WITH STANDARDS – UNLOCK THE POWER OF DATA

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# Is AI/ML A Reality or A Day Dream?

Presented by Harinarayan, Gopichandran
Sr. Director Product Management, Saama Technologies

# Meet the Speaker

Harinarayan, Gopichandran

Title: Sr. Director, Product Management

Organization: Saama Technologies

Around 20 year of experience in Life Sciences R&D.

Designed multiple Products across Clinical Operations & Statistical Programming like Shared Investigator Portal (SIP), Smart Trials & Safety Notification, Smart Auto Mapper (SAM)

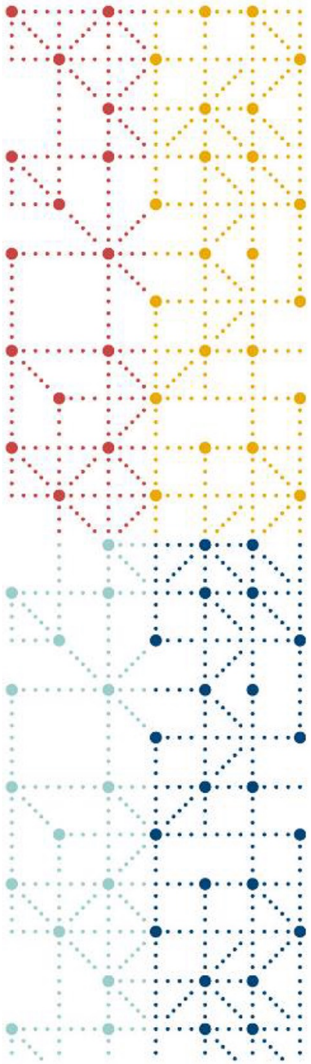
Played different roles in Statistical Programming over 15+ years in Icon, Novartis, Allergan & Cognizant

Lead the Statistical Computing Environment (SCE) for Business Process as a Service (BPaaS)

# Disclaimer and Disclosures

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

*The author has no real or apparent conflicts of interest to report.*



# Why AI/ML?

## Five Reasons Why AI/ML Should be Top of Mind

# Why AI/ML?

“

By now, most organizations have experimented with implementing a machine learning (ML) solution or playing with prototypes of artificial intelligence (AI) algorithms. While the use cases of AI/ML have been exponentially increasing, many organizations — including commercial, nonprofit and government agencies — have not factored AI/ML into their business strategy.

*- Forbes*

1

Increase Organizational Performance

2

Reduce Operational Costs

3

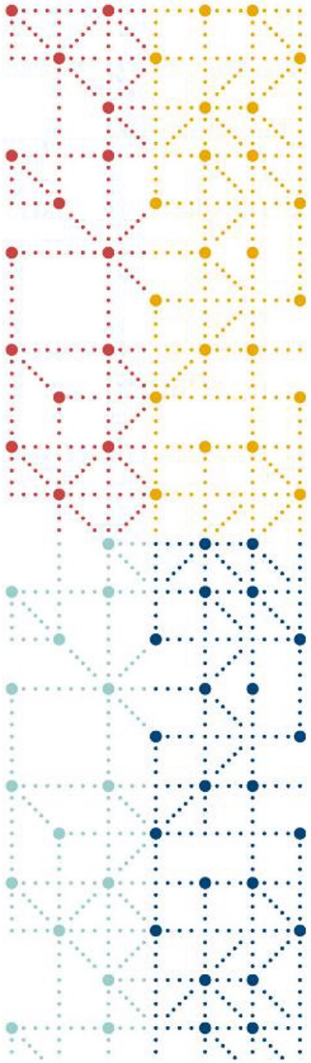
Launch Innovative Products

4

Meet Customer & Patient Expectations

5

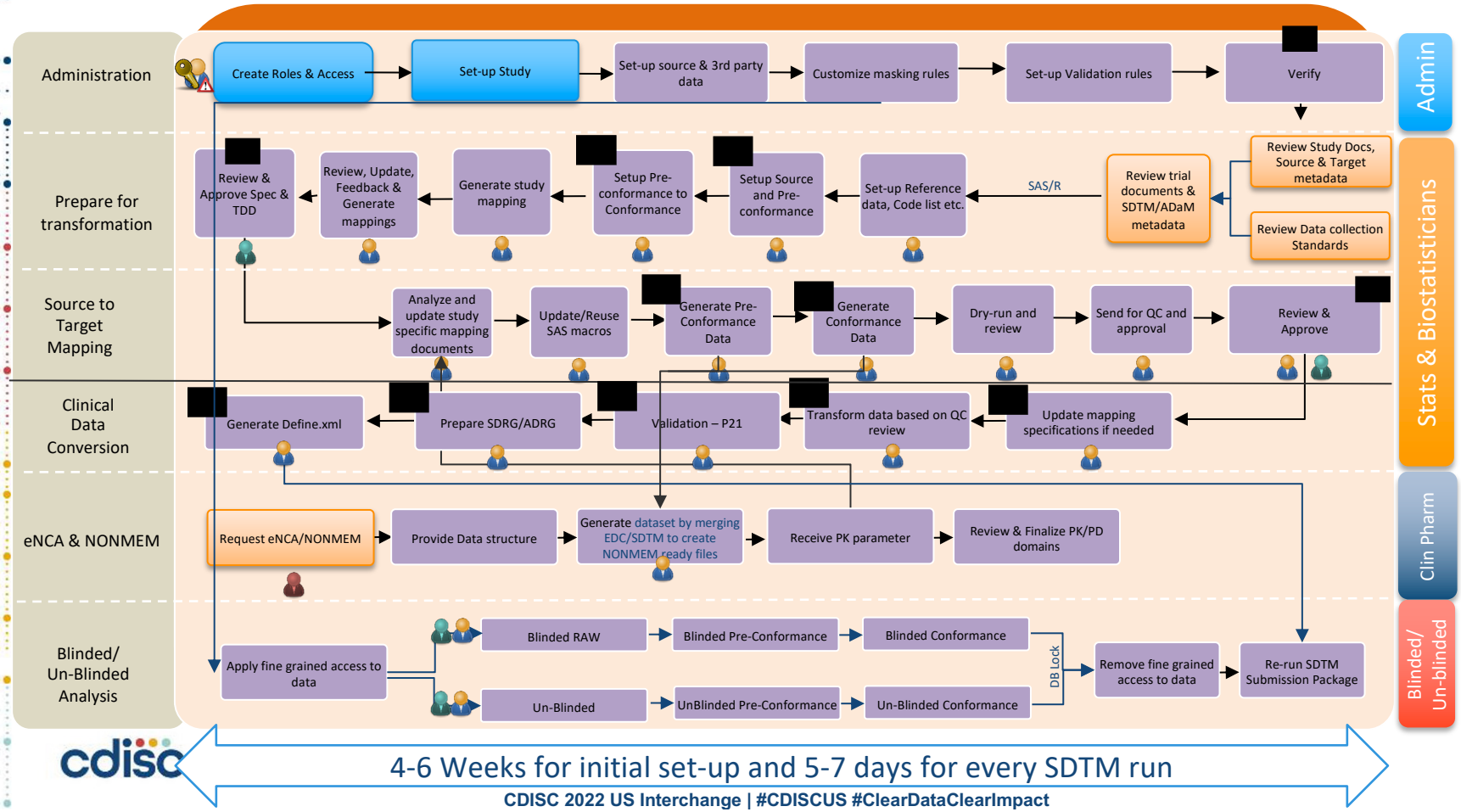
Introduce New Lines of Revenue



# AI/ML in Clinical Research

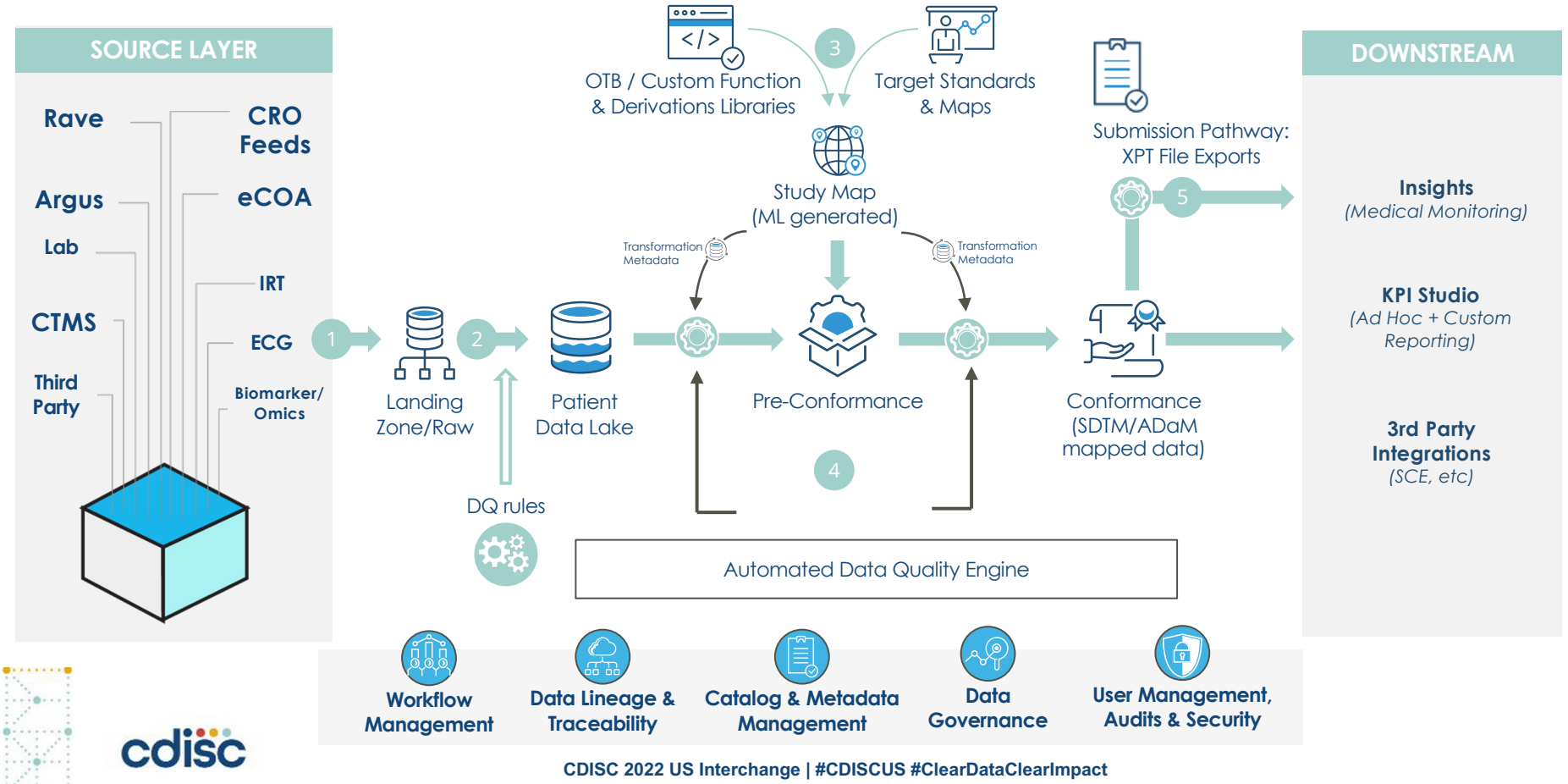
## Apply AI/ML in CDISC Submission

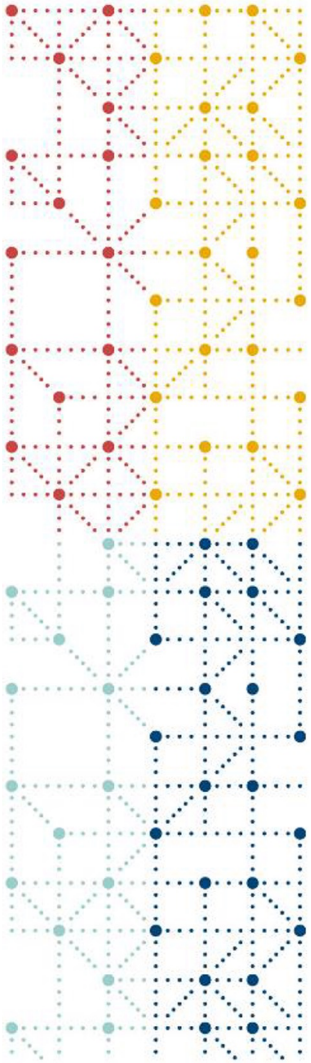
# Traditional Study level SDTM/ADaM Process




4-6 Weeks for initial set-up and 5-7 days for every SDTM run

# Future State Data Flow

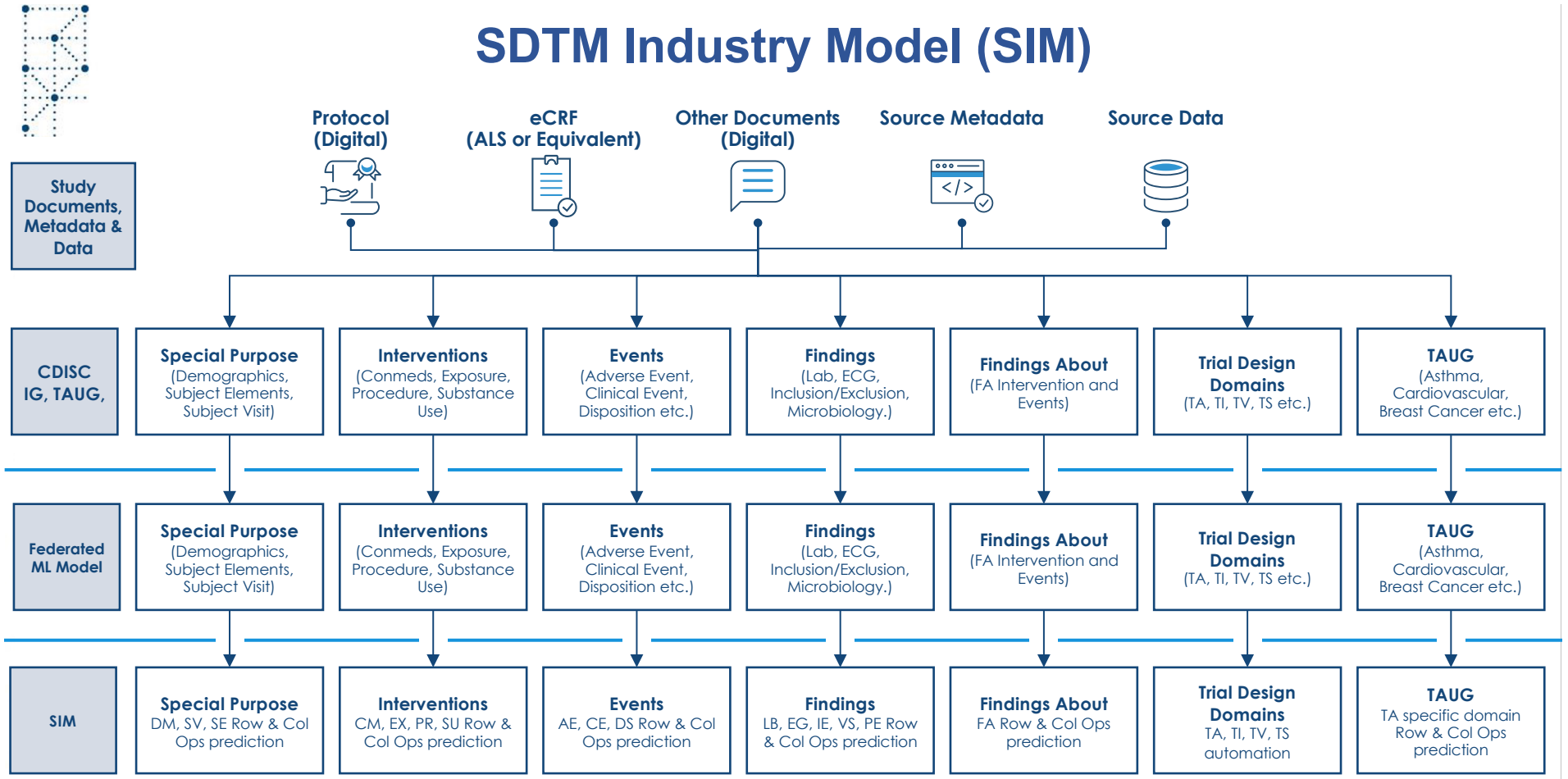




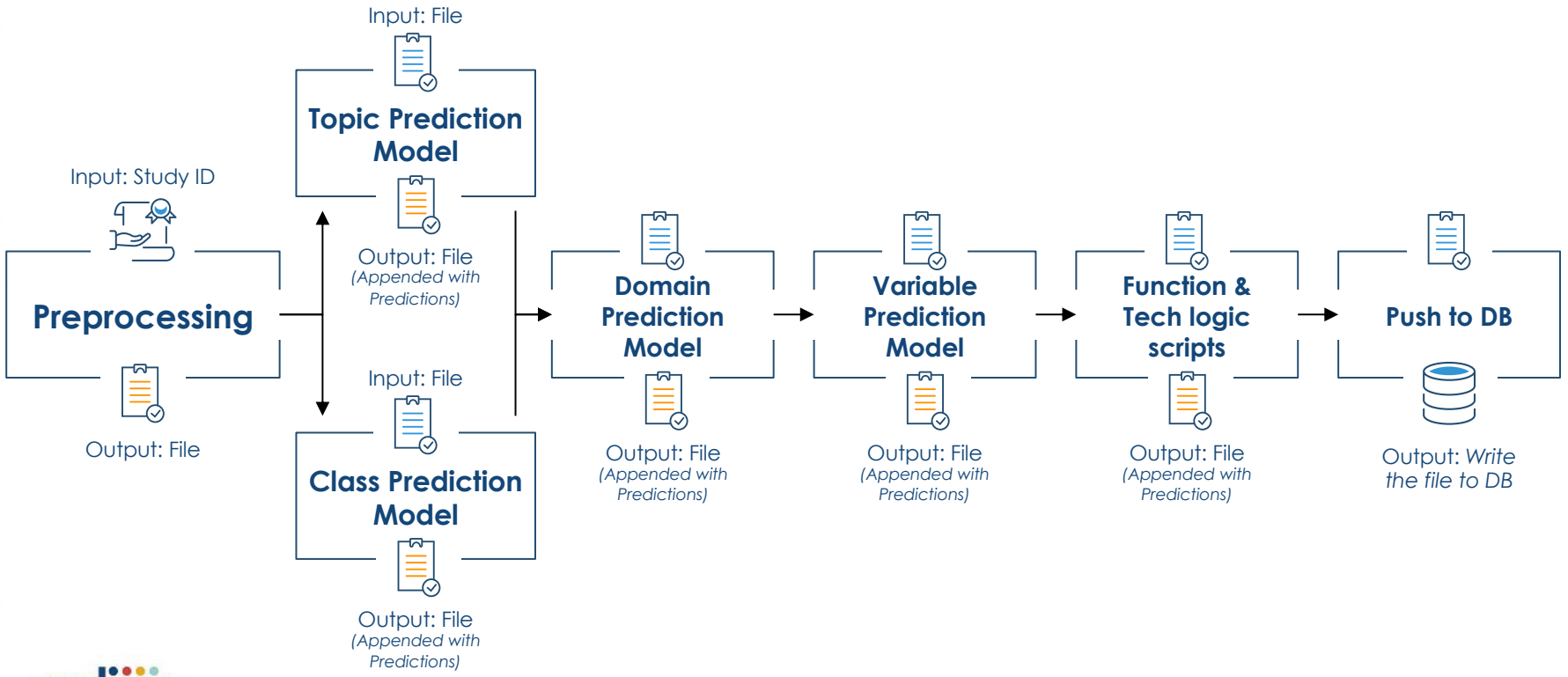
# AI/ML in SDTM/ADaM

## How can we do?

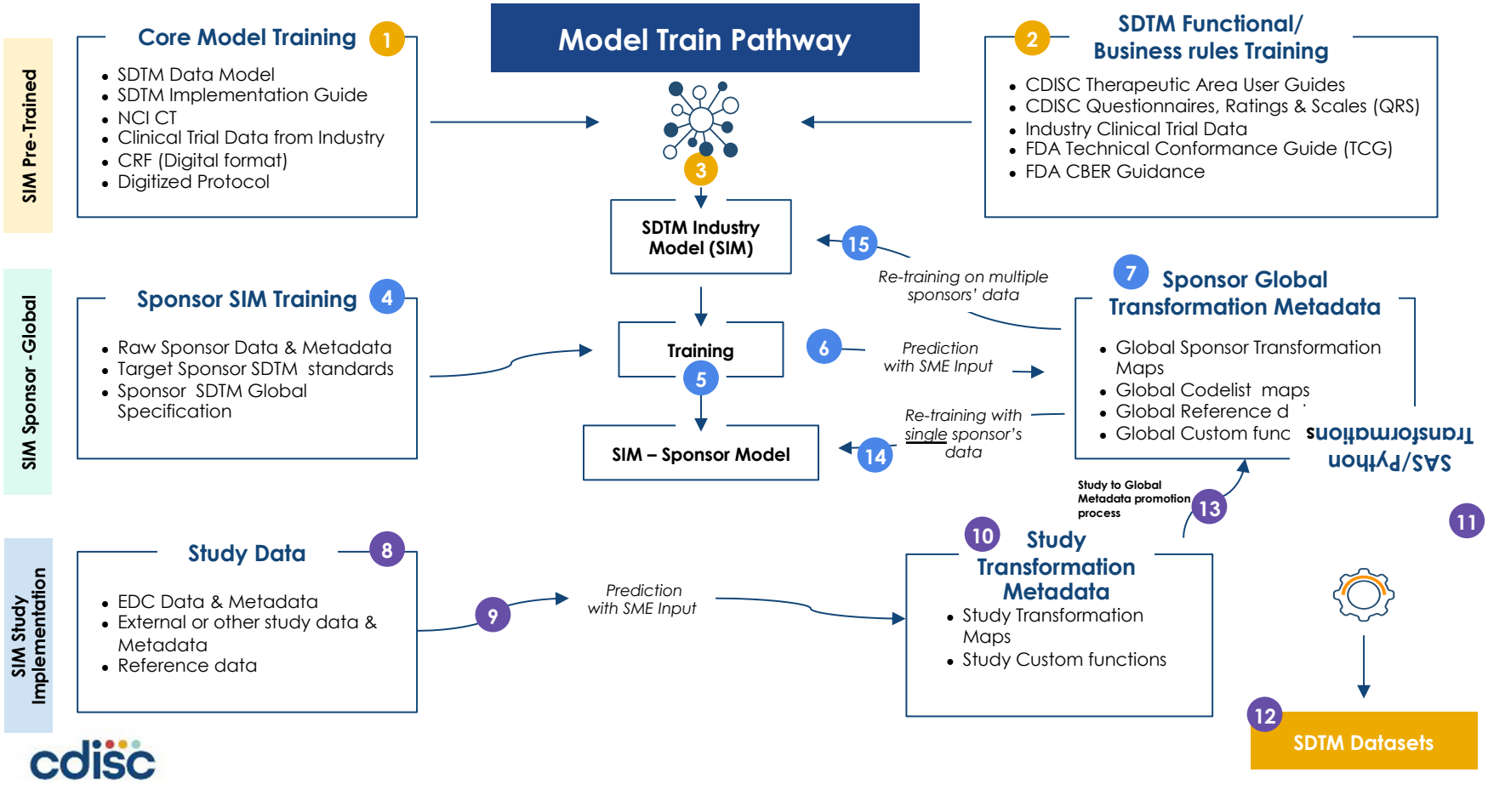
# SDTM Industry Model (SIM)



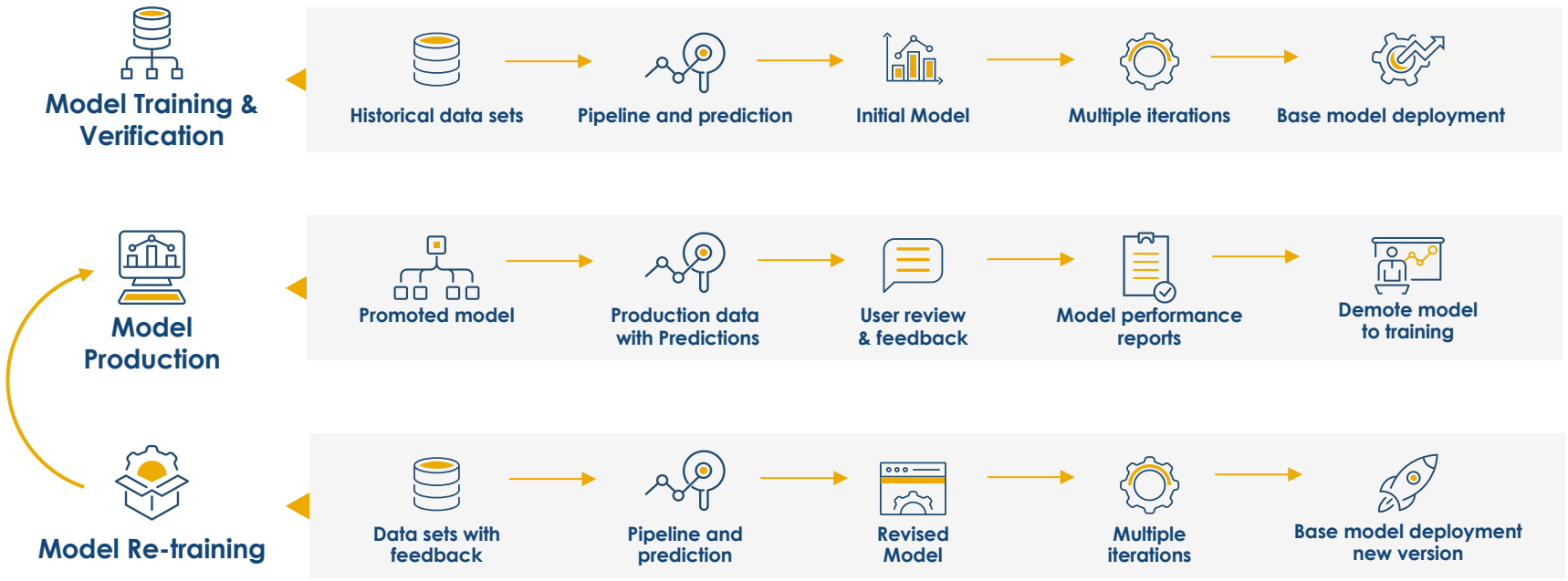
# SIM Model - An Overview

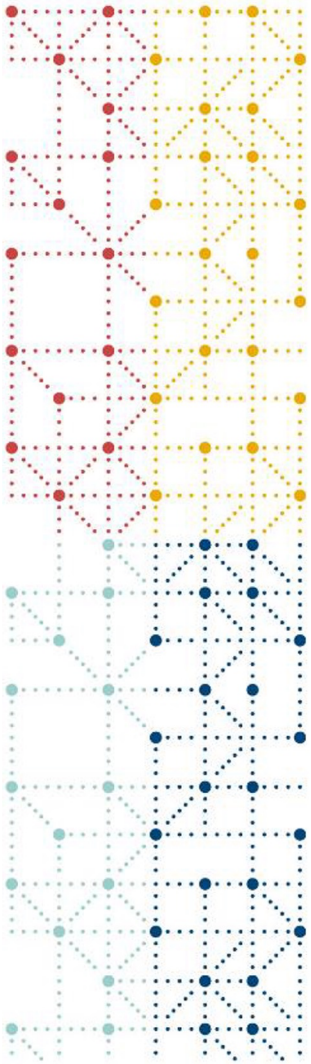


# Training & Re-Training the Pre-Trained Model



# How Does a Model Get Created and Go in to Production





# AI/ML still a Day Dream?

## Don’t think so!

# AI/ML is only a part of the puzzle

Data
Ecosystem

Context
Clinical Trials

Math
AI & Deep Learning

Technology
Big Data

Compute Engine
GPUs

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# Why do we need AI in Pharma/Life Science

## How AI Enhanced Data Analytics can Accelerate Clinical Trials

**Challenges in Clinical Trials**

**Results Achieved with AI**

**Source:** https://www.innoplexus.com/blog/can-ai-enhanced-data-analytics-accelerate-clinical-trials/

# In Summary …

## Objectives

- Enhanced Data ingestion & transformation
- Reduce effort for Metadata Change Management
- Faster Time to create Submission Deliverables
- Learning model, Automation & Accelerators

## Significant Accelerators

- Data Ingestion APIs / Custom Connectors
- Global Library & Standards Management
- Functions and Derivation Library
- AI / ML Based Auto Mapper
- Self Service UI & Data pipelines

## Value

- 20% - 40% TCO Reduction
- 25% - 50% Accelerated Turn-around Time
- Drive Automation & Innovation entire clinical data pipeline
- Industrialization Scale up via standardized harmonization processes

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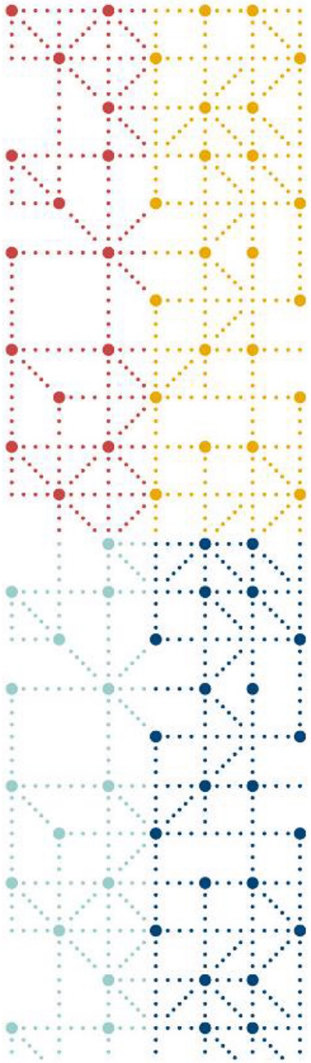

# Thank You!

Apple is one of the most innovative and respected company in the world. Apple makes products such as iMac, iPhone, and iPad, but we don’t really consider Apple as a manufacturing company. The reason is simple; Apple is not selling products, but Apple is selling experiences. With its user-friendly and AI-driven apps, Apple is providing the devices that people enjoy a great user-experience with. Apple is doing all these with data and Machine Learning.

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