

@ris global[®]

Software solutions for life sciences

Leveraging smart integration



EDC + Central Coding + CTMS + Safety + Report Distribution

Improving clinical
development by
streamlining operations
and driving down costs





Aris Global® improves the execution of clinical programs by focusing on **“smart integration”** across core clinical systems, thereby eliminating the overlap of manual and redundant work processes that exist.

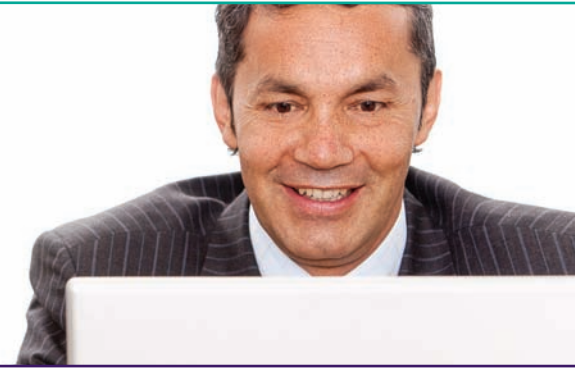
Rising competition, increasing regulatory requirements and the need for speed and quality are the driving forces for integrated platforms for clinical development. Today, the ability to collaborate, extract data, report on an ad hoc basis, and efficiently gather business intelligence are essential elements for improving clinical development. To meet these challenges, life science companies need a level of integration that spans across critical systems.

Aris Global has a long history of providing integrated solutions for life sciences. In the area of clinical development, our approach is to help life sciences companies improve the execution of their clinical programs by focusing on “smart integration” across core clinical systems—electronic data capture (EDC), medical coding, clinical trial management (CTM), clinical safety and safety report distribution. Our **Total Clinical™** suite of integrated solutions enables companies to enter data once and share seamlessly across their enterprise, driving down costs and delivering significant efficiencies. Aris Global offers a full range of delivery services and support options, enabling companies to focus on their core business during the drug development process.

With more than 20 years of life sciences experience, Aris Global understands that every customer has unique requirements and business challenges. Aris Global’s Total Clinical solutions are tailored to meet each customer’s needs—a standalone EDC, a comprehensive CTMS, or the value-added integration of EDC, medical coding, CTMS, clinical safety and safety report distribution.

Backed by a proven history of innovation and our commitment to the life sciences industry, Aris Global continues to partner with leading biopharmaceutical companies and CROs. Our mission remains constant—to provide best-in-class, innovative and integrated solutions that help organizations facilitate regulatory compliance, manage risk and improve operational efficiency with better outcomes. **The final goal: bringing safe and efficacious products to market, faster.**





To drive down your clinical operations costs, Aris Global's Total Clinical solution suite provides a value-added, integrated platform that leverages our long-standing strength in managing safety systems, and is backed by highly skilled teams to service and support these solutions. Each offering strives to be best in class, but further increased value is derived when deployed as part of an integrated solution.

Electronic Data Capture

While many companies now turn to EDC to help them manage their global trials, the harsh reality of a chosen system's inability to handle their growing needs and requirements is often only learned once the trial is underway. Sponsors are forced to revert to paper-based CRFs and perform double-data entry, or explore other expensive workarounds or alternative solutions.

agCapture™ is a proven, full-featured EDC solution that delivers a unified view of your clinical data. Able to support all trials in all phases, agCapture can easily scale to handle a single site, multiple site, as well as complex, international trials. The solution is based on a combination of Aris Global and InferMed software and includes award-winning, integrated decision support functionality to improve trial execution, investigator acceptance and trial outcomes.

- **Value-added integration with Safety:** *Aris Global is one of the few software companies integrating EDC with clinical safety. The integration of agCapture with ARISg™, the market-leading pharmacovigilance and clinical safety system, improves data consistency and accuracy by eliminating redundancies in data entry, coding and serious adverse event (SAE) reconciliation.*
- **Value-added integration with CTMS:** *When agCapture is integrated with agClinical™, Aris Global's clinical trial management solution, relevant data are automatically transmitted from EDC into the CTMS. Study managers and study monitors benefit from more timely and reliable operational data and more effective management of study status.*
- **Value-added integration with Safety and CTMS:** *The value of an integrated eClinical platform is fully realized when agCapture is integrated with ARISg and agClinical. Seamless integration with agClinical pushes subject and eCRF updates and triggers monitor visits. Integration with agXchange SIR™, a unique safety distribution module, delivers clinical safety reports directly to the investigator.*

Central Coding

As global clinical trials become more complex, the critical process of coding safety-related verbatim terms (VTs) to standard coded terms compliant with regulatory standards is increasingly laborious and costly. agEncoder™, Aris Global's centralized coding and dictionary management solution, enables efficient classification, coding and review of verbatim terms entered through agCapture or even through standalone files.

agEncoder helps companies minimize manual coding by automating the process and providing a flexible, configurable workflow. Centralized and advanced coding capabilities enable companies to save time and coding effort using advanced algorithms and synonym lists.

- **Value-added integration with Safety:** *Integration with ARISg improves the consistency of trial safety reporting and reduces SAE reconciliation efforts.*



CTMS

Clinical trial management processes are among the highest costs in drug development. Pharmaceutical companies and CROs are under enormous pressure to use innovative clinical trial management systems to keep their global trials on track, on budget and on time.

Aris Global offers two comprehensive solutions:

agClinical™ is a versatile CTMS that speeds time to market by enabling efficient planning, tracking and controlling of all tasks related to clinical trials management. Through a centralized platform, which allows near real-time information sharing, agClinical provides core trial management functionality and facilitates study set up by automating activities such as study planning, site assessments, clinical supplies monitoring, document distribution and site visit planning.

agClinical NW™ is designed for SAP®-enabled environments and is the only CTMS that combines clinical operations, clinical supplies management and financial accounting functionalities in a single environment. Through a unified interface, clinical processes, as well as SAP® ERP processes, are performed, tracked, documented and reported. As a result, companies efficiently manage and scale their clinical trial processes, significantly reduce trial management cost, improve investigator relationships, reduce financial complexity and cycle times, all while complying with regulatory requirements.

Clinical Safety

By integrating EDC with safety, companies improve data consistency and accuracy by eliminating redundancies in data entry, coding and SAE reconciliation. Aris Global integrates agCapture with the following Aris Global Total Safety™ solutions:

agXchange IRT™ is a clinical safety gateway that enables companies to securely and efficiently receive, review and assess safety data from agCapture before it gets imported into the ARISg safety system. agXchange IRT validates the data are complete and accurate, while providing a complete audit trail of data received from agCapture.

ARISg™ is the market-leading system for clinical safety and pharmacovigilance and provides all the functionality required to meet your regulatory obligations, from case entry to compliance tracking. Fully scalable, ARISg can be used by smaller departments in the early stages of clinical trials or by large organizations with worldwide clinical safety and pharmacovigilance operations.

agXchange SIR™ automates the distribution of clinical safety reports and other clinical documentation to investigators, institutional review boards (IRBs) and ethics committees. Companies significantly reduce costs by eliminating the manual and labor-intensive process required by clinical staff to print, sort and ship the increasing volume of safety information.

Fast, Flexible Delivery Services

Aris Global offers a full range of delivery services, including study design and setup. Our experienced staff designs and develops CDISC/CDASH-compliant eCRFs, and provides user training, data import and export services, medical coding, integration with third-party software, and 24x7 multi-language user support and project management. All operations are controlled by industry best-practices and standard operating procedures.

Total Clinical solutions are available through a fully hosted and managed platform with round-the-clock access and support. Customers are able to reduce their total cost of ownership by eliminating the need to invest in new hardware, software and infrastructure support staff.

@ris global®
The power to protect

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