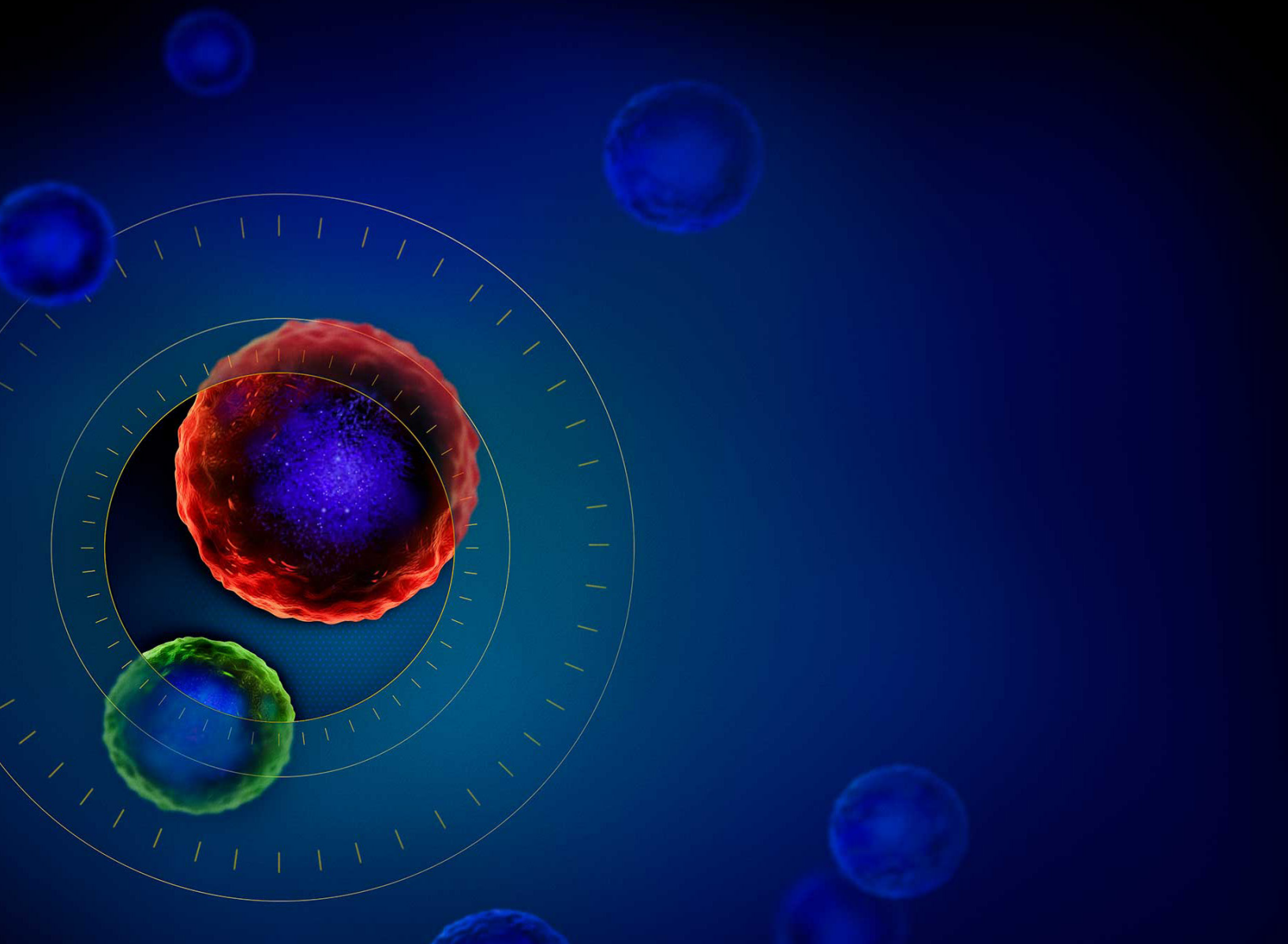


Epic Sciences Structures Requirements, Risk, and Test Management Data with Cockpit® Enterprise

CASE STUDY: EPIC SCIENCES



CHALLENGE

For innovative medical diagnostic devices, accurate test data is critical for effective risk analysis and risk management, in addition to user safety. Manually entering and updating test and regression test data quickly becomes unwieldy and difficult to manage. As shown in Figure 1 below, without automated connections between all of the data, errors compound and manual verification efforts slow development.

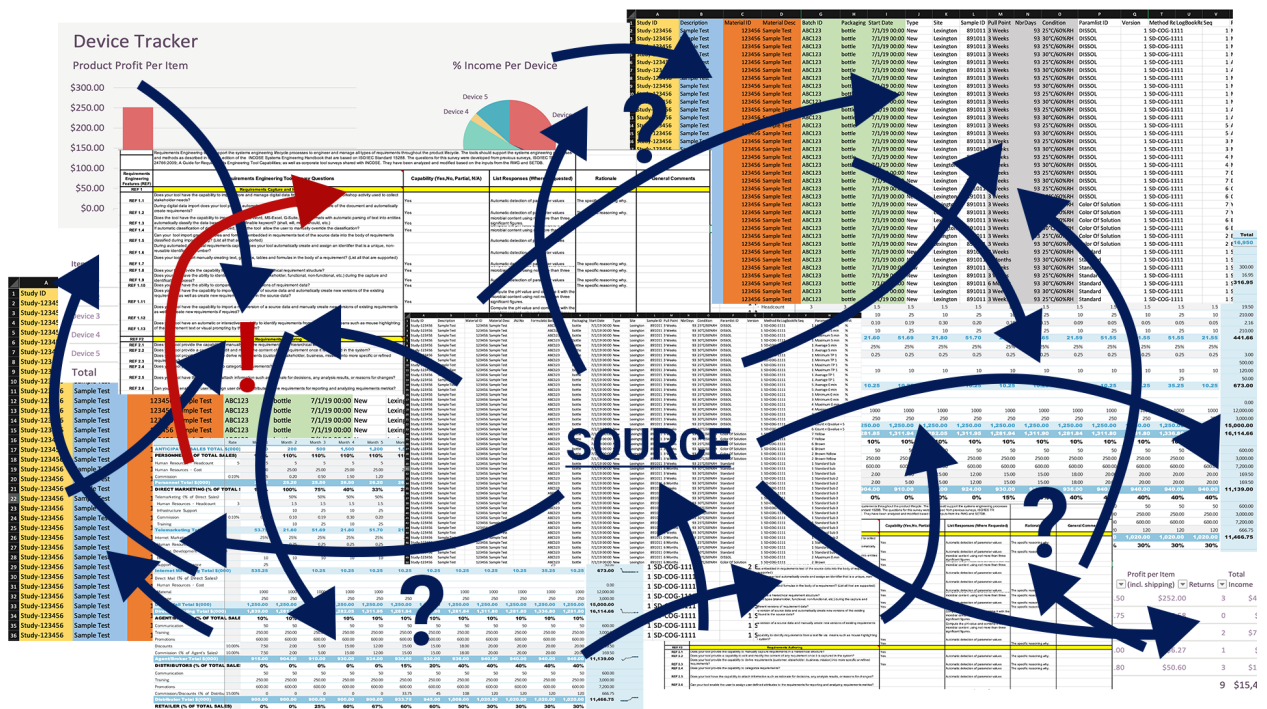


Figure 1 - Manual Data Handling

SITUATION

When requirements, test, and risk data are managed separately—in spreadsheets, documents, or general-purpose databases—there are no connections or context between the data. When changes are made to requirements data, there is no way to ensure that those changes flow through test and risk data.

The team at Epic Sciences was using a requirements management software package to manage requirements data. They would export the requirements into a spreadsheet, then import them into a test management platform where the test data resided. The drawback to this approach is that when changes were made to a requirement in the requirements management software, there was no way to ensure that the change flowed through to testing. An updated spreadsheet was exported with the change(s) highlighted and then changes would need to be manually made in the testing environment.

Similarly, when a requirement went out of scope, there was no way to ensure that information flowed through to testing. The result was that tests in the test management platform would have no requirements linked to them, so engineers would go searching for requirements (that no longer existed) to link the tests to.

Completing verification and validation in this environment was time-intensive and did not provide the level of efficiency or quality that the Epic Sciences team required. Even for small projects, this process results in confusion and errors; at scale, it results in errors upon errors and slows time to market.

“ Our testing and requirements needed to be in one repository where the data could be linked, ”

said Chris Henry, Associate Director, Software Quality Engineering at Epic Sciences.

SOLUTION

Epic Sciences transitioned their data management from an unstructured, manual approach to a structured, automated approach, using Cognition's Cockpit Enterprise Solution for structured medical device design and development data. The setup required properly importing data with quality enforcement and setting up embedded processes, according to Epic's standard operating procedures, that replicated their deliverables with the automatic traces established between deliverables for risk, requirements, and tests.

After that, for every development project, every requirement is linked to the appropriate tests. Using simple tags, when changes are made to a requirement, linked tests are alerted. Likewise, when a requirement goes out of scope, both the requirements and the tests are automatically taken out of the project. According to Epic Sciences, the impact of implementing a structured data approach to product development has been efficiencies that have resulted in less time spent planning and documenting testing and a five-fold increase in time spent doing testing (as shown in Figure 2).

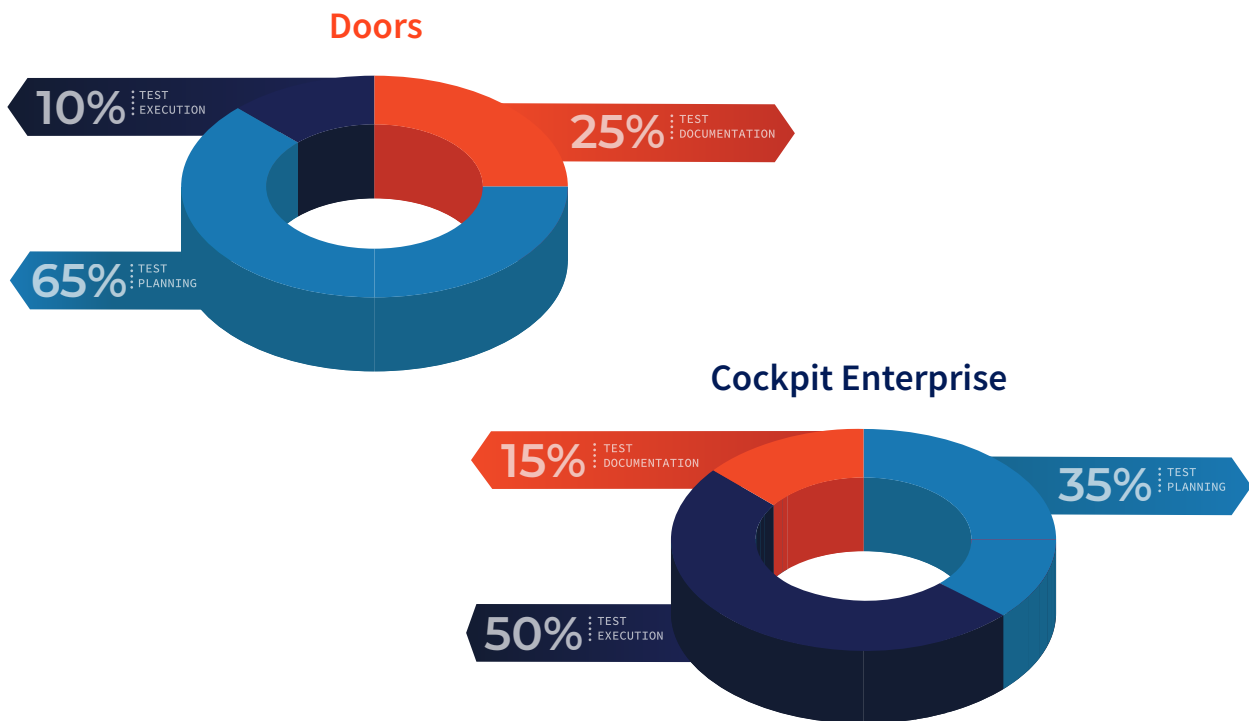


Figure 2 - Test Activity Time Allocation

Automated, Comprehensive Traces Between all Requirement and Tests

Even with tens of thousands of items, when trace matrices are easy to create and accurate, they become the go-to tools for improving efficiency, overall product development, and regulatory preparedness. With Cockpit Enterprise, traces are automatically created based on any data item type or attribute and traced across the project. For example, a trace can be run across all requirements to identify incomplete tests and used to support documentation. It can also provide guidance to the team at Epic Sciences on what needs to be completed. A master trace of the entire project can be used to ensure the product is complete and ready for submission, and is a valuable tool in the event of an audit.

“ When templates are created as your deliverables and the traces are auto-linked in real time as changes happen, it saves the team an incredible amount of time managing and updating documentation and allows them to focus on testing instead, “

said Chris Henry.

Requirements	Risk Related Mitigations (if any identified)	Tests
R PRD0001: Authentication	M MIT0001: Require users to login to the application.	<div> T VOP0001: Invalid User Login <div> <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> Not in Scope </div> </div> <div> T VOP0002: Valid User Login <div> <input type="checkbox"/> Pass <input checked="" type="checkbox"/> Fail <input type="checkbox"/> Not in Scope </div> </div>

Figure 3.1 - Trace by requirements, displays the current status and when completed provides the complete trace of requirements coverage for the project.

Risk	Mitigations	Related Requirement(s)	Related Test(s) - Release - Results
F RISK0001: Unqualified User Access	M MIT0001: Require users to login to the application.	R PRD0001: Authentication	<div> T VOP0001: Invalid User Login <div> <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> Not in Scope </div> </div> <div> T VOP0002: Valid User Login <div> <input type="checkbox"/> Pass <input checked="" type="checkbox"/> Fail <input type="checkbox"/> Not in Scope </div> </div>

Figure 3.2 - Trace by risks to provide clear evidence that all risks have been mitigated.

Document Deliverable Creation

Cockpit Enterprise contains all of the data needed for many critical reports and regulatory deliverables for which document templates can be created. For example, a Test Approval Document can pull in all pre-approved tests and, by just including another tag, a report can be run that shows the requirements to which those tests are linked. For Epic Sciences, this functionality has made a very time-intensive manual task easy and straightforward, reducing the time it takes to create that report from days to minutes.

Product Life Cycle Knowledge

For Epic Sciences, a key value of Cockpit Enterprise is the ability to have a product's complete history at their fingertips—and go back to review requirements in a structured way. To this team, the focus is on the life of the product; ensuring the data is together and coherent makes everyone's job easier.

“ By managing all of our functional data in one system, we increase productivity and accuracy at the same time. With structured data, we can tightly manage our testing with much more efficiency which gives us the time to go beyond requirements to real exploratory testing which our engineers enjoy and which makes our products even safer, “
said Chris Henry.

ABOUT EPIC SCIENCES

Epic Sciences, Inc. is developing novel diagnostics to guide therapy selection and monitor disease progression, personalizing and advancing the treatment and management of prostate and breast cancer. The company's liquid biopsy platform leverages proven and proprietary CTC capabilities, adds ctDNA and immune cell analysis, to provide more complete data for more efficient analysis and clearer insights—Comprehensive Cancer Profiling. Using its full-service CLIA/CAP accredited laboratory and research support services in San Diego, Epic Sciences partners with leading pharmaceutical companies and major cancer centers around the world working to improve patient outcomes.

For more information, visit www.epicsciences.com.

ABOUT COGNITION CORPORATION

Cognition develops, sells, and supports product development and compliance solutions for the medical device and pharmaceutical industries and is trusted by the world's leading life sciences companies. Its Software-as-a-Service platform enables customers to structure their data and automate processes with built-in quality to save time and money and bring products to market faster.

For more information, visit www.cognition.us.