

# How to Create a Data Validation Plan in Clinical Data Management

Whether you're ensuring the ongoing data quality and integrity of a study or readying data for submission from groundbreaking studies, clinical data validation plays a vital role. This guide is designed to help clinical data managers effectively validate data in alignment with regulatory validation rules.

By the time you finish reading, you'll have a clear and actionable plan to deliver quality data in your future regulatory submissions.

## Why create a clinical data validation plan?

There are many advantages to implementing a solid clinical data validation plan:

### 1. Fix data issues upfront

Make clinical trial data review more efficient by identifying errors proactively and resolving them before submission. This ultimately reduces timelines meaning life-changing treatment can be made available sooner and costs are reduced.

### 2. Prioritize fixes

Oversight of your data quality with clear issue categorization by impact throughout the trial will help you target the most critical issues first.

### 3. Maintain oversight and control

Gain visibility into validation progress and data trends across trials using analytics.

### 4. Align with regulators

Stay effortlessly compliant with CDISC standards, regulatory rules, and global regulatory requirements.

### 5. Achieve continuous compliance

Move beyond one-time validations—opt for continuous monitoring to ensure consistent data quality throughout your study lifecycle.

### 6. Validate your way

Tailor validations to your organization's unique standards, business rules, and terminologies, ensuring seamless integration into existing workflows.

Validation is not just a requirement—it's your competitive edge. Proper validation of clinical study data ensures:

- **Integrity:** Accurate, reliable data leads to faster approval timelines, secures trial outcomes and maintains regulatory trust.
- **Efficiency:** Minimize costly rework, saving time and resources.

# Step-by-step guide to creating a data validation plan

Follow these clear steps to establish a data validation plan for clinical trials:

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## Planning

Every successful validation plan starts with robust preparation:

- Define validation procedures and identify the specific checks to be applied, such as conformity to CDISC standards, regulatory validation rules, and ALCOA+ principles.
- Document these procedures in detail and share them with stakeholders, including external data vendors and CROs.
- Use advanced validation platforms like Pinnacle 21 Enterprise to ensure compatibility with the latest regulatory requirements.

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## Implementation

Begin configuring your validation tools, ensuring they align with the outlined plan:

- Tailor the validation platform (e.g., Pinnacle 21 Enterprise) to apply the relevant SDTM and ADaM validation rules.
- Create study and organizational standard level metadata in the software to drive the validation.

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## Validation

This is where the rubber meets the road:

- Run validations on your datasets to identify inconsistencies, missing values, and non-compliance issues.
- Leverage validation scorecards to assess the impact and frequency of errors.

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## Correction and review

Fix flagged issues before submission:

- Collaborate with team members to resolve errors using a centralized hub.
- Prioritize corrections based on their impact on data fitness scores.
- Review the updated datasets and rerun validations to ensure that fixes are successful.

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## Ongoing monitoring

Validation doesn't stop at submission:

- Keep compliance continuous by conducting periodic checks on trial execution data.
- Use versioning tools to track changes and understand data quality trends over time.
- Stay updated with any regulatory announcements or changes to methodology.

# Tips and tricks to maximize results

Here are some expert strategies to supercharge your clinical data validation process:

## 1. Use robust validation tools

Platforms like Pinnacle 21 Enterprise provide automated quality checks, issue-tracking dashboards, and guidance on aligning with regulatory requirements, saving both time and money.

## 2. Validate early and often

Make validation a part of every trial phase—design, execution, and submission preparation.

## 3. Maintain data integrity

Ensure your data is:

- **Complete:** No missing information.
- **Attributable:** Linked to an identifiable source.
- **Secure:** Protected against unauthorized changes.
- **Accurate:** Data should be error-free and accurately represent the activity.

## 4. Keep up with regulatory changes

The FDA and PMDA frequently update their guidelines. Bookmark their official websites and subscribe to bulletins for real-time updates.

## 5. Use issue management

During validation, the issues that arise should be triaged first to determine the cause of the issue, then to decide on the best course of action to resolve or address each one. Using an issue management tool, such as Pinnacle 21 Enterprise's Issue Management feature, allows you to easily address issues with meaningful fix tips and explanations.

# Frequently asked questions

## How do you validate clinical data efficiently?

Advanced platforms like Pinnacle 21 Enterprise provide built-in tools to streamline and automate validation, aligning data with regulatory standards and flagging discrepancies early.

## What challenges can I face during validation, and how do I solve them?

- **Disparate data sources:** Use an integrated platform to unify and validate data.
- **Regulatory updates:** Stay informed about recent changes to avoid compliance gaps.
- **Validation bottlenecks:** Prioritize issues using tools like data fitness scoring that help highlight critical tasks.

## What are the common FDA validation rules to follow?

These include adherence to CDISC standards, controlled terminologies and dictionaries like MedDRA, and agency-specific technical conformance guides for format consistency.

## How does continuous validation benefit submission readiness?

Continuous validation minimizes errors early in the process, shortening review times and ensuring data integrity when regulators inspect your submission.

## Top tips

While using clinical validation tools:

- Double-check configuration settings to ensure correct validation parameters.
- Restrict access to authorized personnel to protect sensitive data.
- Avoid relying solely on automated checks—always perform manual reviews for critical trials.

## What next?

By adopting a comprehensive **data validation plan**, you'll ensure that your trial datasets are robust, compliant, and ready for smooth regulatory approval. Utilize tools like Pinnacle 21 Enterprise to simplify the process, gain actionable insights, and reduce overall risk.

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Start validating smarter today with a detailed look at how Pinnacle 21 can transform your workflow.

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Book a free no-obligation demo



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