

Oracle® AERS Services from CSS Informatics

CSS Informatics is the most established drug safety software consulting practice in the industry with more than sixteen years of continuous innovation and support. Our team of well-educated, industry-proven experts has a consultant average of ten years of pharmaceutical technology experience.

We are privileged to call many top twenty pharmaceutical companies our clients and have served small and mid-sized companies equally as well. In fact, almost 150 pharmaceutical and biotech companies on five continents have found successful solutions through our consulting services since we began in 1990. And, as a division of the billion-dollar CRO PPD, Inc., we have stability and staying power.

We began consulting with Oracle AERS shortly after Oracle acquired EventNet in 2002. Since then, CSS Informatics has provided implementation, training, data migration, validation, and hosting services to dozens of Oracle AERS clients in the U.S. and Europe. Today, while others promote their past role in developing this software, CSS Informatics is proud that we're making it better!

The CSS Informatics Suite of Oracle AERS Services

We believe we offer the most comprehensive set of Oracle AERS services available from one company. Every service listed below represents actual expertise that we've gained from real client projects.

Oracle AERS Installation and Configuration

CSS Informatics has successfully completed a number of Oracle AERS installations. These range in nature from production client systems, to hosted environments, to our own internal infrastructure. We are confident when we say that the breadth of our Oracle AERS implementation experience is comparable to few others.

Oracle AERS Training

We were a leader in pharmaceutical software training long before Oracle AERS was on the scene. Even today, we provide regular AERS training at client facilities throughout North America and Europe. In fact, we have trained almost 4,000 users on Oracle's Life Sciences applications alone. Rest assured that our Oracle AERS material is current, comprehensive, and client tested.

Oracle AERS Data Migration

Since 1995, CSS Informatics has migrated more than 100 clinical and safety data environments. Our proven, proprietary tool, [TableTrans®](#), helps accelerate the mapping and source code generation process. And, yes, we've done more than a dozen data migrations around Oracle AERS. We can help.

Oracle AERS Validation

It's not enough to install Oracle AERS and know how to use it. Regulations require this application to be validated and CSS Informatics has been validating drug safety systems for almost fifteen years. Plus, we have existing, project-ready validation packages for Oracle AERS that have been proven and refined by numerous engagements.

Oracle AERS Services (continued)

Oracle AERS Hosting

By tapping into PPD's multi-million dollar, global IT infrastructure and data centers, CSS Informatics has built the largest, independent Oracle Life Sciences (OLS) hosting service in the world. We are Oracle's Preferred Provider for OLS hosting and we've consistently proven our value and reliability. Even if your company doesn't need hosting services, you can rest confident that the experience we've gained through our hosting business will bring additional value to your Oracle AERS project.

Oracle AERS Staff Augmentation

As experienced resources become harder to find or internal budgets restrict new headcount, CSS Informatics has been pleased to provide full- and part-time staffing solutions. Our professionals are the same skilled consultants that we would provide for project resourcing. We have active staffing engagements on both the east and west coast of the U.S. and references are available upon request.

Oracle AERS Enhancements

Even Oracle AERS doesn't do everything. There are no shrink-wrapped, push-button data migration scripts. For that we provide [TableTrans@](#).

And, while Oracle AERS generates an E2B file nicely, it doesn't provide gateway or web-browser software to transmit ICSRs and monitor their status. For that we offer our [E2B ICSR Browser](#).

Finally, there are custom reports, triggers, and data checks that take time and experience to work through properly. And for that we offer our people – the most valuable resource we have.

Oracle TMS Expertise

As a natural extension of our Oracle Clinical consulting practice (which pre-dated Oracle AERS), CSS Informatics provides support, training, dictionary upgrade, and auto-coding analysis for Oracle TMS. In 2003, we built an automated MedDRA Version Analysis and Upgrade system for a major Hopewell, NJ client. This system allows them to analyze the impact of new MedDRA versions on their drug safety, clinical trials, and supplementary systems (including Oracle TMS) and then automate the upgrade process for the centralized dictionary environment. It is this same creativity, software development expertise, and ability to deliver that we can bring to your project.

Summary

With CSS Informatics, you're not just getting our Oracle AERS expertise. You're benefiting from sixteen years of experience with every major drug safety system in the world! There are different ways of solving the same problem and consulting firms without our range of experience offer limited perspectives. Sure, we've developed a major drug safety application too. But we've moved on. There are better ways to do things now and CSS Informatics is leading the way.