

# SCDM India Industry Symposium

Medidata Designer





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# Why Are Study Build Timelines So Challenging to Compress?

## Protocol Complexity

Translating clinical protocols into operational elements (e.g., CRFs, visit schedules) involves interpreting complex requirements.

## Manual Processes

Manual CRF and edit check creation can be labor-intensive and resource-constrained

## Collaboration Bottlenecks

Strong cross-functional dependencies among data managers, clinical teams, programmers and review cycles could slow down the process.

## Validation & Testing

CRFs, edit checks and workflows must undergo multiple rounds of validation & testing





# Medidata Designer

A centralized study build and configuration tool with a streamlined and intuitive interface that allows users to create, review, update, and maintain all study build components across studies and teams. It does this with complete traceability, delivering higher quality results significantly faster.



A circular graphic with a blue center containing the text 'Medidata Designer'. A hand is pointing at the text. The center is surrounded by a ring of green and yellow dots, and a larger ring of blue dots with lines extending outwards.

# Medidata Designer

Decrease overall study build timelines & improve study build **quality**

Incorporates protocol requirements and organizational standards

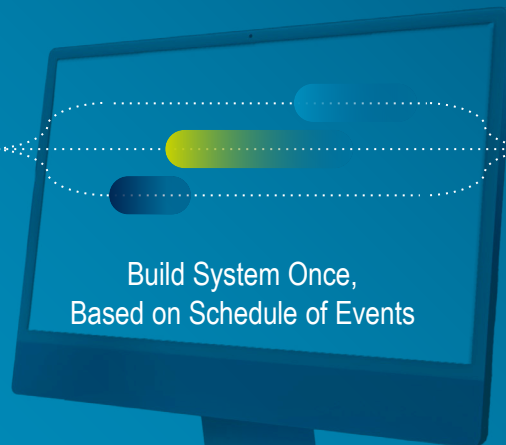
Promotes standards and usage of standards

Tool that serves for a new user along with a seasoned study builder

# Build Your Study Once and Deploy Across All Systems



Study Protocol



Build System Once,  
Based on Schedule of Events



Protocol Dataset  
Defined

Automated Standard Datasets

Visualizations, Reports, Analysis

Other Outputs

Medidata Platform

☒ EDC

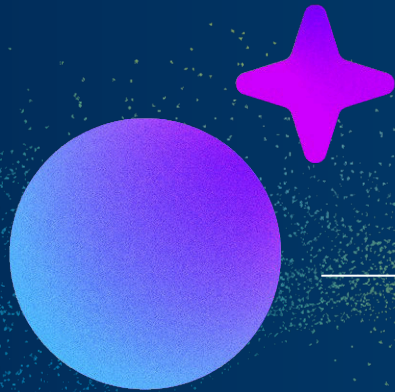
☐ RTSM

☒ eCOA

☐ Imaging

☒ Sensors

☐ Other Systems



# Meet Dot

Medidata's intelligent virtual companion that enhances everyday experiences by automating routine tasks, delivering actionable insights, and helping users navigate complex workflows with speed, precision, and control.

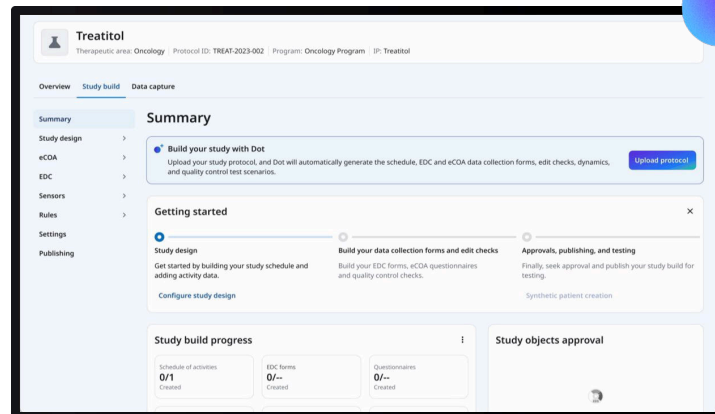
# AI Driven Study Build

Reduce manual workflows and dramatically reduce study build efforts

DATA EXPERIENCE

Auto-generate the SoA for EDC and eCOA

Designer: Upload Protocol



**75%** FASTER STUDY  
BUILD WITH AI<sup>1</sup>



# AI Driven Study Build

Reduce manual workflows and dramatically reduce study build efforts

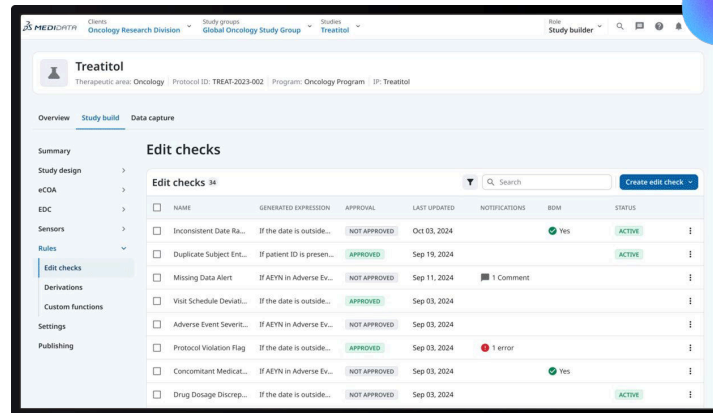
DATA EXPERIENCE

Auto-generate the SoA for EDC and eCOA

Automatically generate edit check requirements, create edit checks, and create test cases

**75%** FASTER STUDY BUILD WITH AI

Designer: Edit Checks & UAT



NAME	GENERATED EXPRESSION	APPROVAL	LAST UPDATED	NOTIFICATIONS	BOM	STATUS
Inconsistent Date Ra...	If the date is outside...	NOT APPROVED	Oct 03, 2024	Yes		ACTIVE
Duplicate Subject Ent...	If patient ID is presen...	APPROVED	Sep 19, 2024			ACTIVE
Missing Data Alert	If AEYN in Adverse Ev...	NOT APPROVED	Sep 11, 2024	1 Comment		
Visit Schedule Deviati...	If the date is outside...	APPROVED	Sep 03, 2024			
Adverse Event Severe...	If AEYN in Adverse Ev...	NOT APPROVED	Sep 03, 2024			
Protocol Violation Flag	If the date is outside...	APPROVED	Sep 03, 2024	1 error		
Concomitant Medicat...	If AEYN in Adverse Ev...	NOT APPROVED	Sep 03, 2024	Yes		
Drug Dosage Discrep...	If the date is outside...	NOT APPROVED	Sep 03, 2024			ACTIVE

# AI Driven Study Build

Reduce manual workflows and dramatically reduce study build efforts

DATA EXPERIENCE

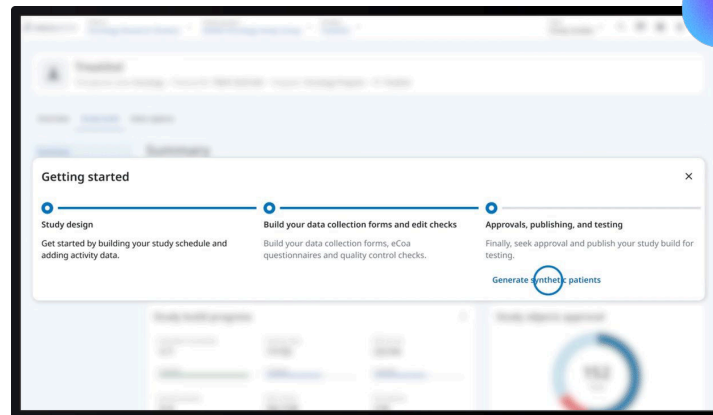


Auto-generate the SoA for EDC and eCOA

Automatically generate edit check requirements, create edit checks, and run test cases

Rapidly create synthetic test data for test case execution

Designer: Synthetic Test Data



**75%** FASTER STUDY  
BUILD WITH AI

● Load Protocol

● Create Schedule of Activities

● Create Forms

● Generate Edit Check Requirements

● Generate Edit Checks

● Generate test cases for edit checks

● Generate test data for the edit checks



AI Driven Study Build



# Load protocol





# Create Schedule of Activities





# Create Forms





# Generate Edit Check Requirements





# Generate Edit Checks





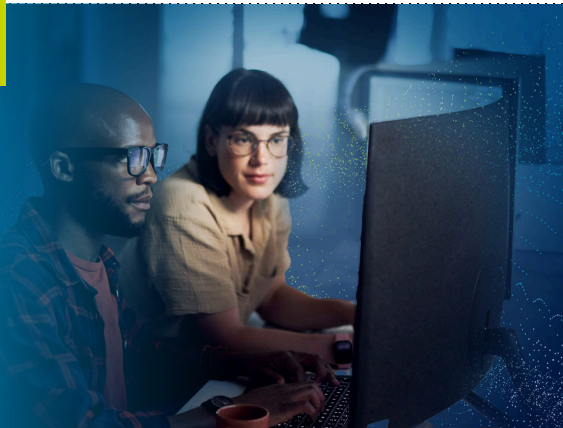


# Generate Test Cases for Edit Checks






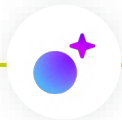




# Generate Test Data for Edit Checks



# AI-Assisted EDC Edit Checks in Designer

## Faster Study Build Process, Flexible Workflow

	Data Manager	Study Builder	AI
 <b>Define User Requirement</b> <ul style="list-style-type: none"><li>• Layman's terms description of what a data validation must do</li><li>• Understanding of data to be collected and protocol</li></ul>	 ✓	 ✓	 ✓
 <b>Configure Data Validation</b> <ul style="list-style-type: none"><li>• Build from requirements</li><li>• Select from Global Library</li></ul>		✓	✓
 <b>Approve / Test Data Validation</b> <ul style="list-style-type: none"><li>• Ensure requirement is met</li><li>• Rules run regardless of source to ensure consistency</li></ul>	✓	✓	✓

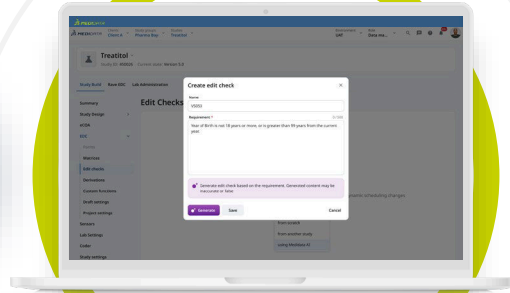
# Designer AI Edit Check Build Allows Flexible Process

**100%  
Manual**

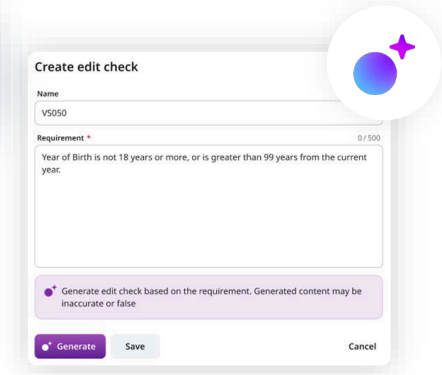
**The journey...**

As users learn and as  
AI learns, users will be able  
to use more AI-assisted  
automation.

50/50



**100%  
Automated**



**Study Build Process**

# Study Build Process Adding AI Overtime

Year 1

20 Forms Require Approval

200 Edit Checks Require Approval

Year 2

10 Forms Require Approval

100 Edit Checks Require Approval

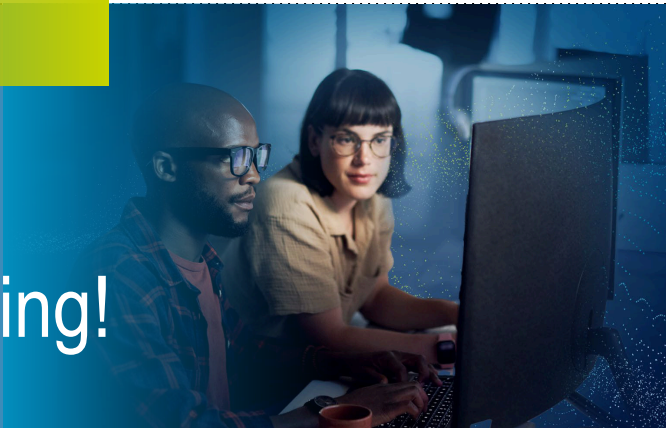
Year 3

5 Forms Require Approval

50 Edit Checks Require Approval



Questions?  
Thank you for joining!



For more demos visit the Medidata Booth