CYMETRYC

New Analyzer Implementations:

Evaluating and Improving the Software Verification Process

Ensuring Test Results Are Reported Accurately to Physicians and Outside Laboratories



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Prepared by:

Deborah Hewett-Smith, Director of Corporate Accounts; Jane Knight, MT(ASCP) , Senior Implementation Specialist and Jennifer Lyle, Chief Innovation Officer

AN INTRODUCTION

Laboratories of all sizes report that they are now constantly implementing new analyzers with smaller lab adding 5 new analyzers annually and large IHNs adding up to 300 in a single year.

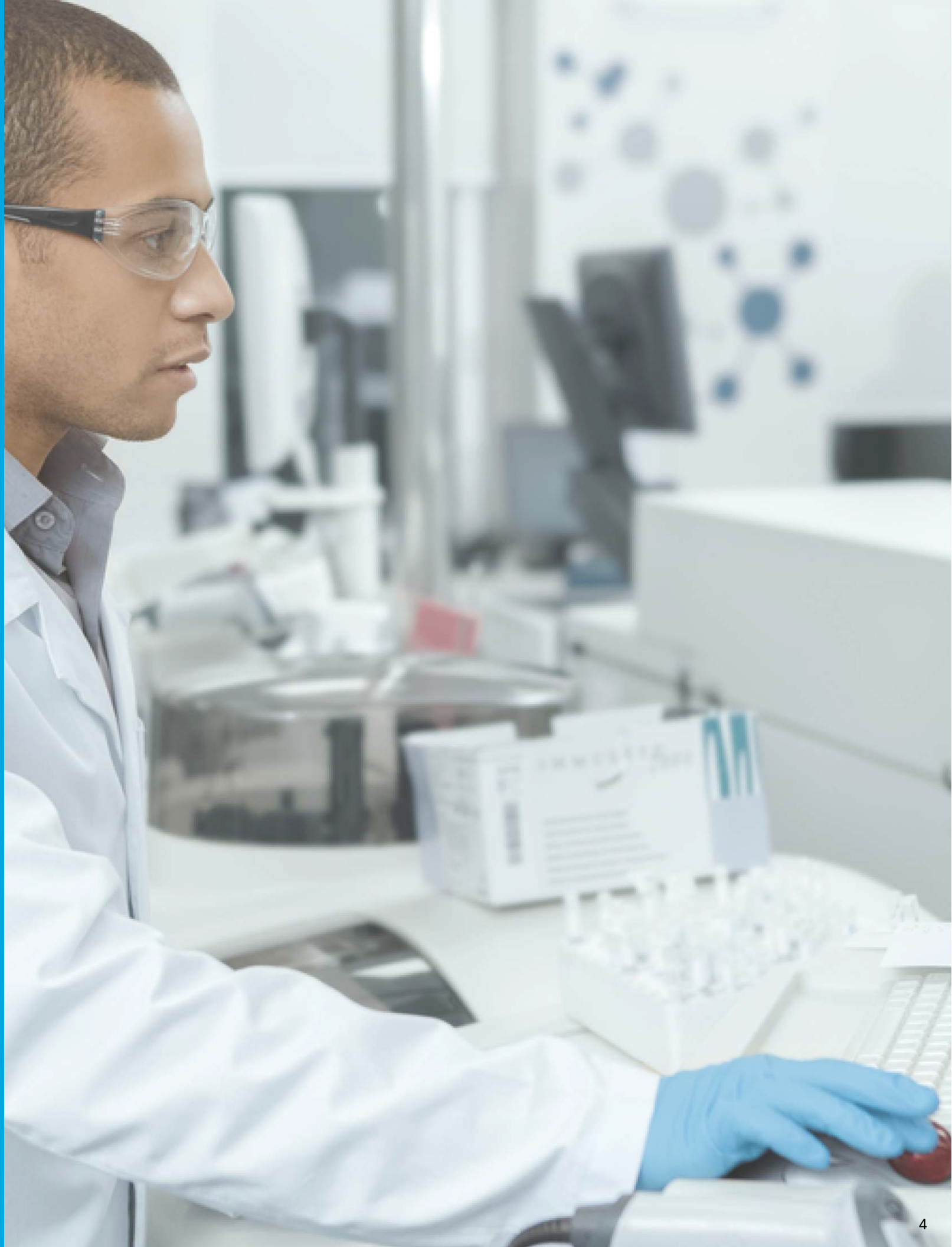
This work is added on to their responsibilities of operating and managing the laboratory's daily work.

Clinical Laboratories are implementing new tests and new test analyzers at a higher rate than ever before. As the demand for lab testing grows, as new tests emerge, so does the demand to implement more tests and new or replacement analyzers and automation for processing them.

As health systems continue to bring on more hospitals (and their laboratories) into their orbit, the complexities increase with the demand to standardize equipment and processes across the enterprise to improve consistency and gain efficiency. Many of these laboratories are joining the march by adopting single vendor platforms, especially for immunochemistry and hematology; they are expanding their molecular and genomic testing and implementing more solutions at the point of care (POC).

Preparing analyzers for production use is a tedious and time consuming process that requires specialized scientific technical expertise; laboratory operational readiness; and effective IT data integration. Yet despite the complexity and impact on patient care, much of the overall process of launching a new analyzer from end-to-end is manually 'plumbed together'.

This white paper will address a critical aspect of analyzer implementation: the laboratory software validation process, for integration testing and wet testing. It will provide a framework for evaluating the software verification process as it relates to new analyzer implementations, strategies to demystify the process, time savings and improved communications with the team and stakeholders involved. It will present examples of how hospital and health system laboratories approached making changes.



DIAGNOSTIC ANALYZER IMPLEMENTATION:
EVALUATING & IMPROVING THE SOFTWARE VERIFICATION PROCESS

The verification that patient results are accurately transmitted from the point of data entry (interfaced instruments and manual input) to patient reports (whether paper or electronic) is the responsibility of the laboratory[1]

The process for validation of an analyzer is an arduous process, even with the help and support of the vendor. The accuracy and reliability of analyzer data is paramount for reportable test results. Yet, even after the analyzer has been validated, data generated by it must also be verified as they pass through the series of applications that store and report test results out to physicians, nurses and other laboratories.

Can those receiving systems, the LIS, the middleware, the EHR, the EMR – can those systems 'get it wrong'? The answer is YES.

Like a game of 'telephone', information can be misinterpreted as it passes from one software system to the next; rules that were assumed to be firing, actually don't; comments may not transmit as expected. The planning and execution of a manageable yet robust software verification demands the development of a written verification test plan and testing strategy designed to identify errors before the analyzer is put into production.

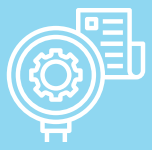


1 College of American Pathologists (CAP) General Checklist Guidelines, GEN.48500

PREPARING A PLAN:

KEY CONSIDERATIONS & IDENTIFYING HIGH RISK AREAS

Preparing a plan helps labs focus on what are the testing priorities rather than trying to ‘do it all’ or worse testing too little; it gives labs a way to collect input from their stakeholders; and it gives the lab a way to pre-identify the risks and plan for mitigation steps.



KEY CONSIDERATIONS:

- Will workflows be standardized across the different lab locations?
- What specimens can be collected for software verification testing?
- Will the ‘build/configuration’ be frozen before testing begins?
- What is the change process once verification testing has begun?
- What is the timeline expectation and what effect will that have on the test plan?

An evaluation of the quality requirements and possible deficiencies in the process of the software verification of lab tests will also serve to ensure quality standards are met.

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The importance of a high quality software verification process cannot be understated. Even an accurate fully verified analyzer can report inaccurate or misleading test results because the receiving software misinterpreted or miscalculated (and therefore reported) inaccurate information. In today's highly connected environment the risk is compounded by ever more end point receiving systems besides the traditional electronic health records system (EHR) and LIS/LIMS. Various middleware products receive the data, electronic medical records systems (EMRs) used by physician offices, and outside reference laboratory systems are often connected electronically.

Comparative Cost of Quality



$1

Defect prevention efforts



$10

Inspection and testing to catch & correct defects



$100

Patient or physician finds or is impacted by error

Inaccurately reported test results, can involve remedial actions, often at considerable cost, including sending corrected reports to patients for inaccurately reported test results, the time to retrace and readdress issues within a system's production (not test) environment, applying corrections and fixes to perhaps more than one system, and documenting the issue and resolution. All of this notwithstanding the potential patient harm as well as the reputational impact.

Proper planning and execution process of software verification testing is a high priority process to ensure accuracy and confidence in a new analyzer's performance and data reporting.

RISK ONE:
HOW MUCH VERIFICATION TESTING IS ENOUGH

Sadly, in today's laboratories the exodus of experienced laboratory professionals represents a 'double hit' of losing workforce in staffing and decades of experience that has led to dangerous gaps in knowledge. One of these knowledge gaps that can pose a risk for accurate laboratory data reporting is determining how much software verification testing is enough to avoid errors and meet stringent regulatory requirements.

Sometimes guidance for testing is provided by the vendor, such as a data collection worksheet (DCW) that was used for middleware build or using an internal build sheet from the LIS/LIMS data as a 'source of truth' can be a good place to start.

Labs can also benefit when they consider how to organize their software verification testing. Three strategic approaches:

Test Code approach:

This approach involves creating one test script/test case for each test code that includes a all of the scenarios and criteria; gathering the screen print evidence related to each test code individually.

Criteria approach:

With this approach, you are creating batches of test scripts/test cases that are organized by criteria, e.g., reference ranges, delta checks, linearity, text results, and applying them to the applicable test codes.

Risk-based approach:

Here you will prioritize the test scripts/test cases such that the highest volume tests are verified first; also tests with rules that change results (e.g., linearity adding < or >, or a calculated result); where there are multiple identical analyzers, verifying one comprehensively, the others would involve a subset of testing.

Yet absent internal expertise to choose the best approach, labs quickly flounder. They set overly ambitious testing requirements that could not possibly be completed in the timeframe allotted, or they limit their verification to minimal spot checks. Still others delegate the laboratory's responsibility to the LIS/LIMS team, in the hope that they will know what to do.

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2 Rodney Rohde, 2/12/2024, "Workforce in the Shadow of Healthcare –An Update on the Survival Status of Laboratory Medicine and Public Health", ASCP.com, www.community.ascp.org

CONVERSION TO A CLOUD BASED SOFTWARE VERIFICATION ACCELERATOR

CYMETRYC INITIATIVE 1

TriCore Reference Laboratory

TRICORE

TriCore was founded in 1998 as an independent, not-for-profit, clinical laboratory, sponsored through a unique collaboration between Presbyterian Healthcare Services and the University of New Mexico Health Sciences Center.

The Laboratory Set Out to

Complete 500 integration test scripts to exercise the new Roche cobas® system implementation and 350 test scripts for new analyzers at the Southern Clinical Lab under ambitious timelines and without cutting corners.

What Helped

A verification testing platform that centralized, streamlined and accelerated the process and communications for both testers and medical directors.

"Without the distraction of tedious manual tasks and cumbersome documentation processes, it was easier for us to spot errors and we gained unprecedented efficiencies of testing which had a direct impact on meeting our timeline goals,"

Veronica Luzzi
PhD, Section Chief and Medical Director



RISK 2:
ENSURING ISSUES ARE ADEQUATELY IDENTIFIED, RESOLVED & RETESTED

A critical part of any verification process is to identify, document, communicate and resolve issues that are detected during the software verification testing process. For most laboratories, this is largely a manual and siloed process. Often issues are communicated and handled through email and captured onto a spreadsheet. The process involves many stakeholders (the analyzer vendor, the lab leadership, lab staff, and lab IT) which compounds the risk of issues falling through the cracks or not resolved in a timely manner or confusion about how to understand or recreate the issue for resolution.

ISSUE MANAGEMENT CONSIDERATIONS

- Identification and explanation
- Priority and risk
- Communication
- Assigning the appropriate resource
- Review and analysis
- Resolution
- Re-testing and documentation

Improving the issue management process means that testers are able to fully document problems in real-time, in a concise way, and have the ability to supply screen print examples of the error. They will need to be able to record problems in a central location that provides access for all of the stakeholders (both internal and external). Centralized issue management ensures that problems don't slip through the cracks and that they get re-tested and that both the initial failure and the re-testing is captured and documented in the final report.

CONVERSION TO A CLOUD BASED SOFTWARE VERIFICATION ACCELERATOR

CYMETRYC INITIATIVE 2

MaineGeneral Health

MaineGeneral Health is a comprehensive non-profit system with the mission of enhancing, every day, the health of its patients, its families and its communities.

The Laboratory Set Out to

Move away from spreadsheet-based testing to a centralized solution to

- Better control project timelines and avoid delays
- Gain visibility of testing plan, testing status and review status
- Eliminate manual preparation of final inspection-ready documentation

What Helped

A testing platform that did not have a big learning curve and was easy to use but still held everyone accountable. Visibility as to progress of testing and knowing in real-time what testing is completed and what is still open.

"I'm not sure that people outside of the lab realize how laborious this effort can be and how it can impact getting new functionality and equipment installed in the laboratory," says Forrest Labbe, Manager ERP & Business Systems. "We knew that we needed to modernize our approach to streamline what we were doing. Essentially, we needed to give our team more tools to cut down on the heavy reliance on manual processes."

RISK 3:

MEETING REGULATORY REQUIREMENTS:
Medical Director Approval and Evidence of Compliance Report

Completing the final report for medical director review and approval and maintaining the report for quality and regulatory compliance purposes typically represents one of the final steps before an analyzer may be put into production for patient care. Approval that the data from the analyzer is correctly communicating to all upstream and downstream systems is often the final check before the analyzer is considered ready for go-live.

The regulatory requirements are specific. Such reports must include the specifics of what was verified, and they must incorporate evidence or proof, namely screen prints, that the data that passes to and from the analyzer maintains its integrity.

The tedious process of capturing screen print evidence, the copy/paste method of applying data and formatting it into a final verification report can cost the laboratory 50% of the overall verification testing process time.[3]

Not only are laboratories tediously cobbling together such verification reports manually and storing them in binders, they are also using them as the method for obtaining medical director review and sign-off of the data verification itself. This means that the 'final report' is not actually a final report, unless the medical director finds no issues during their review.

Solutions that leverage technology offer a way to segregate the process of medical director review/approval from the creation of the final report. No longer bound by using a paper report, they can complete their review and approval from any location and at any time. As issues and questions and errors are identified they can be captured electronically and instantly communicated to the team assigned to address them.

Cutting out time wasters while simultaneously modernizing a vital quality process that better protects patients and staff from errors should be on every laboratory's priority list.

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[3] Source: Software Testing Solutions, LLC. Time study between a laboratory's manual processes and use of a verification testing platform.

CONVERSION TO A CLOUD BASED SOFTWARE VERIFICATION ACCELERATOR

CYMETRYC INITIATIVE 3

New England Medical Center

A large academic medical center, a national leader in clinical care, and the largest essential hospital in New England

The Laboratory Set Out To

Complete wet testing and data integration testing for a hematology middleware upgrade under constrained timelines.

What Helped

A verification testing platform that facilitated site-specific test script generation, centralized issue tracking and streamlined both the testing and review process for testers and medical directors.

"I can't imagine what we would have done without a centralized testing platform. We would have preferred five months to complete our verification testing but we were given just three months," explained the hematology manager. "We were able to streamline the process – no more long email chains – all of our tools and information we needed was at our fingertips."

Hematology Manager

CONCLUSION

THE NEED TO DO MORE WITH LESS WITHOUT SACRIFICING QUALITY

Using a standardized platform that streamlines the clinical laboratory's software verification testing process allows the clinical laboratory scientist (CLS) to stay focused on finding errors before an analyzer is placed into production. The challenge with manual processes today is that the CLS is easily sidetracked, interrupted and spends an inordinate amount of time fighting a process that has become overwhelmingly cumbersome.

Digitizing the software verification not only helps the laboratory accelerate the process it also provides unimagined capabilities that are a hallmark of a centralized cloud-based platform.

Competitive laboratories need better tools to help them expedite the implementation of new tests, new analyzers and automation without sacrificing vigorous testing. They demand to more easily inspect data between systems such as side-by-side screen print review; to view a centralized issues list in real time; and use more automated capabilities that generate regulatory, and accreditation required reports versus having to cobble them together manually. Leveraging digital fit-for-purpose solutions will, in the long run, maximize efficiency of the laboratory's software verification process.



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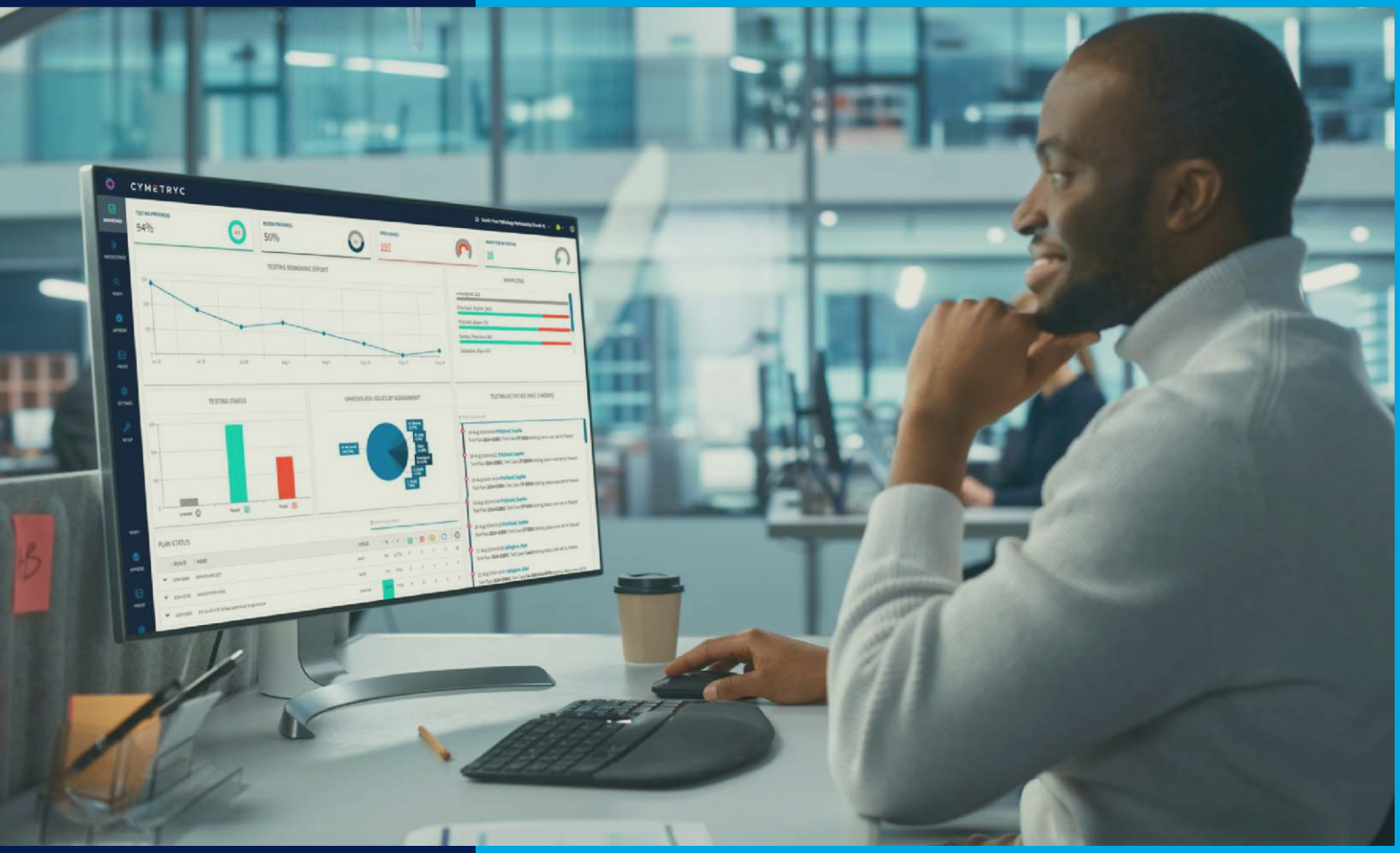

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