

Innovation Theater

Beyond Dashboards – The Future of AI-Native Clinical Trial Oversight

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From Reactive to Proactive Oversight



Traditional Model

- ✓ **Reactive remediation:** Fixing issues after they occur
- ✓ Manual oversight relying on brute force
- ✓ Siloed data leading to delayed insights
- ✓ Static risk thresholds



AI-Driven Model

- ✓ **Proactive prevention:** Predicting risks before escalation
- ✓ Automated, real-time analytics
- ✓ Integrated data ecosystem
- ✓ Dynamic, continuous risk scoring

Advance Data Cleaning & Automated Queries



Live Data Validation:

Sidekick identifies range inconsistencies and cross-form discrepancies across EDC (Medidata, Mednet, Veeva, Oracle, etc.), Lab, and ePRO



One-Click Query Drafting:

Sidekick drafts queries in GxP-compliant language for user approval



Explainable Traceability:

Every flag is traceable to the raw data row

Data Summaries & Trends

SDC Insights™
Clinical Intelligence Platform

Insights | Workspace | AI Studio | System

QD Were there any adverse events that definitely or probably related to study drug? If so, were any considered serious? If yes, please provide AE details per patient with demographics information

There were adverse events reported that were definitely or probably related to the study drug. Among these, some were considered serious.

Key findings include:

- Serious events definitely related to the study drug include "Infusion Related Reaction" in a 71-year-old male patient at University of Florida (UF Health).
- Serious events probably related include "Febrile Neutropenia" also in the same 71-year-old male patient at University of Florida (UF Health).
- Another serious event probably related is "Cytokine Release Syndrome" reported in a 76-year-old male at Rush.
- A 63-year-old male at Baylor University Medical Center reported serious events probably related including "Fever".
- Serious infusion-related reactions also occurred in an 86-year-old female patient at Rhode Island Hospital/Lifespan.

Request SDC to validate events per patient along with basic demographics (age, sex, ethnicity, site) are available for further review if needed.

QD Provide the above in a tabular format

There are adverse events definitely or probably related to the study drug, with some classified as serious. Below is the tabular summary combining adverse event details per patient with demographics:

Patient Identifier	Age	Sex	Ethnicity	Site	Adverse Event Term	Relatedness	Seriousness
11-20-077	71	Male	Not Hispanic or Latino	University of Florida (UF Health)	INFUSION RELATED REACTION	Definitely Related	Serious
11-09-039	63	Female	Not Hispanic or Latino	Blood and Marrow Transplant Group of Georgia - Northside	HYPOTENSION	Definitely Related	Non-Serious
11-10-009	73	Female	Not Hispanic or Latino	University of Iowa	CYTOKINE RELEASE SYNDROME	Definitely Related	Non-Serious
11-10-009	73	Female	Not Hispanic or Latino	University of Iowa	FEVER WITH CHILLS	Definitely Related	Non-Serious

Reply to Sidekick

Data updated on Jan 29, 2026.

Advanced AI Studio and Model Monitoring

The screenshot displays the SDC Insights AI Studio interface. The top navigation bar includes 'Insights', 'Workspace', 'AI Studio', and 'System'. The main content is divided into a left sidebar and a right main panel.

Left Sidebar (Query List):

- 2b1f8b86668b-live (Success): are there more inactive investigator users or research coordinator users? (09/12/2025, 10:00 AM, 17.34s)
- 347545fb6a80-live (Success): Why are subjects screen failing? (09/11/2025, 12:43 PM, 5.28s)
- 347545fb6a80-live (Success): recent login date for Jen Ohme (09/11/2025, 10:59 AM, 20.49s)
- 347545fb6a80-live (Success): last login date for Quan Doan (09/11/2025, 10:59 AM, 12.30s)
- 347545fb6a80-live (Success): when did Quan Doan last log in to Study database (09/11/2025, 10:59 AM, 3.38s)
- 347545fb6a80-live (Success): Are there any diversity gaps in our patient enrollment (09/08/2025, 01:11 PM, 8.82s)
- 2b1f8b86668b-live (Success): Provide a list of the top 5 AEs related to IP

Right Main Panel (Tracing View):

Tracing > 02c95a4bd11b (Success Sep 11, 2025, 12:43 PM)

Interaction & Feedback | Technical Details

Trace Details:

Model	Prompt	Prompt Version	Session ID
v2	SIDEKICK_SYSTEM_PROMPT	2	607c90290cae
Comparison Group	Start Time	End Time	Token Count
5ab141dac009	09/11/2025, 12:43:03 PM	09/11/2025, 12:43:09 PM	43438

Execution Tree:

- 347545fb6a80-live 5.28s
 - dynamic_query 1.07s

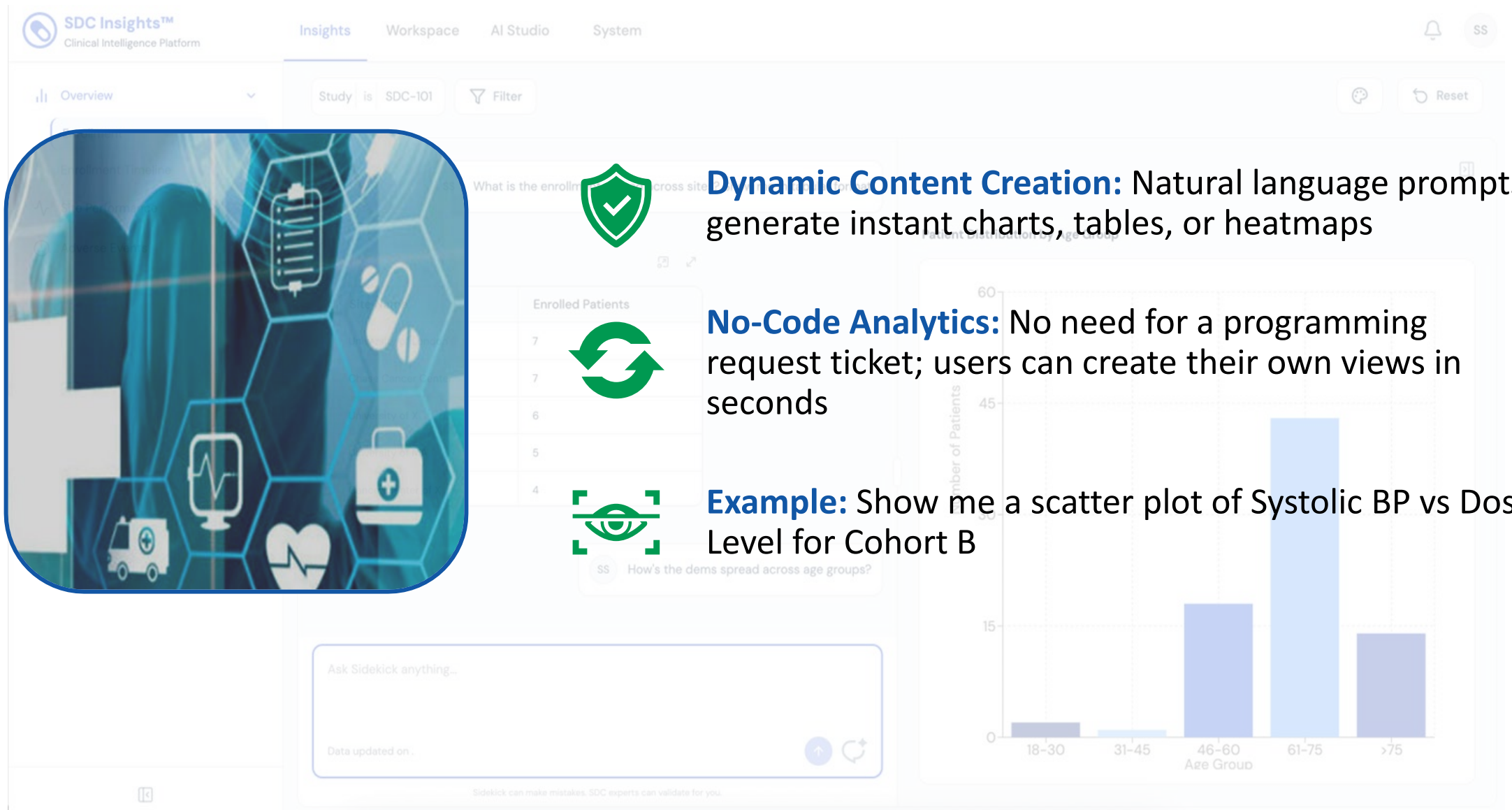
dynamic_query (#7bab9e5ba99e) Success:

Span ID	Duration	Status
7bab9e5ba99e	1.07s	Success
Start time	End time	Parent ID
09/11/2025, 12:43:07 PM	09/11/2025, 12:43:08 PM	966124381926

Metadata:

```
{
  "input": "SELECT DISTINCT DSDECOD AS Screen_Failure_Reason, COUNT(*) AS Number_Of_Patients\nFROM"
}
```

Generative UI (GenUI) – Custom Visuals on Demand



The screenshot displays the SDC Insights Clinical Intelligence Platform interface. At the top, there are navigation tabs for 'Insights', 'Workspace', 'AI Studio', and 'System'. Below this, a search bar contains 'Study is SDC-101' and a 'Filter' button. A large blue-bordered image on the left shows a stylized medical illustration with icons for a heart, ambulance, and pills. The main content area features a table titled 'Enrolled Patients' with the following data:

Enrolled Patients
7
7
6
5
4

Below the table is a search bar with the prompt 'How's the dems spread across age groups?'. To the right, a bar chart titled 'Patient Distribution by Age Group' shows the number of patients in different age categories:

Age Group	Number of Patients
18-30	5
31-45	2
46-60	18
61-75	45
>75	15

Three green icons are overlaid on the interface: a shield with a checkmark, a circular refresh icon, and a magnifying glass over an eye. Each icon is accompanied by a text block explaining a feature of the platform.

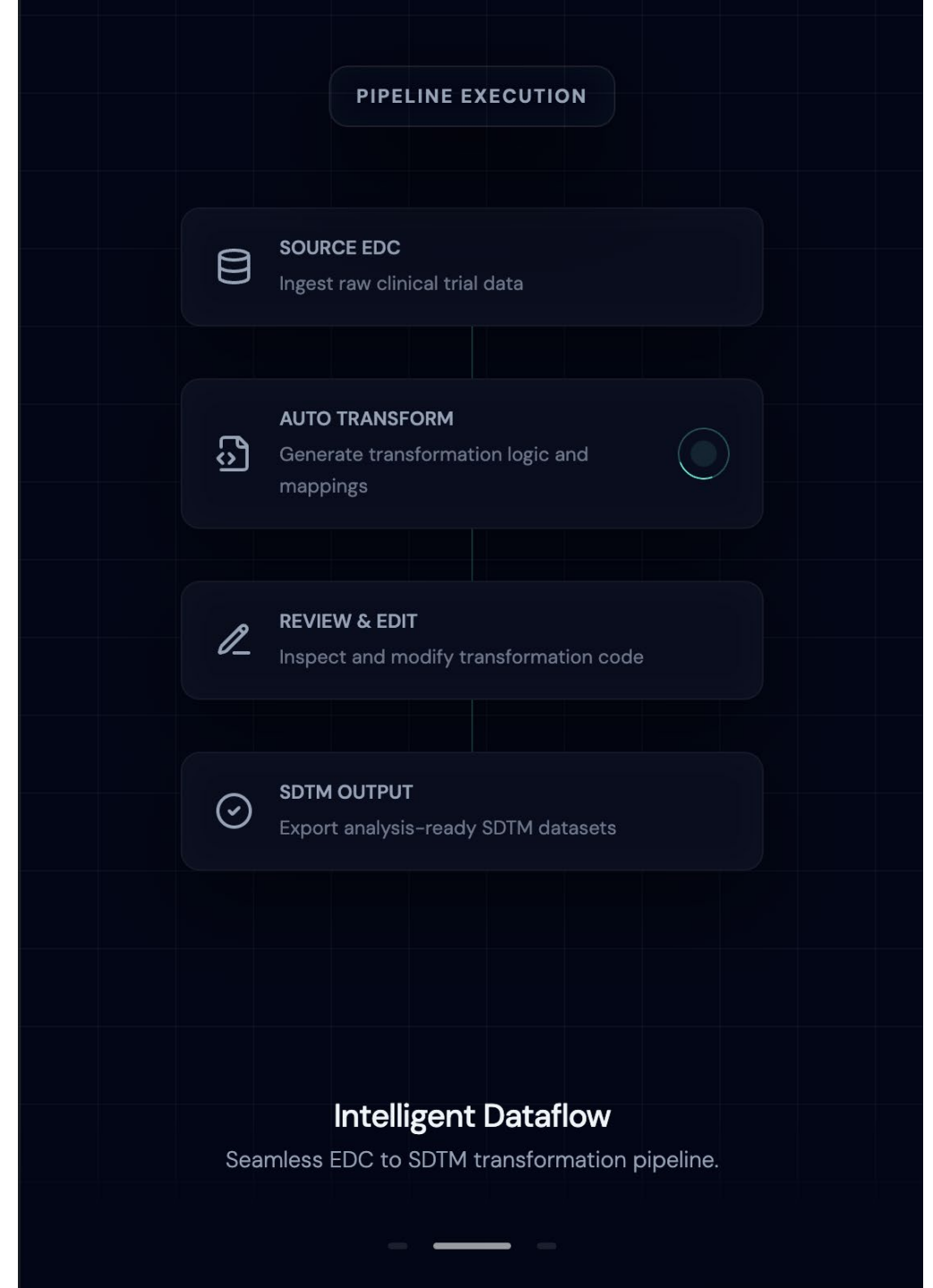
- Dynamic Content Creation:** Natural language prompts generate instant charts, tables, or heatmaps
- No-Code Analytics:** No need for a programming request ticket; users can create their own views in seconds
- Example:** Show me a scatter plot of Systolic BP vs Dose Level for Cohort B

At the bottom of the interface, there is a text input field with the placeholder 'Ask Sidekick anything...' and a 'Data updated on' section with a refresh icon. A disclaimer at the very bottom reads: 'Sidekick can make mistakes. SDC experts can validate for you.'

Customizable AI Agents

Unlike 'standard' AI like chatbots that suggests, an Agentic AI can act, reason, and collaborate across workflows

Personalized “Sidekicks”: Future iteration will allow teams to deploy specialized agents tailored to specific study roles



Agentic Capabilities in Development

Biometrics Agents



Intelligent agent coordinates cross-source reconciliations and automate SDTM mapping

Safety Agents



Identify SAE clusters and draft initial patient narratives for medical review

Monitoring Agents



Monitor site enrollment and trigger recruitment alerts or autonomously suggest a pre-approved recruitment “boost” campaign

Conclusion – Delivering Certainty Today



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Clinical-Trial Trained AI & Visualization

Leveraging and building upon LLM

User-role based personas for your visuals

100% Audit Readiness

Explainable AI – Traceability for your outputs and agents

Human validated responses upon request

Future Proofing

Preparing your data for agentic revolution

Thank You!

Contact SDC



Visit our booth **#1327** for a demo



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