Digital Data Flow (DDF) Initiative

Technology Architecture Scenarios Tool

Spanning study design, information storage and downstream automation

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TransCelerate BIOPHARMA INC.

DDF Technology Architecture Scenarios Tool

Introduction, Purpose & Instructions

INTRODUCTION

The TransCelerate Digital Data Flow (DDF) initiative offers deliverables that facilitate **digitization of clinical study design components (protocol information)** to enable interoperability and reuse. The initiative has developed assets (including a Reference Architecture published as CDISC standards) for the **exchange of structured protocol information between producing and consuming systems**, supporting automation.

Digitized Protocols
Enabling the use of technologies that identify and assemble study elements using a common, industry-standard digital language allows industry to move to digital protocols

Advanced Analytics
Better enabling the use of advanced analytics such as Artificial Intelligence and Machine Learning to improve study designs

Connectivity of Data and Processes
Enabling traceability, automated flow of content to key clinical documents, and automation to clinical & operational systems (e.g.. EDC, CTMS)

Open & Flexible Solution
A functioning, example solution to enable exchange of protocol info between systems that is vendor agnostic, flexible, and provided in open source

PURPOSE

This Architecture Scenarios Tool provides examples of potential implementation patterns for the incorporation of Digital Data Flow assets and related concepts into a sponsor environment. It is meant to aid implementers in **seeing some possible options that may be relevant** to their unique digital transformation and systems landscape. It is not meant to be fully comprehensive of all possible methods of implementation. Sponsors and vendors must make their own decisions about whether and how to use DDF assets.

HOW TO USE THIS TOOL

1. **Review the various architecture scenarios** that interests you or matches to your organization's set-up or vision. NOTE: This tool is intended for a more technical audience such as Systems/Solutions architects, and IT engineers.

2. **Understand the architecture scenario details.** Sponsor companies and clinical solution providers can obtain a better understanding of the end-to-end impact for implementing DDF solutions across different technology environments.

3. It is intended to serve only as **a guide for sponsor companies and clinical solution providers** to learn about some of the options that best fit a company's context, objective and technology landscape.

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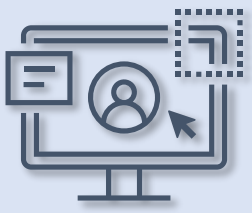
Key Concepts

The following key concepts are part of Digital Data Flow.

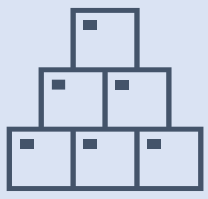
Each of the architecture scenarios described in this tool feature all or most of these concepts in different configurations.

Key Concepts relating to Design and Digitize

Design and Digitize → **Store** → **Retrieve and Execute**



Study Builder/Digitized Study Design Solution
Application or piece of software used to design a study, author a protocol, and produce digitized versions of a protocol. These "producing" systems develop reusable content that describes a study and its design, such as protocol sections or study metadata. Some may leverage AI or natural language processing.



Unified Study Definitions Model (USDM):
Industry standard for specifying and structuring study definitions (design & protocol information) in a digital, machine-readable format promulgated and maintained by CDISC. Supported by CDISC controlled terminology (codelists & values for clinical study terms). Part of CDISC's Reference Architecture for DDF.

Contributors to Study Design & Set-up:
People who contribute expertise to the design and set-up of studies. Source of information tied to key process steps or technology in study start-up, often involving "hands on keyboard." Personas may include Medical Writers, Data Managers, etc.

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Key Concepts

Key Concepts relating to Store, Retrieve and Execute

Design and Digitize → Store → Retrieve and Execute

Application Programming Interface (API) Specifications:
APIs are defined as coding language used to connect and exchange data between systems. For DDF, CDISC has developed API specs that can be implemented to facilitate the exchange of USDM-conformant data (part of CDISC Reference Architecture for DDF).

Adapters
A component that converts between a USDM conformant protocol representation and some other format or standard – either in whole or in part. Adapters facilitate the interoperability of data exchange with systems that do not themselves natively read and process USDM data, but rather some other standard, or bespoke format. Adapters can be implemented in USDM data producing systems, such as study builders, or in data consuming systems, and which approach is optimal depends on the data exchanged.

Clinical Study Documentation:
Human-readable documents which include or rely upon study design information (e.g., protocol, statistical analysis plan).

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Key Concepts

Key Concepts relating to Store, Retrieve and Execute cont'

Conformant Solutions
Systems that provide and expose a conformant implementation of the USDM API specification and all conformance rules – such a system is able to ingest and/or produce USDM conformant data, facilitating interoperability with other conformant systems. Systems can achieve conformance through internal data re-design, or through the implementation of an Adapter at the system interface.

Consuming Systems
Systems that consume digitized protocol information in order to execute a study start-up or study execution task based on the study definition (e.g. EDC, CTMS, Data Hubs).

Repositories
Systems that store information and provide it to other systems/processes which use it to perform a task (e.g. Meta Data Repository (MDR), Data Hubs). May perform a role in governing study metadata.

NOTES

- *Protocol data and content may be retrieved from upstream sources and reused in downstream **document templates**. Where automated workflow exists using CDISC-standard APIs, data may be automatically populated into existing document templates.*
- *Protocol data and content may be exchanged with various **USDM-consuming systems** (e.g. EDC, DCT, CTMS, IRT, Registries, Submission Repositories). New systems can be added at any time if they conform with CDISC's Reference Architecture for DDF (USDM, API Specs).*

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Key Concepts

Key Concepts relating to Store, Retrieve and Execute cont'

Study Definitions Repository (SDR)
A system database to store protocol information that is USDM conformant. This connects upstream and downstream systems

★ **Study Definitions Repository (SDR) Source Code**
Sample SDR implementation source code built by TransCelerate and Accenture to show the art of the possible. The source code is conformant with USDM and acts as a functioning, example approach to store protocol information and connect other producing and consuming systems to achieve interoperability. Source code is available under an open-source license via TransCelerate's DDF GitHub site which permits technical changes, deployment in other environments, and embedding components in other clinical systems.

★ **Study Definitions Repository (SDR) Reference Implementation (RI)**
Sandbox instance of a sample SDR implementation built by TransCelerate and Accenture to show the art of the possible. The SDR RI is conformant with USDM and acts as a functioning, example approach to store protocol information and connect other producing and consuming systems to achieve interoperability; however, it is a good resource for testing but has limited capability for full validated scalable production implementation.

NOTES / DISCLAIMERS

- If your organization needs an SDR, downloading and installing the TransCelerate SDR Source Code can help support implementation with minimal disruption to the existing ecosystem of components
- TransCelerate does not endorse any particular software, system, or service. 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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Scenario Summary

How to use this table

The table below provides a way to quickly navigate to the scenarios that may be relevant to a particular Sponsor based on their ecosystem. It is not meant to be fully comprehensive of all possible implementation pathways.

Columns: Based on the current and planned environment

Rows: Based on the best approach to meet USDM Conformance

		Sponsor Ecosystem Evolution					
		No Study Builder	Study Builder			End-to-End Clinical Platform	
			Without MDR	With Standalone MDR	With Integrated MDR	Without Study Builder	With Study Builder
USDM Conformance	SDR	Scenario 1	Scenario 2				
	Native Conformant MDR + Tools			Scenario 3	Scenario 5	Scenario 4	Scenario 7 (conformant)
	USDM Adapters			Scenario 6			Scenario 7 (non-conformant)

Scenario Considerations

- **Study Builder:** Environments with no Study Builder may require support to generate "source" USDM for ingest into the SDR.
- **SDR:** Implementation of a standalone SDR allows sponsors to introduce a USDM conformant data store with minimal disruption to the existing ecosystem of components.
- **SDR:** Implementation of an SDR will require a company specific configuration.
- **MDR:** An existing metadata repository (MDR) could be either be used without change in combination with a separate SDR, or alternatively it can be extended to subsume the SDR data store and API and become natively USDM conformant
- **Adapters:** Use of Adapters may accelerate integration of sub-systems via USDM conformant data transfers
- **Adapters :** When using Adapters, the lack of stored data in USDM-structure may limit the usability of protocol data for analytics insights
- **Adapters :** In general, third-party tools (Study Builders, MDRs, Platform systems) may natively support and generate USDM conformant data, or a Sponsor can use an "Adapter" to generate and transfer USDM conformant data

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Scenario #1:
Manual Study Authoring and Study Definitions Repository Implementations (Use of an SDR)

		Sponsor Ecosystem Evolution					
		No Study Builder	Study Builder			End-to-End Clinical Platform	
			Without MDR	With Standalone MDR	With Integrated MDR	Without Study Builder	With Study Builder
USDM Conformance	SDR	Scenario 1					
	Native Conformant MDR + Tools						
	USDM Adapters						

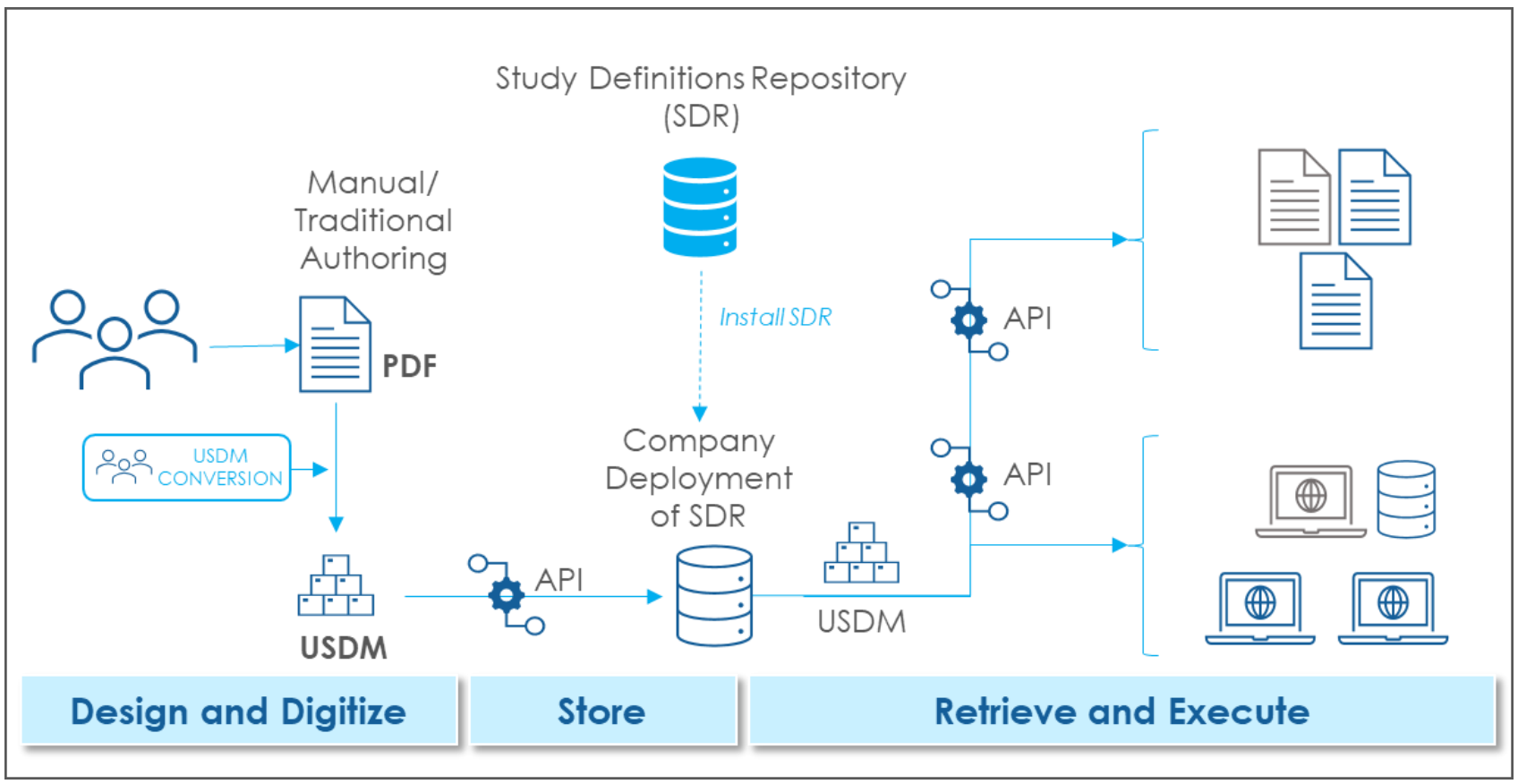
In this scenario, distinct USDM-conformant solutions are used:

- a **Study Definitions Repository (SDR)**
- and several downstream **Consuming Systems**.

Specifically, the **protocol is authored manually, and there is no Study Builder tool**.

Deploy an SDR, either the **SDR Source Code or an alternative SDR,** in a production environment by a pharma sponsor or SaaS provider. Leveraging the existing SDR Source Code could accelerate the set-up process.

There is a required step to convert the protocol into the USDM JSON format, either manually or using some conversion tool such as Excel. This then enables automated, digital data flow between upstream **protocol authoring** and downstream **Consuming Systems** and **Clinical Study Document Templates.**



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Scenario #2:
Distinct Study Builder and Study Definitions Repository Implementations (Use of an SDR)

		Sponsor Ecosystem Evolution					
		No Study Builder	Study Builder			End-to-End Clinical Platform	
			Without MDR	With Standalone MDR	With Integrated MDR	Without Study Builder	With Study Builder
USDM Conformance	SDR		Scenario 2				
	Native Conformant MDR + Tools						
	USDM Adapters						

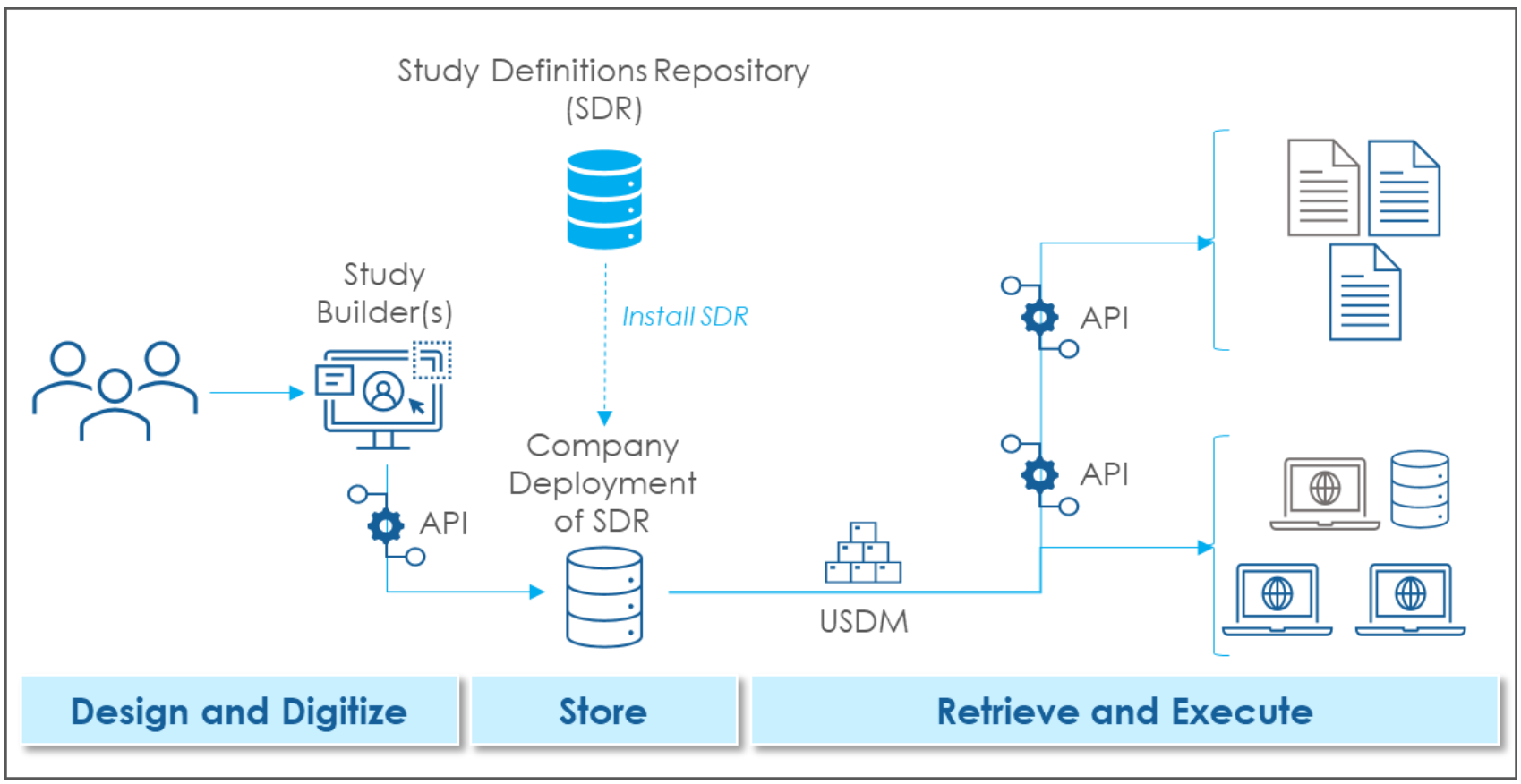
In this scenario, distinct USDM-conformant solutions are used:

- a **Study Builder(s)**,
- a **Study Definitions Repository (SDR)**,
- and several downstream **Consuming Systems.**

Deploy an SDR, either the **SDR Source Code or an alternative SDR,** in a production environment by a pharma sponsor or SaaS provider. Leveraging the existing SDR Source Code could accelerate the IT set-up process.

The **Study Builder** generates USDM conformant output and deposits this to the SDR using the SDR API.

This enables automated, digital data flow between the upstream **Study Builder** solution and downstream **Consuming Systems** and **Clinical Study Document Templates**.



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Scenario #3:
Distinct Study Builder and Study Metadata Repository (No Use of an SDR)

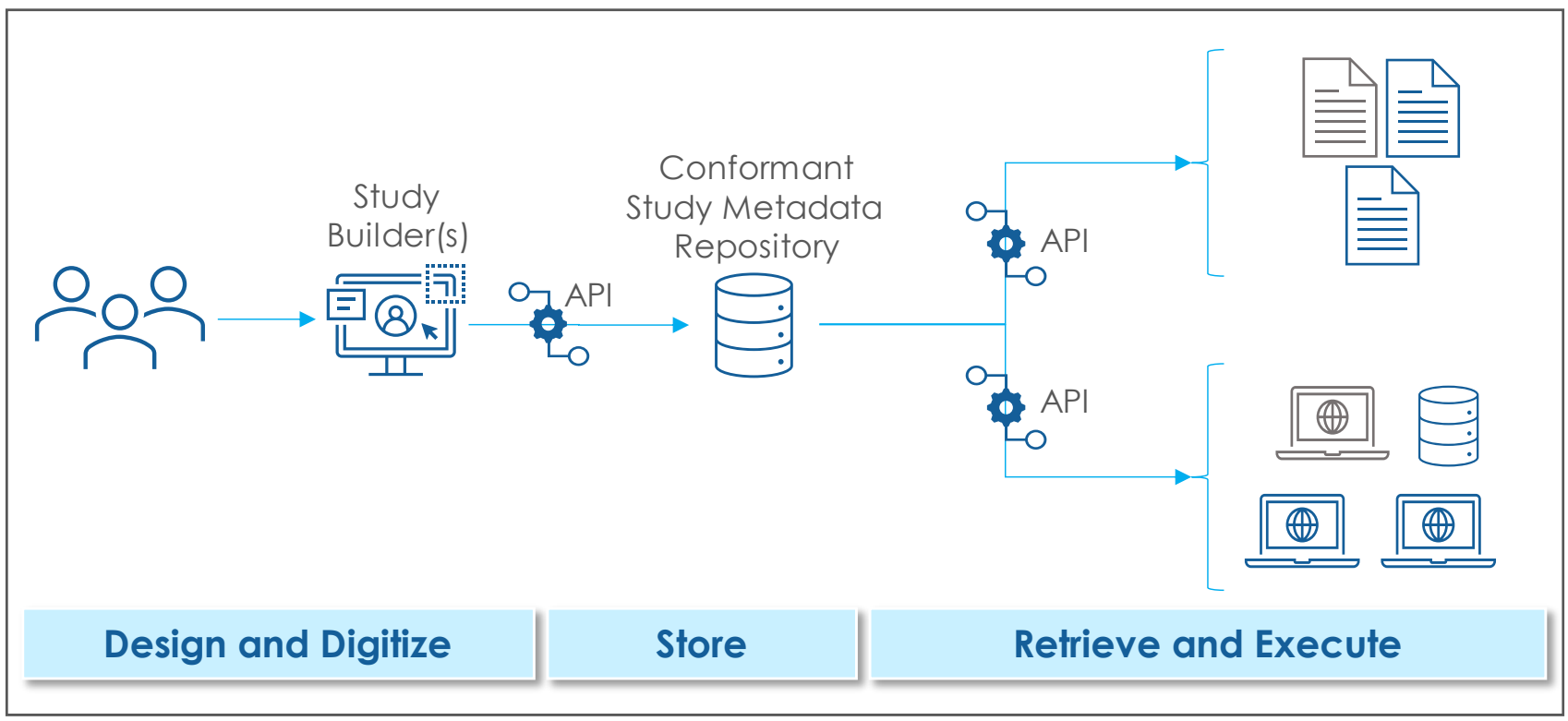
		Sponsor Ecosystem Evolution					
		No Study Builder	Study Builder			End-to-End Clinical Platform	
			Without MDR	With Standalone MDR	With Integrated MDR	Without Study Builder	With Study Builder
USDM Conformance	SDR						
	Native Conformant MDR + Tools			Scenario 3			
	USDM Adapters						

In this scenario, distinct USDM-conformant solutions are used:

- a **Study Builder(s)**,
- a **Study Metadata Repository (MDR)**,
- and several downstream **Consuming Systems.**

A sponsor company or software partner builds or provides a metadata repository (custom or off the shelf) that may function in many of the same ways as an SDR and is made to be conformant with USDM.

This enables automated, digital data flow between the upstream **Study Builder** solution and downstream **Consuming Systems** and **Clinical Study Document Templates**.



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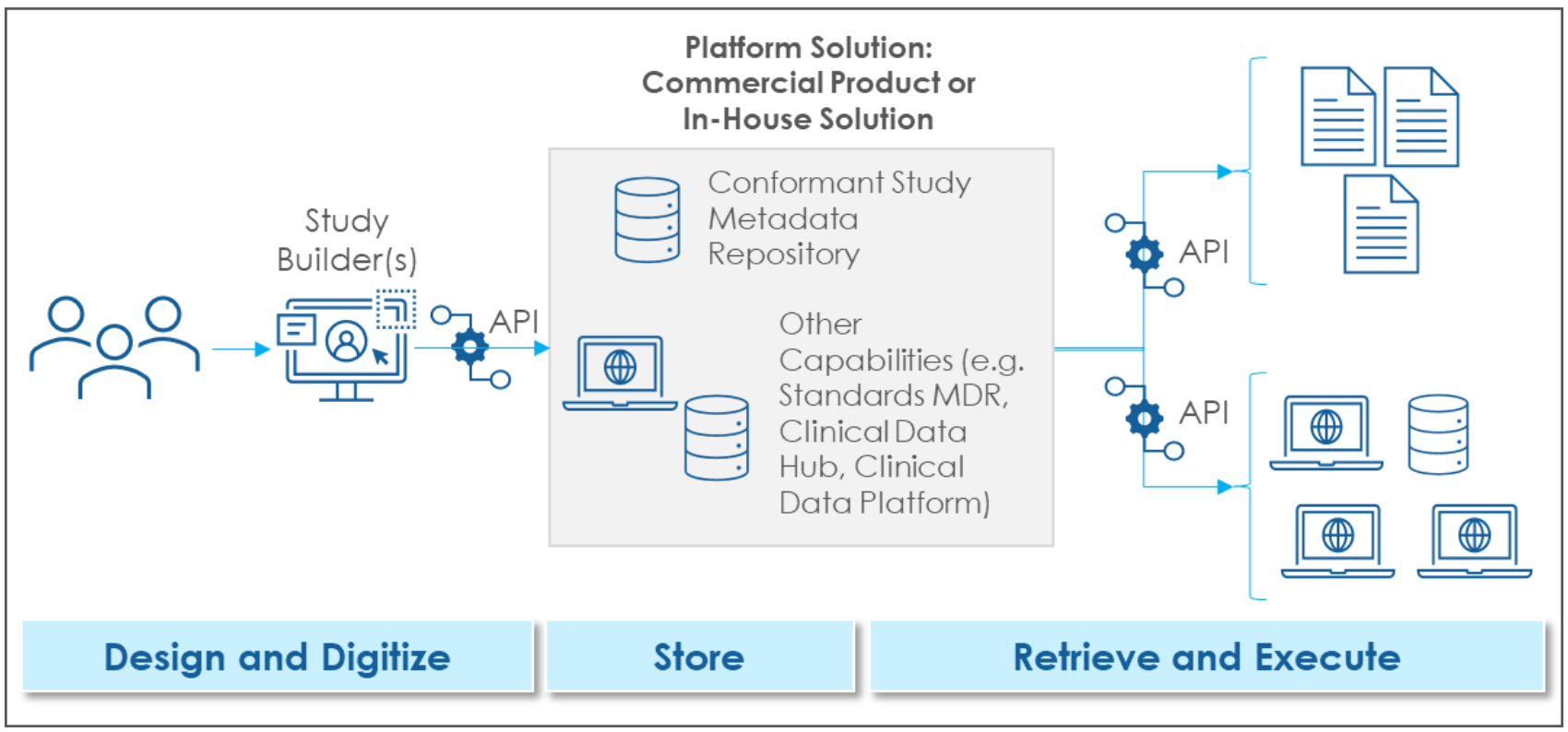
Scenario #4:
Distinct Study Builder and Platform Solution with Study Metadata Repository

		Sponsor Ecosystem Evolution					
		No Study Builder	Study Builder			End-to-End Clinical Platform	
			Without MDR	With Standalone MDR	With Integrated MDR	Without Study Builder	With Study Builder
USDM Conformance	SDR						
	Native Conformant MDR + Tools					Scenario 4	
	USDM Adapters						

In this scenario, distinct USDM-conformant solutions are used:

- a distinct **Study Builder(s)** separate from the end-to-end clinical platform,
- a customized or off the shelf product acting as a Platform Solution which includes a **Study Metadata Repository (MDR),** and several downstream **Consuming Systems.**

Because the solutions are all conformant with USDM, this enables automated, digital data flow between the upstream **Study Builder** solution, the Platform Solution, and downstream **Consuming Systems** and **Clinical Study Document Templates**.



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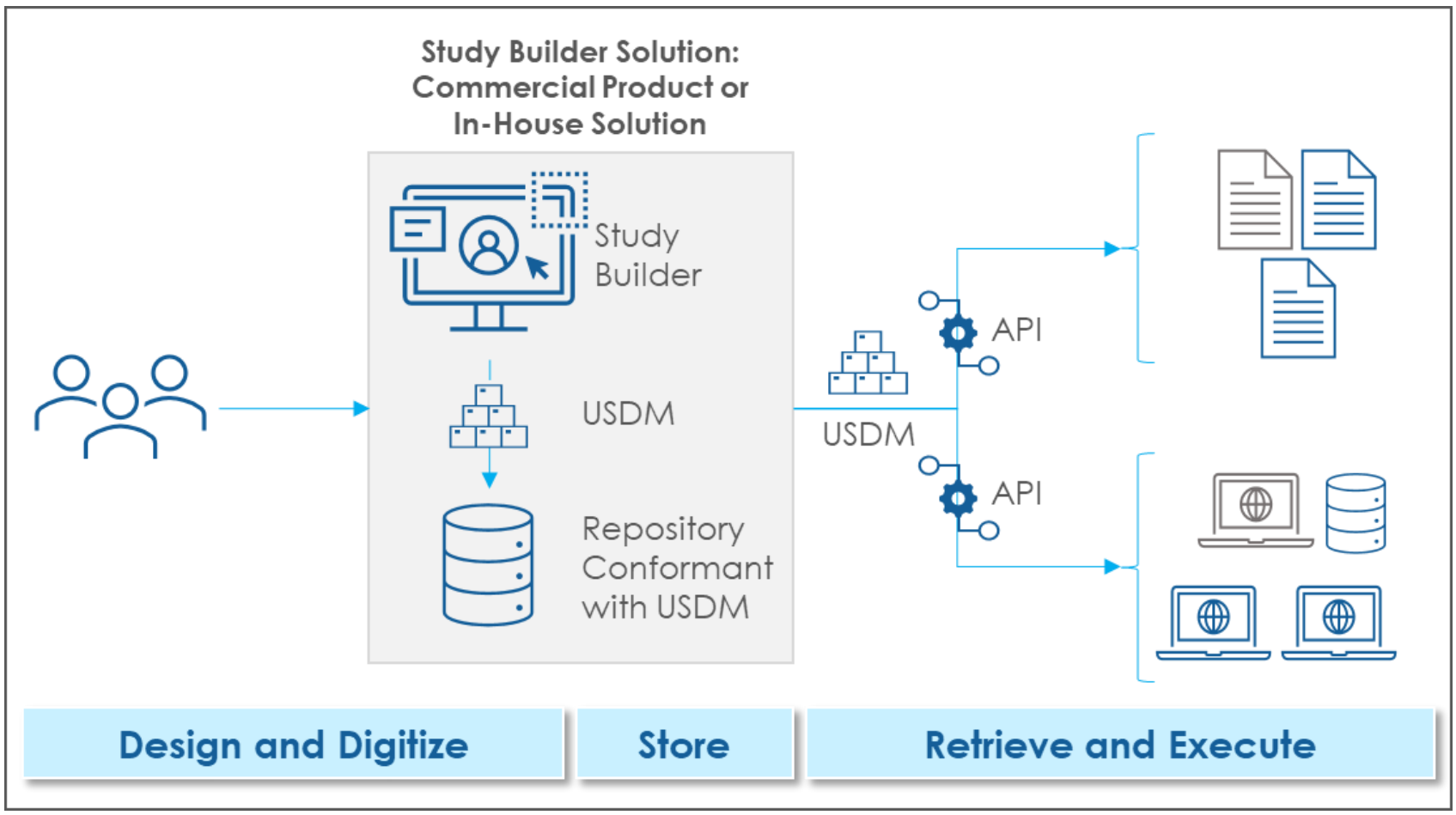
Scenario #5:
Combined Study Builder with USDM-Conformant Repository

		Sponsor Ecosystem Evolution					
		No Study Builder	Study Builder			End-to-End Clinical Platform	
			Without MDR	With Standalone MDR	With Integrated MDR	Without Study Builder	With Study Builder
USDM Conformance	SDR						
	Native Conformant MDR + Tools				Scenario 5		
	USDM Adapters						

In this scenario, a distinct **Study Builder Solution** incorporates, as part of its functionality, a **Repository** that stores study metadata / protocol information.

The overall solution (within the grey box) is conformant with **USDM** and the DDF Reference Architecture maintained by CDISC.

This enables automated, digital data flow to downstream **Consuming Systems** and **Clinical Study Document Templates** directly from the solution.



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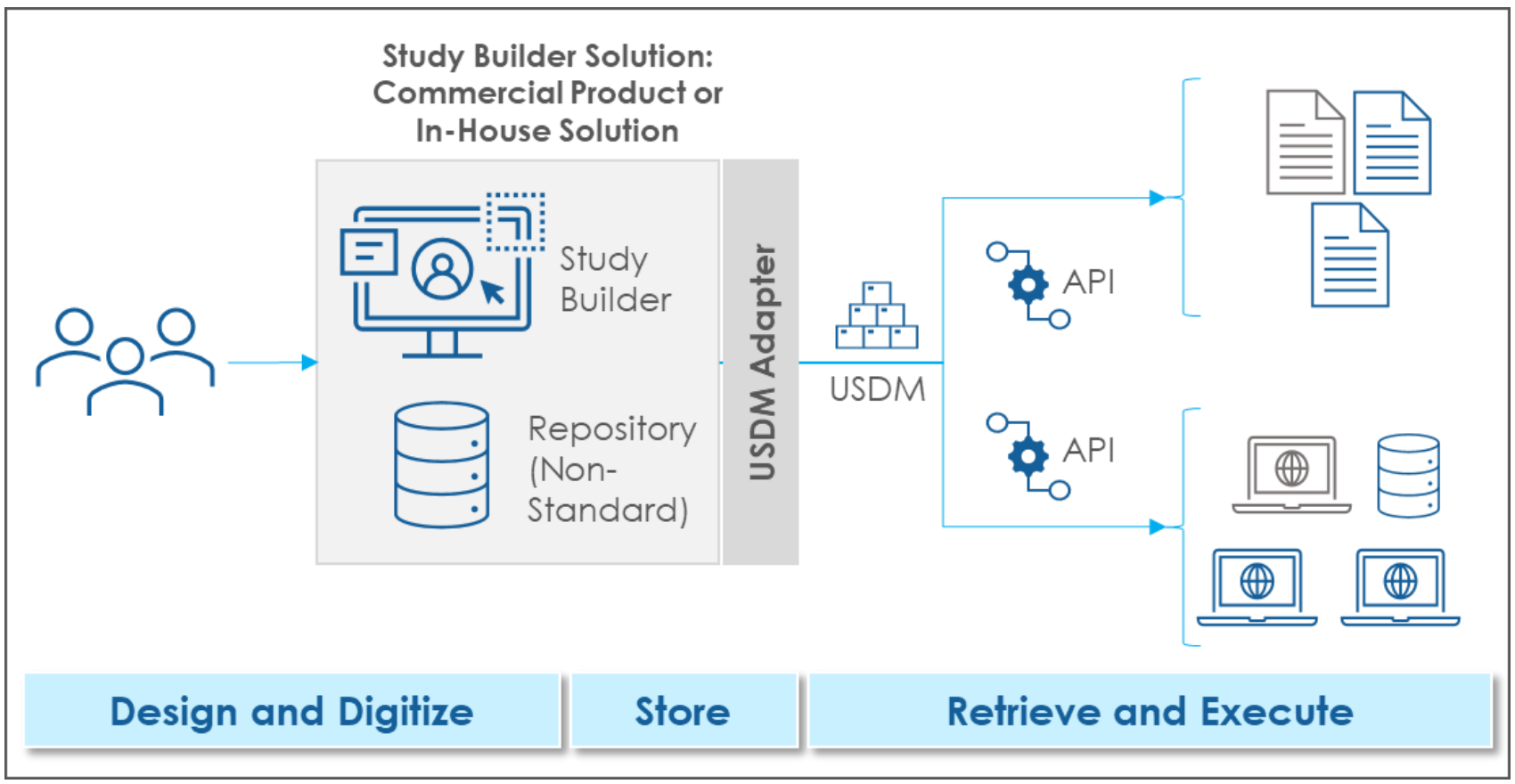
Scenario #6:
Study Builder Providing USDM-Conformant Output

USDM Conformance	Sponsor Ecosystem Evolution					
	No Study Builder	Study Builder			End-to-End Clinical Platform	
		Without MDR	With Standalone MDR	With Integrated MDR	Without Study Builder	With Study Builder
SDR						
Native Conformant MDR + Tools						
USDM Adapters			Scenario 6			

In this scenario, a distinct **Study Builder Solution** incorporates, as part of its functionality, a **Repository** that stores study metadata / protocol information.

The existing solution is <u>not</u> conformant with **USDM**; however, the solution provider develops a bolt-on adapter to convert data in the non-standard metadata model to a USDM-conformant format which allows the sponsor to continue to use their exiting systems without the need to implement full scale USDM conformance.

This enables automated, digital data flow to downstream **Consuming Systems** and **Clinical Study Document Templates** directly from the solution.



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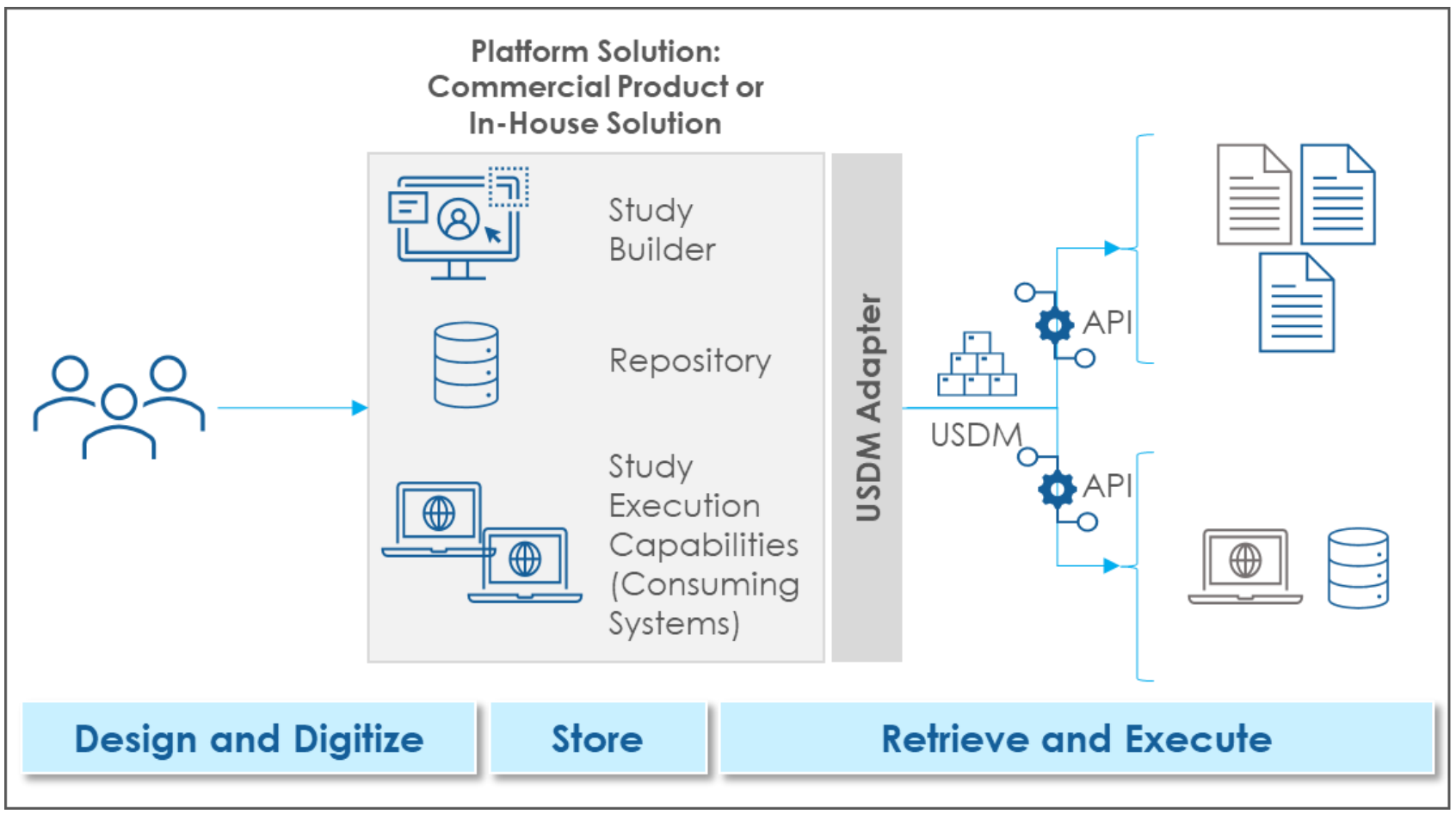
Scenario #7:
Platform Solution with Multiple Capabilities Spanning Study Builder, Repository & Study Execution

		Sponsor Ecosystem Evolution					
		No Study Builder	Study Builder			End-to-End Clinical Platform	
			Without MDR	With Standalone MDR	With Integrated MDR	Without Study Builder	With Study Builder
USDM Conformance	SDR						
	Native Conformant MDR + Tools						Scenario 7
	USDM Adapters						Scenario 7

In this scenario a comprehensive Platform Solution incorporates, as part of its functionality, a **Study Builder**, a **Repository,** and one or more Study Execution capabilities (**Consuming Systems**) that may traditionally exist as distinct/standalone systems.

This Platform Solution *may or may not be natively conformant with USDM*, which may necessitate an adapter to provide study design / protocol outputs in USDM format.

This enables automated, digital data flow to other downstream **Consuming Systems** (not part of the Platform Solution) and **Clinical Study Document Templates** directly from the solution.



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Additional Resources

To learn more about the DDF Initiative, visit the following websites

"Documents to Data: Write Once, Read Many Times"

TransCelerate DDF Initiative Website
https://www.transceleratebiopharmainc.com/assets/digital-data-flow-solutions/

Explore TransCelerate's Study Definitions Repository (SDR)

DDF Website *Hosted on GitHub*
https://transcelerate.github.io/ddf-home/

Explore CDISC's Unified Study Definitions Model (USDM)

CDISC & Digital Data Flow
https://www.cdisc.org/ddf