EXTERNAL VALIDATION OF BIOINFOGATE'S OFF-X FAERS CURATION PROCESS & STATISTICAL SIGNAL EXTRACTION TO BE SUPPORTED BY INTAGE HEALTHCARE'S CZEEKV PRO

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Bioinfogate, a leading healthcare data science organization, today announced it has established an agreement with INTAGE Healthcare to perform an external validation of the methodologies used by Bioinfogate to curate information from FAERS (FDA Adverse Event Reporting System) and extract safety signals using a variety of well-established statistical methods with the CzeekV Pro database system.

Based on its longstanding experience managing and curating information from the FAERS database, INTAGE Healthcare has provided computed reports and signals from a range of drugs and treatments. These results will be used by Bioinfogate as an external validation set and as an additional quality control layer in its translational safety intelligence portal, OFF-X.

INTAGE Healthcare is the producer of the CzeekV Pro database system, offered since 2010, a curated database of FAERS and JADER spontaneous adverse reports and signals based on well-established methods used by a variety of regulatory bodies worldwide.

OFF-X is widely used by pharmacovigilance professionals in major pharmaceutical companies and biotech organizations. By fully integrating FAERS and JADER curated reports and signals into its existing pharmacovigilance functionalities and translational approach, OFF-X will offer a unique integrated view of factual safety intelligence.

About Bioinfogate

Bioinfogate is a forward-thinking, private company working to solve unmet medical needs. Our innovative data science products support the discovery and development of better and safer drugs. We are committed to building industry-leading solutions and identifying and investing in emerging projects that align with our core business in the life sciences and data analytics.

For more information visit bioinfogate.com

About OFF-X®

Launched in 2016, OFF-X® is used across pharma and biotech organizations, in leading research centers and by regulatory bodies around the world, addressing the need for new approaches to enhance safety assessments that can reduce patient burden and avoid costly failures.

The Bioinfogate OFF-X® portal provides integrated target discovery, non-clinical and clinical adverse event intelligence and pharmacovigilance insights for drugs and targets in all phases of drug R&D and post-marketing.

By delivering critical integrated target discovery, preclinical toxicity, clinical adverse event intelligence and pharmacovigilance insights coupled to advanced analytics, Bioinfogate OFF-X, allows safety liabilities to be monitored and anticipated across all phases of drug R&D and post-marketing. OFF-X is updated daily and more than 4,000 expertly curated alerts are added to the portal each week.

As of March 2021, the portal covers a range of over 15,000 targets and 21,500 drugs & biologics, and is populated with more than 1,1 million expertly curated safety alerts associated to over 10,000 adverse effects. OFF-X® is used across pharma and biotech organizations, in leading research centers and regulatory bodies.

For more information visit targetsafety.info

About INTAGE Healthcare

INTAGE Healthcare is a leading healthcare marketing intelligence and evidence provider headquartered in Japan. INTAGE Healthcare provides comprehensive pre-launch and post-launch support to meet the full range of healthcare information needs through real-world data analytics, post-marketing surveillance, and marketing research. They combine their deep knowledge of clinical practice with the INTAGE Group's abundant resources and strength in consumer insights to provide healthcare consumers, providers, manufacturers, and service companies with the information they need to make healthier decisions.

For more information visit intage-healthcare.co.jp

About INTAGE Healthcare CzeekV Pro

The INTAGE Healthcare CzeekV Pro is a system that searches the publicly available spontaneously reported adverse event database for the relationship between drugs and adverse events using statistical analysis methods.

The system integrates JADER and FAERS, and calculates and registers score values indicating the relationship between "drugs-adverse events". The score value is calculated as a statistical method to evaluate significance and adopts the same method as the world's major regulatory institutions and displays four score values.

It is also equipped with an age-specific histogram, signal distribution map, detailed statistical analysis function by age and gender, and a report list browsing function, which are useful as safety monitoring tools and analysis tools.

For more information visit pro.czeek.com