

Foresight Group International AG provides a full range of services to implement and sustain best practice safety and risk management operations world-wide. With over 200 employees in North America, Europe, India and Japan we are the largest professional services firm in the world focused exclusively on drug safety and risk management. All of our services are available in both English and Japanese.

Implementation Services

Foresight provides a full range of implementation services including program management, requirements, design, configuration, installation, interfaces, data migration, custom reports, validation, training and deployment services.

Safety Database Implementation & Upgrades - Foresight has extensive experience with implementing both Argus Safety™ and Aris Global. We've performed more than 50 implementations for small to large companies. Our Argus *FastTrack* methodology can have you up and running in as little as 90 days.

Argus J - Foresight is the world leader in the implementation of Argus J for companies requiring either a single global integrated safety database or a standalone system for Japan. We have designed the Global-Japan business process for 8+ top 50 companies, went live with the first implementation of Argus / Argus J with E2B reporting to the PMDA in December 2013, followed by going live with two more Argus / Argus J implementations in 1H 2014 and four more implementations in process. We have 30+ bi-lingual (English and Japanese) employees world-wide with Argus J experience.

Data Migration - Foresight has performed over 50 data migrations ranging from 3,000 to over 3 million cases, including eight migrations from Japanese data sources (e.g., Perceive, ARISj). Our unique and proven methodology leverages our proprietary PV Data Migration Engine with pre-existing mappings and program logic for migrations to/from Argus, Argus J and Aris Global to reduce delivery timelines, implementation costs and insure high quality.

Custom Reports - We are experts in implementing commercial safety data marts, including the ETL and universe/model extensions required for successful implementations. Our employees are experts in creating custom reports in Business Objects, Cognos and OBIEE. Foresight also provides our PV Query product for robust, self service, ad hoc query capabilities for end users.

Validation - Foresight provides complete validation services in both English and Japanese ranging from validation management to script authoring and execution

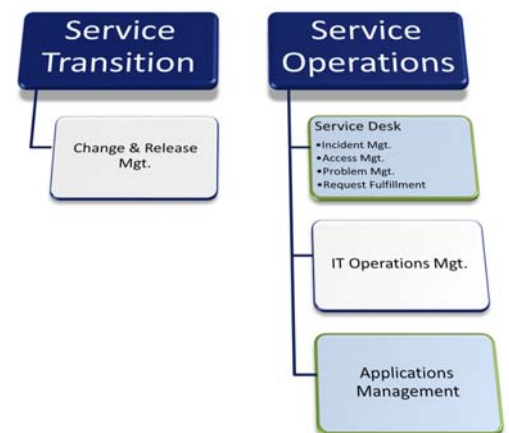
Foresight® Cloud

Hosting - Foresight provides hosting of safety systems via two SSAE 16, validated and redundant data centers in US and EU. We are also safe harbor certified. We presently host PV Monitor® for five (5) top 20 companies, 10+ instances of Argus Safety™, and are implementing Argus / Argus J for a top 50 Japanese HQ company. We also leverage our data centers during implementations for development, testing and migration environments.

Foresight's hosting solutions are flexible to meet your unique requirements. We offer a range of RTO/RPO options, support hosting and integration across products (e.g., Argus integrated with Cognos or Medidata, custom data marts, etc.).

Managed Services - Foresight offers proven managed services. We are presently providing services for multiple top 50 companies and smaller companies for Argus Safety™, ad hoc queries, on-going custom reports, and for PV Monitor®.

For safety database systems, Foresight provides Application Management Services (AMS) that the safety database vendors do not provide such as administration of products, studies and licenses, E2B trading partner configuration, workflow changes, etc.





About Foresight

Foresight Group International AG is a global provider of drug safety and risk management professional services and solutions.

With over 200 employees in North America, Europe, Japan and India — we are the largest professional services firm in the world focused exclusively on drug safety and risk management.

Foresight provides all of our core services in both English and Japanese, including service desk for our managed services.

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

Core Services

- Hosting and Managed Services
- PV Process Design & Optimization
- Safety System Implementation
- Custom Reporting
- Signal Management
- Risk Management
- Inspection Readiness & Response
- Benchmarking and Analytics

Our People

- Experienced (average 8+ yrs.)
- PV process & systems experts
- Program managers
- Analysts and architects
- Developers and testers
- Many from industry
- Bi-lingual English & Japanese
- Local knowledge, globally

Business Transition Services

Foresight has many employees from industry in the US, EU and Japan with extensive clinical, regulatory and drug safety experience prior to joining us - led by a former head of safety for a top 50 global pharmaceutical company.

Foresight uniquely is able to provide both technical and consulting services required by our customers within drug safety and also for each of the departments that interface with safety: clinical operations, regulatory affairs, medical affairs, product technical complaints and labeling & packaging.

We provide lean process design, optimization and harmonization. Foresight's methodology and approach to PV process design & optimization rapidly positions our clients to be best-in-class drug safety organizations. We have extensive experience with PV organization consolidations resulting from mergers and acquisitions, optimizing existing processes to achieve a lower cost of compliance, harmonizing Global and Japan and with creating initial process for companies new to drug safety.

We also provide SOP assessment and authoring, training program design, authoring and delivery - in both English and Japanese.

Risk Management

Risk Commitment Tracking - Foresight's Risk Commitment Tracking Tool helps companies implement an effective and efficient method to manage their increasingly complex risk management commitments world-wide via a single, consolidated and on-line system to track adherence.

Signal Management - Foresight provides an end-to-end solution for signal identification and evaluation. Foresight's proven risk based approach determines the best method and tool to use for each product in your portfolio, which minimizes cost, risk and workload.



In addition to defining your product map, product tiers and signaling tools, Foresight also defines your signal evaluation and tier change processes. Signal management is more than just signal detection tools. Processes are also required to govern when and how to use signaling tools and how to document the results.

For Japan, Foresight hosts a local signal detection product with a Japanese GUI that supports PMDA, FDA and WHO data.

Analytics

Inspection Readiness and Response - Foresight has performed numerous mock audits and also has managed the CAPA process for multiple companies in response to 483 observations and warning letters.

Compliance & Performance Monitoring - Foresight has extensive experience with PV compliance and performance monitoring. We offer a full breadth of services including process and organization design, outsourced compliance monitoring and PV Monitor®, a hosted service that allows organizations to monitor regulatory compliance metrics and internal performance using best practice methods from 7 top 10 global pharmaceutical companies.

Benchmark Surveys - Foresight routinely performs blinded benchmark surveys on behalf of our customers to compare your practices to your peers.

www.foresightgroup.com

North America
119 Cherry Hill Road, Suite 230
Parsippany, New Jersey 07054
Telephone: +1.888.992.8880

Europe
Alpenstrasse 15
6300 Zug, Switzerland
Telephone: +41.44.586.27.36

India
904, 9th Floor, Tower-A,
Advant IT Park, Plot No. 7
Sector-142, Noida, U.P.
National Capital Region
Telephone: +91.120.451.5900

Japan
Kamiyacho MT Bldg 14F
4-3-20 Toranomon
Minato-ku, Tokyo-to 105-0001
Telephone: +81.3.6859.8461