



INTEGRAL

Certara Integral™

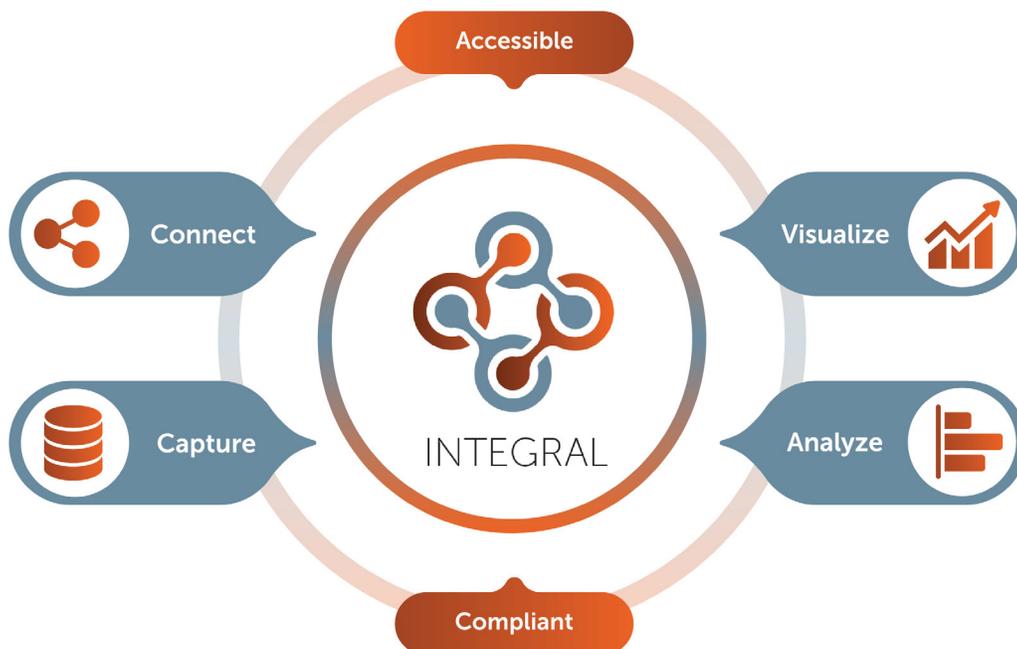
Streamline your clinical pharmacology workflow and drive more informed drug development decisions

Integral – A single, validated, 21 CFR Part 11-compliant repository that easily and quickly organizes all your pharmacokinetic (PK) data

Bringing together all your PK data from multiple, disparate storage methods makes it challenging to manage and organize that data; remain 21 CFR Part 11 compliant for regulatory submissions; and search, visualize, and analyze the data. This is particularly true with the large volumes of PK data that accompany today's more complex trials. Data quickly becomes out of date, and version control is difficult.

Enter Certara Integral - a next-generation cloud-based, software as a service (SaaS), validated data and model repository with an intuitive user interface for collecting, managing, and storing multiple types of data sets for analysis, sharing, and reporting of clinical pharmacology, pharmacometric, and all other clinical data. This regulatory compliant repository significantly improves the clinical pharmacology workflow, providing PK data that is traceable, reproducible, and secure as well as enabling better-informed drug development decisions.

Integral provides the foundation to better PK workflow



Easily collect, manage, store, search, track, and analyze multiple types of data sets in one location

- Secure, pre-validated technology
- Transform CDISC domains to relational database tables
- Agnostic to analytical software used
- Backward compatible with Certara PKS
- Access to historical clinical pharmacology data
- Data control, with visibility into the progress of your analyses
- One-click synchronization of data from workstation to repository
- High-powered elastic search capability
- Meaningful data tabulations and visualizations via D360 add-on
- Model traceability and comparisons
- Automatic data-analyses dependencies
- Tracking of individual file versions and user-specified collections of files, versions, and content
- Comparisons of analyses versions
- Reconstruction of analysis later in time
- Configurable internal security roles

Make data-driven decisions

Efficiently organize and access all your data and associated models in one place with Integral - providing one source of the truth. Notifications are provided when changes to data affect dependent analyses. Make important development decisions earlier in the process.

Increase operational efficiencies

Integral integrates with your IT infrastructure from day one via client applications, plug-ins, or APIs and is data- and analytical-tool agnostic. PK data are organized, searchable, and manageable, providing reproducibility of work and business continuity. Easily find data using categorizations based on clinical study, project, individual experiments, data, or library. Designate files and folders as favorites for easy, direct access. An Oracle database foundation with variable Amazon Web Services (AWS) infrastructure provides load balancing and the ability to scale to meet user demand.

Optimize workflow:
Integral saves Sponsors
resources, budget, and
time

Successfully pass audits by regulatory agencies

The data, data generation, and data storage are all traceable, reliable, accessible, reproducible, and secure – automatically preparing your organization for audits. Furthermore, Integral facilitates 21 CFR Part 11 compliance, providing a compliant chain of custody for electronic records. We have partnered with Okta for single sign-on, authentication, and electronic signatures that can be federated with client authentication systems.

Be confident in the security of your data

Certara has 20+ years' experience in technology validation, testing, and maintenance. Integral also includes a logical separation between each client's data in the Oracle database by providing a unique schema to each customer. Furthermore, based on intensive third-party testing by a top-tier internet security firm, you can be confident in the security of your data.

About Certara

Certara is a leading provider of decision support technology and consulting services for optimizing drug development and improving health outcomes. Certara's solutions, which span the drug development and patient care lifecycle, help increase the probability of regulatory and commercial success by using the most scientifically advanced modeling and simulation technologies and regulatory strategies. Its clients include hundreds of global biopharmaceutical companies, leading academic institutions and key regulatory agencies.

For more information visit www.certara.com or email sales@certara.com.