From Query to Compliance: Leveraging Standards, Technology, and Agile for Efficient Health Authority Responses

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Abstract

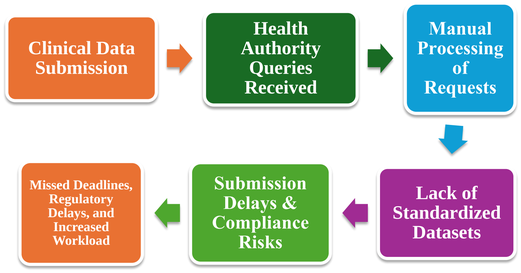
Regulatory queries can feel like an endless roadblock—delaying approvals, increasing compliance risks, and disrupting workflows. But what if we could turn them into a strategic advantage? This poster presents a **smart, streamlined approach** that integrates **clinical data standards (SDTM, ADaM), automation (SAS® Macros, R Shiny), and Agile workflows** to transform query resolution. **SAS Macros** generate targeted analyses in minutes, **Shiny dashboards** provide real-time data exploration, and **Agile methodologies** keep query tracking efficient and responsive. The result? **Faster responses, improved accuracy, and seamless compliance**—turning regulatory challenges into opportunities for success.

From Chaos to Compliance: Turning Regulatory Roadblocks into Opportunities

Imagine this:

📊 *Months of clinical trial preparation... meticulous data cleaning... submission completed.*

But just when you think it's over—**BAM!**—a flood of regulatory queries arrives. Deadlines tighten, workflows break, and manual rework spirals out of control.

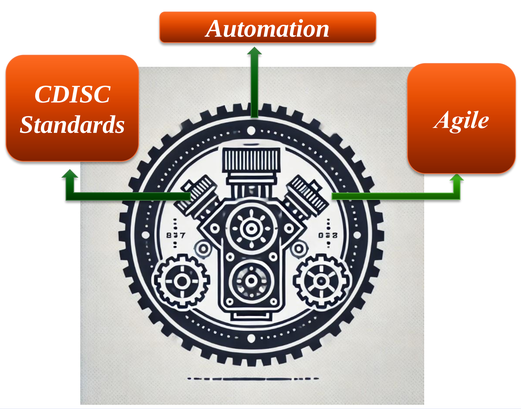


Solution: The Query-to-Compliance Engine 🚀

The Solution: A Smarter Way Forward

By integrating:

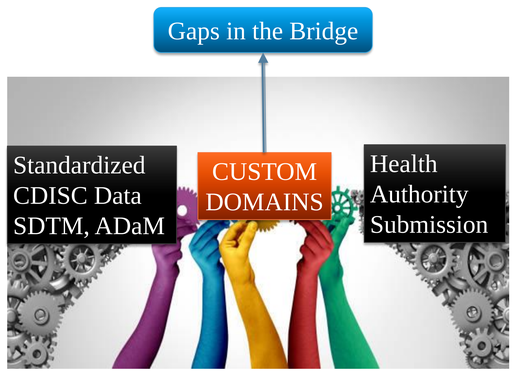
✅ **Clinical Data Standards** (SDTM, ADaM) for structured, audit-ready data.
✅ **Automation** (SAS Macros, R Shiny) for rapid, targeted analyses.
✅ **Agile Workflows** to ensure responsive, synchronized teamwork.



🔹 Standards: The Foundation of Compliance

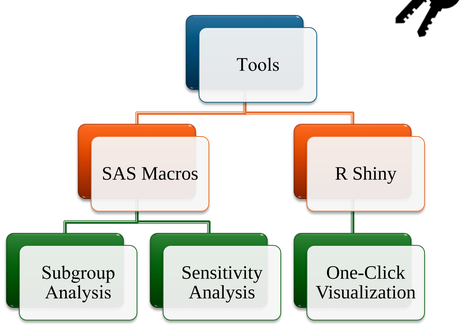
"Bridging the Gap: Navigating the Transition from SDTM to ADaM"

The journey from SDTM to ADaM is not always straightforward. Custom domains act as roadblocks, requiring expertise and collaboration to ensure a smooth transition. Understanding these challenges is key to successfully bridging the gap in clinical data standardization.



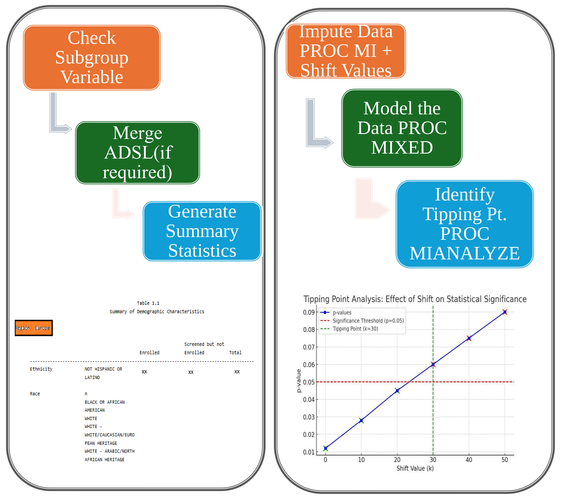
🛠 Solution	⚡ What It Fixes	📌 How It Helps
✅ **Pre-Approved Libraries**	Custom Domains Uncertainty	Ensures consistency with CDISC SDTM/ADaM
🔄 **Automated Mapping**	Manual, Error-Prone Work	Reduces effort & improves accuracy
⏳ **Validation Tools**	Compliance Issues	Uses Pinnacle 21, OpenCDISC, etc.
🤝 **Cross-Functional Teams**	Late-Stage Data Issues	Early alignment prevents rework
📖 **TA Standards**	Different Study Structures	CDISC TAUGs guide dataset creation

Automation: The Key

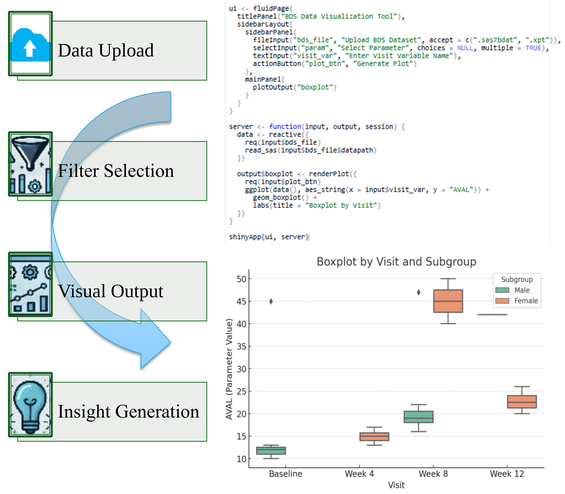


🔹 Automating Subgroup & Sensitivity Analysis with SAS Macros

Aspect	🔹 Subgroup Analysis	🔸 Sensitivity Analysis
Purpose	Identifies treatment effects in specific groups.	Tests result robustness under varied conditions.
Focus	Examines differences by age, gender, etc.	Assesses impact of data handling and model changes.
Automation	Automates subgroup loops for faster insights.	Automates scenario testing with flexible macros.
Key Technique	Uses stratification and interaction tests.	Uses alternative datasets, assumptions, and models.
Outcome	Identifies population segments with distinct responses.	Confirms result stability despite variations.



Integrating R Shiny for Interactive Insights



🔹 Agile: A Modern Approach to Handling Health Authority Requests

✅ **Agile** — Flexible, adaptive, and ideal for evolving requirements.
✅ **Waterfall** — Structured, sequential, and best for stable deliverables.
📊 **In Regulatory Submissions:** Agile accelerates query responses; Waterfall ensures clear milestones.
🚀 **Scrum in Action:** A structured Agile framework designed for managing sprints, roles, and deliverables.

Aspect	Agile 🚗💨	Waterfall 🛠
Workflow	Iterative sprints	Sequential steps
Flexibility	Adapts to changing requests	Rigid and fixed
Deliverables	Frequent updates	Delivered at the end
Feedback	Continuous collaboration	Final-stage review only
Efficiency	Faster turnaround	Longer timelines
Automation	Uses SAS Macros & R Shiny	Mostly manual
Risk Management	Issues addressed early	Risks identified late
Scrum in Action	🔄 Structured Agile framework	❌ Not applicable

Scrum Framework in Action

Sprint Planning
- Define HA request scope and break it into tasks (Data Extraction, Analysis, Reporting).

Sprint Execution
- Develop outputs iteratively using SAS Macros, R Shiny, and automated reporting.

Sprint Review
- Share interim results with stakeholders for early feedback, reducing last-minute changes.

Sprint Retrospective
- Identify process improvements to enhance efficiency for future HA requests

✅ **Outcome:** Continuous stakeholder engagement, automation-driven efficiencies, and faster regulatory compliance—**enhancing the HA response workflow**

Conclusion: Turning Delays into Opportunities

Regulatory delays waste time and resources. Our triple-threat approach transforms delays into an advantage:

📌 **Standards (The Foundation):** Structured SDTM and ADaM data cut query response time by 40%.
⚙️ **Technology (The Turbo):** SAS® Macros deliver targeted analyses fast, while R Shiny dashboards enable real-time data exploration.
🔄 **Agile (The Glue):** Agile methods streamline communication, track queries live, and reduce response timelines from months to days.

By combining these strategies, teams shift from reactive query handling to proactive advantage — boosting compliance, accelerating approvals, and improving outcomes.

References

1.CDISC (Clinical Data Interchange Standards Consortium) Guidelines for SDTM and ADaM Implementation
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Contact Information

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