The Fastest Route to Spec-Conforming Vendor Data

There has to be a better way

From central labs to niche labs, vendors provide more than 70% of today's study data. On average, at least four non-EDC sources provide this data per study, each supplying thousands of data points for hundreds or thousands of patients. Yet our processes for ingesting and validating that data are more antiquated than the most basic eCRF.

- Sponsors and vendors hash out specs on locally stored Word and Excel files
- Vendors email data packages, with no automatic validation upon transfer
- Data managers or their delegates head into an isolated SAS environment to check for spec conformance
- Weeks pass just in identifying discrepancies for one transfer
- More time passes while the vendor makes corrections
- Common sources of error go undetected and undocumented, so delays persist from study to study

The Outcome

Analyses and submissions suffer from delays and discrepant data.

Introducing the better way

To accelerate, collaborate. Pinnacle 21's Data Exchange unites sponsors and vendors in one cloud-hosted environment to:

- Streamline specification design,
- Automate file validation, and
- Measure transfer performance over time.

Now there's a more efficient way to bring clean non-CRF data into your study database for faster time-to-analysis and submission.

The Result

Time savings, cost savings, and confidence that your dataset is ready for your biostatisticians and submission team.

Design

Author specs at every level with your vendor, from file names down to code lists

Elevate specs from artifacts lost in email attachments into a centralized, living communications hub. The latest version of your spec becomes the sole location for discussing requirements and negotiating data deliveries.

- Chat boxes stack in the cloud version of your specs, pointed to specific cells for context
- Walk through unlimited archives to inspect granular changelogs, deploy or revert specific snapshots at will, and compare specs to other studies or standards
- Create sample data files based on your specs

Dataset	
Description	Concentration
Structure	
Variables	
Filename	
Format	

Variable	
Variable	LBTPT
Label	
Type	
Length	
Mandatory	
Blinded	
Codelist	

Value	
Variable	LBTESTCD
Where clause	LBTEST INCLUDES (1H, 2H,4H,6H,8H)
Label	LIVER LABS DAY 1
Type	text
Length	20
Codelist	DAY1LBTST

Apply

Empower your vendors to deliver quality upon transfer

You've designed your specs. Now put them to work. We've streamlined secure file transfers from vendors to sponsor databases. As files are uploaded, they're checked against your predefined structure, format, code lists, and value-level requirements.

- No emails or sFTPs. Secure upload to one "transfer station" for all your vendors
- Validation runs in-stream, generating an actionable list of any issues found, and empowering external vendors to "check their work" along the way
- A task management window accompanies each issue, explaining the error and prompting vendor stakeholders to prioritize and triage corrective actions
- Data Exchange delivers files to the study data repository of your choosing

PROGRESS
66%

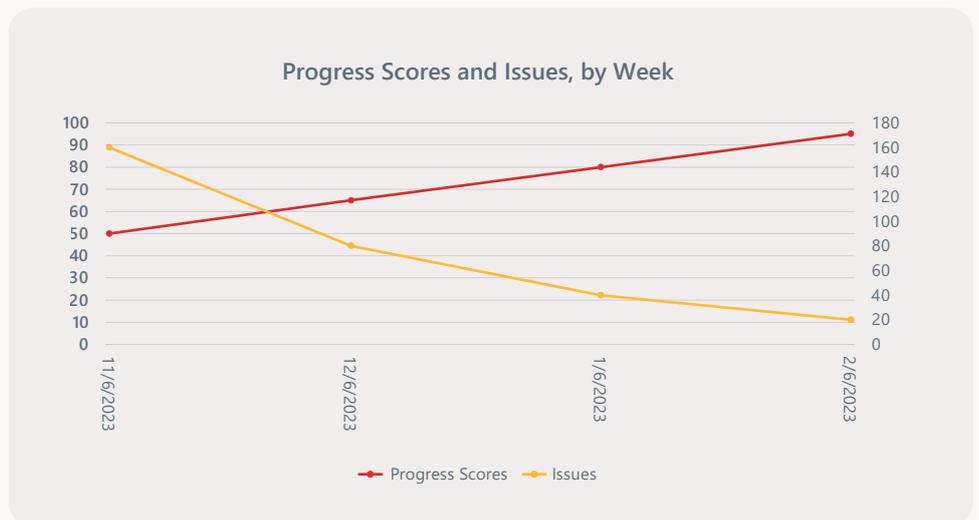| VALUE	MESSAGE	RECORDS AFFECTED	IMPACT
DX1007	Missing required Veeva Key variable	5	Reject
DX3652	LBLOQ value not found in codelist	2	High
DX0007	NULL value in Mandatory variable LBSTAT	1	High

Rule DX0007:
NULL value in Mandatory variable LBSTAT
Impact: HIGH
Dataset: LB_CONC
Record #: 20
STUDYID: 234567
SUBJECTID: 222222
VISIT: DAY 1
LBTPT: 1H
LBTESTCD: ALT
LBSTAT: null

Manage Issue

Status: Open
         Fix Now
         Fix Later
         To Close

Assignee: Carla

Sources: Data

Comments

Benny: I reset your LIMSpassword, @ Carla. Could you please retrieve this value and re-upload the data package?

Learn

Monitor sources of error over time with executive dashboards

Historic reporting by study, vendor, and even rule violations help you spot the roots of common issues and hold stakeholders accountable.

- Track and categorize issues by type
- Compare metrics across departments and vendors
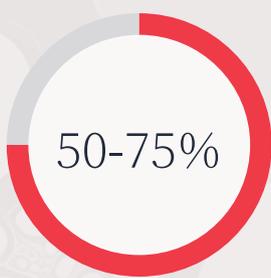- Track turnaround times
- Monitor transfer file quality

Progress Scores and Issues, by Week

— Progress Scores — Issues
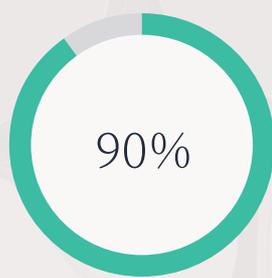
Case study

Process has its payouts

When it came to ingesting and managing external vendor data, one top 10 pharma customer faced a series of manual tasks that turned days into weeks, weeks to months, and months to a year or more. Study teams were stretched thin and end-of-study timelines were growing. This meant costly delays for the sponsor in:

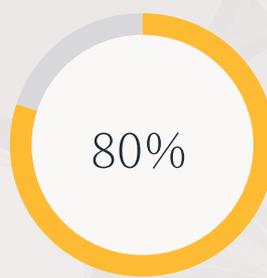Analysis > Submission > Approval > Bringing life-saving treatments to market

With Data Exchange in place, time invested in specification creation and review, transfer, validation, and issue resolution all dropped by at least 50%
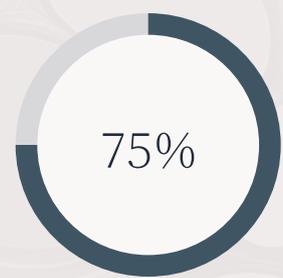
50-75%	90%	80%	75%
Data Transfer Spec Review	File Ingestion Process	Systems Access & Governance	Validation & Issue Management

Let's have an exchange

Your team and your data vendors deserve a faster, easier, and cleaner way to transfer non-CRF data. Correct your vendor data process, schedule a consult and custom demo.

Learn more and connect

About Certara

Certara accelerates medicines using biosimulation software, technology, and services to transform traditional drug discovery and development. Its clients include more than 2,400 biopharmaceutical companies, academic institutions, and regulatory agencies across 70 countries.

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