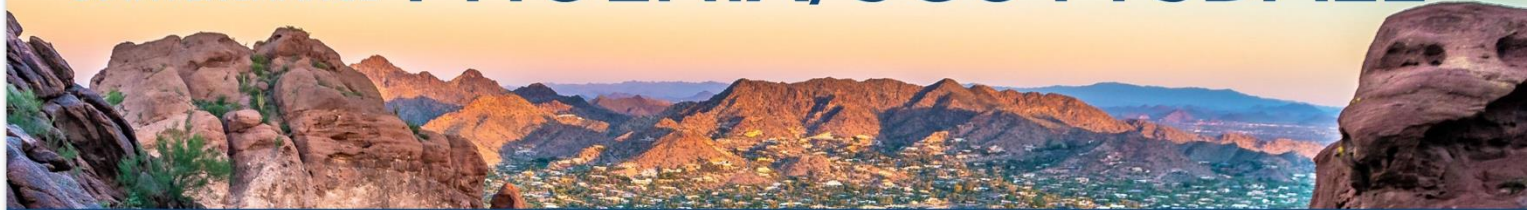




2024 CDISC + TMF  
US INTERCHANGE

**PHOENIX/SCOTTSDALE**



23-24 OCTOBER: CONFERENCE & EXPO | 21, 22, 25 OCTOBER: TRAININGS

**AI-onic eTMFs:**  
*An Interactive Case Study*

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Sr. Director, Site Engagement Delivery  
IQVIA Digital Products & Solutions (DP&S)

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## Speakers



**LOU PASQUALE**

Senior Director, Site Engagement  
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**CHARLES PATTRELL**

Associate Solution Engineering  
Director, IQVIA Digital Products  
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# 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. Rules for an interactive session
2. What's an AI-onic eTMF?
  - a. A little background is helpful
  - b. Let's agree on the following- a common understanding
3. Predictive Model- we love process and the eTMF
4. Validation- making sure it is right
5. What is the next big thing?

# Please Participate!



Polls in Slido



**Scan this QR code to be ready for the polls**

# What's an AI-onic eTMF?

From Bionic to AI-onic

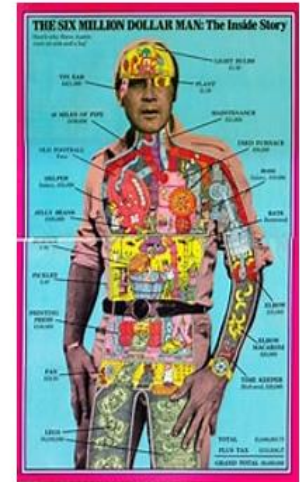
## How we got the Bionic Man, Steve Austin

- Test flight crash
- We can rebuild him...
  - Better
  - Stronger
  - Faster



## How we got AI-onic eTMFs

- Repurposed Document Management Tools  
*(aka Test Flight Crash)*
- We can build better...
  - Study Planning
  - Reports & Metrics
  - Risk-based QC
  - **Artificial Intelligence**





# Rewind - Time Travel

*Do you remember when...?*

## Manual indexing

- People-intensive, varying skill levels

## Manual authoring

- Limited Content Reuse, Repetitive Writing “skills”

## Manual completeness checks

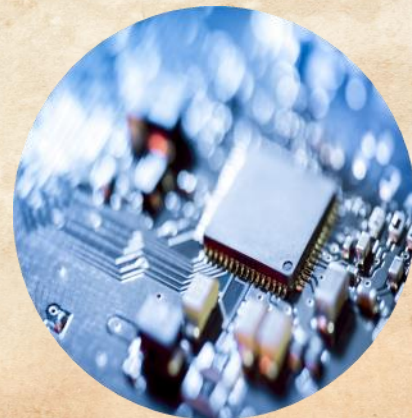
- Excel Trackers Galore!

## Manual cross-checks/File Reviews

- Trackers of Trackers of Trackers

## Onsite, In-person, Inspections

- Hi, Andy!



# Fast Forward to the Present

*...and tomorrow?*

## AI-powered indexing (Predictive Model)

- *Unsupervised Learning*

## AI-powered content generation authoring (Generative AI)

- *Write my Data Management Plan*

## AI-powered Completeness Checks???

- *If I have A, then I need B*

## AI-powered File Reviews???

- *Review Content & Metadata*

## AI-powered Health Authority Inspections???

- *We always knew Andy was not really human...*



# Poll #1 – How are you using AI in your current eTMF?

- A) Don't and won't. It's more fluff than stuff! (Unbelievers)
- B) Don't – am not planning on adopting in the near term (Wait and See-ers)
- C) Can't – Feature Unavailable/Still in the Pipeline (Daydreamers)
- D) Don't – but will in the next 12- 18 months (Eager Beavers)
- E) Already on board with growing use/acceptance (True Believers)
- F) Generative AI/Large Language Model – (Large and In Charge – Kipling's Akela)



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**How are you using AI in your current eTMF?**

ⓘ Start presenting to display the poll results on this slide.

# Sidebar – Artificial Intelligence

## *Common Understanding*

Artificial intelligence leverages computers and machines to mimic the problem-solving and decision-making capabilities of the human mind. (IBM)

Some categories of AI:

### **Predictive Model** - *Power of tireless automation*

- Ideal fit for eTMF
- Document Identification and Indexing

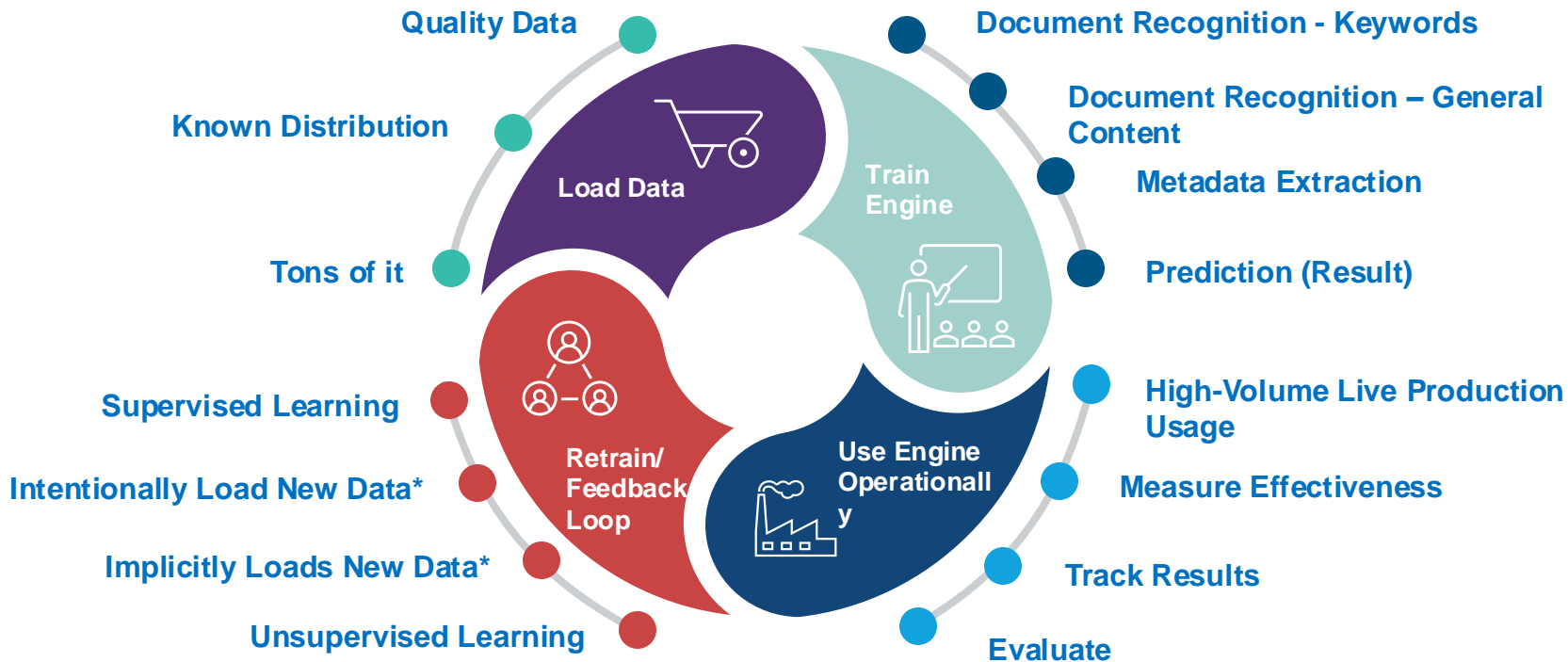
### **Large/Narrow Language Models**

- Large Model – not so much
- Narrow/Small Model – better fit
- Protocol Authoring



# Predictive Model

*In Everyday Use*





# AI in Life Sciences

*From the Perspective of eTMF*

## What makes eTMF a good candidate for AI?

*(Predictive Model)*

- Data Volume
- Data Quality
  - › Creation/Collection
  - › Verification (QC on Intake)
  - › Periodic Review
  - › Regulatory Controls



# AI in Life Sciences

*but wait, there's more...*

## Standards

- CDISC TMF Reference Model
  - › Strong taxonomy
  - › Document Types/Sub-Types
  - › Metadata Elements

The CDISC logo consists of the lowercase letters "cdisc" in a bold, blue, sans-serif font. Above the letters "i", "s", and "c" are three small circles in red, orange, and green respectively.

# Predictive AI

*Automated Document Recognition and Indexing – Monitoring Visit Documents*



## Unknown Document

Deconstructed/Digitized  
Compared to Model



## Monitoring Visit

Additional Processing  
for Sub-Artifact:  
**Confirmation Letter**



## Confirmation Letter

Extract Data:  
Visit Date  
Site Name/Number  
Visit Type

# Predictive AI

*Automated Document Recognition and Indexing – Form FDA 1572*



**Unknown Document**

Deconstructed/Digitized  
Compared to Model



**FDA Form 1572**

Additional Processing  
for Sub-Artifact:  
**<none>**



**FDA Form 1572**

Extract Data:  
PI Name, Sub-I  
Name(s), Protocol, Site  
Name(s)



# AI in Life Sciences

*From the Perspective of TMF Content*

## What makes TMF content a candidate for AI?

*(Narrow/Small Language Model)*

- Known trial design can feed AI
  - › Objectives/Purpose
  - › Study Design
  - › Selection & Exclusion of Subjects
  - › Treatment of Subjects
  - › Assessment of Efficacy
  - › Assessment of Safety

### Large Language Model

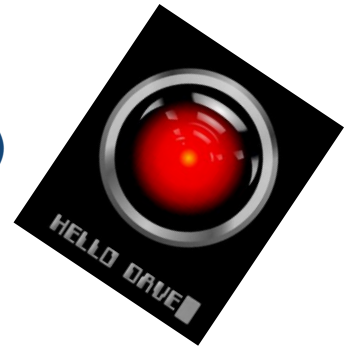
- 2+ trillion parameters
- Complex/General Tasks
- Write me a story about...

### Narrow/Small Language Model

- 100M – 10B parameters
- Specific/Targeted Tasks
- Write my Protocol/DM Plan/Monitoring Plan

## Poll #2 – How are you validating your AI features?

- A) If I do not look under the bed, the monsters cannot get me (*Unbelievers*)
- B) It is a running battle with our Quality/CSV Teams (*Taming the Wild/Lewis, Clark, and Sacagawea Discover Silicon Valley*)
- C) Like other risk-based features (*Everything Old is New Again-ers*)
- D) Overwhelming Response (*Shock and Awe-ers*)
- E) If AI is so intelligent, why cannot it validate itself? (HELLO DAVE )



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**How are you validating your AI features?**

ⓘ Start presenting to display the poll results on this slide.

# General Testing & Validation Concerns

*This is how we live with our current testing mindset*

## “Normal” Testing for “Normal” Features

- End-to-End Testing
- Negative Testing
- Risk-Based Testing
- Risk-Level Features
- Does not suffer from
  - › Data/Document Reuse
  - › Non-Representative/Random Data/Low Data Volume





# Testing AI Features

*Our Future Home*

## Testing the “Engine” vs. Distinct Requirements

- Representative Training Data (lots of it)
  - › Completely Dependent on Perfect\* Training Data
  - › Proper Distribution of Training Data
- Realistic Testing Data Set
  - › Known quality/Known distribution
  - › Unknown to the Engine
- **Shared** responsibility with Vendor

If I do this, then I **should** get that...



# Testing AI Features

*Reaching Good Enough*

## Defining Tolerances/Variations

- Acceptable Results (Good Enough)
- Retune, Retrain, Retest\*

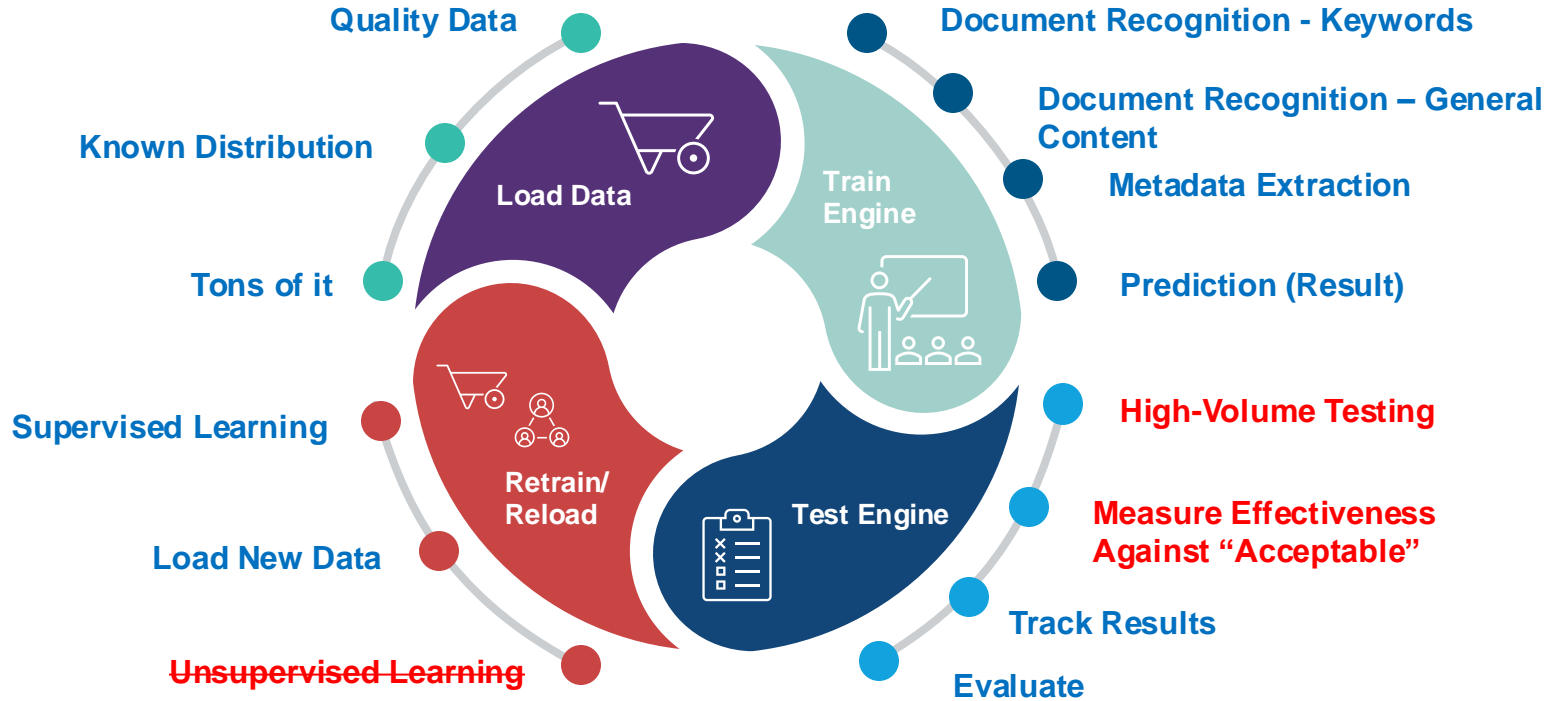
## Other Characteristics

- Suffers from
  - › Low quality/low volume data
  - › Suffers from data reuse\*
  - › Larger testing data footprint than traditional testing (much larger)
- How do I document “good enough”?



# Predictive Model

*In Testing & Validation*



# Validation Head-to-Head Comparison

- *Where are the differences?*

## “Normal” Validation

- Purely Objective Approach
- Distinct Outcomes (If A, then B)
- You own this process
- Easily repeated with no degradation in testing result
- Business as usual

## AI Validation

- Subjective by nature
- Range of Outcomes (If A, then mostly B)
- Shared responsibility with vendor
- Repeat testing relies on new data or complete reload
- Some adaptation of your CSV required

## Poll #3 – What is the next big AI feature in eTMFs?

- A) Makes no difference. I'm not interested. (*Unbelievers*)
- B) Next? I'm still waiting for the first (*Missed the Boat-ers*)
- C) Essential Document List Auto-Population (*Step Two Two-Steppers*)
- D) Generative AI – Protocol/Plan Authoring (*It's Not Plagiarism-ers*)
- E) AI Completeness, Quality, and Cross-checking File Reviews (*The Jetsons*)
- F) AI-onic TMFs. No manual efforts needed (*Still Waiting for Kurt Warner to return to the Cardinals-ers*)

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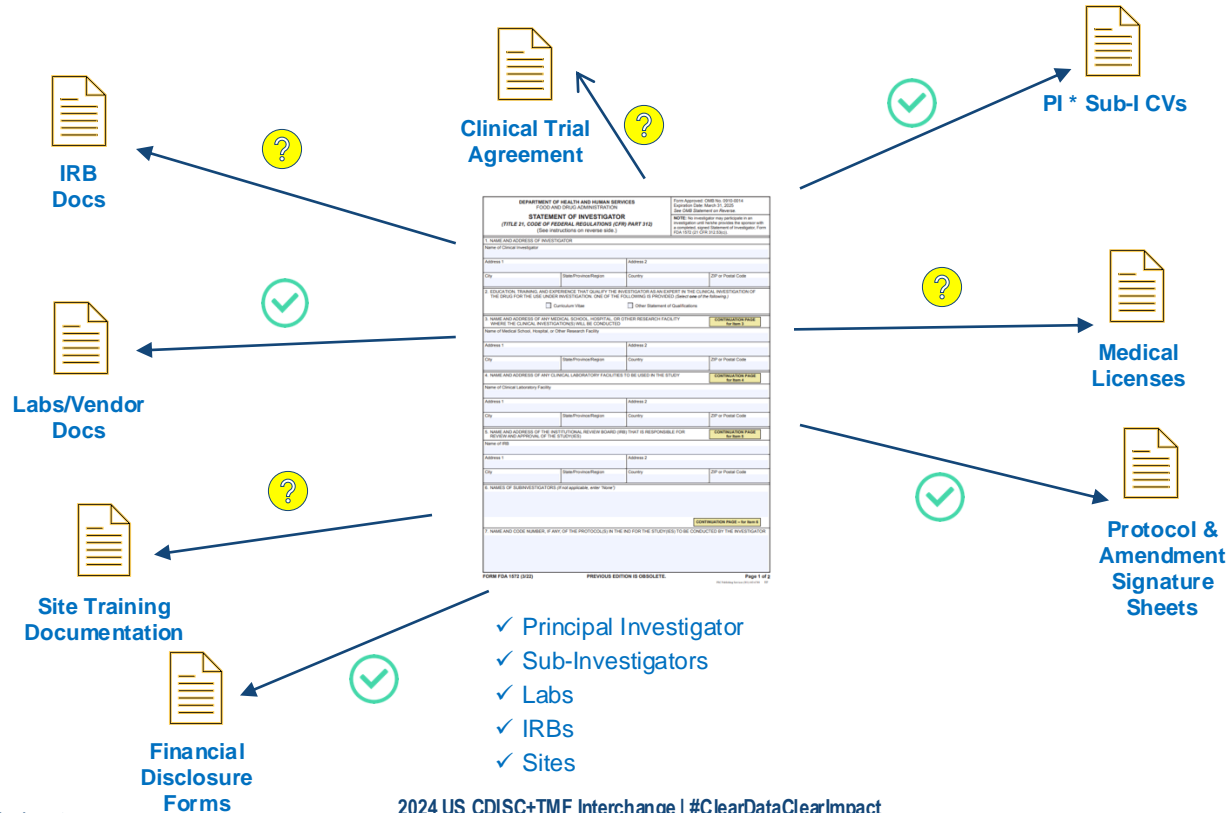
**What is the next big AI feature in eTMFs?**

ⓘ Start presenting to display the poll results on this slide.



# What is the Next Big Thing for AI in eTMFs?

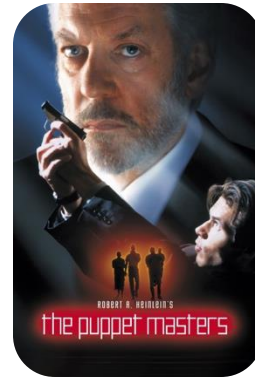
- Automated Completeness Checks – FDA 1572 Example



## Poll #4 – Meet the Puppets

*(Which Speaker is AI? Which is real?)*

- A) Lou Pasquale is not real – I know the real Lou and is not intelligent. Plus, the real Lou would have a reference to Six Degrees of Kevin Bacon!
- B) Charlie Pattrell is not real – no real person would agree to co-present with Lou



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# Meet the Puppets (Which Speaker is AI? Which is real?)

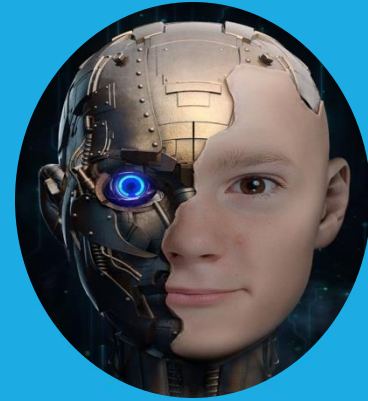
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## Speakers



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**CHARLES PATTRELL**

Associate Solution Engineering  
Director, IQVIA Digital Products  
and Solutions

# Prior Speaking Engagements

- **Which eTMF is Right for You?** *Applied Clinical Trials Webinar Series, September 2024*
- **eTMF Artificial Intelligence and Machine Learning – 2nd Generation**, *TMF Summit, Savannah, GA, March 2024*
- **Validation Considerations for AI-enabled SaaS**, *TMF Summit, London, UK, November 2023*
- **To Validate SaaS or Not to Validate SaaS? That is the Question...**, *Applied Clinical Trials Webinar Series, July 2023*
- **Taking a Risk-based Approach to Quality: It Doesn't have to be Spooky**, *Clinical Quality Oversight Forum (CQOF), Philadelphia, PA, October 2022*
- **Risk-Based Quality Control Approaches for TMF Documents**, *TMF Summit, London, UK/Atlanta GA, November 2020/January 2021*

Thanks and see you next year!!!

