

# A Repository for PK Scientists

# Seamless Workflow with Integral

Pharmacometric teams face many data-related productivity challenges. For example, version control problems and data silos may create weeks of quality control and aggregation work before scientists can begin modeling and analysis.

Those lucky enough to have a single source of data often still struggle to find, access, and work with the data in their analysis and modeling tools. Once found, they may need to manually upload delimited files and then repeat the process all over again each time the data is updated. Too often, these manual processes lead to costly errors and delays.

Stay Compliant



- Capture eSignatures
- Track history
- Create audit reports

Control Your Data



- directly or
  automate via AP
- Grant partners
   access as part of
   vour team

Empower Scientists



- Enable analysis
- Track dependencies
- Seamless integration with Phoenix and management of Phoenix output

Certara Integral is a purpose-built data and model repository for the pharma and life sciences industry. Integral provides complete functionality for PK scientists to manage the data lifecycles for both GxP and non-GxP studies, and helps facilitate their analysis work and drive efficiency.

## Increase efficiency

Integral supports the workflows of your PK scientists. It integrates closely with Certara Phoenix, and keeps the data organized, searchable, and manageable. The Integral REST API enables integration with other repositories to help break down silos.

# Identify impacts

Integral empowers research teams to access and manage all their study data in one secure location. It automatically tracks and highlights changes to data, helping your scientists to understand the impacts.

## Stay inspection-ready

Integral supports 21 CFR Part 11 compliance by enforcing good practices and providing an auditable chain of custody for electronic records. Data generation, modification, and storage are traceable, reliable, replicable, and secure, ensuring audit readiness.



#### Data Flow Made Easy

Integral works closely with Certara Phoenix® and other PK solutions which many organizations depend on for performing PK analysis. The Integral REST API enables automation of workflows between other repositories and Integral, putting that data into your Phoenix users' hands.

# Convenient and secure access

Both Integral and Phoenix use Certara Admin for unified security and access management. Certara Admin provides user account management, license and security administration, Single Sign-On (SSO), user authentication and authorization, and a more seamless experience as your users move between Certara applications.

#### **Enhanced collaboration**

With your PK data housed in Integral, your research team can easily share work and collaborate on producing analyses, TFLs, and reports. These benefits also extend to CROs and other partners, who can be granted appropriate levels of access to work securely alongside your team.

### ISO 27001 certified by BSI

Protecting your clinical and nonclinical information is paramount. Certara's information security management systems hold ISO 27001 certification, ensuring data confidentiality, integrity, and availability. This exemplifies our commitment to robust security controls, rigorous risk assessments, and continuous improvement.

# Easily collect, manage, store, search, and track your clinical research data sets in one location

Repository Feature	Sharepoint	Github	Certara Integral®
21 CFR Part 11 Compliant Electronic Signatures			$\checkmark$
21 CFR Part 11 Compliant Audit Trails			
File Versioning	$\checkmark$	√	
Project Save Points			
Dependency Tracking/Identify Altered Records			√
File Linking			
Configurable Security Access	√	√	
Roll-Based Privileges			
Blinding and Archiving	√		√
Validated			√
Software as a Service	√	√	√
Single Sign-on Capable	√	$\overline{}$	
Configurable Folder Structure			
Configurable Metadata			
Metadata Filtering			
Searchable Content			
Content Synchronization	OneDrive		
Content Display		Text Files	
Large File Support	√		
Text Editor and File Diffs		$\overline{}$	
Favorites List			
Alerts and Notifications	√		√
Phoenix Plugin, Browser, Windows & Linux clients		√	√
Variable Infrastructure			√
REST API			

When compared to traditional collection methods, Certara Integral is the most comprehensive and cost-effective option!



Learn more at certara.com/Integral



#### About Certara

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