any ICSRs into the SWS during the reporting period.

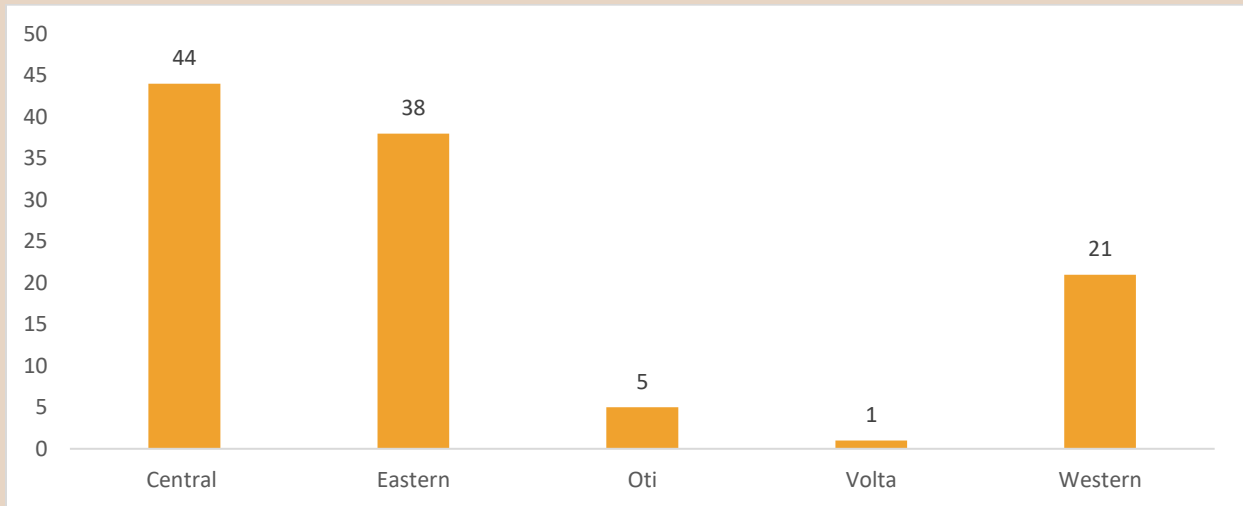


Fig. 5: Entry of ICSRs into the SafetyWatch System

You may reach out to the Safety Monitoring Department on the underlisted contacts for information on the safety of medicines, vaccines, blood and blood products, medical devices and other regulated health products:

Telephone : 024 4310 297

Email : drug.safety@fda.gov.gh