



# SCDM India Industry Symposium

Medidata Designer

A hand is pointing at a digital tablet screen. The screen displays a 'Schedule of activities' interface. At the top, it says 'NOT APPROVED' and 'Study structure'. Below that is a table with columns: ACTIVITIES, PATIENT, SCREENING, VISIT 1, VISIT 2, VISIT 3, AE/CM, and END OF STUDY. The 'PATIENT' column has a value of '1000000000000000000'. The 'VISIT 1' column has a value of '7'. The 'VISIT 2' column has a value of '14'. The 'VISIT 3' column has a value of '21'. The 'AE/CM' column is empty. The 'END OF STUDY' column has a value of '28'. Below this table is a large grid with 'ACTIVITIES' on the left and 'VISIT 1' through 'VISIT 3' across the top. Each cell in the grid contains a checkmark ('✓').

ACTIVITIES	PATIENT	SCREENING	VISIT 1	VISIT 2	VISIT 3	AE/CM	END OF STUDY
	1000000000000000000		7	14	21		28



## Wayne Walker

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SVP Data Experience



## George Pateman

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Solution Consultant

# 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.

## Collaboration Bottlenecks

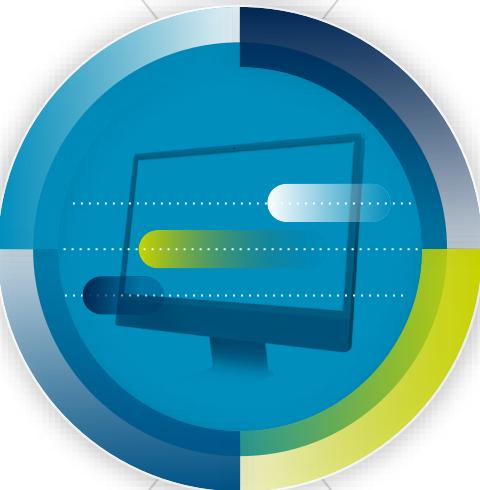
Strong cross-functional dependencies among data managers, clinical teams, programmers and review cycles could slow down the process.

## Manual Processes

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

## Validation & Testing

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

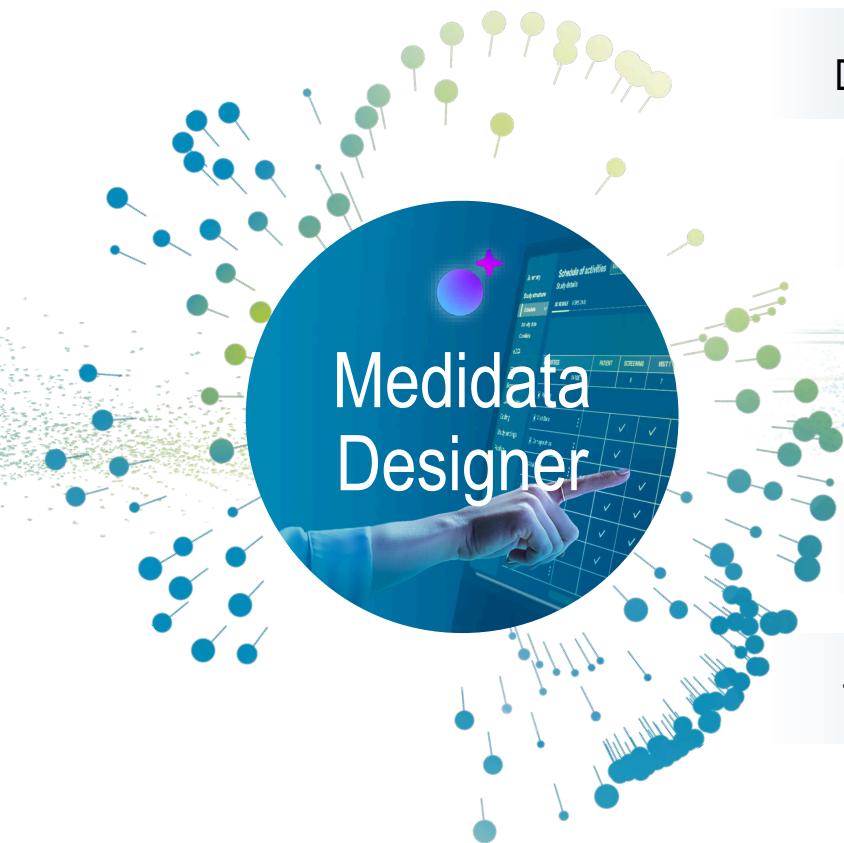




# Medidata Designer

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.





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

Incorporates protocol requirements and organizational standards

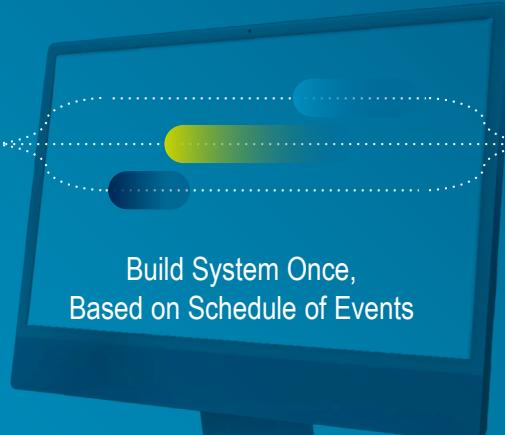
Promotes standards and usage of standards

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

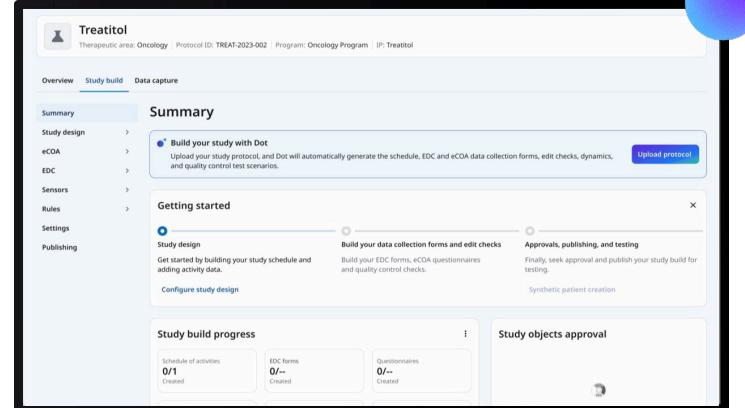
Reduce manual workflows and dramatically reduce study build efforts

Auto-generate the SoA for EDC and eCOA

DATA EXPERIENCE

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

Designer: Upload Protocol



The screenshot shows the Dot software interface for study build. The top navigation bar displays the study name 'Treatitol', therapeutic area 'Oncology', protocol ID 'TREAT-2023-002', program 'Oncology Program', and study ID 'IP-Treatitol'. The main menu includes 'Overview', 'Study build' (which is selected), and 'Data capture'. The 'Study build' tab is divided into sections: 'Summary', 'Getting started', 'Study build progress', and 'Study objects approval'. The 'Summary' section contains a callout bubble with the text 'Build your study with Dot' and 'Upload your study protocol. Dot will automatically generate the schedule, EDC and eCOA data collection forms, edit checks, dynamics, and quality control test scenarios.' A blue button labeled 'Upload protocol' is visible. The 'Getting started' section includes a 'Study design' step with sub-tasks 'Get started by building your study schedule and adding activity data.' and 'Configure study design'. It also lists 'Build your data collection forms and edit checks', 'Approvals, publishing, and testing', and 'Synthetic patient creation'. The 'Study build progress' section shows 'Schedule of activities 0/1 Created', 'EDC forms 0/-- Created', and 'Questionnaires 0/-- Created'. The 'Study objects approval' section is currently empty.

# AI Driven Study Build

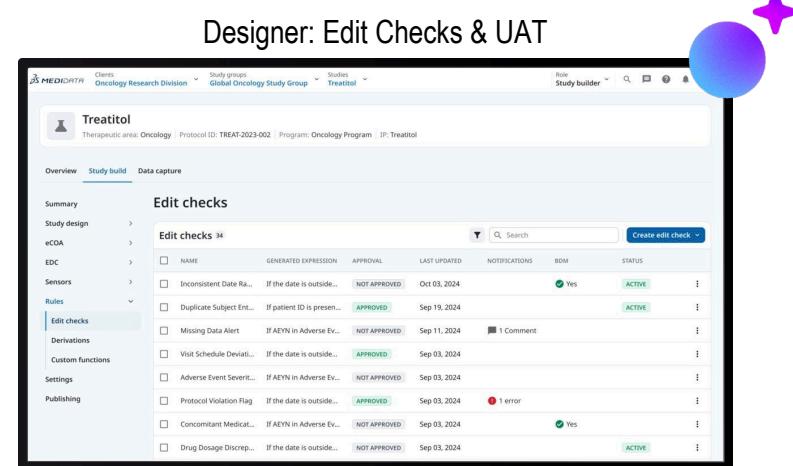
Reduce manual workflows and dramatically reduce study build efforts

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

DATA EXPERIENCE



Designer: Edit Checks & UAT

NAME	GENERATED EXPRESSION	APPROVAL	LAST UPDATED	NOTIFICATIONS	BDM	STATUS
Inconsistent Date Range	If the date is outside...	NOT APPROVED	Oct 03, 2024	Yes	ACTIVE	
Duplicate Subject Entry	If patient ID is present...	APPROVED	Sep 19, 2024		ACTIVE	
Missing Data Alert	If AEYN in Adverse Ev...	NOT APPROVED	Sep 11, 2024	1 Comment		
Visit Schedule Deviations	If the date is outside...	APPROVED	Sep 03, 2024			
Adverse Event Severity	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 Medications	If AEYN in Adverse Ev...	NOT APPROVED	Sep 03, 2024	Yes		
Drug Dosage Discrepancy	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

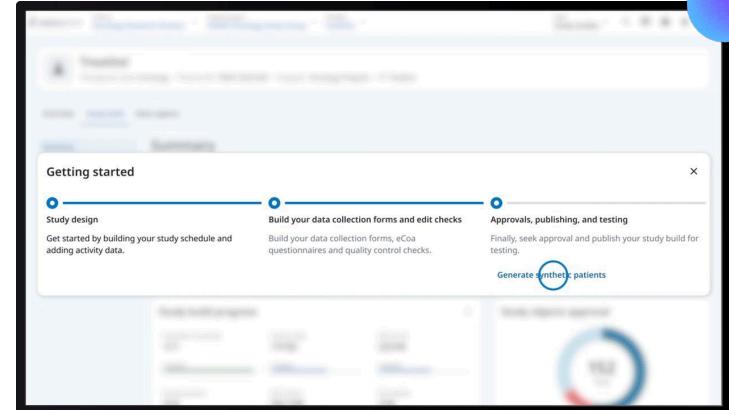
Auto-generate the SoA for EDC and eCOA

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

Rapidly create synthetic test data for test case execution

**75%** FASTER STUDY  
BUILD WITH AI

Designer: Synthetic Test Data



● Load Protocol

- Create Schedule of Activities
- Create Forms
- Generate Edit Check Requirements
- Generate Edit Checks
- Generate t



## 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



### Define User Requirement

- Layman's terms description of what a data validation must do
- Understanding of data to be collected and protocol

Data Manager



Study Builder



AI



### Configure Data Validation

- Build from requirements
- Select from Global Library



### Approve / Test Data Validation

- Ensure requirement is met
- Rules run regardless of source to ensure consistency



# Designer AI Edit Check Build Allows Flexible Process

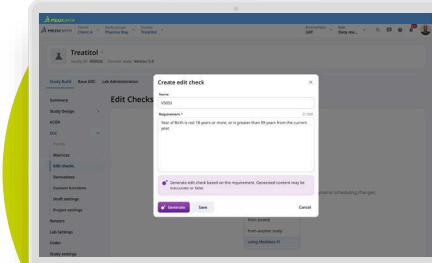
**100%**  
**Manual**

**The journey...**

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



50/50



**100%**  
**Automated**

Create edit check

Name

V5050

Requirement \*

Year of Birth is not 18 years or more, or is greater than 99 years from the current year.

Generate edit check based on the requirement. Generated content may be inaccurate or false.

Generate

Save

Cancel



## Study Build Process

# Study Build Process Adding AI Overtime

Year 1

20 Forms 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