

1. "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."
2. "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."



## Sponsor Ecosystem Evolution

		No Study Builder	Study Builder			End-to-End Clinical Platform	
			No MDR	Standalone MDR	Integrated MDR	No Study Builder	Study Builder
USDM Conformance	SDR	<b>Scenario 1</b> 	<b>Scenario 2</b> 				
	Native conformant MDR + Tools			<b>Scenario 3</b> 	<b>Scenario 5</b> 	<b>Scenario 4</b> 	<b>Scenario 7</b> 
	USDM Adapters			<b>Scenario 6</b> 			

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

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

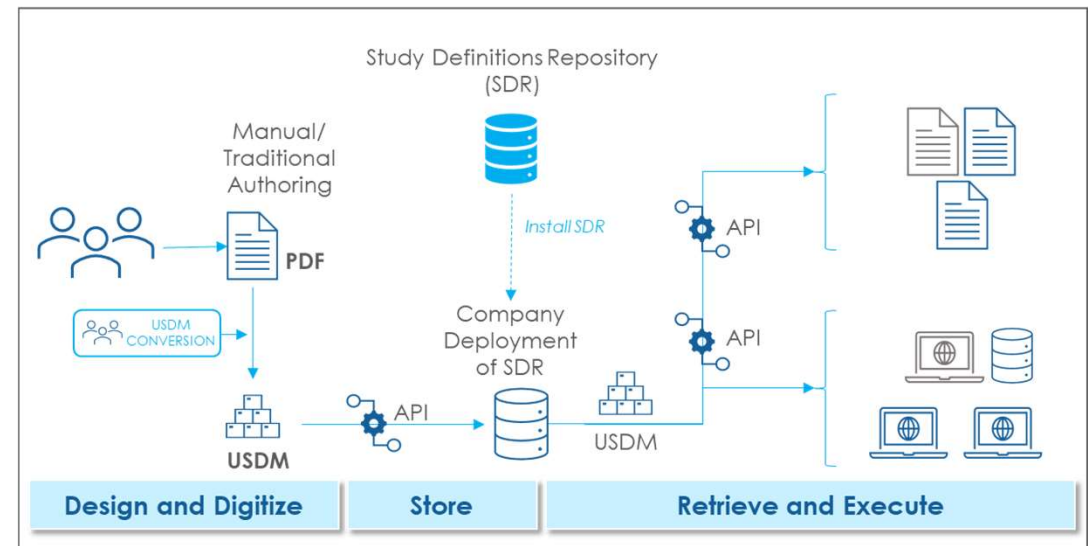
- a **Study Definitions Repository (SDR)**
- and several downstream **Consuming Systems**.

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**.

		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						



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

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

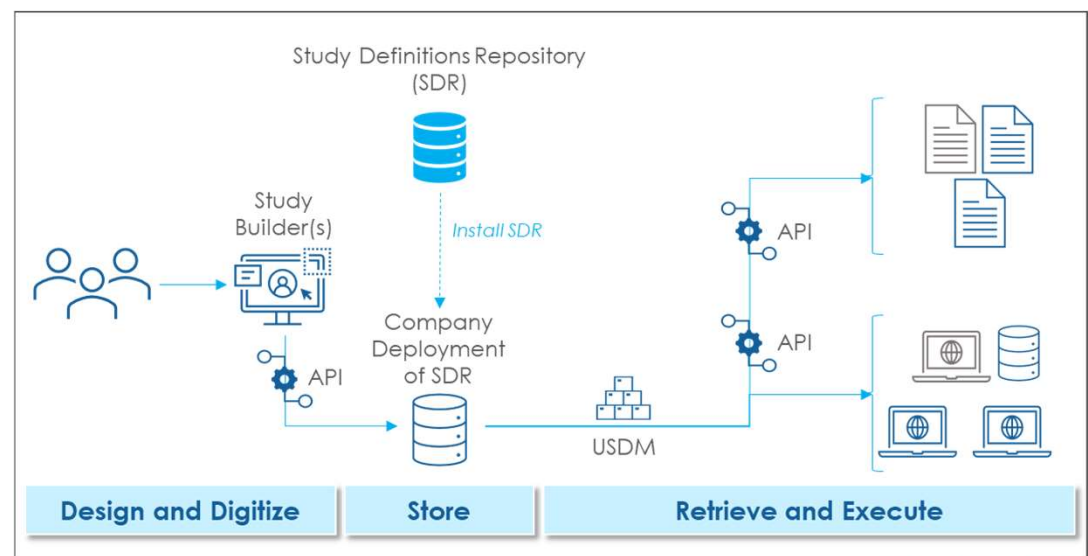
- a **Study Builder(s)**,
- a **Study Definitions Repository (SDR)**,
- and several downstream **Consuming Systems**.

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**.

		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						



**Scenario #3:** Distinct Study Builder and Study Definitions Repository Implementations (Use of an SDR)

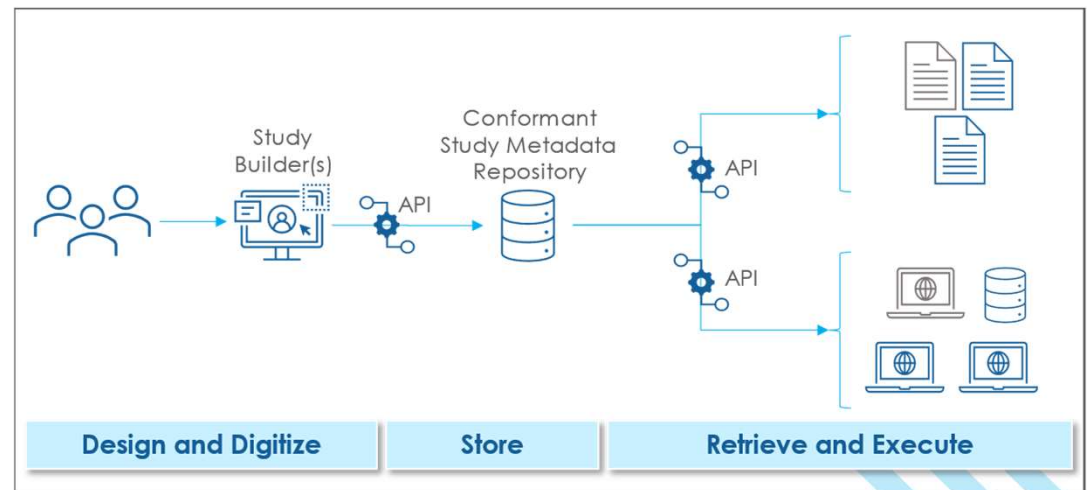
In this scenario, distinct USDM-conformant solutions are used:

- 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**.

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



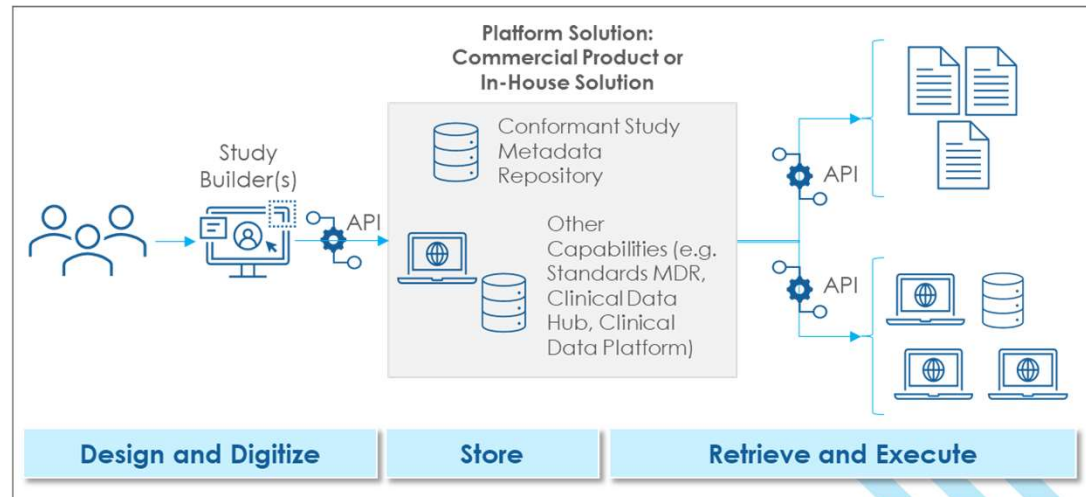
## Scenario #4: Distinct Study Builder and Platform Solution with Study Metadata Repository

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**.

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



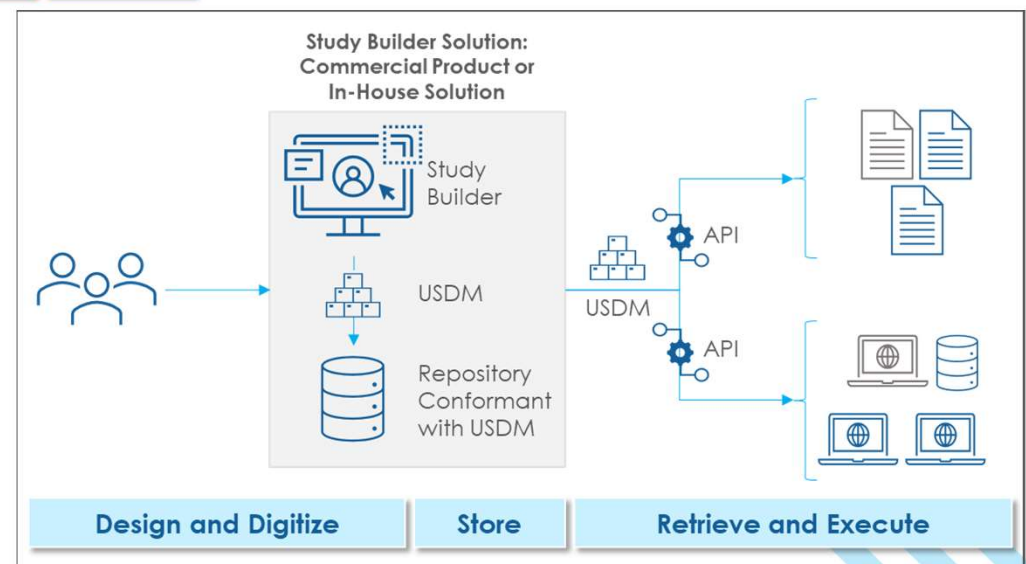
Scenario #5: Combined Study Builder with USDM-Conformant Repository

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.

		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						



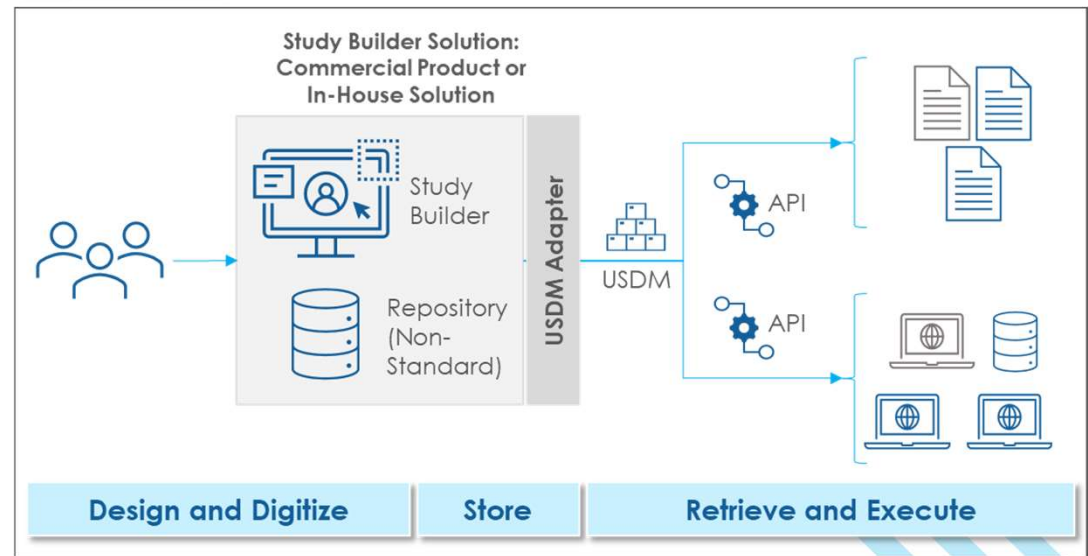
Scenario #6: Study Builder Providing USDM-Conformant Output

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 not 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.

		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						
	USDM Adapters			Scenario 6			





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

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.

		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

