



Translational safety intelligence

Leverage class safety intelligence to anticipate adverse drug reactions and mitigate safety liabilities for drugs across all phases of R&D and post-marketing.

OFF-X™ helps you de-risk your patient safety and pharmacovigilance programs:

- Benchmark daily updated drug safety profiles of investigational, launched and discontinued products grouped by target classes to enable pro-active pharmacovigilance. (See Figure 1)
- Enable mechanistic deconvolution of unexpected safety findings to support de-risking strategies.
- Assess and validate safety signals from FAERS/JADER leveraging contextual safety intelligence for both drugs and target classes. (See Figure 2)
- Analyze the role of concomitant medications on Suspected Unexpected Serious Adverse Reactions (SUSARs).

**Signal detection
and assessment
driven by
translational safety
intelligence
and analytics.**

Figure 1: Comparative drug safety by target class.

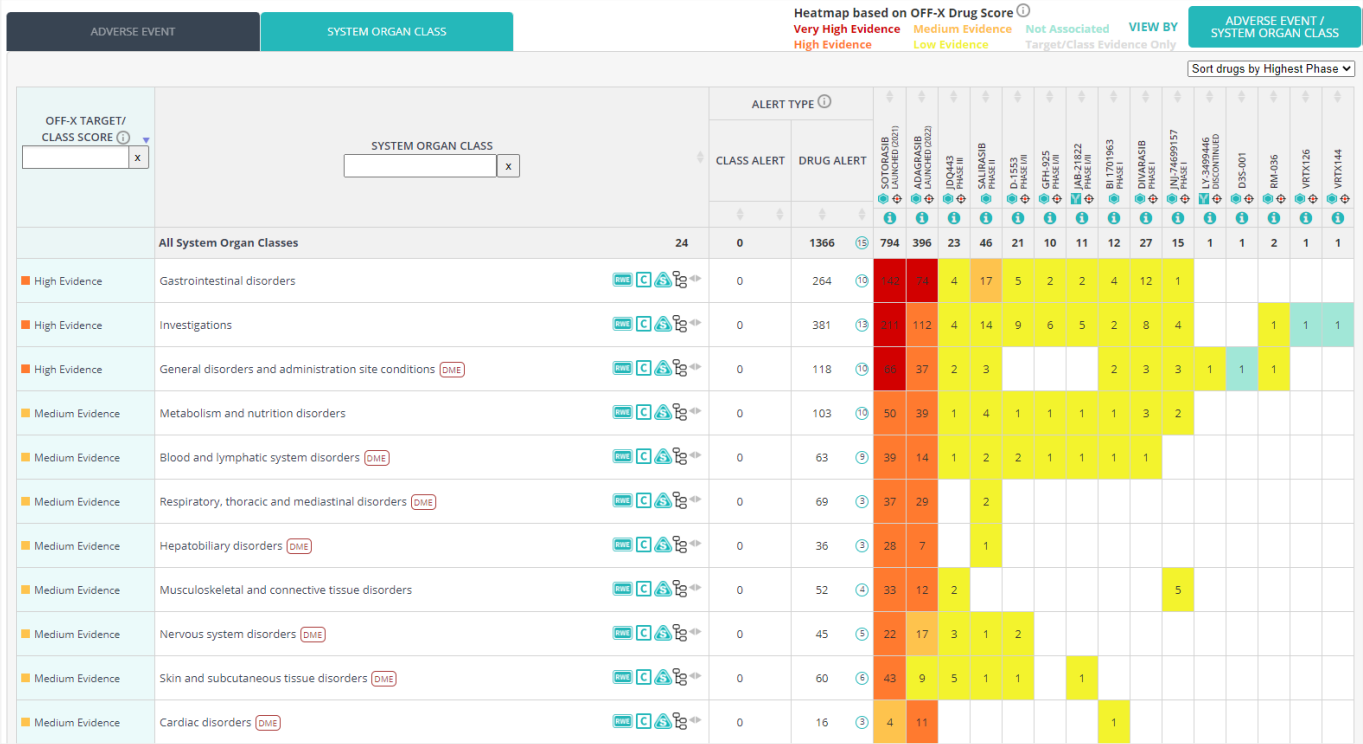
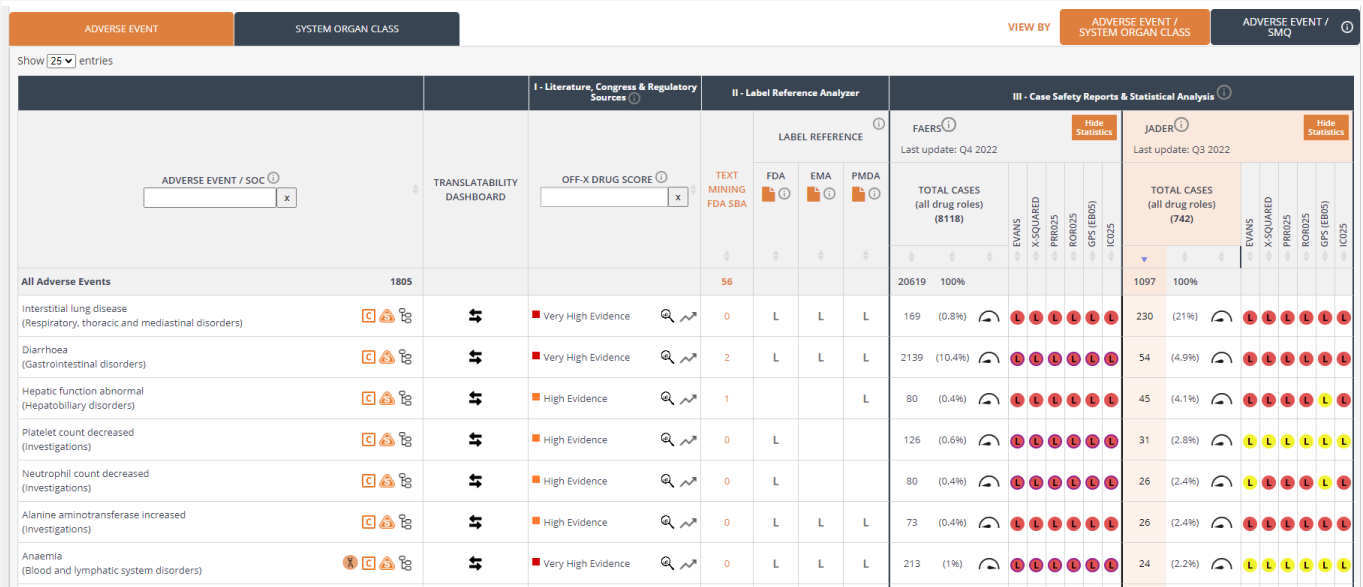


Figure 2: RWE dashboard correlating FAERS/JADER signals with curated safety data.





OFF-X empowers pharmacovigilance workflows with unique and unrivalled high quality curated data to:

- Save time searching and compiling safety data for signal assessment, the preparation of aggregated reports and comprehensive responses to health authorities' requests
- Explore data faster with unmatched visualization capabilities e.g. comparative safety tables, RWE dashboard, translatability dashboard, drug label comparison
- Keep up with critical safety information impacting your assets with daily updates (including label changes and announcements of clinical holds due to serious adverse events)
- Access expertly curated data from a broad range of sources including journal articles, conferences, company communications, clinical trial registries, regulatory documents and FAERS/JADER.



OFF-X provides unique value to pharmacovigilance workstreams with:

- Unique target class approach helps you anticipate risks for drugs in early clinical development based on other members of the class
- Assessment and comparison of the safety profile of drugs and classes with specific patient populations and conditions
- Seamless navigation and integration of a broad range of critical data sources reducing time to answers
- Better safety insights with advanced analytics and visualization tools.

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