Safety One

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

PLATFORM 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

120+ Oracle safety customers in the last 3 years

3 out of 5 companies use Oracle safety software

300+ years of experience in the Oracle safety team

50% reduction in overall case processing time with Safety One Intake

750+ Oracle Safety Consortium members

DETECT EARLY

Detect safety signals early in Argus, WHO/UMC VigiBase, FDA FAERS, FDA VAERS, PMDA JADER, and other data with Empirica Signal

Empower your business users with immediate insights into operational risks and patient data in Argus Enterprise Edition using powerful, flexible analytics

Prioritize and manage your signals with Empirica Topics to avoid recalls, lawsuits, regulatory penalties, and inspection findings

Accelerate your case processing with Safety One Intake, allowing downstream aggregate analyses and periodic reports to run sooner

AUTOMATE PROCESSES

Harness the AI power of Safety One Intake to automatically structure and ingest your safety source documents, significantly easing the pressure of increasing case loads

Optimize your case management workflow using built-in features in Argus to automate routine steps and reduce manual work, cutting down your processing times by 50%

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 need for case ownership with Safety One—integrating Argus, Empirica, 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

Employ Empirica to comprehensively flag signal management regulations such as EU GVP Module IX Rev 1 and COCOS VIII

Move cases through your workflow twice as fast with Safety One Intake, expediting on-time ICSR delivery to health authorities

Use Safety One to comply with HIPAA, 21 CFR Part 11, and multivigilance requirements for pre- and post-market drugs, biologics, vaccines, devices, and combination products

SAFETY ONE

offers the industry’s broadest platform of integrated systems and workflows to drive greater compliance and data insight while automating processes

For more information visit oracle.com/safety-one

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