



Third Party Terms

These additional terms apply to third party providers' data and/or software and take priority over all other terms of the agreement.

Integrity Toxicology/ OFF-X

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The OFF-X Drug Score used in OFF-X classifies the estimated strength of evidence supporting a given drug-adverse event association ("Score") based on third party evidence which includes, among others, publications, congress references and case reports ("Third Party Evidence") available in the OFF-X portal. Third Party Evidence is obtained from sources that Bioinfogate considers to be relevant and reliable, but Bioinfogate does not audit or undertake any independent verification of such sources, which are not under its control.

The OFF-X Drug Score is not an association score and does not confirm the causal relationship or frequency between a drug and an adverse event. The OFF-X Drug Score does not describe the severity of an adverse event or adverse drug reaction.

Scores are categorized by a proprietary algorithm that screens and weights the available Third Party Evidence according to several parameters previously determined by Bioinfogate. Bioinfogate assumes no obligation to update or correct the Scores or the contents of the Third Party Evidence in which such Scores are based. The Scores may contain errors and, although Bioinfogate shall not be liable for such errors, and does not assume any obligation to correct them, Users can report such errors at info@bioinfogate.com.

Scores shall be considered statements of opinion as of the date they are displayed, and not statements of fact. Scores are provided for investigation purposes (not for patient diagnosis or treatment) and shall not be relied on and are not intended to substitute the skill, judgment and experience of the User nor the need to conduct further research and/or replace clinical judgment or the need to conduct experimental studies to verify the obtained results. It is the User's responsibility to verify the accuracy, adequacy, completeness, reliability and timeliness of the relevant Third Party Evidence that supports each Score. The Scores and the Third Party Evidence shall not be used for any unlawful purpose.

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OFF-X TARGET/CLASS SCORE.

OFF-X Target/Class Score classifies the estimated strength of evidence supporting a given target-action-adverse event association ("Score") based on third party evidence which includes, among others, publications, congress references and case reports ("Third Party OFF-X Target/Class Score") available in the OFF-X portal. Third Party OFF-X Target/Class Score is obtained from sources that Bioinfogate considers to be relevant and reliable, but Bioinfogate does not audit or undertake any independent verification of such sources, which are not under its control.



The OFF-X Target/Class Score is not an association score and does not confirm the causal relationship or frequency between a target-action and an adverse event. The OFF-X Target/Class Score does not describe the severity of an adverse event or adverse drug reaction.

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OFF-X REAL-WORLD EVIDENCE.

The OFF-X Real-World Evidence (RWE) dashboard supports the validation and analysis of potential pharmacovigilance signals. THE OFF-X RWE dashboard cannot be considered as a signal detection method and does not comply with any specific pharmacovigilance regulation. It is not required by legislation and it is intended to provide an additional tool for research purposes only. The OFF-X RWE dashboard is based on third party evidence which includes curated case safety reports from the FAERS and JADER databases ("Third Party RWE"). Third Party RWE is obtained from sources that Bioinfogate considers to be relevant and reliable, but Bioinfogate shall not assume any liability arising from its use, in connection or in relation thereto, since it does not audit or undertakes any independent verification of such sources, which are not under its control. The values displayed (including among others the number of case safety reports, statistical analysis, values, etc.) do not confirm the causal relationship or frequency between a drug or class and an adverse event. The values do not describe neither the severity of an adverse event or adverse drug reaction. Case safety reports are curated and de-duplicated following a series of in-house data processes and can be different from others used by regulatory bodies, other third party solution providers or your internal organizational ones. In this context and because of the difference in the number of case safety reports, statistical values although computed using established statistical methods can be different as well.

Values and statistical results are calculated using a series of statistical methods that are applied over the curated case safety report according to several parameters previously determined by Bioinfogate. Bioinfogate assumes no obligation to update or correct any statistical result, value or the contents of the Third Party RWE in which such results are based. The values and statistical results may contain errors or inconsistencies and, although Bioinfogate shall not be liable for such errors or inconsistencies, and does not assume any obligation to correct them, you can report such errors or inconsistencies by sending an e-mail at the following address offxsubscription@bioinfogate.com

The values and statistical results shall be considered statements of opinion as of the date they are displayed, and not statements of fact. The values and statistical results are provided for investigation purposes (not for patient diagnosis



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The OFF-X RWE dashboard values are derived from the analysis of Third Party RWE, including the JADER database and the FDA FAERS database (data provided by the U.S. Food and Drug Administration available at the following website <https://open.fda.gov>).

By using the OFF-X RWE dashboard and on top of the OFF-X terms and conditions, you are accepting the following terms and conditions:

- **FDA Adverse Event Reporting System (FAERS) terms and conditions:** available at the following websites: <https://open.fda.gov/data/faers/>
- **PMDA JADER terms of use:** available at the following website: <https://www.pmda.go.jp/safety/info-services/drugs/adr-info/suspected-adr/0003.html> (courtesy English translation of the PMDA JADER terms of use available at: <https://demo.targetsafety.info/jader-terms-of-use-english-courtesy-translation>)

Translation shall not be deemed a binding version, given that the Japanese language shall be the binding language in all respects for these terms of use.

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