

Study Definition Repository (SDR) Reference Implementation

Infra Migration Guide (Release 0.5 to Release 2.0.1)

Version 1.0

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Document History

Version No.	Date	Author	Revision Description
V1.0	19-Jun-2023	ACN	 Additional changes on top Release V2.0 migration guide. Updated documents reference links in section 2.2, Updated APIM Route configurations in section 3.2.2. Updated Key Vault secrets links in section 3.3.1 Added a DB query to update parent element to "study" in section 3.2.5

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1 Introduction

1.1 Overview

This document details the steps required to migrate SDR Reference Implementation infrastructure from release Version 0.5 to Version 2.0.1 for users who have set up their own SDR instance for the Study Definition Repository – Reference Implementation on Azure Cloud Platform¹. It provides details for deploying the new resources using azure portal. Additionally, it provides details of containerized deployment for the SDR RI API and UI applications.

1.2 Scope of Document

Scope of the document includes steps how to migrate SDR RI infrastructure from release 0.5 to release 2.0.1 on Azure Cloud.

1.3 Intended Audience

This document assumes a good understanding of Azure concepts and services. The audience for this document is users who have set up their own SDR instance (on Azure Cloud) and running version of SDR Release V0.5.

1.4 Definitions and Acronyms

Term / Abbreviation	Definition		
API	Application Programming Interface		
DB	Database		
DDF	Digital Data Flow		
HTTP	Hypertext Transfer Protocol		
JSON	JavaScript Object Notation		
LLD	Low Level Design		
REST	Representational State Transfer		
SDR	Study Definition Repository		
UI	User Interface		
URL	Uniform Resource Locator		
VNet	Virtual Network		
CDISC USDM	Unified Study Definitions Model (USDM versioning is		
	supporting major versions of CDISC USDM versions)		
USDM Versioning	Hosting studies conformant to multiple versions of CDISC USDM in a single instance of SDR		

¹ 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.

Users are free to download the source code for the SDR from GitHub and design their own implementations. Those implementations can be on an environment of the user's choice, and do not have to be on Azure.

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Change Audit	Capturing the audit information including user, date, time and		
_	action of study data CRUD activities		

1.5 Out of Scope

This document does not include any instructions to upgrade SDR on Cloud platforms other than Azure. Nonetheless, the SDR Platform Agnostic Recommendations can be referred to for corresponding resource configurations to Infrastructure changes for Release V2.0.1.

2 Infrastructure changes for Release V2.0.1

2.1 Summary

As part of SDR Azure infrastructure migration, the below changes have been implemented and configured to upgrade from Release V0.5 to V2.0.1

- For Change Audit feature, below list of new resources have been added.
 Additionally, a new collection in CosmosDB has been created to hold change audit information.
 - o Azure Service Bus
 - App Service Plan for Function App
 - Function App
 - Storage Account
- For USDM Versioning below changes have been done to APIM and Cosmos DB
 - New APIs have been implemented and APIM routes configured.
 - New common collection has been created to hold studies conformant to all USDM versions supported by SDR V2.0.1.
 - Additionally, Data updates have been done on USDM version 1.0 studies which will be covered in the data migration section.
- The certificate authentication has been removed for API endpoints supporting SDR UI and now is enabled only for SDR API endpoints.
- These are the resources that have been created to support Containerized Deployment. Existing App Service plans and App Services have been deleted.
 - Azure Container Registry
 - App Service Plan and App Service for UI App Service
 - App Service Plan and App Service for API App Service
- GitHub actions have been introduced to support containerized deployment. Containerized deployment is optional, and users can also use the existing standard way of deployment of build to the existing App services.

The users who want to install a new version of SDR from scratch can export data or redo their SDR setup from scratch, they can refer to the platform setup and deployment guide. Before that, users should take a backup of existing data. For data migration of existing data into new SDR setup user can use one of the recommended tools to export data collections and then import back to new environment.

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2.2 References

Please refer to the documents below for information on latest SDR Architecture and Azure Resource Configurations.

Document Name	Document Link
SDR Solution Architecture	ddf-sdr-ri-solution-architecture-v4.0
Low Level Design	ddf-sdr-ri-platform-low-level-design-v4.0
Platform agnostic recommendations	ddf-sdr-ri-platform-agnostic-recommendations-v2.0
SDR Platform Setup and Deployment Guide	ddf-sdr-ri-platform-setup-and-deployment-guide-v5.0

3 Steps to Migrate

PRE-REQUISITES:

- SDR Running instance on Azure (SDR Release V0.5).
- Minimum Contributor level of access at Subscription Level.
- Optionally, basic understanding of containerized deployments.

3.1 Resources Configurations for Change Audit Feature

3.1.1 Create Delegated Subnet STEPS

- 1. Login to Azure Portal
- 2. Click on the resource groups tab.
- 3. Select the **sdrcore** resource group.
- 4. Refer the LLD and create a new delegated subnet.
 - Name
 - Subnet address range
 - Add IPv6 address space.
 - NAT gateway
 - Network Security Group
 - Route table
 - Services
 - Delegate subnet to a service

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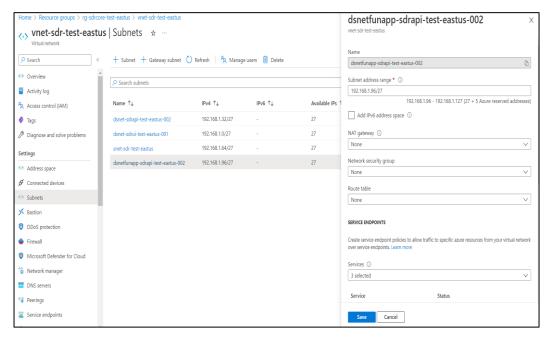


Figure 1 Delegated Subnet

3.1.2 Create Azure Service Bus

STEPS

- 1. Login to Azure Portal
- 2. Click on the Resource Groups tab.
- 3. Select the **sdrapp** resource group.
- 4. Refer the LLD document and create a new azure service bus.

SERVICE BUS CONFIGURATION

STEPS

- 1. Login to Azure Portal.
- 2. Click on the Resource Groups tab.
- 3. Select the *sdrapp* resource group.
- 4. Select the Service Bus Namespace and navigate to queues tab.
- 5. Create a Queue with name (changeauditqueue) then click on create.
- 6. Navigate to changeauditqueue, click on Shared Access Policies.
- 7. From Shared Access Policies add SAS Policy with Manage entity and capture the connection string values.
- 8. Go to Monitoring Tab and select Diagnostic Setting.
- 9. Click on add Diagnostic Settings and give the Diagnostic Setting Name.
- 10. Select Logs and Metrics and check "Send to Log Analytics Workspace".
- 11. Save the settings.

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Note: Please make a note of Queue name and connection string value required to be added in **Key Vaults Configurations Section 3.3.1 and Function App Application Settings Section 3.1.4.**

Figure 2 Service Bus Namespace Queue Configurations

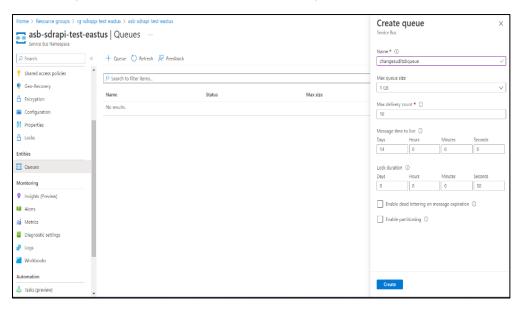
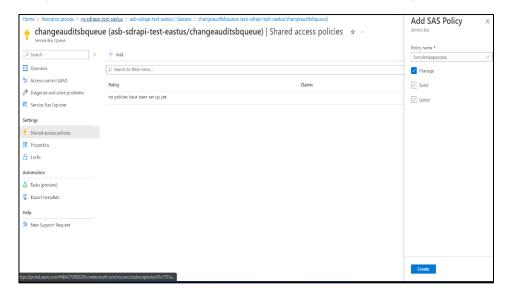


Figure 3 Service Bus Namespace Queue Shared access policies Configurations



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SAS Policy: functionappaccess changeauditsbqueue (asb-sdrapi-test-eastus/changeauditsbqueue) | Shared access 🗟 Save 💢 Discard 🗓 Delete 🗘 Regenerate Primary Key ,○ Search Manage Overview . Search to filter items. ✓ Send PR Access control (IAM) Diagnose and solve problems Service Bus Explorer 5gq0UHjHDPxXXOuyqoS3fyTuKV&F4rZPYLQWV\akfpOU0 hUOMiD4zpS7lp/Ddpq9hiPFjlnq662iw3SN1DASin A Locks Endpoint-sb://asb-sdrapi-test-e Tasks (preview) Export template SAS Policy ARM ID New Support Request

Figure 4 Service Bus Namespace Queue Shared access policies

3.1.3 Create App Service Plan for Function App STEPS

- 1. Login to Azure Portal.
- 2. Click on the Resource Groups tab.
- 3. Select the **sdrapp** resource group.
- 4. Refer the LLD document and create a new app service plan for function app.

3.1.4 Create Function App

STEPS

- 1. Login to Azure Portal.
- 2. Click on the Resource Groups tab.
- 3. Select the **sdrapp** resource group.
- 4. Refer the LLD document and create a function app.

FUNCTION APP CONFIGURATION

STEPS

- Login to Azure Portal.
- 2. Click on the Resource Groups tab.
- 3. Select the **sdrapp** resource group.
- 4. Select the Function App and navigate to networking tab.
- 5. Click on Access Restrictions and Add Rule
- 6. Click on VNet Integration and Add VNet and Subnet then click on Ok.
- 7. Go to Monitoring Tab and select Diagnostic Setting
- 8. Click on add Diagnostic Settings and give the Diagnostic Setting Name
- 9. Select Logs and Metrics and send to Log Analytics Workspace

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- 10. Save the settings.
- Go to Identity tab and enable System assigned managed identity and save the settings.
- 12. Navigate to Settings tab and click on Configuration tab.
- 13. Click on new application setting and add new Application Settings by using below mentioned table.
- 14. Save the settings.

Figure 5 Function App Inbound Traffic Configurations

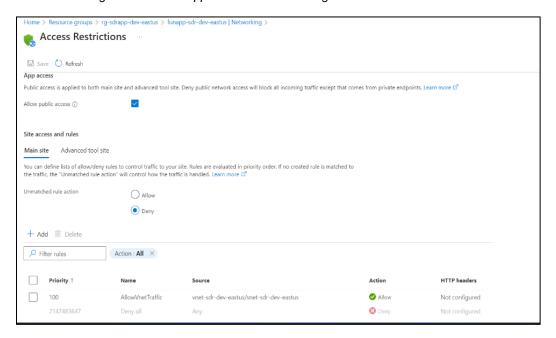
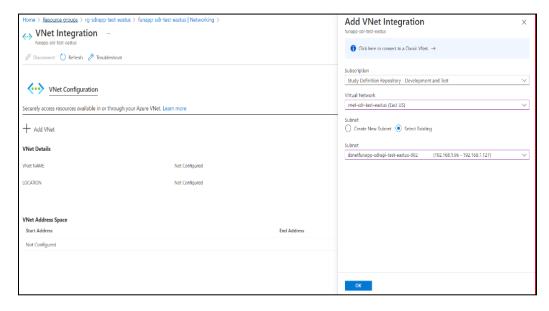


Figure 6 Function App Outbound Traffic Configurations



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Figure 7 Function App Diagnostic Configurations

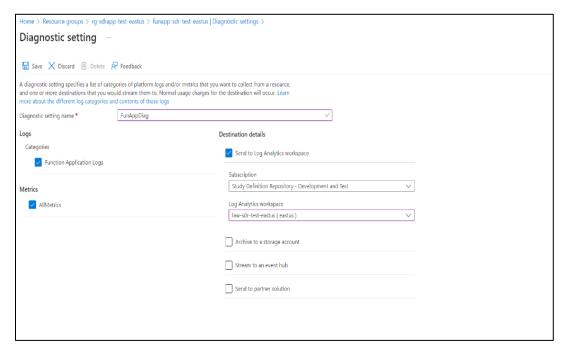
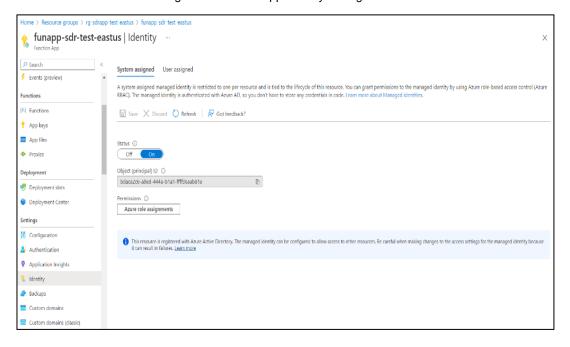


Figure 8 Function App Identity Configurations



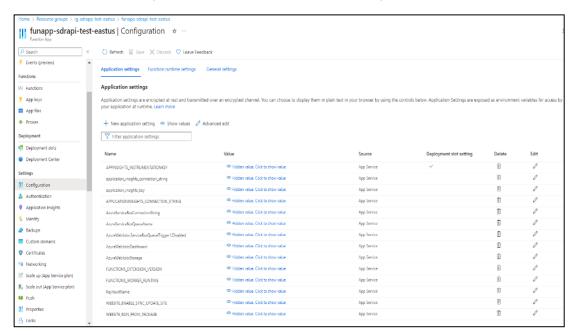
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Function App Application Settings

Name	Value
AzureServiceBusConnectionString	Refer to Service Bus Configuration Section
AzureServiceBusQueueName	Provide Azure Service Bus Queue Name
KeyVaultName	Provide Key Vault URL form Key Vault

Figure 9 Function App new Application settings



3.1.5 Changes to Cosmos DB Collections STEPS

- 1. Login to Azure Portal.
- 2. Click on the Resource Groups tab.
- 3. Select the **sdrapp** resource group.
- 4. Select Azure Cosmos DB for MongoDB and navigate to networking tab.
- Go to public access and select Selected networks, under existing VNet, add a new subnet with name as per the naming convention (E.g., dsnetfunappsdrapi-qa-eastus-002) then save the settings.
- 6. Go to Data Explorer and click on New Collection and give the existing database i.e., SDR and give the Collection id (**ChangeAudit**) then click on Ok.
- 7. Navigate to **ChangeAudit** data Collection and click on settings.
- 8. Click on add indexing Policy and add index as per below table.

Index Policy table

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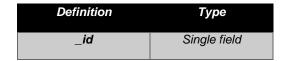


Figure 10 Network Configurations for Azure Cosmos DB for MongoDB

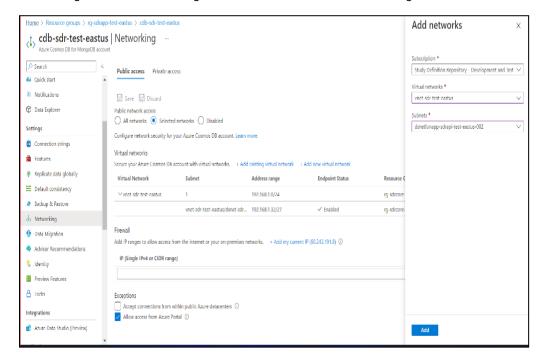
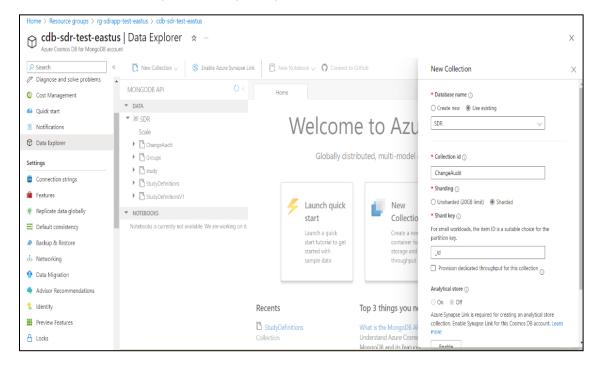


Figure 11 Adding ChangeAudit Data Collections



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cdb-sdr-test-eastus | Data Explorer * Azure Cosmos DB for MongoDB accou □ ✓ ♠ Bave Discard > New Shell **□** ∨ **③** ® □ Diagnose and solve problems MONGODB API Scale & Settin... X Cost Management ▼ DATA Quick start ▼ 🦅 SDR Scale Settings Indexing Policy Notifications Data Explorer ▼ 🖺 ChangeAudit For queries that filter on multiple properties, create multiple single field indexes instead of a compound index. Compound indexes are only used for sorting query results. If you need to add a compound index, you can create one using the Mongo shell. Documents Settings ∨ Current index(es) Connection strings ▶ ☐ Groups Features ▶ 🖺 study Definition Туре Drop Index ▶ 🖺 StudyDefinitions Replicate data globally Single Field ► 🖺 StudyDefinitionsV1 □ Default consistency Select an index type Backup & Restore Notebooks is currently not available. We are working on it. Networking Data Migration ✓ Index(es) to be dropped Advisor Recommendations % Identity Preview Features A Locks

Figure 12 Adding Indexing Policy for ChangeAudit Data Collection

3.1.6 Key Vault access for function app STEPS

- 1. Login to Azure Portal.
- 2. Click on the Resource Groups tab.
- 3. Select the *sdrcore* resource group.
- 4. Select Azure Key Vault and go to Access policies tab.
- 5. Click on Create and select Secret Management Configure from a template.
- 6. Click on Next and search for function app name and select Function App (E.g., funapp-sdrapi-qa-eastus).
- 7. Click on Next and click on Create.

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Backup

Restore

Home > Key vaults > kv-sdr-test-eastus | Access policies > Create an access policy 2 Principal 3 Application (optional) 4 Review + create Configure from a template Secret Management Key permissions Secret permissions Certificate permissions Certificate Management Operations Key Management Operations Secret Management Operations Select all Select all ✓ Select all Get Get List ✓ List List Update ✓ Set Update Create ✓ Delete Create ___ Import ✓ Recover Import Delete ✓ Backup Delete Recover Restore Recover

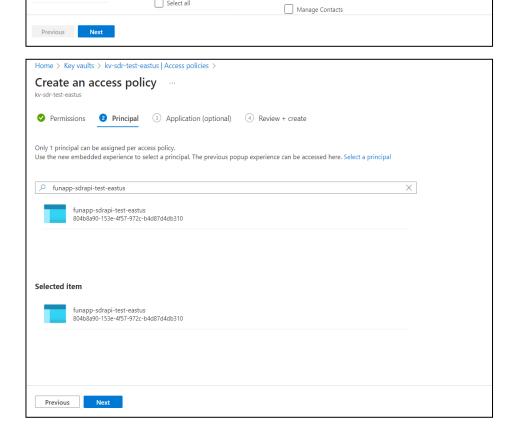
Privileged Secret Operations

Select all

Backup

Restore

Figure 13 Providing Access Policy for Function App



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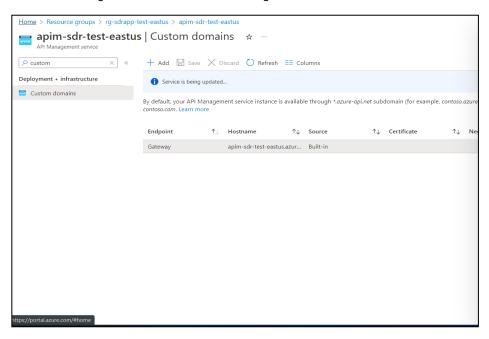


3.2 Resources Configuration for USDM Versioning

3.2.1 Disable Client Certificate in APIM Custom Domain STEPS

- 1. Login to Azure Portal.
- 2. Click on the Resource Groups tab.
- 3. Select the *sdrapp* resource group.
- 4. Select the API Management service and search for Custom domains.
- 5. Go to Custom domains and unselect Negotiate client certificate.
- 6. Update the settings.

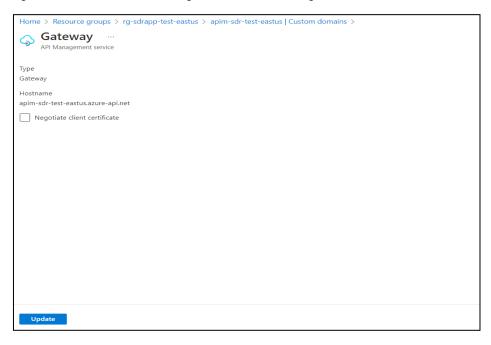
Figure 14 Custom domains Configuration



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Figure 15 Custom domains Configuration – Uncheck Negotiate Client Certificate



3.2.2 APIM Route Configuration

First, user must clear all existing routes and reconfigure the routes as per the table below. One example is given below to configure route and same steps should be followed for all the routes.

Method	API Name	Name	APIM Route	URL	Respo nses
GET	SDR API	Common - Get Study History	/api	/studydefinitions/history	200 OK
GET	SDR API	Common - Get Revision History	/api	/studydefinitions/{studyld}/revi sionhistory	200 OK
GET	SDR API	Common - Get Change Audit	/api	/studydefinitions/{studyld}/cha ngeaudit	200 OK
GET	SDR API	Common - Get API Versions	/api	/versions	200 OK
GET	SDR API	Common - Get Study Raw Data	/api	/studydefinitions/{studyld}/raw data	200 OK
GET	SDR UI Admin	Check Group Name	/api/ui/admin	/usergroups/checkgroupname	200 OK
POST	SDR UI Admin	Get Group List	/api/ui/admin	/usergroups/getgroups	200 OK

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GET	SDR UI	Get Groups	/api/ui/admin	/usergroups/getgrouplist	200 OK
	Admin				
POST	SDR UI Admin	Get Users	/api/ui/admin	/usergroups/getusers	200 OK
GET	SDR UI Admin	List Users	/api/ui/admin	/usergroups/listusers	200 OK
POST	SDR UI Admin	Post Group	/api/ui/admin	/usergroups/postgroup	200 OK
POST	SDR UI Admin	Post User	/api/ui/admin	/usergroups/postuser	200 OK
POST	SDR UI	Usage Reports	/api/ui	/reports/usage	200 OK
POST	SDR UI	Search API	/api/ui	/studydefinitions/search	200 OK
POST	SDR UI	Search Study Title	/api/ui	/studydefinitions/searchstudyti tle	200 OK
GET	SDR UI	Common - Get Version History	/api/ui	/studydefinitions/{studyld}/auditTrail	200 OK
GET	SDR UI	V1 Get Study Definition	/api/ui	/v1/studydefinitions/{studyId}	200 OK
GET	SDR UI	V2 Get Study Definition	/api/ui	/v2/studydefinitions/{studyId}	200 OK
GET	SDR UI	Get Study Links	/api/ui	/studydefinitions/{studyld}/link s	200 OK
GET	SDR UI	V2 Get Study Design SOA	/api/ui	/v2/studydefinitions/{studyld}/s tudydesigns/soa	200 OK
GET	SDR API	V1 Get Study Definition	/api	/v1/studydefinitions/{studyld}	200 OK
POST	SDR API	V1 Post Study Definition	/api	/v1/studydefinitions	201 Created
GET	SDR API	V1 Get Study Design	/api	/v1/studydesigns	200 OK
GET	SDR API	V2 Get Study Definition	/api	/v2/studydefinitions/{studyId}	200 OK
POST	SDR API	V2 Put Study Definition	/api	/v2/studydefinitions	201 Created
PUT	SDR API	V2 Post Study Definition	/api	/v2/studydefinitions	201 Created
GET	SDR API	V2 Get Study Design	/api	/v2/studydesigns	200 OK
GET	SDR API	V2 Get Study Design SOA	/api	/v2/studydefinitions/{studyld}/s tudydesigns/soa	200 OK

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GET	SDR API	V2 Get eCPT	/api	/v3/studyDefinitions/{studyId}/ studydesigns/eCPT	200 OK
GET	SDR API	V3 Get Study Definition	/api	/v3/studydefinitions/{studyId}	200 OK
POST	SDR API	V3 Put Study Definition	/api	/v3/studydefinitions	201 Created
PUT	SDR API	V3 Post Study Definition	/api	/v3/studydefinitions	201 Created
GET	SDR API	V3 Get Study Design	/api	/v3/studydesigns	200 OK
GET	SDR API	V3 Get Study Design SOA	/api	/v3/studydefinitions/{studyld}/s tudydesigns/soa	200 OK
GET	SDR API	V3 Get eCPT	/api	/v3/studyDefinitions/{studyId}/ studydesigns/eCPT	200 OK
POST	SDR API	V3 Validate USDM Conformance	/api	/v3/studyDefinitions/validate- usdm-conformance	200 OK
GET	SDR API	V3 Get Version Comparison	/api	/v3/studyDefinitions/{studyId}/ version-comparison	200 OK

• SDR API Route Configuration

STEPS

- 1. Login to Azure Portal.
- 2. Click on the Resource Groups tab.
- 3. Select the **sdrapp** resource group ration.
- 4. Select the API Management service and navigate to APIs Tab.
- 5. Select SDR API and click on Add operation.
- 6. Provide the details as per table above.
- 7. Save the settings.
 - i. Display Name
 - ii. Name
 - iii. URL
 - iv. Responses
- 8. Follow the same steps for all the routes.

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→ apim-sdr-test-eastus | APIs 🖈 … 🖸 Developer portal 👂 Send us your feedback REVISION 1 CREATED Mar 6, 2023, 10:07:44 PM \ Overview O Search APIs ▼ Filter by tags Revisions (1) Change log Activity log Group by tag Access control (IAM) P Search operations SDR API > Add operation ♦ OpenAPI specification Vie Filter by tags + Add API Diagnose and solve problems Group by tag Frontend Events Display name Common - Get API Versions + Add operation Settings SDR API common-get-api-versions All operations Properties GET ____/versions SDR MVP ≜ Locks No operations to display. SDR UI Admin SDR UI API e.g. Booking Products † Subscriptions Named values Backends Template parameters Policy fragments API Tags Discard

Figure 16 SDR API Route Configuration

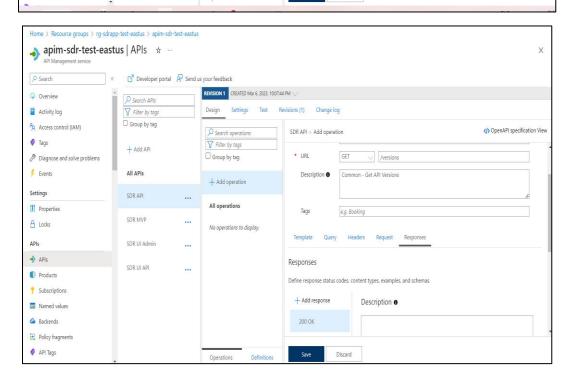
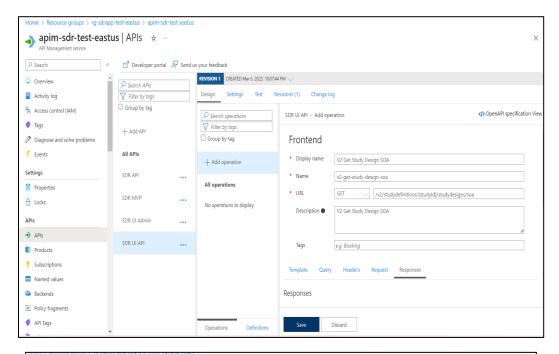
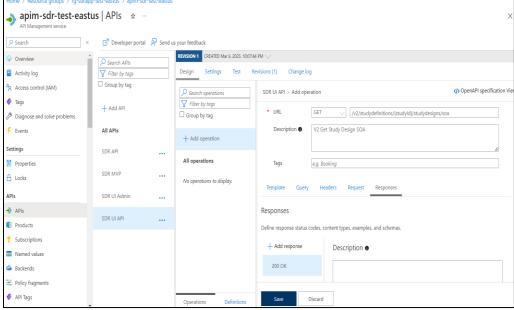


Figure 17 SDR UI Route Configuration

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3.2.3 Enable Client Certificate on API Group Inbound Policies

- Configure Inbound policy on SDR API endpoint for client certificate validation
 - Configure the policy on SDR API to validate one or more attributes of a client certificate used to access APIs hosted in API Management instance.

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 Go to APIs -> Select the SDR API -> Select "All Operations" -> Inbound processing -> Select Policies

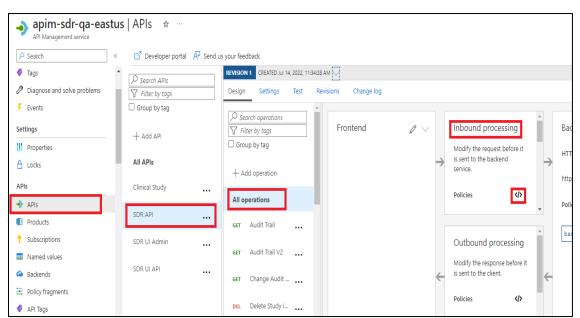


Figure 18 APIM Inbound Processing

 Add the policy code below to check the thumbprint of a client certificate against certificates uploaded to API Management

```
<policies>
 <inbound>
  <set-variable name="EmailAddress" value="@{</pre>
    string" name = "EmptyAuthToken"
   var="" authHeader = context.Request.Headers.GetValueOrDefault
   return="" authHeader.AsJwt()?.Claims.GetValueOrDefault=""("email", "EmptyAuthToken");
    }" />
  <set-variable name="UserName" value="@{</pre>
    string" name = "EmptyAuthToken"
  var="" authHeader = context.Request.Headers.GetValueOrDefault
  return="" authHeader.AsJwt()?.Claims.GetValueOrDefault=""("name", "EmptyAuthToken");
    }" />
  <choose>
   <when condition="@((context.Variables["EmailAddress="""]) != null)">
    <trace source="My Global APIM Policy" severity="information">
     <message>@(String.Format("{0} | {1}", context.Api.Name, context.Operation.Name))</message>
     <metadata name="EmailAddress" value="@((string)context.Variables["EmailAddress="""])" />
     <metadata name="UserName" value="@((string)context.Variables["UserName="""])" />
    </trace>
   </when>
   <otherwise>
```

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```
<trace source="My Global APIM Policy" severity="information">
     <message>@(String.Format("{0} | {1}", context.Api.Name, context.Operation.Name))</message>
     <metadata name="EmailAddress" value="Not Available" />
     <metadata name="UserName" value="Not Available" />
    </trace>
   </otherwise>
  </choose>
  <base />
  <choose>
   <when condition="@(context.Request.Certificate == null || !context.Deployment.Certificates.Any(c =>
c.Value.Thumbprint == context.Request.Certificate.Thumbprint)
   || context.Request.Certificate.NotAfter"
    <DateTime.Now)">
    <return-response>
     <set-status code="403" reason="Invalid client certificate" />
    </return-response>
   </when>
  </choose>
  <cors allow-credentials="true">
   <allowed-origins>
    <origin>Add Backend APP Service URL</origin>
    <origin>http://localhost:4200</origin>
    <origin>https://localhost:4200</origin>
    <origin>Add API Management URL
    <origin>Add Frontend (UI) URL</origin>
   </allowed-origins>
   <allowed-methods preflight-result-max-age="300">
    <method>GET</method>
    <method>POST</method>
    <method>PATCH</method>
    <method>DELETE</method>
   </allowed-methods>
   <allowed-headers>
    <header>*</header>
   </allowed-headers>
   <expose-headers>
    <header>*</header>
   </expose-headers>
  </cors>
 </inbound>
 <backend>
  <base />
 </backend>
 <outbound>
  <base />
 </outbound>
 <on-error>
  <base />
 </on-error>
```

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Figure 19 APIM (API Management) - Inbound Policy

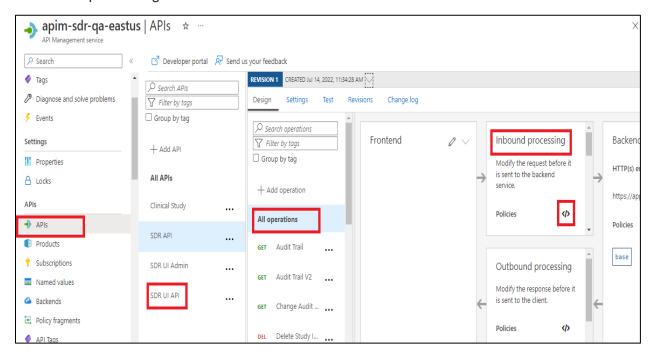


Remove Certificate Inbound policy on SDR UI API & SDR UI ADMIN endpoints

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- Configure the policy on SDR UI API and SDR UI Admin to validate the inbound requests to access APIs hosted in API Management instance.
- Go to APIs -> Select the SDR UI API -> Select "All Operations" -> Inbound processing -> Select Policies



Add the policy code and make sure the inbound policy looks like below.

```
<policies>
 <inbound>
  <set-variable name="EmailAddress" value="@{
    string" name = "EmptyAuthToken"
   var="" authHeader = context.Request.Headers.GetValueOrDefault
   return="" authHeader.AsJwt()?.Claims.GetValueOrDefault=""("email", "EmptyAuthToken");
    }" />
  <set-variable name="UserName" value="@{
    string" name = "EmptyAuthToken"
  var="" authHeader = context.Request.Headers.GetValueOrDefault
  return="" authHeader.AsJwt()?.Claims.GetValueOrDefault=""("name", "EmptyAuthToken");
    }" />
  <choose>
   <when condition="@((context.Variables["EmailAddress="""]) != null)">
    <trace source="My Global APIM Policy" severity="information">
      <message>@(String.Format("{0} | {1}", context.Api.Name, context.Operation.Name))</message>
      <metadata name="EmailAddress" value="@((string)context.Variables["EmailAddress="""])" />
      <metadata name="UserName" value="@((string)context.Variables["UserName="""])" />
    </trace>
   </when>
   <otherwise>
```

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```
<trace source="My Global APIM Policy" severity="information">
     <message>@(String.Format("{0} | {1}", context.Api.Name, context.Operation.Name))</message>
     <metadata name="EmailAddress" value="Not Available" />
     <metadata name="UserName" value="Not Available" />
    </trace>
   </otherwise>
  </choose>
  <base />
  <cors allow-credentials="true">
   <allowed-origins>
    <origin>Add Backend APP Service URL</origin>
    <origin>http://localhost:4200</origin>
    <origin>https://localhost:4200</origin>
    <origin>Add API Management URL
    <origin>Add Frontend (UI) URL</origin>
   </allowed-origins>
   <allowed-methods preflight-result-max-age="300">
    <method>GET</method>
    <method>POST</method>
    <method>PATCH</method>
    <method>DELETE</method>
   </allowed-methods>
   <allowed-headers>
    <header>*</header>
   </allowed-headers>
   <expose-headers>
    <header>*</header>
   </expose-headers>
  </cors>
 </inbound>
 <backend>
  <base />
</backend>
<outbound>
  <base />
 </outbound>
 <on-error>
  <base />
</on-error>
</policies>
```

- Repeat the above steps to configure the inbound policy on SDR UI Admin endpoint.
- Now for SDR UI API and SDR UI Admin the certificate Authentication is removed.

3.2.4 Cosmos DB Updates STEPS

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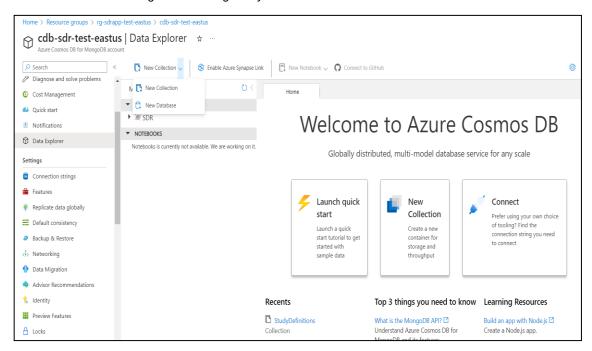


- 1. Login to Azure Portal.
- 2. Click on the Resource Groups tab.
- 3. Select the **sdrapp** resource group.
- Go to Data Explorer and click on New Collection tab and use existing database i.e., SDR and give the Collection id (StudyDefinitions) then click on Ok.
- 5. Navigate to **StudyDefinitions** and click on settings.
- 6. Click on add indexing Policy and add indexes as per below table.

Index policy table for StudyDefinitions

Definition	Type
_id	Single Field
clinicalStudy.studyld	Single Field
auditTrail.entryDateTime	Single Field
clinicalStudy.studyTitle	Single Field
auditTrail.usdmVersion	Single Field

Figure 20 Adding StudyDefinitions Data Collections



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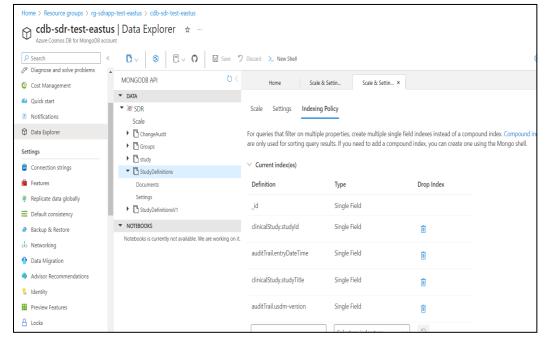


Figure 21 Adding Indexing Policy for StudyDefinitions Collection

3.2.5 Data Migration

STEPS

- 1. Launch Mongo shell and connect to the database using the connection string.
- 2. The old collection "StudyDefinitionsV1" must be updated to add "usdmVersion" parameter under AuditTrail section.
- 3. To add usdmVersion attribute on all documents in "StudyDefinitionsV1" collection run below command.

4. Run below commands to move the documents from "StudyDefinitionsV1" collection to the new common "StudyDefinitions" collection.

- The merge operation mentioned in previous step is supported only for MongoDB version 4.4 and above. For other lower Mongo DB versions, this activity can be done by exporting the documents from the source collection and importing into the destination collection by using any third-party IDE tools for MongoDB.
- 6. Run below command to update the attribute name from uuid to studyld for all USDM V1.0 documents in the new common "StudyDefinitions" collection.

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db.getCollection("StudyDefinitions").updateMany({"auditTrail.usdmVersion": "1.0"}, {\$rename:{"clinicalStudy.uuid": "clinicalStudy.studyId"}}, false, true)

7. Run below command to update the parent attribute name from "clinicalStudy" to "study" for all the documents in the new common "StudyDefinitions" collection.

3.3 Additional Cloud Configurations

3.3.1 Key Vault Configurations STEPS

- 1. Login to Azure Portal.
- 2. Click on the Resource Groups tab.
- 3. Select the **sdrcore** resource group.
- 4. Go to Objects tab and Click on Secret.
- 5. Click on Generate/Import tab and create secrets by using below table.

Name	
Env-Name	Provide a key word for the deployed environment (dev,qa,stage etc.)
ApiVersionUsdmVersionMapping	Refer to sdr-api-usdm-version-mapping.json
	Refer to sdr-cpt-master-data-mapping.json
SdrCptMasterDataMapping	
ConformanceRules	Refer to <u>usdm-conformance-rules-configuration.json</u>
AzureServiceBusConnectionString	Refer to Service Bus Configuration Section
AzureServiceBusQueueName	Refer to Service Bus Configuration Section

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Figure 22 Create Secret

3.4 Build and Deployment Updates

3.4.1 GitHub Secrets updates for deploying Function App

Create GitHub Secret in **ddf-sdr-api** repo required for Function App deployment.

Adding Secret in GitHub

STEPS:

- 1. Go to repo settings.
- 2. On the lower left-hand side of the screen, click on Secrets.
- 3. Under that click on Actions.
- 4. Then click on New Repository Secret.

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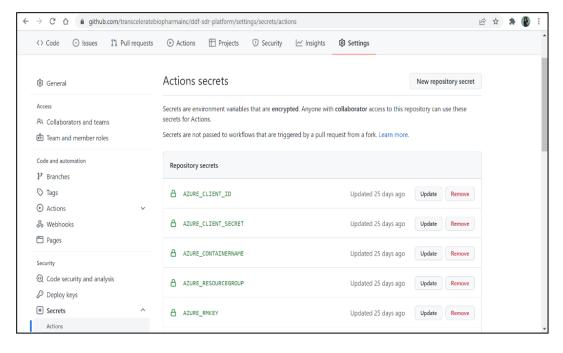


Figure 23 GitHub Actions Secrets

 After clicking New Repository Secret, fill the details of the secret (name and value) in the boxes. Name – AZURE_FUNCTIONAPP_NAME and Value – name of function app resource created in Azure e.g.: funapp-sdr-deveastus.

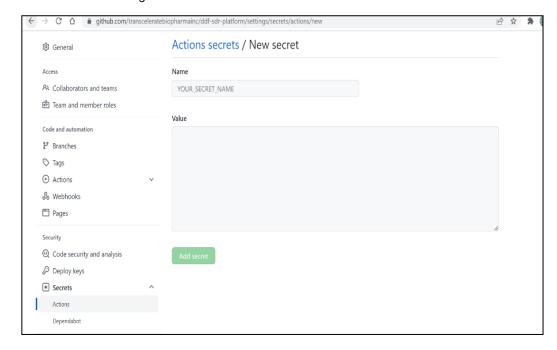


Figure 24 Add new GitHub Action Secret

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⊞ Environments Pages ☐ Wait timer Set an amount of time to wait before allowing deployments to proceed. $\hfill \square$ Do not let admins bypass protection rules @ Code security and analysis Prevent admins from being able to bypass the configured protection rules. Deploy keys * Secrets and variables Deployment branches All branches ▼ Can be used to limit what branches can deploy to this environment using branch name patterns 88 GitHub apps Secrets are encrypted environment variables. They are accessible only by GitHub Actions in the context of this environment. ACR_NAME Updated on Dec 29, 2022 💋 🗓 ACR_PASSWORD Updated on Dec 29, 2022 Updated on Dec 29, 2022 ACR_USERNAME △ AZURE_FUNCTIONAPP_NAME Updated on Dec 29, 2022 0 0 AZURE_SP 0 0 Updated on Dec 29, 2022

Figure 25 Function App GitHub Secret

 Update GitHub Action yml file in ddf-sdr-api repo. A new task has been created to publish function App Artifacts. Please refer the below screen shot.

Figure 26 Adding a new task in yml file to Publish Function App Build Artifact

```
- name: Zip publish files
shell: push
# Zip the Function App build artifact publish folder
run: |
Compress-Archive -Path "${{ github.workspace }}/src/TransCelerate.SDR.AzureFunctions/bin/Release/net6.0/publish/**" -DestinationPath "${{ github.workspace }}\FunAppa

- name: 'Publish Function App Artifact: Artifact'
uses: actions/upload-artifact@v2
# Publish the Function App Build artifact in github
with:
path: '${{ github.workspace }}/FunAppPublish.zip'
name: FunctionAppBuild-Artifact
```

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```
- name: Azure Functions Action
uses: Azure/functions-action@v1.4.7
with:
# Name of the Azure Function App
    app-name: ${{ secrets.AZURE_FUNCTIONAPP_NAME }} # Replace with Function app name
# Path to package or folder. *.zip or a folder to deploy
    package: '${{ github.workspace }}/FunAppPublish.zip'
```

· ddf-sdr-ui repo YAML script Changes

- 1. A new Key vault variable is added in yml file to display the Environment in the System Usage report.
- 2. Additionally, the node.js version from 12.x to 14.x. Please refer the below screen shots

Figure 27 Adding new key vault value in yml file

```
- name: Fetch Keyvault values
   uses: Azure/get-keyvault-secrets@v1
   with:
       # Name of the azure key vault
       keyvault: ${{ secrets.KEYVAULT_NAME }} # name of key vault in Azure portal
       # Name of the secret to be fetched
       secrets: 'AzureAd-TenantId, AzureAd-Authority, AzureAd-ClientId, AzureAd-Audience, AzureAd-RedirectUrl, AzureAd-LoginUrl, Aoim-BaseUr
                                                                                                                                                                                                                                                                                                     # comma separated list of s
   id: keyvaultSecretAction # ID for secrets that you will reference
- name: Find and Replace User Name - Using Build Variable
   # Variables in environment.ts is replaced using the find script while fetching it from keyvault through secrets
       find $\{\{\ github.workspace\ \}\}/SDR-WebApp/src/environments/environment.ts \ -type\ f\ -exec\ sed\ -i\ ''s\{\{\ AzureAd-TenantId\}\}e''\\ \{\{\ steps.keyvaultSecretAction.outputs.AzureAd-TenantId\}\}e''\}, for the sum of the sum 
        find ${{ github.workspace }}/SDR-WebApp/src/environments/environment.ts -type f -exec sed -i ''s@{#AzureAd-Authority#}@'${{ steps.keyvaultSecretAction.outputs.AzureAd-
       find ${{ github.workspace }}/SDR-WebApp/src/environments/environment.ts -type f -exec sed -i ''s@{#AzureAd-ClientId#}@'${{ steps.keyvaultSecretAction.outputs.AzureAd-C
       find ${{ github.workspace }}/SDR-WebApp/src/environments/environment.ts -type f -exec sed -i ''s@{#AzureAd-Audience#}@'${{ steps.keyvaultSecretAction.outputs.AzureAd-A
        find ${{ github.workspace }}/$DR-WebApp/src/environments/environment.ts -type f -exec sed -i ''s@(#AzureAd-RedirectUrl#)@'${{ steps.keyvaultSecretAction.outputs.AzureA
        find ${{ github.workspace }}/SDR-WebApp/src/environments/environment.ts -type f -exec sed -i ''s@{#AzureAd-LoginUrl#}@'${{ steps.keyvaultSecretAction.outputs.AzureAd-L
        find ${{ github.workspace }}/SDR-WebApp/src/environments/environment.ts -type f -exec sed -i ''s@{#Env-Name#}@'${{ steps.keyvaultSecretAction.outputs.Env-Name }}'@g'
    name: Use Node 14.x
      node-version: 14.x
```

3.4.2 Code Deployment

To enable containerized deployment of SDR application, please skip this step and refer to section 4. Otherwise, the UI and API code deployment to respective App services can be done using the below updated scripts.

ddf-sdr-api/release.yml at develop · transcelerate/ddf-sdr-api (github.com)
ddf-sdr-ui/release.yml at develop · transcelerate/ddf-sdr-ui (github.com)

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4 Containerized Deployment

The UI and API builds have been containerized as a part of SDR Release V2.0. The same has impacted the App Services on which the SDR Application is hosted. This section details the steps to enable containerized build and deployment.

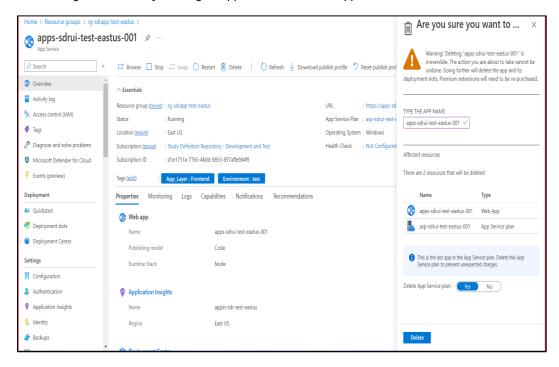
This is an optional step. To continue with existing way of deployment of SDR use current App Service and Service Plan configuration and B&D scripts for UI and API for deployment as mentioned in section 3.4.2.

4.1 Recreate App Service Plans and App Services

4.1.1 Destroy existing UI app service Plan and App Service Steps

- Login to Azure Portal
- 2. Click on the Resource Groups tab.
- 3. Select the **sdrapp** resource group.
- 4. Select the UI App Service and Click on Delete from the Overview Page and delete both App service and App Service Plans

Figure 28 Destroy existing UI app service Plan and App Service



4.1.2 Recreate UI app Service Plan

STEPS

- 1 Login to Azure Portal
- 2. Click on the Resource Groups tab.
- 3. Select the **sdrapp** resource group.

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4. Refer the LLD document and create an App Service plan for SDR UI

4.1.3 Recreate UI App Service

STEPS

- 1. Login to Azure Portal.
- 2. Click on the Resource Groups tab.
- 3. Select the *sdrapp* resource group.
- 4. Refer the LLD document and create an App Service for SDR UI.

4.1.4 SDR UI App Service Configuration

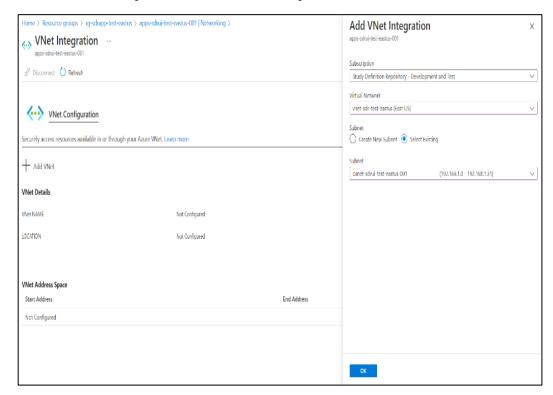
STEPS

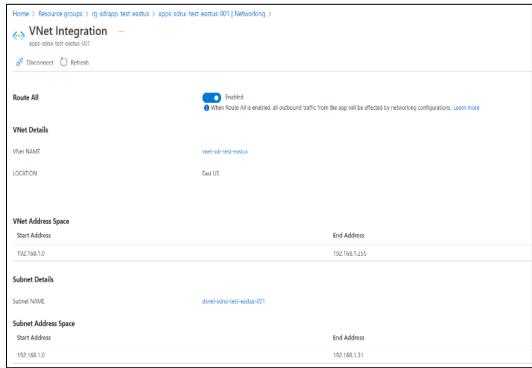
- 1. Login to Azure Portal.
- 2. Click on the Resource Groups tab.
- 3. Select the *sdrapp* resource group.
- 4. Select the UI App Service and navigate to networking tab.
- 5. Click on VNet Integration and add VNet and subnet then click on Ok.
- 6. Go to Monitoring Tab and select Diagnostic Setting.
- 7. Click on add Diagnostic Settings and give the Diagnostic Setting Name.
- 8. Select Logs and Metrics and check "Send to Log Analytics Workspace"
- 9. Save the settings.

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Figure 29 SDR UI Network Configuration





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Home > Resource groups > rg-sdrapp-test-eastus > apps-sdrui-test-eastus-001 | Diagnostic settings > Diagnostic setting ☐ Save X Discard ☐ Delete 🖗 Feedback A diagnostic setting specifies a list of categories of platform logs and/or metrics that you want to collect from a resource, and one or more destinations that you would stream them to. Normal usage charges for the destination will occur. Learn more about the different log categories and contents of those logs. Logs Destination details Categories Send to Log Analytics workspace HTTP logs App Service Console Logs Study Definition Repository - Development and Test Log Analytics workspace App Service Application Logs law-sdr-test-eastus (eastus) Access Audit Logs Archive to a storage account IPSecurity Audit logs Stream to an event hub App Service Platform logs Send to partner solution Metrics All Metrics

Figure 30 SDR UI Diagnostic Configuration

4.1.5 Destroy existing API app service Plan and App Service

STEPS

- 1. Login to Azure Portal.
- 2. Click on the Resource Groups tab.
- 3. Select the *sdrapp* resource group.
- 4. Select the API App Service and Click on Delete from the Overview page and delete both App Service and App Service Plan

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 $\hat{\mathbf{x}}$ Are you sure you want to ... \times Home > Resource groups > rg-sdrapp-test-eastus > apps-sdrapi-test-eastus-002 \varkappa ... Warning! Deleting "apps-sdrapi-test-eastus-002" is irreversible. The action you are about to take cannot be undone. Going further will delete the app and its 🖾 Browse 🔲 Stop 😅 Swap 🖒 Restart 🗓 Delete 📗 🖒 Refresh 🛂 Download publish profile 🍏 Reset publish prof deployment slots. Premium extensions will need to be re-purchased Overview ∧ Essentials Activity log : https://apps-sd Resource group (move): rg-sdrapp-test-eastus Access control (IAM) TYPE THE APP NAME Status : Running App Service Plan : asp-sdrapi-testapps-sdrapi-test-eastus-002 ✓ **∅** Tags Location (move) : East US Operating System: Windows Diagnose and solve problems Health Check : Not Configured Subscription (move) : Study Definition Repository - Development and Test Subscription ID : d1e1751a-7763-4b0d-9853-857affe984f9 Microsoft Defender for Cloud There are 2 resources that will be deleted F Events (preview) App_Layer : Backend Environment : test Deployment Properties Monitoring Logs Capabilities Notifications Recommendations Quickstart apps-sdrapi-test-eastus-002 Web App Web app Deployment slots asp-sdrapi-test-eastus-002 App Service plan apps-sdrapi-test-eastus-002 Deployment Center Publishing model Code f) This is the last app in the App Service plan. Delete this App Settings Runtime Stack Dotnet Configuration Delete App Service plan: Yes No Authentication Application Insights Application Insights appin-sdr-test-eastus % Identity East US Delete Backups

Figure 31 SDR API App Service Details

4.1.6 Recreate API App Service Plan

STEPS

- 1. Login to Azure Portal
- 2. Click on the Resource Groups tab.
- 3. Select the **sdrapp** resource group.
- 4. Refer the LLD document and create an App Service plan for SDR API

4.1.7 Create API App Service

STEPS

- 1 Login to Azure Portal.
- 2. Click on the Resource Groups tab.
- 3. Select the *sdrapp* resource group.
- 4. Refer the LLD document and create an App Service for SDR API.

4.1.8 SDR API App Service Configuration

STEPS

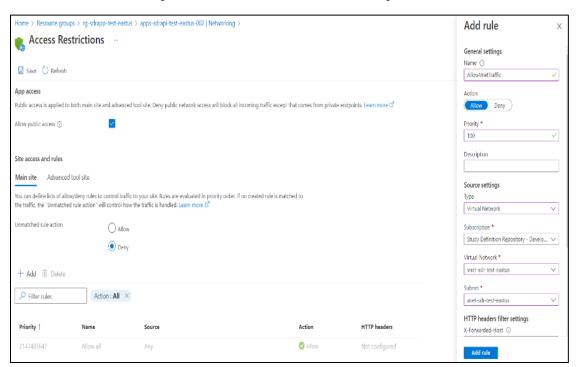
- 1. Login to Azure Portal.
- 2. Click on the Resource Groups tab.
- 3. Select the **sdrapp** resource group.
- 4. Select the API App Service and navigate to networking tab.
- 5. Click on Access Restrictions and Add Rule.

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- 6. Click on VNet Integration and add VNet and subnet. Then and Disable **Route All** option and click on Ok.
- 7. Go to Monitoring Tab and select Diagnostic Setting.
- 8. Click on add Diagnostic Settings and give the Diagnostic Setting Name.
- 9. Select Logs and Metrics and send to Log Analytics Workspace
- 10. Save the settings.
- 11. Go to Identity tab and enable System assigned managed identity and save the settings.
- 12. To enable KeyVault access for API app service, Navigate to **sdrcore** resource group.
- 13. Select Azure Key Vault and navigate to Access policies tab.
- 14. Click on Create and select **Secret Management** option from the **Configure a template** dropdown.
- 15. Select all applicable secret management operations
- 16. Click on Next and search for API app name and select API App Service (E.g., apps-sdrapi-qa-estus-002).
- 17. Click on Next and click on Create.

Figure 32 SDR API Access Restriction Configuration



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Figure 33 SDR API Network Configuration

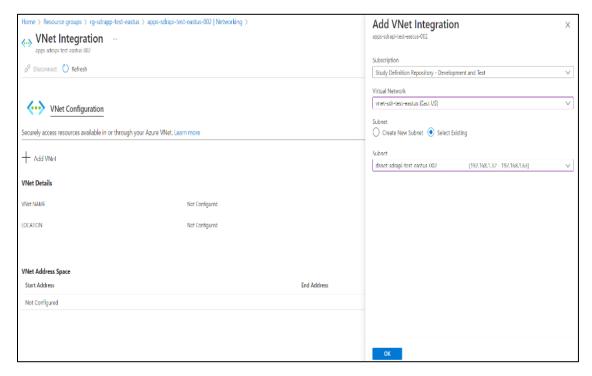
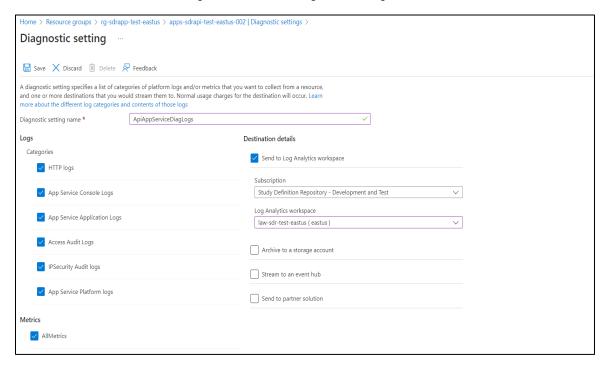


Figure 34 SDR API Diagnostic Configuration



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Figure 35 SDR API Identity Configuration

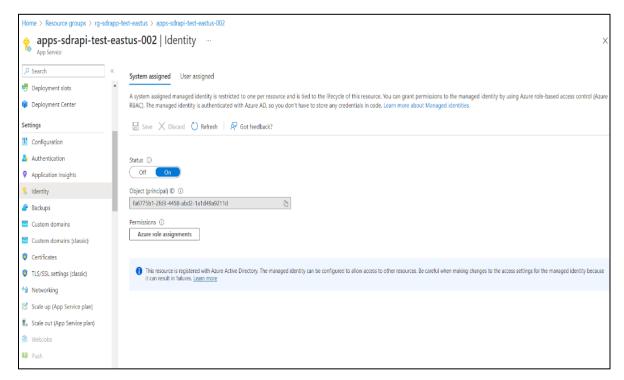
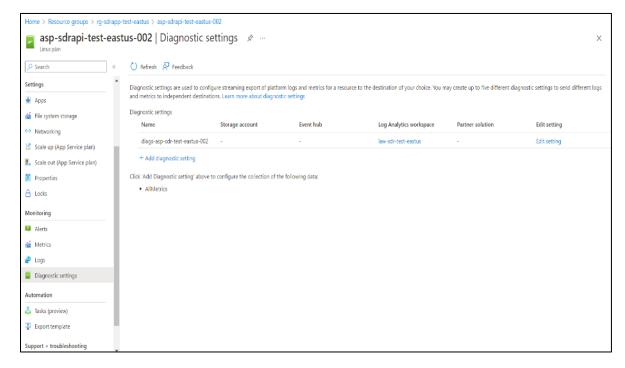


Figure 36 SDR API Diagnostic Configuration



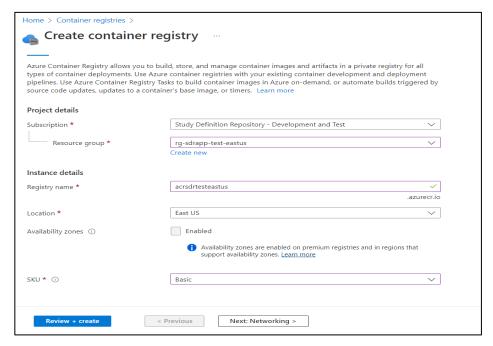
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4.1.9 Create Azure Container Registry STEPS

- 1. Login to Azure Portal.
- 2. Click on the Resource Groups tab.
- 3. Select the **sdrapp** resource group.
- 4. Refer the LLD document and create an Azure Container Registry
 - Basics Details (Subscription, Resource Group)
 - Instance Details (Registry name, Location, Availability Zones, SKU)
 - Networking
 - Encryption
 - Tags

Figure 37 Container Registry Basics Details



4.1.10 Container Registry ConfigurationSTEPS

- Login to Azure Portal.
- 2. Click on the Resource Groups tab.
- 3. Select the **sdrapp** resource group.
- 4. Select Container Registry and navigate to Access key and enable Admin user setting.
- 5. Capture Username, Password and Login Server URL.

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Note: Please make a note of Username, Password and Login Server URL values required to be added in UI & API Application Settings.

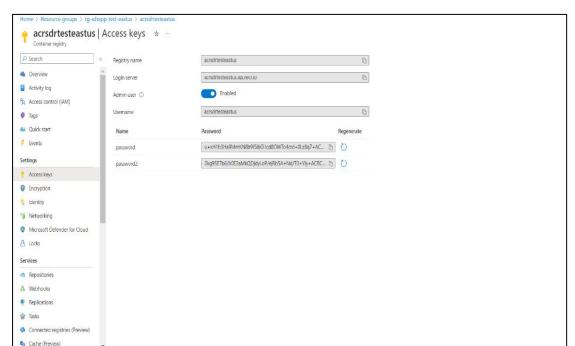


Figure 38 Enabling Admin User Settings

4.2 GitHub Actions/YAML/Build & Deploy Script Updates

PRE-REQUISITES:

- Read access to fetch Key Vault secrets in Azure Portal
- User Should have access policies set to read/retrieve secrets from Azure Key Vault in Azure Portal
- User should have Repo Admin level of Access to add/replace the GitHub secrets in GitHub.

Below are the steps to Containerize an application and deploy via ci/cd pipeline.

- Create a docker file and add it in the root folder of the GitHub repo of source code.
- Create an Azure Container Registry to store container images.
- Create GitHub Actions workflow to build the container and deploy it to App service.

The "Dockerfile" file is used by the docker build command to create a container image.

By selecting Create a new project and Docker is enabled, the "Dockerfile" and ".dockerignore" files are automatically generated for an ASP.NET Core Web app in Visual Studio.

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4.2.1 GitHub Actions to deploy container image to UI App Service

The Azure Web Deploy action automates the workflow to deploy custom container image to app service.

PRE-REQUISITES

- Dockerfile in the project folder
- Azure Container Registry login credentials
- App Service for containers.

Below are the secrets and GitHub Actions that need to be added to GitHub workflow.

Secrets:

- ACR_NAME: Azure Container Registry URL
- ACR USERNAME: ACR Username
- ACR_PASSWORD: ACR Password
- AZURE_WEBAPP_NAME: UI App Service Name

Workflow Actions:

Build and push Docker image to ACR

The actions below will be used in deployment Job to build containers using an Azure Container Registry.

Figure 39 GitHub Action for Containerized Build

```
- name: Azure Container Registry Login
  uses: Azure/docker-login@v1
with:
    # Container registry username
    username: ${{ secrets.ACR_USERNAME }} # default is
    # Container registry password
    password: ${{ secrets.ACR_PASSWORD }} # default is
    # Container registry server url
    login-server: ${{ secrets.ACR_NAME }} # default is https://index.docker.io/v1/
- run: |
    cp '${{ github.workspace }}/Dockerfile' '${{ github.workspace }}/SDR-WebApp/dist/SDR-WebApp'
    cp '${{ github.workspace }}/nginx.conf' '${{ github.workspace }}/SDR-WebApp/dist/SDR-WebApp'
    cd ${{ github.workspace }}/SDR-WebApp/dist/SDR-WebApp
    ls
    docker build . -t ${{ secrets.ACR_NAME }}/sdruibuild:latest
    docker push ${{ secrets.ACR_NAME }}/sdruibuild:latest
```

Deploy to App Service

The below GitHub action will be used in deployment Job to deploy container to App Service.

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```
- uses: azure/webapps-deploy@v2
with:
   app-name: ${{ secrets.AZURE_WEBAPP_NAME }}
   images: '${{ secrets.ACR_NAME }}/sdruibuild:latest'
```

4.2.2 GitHub Actions to deploy container image to API App Service

The Azure Web Deploy action automates the workflow to deploy custom container image to app service.

PRE-REQUISITES

- Dockerfile in the project folder
- Azure Container Registry login credentials
- App Service for containers.

Below are the secrets and GitHub Actions that need to be added to GitHub workflow.

Secrets:

- ACR_NAME: Azure Container Registry URL
- ACR USERNAME: ACR Username
- ACR PASSWORD: ACR Password
- AZURE_WEBAPP_NAME: API Web App Name

Workflow Actions:

Build and push Docker image to ACR.

The actions below will be used in deployment Job to build containers using an Azure Container Registry.

```
- name: Azure Container Registry Login

uses: Azure/docker-login@v1

with:

# Container registry username

username: ${{ secrets.ACR_USERNAME }} # default is

# Container registry password

password: ${{ secrets.ACR_PASSWORD }} # default is

# Container registry server url

login-server: ${{ secrets.ACR_NAME }} # default is https://index.docker.io/v1/

- run:

cp '${{ github.workspace }}/Dockerfile' '${{ github.workspace }}/src/TransCelerate.SDR.WebApi/bin/Release/net6.0/publish/'

cd ${{ github.workspace }}/src/TransCelerate.SDR.WebApi/bin/Release/net6.0/publish/

ls

docker build . -t ${{ secrets.ACR_NAME }}/sdrapibuild:latest

docker push ${{ secrets.ACR_NAME }}/sdrapibuild:latest
```

Deploy to App Service

The below GitHub action will be used in deployment Job to deploy container to App Service.

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```
- uses: azure/webapps-deploy@v2
with:
   app-name: ${{ secrets.AZURE_WEBAPP_NAME }}
   images: '${{ secrets.ACR_NAME }}/sdrapibuild:latest'
```

The below GitHub action will be used in build and deployment Job to Publish Function App folder.

```
- name: Zip publish files
shell: pwsh
# Zip the Function App build artifact publish folder
run: |
Compress-Archive -Path "${{ github.workspace }}/src/TransCelerate.SDR.AzureFunctions/bin/Release/net6.8/publish/**" -DestinationPath "${{ github.workspace }}\FunAppR

- name: 'Publish Function App Artifact: Artifact'
uses: actions/upload-artifact@v2
# Publish the Function App Build artifact in github
with:
path: '${{ github.workspace }}/FunAppPublish.zip'
name: FunctionAppBuild-Artifact
```

```
- name: Azure Functions Action
uses: Azure/functions-action@v1.4.7
with:
# Name of the Azure Function App
    app-name: ${{ secrets.AZURE_FUNCTIONAPP_NAME }} # Replace with Function app name
# Path to package or folder. *.zip or a folder to deploy
    package: '${{ github.workspace }}/FunAppPublish.zip'
```

4.2.3 GitHub Secrets used in Workflow

The Below mentioned additional GitHub Secrets need to be added in UI and API Repo Secrets.

STEPS:

- 1. Login to azure portal, select resource group section.
- 2. Navigate to the deployed Azure Container Registry and copy the Login Server name from Overview blade. This will be the ACR_NAME for both ddf-sdr-ui & ddf-sdr-api repo secrets.
- 3. Navigate to the deployed Azure Container Registry and copy the Username & Password from Access Keys blade. This will be the

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- ACR_USERNAME & ACR_PASSWORD for both ddf-sdr-ui & ddf-sdr-api repo secrets.
- 4. Navigate to the deployed Function App Service for SDR API and copy the name from Overview blade. This will be the AZURE_FUNCTIONAPP_NAME for ddf-sdr-api repo secrets.
- Login to GitHub and navigate to ddf-sdr-api -> Settings-> Secrets ->
 Actions and add/replace values for ACR_NAME,
 ACR_USERNAME, ACR_PASSWORD, AZURE_FUNCTIONAPP_NAME
 by clicking on update.
- Login to GitHub and navigate to ddf-sdr-ui -> Settings -> Secrets ->
 Actions and add/replace values for ACR_NAME,
 ACR_USERNAME, ACR_PASSWORD by clicking on Update.
- 7. Update the Deployment yml script with Azure Container Registry in both ddf-sdr-api & ddf-sdr-ui repos.

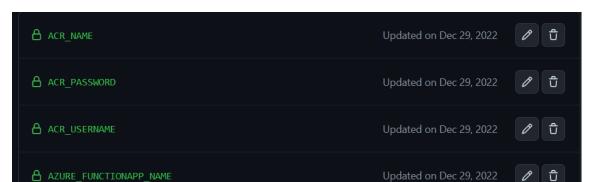
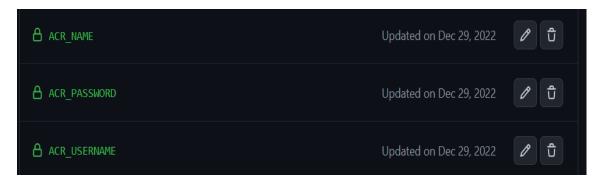


Figure 40 Container Registry GitHub Secrets for API

Figure 41 Container Registry GitHub Secrets for UI App Service



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