CERTARA

Fact sheet

External Data Accelerator

Your standards-first team and technology for conformant vendor data

One team, one set of standards, from setup to submission

External vendors now supply more than 70% of study data, from central labs and omics to PK and ECG, each with its own format and delivery timeline. External Data Accelerator pairs Certara's external data management services with Pinnacle 21® Data Exchange, embedding standards and validation from day one so your data lands clean and your study moves toward submission readiness.

Standards from the start

Certara external data specialists author unambiguous, standards-aligned transfer specifications with your vendors, so data arrives with a clear path to its CDISC dataset.

Real-time, automatic validation

Data Exchange validates every vendor file on upload against those specifications, flags all issues immediately, and routes clean files to your database.

Issue intelligence

A dashboard surfaces error and success trends by data source, issue, and vendor, giving your team a factual basis for continuous improvement.

5 reasons to choose External Data Accelerator

1. Specifications, standards, and validation are set before data flows at scale
2. Vendor issues are caught at upload, while there is still time to correct them
3. One environment governs specifications, metadata, validation, and quality visibility
4. Certara specialists absorb the internal lift of spec writing and vendor follow-up
5. Decades of hands-on FDA, EMA, and PMDA submission experience inform every deliverable

CERTARA

External data management designed to work with your team

What we manage

- Centralized, structured transfer specifications for every incoming data type
- Automatic validation of lab, PK, imaging, ECG, and other non-EDC files on upload
- Delivery of clean files to your preferred repository
- Dashboard monitoring of transfer speed and quality by study, vendor, and rule
- Controlled terminology and metadata available for SDTM mapping

Who it serves

- Established sponsors: augments the standards and data management workflows your team already run
- Sponsors building processes: a repeatable framework for external data collection across studies
- Emerging biotechs: a turnkey approach without internal infrastructure
- CROs: hand-in-hand collaboration on sponsor programs

What this means for your program

Fewer downstream surprises

Problems surface at upload and get corrected while the study is running.

A shorter path to submission

Standards carry through from setup, reducing a reconciliation phase.

Reduced internal lift

Certara writes specs, runs validation, and manages vendor follow-up.

Visibility across vendors

One dashboard replaces fragmented email and spreadsheet tracking.

A cleaner path for external data from the start of your study, backed by the standards regulators trust.

Learn more about
External Data Accelerator

About Certara

Certara transforms drug discovery and development for good, helping scientists and clinical teams generate regulatory-grade evidence faster. Its solutions combine biosimulation, clinical intelligence, and regulatory science, and are embedded in the workflows of drug developers worldwide. Certara clients include more than 2,600 biopharmaceutical companies, academic institutions, and global regulatory agencies. Learn more at certara.com.

CERTARA