VALGENESIS®

E-BOOK

How to Calculate the ROI of Digitized Validation

Find out how much time and money you could save by digitizing your validation processes with the #1 VLMS provider to the life sciences.

Calculating the Value: **Digitized Validation**

Virtually every aspect of operations in every industry can be improved by adopting and employing smarter technology that simplifies workflows, yields more reliable data, and accelerates time to market. The life sciences industry is no exception.

Regulatory authorities recognize the advantages of going digital and encourage the industry to embrace technology tools. One example is the FDA's computer software assurance (CSA) guidance. The International Society for Pharmaceutical Engineering's revised GAMP 5® guide (GAMP 5, Second Edition) is another. The message is clear: to stay competitive and compliant, life sciences manufacturers must move out of legacy comfort zones and into the digital world.

The adoption of a digitized validation lifecycle management system (VLMS) is one of the best opportunities for digital transformation because the ROI is so clear.

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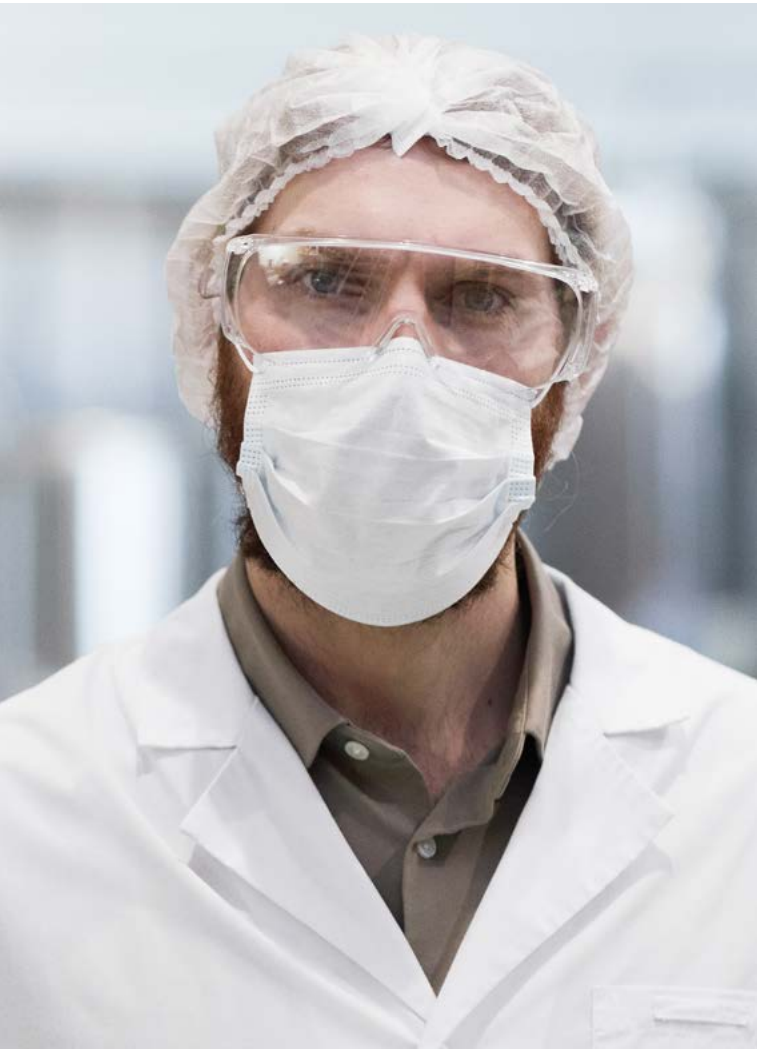
A paperless VLMS helps regulated companies overcome the unique and difficult challenges that slow their development and manufacturing processes. But how do you convince stakeholders the cost is worth the price tag?

The first half of this guide explores the leading causes of digital resistance in the life sciences industry — and challenges them with compelling arguments you can use to advocate for change in your organization.

The second half backs up these arguments with real ROI data from real ValGenesis customers. We break down every stage of the validation lifecycle — looking at both core and supporting validation activities — and detail the efficiencies gained at each step. Armed with knowledge and numbers, you can build a bulletproof business case for digitizing validation.

Reasons for **Digital Resistance**



There has never been higher pressure to develop drugs and devices faster and more cost-effectively. Everyone wants a competitive edge — the secret sauce that will reduce the cost of production, ship products to market sooner, and ultimately generate more revenue. Technology provides that edge.

The life sciences industry has invested significantly in core digital systems like enterprise resource planning (ERP) and document management systems (DMS), but validation processes remain manual, and validation data is poorly managed. Validation professionals have been left to struggle with paper and spreadsheets — creating an offline data gap. This digital disconnect jeopardizes data integrity and compliance and slows collaboration, production, and product release.

Paper-based validation poses a challenge to any company. It's unreliable, inconsistent, inefficient, and stifles innovation. Unfortunately, paper-based validation has been baked into standard operating procedures for decades. Convincing stakeholders to ditch paper may take real effort. The conversations outlined here will help you overcome common hurdles to digitizing validation.

Build Your **Business Case**

#1. How to obtain a commitment from leadership

Getting executive buy-in is essential for any IT investment. Focusing on these three points when engaging with leadership will demonstrate that digital validation is worth the time and resources.

Better decision-making. It's too easy for companies to print validation documentation, store it, and forget about it until it's time for an audit. Automating validation through digitization allows for the creation of a living document that empowers business leaders to identify and remove bottlenecks in real time. More importantly, this access to data and insight enables more informed decision-making through the product development lifecycle, enabling leaders to take proactive steps instead of reacting to a document based on data that's weeks (or months) old.

Fast ROI. Companies can expect efficiency gains of 50% or more throughout the validation lifecycle. Activities that support validation, such as tracking status, planning for audits, and allocating validation resources, see a 70% efficiency improvement — and sometimes even more. All told, digital workflows cut the timeline for validation processes in half. As validation makes up 20% of product development, digital validation cuts the timeline and cost of product development by 10%. The return on investment will compound project after project. We'll dive deeper into this in the second half.

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Support the move to Pharma 4.0. As described by ISPE, the Pharma 4.0 operating model represents the push to embed digitization and automation into pharmaceutical product development in a similar manner to traditional manufacturing processes. If pharma companies aim to transition to Pharma 4.0 — and gain a significant competitive advantage — they can't do it with a paper-based validation process.

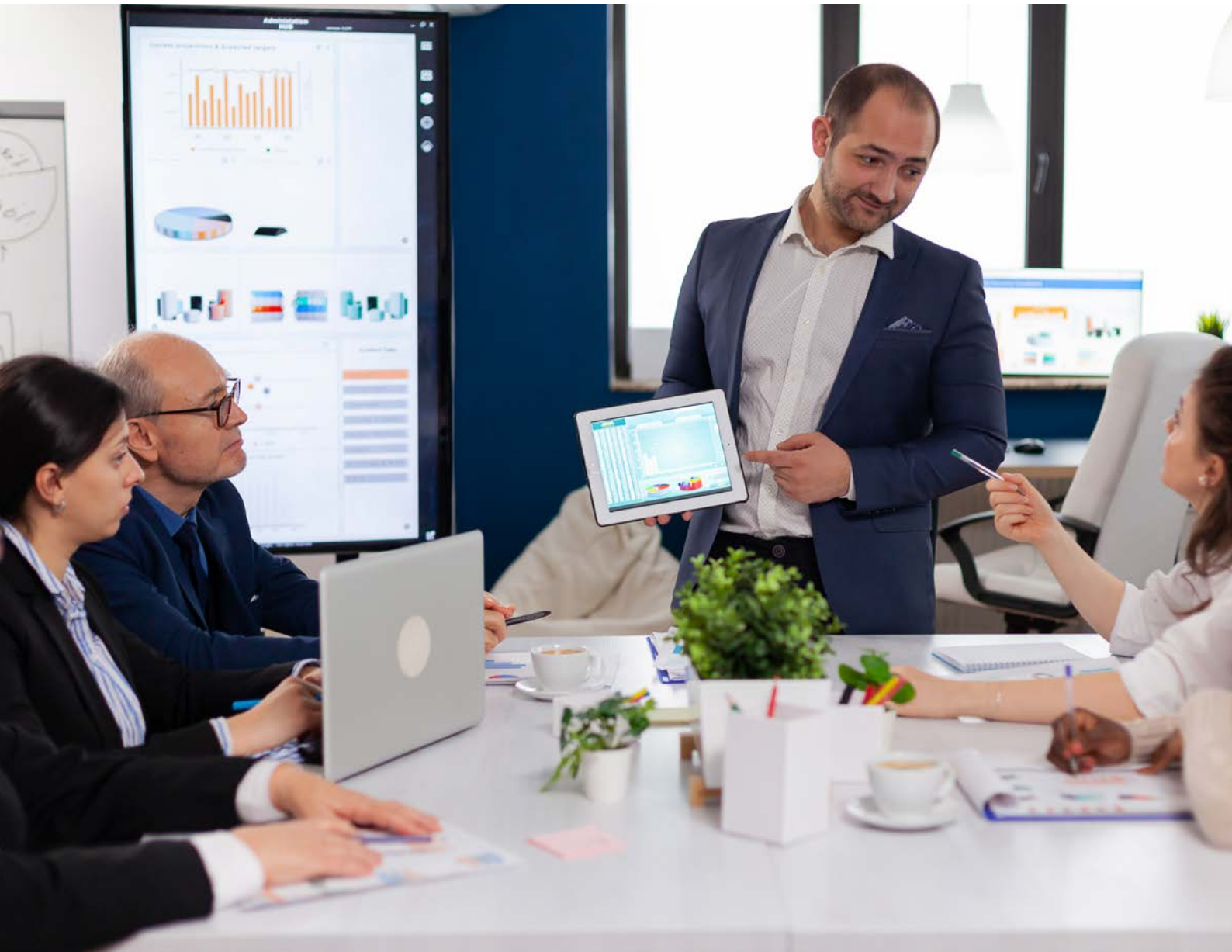
#2. How to articulate benefits to business lines

Business unit leaders will benefit from seeing how their workflows improve the performance of the teams they manage. Use the following discussion points to lead conversations with department heads.

Validation teams gain access to a traceability matrix that's generated and maintained in real time. This allows validation to happen in a much more agile manner throughout the product development lifecycle. It also enables teams to identify and mitigate issues before they pose a substantial risk to the product.

Quality assurance benefits from an enforced standardized process, which results in more consistent reviews regardless of which internal and external stakeholders contribute to the effort. QA teams can also spend less time on the minutia and more time reviewing the technical controls that impact product quality and compliance.

Manufacturing and IT dramatically improve efficiency through digitization. Electronic workflows for creating and approving validation plans, generating traceability matrices, executing validation protocols, conducting risk assessments, maintaining revalidation schedules, and other tasks can lead to efficiency gains of 50% or more.



#3. How to emphasize the existing precedent for automation

Does digitizing validation represent a significant change for life sciences companies? Yes. However, it's also true that other business units have already embraced automation. Highlight how these departments have benefited from agile and digital workflows to show that the learning curve doesn't need to be steep.

DevOps leverages autonomous maintenance and monitoring to enable continuous delivery and incremental improvement of software products. Manual processes for maintenance and monitoring impede productivity, making agile software development nearly impossible.

Security uses continuous threat monitoring and automated remediation to identify and respond to far more cybersecurity threats than individual security analysts could find using manual steps.

Quality assurance automates the software testing process into a routine throughout the development lifecycle. Bugs and performance issues can be fixed in real time, long before they impact additional features downstream.

#4. How to demonstrate the potential for proactive decision-making

It's difficult for decision-making based on paper documentation to be anything but reactive. In the mere minutes it takes to print a validation document, an engineering team can execute large-scale changes to the application being validated, rendering the printed document obsolete. One of the biggest benefits of digitization is that it enables validation to shift from a retrospective process to one that's more proactive and prescriptive. Highlight:

Continuous validation. Traditional validation spends high effort on the initial project. Revalidation is resisted because that initial validation required too much time and effort. Automation allows validation to occur continuously throughout the development lifecycle — in minutes instead of months.

Up-to-date traceability. Likewise, automation enables dynamic traceability matrices throughout software development and validation. Matrices are updated in real time, creating a living document, instead of reconstructing them at the end of the project. These matrices are then instantly available during an audit.

Issue resolution. Real-time validation identifies and prioritizes issues with a software product. One obvious benefit is fixing bugs as they arise. Another benefit is the ability to flag issues likely to cause downstream trouble. This lets engineers address these problems in the moment before they require significant and time-consuming rewrites to the application.

Process transformation. One of the biggest dangers of digitizing a manual process is bringing along the inefficiencies of working with paper, whether it's data entry, version control, or communication with reviewers. Automating these aspects of validation transforms them into highly streamlined processes that occur in the background so reviewers can focus on tasks that require their full attention.

New standard operating procedures. Paper-based validation workflows have remained in place for so long because they've been the de facto standard operating procedure. The efficiencies and savings associated with digitized validation, from planning and tracking to execution and maintenance, allow companies to rewrite the SOPs for vaVlidation once and for all.

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Real Customers
Real ROI

When it comes to investing in a new software system, it's all about ROI. Not features. Not even benefits. Executives want to know: How much do I get out of this investment — and how fast? To find out, we surveyed ValGenesis customers about their validation processes before and after implementing the ValGenesis VLMS. The goal was to determine the savings and efficiency gains customers realized from digitizing both their core and supporting validation activities with ValGenesis.

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Validation Activity Breakdown

- **5%** Creating, reviewing, and approving validation plans and projects
- **25%** Authoring, reviewing, and approving validation protocols
- **10%** Creating and maintaining traceability matrices and requirements
- **25%** Executing, reviewing, and approving validation protocols
- **10%** Performing, reviewing, and approving risk assessments
- **5%** Creating and maintaining periodic reviews and revalidation schedules
- **20%** Supporting validation activities

The chart below takes you through the manual processes and challenges associated with each core validation activity and the efficiency gains you can expect when you automate with ValGenesis.

	Paper-Based Process	ValGenesis Process	Efficiency Gain
1.1	Creating, reviewing, and approving validation plans and projects: 5% of the effort in the validation lifecycle process		20 – 30%
1.1.1	Manually create validation plans and projects, then route them for review and approval through interoffice mail. Approved validation plans are available as a reference and may not effectively control the process due to their paper-based nature.	Electronically create validation plans and projects, then route them for review and approval through an automated electronic workflow. Approved validation plans and requirements can be enforced in the process and eliminate the risk of excursion from the plan, preventing noncompliance.	
1.2	Authoring, reviewing, and approving validation protocols: 25% of the effort in the validation lifecycle process		20 – 30%
1.2.1	After a protocol is authored or executed, it is physically routed to reviewers or approvers through interoffice mail or other delivery options. Documents may be lost in the routing process or languish on someone's desk. Physically routing documents from one location to the next adds additional delays, as typically, the approval process requires sequential review and approval.	After a document is authored in ValGenesis, the authored document is routed electronically and is available for review and approval in real time. ValGenesis supports sequential, simultaneous, and hybrid workflows for reviews and approvals to expedite the final approval process. Every document, history, and current status is available electronically, ensuring document control. Documents can be reviewed in parallel, whereby all reviewers can review the document simultaneously.	
1.2.2	There is no automated way to alert reviewers and approvers to target dates and/or delays in the process. It is difficult to transfer tasks to different reviewers and approvers in the event of a delay.	Reviewers are alerted in real time via alert notification to any review or approval task through corporate email.	
1.2.3	Physical access to the document is required to review and approve the paper document. Review and approval get delayed if the reviewer and approver are not physically present.	No physical access is required. Documents can be accessed securely through corporate intranets or networks.	

#	Paper-Based Process	ValGenesis Process	Efficiency Gain
1.3	**Creating and maintaining traceability matrices and requirements: 10% of the effort in the validation lifecycle process**		**40 – 50%**
1.3.1	Creating and maintaining traceability matrices through a manual process is a time-consuming task. The traceability of the test cases to the requirements may be buried in the paper-based documentation and may not provide any real-time information at the time of tracing, making it challenging to assess the change impact.	The traceability matrix function within ValGenesis improves change management by accurately assessing its impact by identifying related requirements, design elements, and test scripts. It also helps to scope the regression testing clearly and accurately. During test case execution, the deviations observed in a test case can be tracked and traced back to the associated design elements in the traceability matrix. During audits and inspections, the traceability matrix provides a clear, real-time view of the requirements and test coverages based on the risk level.	
1.3.2	Coordinating the development of requirements with all users takes significant time. Requirements are subject to frequent changes, making it time-consuming and challenging to maintain them using a paper-based process.	ValGenesis brings users together through collaboration, effectively reducing the time to complete the requirement-gathering process.	
1.4	**Executing, reviewing, and approving validation protocols: 25% of the effort in the validation lifecycle process**		**40 – 50%**
1.4.1	Documents must be executed manually using a pen and an approved paper protocol. Screenshots and supporting files like reports must be printed and subsequently attached within the document being executed as attachments.	Documents are executed electronically using a tablet, laptop, or desktop, and screenshots are attached at the test-case-row level with a single click. Screenshots are captured with a complete audit trail and watermark at the test-step level. Additional supporting files can be attached at the row level.	
1.4.2	Deviations or exceptions are handled manually using paper-based documentation. Each deviation is taken through a separate, time-consuming paper-based workflow.	Deviations are handled electronically, and the deviation workflows are concurrent for any number of deviations, expediting the execution process.	

	Paper-Based Process	ValGenesis Process	Efficiency Gain
1.4.3	During the test case execution, handwritten results can be challenging to read and may contain spelling and grammatical errors.	ValGenesis provides spell-checking, and all content is digitized, legible, human readable, and readily accessible.	
1.4.5	Once the document has been executed, it must be physically sent to the corresponding reviewers and approvers through interoffice mail or other delivery options. Routing documents from one location to the next adds additional delays, as typically, an approval process requires sequential review and approval. This process flow creates obvious inefficiencies.	In ValGenesis, executed documents are routed electronically and available for review and approval in real time. The system supports simultaneous (parallel), sequential (serial), and hybrid (a combination of simultaneous and sequential) reviews and approvals to expedite the final approval process. ValGenesis supports the reuse of requirements and developed protocols through binding and linking processes to other similar systems to be validated across the organization.	
1.4.6	There is no automated way to alert reviewers and approvers to target dates and/or delays in the process.	Reviewers are alerted in real time via alert notification to any review or approval task through corporate email. Tasks may be transferred to other reviewers and approvers automatically (using a compliant process) in case of delay. Management is notified of delays and can take action to remove barriers as required.	
1.4.7	Physical access to the executed document is required to review or approve the document. Review or approval gets delayed if the reviewer or approver is not physically present.	No physical access is required; documents are approved through secure networks.	
1.4.8	There is a potential to misplace or lose the executed document during transfers.	Documents are available in electronic format and stored centrally for secure, easy access.	

	Paper-Based Process	ValGenesis Process	Efficiency Gain
1.5	**Performing, reviewing, and approving risk assessments: 10% of the effort in the validation lifecycle process**		**40 – 50%**
1.5.1	Risk assessment is done manually at the system or requirement/functional level and requires feedback from various stakeholders. Collaborating effectively with all the stakeholders is challenging. Risk assessment results are maintained as a separate document without a direct link to the testing, validation, change managment, or periodic review activities.	All the required stakeholders collaboratively perform risk assessment at the system or requirement/functional level. Risk assessment results are linked with testing, validation, change management, and periodic review activities.	
1.5.2	Risk assessments are approved manually, which is time-consuming.	Risk assessments are approved through a comprehensive electronic workflow.	
1.6	**Creating and maintaining periodic review and revalidation schedules: 5% of the effort in the validation lifecycle process**		**40 – 50%**
1.6.1	Periodic review and revalidation schedules are maintained in paper format or Excel. This process is time-consuming and error-prone.	ValGenesis provides a dynamic validation calendar for upcoming periodic reviews and revalidations, preventing possible delays. The system alerts the appropriate user groups if there is a delay with a periodic review task for any GxP system or process to eliminate human errors in the revalidation program.	
1.6.2	Periodic review and revalidation schedules are approved manually.	Periodic review and revalidation schedules are approved through electronic workflows.	
1.6.3	There is no automated way to alert users to upcoming periodic reviews or revalidations.	Users receive notification alerts for upcoming periodic reviews and revalidations. This prevents the possibility of delays and missed tasks.	

Supporting Validation Activities

Four supporting activities account for 20% of a company's corporate validation efforts.

Here is the breakdown:

- Tracking the validation status: 10%
- Audit preparation for internal and external audits: 3%
- Document retrieval: 2%
- Tracking validation metrics for resource and budget planning: 5%

	Paper-Based Process	ValGenesis Process	Efficiency Gain
2.1	**Tracking the validation status: 10% of the effort in the validation lifecycle process**		**70 – 80%**
2.1.1	Tracking the validation status is complicated, as it often requires email or phone calls to prospective reviewers, approvers, and document specialists.	ValGenesis' built-in tracking functions allow users to locate an authored or executed document easily and in real time. These functions include developing and executing pie charts from the dashboard, an inventory manager with search capabilities, barcode scanning from the production floor, and transparent audit trails available to any user involved in developing, executing, reviewing, or approving any document.	
2.2	**Audit preparation for internal and external audits: 3% of the effort in the validation lifecycle process**		**80 – 90%**
2.2.1	Documents are often stored in bulky binders in an off-site repository. Locating, assembling, and transporting paper documents is a massive burden, especially when preparing for an audit or inspection.	Documents are generated electronically with audit trails and can be retrieved from the system's electronic document repository easily, in real time. When audits occur, data is already organized, stored, and readily available with minimal prep work.	
2.3	**Document retrieval: 2% of the effort in the validation lifecycle process**		**70 – 80%**
2.3.1	Paper-based document search and retrieval methods are painfully slow and often require users to travel to an off-site repository. What's more, creating and maintaining a competent paper-based archive requires significant effort and work hours.	With information digitized, indexed, and centralized, document searching is near-instant. There is also the added benefit of mobility. Users can search and retrieve documents from multiple sites without being physically on-site.	

2.4	**Tracking validation metrics for resource and budget planning: 5% of the effort in the validation lifecycle process**		**50 – 60%**
2.4.1	Metrics are not available in a paper-based system, making it challenging to control project costs and estimate budgets.	ValGenesis provides metrics for budgeted vs. actual results for efficient planning and cost control.	
2.4.2	There is no mechanism to track the individual performance of users involved in the validation process.	ValGenesis tracks the performance of individual users within the system.	

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