Safety One

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

**DETECT EARLY**
- 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 aggregators and periodic reports to run sooner
- Detect safety signals early in Argus, WMS/CAC Suspense, ODA, FDA TAPS, FDA NDAX, PINDA JAVEX, and other data with Empirica Signal

**AUTOMATE PROCESSES**
- Reduce the amount of work for your signal evaluators in Empirica by simplifying a user interface and algorithms that prioritize positives
- Harness the AI power of Safety One Intake to automatically structure and ingest your 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%
- Bring down your total cost of ownership with Safety One Intake, integrating Argus, Empirica, and Safety One Intake for workflow-to-end multivigilance in a SaaS model

**INCREASE COMPLIANCE**
- Prioritize and manage your signals with Empirica Topics to avoid recalls, lawsuits, regulatory penalties, and inspection findings
- Detect safety signals early in Argus, WMS/CAC Suspense, ODA, FDA TAPS, FDA NDAX, PINDA JAVEX, and other data with Empirica Signal
- More cases through your workflow twice as fast with Safety One Intake, expediting on-time ICIS delivery in health authorities
- Use Oracle Safety One to comply with HIPAA, 21 CFR Part 10, 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 for your aggregate and expedited reporting via E2W2S, 21 CFR 803, 21 CFR 804, 21 CFR 807, 21 CFR 812, and others
- 140+ new Oracle safety customers in the last 5 years
- 300+ years of experience in the Oracle safety team
- 1200+ Oracle Safety Consortium members
- 50% reduction in overall case processing time with Safety One Intake

**Safety One**

Offers the industry's broadest platform of integrated systems and workflows to drive greater compliance and data insights while automating processes