

ML25: Accelerating Study Build Using AI Enabled CRF Design

2026 PHUSE US Connect

MARCH 2026

Agenda

1	Vision for the Solution
2	Prior Process vs. Future Process
3	How Standards are Used in the Process
4	Architecture and AI Technology
5	The User Journey

Corporate Disclaimer

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VISION

The AI for DM product(s) is designed to streamline and accelerate key study startup activities by generating first drafts of Case Report Forms (CRFs) and edit checks specs generation. This solution represents a step toward a more intelligent, efficient, and technology-enabled approach to clinical data management and study start activities.

Who does it serve?

**Clinical Data
Management Team**

What value does it generate?



- ✓ Speed to first draft begins iterative review process faster
- ✓ First draft ready decreases turn-around times
- ✓ Ability to generate and insert on-the-fly reduces study team review cycle

How does it Support Data Management Users

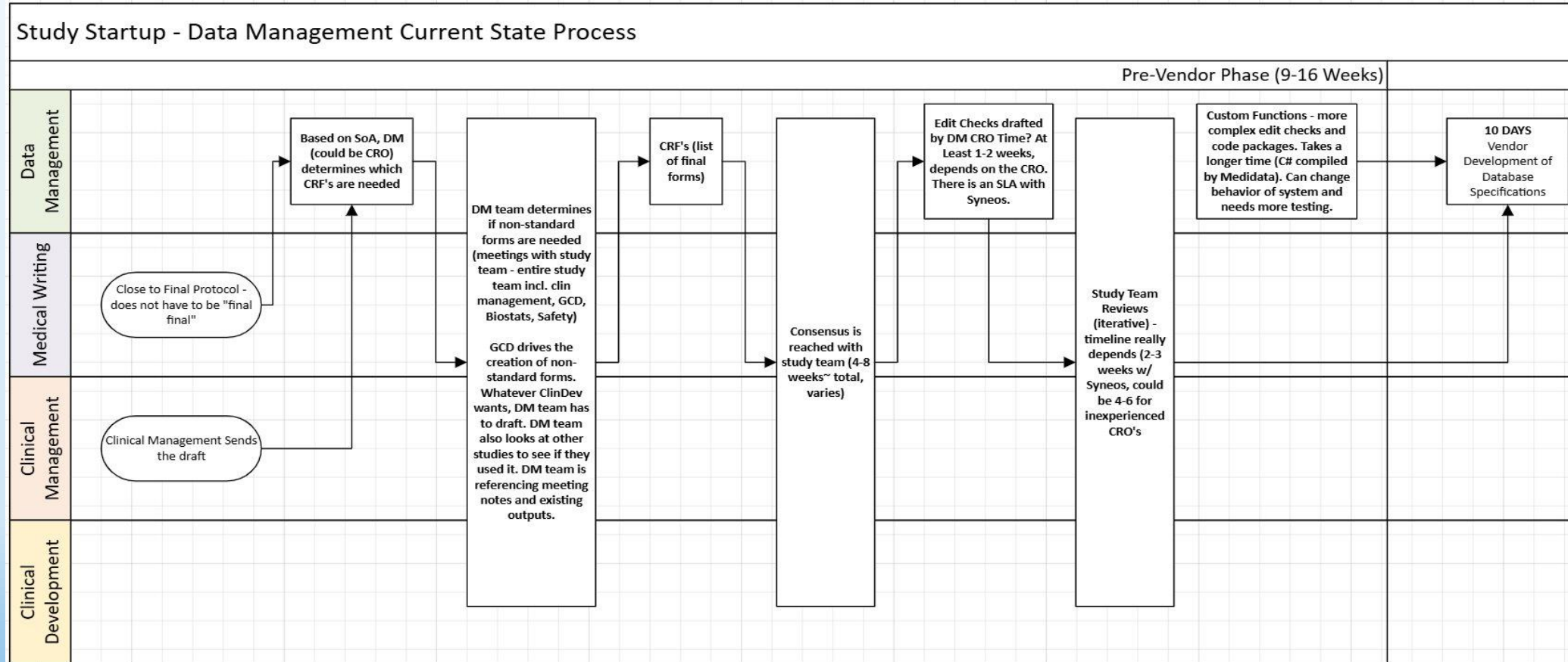
CRF Generation agent leverages existing CRFs from Data standards (wherever available) and generates new CRFs based on provided input protocol

Edit Check Specifications generation agent helps with the creation of edit checks for each of the fields with a CRF based on Data standards (wherever available) and generates new specs based on provided input protocol



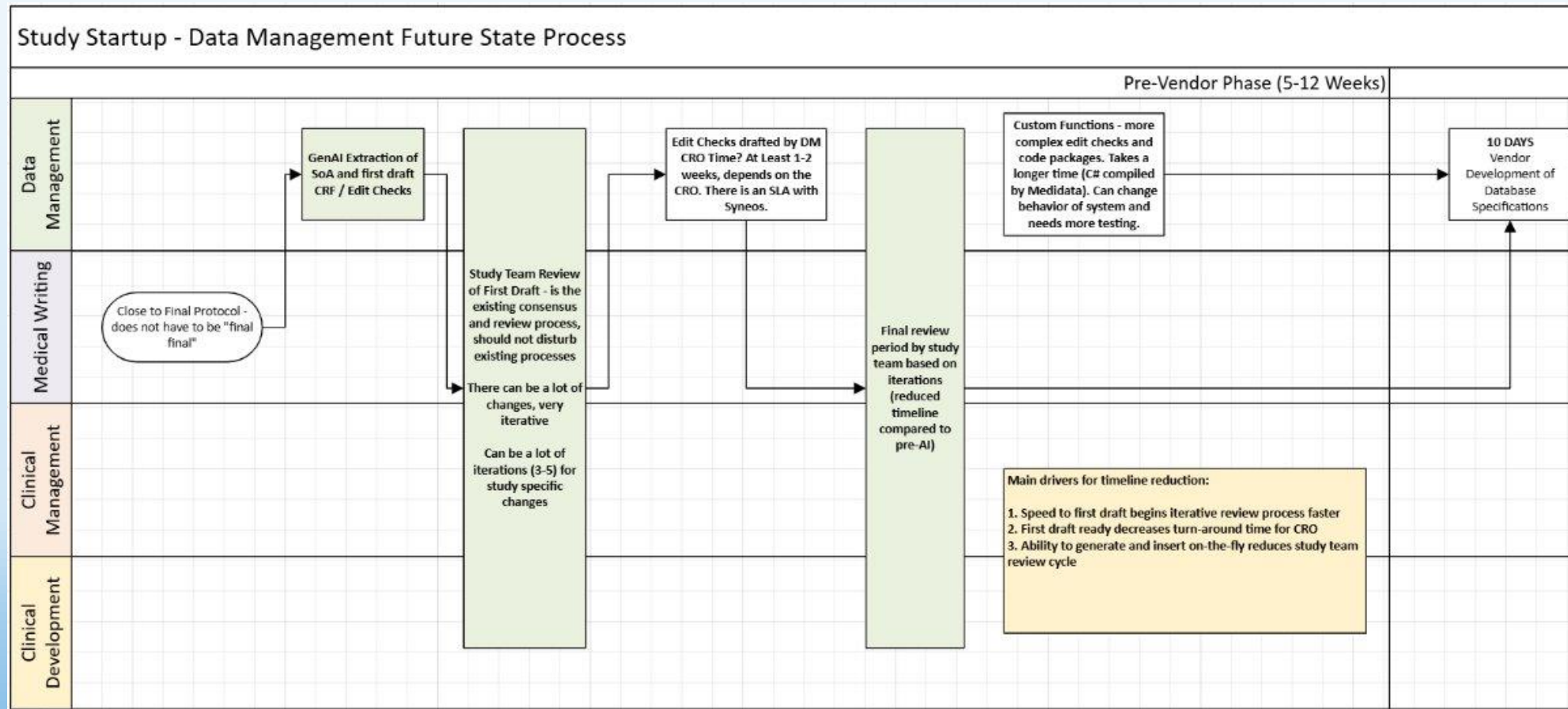
Prior Process vs. Future Process

Prior process takes up to 4 months, with most of the time for CRF review



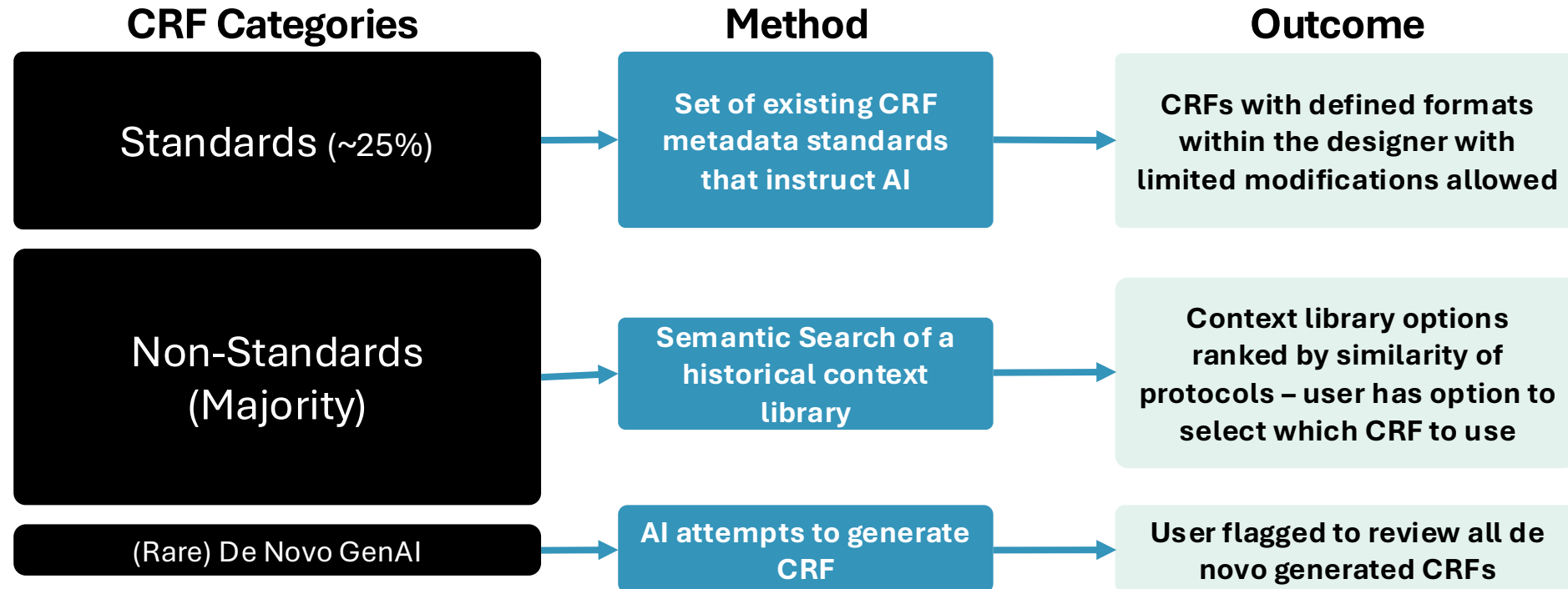
Prior Process vs. Future Process

Future process will start earlier in the protocol development process and reduce time for CRF and edit check selection and development, saving up to 1 month



How Standards Are Used in the Process

- Standard clinical metadata is the primary source for matching the CRFs and edit checks
- Currently the standard metadata matches about 25% of the time
- As new clinical metadata standards are created, match expected to increase to about 80%



Architecture and AI Technology

Use cases are built on scalable platforms and add to platforms – and add new patterns

R&D application examples

Writing Assistant

CRF Generation

ICF Generation

Edit Check
Specification

Gen AI Platform

Agents

Critique Agent

Image Copy
AgentSummarization
Agent

Data Copy Agent

Inferencing Agent

Supervisor Agent

Tone Agent

Content
Customization
Agent

Reflection Agent

CRF Generation
Agent

Planner Agent

Ask AI Agent

LLM Connectors

LLM
Gateway

LLM Models

Embedding Models

Data
ExtractionData Extraction/Parsing-
Docx / PDF/PPTx

Chunking

Vector
Embedding &
IndexingGen AI
UtilitiesVector DB
ConnectorModel
Evaluation

Re-ranking

Context
RetrieverFeedback
CaptureVector DB Data
Cleanup

Data Retrieval

LLMOps

LLM User
SecurityUsage
GuardrailsPerformance
MonitoringCentralized Cost
Dashboard & LLM
Usage TrackingAudit Trail &
LoggingAdoption
DashboardAccess
ComponentsContent
Generation APIsContent
Management APIs

Data Access Pipeline

Data Layer

Source data – Standardized
& Unstandardized PDFs

Vector DB

Metadata Store

Feedback Store

Infrastructure

Compute

SSO Login

Infra
Monitoring

O365 Plugin

GBAC – Group
Based Access
ControlWeb App
Hosting

AI Evaluation

Data Science Perspective utilizes “Gold Standard Testing Dataset” to automate validation testing

Automation script developed to automatically validate test dataset against CRF Generation outputs

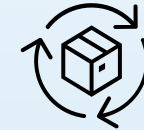
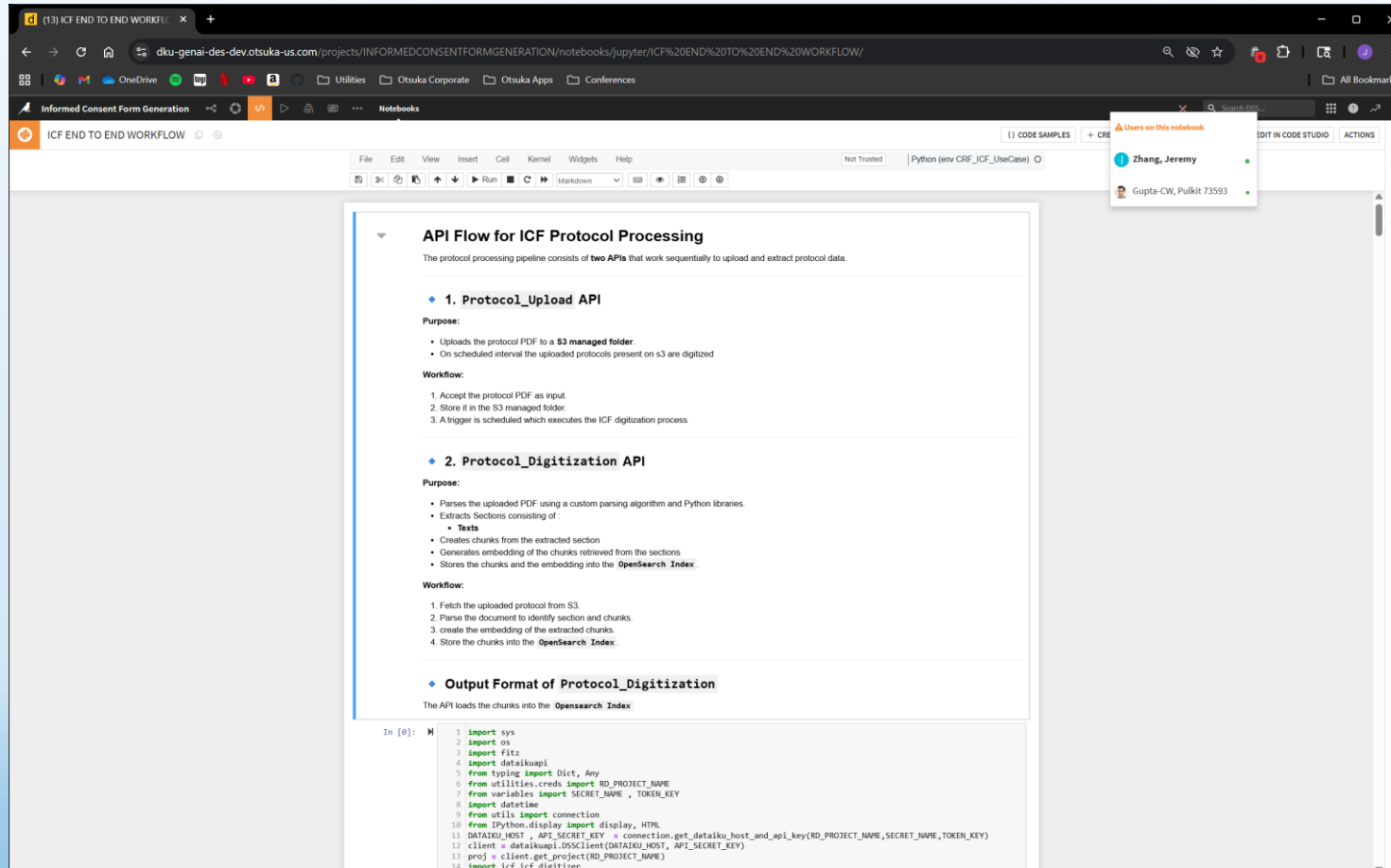
Five representative studies chosen as validation dataset



Protocol ID redacted

Testing Parameters			Gold Standard Testing Dataset (CRF)				Actual Output (CRF Tool)					Triage	
Protocol ID / Name	CRF Document Name	Date/Time of Test	Expected Form Name	Expected Field Name	Expected Field Value	Expected CRF Type (Standard, Historical, LLM)	Output Form Name	Output Field Name	Output Field Value	Output CRF Type (Standard, Historical, LLM)	Comments / Attachments	Product Owner Triage	Development Team Comment
Protocol ID redacted		10:13 am 9/29	only 116/121 forms are generated but the bar shows 121										
		10:13 am 9/29	Adverse Events	forms are generated as expected	values are displaying as expected	Standard	all the forms are generated as expected	fields are also generated as per standard CRF	values are also generated as expected	standard			
		10:13 am 9/29	Prior and concomitant medications	forms are generated as expected	values are displaying as expected	standard	all the forms are generated as expected	fields are also generated as per standard CRF	values are also generated as expected	standard			
		10:13 am 9/29	demographics	forms are generated as expected	values are displaying as expected	standard	all the forms are generated as expected	fields are also generated as per standard CRF	values are also generated as expected	standard			
		10:13 am 9/29	Informed Consent	forms are generated as expected	values are displaying as expected	standard	all the forms are generated as expected	fields are also generated as per standard CRF	values are also generated as expected	standard			
		10:13 am 9/29	medical history	forms are generated as expected	values are displaying as expected	standard	all the forms are generated as expected	fields are also generated as per standard CRF	values are also generated as expected	standard			
		10:13 am 9/29	12-lead ECG	forms are generated as expected	values are displaying as expected	Historical	all the forms are generated as expected	fields are also generated as per standard CRF	values are also generated as expected	historical			
		10:13 am 9/29	IMP Administration			Historical	all the extracted forms	Randomization fields are present in addition to required fields	Randomization values are present in addition to required values	historical(384-201-00002_ Annotated Unique CRF_04Nov2024 .pdf)	attachment in sheet 6		
		10:13 am 9/29	Inclusion/exclusion			historical	screening -28to-2 form	footer values are displaying as fields	page numbers from historical CRF is displaying in values	historical(384-201-00002_ Annotated Unique CRF_04Nov2024 .pdf)	attachment in sheet 6		

Testing at scale – using LLMOps to automate AI testing and validation (incl. LLM as judge)



During development, automated LLMOps and testing provides continuous updates to AI engineering team on the **directional quality of iterative AI development.**

Extended Accuracy Testing

Shows significant accuracy relative to protocol SoA and ground truth CRF's

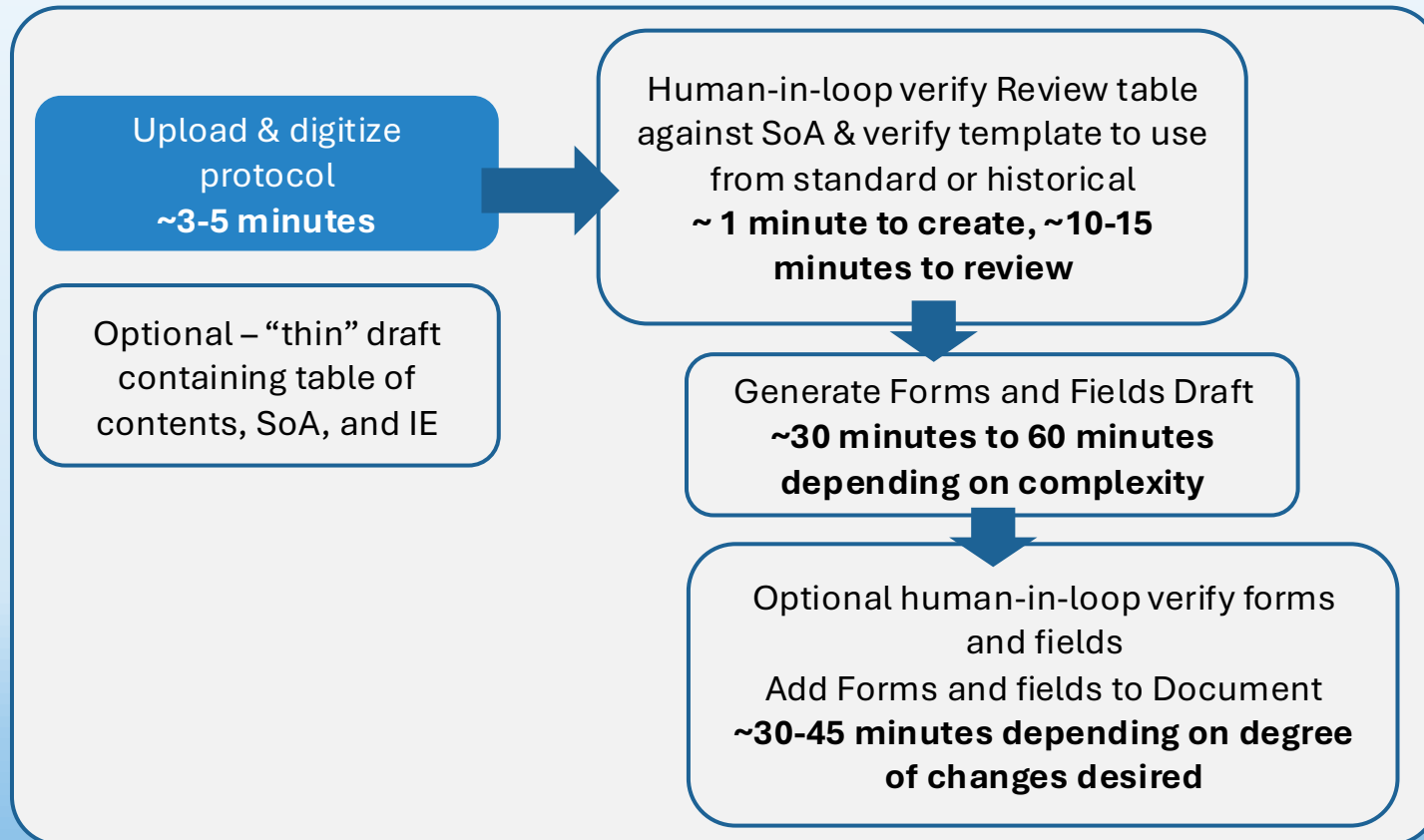
Protocol	Accuracy
Protocol #1	100%
Protocol #2	100%
Protocol #3	98.60%
Protocol #4	100%
Protocol #5	100%

- At a form level compared to ground truth SOA – the GenAI tool exhibits nearly 100% accuracy on a set of ground truth protocols.
- At a field level > based on system qualification testing anticipate per protocol ~4 to 5 forms require field updates for non-standard forms.
- Overall, less than 1% of forms and less than 5% of Form-Fields anticipated to require human intervention, meeting project goal of less than 10% interventions required.

The User Journey

CRF Workflow

- Approximate operating time 45-60 minutes
- Approximate review time 30-45 minutes



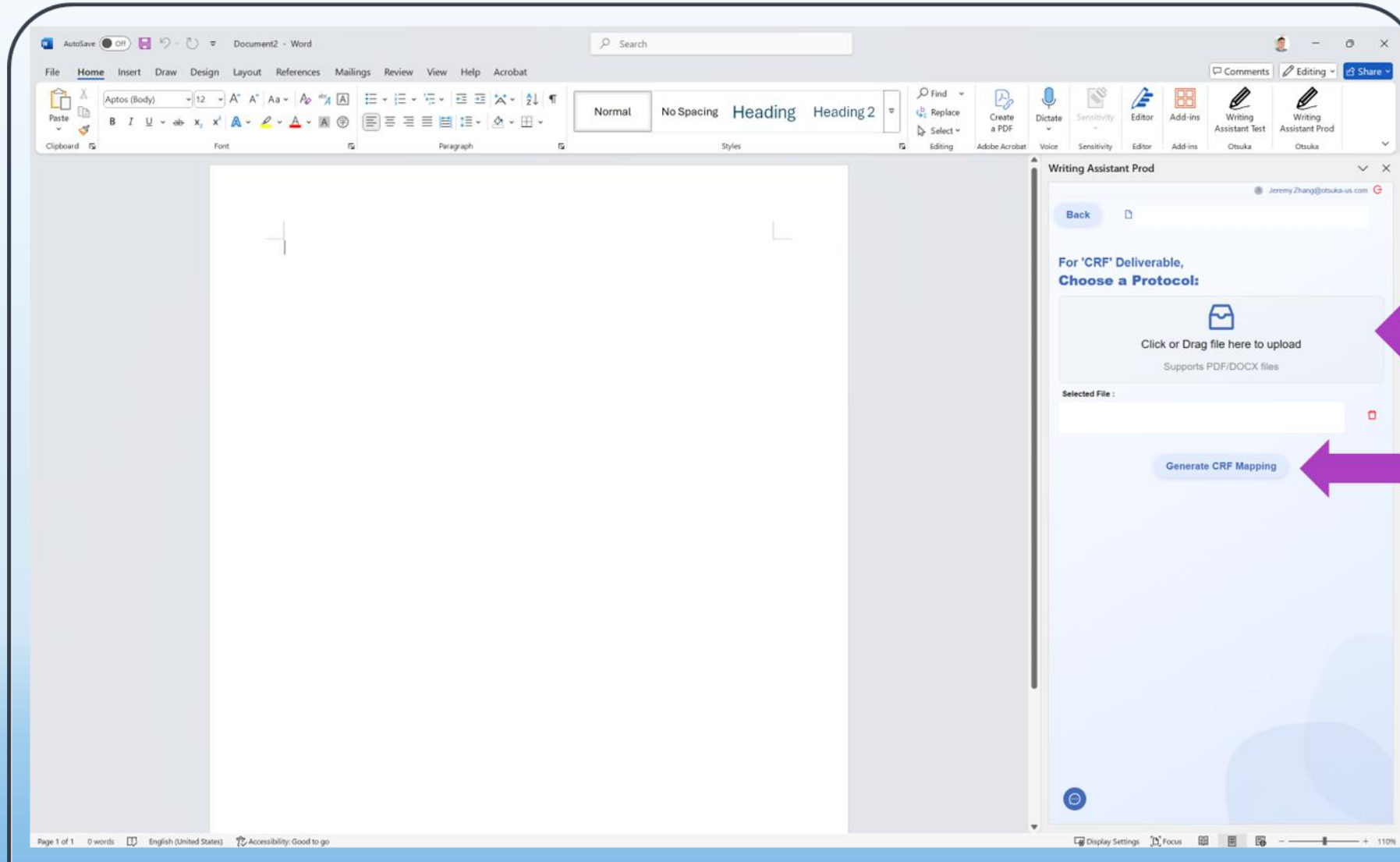
Outcomes

Early review with study teams – enabling parallel review of CRF content during protocol finalization

Concise initial requirements for CRO to conduct CRF entry – decreasing time to generate final CRF

Early generation of draft ECS for review with study teams

Upload Protocol and Generate Mapping



Upload protocol

Generate CRF Mapping

Mapping Results with Visit Schedule

Q Search Form Name

Form Name	Source	Select Template	Screening/PA w...	Check-in_1	Treatment_14	Washout (in-cli...	Discharge/ ET...
Informed Consent	Standard CRF	Global metadata specifications	☒	☐	☐	☐	☐
Demographics	Standard CRF	Global metadata specifications	☒	☐	☐	☐	☐
Inclusion/Exclusion Criteria	Historical CRF	Prior protocol CRF P#X	☒	☒	☐	☐	☐
Medical History	Standard CRF	Global metadata specifications	☒	☐	☐	☐	☐
Heightb	Historical CRF	Prior protocol CRF P#X	☒	☐	☐	☐	☐
Weight, BMI, and Waist Circumferenceb	Historical CRF	Prior protocol CRF P#X	☒	☒	☒	☒	☒
Pregnancy Test (POCBP)d	Historical CRF	Prior protocol CRF P#X	☒	☒	☐	☐	☐
FSH test	Historical CRF	Prior protocol CRF P#X	☒	☐	☐	☐	☐

For historical library, user is able to select the historical protocol from which to pull the CRF

Schedule of Assessments Review

Each time point corresponds to assessment on the SoA and can be reviewed to ensure consistency

Form Name	Screening/PA w...	Check-in_1	Treatment_14	Washout (in-cli...	Discharge/ ET...
Informed Consent	1 ☒	☐	☐	☐	☐
Demographics	2 ☒	☐	☐	☐	☐
Inclusion/Exclusion Criteria	☒ 3a	☒ 3b	☐	☐	☐
Medical History	4 ☒	☐	☐	☐	☐
Height ^b	5 ☒	☐	☐	☐	☐
Weight, BMI, and Waist Circumference ^b	☒ 6a	☒ 6b	☒ 6c	☒ 6d	☒ 6e
Pregnancy Test (POCBP) ^d	☒ 7a	☒ 7b	☐	☐	☐
FSH test	8 ☒	☐	☐	☐	☐

Table 1.3-1 Schedule of Assessments for Cohorts 1 to 3																			
Period	Screening/PA washout ^a	Check-in	Treatment														Washout (in-clinic)	Discharge ^a / ET ^a	Telephone follow-up
Trial Day	-28 to -1	-1	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15 to 17	18	44 (+ 2)
ENTRANCE/HISTORY																			
Informed Consent	X 1																		
Demographics	X 2																		
Inclusion/Exclusion Criteria	X 3a	X 3b																	
Medical History	X 4																		
Height ^b	X 5																		
Weight, BMI, and Waist Circumference ^b	X 6a	X 6b														X 6c	X ^c 6d	X 6e	
Pregnancy Test (POCBP) ^d	X 7a	X 7b																	
FSH test	X 8																		

Review Forms and Fields and Make Adjustments

Writing Assistant Prod

Back 384-201-00002 Protocol Amendment

Form	Field Label	Value	Actions
inclusion/exclusion criteria	Were measurements performed?	☐ Y x ☐ N x New option...	
inclusion/exclusion criteria	If no, specify		
informed consent	Date		
medical history	Time		
heightb	Derived date		
weight, bmi, and waist circumferenc	Weight		
weight, bmi, and waist circumferenc	BMI		
weight, bmi, and waist circumferenc			
weight, bmi, and waist circumferenc			
pregnancy test (pocbp)d			
pregnancy test (pocbp)d			
fish test			
weight, bmi, and waist circumferenc			
hepatitis and hiv screen			
check-in			
alcohol and drug screene			

Epoch: dischargea/ eta_18
Form: weight, bmi, and waist circumferencb
Note: section 5.2.1

New field label Text Add Field

Review individual form and fields

Fields can be changed or deleted as needed

For Standard CRFs Only Allowable Modifications Can Be Made

Fields for standards are pre-populated according to the standard.

Writing Assistant Prod - [https://aiwriter-prod.otsuka-us.com/CRFReviewDialog.html?_host_Info=Word\\$Win32\\$16.01\\$en-US\\$telemetry\\$isDialog\\$\\$0](https://aiwriter-prod.otsuka-us.com/CRFReviewDialog.html?_host_Info=Word$Win32$16.01$en-US$telemetry$isDialog$$0)

Epoch: screening/pa washout_28 to 1

Form: informed consent

Note:

Field Label	Value	Actions
Type of Consent	☐ DNA Storage × ☐ Future Testing × ☐ General × ☐ Genetic testing × ☐ Genetic Testing and DNA Storage × ☐ Study Participation × ☐ Study Treatment × New option...	
Protocol Version Number	☐ Original × ☐ Amendment 1 × ☐ Amendment 2 × ☐ Amendment 3 × ☐ Amendment 4 × ☐ Amendment 5 × ☐ Amendment 6 × ☐ Amendment 7 × ☐ Amendment 8 × ☐ Amendment 9 × ☐ Amendment 10 × New option...	
Was informed consent obtained?	☐ No × ☐ Yes × New option...	
Date of Consent		
Time of Consent		
Signed by	☐ Parent/Guardian × ☐ Subject × New option...	

New field label Text

Fields can be modified or deleted per the clinical metadata standards

Identified in global clinical metadata standards as form fields that should not be edited

After Review User Adds Forms to the CRF

AutoSave Off Document1 - Word

File Home Insert Draw Design Layout References Mailings Review View Help Acrobat

Clipboard Font Paragraph Styles Editing Adobe Acrobat Voice Sensitivity Editor Add-ins Comments Editing Share

CRF Page 4

Epoch: screening/pa washout_28 to 1

Form: medical history

Source: Standard CRF

What was the date that the medical history was collected?

Has the subject experienced any past and/or concomitant diseases or past surgeries?

☐ No
☐ Yes

What is the medical history identifier?

Category for Medical History

Subcategory for Medical History

What is the verbatim term for the medical history condition/event?

Page 2 of 3 119 words English (United States) Accessibility: Good to go

Writing Assistant Prod

Back 384-201-00002 Protocol Amendment_v20Mar2025 20 Mar 2025.pdf

Form	Folder	Action
inclusion/exclusion criteria	check-in_1	
inclusion/exclusion criteria	screening/pa washout_2...	
informed consent	screening/pa washout_2...	
medical history	screening/pa washout_2...	
heightb	screening/pa washout_2...	
weight, bmi, and waist circumferencecb	washout (in-clinic)_15 to 17	
weight, bmi, and waist circumferencecb	screening/pa washout_2...	
weight, bmi, and waist circumferencecb	check-in_1	
weight, bmi, and waist circumferencecb	treatment_14	
pregnancy test (pocbpd)	screening/pa washout_2...	
pregnancy test (pocbpd)	check-in_1	
fish test	screening/pa washout_2...	
weight, bmi, and waist circumferencecb	discharge/eta_18	
hepatitis and hiv screen	screening/pa washout_2...	
check-in	check-in_1	
alcohol and drug screene	check-in_1	
randomization	treatment_1	
alcohol and drug screene	screening/pa washout_2...	
mini	screening/pa washout_2...	
imp administration	treatment_5	
imp administration	treatment_4	
imp administration	treatment_1	
imp administration	treatment_3	
imp administration	treatment_2	
imp administration	treatment_9	
imp administration	treatment_10	
imp administration	treatment_7	
imp administration	treatment_8	
imp administration	treatment_6	
discharge	discharge/eta_18	
imp administration	treatment_13	
imp administration	treatment_14	

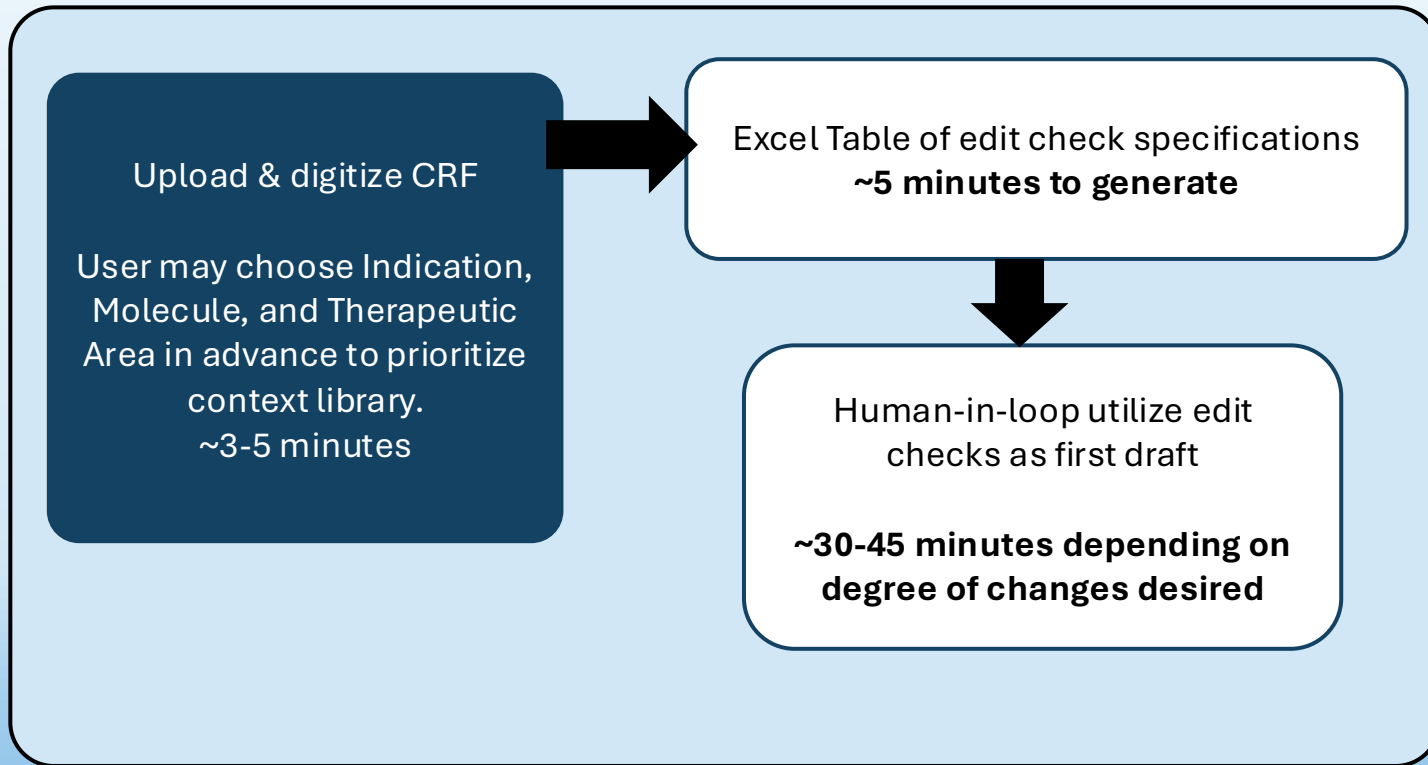
Click Word icon to add to document

Click to add enforces human-in-the-loop

To reduce time to generate, forms are created streaming so items can be reviewed in advance

Edit Check Specification Workflow

- Approximate operating time 5-10 minutes
- Approximate review time 30-45 minutes



Outcomes

Early review with study teams

Concise initial draft and requirements for edit check specifications for CRO to enter

Edit Check Specification Output Example

Including cross-form checks, ECS expected to generate 90%+ edit checks accurate to standards and historical references

Validation ID	Indication	Molecule	Therapeutic	Domain Name	Field OIDs	Variable	Source	Validation Logic	Reasoning	Action
1	DYN_EG_LOG_EGABN_S			12-Lead ECG Triplicate	['EGPERF', 'INTP_EGORRES', 'EGABN', 'EG Historical				nan	Set Datapoint Visibl
2	DYN_EG_LOG_EGPERF_S			12-Lead ECG Triplicate	['EGPERF', 'EGPOS', 'EGDAT', 'EGTIM', 'EG Historical				nan	Set Datapoint Visibl
3	DYN_EG_LOG_EGREASN			12-Lead ECG Triplicate	['EGPERF', 'EGREASND']				nan	Set Datapoint Visibl
4	EG_TRIP_LOG016			12-Lead ECG Triplicate	['PRAG_EGORRES']				nan	Open Query
5	EG_TRIP_LOG017			12-Lead ECG Triplicate	['QRSAG_EGORRES', 'QRSAG_EGORRES']				nan	Open Query
6	EG_TRIP_LOG024			12-Lead ECG Triplicate	['EGHRMN_EGORRES']				nan	Open Query
7	DYN_EG_EGABN_SET_V			12-Lead ECG Triplicate - 3 Hc	['EGPERF', 'INTP_EGORRES', 'EGABN', 'EG Historical				nan	Set Datapoint Visibl
8	DYN_EG_EGPERF_SET_V			12-Lead ECG Triplicate - 3 Hc	['EGPERF', 'EGPOS', 'EGDAT', 'EGREPNUM Historical				nan	Set Datapoint Visibl
9	DYN_EG_EGREASN_SET_V			12-Lead ECG Triplicate - 3 Hc	['EGPERF', 'EGREASND']				nan	Set Datapoint Visibl
10	EG_TRIP002			12-Lead ECG Triplicate - 3 Hc	['EGDAT', 'EGTIM', 'EG_TRIP_EGREPNUM Historical				nan	Open Query
11	EG_TRIP003			12-Lead ECG Triplicate - 3 Hc	['EGHRMN_EGORRES', 'EGHRMN_EGORR Historical				nan	Open Query
12	EG_TRIP005			12-Lead ECG Triplicate - 3 Hc	['PRAG_EGORRES', 'PRAG_EGORRES']				nan	Open Query
13	EG_TRIP006			12-Lead ECG Triplicate - 3 Hc	['QRSAG', 'QRSAG_EGORRES']				nan	Open Query
14	DYN_EG_LOG_EGABN_S			12-Lead ECG Triplicate Log	['EGPERF', 'INTP_EGORRES', 'EGABN', 'EG Historical				nan	Set Datapoint Visibl
15	DYN_EG_LOG_EGPERF_S			12-Lead ECG Triplicate Log	['EGPERF', 'EGPOS', 'EGDAT', 'EGTIM', 'EG Historical				nan	Set Datapoint Visibl
16	DYN_EG_LOG_EGREASN			12-Lead ECG Triplicate Log	['EGPERF', 'EGREASND']				nan	Set Datapoint Visibl
17	EG_TRIP_LOG016			12-Lead ECG Triplicate Log	['PRAG_EGORRES']				nan	Open Query
18	EG_TRIP_LOG017			12-Lead ECG Triplicate Log	['QRSAG_EGORRES', 'QRSAG_EGORRES']				nan	Open Query
19	EG_TRIP_LOG024			12-Lead ECG Triplicate Log	['EGHRMN_EGORRES']				nan	Open Query
20	DYN_RS_PWC_RSYN_SE			20-Item Physician Withdraw	['RSYN', 'RSDTC', 'RSTIM', 'PWC0101_RSC Historical				nan	Set Datapoint Visibl
21	DYN_RS_AIMS_RSYN_SE			Abnormal Involuntary Movem	['RSYN', 'RSDTC', 'RSTIM', 'AIMS0101_RSC Historical				nan	Set Datapoint Visibl
22	MVAL_AE030			Adverse Events	['AEONGO', 'AEENDAT']				If AE is not onq AE.AEENDAT is ente	
23	MVAL_AE030			Adverse Events	['AEONGO', 'AEENDAT']				If AE is not onq AE.AEENDAT is ente	
24	MVAL_AE031			Adverse Events	['AEONGO', 'AEENTIM']				If AE is not onq AE.AEENTIM is ente	
25	MVAL_AE031			Adverse Events	['AEONGO', 'AEENTIM']				If AE is not onq AE.AEENTIM is ente	
26	MVAL_AE033			Adverse Events	['AESER', 'AESCONG']				If AE is serious AE.AESCONG is ente	
27	MVAL_AE033			Adverse Events	['AESER', 'AESCONG']				If AE is serious AE.AESCONG is ente	
28	MVAL_AE033			Adverse Events	['AESER', 'AESDISAB']				If AE is serious AE.AESDISAB is ente	
29	MVAL_AE034			Adverse Events	['AESER', 'AESDISAB']				If AE is serious AE.AESDISAB is ente	
30	MVAL_AE034			Adverse Events	['AESER', 'AESDTH']				If AE is serious AE.AESDTH is ente	
31	MVAL_AE035			Adverse Events	['AESER', 'AESDTH']				If AE is serious AE.AESDTH is ente	
32	MVAL_AE035			Adverse Events	['AESER', 'AESDTH']				If AE is serious AE.AESDTH is ente	
33	MVAL_AE036			Adverse Events	['AESER', 'AESHOSP']				If AE is serious AE.AESHOSP is ente	
34	MVAL_AE036			Adverse Events	['AESER', 'AESHOSP']				If AE is serious AE.AESHOSP is ente	
35	MVAL_AE037			Adverse Events	['AESER', 'AESLIFE']				If AE is serious AE.AESLIFE is ente	
36	MVAL_AE037			Adverse Events	['AESER', 'AESLIFE']				If AE is serious AE.AESLIFE is ente	
37	MVAL_AE038			Adverse Events	['AESER', 'AESMIE']				If AE is serious AE.AESMIE is ente	
38	MVAL_AE038			Adverse Events	['AESER', 'AESMIE']				If AE is serious AE.AESMIE is ente	
39	MVAL_AE041			Adverse Events	['AETERM']				Field must not prompt user with AC	
40	MVAL_AE041			Adverse Events	['AETERM']				Field must not prompt user with AC	
41	MVAL_AE042			Adverse Events	['FAORRES', '<AETERMCD>']				Field must not prompt user with AC	
42	MVAL_AE042			Adverse Events	['FAORRES', '<AETERMCD>']				Field must not prompt user with AC	
43	MVAL_AE045			Adverse Events	['AESTDAT']				Field must not prompt user with AC	
44	MVAL_AE045			Adverse Events	['AESTDAT']				Field must not prompt user with AC	
45	MVAL_AE046			Adverse Events	['AESTDAT']				Field must not prompt user with AC	

12-Lead ECG Edit Check
“Block” retrieved from prior
study and validated against
FIELD OIDs generated by LLM
from CRF upload

Standard AE Edit Checks
populated from global clinical
metadata standards

Concluding Remarks

- Agentic AI has evolved the AI implementation strategy
- Context is king
- End-to-end standards or MDR are not necessary precursors for value
- Change management matters more than technology

Presenters

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