Smart BioMedical Concepts

Saama - October 2025

Meet the Speakers

Yatesh Midha

Title: Associate Vice President, Product Management

Organization: Saama

Yatesh Midha has over 20 years of combined experience in healthcare and life sciences. During this time, he has used his industry experience along with his background in engineering and product development to develop standards driven solutions aimed at fostering innovation, productivity, and quality.

Panikos Christofi

Title: Associate Vice President, Customer Success

Organization: Saama

Panikos Christofi leads delivery of AI-enabled products and solutions for clinical trials. With experience in the clinical research industry since 2009, he bridges Clinical, Business, and Technical domains.

Panikos is highly knowledgeable in applying AI, analytics, and data warehousing to clinical systems, and is a strong advocate for data standardization, supporting initiatives such as DDF, CDISC USDM, and CDISC 360i.

Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

Agenda

1. Unlocking Clinical Data
2. Our Solution – Smart Biomedical Concepts
3. Overall Process Flow
4. Demo
5. Where Can We Go Next?

The Team Behind this Work

Recognizing our researchers who couldn't join us in Nashville

Murugesan Vadivel

Principal Research Engineer

Rachinnth Ravichandran

Research Engineer

Anusha Sekar

Analytics Developer

Due to visa restrictions, our research team is represented in spirit today.

Unlocking Clinical Data
Realizing the CDISC360i Vision

The Problem: Even with CDISC standards in place, clinical research workflows remain fragmented.

The lack of **semantic interoperability** prevents the **automation and traceability** envisioned in CDISC360i, blocking true machine-executable studies.

Biomedical Concepts (BCs) are the missing glue needed to connect study design, execution, and analysis into a unified digital flow.

Why It Matters:

- Manual, high-effort BC curation slows research and limits reusability
- Absence of standardized BC libraries hinders USDM enablement and cross-system interoperability
- Legacy knowledge remains untapped, preventing faster study design and higher data quality

The Opportunity: Automating BC extraction and alignment with **CDISC standards and the Unified Study Definition Model (USDM)** accelerates the shift toward a **fully connected CDISC360i ecosystem**.

AI-driven BC curation delivers semantic traceability, faster study startup, and seamless integration from protocol through SDTM — **bringing the CDISC vision of automation and connected standards to life.**

Our Solution - Smart BioMedical Concepts

What We Built

AI-driven engine that automatically extracts, structures, and validates Biomedical Concepts (BCs) from clinical documents

How It Works

Parsing Layer: Converts diverse formats (PDF, JSON, CSV) into a unified structure

Analysis Layer: Fine-tuned LLM identifies and filters clinical entities

Curation Layer: Human-in-the-loop review ensures accuracy and quality

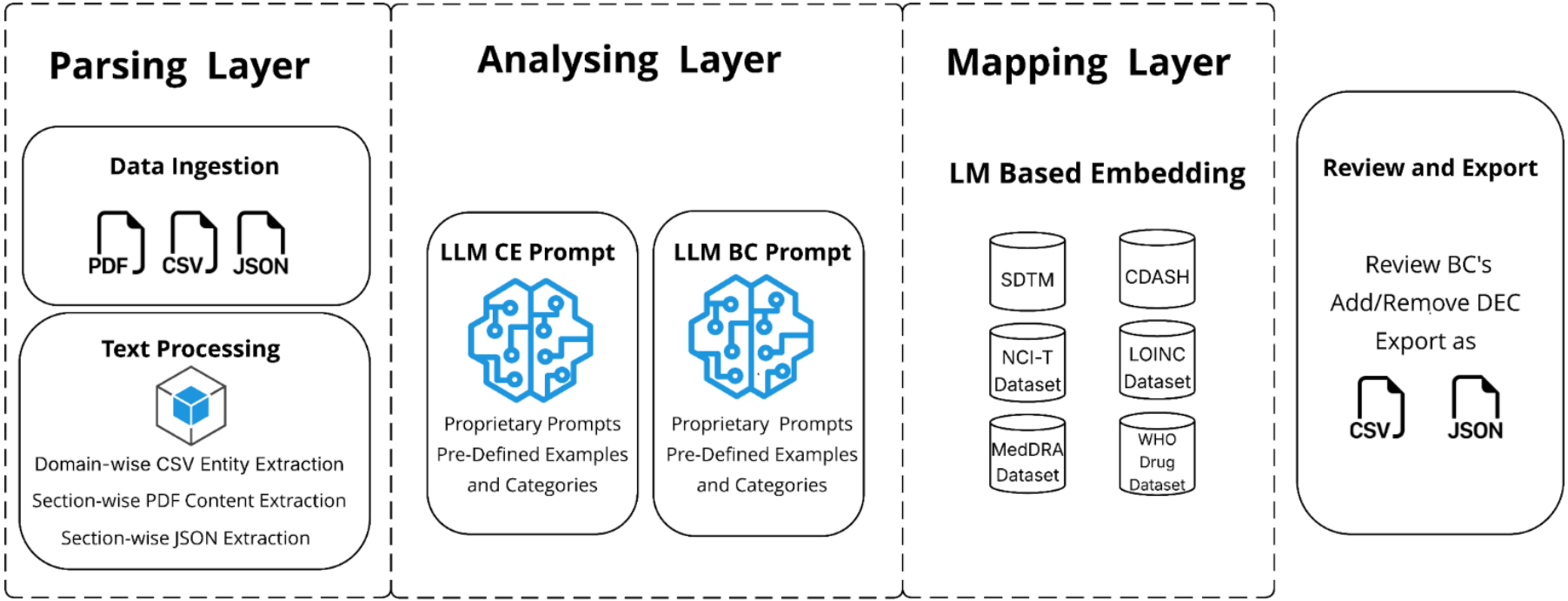
What's Novel

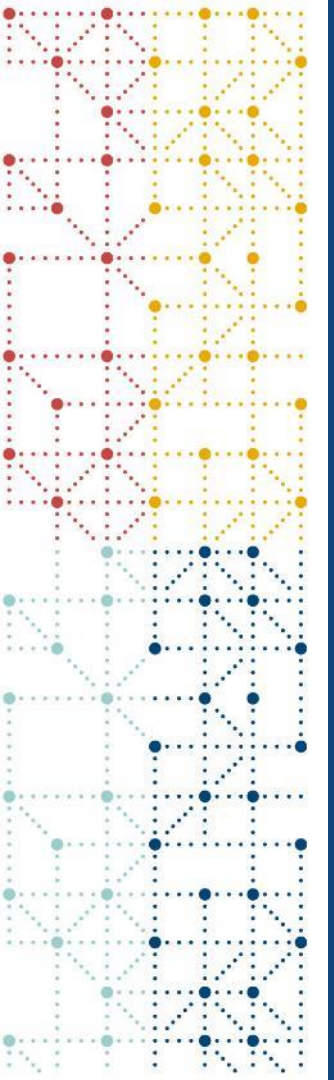
Transforms text into standardized BCs aligned with CDISC and ICH M11

Creates the "glue" between standards, connecting protocol, CRFs, SDTM, and RWD

Turns weeks of manual mapping into minutes of AI-assisted automation

Overall Process Flow





Demo

Where Can We Go Next
Toward A Connected Data Ecosystem

Today	Next Steps	The Vision
Smart Biomedical Concepts bridges the gap between unstructured content and standardized metadata. It demonstrates that AI can deliver accuracy, speed, and scale without sacrificing compliance or traceability.	• Expand curation to support direct BC submission via the CDISC API • Enrich the model with new terminologies and standardized vocabularies • Enable broader adoption to seamlessly link protocol text, CRFs, SDTM, and RWD	A fully connected clinical data ecosystem where structured, reusable biomedical concepts accelerate research, improve quality, and bring therapies to patients faster.

Thank You!