PROBLEM STATEMENT
A CRO needed to rapidly and cheaply implement a new safety database to support processing of clinical and post marketing adverse events on behalf of a sponsor. The CRO needed to access the new system from safety offices in the US and Europe. The business drivers were as follows:

• A new sponsor contracted the CRO for adverse event processing
• Increase compliance and user productivity by implementing a commercial safety system to replace manual processes and an insufficient custom system
• The workflows at the two user sites were disjointed
• The old system did not support e2b submissions
• The old system’s maintenance cost was high and to it was a major overhead to add a new sponsor database

SOLUTION
Foresight employed our proven Argus FastTrack methodology to implement Oracle Argus Safety within 90 days.

Foresight’s involvement started with a buy versus build analysis where the business needs of the CRO were analyzed and all major off the shelf drug safety systems were analyzed. As a result of this analysis Oracle Argus Safety was chosen to be implemented at the CRO. Foresight performed the following tasks during the 90 day implementation phase:

• Business workshops were quickly conducted with end users to refine the business requirements/processes such as user sites, products, clinical studies, workflow etc. Foresight’s standard configuration baseline document (CBD) was updated based upon the workshops
• The Foresight team assisted the CRO IT operations team with infrastructure planning for the development, validation and production environments
• Oracle Argus Safety was installed in the development environment and trainings were conducted for the business and IT users on the system and EudraVigilance submissions
• A web portal was created to insert e2b header in the Argus generated e2b XML file to make the file EudraVigilance submission ready. This was required as the CRO did not intend to implement Argus Interchange for electronic submissions during Phase I due to budget constraints.
Oracle Argus Safety FastTrack Implementation

SOLUTION, CONTINUED

• A new business process was defined for EudraVigilance submissions.
• The defined configuration was applied in the development environment for verification and dry runs.
• The vendor provided IQ scripts were dry run and rapidly modified by Foresight for the CRO’s needs.
• Based upon the business requirements a subset of the vendor provided OQ scripts were selected for the validation. Foresight assisted the client to develop PQ scripts for critical business scenarios.
• Foresight installed and configured the validation environment. The validation scripts were executed in this environment and a validation summary report was prepared.
• Trainings on Argus Safety usage for business users and on administering and maintaining the web server & database targeted specifically for the IT users were conducted.
• A repeatable business/IT process to add a new sponsor was defined.
• The production environment was installed and configured. Post go live support was provided for 2 weeks.
• Subsequently the client engaged Foresight to provide post-production level 2 support on a retainer basis

RESULTS ACHIEVED

By using Foresight Group’s Argus FastTrack methodology, the Oracle Argus Safety system was successfully implemented at the CRO within 90 days. The following results were achieved:

• A global workflow was defined for the CRO so that users in US and Europe could collaborate seamlessly
• Enhanced features implementation and detailed trainings lead to improved productivity by business users
• EudraVigilance submissions were enabled through the custom portal
• The process to add a new sponsor database lead to huge cost and time savings for the CRO

About Foresight
Foresight Group International AG is a global management and technology services company focused exclusively on clinical and post-marketing drug safety and surveillance. We offer a full range of services with experienced pharmacovigilance experts in every major PV market in the world: North America, Europe, India and Japan. Our best-in-class partnership with Oracle for the implementation of Oracle Argus Safety Suite coupled with our deep expertise in drug safety lets Foresight offer clients the most comprehensive pharmacovigilance services and solutions available in industry today. All of our services and solutions are delivered with precise, timely and cost-effective execution to help our clients achieve and sustain regulatory compliance and manage risk.

To learn more about Foresight, visit www.foresightgroup.com.

Core Services including:
• Safety System Implementation
• Data Migration
• PV Process Analysis, Design, Optimization & SOP Creation
• Compliance Monitoring & Improvement
• Safety Data Mart Implementation & Custom Report Development
• Labeling and Packaging
• Inspection Preparation and Response (CAPA)
• Clinical EDC & Safety Database integration
• Validation

Our People
• Experienced (average 8+ yrs)
• Know drug safety processes & systems
• Program managers
• Analysts and architects
• Developers and testers
• Healthcare professionals