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Unify Public Cloud for Microsoft

Prepared for <client name>

*An innovative solution to accelerate
your regulated workload with*



20+

**Years Regulatory
Compliance
Experience**

700+

Clients Globally
8 of Top-10 Pharma
15 of Top-20 Med Dev
100+ Emerging

200+

**Cloud
Assurance
Subscribers**

20+

**World-Class
Technology
Partnerships**



COMPLIANCEQUEST
Quality . Compliance . Collaboration . Communication

DocuSign

salesforce

servicenow

okta

ORACLE

SERVICEMAX



ptc

veeva

DOMAIN KNOWLEDGE

- Pharma, Med Dev, Biotech Experience
- Global Regulations
- Quality Strategy and Execution
- Compliance Strategy and Execution
- Life Science Uses and Best Practices

TECHNOLOGY EXPERTISE

- Implementations and Integrations
- CSV / CSA / Automated Testing
- IS Health Check
- Workflow Optimizations
- SaaS, PaaS, IaaS Validation Framework

DIGITAL TRANSFORMATION

- Cloud Assurance™ Continuous Compliance
- Strategy and Roadmap Planning
- Process Improvements
- Platform Integrations
- Advanced Analytics AI / ML / NLP

Life Sciences Cloud Adoption

CHALLENGES



TIME VS COST PRESSURE Constant pressure to reduce costs, outsource IT, focus on core competencies, and still innovate faster.



CLOUD NOW Covid has created an urgent need to move to the cloud. IT priorities are constantly shifting and managing IT spend is challenging.



HIGHLY REGULATED ENVIRONMENT Agency requirements impact the way we implement, validate, and maintain systems and records.

OPPORTUNITIES



SPEED Utilizing 3rd-party expertise can speed implementation and validation, saving time and money so you can unlock the value of your data faster.



SECURITY / SCALE Cloud offers better security, stability, accessibility, collaboration, and data management to enable greater functionality as you need it.

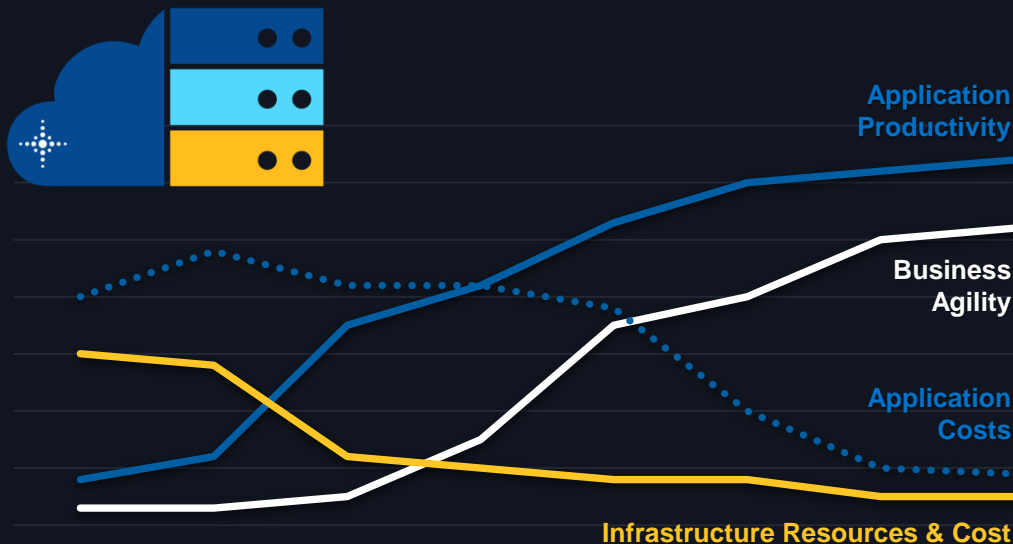


GLOBAL REGULATIONS EVOLVING The FDA openly supports the use of modern IT, automation, advanced analytics, and minimized validation documentation to drive enhanced quality and safety with CSA.

Unify Public Cloud for Azure

- Rapid implementation, validation, and maintenance to achieve a continuously compliant tech-stack (SaaS, PaaS, IaaS)
- Faster delivery through accelerators built on life sciences best practices
- Bundled solution to minimize and control cloud expenses
- Security and compliance built-in
- Flexible cloud adoption model to migrate your GxP workload
- Unlocks the value of your data made possible with Azure

Value Generated from Rapid Cloud Adoption



Continuous Cloud Compliance

50-80%
faster delivery

30-50%
less infrastructure costs

25-75%
efficiency gains

Unify Public Cloud

Compliant foundation for your tech stack

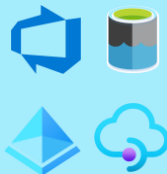
With UPC, your applications and services can be efficiently assessed, readied for GxP use, and maintained in a continuously compliant state to unlock the value of your data.

Azure UPC
Standard Configuration

Optional Applications,
Services, and more



Azure Software
Validated SaaS Applications






Azure Platform
Qualified PaaS Layer



Azure Infrastructure
Qualified IaaS Layer

Unify Public Cloud

Continuous compliance subscription to enable GxP innovation

	 SERVICES	 ACCELERATORS	 DELIVERABLES
Business Applications	<ul style="list-style-type: none">✓ Gap Assessment✓ SaaS Validation	<ul style="list-style-type: none">✓ Best Practices✓ GxP Configuration	<ul style="list-style-type: none">✓ Validation Plan✓ SRS/CS✓ Test Scripts✓ Validation Report
Specific Build / Infrastructure for Commissioning a Service	<ul style="list-style-type: none">✓ Gap Assessment✓ PaaS Qualification	<ul style="list-style-type: none">✓ Best Practices✓ GxP Configuration✓ Impact Assessment	<ul style="list-style-type: none">✓ Procedures✓ Technical Configuration(s)✓ Assessment Tool(s)
Infrastructure & Platform Management	<ul style="list-style-type: none">✓ Gap Assessment✓ IS Health Check✓ IaaS Qualification	<ul style="list-style-type: none">✓ PaaS Assurance Pack✓ IaaS Assurance Pack	<ul style="list-style-type: none">✓ Validation Plan✓ SRS/CS✓ Test Scripts✓ Validation Report
Cloud Management		<ul style="list-style-type: none">✓ Best Practices✓ Cloud Management Procedures	<ul style="list-style-type: none">✓ Procedures✓ Technical Configuration(s)
Virtual Infrastructure & Platform Services	<ul style="list-style-type: none">✓ Annual Vendor Audit✓ Real Time Monitoring✓ Periodic Reviews✓ Supplier Agreement Reviews	<ul style="list-style-type: none">✓ Best Practices✓ QMS Quality Manual	<ul style="list-style-type: none">✓ Vendor Assurance Report
Data Centers & Physical H/W			

Cloud Assurance™ Continuous Compliance

AI Chatbots to Support GxP Content for Clinical Trials

SITUATION

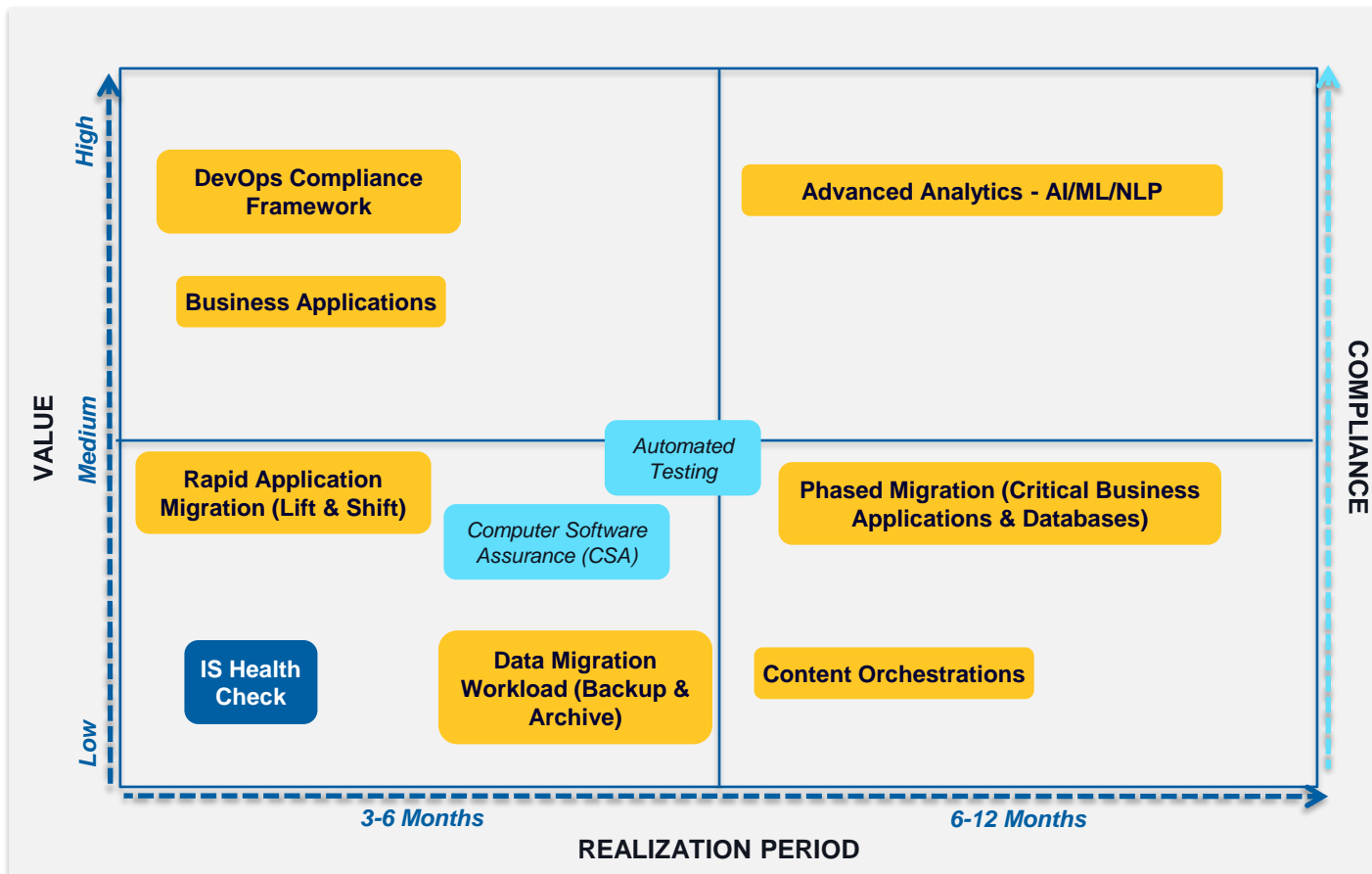
- **SDLC:** No formal SDLC governing the Azure DevOps stack
- **CSV:** No DevOps specific CSV and SOPs (assumption was that global CSV/SOPs would apply)
- **Infrastructure:** Azure infrastructure is already qualified for non-GxP use
- **Intended Use:** Using the DevOps framework for a pilot program to develop chatbots for automated assistance. They were non-GxP and used Azure and NLP tools for processing. The team was asked to develop chatbots that could be used to provide GxP content to their clinical sites.
- **Concerns using DevOps for GxP:**
 - Lack of enforcement of sequence of steps
 - Limited approval functionalities
 - Lack of understanding on how best to use DevOps tools to meet GxP validation requirements

SOLUTION

- **Scope of Project:** USDM helped client with an AI pilot program using Azure stack + NLP tools to develop chatbots for GxP content to support clinical trials
- USDM developed a **governance structure and workflows** to support GxP use cases
- USDM educated on best practices to use DevOps framework to meet GxP validation requirements
- USDM solved for **using electronic signatures natively in Azure** to manage approvals and saved time avoiding custom development work
- USDM developed a **Master Assurance Plan (MAP) that distinguished GxP, non-GxP, and SaMD** to differentiate between formal testing and informal testing to meet global regulatory requirements

USDM built a continuously compliant infrastructure to scale AI bot uses to innovate faster

Value Realization by Business Use





Why USDM

Better business outcomes through simplicity, scalability, and security

	Traditional	USDM
Cost	\$\$\$\$	\$
Complexity	High	Low
Coverage	Siloed Point Solution	Bundled SaaS, PaaS, IaaS
Deployment	Waterfall Months/Years	Agile 3 months
Flexible/ Scalable	10%	100%
Continuous Compliance	0%	100%

Thank you!

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Appendix

Azure Assurance

Cloud Assurance			Services	Accelerators	Deliverables	Cloud Assurance
CUSTOMER	<ul style="list-style-type: none">• SharePoint Online• Office 365 apps*	Business Applications	<ul style="list-style-type: none">• Cloud Application Validation• Gap Assessment	<ul style="list-style-type: none">• Best Practice Standards• Compliant Configuration	<ul style="list-style-type: none">• Validation Plan• SRS/CS• Test Scripts• Validation Report	
	<ul style="list-style-type: none">• Azure DevOps• Azure Data Lake	Specific Build / Infrastructure for Commissioning a Service	<ul style="list-style-type: none">• Cloud Services Qualification• Gap Assessment	<ul style="list-style-type: none">• Best Practice Standards• Compliant Configuration• Impact Assessment	<ul style="list-style-type: none">• Procedures• Technical Configuration(s)• Assessment Tool(s)	
	<ul style="list-style-type: none">• Azure AD• API Management• Change Management• Account / Access Management• Provisioning of Cloud Services	Infrastructure & Platform Management	<ul style="list-style-type: none">• Initial Qualification• IS Health Check• Gap Assessment	<ul style="list-style-type: none">• Initial Qualification Pack for Azure Platform (IaaS and PaaS)	<ul style="list-style-type: none">• Qualification Plan• SRS/CS• Test Scripts• Qualification Report	
		Cloud Management		<ul style="list-style-type: none">• Cloud Management Procedures• Best Practice Standards	<ul style="list-style-type: none">• Procedures• Technical Configuration(s)	
AZURE	<ul style="list-style-type: none">• Foundational Services	Virtual Infrastructure & Platform Services	<ul style="list-style-type: none">• Annual Vendor Audit• Real Time Monitoring• Periodic Reviews• Supplier Agreement Reviews	<ul style="list-style-type: none">• Cloud Vendor (QMS) Quality Manual• Best Practice Standards	<ul style="list-style-type: none">• Vendor Assurance Report• USDM Vendor Certification	
	<ul style="list-style-type: none">• Global Infrastructure	Data Centers & Physical H/W				

*must be scoped separately

Unify Public Cloud Subscription



Services

- Annual Vendor Audit
- Infrastructure Qualification
- Cloud Application Validation
- Cloud Services Qualification
- IS Health Check



Accelerators

- Impact Assessment
- Procedures & Controls
- Change Management
- Qualification Package



Deliverables

- Qualification(s)
 - Qualification Plan
 - System Requirements
 - Configuration Specification
 - CQ/PQ
 - Qualification Report
- Assurance Report
- Vendor Certification

Cloud Assurance™ Continuous Compliance

Definitions **Services**



ITEM	DESCRIPTION
USDM Services	Twenty years of life sciences solution delivery, best practices, and regulatory expertise leveraged to create defensible deliverables for your intended use.
Annual Vendor Audit	Annual review of the Vendor's design, development, testing, qualification, and maintenance methodologies used in the construction of the infrastructure and GxP functionality.
Infrastructure Qualification	The process of qualifying the Cloud Infrastructure to provide documented evidence of the qualified Infrastructure, and on which GxP applications can be deployed.
Cloud Application Validation	A part of the Infrastructure Qualification activity or as add-on activities. The process of validating the Application to provide documented evidence that the service performs as intended.
Cloud Services Qualification	A part of the Infrastructure Qualification activity or as an add-on activities. The process of qualifying the Cloud Services to provide documented evidence that the service performs as intended.
IS Health Check	A structured journey map designed with the purpose of scoping and planning a more detailed strategy and roadmap. Designed to provide an indication of the relative state of regulatory compliance and IS efficiency based on the IS Compliance Maturity Model.

Definitions Accelerators



ITEM	DESCRIPTION
Accelerators	Fast-start tools based on 20 years of life sciences solution delivery, best practices, and regulatory expertise.
Cloud Assurance	USDM's Cloud Assurance™ is a managed service where USDM handles the entire compliance workload from cloud vendor selection through ongoing maintenance of the validated state, providing customers with a harmonized, consistent compliance experience across all their cloud vendors.
Assessment Report	Detailed summary of the assessment of the customer's procedural and technical control against regulations and best practices.
Procedures & Controls	Continuously growing repository of written and technical standards and best practices for compliance. Includes topics such as Change Management, API Management, Impact Assessment (HLRA) .
Cloud Assurance Subscription	USDM's Cloud Assurance™ is a subscription where USDM handles the entire compliance workload from cloud vendor selection through ongoing maintenance of the validated state, providing a harmonized, consistent compliance experience across all cloud vendors.

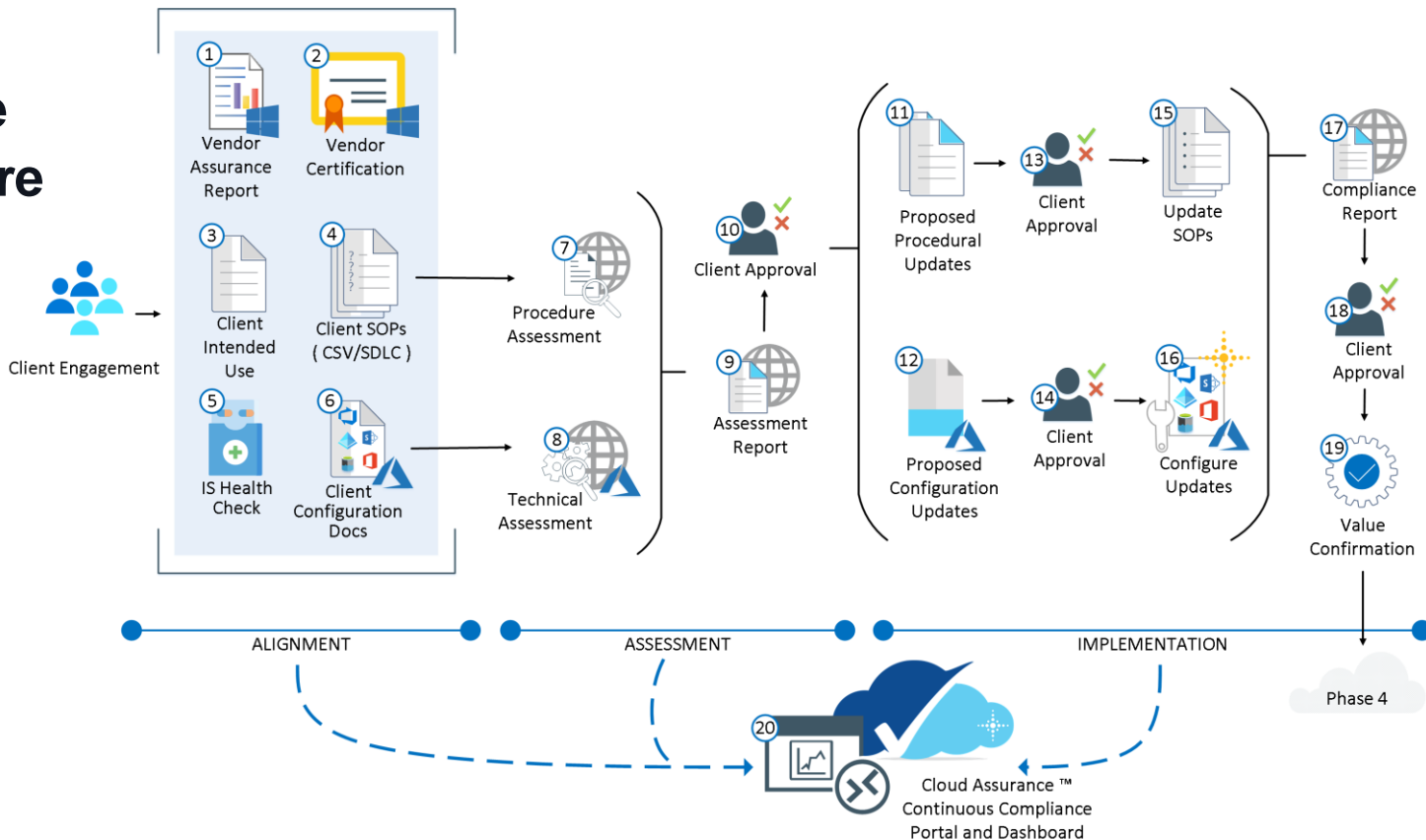
Definitions Deliverables



ITEM	DESCRIPTION
Vendor Assurance Report	An in-depth summary of the annual vendor audit. This report may be leveraged as documented evidence of the Vendor's procedures and results of the verification and validation activities performed.
Qualification Package	Accelerators Qualification Package
<ul style="list-style-type: none">Qualification Plan (QP)	Approved document which defines the plan to ensure and provide documented evidence that Infrastructure is qualified based on intended use.
<ul style="list-style-type: none">System Requirements (SRS)	Approved document that describes the user need and functionality required to meet the regulatory requirements and intended use of the system.
<ul style="list-style-type: none">Configuration Specification (CS)	Approved document that describes the configuration required to meet the requirements as detailed in the SRS.
<ul style="list-style-type: none">Configuration Qualification (CQ)	Approved documented test script, that confirms an object or system is configured according to written and approved specifications.
<ul style="list-style-type: none">Performance Qualification (PQ)	Approved documented test script, that confirms a system is capable of consistent performance in fully integrated and loaded conditions.
<ul style="list-style-type: none">Qualification Report	Approved document that provides a summary of the system, the results of qualification testing, including the traceability matrix, deviations encountered, and their resolutions.

Azure Assurance Architecture

Phase 1-3



Azure Assurance Architecture

Phase 4+

