

Clinical Data Management and Analysis

with **HMS** 

Tailored to your needs.

- ✔ Use your favorite programming languages to manage and analyze clinical trial data.
- ✔ Design a custom user interface that people will love using.
- ✔ Choose a tech stack that aligns with your IT strategy.
- ✔ Adopt short release cycles and avoid getting bogged down by lengthy manual validation processes.

~ From Package to Platform – What HMS Delivers

HMS supports life science organizations in building and operating modular Statistical Computing Environments – from individual components to complete validated platforms. Our services are flexibly bookable and cover all critical areas across data, processes and technology.

Our services at a glance

① Support for Analysts and Data Scientists

We provide development services and reproducible workflows in compliant analytics:

- R programming and R package development and validation (CSV-compliant)
- SAS programming, macro development and migration to R or Python
- Python programming support on request

② Engineering and Integration of SCE Platforms

We design, implement and validate tailored computing environments:

- Platform engineering: on-premise, cloud or hybrid
- Integration with R (e.g. via container platforms), SAS or Python tools
- Modular setup: from assessment to architecture, deployment, validation and knowledge transfer
- Manage data assets

③ Package Development and Validation

We help teams manage and maintain validated R packages or develop custom functionality:

- Development and validation according to CSV or GxP requirements
- Integration into SCE platforms and version control

④ Change Management and Migration Support

We support teams in modernizing their analytics infrastructure:

- System migration from legacy environments (e.g. SAS9)
- Modernization of processes and toolchains within regulatory frameworks

How we can support your workflow

HMS services are aligned with the operational flow of modern analytics environments. Whether your team needs support in developing code, setting up a secure and scalable platform, validating critical components, or managing change – each service area connects directly to one or more of the six core SCE functions. Our modular offering ensures that you can engage HMS exactly where value and urgency align.

~ Why a Modern SCE Matters

Fragmented systems and outdated tools slow down clinical trial data management and analysis, ultimately delaying report submissions to regulatory authorities. A modern SCE enables scalable, reproducible analytics that meet compliance standards and accelerate market access.

A modern SCE is essential to

- Automate deployment and testing processes aiming for agile development and short release cycles (Continuous Validation)
- Support exploratory and submission workflows
- Follow IT strategy requiring platform modernization

What defines a modern SCE?

A capable SCE supports both compliance and innovation. It finds the agreement between reproducibility, flexibility and functionality you need.

Core functions a modern SCE should support include:

</> Build Analyses & Models

Analysts explore data flexibly and prepare submission-ready analyses in validated environments using tools they embrace.



Communicate

Analysis outputs are shared reproducibly.



Consume & Decide

Reports are accessible through secure, role-specific interfaces.



Trace & Document

Compliance is ensured from input to output as needed.



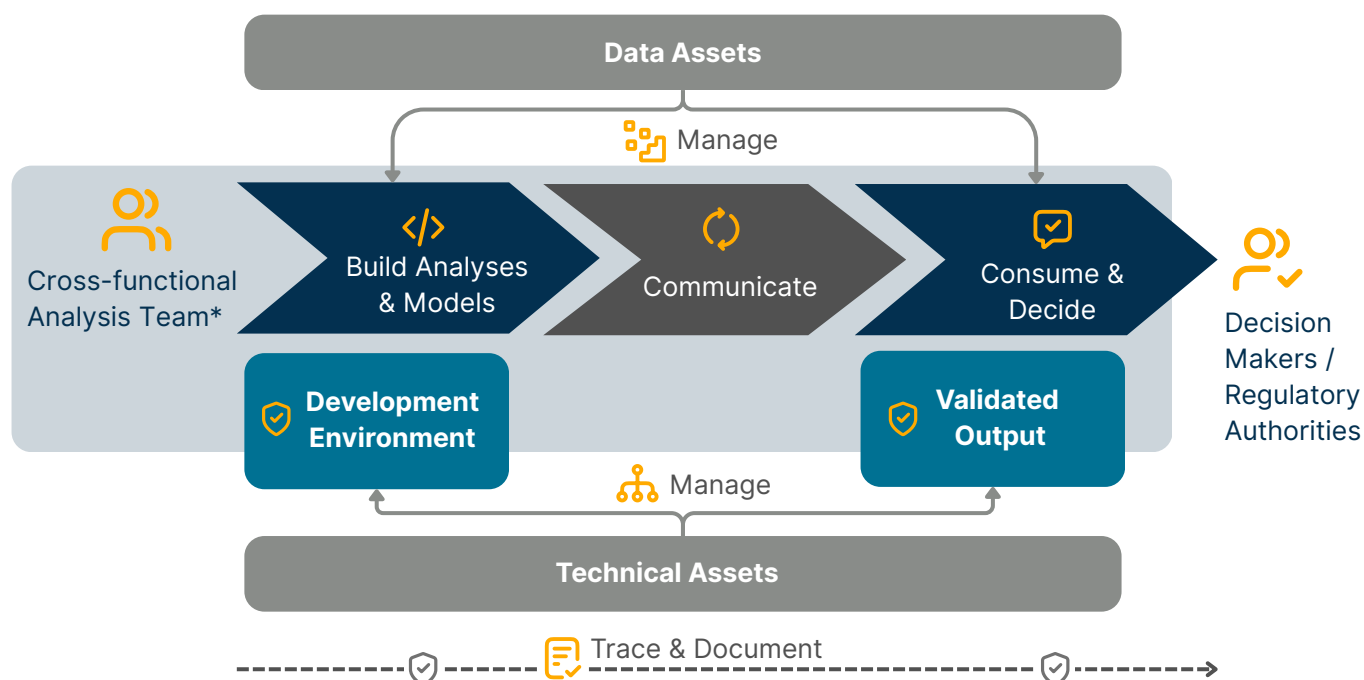
Technical Assets

Individual scripts, shared, validated code (SAS macros, R/python packages) etc.



Data Assets

Data sources and transformation ensuring GxP compliant user access management.



*Includes statistical programmers and biostatisticians, backed by platform engineers and QA roles.

Cloud-native Statistical Computing Environment for Boehringer Ingelheim

Initial Situation

Pharmaceutical companies require a statistical computing environment (SCE) for data analysis in clinical trials that meets the highest regulatory requirements in terms of data security and consistency.

Boehringer Ingelheim, the largest research-based pharmaceutical manufacturer in Germany, was using a central, 25-year-old SAS-based, business-critical system that should be replaced.

Solution

HMS implemented a cloud-native Statistical Computing Environment (SCE) providing key features of the predecessor application but also additional user comfort features to increase business efficiency. The system was designed to assure security and data consistency and supports highly automated validation to streamline updates and compliance. SAS Studio and R Studio are supported as IDEs.

Challenges

- Outdated infrastructure lacking scalability for future demands.
- Ensuring strict data security and regulatory compliance.
- Seamless integration with tools like SAS Studio and R Studio.
- Aiming for automation and continuous validation

Key Features

- Cloud-native design with AWS
- User-friendly interface tailored to client requirements
- Integration of multiple IDEs (SAS Studio, R Studio, Python) is supported
- Facilitating OpenDevStack Framework for building, deploying, testing, documenting, releasing and running applications compliantly

This project was presented at PHUSE EU 2024. Scan the QR code to view the full presentation.



Technologies

AWS, SAS Viya, SAS Studio, Angular, OpenDevStack, Posit Workbench

Architecture

The cloud-native architecture lever-ages an AWS backend, integrating the SCE web app with SAS Viya and SAS Studio as IDE as well as Posit Workbench with RStudio as IDE.

Solution Approach

Establishing a cloud-native SCE with an intuitive interface customized to meet the customer's specific needs and integrated with SAS Viya and Posit Workbench for scalable, secure, and compliant data analysis.

Validated R Package for Automated Statistical Reporting at Roche Diagnostics

Initial Situation

Roche Diagnostics, a global leader in invitro diagnostics, operates in a highly regulated environment. Statistical reporting for performance studies must meet stringent accuracy and compliance standards. Maintaining these requirements through manual processes was increasingly inefficient. To strengthen quality and efficiency, Roche launched a strategic initiative to improve consistency, automate analyses, and streamline collaboration to meet FDA and EMA expectations.

Solution

To meet these goals, Roche partnered with HMS to develop TLGcat (Tables, Listings, and Graphics catalog), a validated R package for efficient and compliant statistical reporting in performance studies. TLGcat standardizes analyses with predefined functions for precision analysis, reference ranges, and qualitative method comparisons. It automates reporting, reduces manual formatting, and ensures consistent outputs. Validation is built-in through automated testing and documentation, aligned with Roche's quality framework.

Challenges

- Manual implementation and validation required significant effort
- Complex statistical methods create significant demand for testing and validation
- Efficiency gains and auditability were key drivers for modernization

Key Features

- Predefined statistical functions for recurring analyses
- Automation of TLG reporting with consistent formatting
- Built-in testing and regulatory documentation
- Seamless integration into existing biostatistics workflows

This project was presented at PHUSE EU 2024. Scan the QR code to view the full presentation.



Technologies

R, testthat, rmarkdown, Git, CI/CD pipeline, VCA

Architecture

Validated R package with integrated testing and documentation. The package is organized into dedicated modules for different statistical analyses, each featuring a result layer for computation and a publication layer for standardized reporting

Solution Approach

HMS delivered a robust, scalable R package with user-reported demonstrable reduction in programming effort and significant acceleration of reporting. Designed to support future expansion and public release.

Your Team. Your Goals. Our Expertise.

Whether you are starting with a single validated R package or planning a full platform transformation – HMS is your partner for scalable, compliant and efficient analytics environments. Our cross-functional team combines deep engineering know-how with life science domain expertise to support you wherever you are in your journey.

Let's talk about your analytics future!



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