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FDA gets biomarker database license from GVK Bio

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Singapore: GVK Biosciences is extending its Clinical Biomarker Database (Gobiom) license to the Biomarker Qualification Group of the US FDA. The Gobiom database, which has the latest and recently updated information on all the biomarkers reported in various clinical and preclinical studies, will be beneficial to the US FDA in its biomarker qualification process.

Gobiom database is a comprehensive compilation of all the clinically evaluated, exploratory and preclinical biomarkers associated with different therapeutic areas reported in global clinical trials, clinical and preclinical studies.

Gobiom contains information on 20,000 biomarkers comprising of biochemical, genomic, imaging, metabolite, cellular and physiological markers, along with multiple data points comprising of experimental, analytical, clinical and statistical data with their qualifications under different medical interventions.

Mr Sreeni Devidas, VP, sales and marketing, Informatics, said that, "The collaboration with the US FDA has helped GVK BIO in developing the safety biomarker content in Gobiom. The interconnectivity between organ toxicities to the drug, dose and population was developed with equal emphasis on its preclinical qualification."

He added, "Biomarker analysis tools were integrated into the database in a manner that has facilitated the user to make a comparative analysis between the biomarkers of their interest. We look forward to continue working and collaborating with the FDA with a view to enhancing the utility of the product further."