

Quintiles Infosario™



How is my trial going? How do I know if my patients are safe?

Have you ever dreamed of immediately tracking key metrics like subject recruitment, adverse events or missing pages — instead of waiting for weekly or monthly status reports? Are you frustrated by the numerous data silos and fragmented systems that inhibit your ability to help ensure the safety of your subjects?

Imagine looking across multi-sourced data and quickly exploring a complete patient profile, adverse events, vital signs, labs and medical history, all in one harmonized system. Think what it would be like to immediately track your study's progress, accessing up-to-date information all in one place. Quintiles Infosario™ delivers this and much more.

Turning Harmonized Data into Insights, Insights into Outcomes

Quintiles Infosario is a new, comprehensive suite of services that enables optimized drug development. Leveraging data, processes, systems and expertise, Quintiles Infosario provides current, quality information that gives an immediate picture of study status and subtle underlying trends. It allows you to make important connections to proactively address issues quickly and efficiently.

You can customize Quintiles Infosario to address your specific needs. It visually presents your information in ways that are meaningful, useful and actionable. You can access it right away. Drill down on it. Report on it. Drive work processes in clinical development. Convert and archive legacy studies into industry standard formats. Quintiles can even host your data in our state-of-the-art systems.

A multi-phase program, Quintiles Infosario is comprised of four major services

Reporting & Analytics

A Complete Study Picture

- Comprehensive, up-to-date information
- Continuously integrated source systems
- Secure portal
- Role-based views

Data Driven Processes

Triggered Work Flows

- Fully integrated, data-driven processes
- The right people get the right information
- Triggered monitoring
- Centralized query management

Data Archival & Warehousing

Leveraging Legacy Data

- Legacy data transformed and archived per industry standards
- Easily accessible for feasibility, site identification, and modeling & simulation

Systems as a Service

IT as a Variable Cost

- Configured systems and data hosting with integrated data and services as a value add
 - Lifecycle Safety Management
 - Clinical Endpoint Management
 - Clinical Trial Management

Quintiles Infosario Reporting & Analytics

The First Step: Harmonized Data to Insights

The first component of a multi-year rollout, Quintiles Infosario Reporting & Analytics is an innovative decision-support system that continuously integrates subject, operational and support data across multiple source systems (e.g. labs, ECG, eDC, IRT/IVR, CTMS, Finance, HR and others).

Data is synchronized and normalized immediately in Quintiles' proprietary and state-of-the-art Data Factory. There, authorized users can access comprehensive, role-based views, not just across one study but a range of studies. With data that's harmonized — not just integrated — you can track, investigate and proactively manage your trial's safety, performance and quality parameters. Intuitive visualizations let you quickly spot and explore data falling outside expected parameters. You can then immediately drill down to further explore and quickly determine appropriate action.

Turning Insights into Outcomes

Faster access to reliable clinical data can improve decision-making and patient safety while accelerating your overall clinical development. Below are a few of the benefits Quintiles Infosario provides.

Capabilities	Benefits
Continuous transparency	On-demand safety and performance tracking results in better outcomes
Integrated, multi-sourced data	Holistic view of information improves collaboration and enables better decision making
Intuitive data visualizations	Actionable information prompts appropriate course of action
Quality data accessible on demand	Increased operational and cost efficiencies with rapid access to current data
Drill-down capabilities	Flexible views and data reporting for early identification of potential issues
Pattern and trend detection	Access to current study insights and trends allows better forecasting and planning
Guided navigation	Facilitated data exploration exposes subtle connections

Your Ally in the New Health

Data is foundational — but combined with Quintiles' capabilities and expertise — it becomes transformational. As the only platform that provides fully integrated systems, data and processes, Quintiles Infosario can help you stay ahead by staying on top of your drug development process.

Quintiles Infosario Use Cases

Minimizing Protocol Deviations

Challenge: New cholesterol medication trial protocol deviation rate was higher than expected.

Insight: Scatter plot from Quintiles Infosario immediately revealed deviations were higher in only two regions, France and Montreal. Drill down into deviation types indicated a medication storage problem.

Outcome: Quick identification of root cause: failure to translate refrigeration instructions. Packaging corrections were promptly made — in days, not weeks.

Investigate Adverse Events Sooner

Challenge: Sudden climb of adverse event rates in a diabetes study.

Insight: Graph from Quintiles Infosario aggregated adverse events by type. A quick drill down into holistic patient profiles eliminated lengthy manual patient-by-patient document sorting. Latest lab data revealed that at-risk patients had all been exposed to a flu outbreak at two sites within a single region.

Outcome: Abnormal patient lab values were quickly and appropriately interpreted. The trial protocol continued without revisions.

For more information about Quintiles Infosario, visit us at: www.quintiles.com/infosario or contact us at clinical@quintiles.com.

Join us for success in the New Health.

We're here for you.

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Navigating the new health