Platform Agnostic Recommendations for Study Definition Repository (SDR)

Release Version 3.0

Document History

Version No.	Date	Author	Revision Description
V1.0	March 22, 2022	ACN Team	Initial Version
V2.0	March 23, 2023	ACN Team	Updated list of resources in other platforms for newly added azure components in SDR Release V2.0
V3.0	October 27, 2023	ACN Team	Updated architecture diagram after incorporating API-Key Authorization in SDR RI APIs

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1. SDR Overview

The Study Definition Repository is a vision to catalyze industry-level transformation, enabling digital exchange of study definition (e.g., protocol) information by collaborating with technology providers and standards bodies and is based upon a standardized model – the CDISC Unified Study Definitions Model (USDM). The SDR seeks to transform the drug development process by enabling a digital workflow to move from a current state of manual asset creation to a future state of fully automated and dynamic readiness to support clinical study execution.

The architecture for the SDR Reference Implementation has been designed to achieve the following key Objectives, and components are chosen in a way that avoid the architecture being tied to specific hardware, operating systems, or tools.

Cloud Agnostic / Open-Source – Create an application that is relatively cloud agnostic from an implementation perspective by choosing the technology stack and cloud components/services that offer extensibility and portability to the application.

Accelerate study start-up / execution by enabling the automation of data flow to downstream clinical systems reducing the need for duplication, manual input and transcription.

Reduce Manual input by creating an application that automates data flow.

2. SDR Reference Implementation Architecture

To be clear, TransCelerate does not endorse any particular software, system, or service. And the use of specific brands of products or services by TransCelerate and its collaboration partners in developing the SDR Reference Implementation should not be viewed as any endorsement of such products or services. To the extent that the SDR Reference Implementation incorporates or relies on any specific branded products or services, this resulted out of the practical necessities associated with making a reference implementation available to demonstrate the SDR's capabilities.

Figure below depicts a high-level architecture of the SDR Reference Implementation which is built using Angular Front End and .NET Core Backend and deployed on Microsoft Azure Cloud[1]. The solution architecture components are chosen in a way so as to make the future release of the reference implementation portable to other deployment environments such as Amazon Webservices Cloud (AWS)[1], and Google Cloud Platform (GCP)[1].

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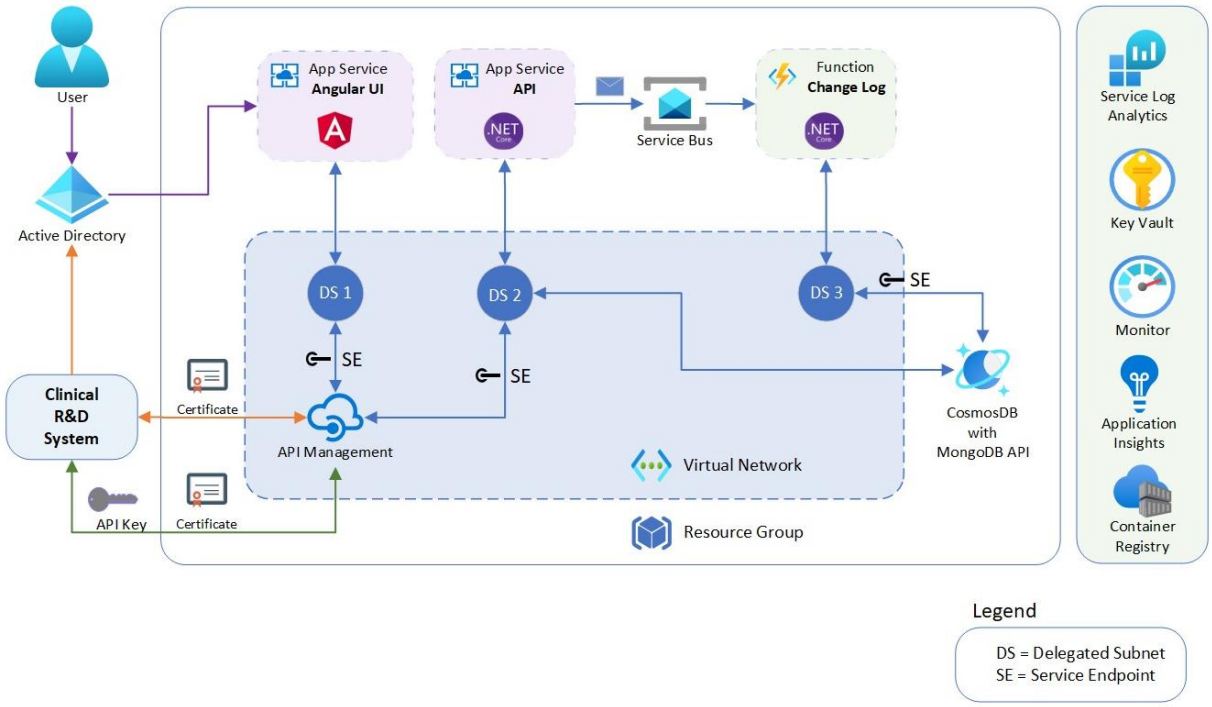

3. Porting SDR to Other Cloud Environments

The table below gives high level recommendations for moving SDR Architectural and Application components to other Cloud Environments such as Amazon Web Services (AWS) and Google Cloud Platform (GCP).

Architecture Area	Configuration Items	Public Cloud			Comments
		Azure	AWS	GCP	
Account Management	Cloud Platform Logical Landing Zone	Subscription	Account	Google Cloud Project	
Dev Ops	Tools for Version Control	Github (Repos)	Github (Repos)	Github	
	Tools for Build & Deployment	Github (Pipelines)	Github (Pipelines)	Cloud Build	
	Tools for Testing	JMeter, Postman	JMeter, Postman	Jmeter, Postman	
	forwiki	Github	Github	No specific propritary of GCP	
	Continous Delivery (IaC)	Terraform	Terraform	Terraform	Infrastructure as a Code(Terraform Scripts needs to be updated as per the cloud resourcing classification)
Governance	Tagging	Azure Tags	AWS Tagging	Labels	
	Naming Convention	https://docs.microsoft.com/en-us/azure/cloud-adoption-framework/ready/azure-best-practices/resource-naming		https://cloud.google.com/compute/docs/naming-resources	

Architecture Area	Configuration Items	Public Cloud			Comments
		Azure	AWS	GCP	
	Resource Group	Azure Resource Groups	AWS Resource Group	NA	
	Cost Management	Azure Cost Management Billing	Cost Explorer	Cost Management	
Subscription & Regions	Total Subscriptions (Dev & Demo)	2	2	2	
	Total Regions (US East)	1	1	1	
Networking	IPAM	/24	/24	/24	
	VNET for PaaS integration	1	1	1	
	Subnet	3 Delegated Subnets 1 subnet for APIM	Subnet	Subnet	
	DNS	Azure DNS	Route 53	Cloud DNS	
Connectivity	Remote Access to internet facing resources	Direct connect from Internet	Depends how it has been setup	Depends how it has been setup	
Identity	Identity Provider	Azure AD	AWS Identity Services(AWS Managed	Cloud Identity	minor code changes needed on SDRUI and SDR API apps to work with other Active Directory or Auth Systems

Architecture Area	Configuration Items	Public Cloud			Comments
		Azure	AWS	GCP	
			Microsoft AD)		
	Users	Active Directory Users	Users	IAM	
	Groups	AAD Security Groups	Groups	IAM	
	Service Principals	AAD SP	AWS Service Principal	Service Accounts	
	Managed Identity	Azure Manged Identities	Identity Providers	Identity and Access Management	
	RBAC	AAD & Subscription roles	AWS Roles	GCP Roles	
Security	Security Monitoring	Azure Defender	AWS Shield	Security Command Center	
	Baseline Policy	Microsoft Security Baseline	AWS Security		
	Key Management	Azure Key Vault	AWS Secret, AWS KMS	Secret Manager, Cloud KMS	
	DDOS	Basic DDOS for VNET	AWS Shield	Google Cloud Armor	
	APIM Inbound Control	APIM Inbound Policies	API Management	Apigee API Management	

Architecture Area	Configuration Items	Public Cloud			Comments
		Azure	AWS	GCP	
	Cosmos DB Inbound Control	Managed Identity	AWS IAM	Cloud Identity	
Resource	Service to Host Frontend UI	App Service instance 1	AWS BeanStalk	App Engine	Configuration changes to AWS Beanstalk, Google App Engine to be deploy the SDR code
	Service to Host APIs	App Service instance 2	AWS BeanStalk	App Engine	Configuration changes to AWS Beanstalk, Google App Engine to be deploy the SDR code
	API Gateway	API Management	AWS API Gateway	APIgee API management	
	No SQL Database	Cosmos DB with Mongo API	Document DB	Cloud BigTable	AWS DocumentDB can be used with existing configuration
	Storage to host TF State File	Azure Storage Account	s3 bucket	Cloud Storage	
	Storage to host Other Bulk import/Export	Azure Storage Account	s3 bucket	Cloud Storage	
	Message broker with message queue	Azure Service Bus	SNS	Google Cloud Pub/Sub	
	Service to process messages in queue	Azure Function App	AWS Lambda	GCP Functions	
	Service to build, store, and manage container images and related artifacts	Azure Container Registry	Amazon ECR	Container Registry	

Architecture Area	Configuration Items	Public Cloud			Comments
		Azure	AWS	GCP	
BC, HA and DR	Backup	Member company preference	Member company preference	Member company preference	
	HA	PaaS Services as per MS SLA	Paas Services as per SLA	Paas Services as per SLA	
	DR	PaaS Services as per MS SLA	Paas Services as per SLA	Paas Services as per SLA	
Operations	Logging	Azure Monitor Logs	Cloudwatch -Logs Insights	Cloud Logging	
	Application Performance Management	App Insights	AWS X-Ray	Cloud Trace	
	Monitoring	Azure Monitor	CloudWatch	Cloud Monitoring	
	Security & Compliance Monitoring	Azure Defender	AWS Guard Duty, AWS Security Hub	Security Command Center	