CYMETRYC

Taming the Epic Beaker Validation Wave

Stay above water with faster, easier, fully compliant testing

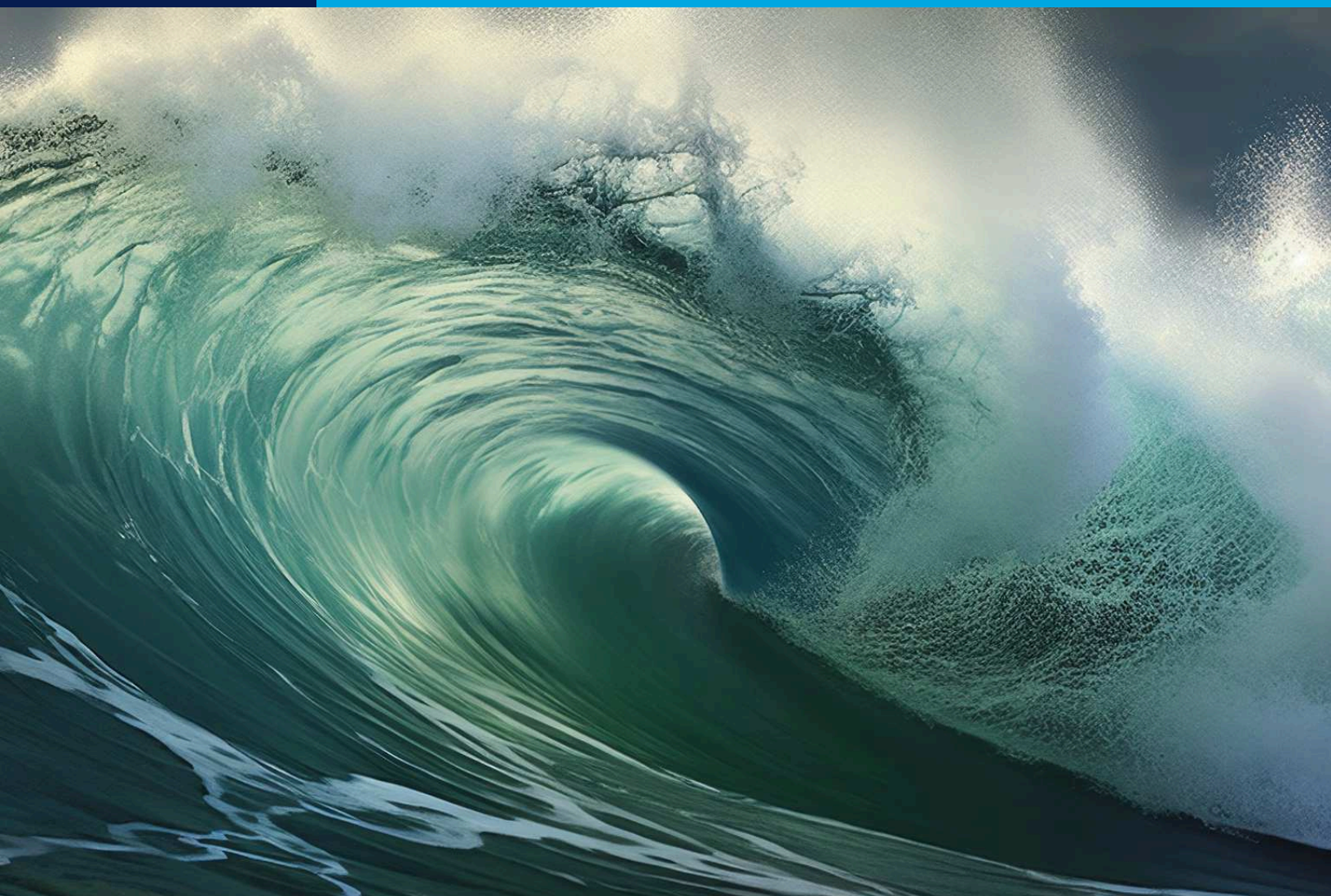


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EXECUTIVE SUMMARY

Implementing Epic Beaker is one of the most complex and high stakes projects a laboratory can undertake. With more than 70 percent of a patient record driven by laboratory results, the success of your Beaker go live will directly impact patient care, operational efficiency, and regulatory standing.

Epic provides a clear Clinical Content Validation (CCV) methodology for building and testing. However, Epic project tools are not designed to produce the compliance grade documentation required by CAP, CLIA, ISO 15189, or internal quality systems. That responsibility rests with the laboratory. In the rush to follow the Epic way, compliance work can be unintentionally minimized.

At the same time, Beaker projects place extraordinary demands on lab operations teams:

- High testing volume - often thousands to tens of thousands of test cases acrossCCV2 and CCV3.
- Tight timelines - fixed go live dates tied to enterprise Epic deployments.
- Resource constraints - SMEs balancing validation duties with their full clinical workload.
- Relying only on spreadsheets and shared drives to manage this complexity creates avoidable risks such as missed defects, incomplete evidence, delayed approvals, and even failed inspections.





Cymetryc: Compliance Without Compromise

Cymetryc is a purpose built, cloud based testing and validation platform for health IT, including Epic Beaker. It complements Epic CCV by doing the following:

- Generating workflow specific, regulator ready test cases from the approved CCV1 build export using TestGenisys.
- Capturing compliance grade evidence in real time, embedded directly into each test case.
- Rolling up progress and status into Epic Excel based CCV trackers for project reporting.
- Enabling paperless, parallel approvals by medical directors and reviewers.
- Producing one click, inspection ready reports that meet CAP, CLIA, and ISO 15189 requirements.
- Providing a secure repository that is permitted by Epic to store Epic screenprints for validation evidence.

Proven impact in complex lab implementations includes:

- 40 to 50 percent reduction in SME testing effort by eliminating manual tracking and evidence formatting.
- Faster defect resolution with linked retests and integrated issue tracking.
- Improved compliance confidence with complete, searchable, and traceable validation records.

Your Beaker go live will happen once. The quality of your CCV process will determine whether it happens on time, on budget, and with full quality and regulatory confidence. Cymetryc ensures that every test case, every defect, and every approval is documented to the standard your accrediting body expects while keeping the Epic implementation workflow intact.

THE STATE OF LIS IMPLEMENTATIONS TODAY

In modern healthcare, the Laboratory Information System (LIS) has evolved from being a departmental tool to becoming a mission-critical component of the entire care delivery ecosystem. A well-implemented LIS directly influences patient safety, diagnostic turnaround times, and regulatory compliance — all while serving as the data engine behind more than 70% of the information in a patient's medical record.

From Standalone to Integrated

Historically, LIS platforms operated in silos, interfacing loosely with the electronic health record (EHR) through a patchwork of HL7 connections. Today, that model is giving way to fully integrated solutions such as Epic Beaker, where lab data flows seamlessly into the broader patient chart. The shift offers undeniable clinical benefits:

- Reduced data transmission errors through direct result posting
- Unified patient records across inpatient, outpatient, and specialty settings
- Better data analytics for population health and operational planning

However, with integration comes complexity. The LIS is no longer "owned" solely by the lab; it must align with enterprise EHR strategies, information security policies, and coordinated upgrade cycles. This makes implementation a multi-stakeholder endeavor, often involving dozens of interdependent teams.

The Acceleration of Change

Healthcare organizations are facing shorter technology refresh cycles and more frequent major upgrades. Drivers include:

- **Vendor-driven upgrade roadmaps:** EHR and LIS vendors set aggressive release schedules to deliver new features and maintain security compliance.
- **Regulatory evolution:** Standards from CLIA, CAP, and ISO 15189 are increasingly explicit about software validation, traceability, and test evidence retention.
- **Operational pressures:** Post-pandemic staffing shortages and cost-containment initiatives mean lab teams must deliver transformation projects without additional headcount. Validation has shifted from a periodic task to a continuous requirement.
- **Rapidly advancing technology:** New instrumentation, automation, and emerging uses of AI in laboratory workflows are accelerating the pace of change and raising the stakes for validation.

What was once a three-to-five-year LIS or EHR-integrated lab upgrade cycle is no longer sustainable. Today, organizations must plan for seasonal updates and expect to take at least two major updates each year just to stay current.



Why Epic Beaker Leads Many Implementations

Epic's dominance in the EHR space has naturally extended into the LIS market through Beaker. Organizations adopting or migrating to Beaker cite:

- The strategic advantage of a unified Epic platform
- Reduced complexity in maintaining multiple vendor systems
- Native Epic reporting and analytics capabilities
- Improved clinician workflows due to shared user interface and patient record structure

For many organizations, implementing a new LIS from the ground up is a once-in-a-career event. Some hospital systems have relied on the same LIS for decades, often since their first adoption of laboratory information technology. Today's LIS platforms are far more powerful, but also significantly more complex—testing a brand new build means accounting not only for the LIS itself, but also for the many connected instruments, middleware systems, and point-of-care devices that must all be exercised and proven accurate and reliable. The clinical content validation (CCV) process is not a simple "swap out the old LIS" exercise—it requires structured, evidence-heavy scrutiny across build data, functional workflows, and integration points, all under the oversight of regulatory bodies and accreditation agencies.

Impact on Lab Operations

In virtually every Beaker project, Lab Operations Subject Matter Experts (SMEs) bear the brunt of testing and validation. While IT manages the build, only lab SMEs can confirm clinical accuracy — and they must do so in addition to their full workload of processing thousands of patient results daily. This dual responsibility creates several systemic risks:

- **Burnout and errors** from sustained workload spikes that can lead to patient safety risk
- **Testing delays** when SMEs are pulled back to daily operations
- **Compromised compliance** if evidence is incomplete or approvals are rushed
- **Inefficient workflows** when relying on generic tools like spreadsheets for tracking thousands of test cases

As LIS technology becomes more sophisticated, the mismatch between the complexity of testing requirements and the limitations of legacy validation processes becomes increasingly untenable. The next sections of this paper explore why this gap matters — and how modern, purpose-built validation platforms can close it.

Although we had always done it that way, we could not meet our goals without changing our validation approach. Onboarding Cymetryc was straightforward across a range of skill sets, and we began using it quickly.

THE BEAKER CHALLENGE

CCV AS A COMPLIANCE HEAVY PROCESS

Epic Beaker offers clear advantages in integration, workflow efficiency, and enterprise reporting. Yet for lab operations teams, the most defining feature of a Beaker project is not the go-live date — it is the Clinical Content Validation (CCV) process that dominates the build-to-launch timeline. CCV is not just a testing cycle; it is a regulatory-grade verification effort designed to ensure every detail in the laboratory information system is accurate, complete, and fit for clinical use.

The Beaker CCV process is typically broken into three major phases, each with its own scope, deliverables, and risks.

CCV1 - Clinical Content Review

CCV1 occurs after the Beaker build is substantially complete but before functional testing begins. It involves a meticulous review of the build output to confirm clinical correctness and data integrity. SMEs review Epic's system output documents line by line, checking:

- **Procedures** — specimen source/type, names, ordering questions
- **Tests** — accessioning logic, container specifications, turnaround times, expiration dates, test methods, mnemonics, collection questions, reflex algorithms
- **Containers** — names, types, label names, specimen types, volume requirements
- **Result Components** — reference ranges, units of measure, LOINC codes
- **Specimen & Task Protocols** — names, abbreviations, synonyms, specimen sources, associated tasks
- **Organism Build** — microbiology data accuracy

Even small errors in CCV1 — a misplaced decimal point in a reference range, an incorrect unit of measure, a misspelled organism name — can cause cascading issues in later testing phases. A clean CCV1 directly reduces rework in CCV2 and CCV3, freeing SMEs to focus on operational validation rather than troubleshooting minor data problems.



CCV2 - Functional Testing

CCV2 is where Beaker begins to operate as a live laboratory system in a controlled test environment. Here, the team simulates the full order-to-result workflow, validating that each function behaves exactly as specified. This is the first phase where regulatory-grade validation evidence must be collected and retained.
Key elements of CCV2 include:

- Translating Epic's large, multi-tab spreadsheets into discrete, executable test cases
- Capturing step-by-step evidence (often hundreds of screenshots per tester)
- Documenting actual vs. expected results
- Logging defects and routing them to the build team for correction
- Obtaining clinical review and approval for each test case before closure

The scale of CCV2 can be immense. While an average single-site implementation might involve 2,800–3,000 test cases, one large, leading New England health care system executed over 14,500 CCV2 test cases and identified more than 1,580 issues requiring resolution. Managing that scale of testing with spreadsheets and shared drives is inefficient at best — and can jeopardize evidence completeness and defect tracking.

CCV3 - Integration and End to End Testing

CCV3 extends functional testing into the full enterprise ecosystem. This phase validates Beaker's interactions with instruments, middleware, and other Epic modules — from order entry in EpicCare to result posting in Hyperspace, and data flow into billing, analytics, and reporting systems.

Because CCV3 touches multiple departments, coordination is more complex, requiring:

- Cross-team scheduling for integrated workflows
- Concurrent defect management across multiple systems
- Additional approvals from clinical and operational leaders outside the lab

The New England health care system example highlights this complexity: CCV3 at that organization involved over 7,500 additional test cases and uncovered more than 1,100 issues needing remediation before go-live. This level of volume and cross-system coordination makes real-time visibility, streamlined evidence capture, and efficient defect resolution essential.

The Compliance Dimension

Inspectors tend to focus less on the software itself and more on whether the lab's documented process demonstrates compliance. Every CCV phase produces regulatory artifacts. Under CAP, CLIA, ISO 15189, and other standards, labs must be able to demonstrate:

- Defined acceptance criteria for each test
- Complete evidence that criteria were met (including screen captures and audit trails)
- Independent review and approval by qualified personnel
- Traceability between requirements, test cases, and results

Failure to produce this documentation during an inspection can lead to citations, mandatory remediation, and in severe cases, suspension of testing for affected services.

Why the Process Overwhelms Labs

CCV demands not just technical accuracy, but also volume discipline: every test case, every approval, every screenshot must be tracked without gaps. For SMEs who are not professional software testers, this is a steep operational hill to climb. The challenges are amplified by:

- Fragmented tools — Epic spreadsheets, shared drives, email threads
- Interrupted testers — SMEs pulled back into live lab duties mid-test
- Delayed approvals — clinical reviewers waiting on complete evidence packages
- Limited visibility — project managers lacking real-time progress or defect resolution status.

"With Cymetryc, progress was visible to managers and testers across sites, which made data factual rather than interpretive. Issue logging and tracking were easier because screenshots and details were captured with each case."

In the next section, we will look at why the traditional tools used to manage CCV — primarily spreadsheets and manual evidence folders — consistently fall short in the context of a Beaker project, and why this gap creates both operational and compliance risk.

WHY TRADITIONAL TOOLS FAIL IN BEAKER TESTING

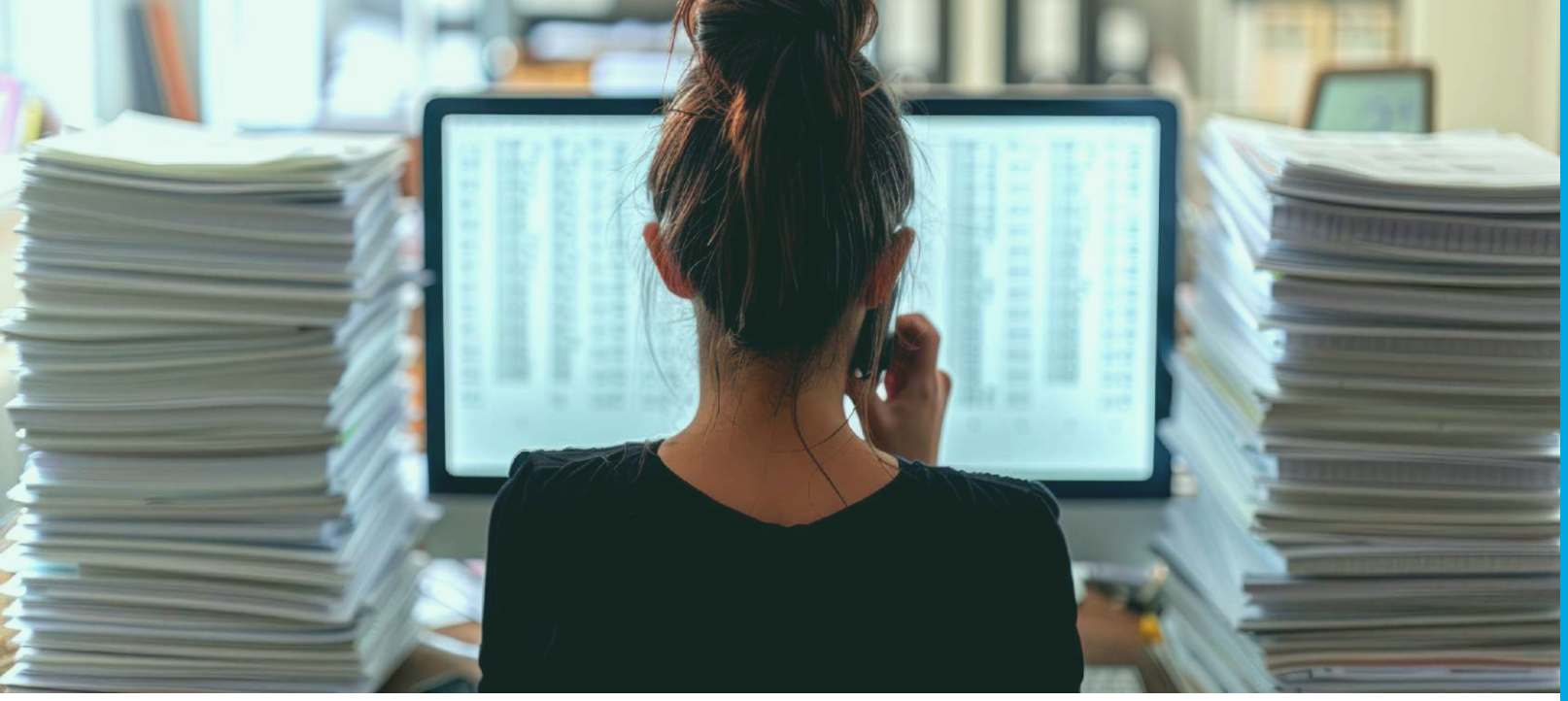
Epic delivers Beaker with robust technical capabilities and a structured implementation methodology. The tools Epic provides — such as the Clinical Content Validation (CCV) spreadsheets — are well-designed for tracking build elements, sequencing testing, and managing project tasks. They are not, however, built with regulatory compliance as the primary objective. And that's by design.

Epic's Focus vs. the Lab's Responsibility

Epic delivers a functional, technically sound laboratory information system, with project tools designed to guide teams through the build and testing process. These tools are highly effective for managing the implementation within the Epic ecosystem. What they are not intended to provide, however, is the full scope of compliance documentation, evidence retention, and audit readiness required by regulators — responsibilities that remain with the laboratory.

The challenge arises when project teams, focused on staying aligned with Epic's process and timelines, unintentionally underemphasize compliance needs. This is rarely deliberate; more often it reflects resource pressures, aggressive deadlines, and the assumption that passing functional testing is sufficient. In practice, regulatory obligations demand more: complete, traceable, inspection-ready validation evidence. Epic's CCV tools ensure a rigorous build and test process, and platforms like Cymetryc complement them by ensuring the compliance side of the equation is met with equal discipline. Importantly, Cymetryc is also permitted by Epic to store Epic screenprints, creating a seamless bridge between CCV execution and regulatory documentation.





Limitations of Spreadsheets and Shared Drives

Most Beaker CCV efforts rely on a combination of large Excel trackers, shared file repositories, and email threads to coordinate test execution and evidence collection. This approach, while familiar, carries inherent weaknesses:

1. **Evidence Fragmentation**
   Screenshots and documents are often stored separately from the test case results. Finding the right evidence during a review or inspection can mean hours of manual searching.

2. **Manual Data Handling**
   Copying results, linking screenshots, and updating status cells in spreadsheets is repetitive, error-prone work — particularly when thousands of test cases are involved.

3. **Limited Real-Time Visibility**
   Spreadsheet status updates lag behind actual tester activity. Project managers cannot see instantly which tests are blocked, which defects are unresolved, or which approvals are pending.

4. **Version Control Issues**
   With multiple testers working from copies of the same spreadsheet, discrepancies in data versions are almost inevitable.

5. **No Built-In Compliance Formatting**
   Regulators expect structured, standardized documentation with embedded evidence, tester and approver credentials, and clear traceability. Spreadsheets do not produce this without substantial manual formatting and compilation.

The Impact at Scale

When test volumes are modest, these limitations are inconvenient but manageable. In a Beaker implementation — especially for multi-site health systems — they can derail timelines and compromise audit readiness. Consider the New England health care system example from the previous section:

- 14,500 CCV2 test cases and 1,580+ issues
- 7,500 CCV3 test cases and 1,100+ issues

Coordinating that volume of work with spreadsheets and file shares means thousands of opportunities for delays, missed cases, or incomplete evidence.

Compliance is the Lab's Job — and Cannot Be Deferred

Regulatory bodies such as CAP, CLIA, and ISO 15189 place the compliance burden squarely on the laboratory. That includes:

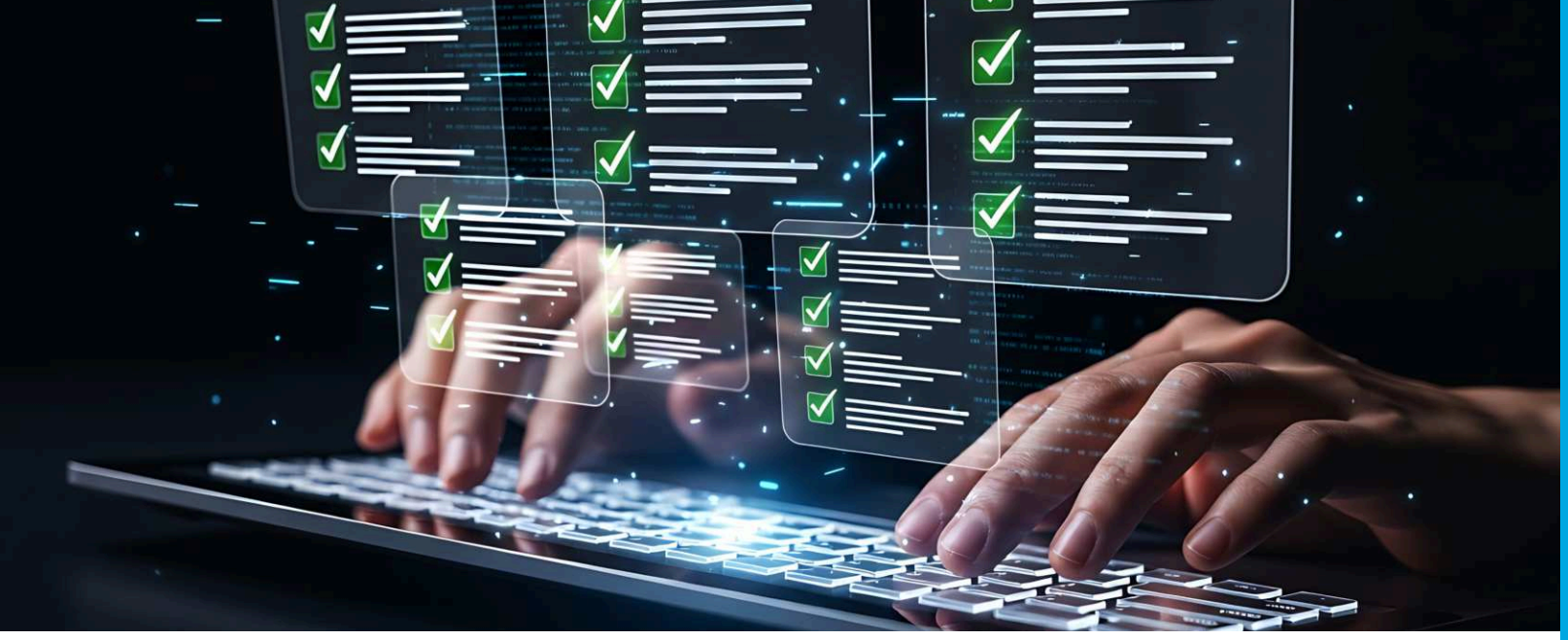
- Ensuring that every executed test case has corresponding evidence
- Verifying that all evidence is reviewed and approved by qualified personnel
- Maintaining traceability between requirements, test cases, and results
- Producing documentation in a format acceptable for inspection

Epic's tools were never intended to fulfill these obligations — nor should they be. But unless the lab has a parallel process for capturing and compiling compliance-grade validation evidence, there is a real risk that in "following the Epic way" these requirements will be partially met or overlooked entirely.

Cymetryc was designed from the ground up to solve the exact problem Beaker CCV creates for laboratory operations: how to execute thousands of test cases, collect complete regulatory evidence, and keep stakeholders informed — all without slowing the project or burning out subject matter experts.

Unlike generic project management tools or ad hoc spreadsheet trackers, Cymetryc is purpose-built for health IT testing and validation, making it uniquely suited for the dual demands of a Beaker implementation:

- Follow Epic's methodology for CCV execution
- Simultaneously meet the laboratory's compliance, evidence, and audit requirements



From System Build to Actionable Test Cases

Rather than manually crafting test cases from Epic's CCV spreadsheets, Cymetryc starts with standard system build export reports from the Beaker environment. Using TestGenisys, Cymetryc's intelligent test case builder:

- Instantly generates detailed, workflow-specific test cases tailored to the client's operational and regulatory needs
- Ensures each case includes precise instructions, expected outcomes, and evidence capture prompts
- Eliminates the manual step of parsing Epic trackers or vendor documents into a testing format suitable for CCV execution

The result: your lab receives ready-to-execute, regulator-ready test cases that align with your actual workflows — not just generic "one size fits all" scripts.

Feeding Epic's Tracking Without Double Entry

Cymetryc's goal is not to replace Epic's CCV trackers — it's to make them more accurate, more current, and far less burdensome to maintain.

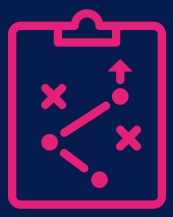
As testers work in Cymetryc, the platform automatically:

- Captures progress, pass/fail status, defect counts, and approval status in real time
- Formats this data so it seamlessly rolls up into Epic's Excel-based CCV trackers
- Ensures Epic's roll-up reports stay current without manual spreadsheet updates or status chasing

This integration preserves Epic's visibility model while giving the lab a more sophisticated, compliance-ready execution environment.

Cymetryc for Beaker

1



Plan & Manage

Generate regulator-ready test cases directly from build exports using TestGenisys.

Assign cases to SMEs by site, discipline, or workflow “bucket” to maximize efficiency.

2



Execute with Embedded Tools

Side-by-side testing interface for Beaker and Cymetryc, so testers never leave the application under test.

Integrated screenshot capture, attachment upload, and issue creation at the step level.

3



Monitor Progress in Real Time

Dashboards display progress, open defects, & pending approvals.

Instant insight into bottlenecks to reassign or reprioritize work without waiting for end-of-week updates.

4



Approve Paperlessly

Clinical reviewers can approve or reject online, with side-by-side evidence viewing for end to-end validation.

Approvals are time- and user-stamped for audit readiness.

5



Document with One Click

Produce inspection-ready compliance reports with embedded evidence, approver credentials, and traceability — all formatted to meet CAP, CLIA, and ISO 15189 standards

Designed for Multi-Site Complexity

For multi-hospital or regional lab networks implementing Beaker, Cymetryc offers centralized oversight without compromising local accountability. Project managers can:

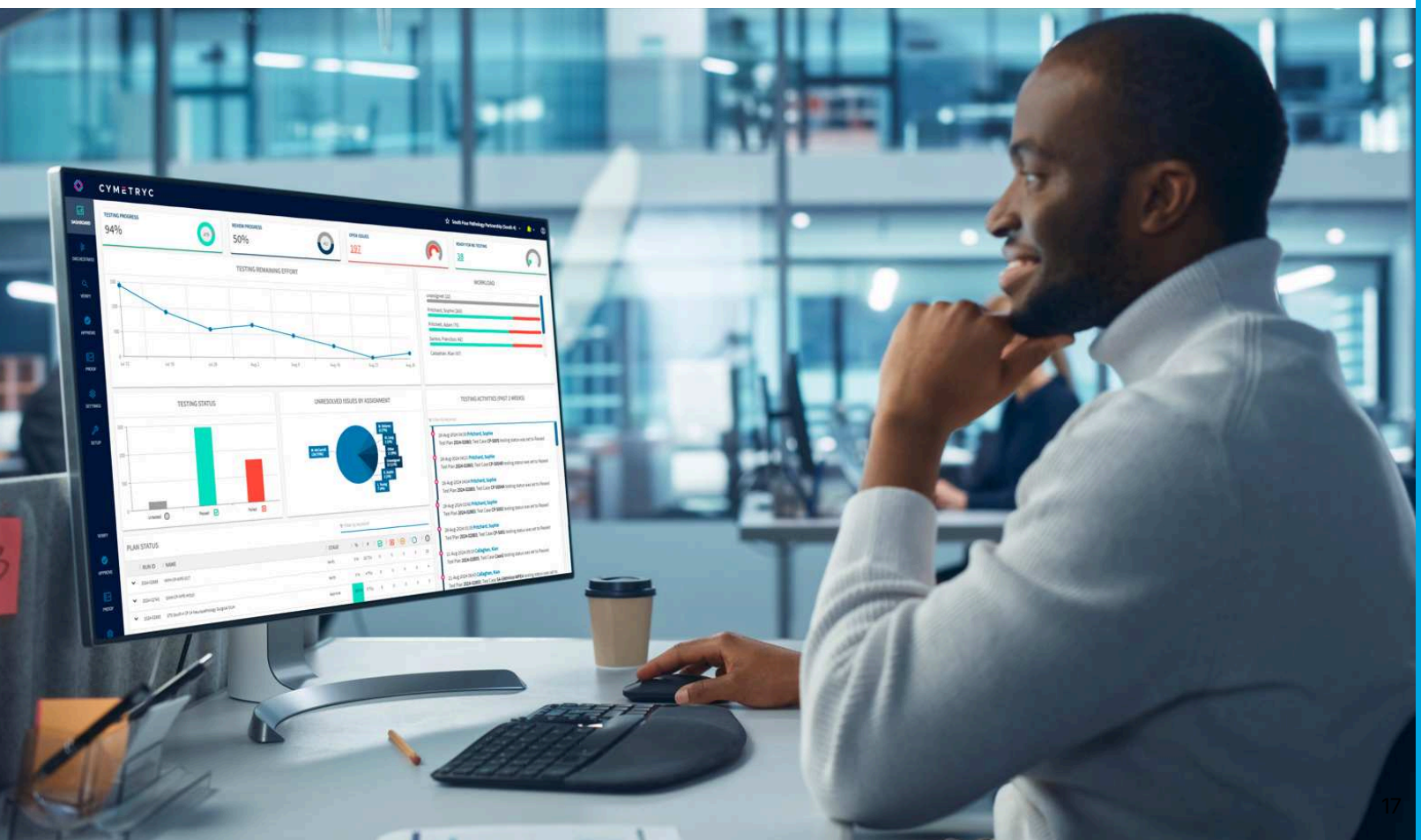
- See aggregated progress across all sites and phases
- Drill down to specific issues at an individual location
- Push status updates directly into Epic's roll-up reporting with no extra work

This eliminates the constant back-and-forth of emailing spreadsheets, reconciling versions, and waiting days for status consolidation.

The Net Effect: Less Burden, More Control

By pairing Cymetryc's TestGenisys-generated test cases with Epic's CCV reporting structure, labs:

- Preserve Epic's process consistency and visibility
- Eliminate duplicate data entry
- Gain compliance-grade documentation automatically
- Give SMEs a faster, more intuitive way to test and capture evidence [Comment: Define 'SME' on first use (Subject Matter Expert).]
- Provide leadership with real-time progress and issue tracking across all phases and sites



CCV PHASE BY PHASE – WHERE REGULATORY DOCUMENTATION FITS

The site medical director determines where formal regulatory documentation is required. The mapping below reflects common practice we observe. Cymetryc takes a fresh export only after CCV1 approval so that CCV2 and CCV3 start from a clinically verified baseline.

Epic Beaker Stage	Typical Compliance Requirements	Cymetryc Support
CCV2 - Workflow Scenario Testing	Execution records and evidence for each scenario, defect and retest linkage, reviewer approval	Auto generated cases, embedded evidence, issue tracking, inspection ready reports
CCV3 - Analyzer and Device Integration	Instrument specific validation, correct result routing and exceptions, approvals	Organize by instrument, capture evidence step by step, dashboard oversight Autoverification (AV Rules)
Autoverification (AV Rules)	Evidence that rules perform as intended, overrides with rationale, approval	Generate AV cases, record results and exceptions, capture reviewer sign off
Integrated or PRCT	End to end scenario documentation across systems with approvals	Cross system evidence capture, side by side viewing, time and user stamped approvals

Note: the medical director has final discretion on where evidence is captured and retained.

COMPLIANCE WITHOUT COMPROMISE

Regulators assess whether the lab has documented, reviewed, and approved the system in a way that meets standards. They do not assess whether the project used a specific vendor methodology. Cymetryc provides the compliance layer that rides alongside Epic CCV so both are satisfied.

Meeting CAP, CLIA, and ISO 15189

- Capture evidence in real time during testing to avoid post hoc reconstruction.
- Link evidence directly to test cases and requirements to ensure traceability.
- Embed tester and approver credentials in the final reports.
- Maintain a permanent, searchable repository of validation activities for audits.

"Cymetryc delivered a 25% reduction in effort for my role by holding all the data in one place… I think Cymetryc helped us find and resolve 50+ issues that might have otherwise been missed."



Cymetryc Epic Beaker Implementation Roadmap

A guide to the phases of our **Epic implementation process**, ensuring alignment and readiness for go-live.

PHASE 1

Early Engagement and Planning

Align with **Epic CCV milestones**, define where regulatory evidence is required, and plan resource assignments.



PHASE 2

Export After CCV1 Approval

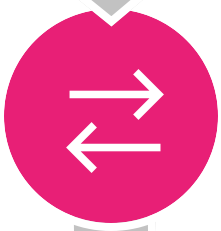
Take a fresh approved build export and use **TestGenisys** to generate detailed CCV2 and CCV3 cases.



PHASE 3

CCV2 Execution in Cymetryc

SMEs execute with **real time evidence capture**. Defects are linked to cases. Status rolls into Epic trackers.



PHASE 4

CCV3 Execution in Cymetryc

SMEs now validate instruments, middleware and module integrations with linked evidence and dashboards.



PHASE 4

Autoverification, Interfaces, PRCT

Complete specialized validations with **traceability and approvals**.



PHASE 6

Review and Approval

Enable **continuous paperless approvals** to avoid bottlenecks.

This process ensures all regulatory and validation requirements are met for go-live.

CONCLUSION:
Turning the Beaker Wave into Measurable Success

Epic Beaker delivers unmatched advantages for laboratory integration — but its Clinical Content Validation (CCV) process can overwhelm even the most prepared teams if managed with spreadsheets and shared drives. Compliance, completeness, and traceability at scale demand a modern approach.

Why Cymetryc

Cymetryc aligns seamlessly with Epic's CCV methodology while providing:

- 40–50% less SME effort through automated test case generation and evidence capture
- Hundreds of hours saved by eliminating manual compilation
- Faster issue resolution with integrated retest tracking
- Inspection-ready reports that meet CAP, CLIA, and ISO 15189 standards

Confidence at Go-Live

Your Beaker go-live will happen once. The quality of your validation process will determine whether it happens on time, on budget, and with complete assurance of patient safety and compliance.

"The instant inspection-ready reports eliminated the need for manual evidence collection and saved hundreds of hours. Investigators were impressed with the level of evidence and traceability we had."

NEXT STEP

Stay ahead of the validation wave. See how Cymetryc helps leading health systems modernize Beaker validation.

Visit **www.cymetryc.com** or contact us today for a tailored walkthrough.

CYMETRYC