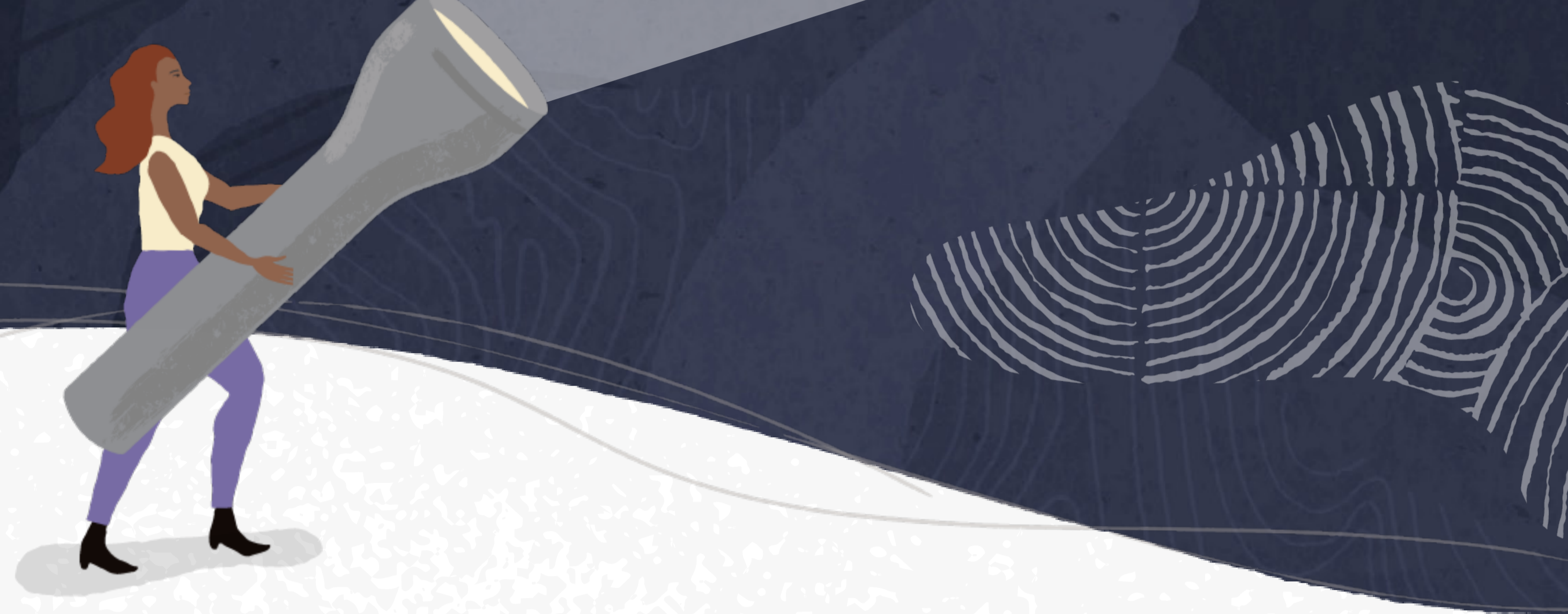


Safety One

Detect risks earlier, automate processes, and increase compliance with unified multivigilance



DETECT EARLY



- Detect safety signals early in Argus, WHO/UMC VigiBase, FDA FAERS, FDA VAERS, PMDA JADER, and other data with **Empirica Signal**
- Prioritize and manage your signals with **Empirica Topics** to avoid recalls, lawsuits, regulatory penalties, and inspection findings
- Empower your business users with immediate insights into operational risks and patient data in **Oracle Analytics**
- Accelerate your case processing with **Safety One Intake**, allowing downstream aggregate analysis and periodic reports to run sooner

AUTOMATE PROCESSES



- Harness the AI power of **Safety One Intake** to automatically structure and ingest your source documents, significantly easing the pressure of increasing caseloads
- Optimize your case management workflow using built-in features in **Argus** to automate routine steps and reduce manual work, cutting down your processing times in half
- Reduce the amount of work for your signal evaluators in **Empirica** by employing a smart user interface and algorithms that curtail false positives
- Bring down your total cost of ownership with the **Safety One Platform** – integrating Argus, Empirica, Oracle Analytics, and Safety One Intake for end-to-end multivigilance in a SaaS model

INCREASE COMPLIANCE



- Ensure global compliance with **Argus** for your aggregate and expedited reporting via E2B(R3), E2B(R2), eVAERS, eMDR(R2), MIR, and more
- Move cases through your workflow twice as fast with **Safety One Intake**, expediting on-time ICSR delivery to health authorities
- Employ **Empirica** to comprehensively fulfill signal management regulations such as EU GVP Module IX Rev 1 and CIOMS VIII
- Use the **Safety One Platform** to comply with HIPAA, 21 CFR Part 11, and multivigilance requirements for pre- and post-market drugs, biologics, vaccines, devices, and combination products

PERFORMANCE AT A GLANCE

#1

in safety case management with **Argus** and in safety signal management with **Empirica** means less risk for you as a customer

3 OUT OF 5

companies use **Oracle safety software**

90%

increased efficiency using **Safety One Intake** together with **Argus** automations

140+

new **Oracle safety customers** in the last 3 years

300+

years of experience in the **Oracle safety team**

1400+

Oracle Safety Consortium members

Safety One Platform Innovative evolution via data science

Industry challenges

- Growing case volumes
- Many low-value cases
- Mining multiple datasets
- Manual workflow
- Signaling accuracy
- Business continuity
- Resource allocation
- Managing CRO quality
- Regulatory compliance
- Protecting patients



Business benefits

- Reduced costs
- Improved efficiency
- Improved data quality
- Better user experience
- Optimized resourcing
- Higher compliance
- Greater insights
- Earlier signals
- Precision PV
- Safer products

Next-generation solutions for pharmacovigilance and multivigilance

Discover how Oracle is improving safety by driving greater insight, efficiency, and compliance in case management and signal management.

oracle.com/safety >

