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Regardless of the efforts of a pharmaceutical company and of the US Food and Drug Administration (FDA) to identify harmful side effects prior to regulatory approval of a new drug, it is not possible to identify all such serious adverse events (SAE’s). There are many reasons for this; chief among them is the fact that the number of patients in clinical development programs of new drugs to prove efficacy are inadequate to detect rare SAE’s. It is therefore in a company’s best interest to develop a post marketing risk based monitoring plan (RBMP) of their drug as it is made available to patients through physician prescriptions after regulatory approval.

This manuscript provides information to those developing monitoring plans for SAE’s following regulatory approval of a new drug. In addition, we (1) illustrate how many patients would need to be treated in order to have high confidence of seeing at least 1 pre-specified SAE, (2) show that absence of proof of a SAE is not proof of absence of that SAE, and (3) identify statistical methodology that could be used for formal statistical monitoring of SAE’s.

“Monitoring for Adverse Events Post Marketing Approval of Drugs,” is published in the International Journal of Allergy Medications.

Dr. Karl E. Peace, professor of biostatistics at JPHCOPH and Georgia Cancer Coalition Distinguished Cancer Scholar was the lead author and Dr. Macaulay Okwokenye, alumni of the Doctor of Public Health in Biostatistics program at the Jiann-Ping Hsu College of Public Health (JPHCOPH) at Georgia Southern University was the co-author.

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