



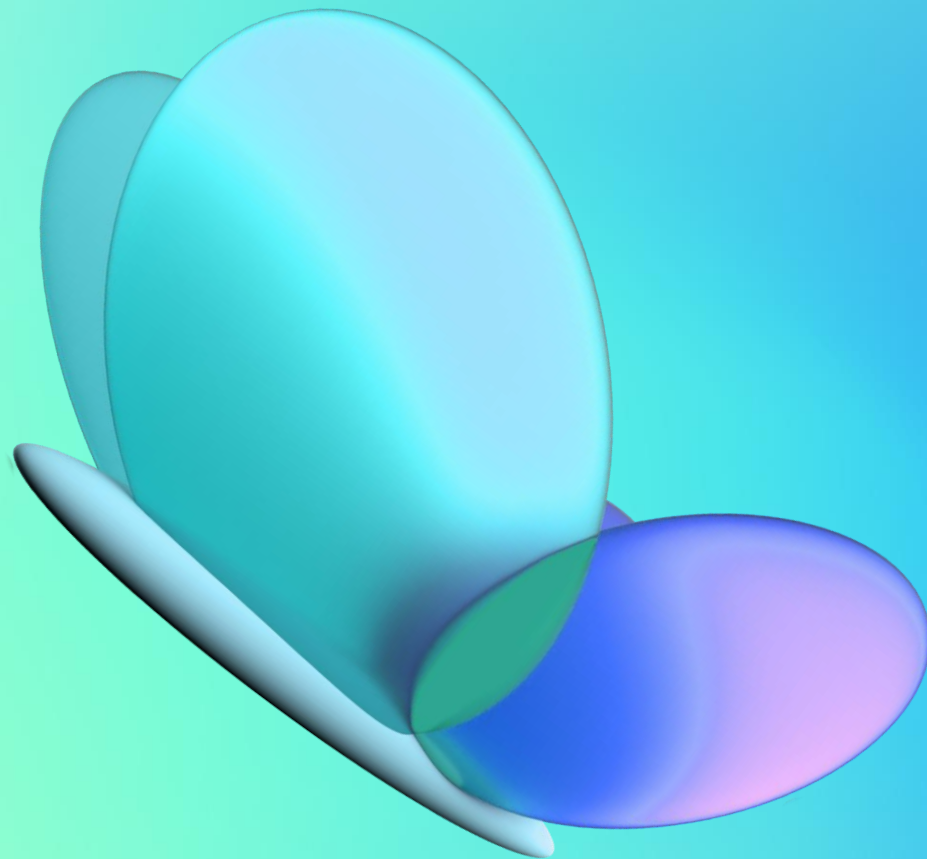
## ML01

# Accelerating Clinical Study Startup: Automated eCRF Generation from Clinical Protocol Document

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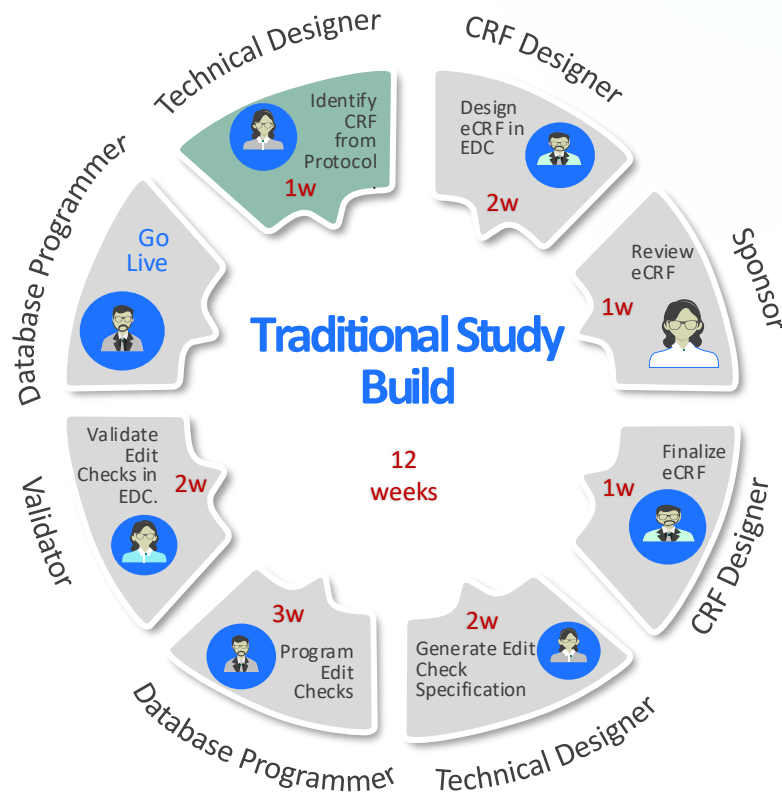
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# Problem Statement & Context



Even before the clinical trial begins, building a validated EDC system involves multiple handoffs and manual interpretation of protocol content. Each step adds delay – **not because of science, but because of process.**



Each stage relies on manual interpretation, cross-functional coordination, and repeated reviews, slowing down the entire study startup



## Why This Problem matters ?

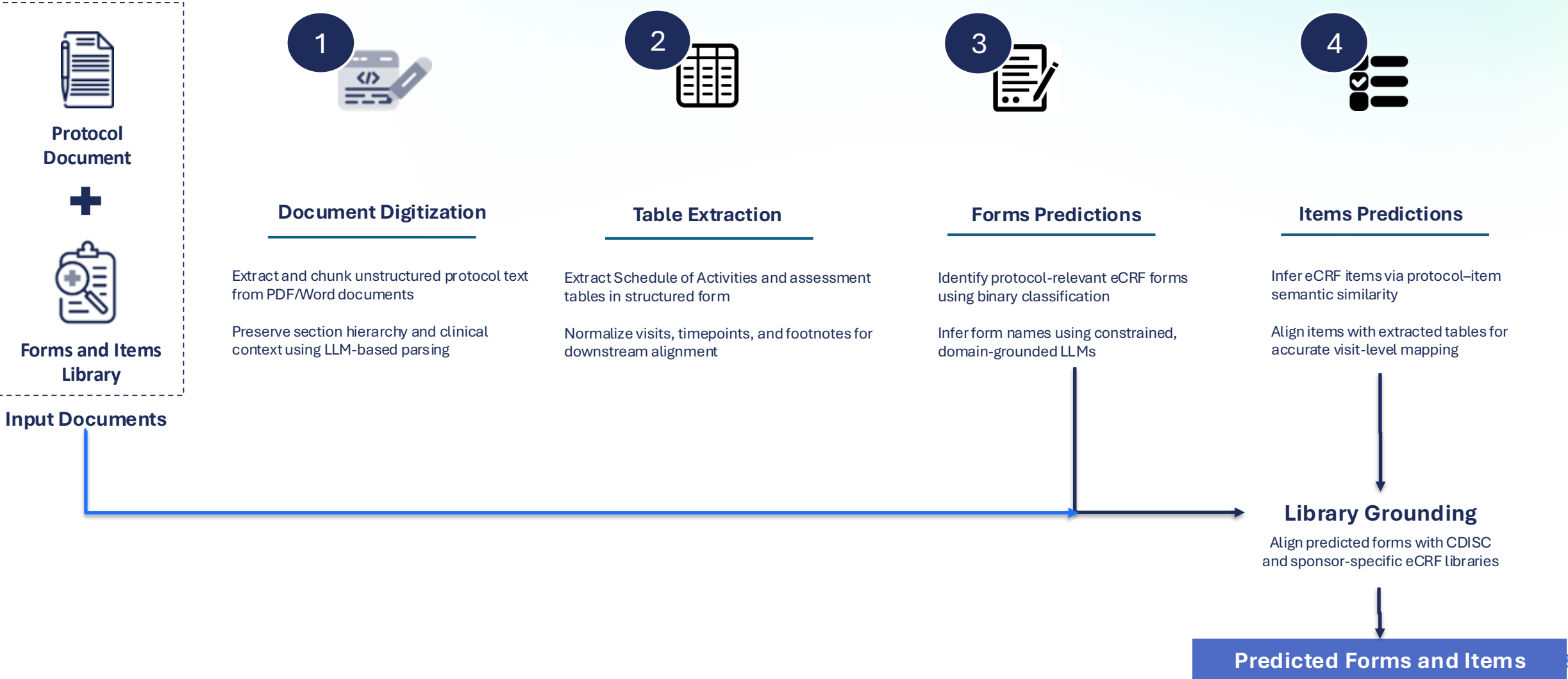
- Due to complex study designs, need specialized Skills and **TA specific** experts
- Weeks are lost to back-and-forth **reviews and approvals**
- **Time-consuming specifications** and programming slow progress
- Rework due to **misalignment** adds hidden costs
- A **single protocol change** can ripple across the entire lifecycle



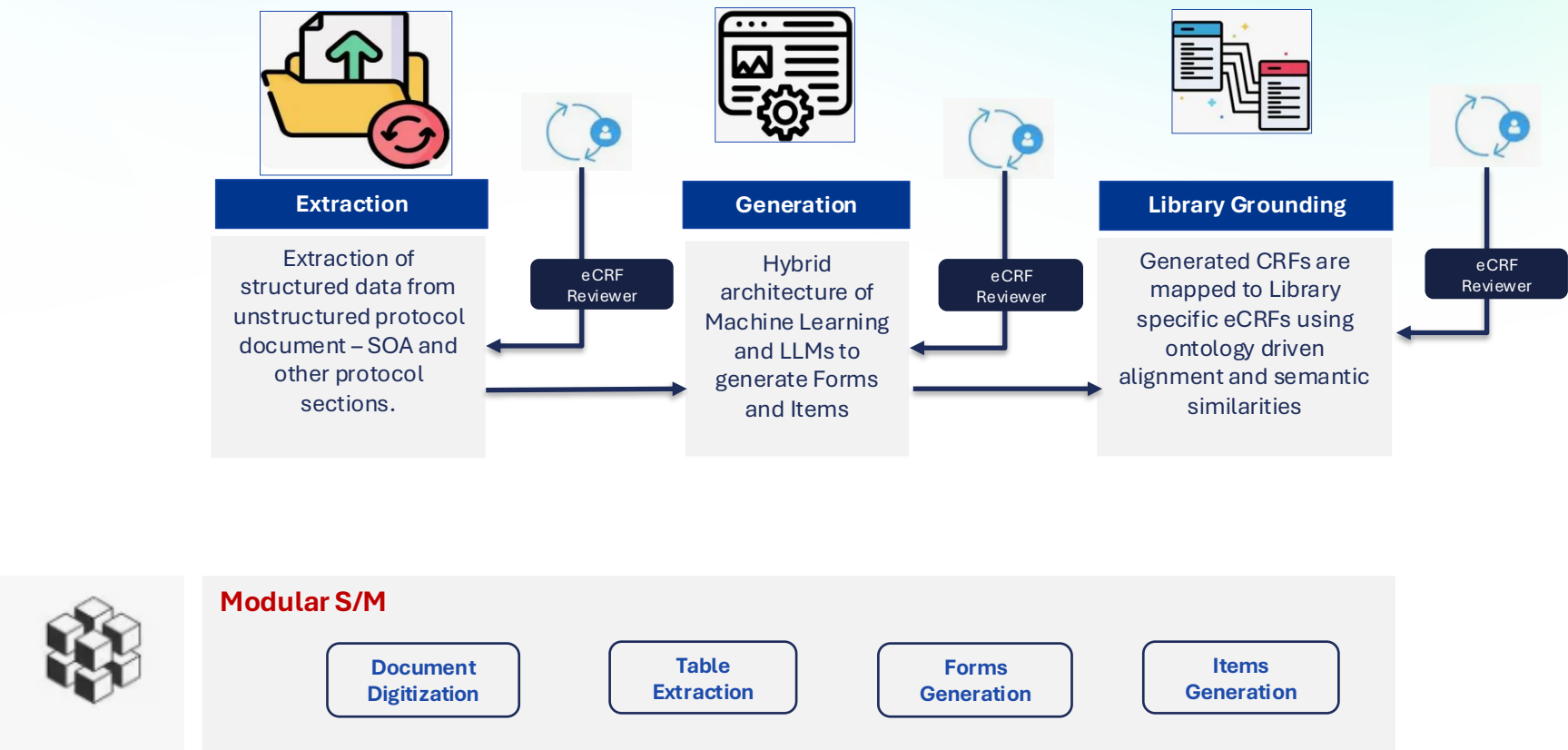
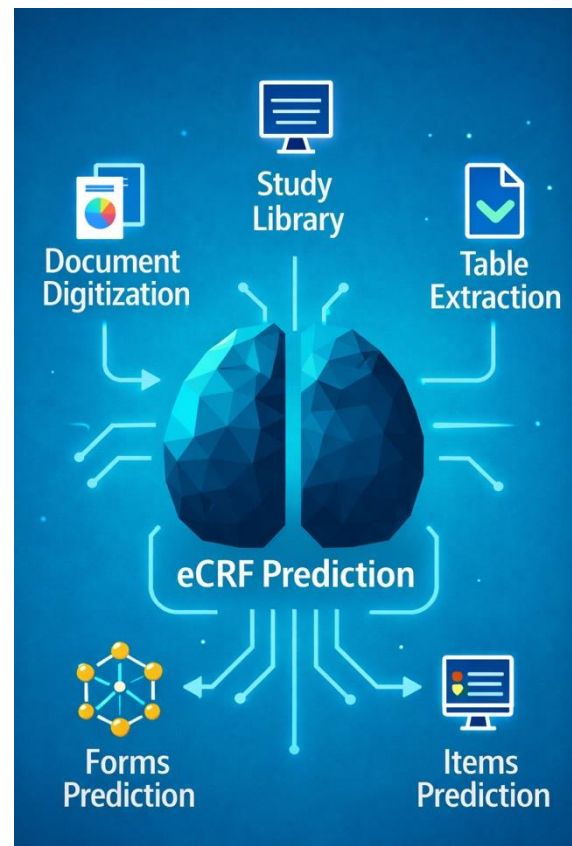
## Core Challenges

- **Manual and Resource Heavy**
  - ✓ Requires constant Oversight
  - ✓ High Dependence on Individual Expertise
  - ✓ Hard to Scale
- **Poor Re-Use of Knowledge**
  - ✓ Limited Capitalization on Metadata Standards and Curated Libraries
  - ✓ No Active Learning
- **Risk and Inconsistency**
  - ✓ Quality Issues
  - ✓ Manual Interpretations

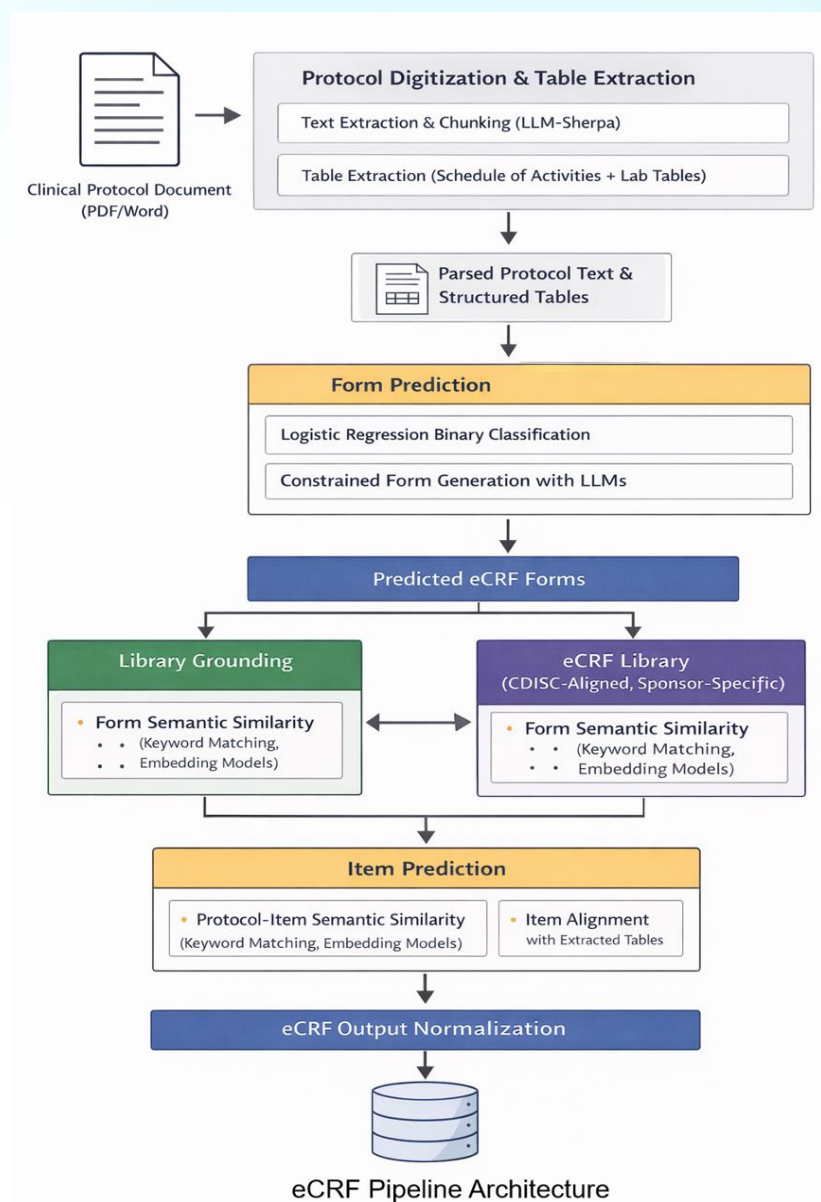
# Proposed Approach



# Concept overview



# System Architecture



# Business & Operational Impact



## Operational Efficiency



- Automates eCRF form and item derivation, significantly **reducing protocol-to-EDC timelines**
- **Eliminates SME <> POC <> Developer loops**
- Study build cycles become **faster, cleaner and more accurate**



## Traceability, Quality & Reproducibility



- eCRFs generated are **reproducible, consistent and deterministic**
- Higher accuracy, quality and confidence using **hybrid modelling** architecture
- **Traceable linkage** between protocol evidence and generated forms/Items



## Compliance and Governance



- Supports regulatory and standards compliance.
- **Transparent, auditable decision flow** facilitates readiness and quality assurance processes

# Outlook - Protocol to First-Patient-In & Efficiency



Week

## Traditional Study Build

eCRF Build

eCRF Finalization

Edit Check Spec Creation

12 Weeks from  
Protocol to FPI

Test Case Creation

Edit Check Programming

Edit Check Validation

FPI

## CSAT Study Build

eCRF Build | eCRF Finalization  
Edit Check Spec Creation

Edit Check Spec Finalization | Edit Check  
Programming | Test Case Creation

Edit Check Validation | FPI

3 Weeks\* from  
Protocol to FPI

*\*All activities can be done on  
the same day, however  
considering review cycle the  
CSAT can take maximum of 3  
weeks for Protocol to Go Live*

80%

eCRF Design

95%

Forms Prediction

85%

Items Prediction

Efficiency Gain in  
eCRF Prediction Pipeline



# Thank You

Questions and Discussion