

FORESIGHT® PV QUERY TOOL

The Foresight® PV Query Tool (PVQ) is a state of the art tool for performing ad-hoc querying and reporting against the Argus Safety™ database. PVQ enables all types of users (including Safety Scientists and Physicians) to perform Safety database queries and produce report outputs. With PVQ, Foresight customers realize substantial business benefits:

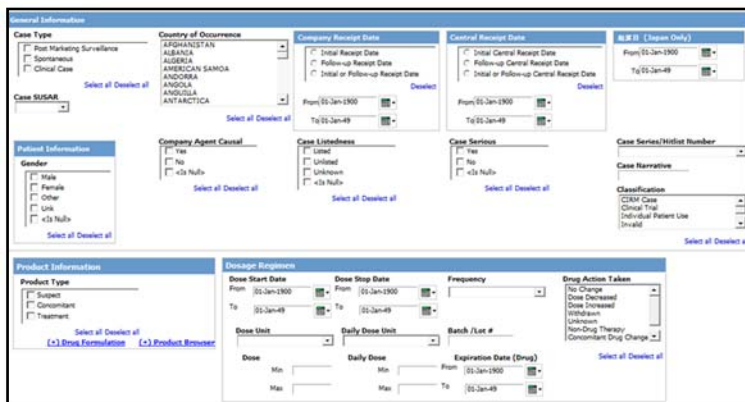
- Self-service for end users, through easy to use interface
 - Reduces dependency on external informatics group
 - Less custom reports needed
 - Improved time to respond to queries
- Helps in responding to unplanned queries
 - During inspections and audits
- Ensures data quality and consistency
 - Help Safety users understand their data more
 - Help identify data quality issues
- Ensures data availability
 - Query on almost all relevant Safety case data fields, including key Japanese fields
 - Report on almost all relevant Safety case data fields, including many Japanese fields
- Works on Argus Standard and Argus Enterprise

PVQ is developed using Cognos reporting tool and is accessible via a web-based interface. The tool is integrated with Argus Safety / Argus J in the Foresight® Cloud, enabling small companies to have the same advanced features typically only affordable by large companies. PVQ can also be implemented on premise.

FEATURES

The Foresight® PV Query Tool has three modules. The **Querying Tool** allows the user to create, execute, save and load an ad hoc query, which when executed will result in a case series / hit list being created.

It is an easy to use interface, with most common querying fields (like Receipt Dates, Drugs, Event Terms, SMQs, Study Information, Submission Information) on one single screen and capability to add additional not-so-common fields (like Study Type, Study Center) by selecting on the first screen.



The screenshot displays the 'General Information' section of the query tool interface. It includes several filter panels:

- Case Type:** Post Marketing Surveillance, Spontaneous, Clinical Case.
- Country of Occurrence:** A dropdown menu with options like ALBANIA, ALGERIA, AMERICAN SAMOA, ANDORRA, ANGOLA, ANTARCTICA.
- Company Receipt Date:** Radio buttons for 'Initial Receipt Date' and 'Follow-up Receipt Date'.
- Central Receipt Date:** Radio buttons for 'Initial Central Receipt Date' and 'Follow-up Central Receipt Date'.
- Case SUSAR:** A dropdown menu.
- Company Agent Causal:** Radio buttons for 'Yes', 'No', and '<+ Null>'.
- Case Unintended:** Radio buttons for 'Linked', 'Unlinked', 'Unknown', and '<+ Null>'.
- Case Serious:** Radio buttons for 'Yes', 'No', and '<+ Null>'.
- Case Series/Histlist Number:** A dropdown menu.
- Case Narrative:** A text input field.
- Classification:** A dropdown menu with options like 'CRIM Case', 'Clinical Trial', 'Individual Patient Use', and 'Invalid'.
- Product Information:** Radio buttons for 'Suspect', 'Concomitant', and 'Treatment'.
- Dosage Regimens:** Fields for 'Dose Start Date', 'Dose Stop Date', 'Frequency', 'Dose Unit', 'Daily Dose Unit', 'Bank / Lot #', and 'Expiration Date (Drug)'.
- Drug Action Taken:** A dropdown menu with options like 'No Change', 'Dose Decreased', 'Dose Increased', 'Initiation', 'Unknown', 'Non-Drug Therapy', and 'Concomitant Drug Change'.

Once a query is executed, a hit list / case series is saved in the database, and can be used for generating ad-hoc reports or pre-canned reports.



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

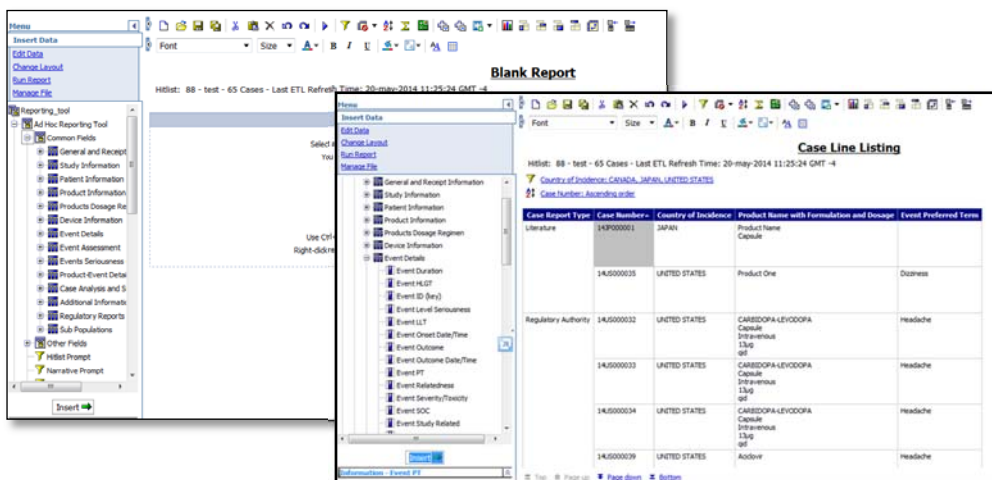
- Experienced (average 8+ yrs.)
- PV process & systems experts
- Program managers
- Analysts and architects
- Developers and testers
- Many from industry
- Bi-lingual English & Japanese
- Local knowledge, globally

FEATURES (CONTINUED)

Reporting Tool

This component allows the user to create, execute, save and load an ad-hoc report that refreshes for a previously created case series / hit list and will result in an output that can be viewed, printed and/or saved to a file.

It is an easy to use interface to drag and drop the fields, apply sorting, grouping and filtering to generate ad-hoc reports on the fly within minutes.



Hit list Manipulation Tool

This component allows the user to create, load, save, edit and provides the ability to merge operations on newly and previously created hit list through the querying tool.

