



Intelligent build from protocol to EDC CDISC US Interchange – COSA Workshop

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Introduction

Working with OpenStudyBuilder

Clinical Automation

Demonstration

Metadata Extraction POC for Schedule of Activities EDC Study Build Automation

Moving forward

Metadata extraction potential applications Synthetic data generation



Introduction

Working with OpenStudyBuilder Clinical Automation

Oracle Life Sciences, Center of Excellence

Innovation projects

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Integration successful!...





... What's next?

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Automation

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STI DY BUILDER

Protocol metadata extraction

- Extracting clinical terminology (OCI Language, NLP)
- Schedule of Activities (OCI Vision & Document understanding)

OpenStudyBuilder

- Repository for study metadata
- Ensuring compliance
- Supporting downstream standards

Clinical One EDC

- Metadata pushed to study (or library)
- Study design validation
- Study conduct

Demonstration

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Metadata Extraction POC for Schedule of Activities

Schedule of Assessments (SoA) in PDF

STUDY EPOCH	SCREENING	TREATMENT	DOSE ESCALATION		FOL	LOW-UP	
VISIT SHORT NAME	V1	V2	V3	V4	V5	V6	V7
STUDY DAY	-14	1	29	57	85	91	101
VISIT WINDOW (DAYS)	±1	±1	±1	±1	±1	±1	±1
INFORMED CONSENT	X						
DEMOGRAPHY	X						
VITAL SIGNS	X	Х	Х	Х	х		
BODY MEASUREMENTS	X		Х	Х	Х		
MEDICAL HISTORY/CONCOMITANT ILLNESS	X						
PREGNANCY TEST	X	Х	Х	Х	Х		
RANDOMISATION		Х					
LABORATORY ASSESSMENTS	X	Х	Х	Х			
EPRO		Х	Х	Х			
COMPLIANCE WITH STUDY MEDICATION			Х	Х	х	х	
END OF STUDY							х
ADVERSE EVENT		Х	Х	Х	Х	х	х
CONCOMITANT MEDICATION	X	Х	Х	Х	Х	x	Х

OCI Vision Text Detection

Vision	Text detection	
	Detect and recognize text in an image	
Overview	Image source	
Image classification	Local file Object storage	Results (i)
Object detection	Upload image	
		Extraction by
Face detection	$\langle \uparrow \rangle$ Drop a file or <u>select one</u>	Une word
Text detection	Upload image	Q Search text
Custom models	STUDIERPOCH RCHATMART RECEIVANT EDSE ROLLOW-CH	STUDY EPOCH SCREENING
	VIETERADATE DE LE	TREATMENT DOSE FOLLOW-UP
Projects	NERTHANDOW/DATES III III III III III III III III III I	TREATMENT DOSE FOLLOW-UP
		ESCALATION VISIT SHORT NAME V1
	MEDICAL INSTONY/CONSISTANTILINESS R	V2 V3 V4 V5 V6 STUDY DAY
Model scope	RANDOMISATION KARDIATONYASSESSMENTE VERS	
Compartment	ECOMPLIANCE WITH STUDY MEDICATION	-14
Al-for-healthcare		Show more
oraseemeawest (root)/UKIE/NathanMolone	Images	
healthcare	//AFIOF	
		Request
	Belt Route	
		Response

OCI Document Understanding Table extraction

Document Understanding	Table extraction Identify tables in a document and extract their contents					
Overview Text extraction	Document source Demo files Local files Object storage	Results (i)	011		7777	
Table extraction	Upload image	Table results: (1)				
Key value extraction	C₁⊃ Drop a file or <u>select one</u>					
Document classification	Upload image	Tabl 🗘 🔍 Searc	ch text			
Custom models	Output location: Health-ai/OCI4RES34RCH Select to change output location	VISIT SHORT NAME		V2	V3	VA
Projects		STUDY DAY	-14		29	
	STUDY EPOCH SCREENING TREATMENT DOSE FOLLOW-UP	VISIT WINDOW (DAYS) CONSENT		IF	IF	IF
Model scope	VIST SHORT NAME V1 V2 V4 V4 V6 V2 STUDY CAV. EM 1 28 57 EM 11 12 VIST WINDOW (DAYS) L1 EM L1 EM L1 EM L1	INFORMED	+			
Compartment	LINI-ORXEE COMSENT # DIMOGRAPHY # VTTAL SIGNS X X X X	DEMOGRAPHY	+			
oraseemeawest (root)	BODY MEASUBERNINTS X X S MERICAL HISTORY/CONTANT ILLNESS X PRECINALCY TEST	VITAL SIGNS				
	BANDOMISATION N Lateromisation N	BODY MEASUREM SIN HISTORY/CO				
	ICONCOMITANT MEDICATION 4- 20 8 8 X X 8 Images	MEDICAL				
		PREGNANCY TEST		•		+
	Specific and specific	RANDOMISATION LABORATORY ASS	x	*	+	
	Selected: Screenshot 2024-10-17 at 11.54.56.png	EPRO		+ 1		+
		SMEN W COMPLIANCE W			+	
		END OF STUD				

OCI Data Science Example of scripts

ORACLE Cloud

Output: OSB specific JSON format

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Filter files by na	ame Q	B + %	C 🗋 🖹 ▶ ■ C → Code ∨ 🕴 Python 3 (ipykernel) C				
I							
			OCI Data Science - Useful Tips				
Name A	Last Modified		▼ Check for Public Internet Access				
<pre>{:} follow_up</pre>	a month ago		import requests				
📕 getting_s	4 months ago		<pre>response = requests.get("https://oracle.com") assert response.status code==200, "Internet connection failed"</pre>				
📕 getting_s	a month ago		► Helpful Documentation				
• 📃 getting_s	9 days ago		Typical Cell Imports and Settings for ADS				
📕 getting_s	9 days ago		Useful Environment Variables				
🍫 ich-m11-t	4 months ago	[2]: import pandas as pd					
• 📃 load_dat	9 days ago						
(:) matrixap	3 months ago		<pre># Example DataFrame simulating the extracted SOA table data = {</pre>				
• 📃 natural_l	4 months ago	'STUDY EPOCH': ['Screening', 'Treatment', 'Dose Escalation', 'Follow-up', 'Follow-up'], 'VISIT SHORT NAME': ['V1', 'V2', 'V3', 'V4', 'V5'],					
• 📃 ner-batc	a day ago		'STUDY DAY': [-14, 1, 29, 57, 85],				
<pre>{:} osb_json</pre>	a month ago		'VISIT WINDOW (DAYS)': ['±1', '±1', '±1', '±1'] }				
<pre>{:} sdtm_dat</pre>	3 months ago						
📕 sentimen	4 months ago	[3]:	: def convert_to_osb_format(row): # Extract the visit window range (e.g., ±1 becomes min and max values)				
{:} SOA-11_c	2 months ago		<pre>visit_window = row['VISIT WINDOW (DAYS)']</pre>				
SOA.json	3 months ago		<pre>min_visit_window_value = -int(visit_window.replace('±', '')) max_visit_window_value = int(visit_window.replace('±', ''))</pre>				
<pre>{:} study_ac</pre>	3 months ago		# Create the desired format				
📃 Untitled.i	4 months ago		<pre>osb_entry = { 'epoch_name': row['STUDY EPOCH'],</pre>				
🗅 untitled.txt	4 months ago		'time_value': row['STUDY DAY'], 'time_unit': 'days',				
📃 Untitled1	4 months ago		'max_visit_window_value': max_visit_window_value,				
• Untitled1 imple 2	2 minutes ago		<pre>'min_visit_window_value': min_visit_window_value, 'window_value': min_visit_window_value,</pre>				

(?) → Sian Out

Session remaining: 14min Extend

Video showing interface to upload JSON file, parse it and import SoA parts into OpenStudyBuilder:

(available from November)

https://novo-nordisk.gitlab.io/nnpublic/openstudybuilder/projectdescription/info_integrations/

Demonstration

EDC Study Build Automation

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Intelligent Study Build

API integration with Clinical One

Setup

Standards and study definition **OpenStudyBuilder**

Automated build

Metadata transfer Oracle Clinical Automation Study reveal **Clinical One**

Testing

UAT of study design **Clinical One**

Video showing setup in OpenStudyBuilder and automated import into EDC Oracle Clinical One

<u>https://novo-nordisk.gitlab.io/nn-</u> <u>public/openstudybuilder/project-</u> <u>description/info_integrations/</u>

Summary

OpenStudyBuilder (OSB)

- Metadata standards across studies and systems
- Consistent collaboration with multiple vendors (best-of-breed)

API integration

Automation reducing human error

Oracle Clinical Automation

- Simple, easy-to-use interface to manage automation
- Scalability for automating integrations
- Control over automation (push and pull from OSB)

Better collaboration to drive innovation

Moving forward

What's next

Implementing more **complex study designs***

- Branches
- Cycle visits (using repeating visits?)
- Randomization schemes
- Drug kits
- Titrations

* Dependent on OSB releases

What's next

Metadata extraction potential applications

• From protocol to... trial management, data management, data analysis

Synthetic data generation

- Avoid manually entered test data, which is labor-intensive and therefore costly
- Accelerate the trial design process by providing readily available data for validation
- Learn about how Oracle can support this:

https://blogs.oracle.com/machinelearning/post/announcing-select-ai-for-synthetic-data-generation