

PRESS RELEASE

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FDA AND BIOINFOGATE AGREE TO EXTEND FOR 2 ADDITIONAL YEARS THE MATERIAL TRANSFER AGREEMENT (MTA) TO PROVIDE AGENCY-WIDE ACCESS TO THE OFF-X TRANSLATIONAL SAFETY INTELLIGENCE PORTAL

The agreement aims to evaluate new approaches to enhance safety assessments of human pharmaceuticals and their associated molecular targets, supporting the FDA's mission of protecting public health.

May 12, 2021

Under this MTA, the FDA has agency-wide access to Bioinfogate's translational safety intelligence portal, OFF-X. The primary objective of the agreement is to evaluate the use of Bioinfogate OFFX™ as a research tool to anticipate adverse events associated with molecular targets, as well as with new and marketed drugs. The MTA also aims to evaluate OFF-X's utility in the regulatory review process. As the collaboration enters its fourth year, the FDA will continue to provide feedback on the utility of the OFF-X database and/or any aspects related to new functionalities.

Unexpected safety issues constitute one of the most disruptive events in clinical research. A translational approach to drug safety that integrates preclinical and clinical data can significantly reduce patient burden and avoid costly failures. In this context, it is essential to detect as early as possible in the drug R&D process the potential safety liabilities associated with new targets, drugs under development and recently marketed compounds.

About FDA CDER

FDA/CDER performs an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. As part of the FDA, CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. FDA/CDER's mission is to protect and promote public health by helping to ensure that human drugs are safe and effective, meet established quality standards, and are available to patients.

About Bioinfogate OFF-X

Bioinfogate, a leading data science organization, is the producer of the OFF-X translational safety intelligence portal. By delivering critical integrated preclinical toxicity and clinical adverse event intelligence coupled to advanced analytics, OFF-X allows safety liabilities to be monitored and anticipated across all phases of drug R&D and postmarketing. Updated daily with expertly curated safety alerts, as of May 2021, the portal covers a range of over 15,000 targets and more than 22,000 drugs & biologics, and is populated with almost 1.2 Million expertly curated safety alerts associated to 10,000 adverse effects and toxicity endpoints. OFF-X covers targets and drugs in all stages of drug R&D from emerging and first-in-class targets to drugs that have reached the market. OFF-X aims to promptly identify toxicology and safety liabilities, de-risk R&D programs and facilitate the analysis of pharmacovigilance signals. For more information please contact us at info@bioinfogate.com or visit www.bioinfogate.com.