

Intelligent Integration: Enabling Collaborative Clinical Insights with an SCE and R

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ABSTRACT

As clinical research evolves to be less centralized and more data-rich, there is a growing need for seamless collaboration across statisticians, programmers and data scientists. At the same time, regulatory requirements demand traceability, security and compliance. This presentation showcases how an SCE such as entimICE FastTrack integrates tightly with Posit Workbench, Connect and Package Manager to deliver a single, compliant environment for collaborative clinical analytics. Users can build, validate, and run programs and R Shiny apps directly on clinical data without exports, snapshots, copies or any compliance risk. We demonstrate how this integrated stack supports role-based access, real-time collaboration and reproducible analytics, all within a cloud-native GxP-compliant SCE. The result: Clinical teams can work together securely, visually, and intelligently.

INTRODUCTION

The increasing adoption of R Shiny applications in clinical development reflects a growing demand for interactive and near real-time visualization of clinical data. R Shiny, a web application framework built on the R programming language, allows developers and data scientists to create dynamic applications for exploring, analyzing, and presenting trial data. However, providing Shiny applications with access to clinical data remains challenging, as such data are typically stored in GxP-compliant repositories that are tightly governed and not easily accessed by external tools. As a result, organizations often face trade-offs between enabling exploratory analytics and maintaining regulatory compliance. A Statistical Computing Environment (SCE) can address these challenges by providing a controlled execution layer that enables Shiny applications to interact with regulated clinical data while preserving governance, traceability, and FAIR principles.

TRADITIONAL APPROACHES TO DATA ACCESS

To provide data from a clinical data repository to an R Shiny app in a traditional setting, there are several possible solutions. Many of them come with some degree of compromise regarding data integrity, security or compliance:

Many first-generation SCEs rely on a check-out and check-in mechanism, in which data are transferred from the central repository into a personal working environment for processing or visualization. While straightforward to implement, this approach involves physical data movement, which becomes increasingly costly and time-consuming as data volumes grow. Activities performed outside the controlled environment may lack full traceability, and checked-out datasets are typically locked in the repository, preventing updates from concurrent processes such as new data deliveries.

An alternative approach involves generating snapshot copies of relevant datasets and artifacts for use in exploratory analysis and visualization. These snapshots are periodically refreshed to reflect ongoing trial activity. Although this method provides quick access to data, it introduces risks related to uncontrolled distribution, outdated information, and potential violations of access restrictions or blinding rules. In addition, governance over snapshot refresh frequency and usage is often limited, increasing the likelihood that analyses are performed on stale data.

In some cases, automated export mechanisms are implemented to feed data into Shiny applications on demand. While automation reduces the risk of using outdated data, it increases the volume of data transfers from the compliant repository and introduces additional development and maintenance complexity. Furthermore, once data are exported, residual copies may remain in non-secured environments, creating ongoing compliance risks that are difficult to fully mitigate.

INTEGRATION OF POSIT TOOLS WITH AN SCE

entimICE FastTrack is a cloud-native, language-agnostic Statistical Computing Environment built on a containerized, microservices-based architecture. Its browser-based user interface is tightly integrated with Posit Workbench, Posit Connect, and Posit Package Manager, enabling the development, execution, and sharing of R Shiny applications directly within the governed environment. Access to Posit tools is provided via single sign-on from the SCE, ensuring that users interact with clinical data strictly according to their assigned privileges.

This integrated setup applies consistently across development, validation, and production use of Shiny applications. Programmers can build and test applications within the SCE. Once an application is ready, it is published directly from Posit Workbench to Posit Connect using built-in deployment workflows. This creates a controlled, traceable sync between development and production:

- The exact application version
- The execution environment (packages, dependencies)
- The publishing user and timestamp
- Associated data sources and permissions

are all captured automatically. entimICE FastTrack maintains visibility and auditability over this workflow, ensuring that only validated and authorized apps are promoted to production. Published apps can then be accessed by other stakeholders through Posit Connect without requiring data exports or manual handovers. All data access, transformations, and generated outputs are tracked and recorded in the system audit trail. As a result, clinical data remain within a single, compliant repository, eliminating the need for snapshots or duplicate copies while remaining accessible to other authorized users and processes. This architecture preserves data integrity and supports FAIR principles by ensuring that data are findable, accessible, interoperable, and reusable within the SCE.

CONCLUSION

The integration of entimICE FastTrack with Posit Workbench, Connect and Package Manager overcomes traditional barriers for compliant and FAIR access to clinical data. Programmers can easily develop and share R Shiny apps with the user community. Data scientists can run these apps from entimICE with minimal effort and gain valuable insights into ongoing or finished trials, resulting in quicker and well-founded decisions.

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