

Argus

Trusted safety case management

SOLUTION BRIEF

With caseloads inflating by 30–50% annually and regulations undergoing continuous change, efficient case management and maintaining compliance are important concerns. What if you could address these concerns while also reducing the manual effort of your safety and pharmacovigilance team by 50%?

Maintain safety compliance

A case management solution forms the cornerstone of any multivigilance system—it is the central location for documenting all data about adverse events including source documents, follow-up information, coding, assessments, and regulatory reports, and it's the single source of truth for downstream aggregate analytics and signal detection. You can depend on Oracle Argus Cloud Service (Argus), a mature, reliable solution providing proven compliance with drug, vaccine, and device regulations in all regions of the world, including E2B(R3), E2B(R2), eVAERS, eMDR, and IDMP. Argus' market leadership and its ever-growing customer base gives sponsors, manufacturers, and CROs confidence that it's the right choice for companies of any size in any country.

Reduce manual work

Argus offers “case form helpers” such as auto-complete, field filtering based on report type, coding browsers, validation flags, and context-sensitive help, which accelerate case processing while ensuring accurate data capture. A special medical review screen summarizes relevant case information in one place to help you make assessments faster. Built-in automation features—for intake, case prioritization, field validations, letters, action items, coding, listedness, narrative, case lock, submission, and archiving—can reduce manual work by 50% or more.

“We were looking to have the best software solution from a leader in the pharmacovigilance industry. Being a world-renowned brand, Oracle Argus is that leader. In that respect, the product's reputation inspires confidence from our clients.”

DR. YATHENDRA MADINENI
CEO
4C PHARMA SOLUTIONS LLC

Argus is the market-leading solution for processing, analyzing, and reporting adverse event cases originating in pre-and post-market drugs, biologics, vaccines, devices, and combination products.

Match the needs of your business

When it comes to managing safety, business needs can vary and generate new requirements. Argus is designed to scale to meet your needs. Whether you just need single case processing with expedited and periodic reporting, or powerful analytics, or support for Japan's PMDA compliance, Argus has you covered. In addition, Argus has out-of-the-box integrations for leading safety case intake, signal detection, and clinical trial solutions.

Lower costs by choosing the cloud

With our software-as-a-service (SaaS) cloud, you can relieve pressure on IT while lowering your costs. Compared with on-premise solutions, Argus includes services that you don't have to do yourself, such as management of the application, dictionaries, platform, and infrastructure. Compared with third-party hosted solutions, you don't have to pay extra for those services and only have one vendor to manage. And, with Argus, it's all in a cloud you can trust—secure, private, and certified for protected health information.

Feel confident and assured

Argus provides proven compliance with continuously changing worldwide regulations. Its built-in automations, integrations, and usability significantly reduce manual work and maximize efficiency. And, its field validation features help ensure that data quality is kept to a high standard. Argus delivers end-to-end, scalable, and secure case management in the cloud and serves as the core foundation for your safety solution landscape.

About Oracle Health Sciences

As a leader in Life Sciences cloud technology, Oracle Health Sciences' Clinical One and Safety One are trusted globally by professionals in both large and emerging companies engaged in clinical research and pharmacovigilance. With over 20 years' experience, Oracle Health Sciences is committed to supporting clinical development, delivering innovation to accelerate advancements, and empowering the Life Sciences industry to improve patient outcomes. *Oracle Health Sciences. For life.*

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“Oracle Argus enabled greater and faster insight into product safety, improved productivity, and streamlined and automated safety reporting. Acorda is committed to patient safety, and the Oracle Argus platform helps us maintain high compliance standards.”

THOMAS AQUILINA
VP, DRUG SAFETY & RISK MANAGEMENT
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