

atWATCH-e

Manage

- Product inquiries
- Product complaints
- Serious adverse events
- Regulatory reporting

clinical trials post marketing product complaints
drugs, medical devices, pharmaceuticals & biologics

Monitor

- Product quality
- Corrective actions
- Investigations
- Manufacturing dispositions and repairs
- Customer complaints and notifications
- Product registration
- Medical device and SAE reporting

atWATCH-e helps users collaborate and manage adverse events, product complaints, and inquiries quickly and efficiently with the right level of security. **atWATCH-e** makes document management accessible to all users, in a creative, yet secure collaborative environment.



& biologics
 pharmaceuticals

INQUIRE

- Enter, scan, e-mail, and fax adverse events, technical inquiries, product complaints, serious adverse events, and follow-ups into the atWATCH electronic repository.
- Maintain audit trails of document changes at the field level, reporting status on all documents and supporting evidence for each case.
- Collaborate with all members of the product team – clinical operations, research, safety, quality assurance, regulatory affairs, marketing, sales, and manufacturing
- Alert reporters immediately upon event entry about other events involving the same lot, serial, model, patient, reporter, and other criteria

INVESTIGATE

- Identify causes and initiate corrections
- Analyze inquiries, adverse events, and complaints for trends
- Involve key company departments via electronic action items
- Ensure appropriate levels of security and information access

RESOLVE

- Initiate quality and product improvement programs
- Comply with ICH Guidelines and FDA's 21 CFR Part 11 regulations for electronic records, signatures, and validations
- Initiate, perform, track, and report on corrective actions
- Communicate and collaborate with clinical trial partners

REPORT

- Support user-supplied coding dictionaries including COSTART, WHOART, and MedDRA
- Report to health agencies including CIOMS and MedWatch
- Provide a powerful forms letter database to facilitate consistent reporting to customer populations, investigators, and health agencies
- Initiate Dear Doctor correspondence

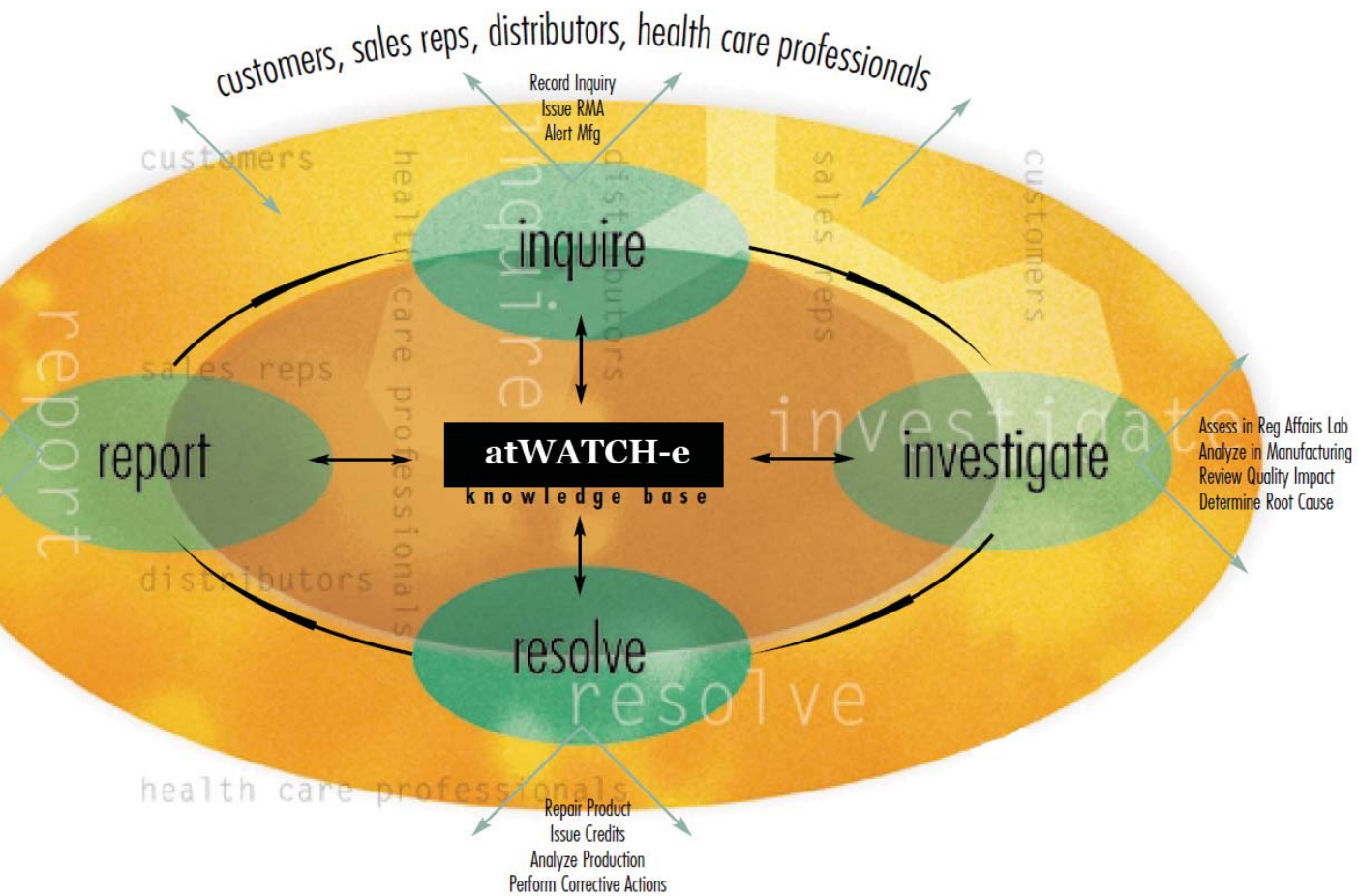
KNOW

- Provide a powerful, comprehensive knowledge base repository
- Replicate documents, information, and action items with enterprise-wide servers and users
- Interface to other company ERP and statistical systems and repositories including SAP, JD Edwards, Solomon, Oracle, SAS, DB2, Access and SQL Server
- Allow and assist users to perform text-based searches and queries using commonly understood search rules

KEY FEATURES AND FUNCTIONS:

Report to Health Agencies
 Send Dear Doctor Letters
 Develop Baseline Reports
 INQUIRE Analyze
 Trends and Stats





EASY TO USE

- Single site and multiple site deployment with global accessibility
- Global connectivity via the corporate WAN, internet
- Intuitive design and automated workflow that mirrors the performance of Clinical Operations, Quality Assurance, Safety, Customer Service and Regulatory Affairs
- Supports any workflow – fully customizable system between sites and across the enterprise
- Scalable architecture offers single-site to global enterprise use
- Consistent user interface and table-driven checklists increase user performance and data integrity
- On-line help reference guide
- Full-text search provides access to knowledge base
- Sophisticated built-in, multi-level security – by site and department
- Enterprise-wide replication ensuring up-to-the-minute data synchronized across all locations



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SUPERIOR KNOWLEDGE - PRACTICAL APPLICATION

Atlant Systems has been serving the medical industry since 2010. Our strength lies in our combined knowledge of GMP and regulatory practices, workflow processes and the application of technology to critical business systems.

Our Goal. To provide leadership and knowledge that complements our clients' expertise. To meet and exceed the expectations of our enterprise clients.

Our Mission. To provide our clients with the highest quality, most efficient technology to solve their business problems.

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