

Personas & Customer Use Cases

AI-assisted review, correction, traceability and audit evidence for regulated quality documentation

TrialVerity helps document authors, engineers, quality teams and reviewers identify document-quality issues earlier, review AI-assisted findings consistently, produce controlled corrections and preserve review evidence — while keeping the human reviewer in control.

Potential Customer Discussion Document

Illustrative workflows; exact deployment, validation and regulatory scope are customer-specific.

1. What TrialVerity Helps Teams Do

TrialVerity provides a common review workflow across multiple regulated document types. Rather than replacing subject-matter experts or quality reviewers, it assists them by applying controlled, document-type-specific review configurations and presenting structured findings for human disposition.

- Review DOCX/PDF documents using document-type-specific review configurations.
- Identify issues such as inconsistent terminology, missing acceptance criteria, unresolved placeholders, formatting drift, ambiguous pass/fail language and configured traceability problems.
- Generate structured findings and proposed corrections, including Word redlines where applicable.
- Support linked-document and cross-document consistency checks.
- Allow reviewers to accept, reject or modify findings and preserve the human decision trail.
- Maintain review-run, configuration, model and audit provenance for reconstructing review activity.
- Support controlled administration of document types and review configurations without a separate hard-coded review engine for every document type.

Human authority remains central

TrialVerity is an assistive review platform. It does not autonomously approve or finalize regulated documents. Final review decisions remain with authorized customer personnel.

2. Primary Personas

Persona	Typical Objective & Activities
Document Author / Engineer	Prepare review-ready documents; upload drafts, confirm type, run review, correct issues and download redlined output.
Quality Reviewer	Inspect findings and evidence; accept, reject or modify recommendations; add notes and complete human review.
Quality Manager / Quality Admin	Control review standards; manage document types/configurations; publish versions and oversee quality workflows.
Clinical / Regulatory Specialist	Review CERs, clinical plans/reports, PMS documents and related content for configured completeness and consistency requirements.
Design / V&V Engineer	Review SRS, DVP, trace matrices and protocols for missing requirements, inconsistent IDs, ambiguous criteria and cross-document discrepancies.
Manufacturing / Validation Engineer	Review IQ/OQ/PQ protocols and reports for missing criteria, placeholders, terminology issues and execution/report inconsistencies.
Post-Market / Quality Specialist	Review PMS and related quality documents for configured required sections, terminology, evidence and linked-document consistency.
Auditor / Viewer	View documents, findings, review history, human dispositions and available provenance without changing records.
Organization / System Admin	Manage users/roles, processing controls, sensitive/PHI permissions and operational administration.
Compliance / Validation Lead	Inspect review provenance, audit history, configuration versions, human dispositions and available evidence.

3. Representative Customer Use Cases

1. Review a New Document

Primary personas: Author / Engineer; Reviewer

Workflow: Upload a DOCX/PDF, confirm type and sensitivity, apply the published review configuration, run AI-assisted review and evaluate structured findings.

Customer value: Earlier identification of quality issues before formal approval workflows.

2. Produce a Corrected Word Redline

Primary personas: Author / Engineer; Reviewer

Workflow: Generate a DOCX with native Word tracked changes for proposed edits where placement is possible; surface unplaced edits for human handling.

Customer value: A familiar Word review experience while preserving human control.

3. Perform Human Disposition of AI Findings

Primary personas: Quality Reviewer

Workflow: Review findings/evidence, accept, reject or modify recommendations, and add reviewer notes.

Customer value: Controlled human review rather than autonomous AI decision-making.

4. Check Design-Control Traceability

Primary personas: Design / V&V Engineer; Reviewer

Workflow: Review linked SRS, trace matrices, DVPs and protocols/reports for configured reference and consistency problems.

Customer value: Helps surface broken or inconsistent traceability earlier.

5. Review Validation Protocols and Reports

Primary personas: Validation Engineer

Workflow: Review IQ/OQ/PQ documentation for missing acceptance criteria, unresolved placeholders, ambiguous pass/fail statements and configured consistency requirements.

Customer value: More consistent pre-review quality checks.

6. Review Clinical / Regulatory Documents

Primary personas: Clinical / Regulatory Specialist

Workflow: Apply controlled document-specific configurations to CERs, clinical plans/reports, PMS documents and related documentation.

Customer value: Repeatable review while preserving SME authority.

7. Add a New Document Type Without a New Review Engine

Primary personas: Quality Admin / SME

Workflow: Configure aliases, required sections, linked types, style rules, instructions, examples, common errors and severity guidance; version and publish.

Customer value: Expand document coverage through controlled configuration.

8. Version Review Standards

Primary personas: Quality Admin / SME

Workflow: Publish updated review configurations while retaining the configuration/version provenance used by historical review runs.

Customer value: Controlled evolution of review criteria.

9. Investigate a Finding

Primary personas: Reviewer; Quality Manager

Workflow: Inspect source version, review run, evidence, applicable configuration and model information, then record the human disposition.

Customer value: Improved explainability and review accountability.

10. Reconstruct a Historical Review

Primary personas: Auditor / Compliance Lead

Workflow: Review available document/version, run, configuration, model, findings, timestamps, decisions and audit events.

Customer value: Reconstructable review evidence within the validated scope.

11. Re-run After Document Revision

Primary personas: Author / Engineer; Reviewer

Workflow: Upload a new version and initiate a new review while preserving prior review history.

Customer value: Iterative improvement without overwriting prior evidence.

12. Batch Review Documents

Primary personas: Quality Team / Manager

Workflow: Submit multiple documents for asynchronous review, monitor progress and safely retry failed processing where supported.

Customer value: Higher throughput for larger document sets.

13. Control Sensitive / PHI Processing

Primary personas: Admin / Quality Admin

Workflow: Assign sensitivity and enforce deployment- and organization-level authorization before sensitive/PHI-designated documents can be AI reviewed.

Customer value: Explicit governance gates around sensitive AI processing.

14. Monitor Review Operations

Primary personas: Admin / Quality Manager

Workflow: Monitor recent activity, batches and jobs needing attention; investigate failures and use Retry or Re-run appropriately.

Customer value: Operational visibility and recovery.

15. Support Audit / Inspection Preparation

Primary personas: Quality Manager; Auditor / Compliance Lead

Workflow: Retrieve available review history, configuration provenance, findings, human dispositions and audit evidence.

Customer value: Helps assemble evidence of how a review was performed.

4. Four Simple Ways to Enter the Product

For customer adoption, complex capabilities can be organized around four straightforward jobs-to-be-done:

Customer Goal	Typical Users
I need to review a document	Authors, engineers, clinical/regulatory personnel
I need to review AI findings	Quality reviewers and SMEs
I need to manage our review standards	Quality admins and SMEs
I need to see what happened	Quality managers, auditors and compliance/validation personnel

5. Example End-to-End Customer Journey

1. Author uploads a draft regulated document.
2. TrialVerity presents a document-type suggestion; the user confirms the type.
3. An authorized user assigns the appropriate data-sensitivity designation.
4. TrialVerity retrieves the applicable published review configuration.
5. AI-assisted review produces structured findings and proposed edits.
6. The Quality Reviewer evaluates findings and records human dispositions.
7. Where applicable, a Word redline is generated with tracked changes for placed edits.
8. The revised document can be uploaded as a new version and reviewed again.
9. Quality or audit personnel can later inspect available review history and provenance.

6. Potential Customer Pilot

A practical evaluation can start with a small set of synthetic or customer-approved non-sensitive documents representing two or three high-value document types. The pilot can measure seeded-issue detection, false positives, reviewer usability, redline quality, review time and the usefulness of the resulting audit evidence.

Suggested pilot participants: 1–2 document authors/engineers, 1–2 quality reviewers, a quality admin/SME and a quality or validation lead.

7. Important Scope Notes

- TrialVerity assists qualified personnel; it does not autonomously approve or finalize regulated documents.
- Document sensitivity is designated by authorized users; TrialVerity should not be treated as automatically determining whether content contains PHI.
- Regulatory validation, Part 11/Annex 11 applicability, HIPAA/GDPR obligations, BAA/DPA requirements, retention policies and deployment controls depend on the customer's intended use and validated implementation.
- Specific standards, document types, rules and integrations should be configured and validated with the customer's subject-matter experts.

TrialVerity

AI-Assisted Quality Document Review & Correction