PHARMASOL
enabling excellence

WHITE PAPER
Argus rapidLIVE

argus safety rapidlive - enabling a ready to use argus implementation

An effective Pharmacovigilance system is essential for pharmaceutical and biotech companies with products in development or on the market, as well as for CROs offering services to these businesses. At the center of such a system is the safety database, which collects all adverse event reports. Argus Safety from Oracle is the industry leading solution for safety databases, but implementing the system can be an arduous process. Custom configuration typically takes more than one year and significant investment. Each companies' specific requirements must be defined, implemented and validated.

The rapidLIVE approach

After the success of Oracle Clinical rapidLIVE, a pre-configured Clinical Data Management system, pharmasol challenged the traditional implementation model of safety databases. The result is Argus rapidLIVE. Major components of a traditional Argus Safety implementation that previously took months to develop, configure and validate, are now preset, based on industry best practice, and are ready to use.

The rapidLIVE workflow

Argus Safety offers the opportunity to develop tailor-made workflows for case processing. Argus rapidLIVE comes with an industry-best practice workflow consisting of Data Entry, Medical Review, and Reporting.

The rapidLIVE access management

Argus rapidLIVE provides user and group access management that are aligned with the rapidLIVE workflow and include:

- Data Entry Group Record new cases and enter all relevant case information.
- Medical Review Group Evaluate cases with regards to seriousness, expectedness, and causality and provide a comprehensive narrative based on the data entered.
- Report Group Transmit cases to relevant authorities and license partners.
- Admin Group Configure products and licenses, clinical trials, and users.
- Guest Group Provide colleagues not directly involved in case processing readonly access to cases.

The rapidLIVE auto-narrative

One of the biggest tasks during the processing of an Adverse Event Report is the creation of a comprehensive narrative that is consistent with the information provided in the case. Argus rapidLIVE supports the Medical Reviewer by automatically creating a narrative, incorporating the relevant information from the case. This frees up the reviewer to concentrate on the medical assessment.

The rapidLIVE training

Comprehensive Training is part of any rapidLIVE offering. The core Argus Safety functionality is integrated with the pre-configurations and workflow in the Argus rapidLIVE training. Users learn about the system through instructor-led demos and hands on exercises, resulting in much better system acceptance at Go-Live.

The need:
Argus Safety offers many options that require configuration prior to implementation.

The solution:
pharmasol developed the Argus Safety rapidLIVE package, incorporating industry best practice to provide a ready-to-use Argus Safety system, including validation documentation.

The benefit:
Small and mid-sized companies in need of a safety solution implement Argus Safety rapidLIVE in less than 4 months, saving time, money and effort.

> "We continuously update our Argus rapidLIVE package to meet the challenges of a changing regulatory landscape"

Cheryl James
--
Director, Pharmacovigilance

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The rapidLIVE validation

The Validation of a safety database can be a burdensome activity. With Argus rapidLIVE, pharmasol provides a complete set of validation documentation, which has successfully passed multiple inspections and audits for our customers. There is no need to create documentation from scratch. You just execute the Argus rapidLIVE scripts.

Adjusting rapidLIVE

With every Argus rapidLIVE implementation pharmasol offers a consulting package to adjust Argus rapidLIVE to your specific needs. As our consultants have many years of experience in Pharmacovigilance and Argus Safety, we can recommend industry best practices for all of your issues.

The rapidLIVE support

Based on our implementation experience, we know that the true Argus experience at your company starts only after Go-Live. Therefore our Argus rapidLIVE package includes 3 months of free support by our experts to help you over the first bumps in the road to high performance.

The rapidLIVE Multi-Tenancy set-up

With the latest release of Argus rapidLIVE, the multi-tenancy option of Argus Safety comes pre-configured, allowing CROs to have comprehensive oversight across their client databases whilst maintaining data integrity through separation of data by sponsor.

The rapidLIVE license

As an Oracle Gold partner, pharmasol can provide you with the required licenses tailored to your Argus rapidLIVE environment.

The rapidLIVE virtual machines

Argus rapidLIVE includes three environments: Development, Validation, and Production. All environments are easily rolled out with fully installed and configured virtual machines based on VMware. The environments are populated with validation seed data to kick-start training and validation tasks.

The pharmasol Life Science Data Center

Argus rapidLIVE can be easily deployed at your company. But if you do not have the resources to deploy a Pharmacovigilance database, pharmasol will host Argus rapidLIVE for you.

At Pharmasol, we know that many hosting providers are not aware of our industry specific regulations. Therefore we offer hosting services through our Life Science Data Center, located in Germany. It was designed and is maintained to comply with regulations like 21 CFR Part 11.

The rapidLIVE benefits

The Argus rapidLIVE implementation package provides all the components a small or mid-sized pharmaceutical, biotech or CRO needs to set up Argus Safety, saving time, effort and money compared to a traditional approach.

> “After our success with Oracle Clinical rapidLIVE, we are proud to provide a comprehensive package making Argus Safety ready to use.”

Torsten Adam
--
CEO

A pharmasol PV white Paper **Argus rapidLIVE**

For More Information

To learn more about pharmasol services or software solutions, please contact info@pharmasol.de or visit www.pharmasol.de

pharma solutions international GmbH
Lothringer Dell 27
67659 Kaiserslautern
Germany

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