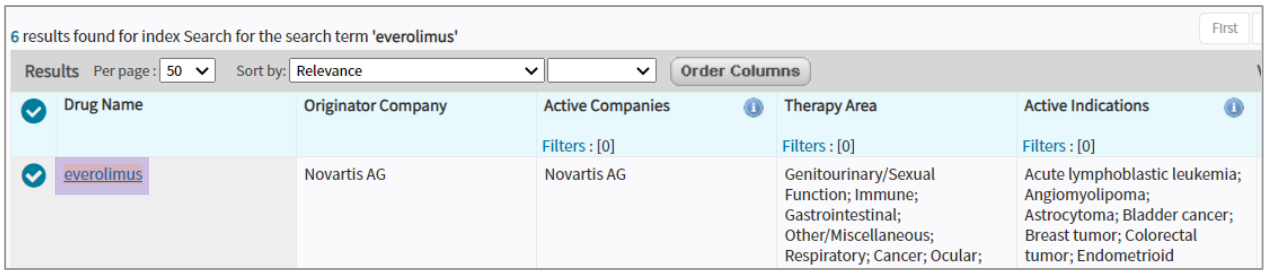
Access adverse event data to track drug toxicity and safety issues

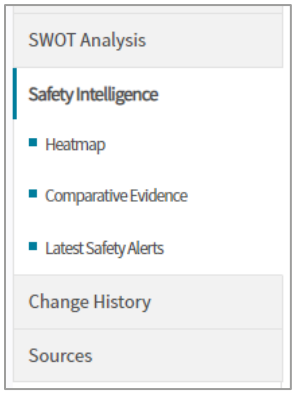
Cortellis Competitive Intelligence

Utilize actionable safety intelligence to reduce patient burden and avoid costly failures.

1. Run your search and apply filters. Open the drug report of interest.

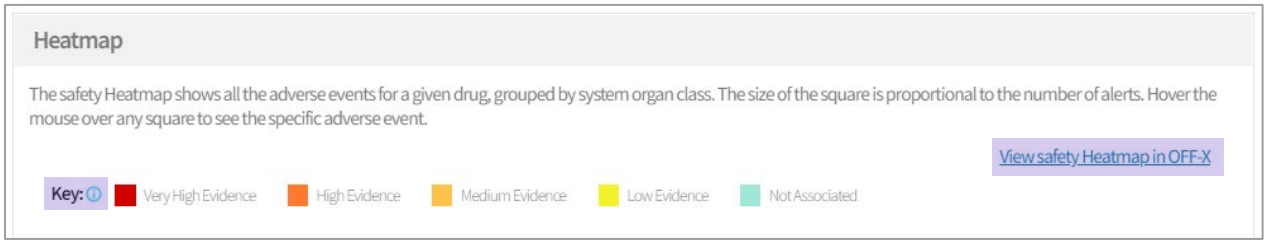


2. Select the Safety Intelligence tab near the bottom of the list.

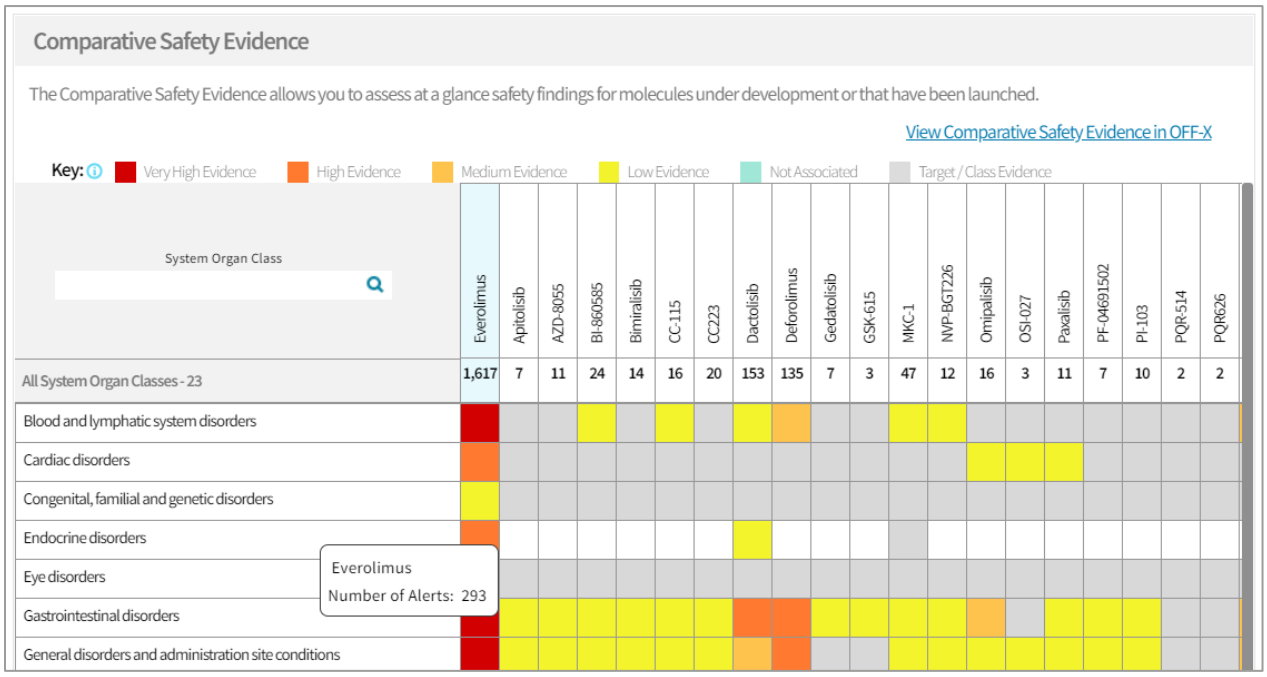


3. The safety Heatmap shows all the adverse events for a given drug, grouped by system organ class. The size of the square is proportional to the number of alerts and squares are color-coded based on the strength of safety evidence. You can hover over a square to see the specific adverse event and the number of related alerts.

4. There are also links to get more detailed information. Click **View safety Heatmap in OFF-X** to access your OFF-X subscription or to request a trial. Click the **Key** icon to learn about the OFF-X Drug Score Methodology (see Appendix for more detail).



5. The Comparative Safety Evidence allows you to assess safety findings for drugs under development or on the market. Squares are color-coded based on the strength of safety evidence. Hover over a square to see the number of alerts.



6. The Latest Safety Alerts keep you informed of the top 10 latest alerts from regulatory safety agencies for a particular drug.

APPENDIX

The **OFF-X Drug Score** aims to facilitate the exploration of factual safety insights published in OFF-X. The **OFF-X Drug Score** classifies the estimated strength of evidence supporting a given Drug-Adverse Event association based on the safety alerts available in OFF-X (more than 790,000 discrete alerts as of July 2020). The score is updated in real time as an average of over 500 alerts are added to the portal each day. Alerts are expertly curated by Bioinfogate's analysts using information from a variety of sources, including scientific publications and congresses, regulatory agencies, clinical trial registries and company communications. The **OFF-X Drug Score** is powered by Bioinfogate's **unique curated data pool** and an **advanced rule-based algorithm** that screens and weights all the individual pieces of evidence available in OFF-X. The weighting score considers the following parameters:

1.**Number of alerts** reporting a given drug-adverse event association, considering also the proportion of drug alerts with this association

2.Type(s) of **primary source** where each piece of evidence has been reported (regulatory agency, congress, journal publication, etc.)

3.**Type of study** reported (meta-analysis, clinical study, retrospective study, case report, etc.)

4.**Level of evidence** associated to each individual alert (confirmed, suspected or refuted) as determined by Bioinfogate's editorial guidelines

5.**Development phase** where the adverse event has been reported (discovery, preclinical studies, clinical studies or postmarketing)

The OFF-X score considers contradictory alerts for a given Drug-Adverse Event association published in the portal. Given the above, the estimated strength of evidence supporting a given Drug-Adverse Event association (based on content published in OFF-X) can be labeled as:

Very High Evidence
When there is confirmatory evidence from a regulatory body supporting a Drug-Adverse Event association and there are multiple reports from other sources supporting it.

High Evidence
When at least one regulatory body has reported evidence supporting a Drug-Adverse Event association or, in the absence of communications from regulatory bodies, the evidence is supported by a significant number of publications from other data sources.

Medium Evidence
When the evidence supporting a Drug-Adverse Event association has been reported in several data sources or is under review by a regulatory agency.

Low Evidence
When some preliminary evidence supporting a Drug-Adverse Event association has been reported either in humans or during preclinical studies.

Not Associated
When there is evidence that refutes a Drug-Adverse Event association.

Target/Class Evidence Only
When only class alerts are available for a given adverse event and the drug of interest was not explicitly mentioned in the data source(s). This score label also includes alerts associated to target genetic studies / mutations.

OFF-X Score algorithm version 2.2 (released July 1st, 2020)

IMPORTANT DISCLAIMER

OFF-X Drug Score 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 undertakes 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 by emailing **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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