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advancing data science for health

PRESS RELEASE

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FDA AND BIOINFOGATE AGREE TO EXTEND 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 26, 2020

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 potential use of Bioinfogate OFF-X™ as a research tool to anticipate adverse events associated with molecular targets and evaluate its utility in the regulatory review process. In addition and as the collaboration enters its third year extension, the FDA will continue to provide feedback on the utility of the OFF-X database and/or any aspects related to new functions.

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 (https://www.targetsafety.info/). 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 post-marketing. Updated daily with expertly curated safety alerts and as of May 2020, the portal covers a range of close to 15,000 targets and over 16,000 drugs & biologics, and is populated with more than 670,000 expertly curated safety alerts associated to over 8,000 adverse effects. 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 signals and de-risk R&D programs. For more information please contact us at info@bioinfogate.com or visit www.bioinfogate.com