ORACLE
Life Sciences

Intelligent build from protocol to EDC

CDISC US Interchange – COSA Workshop

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Agenda

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,
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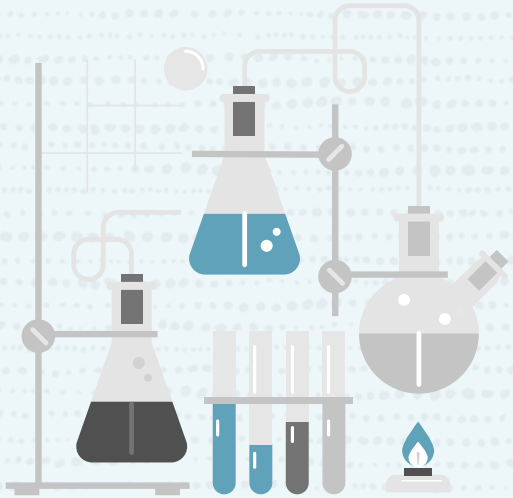
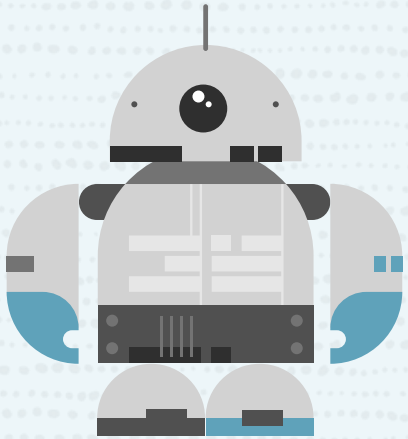
Innovation projects





Automation

Integration successful!...

… What's next?

Automation

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

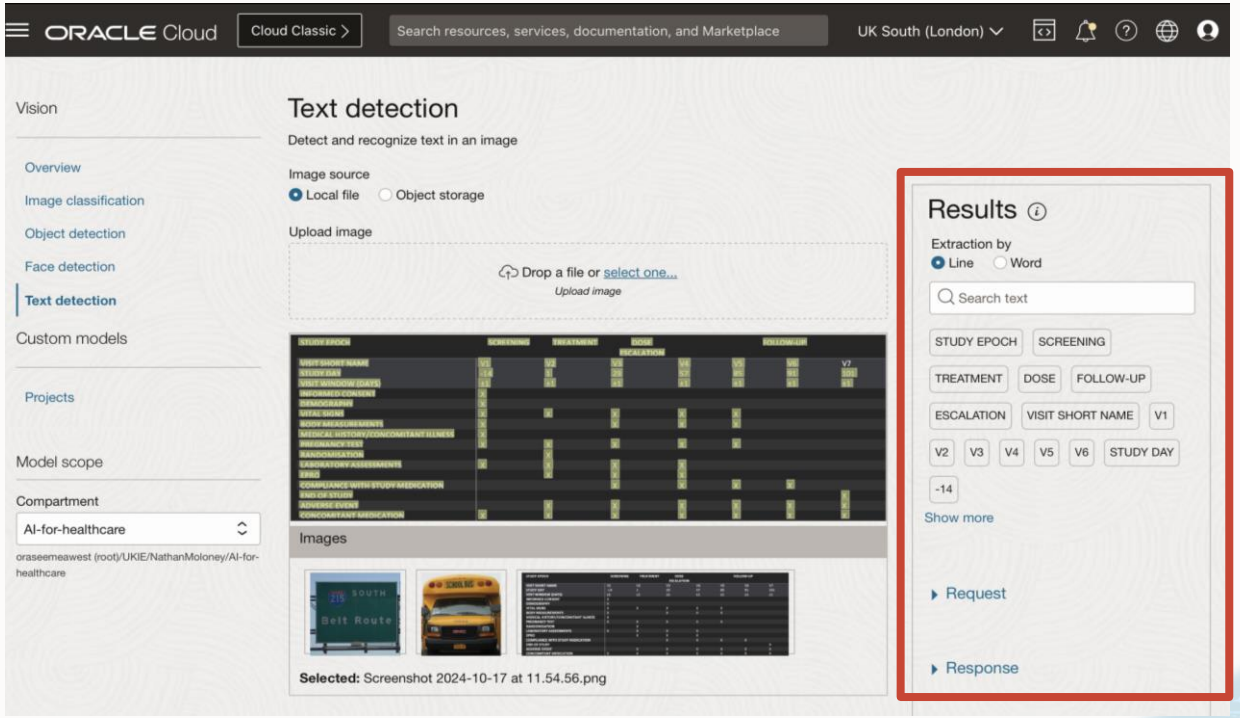
Metadata Extraction POC for Schedule of Activities

Schedule of Assessments (SoA) in PDF

STUDY EPOCH	SCREENING	TREATMENT	DOSE ESCALATION			FOLLOW-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	X	X	X	X		
BODY MEASUREMENTS	X		X	X	X		
MEDICAL HISTORY/CONCOMITANT ILLNESS	X						
PREGNANCY TEST	X	X	X	X	X		
RANDOMISATION		X					
LABORATORY ASSESSMENTS	X	X	X	X			
EPRO		X	X	X			
COMPLIANCE WITH STUDY MEDICATION			X	X	X	X	
END OF STUDY							X
ADVERSE EVENT		X	X	X	X	X	X
CONCOMITANT MEDICATION	X	X	X	X	X	X	X

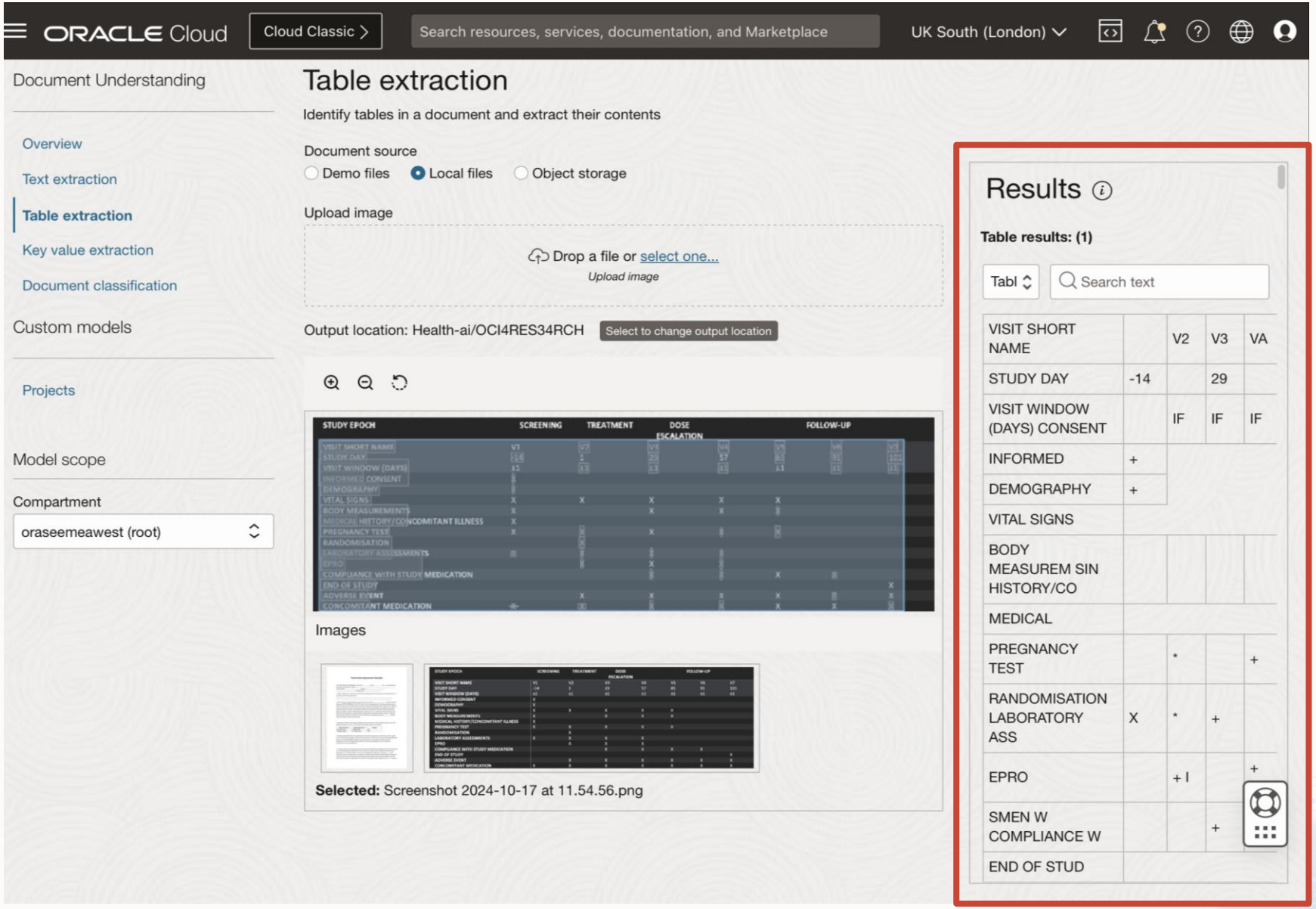
OCI Vision

Text Detection



OCI Document Understanding

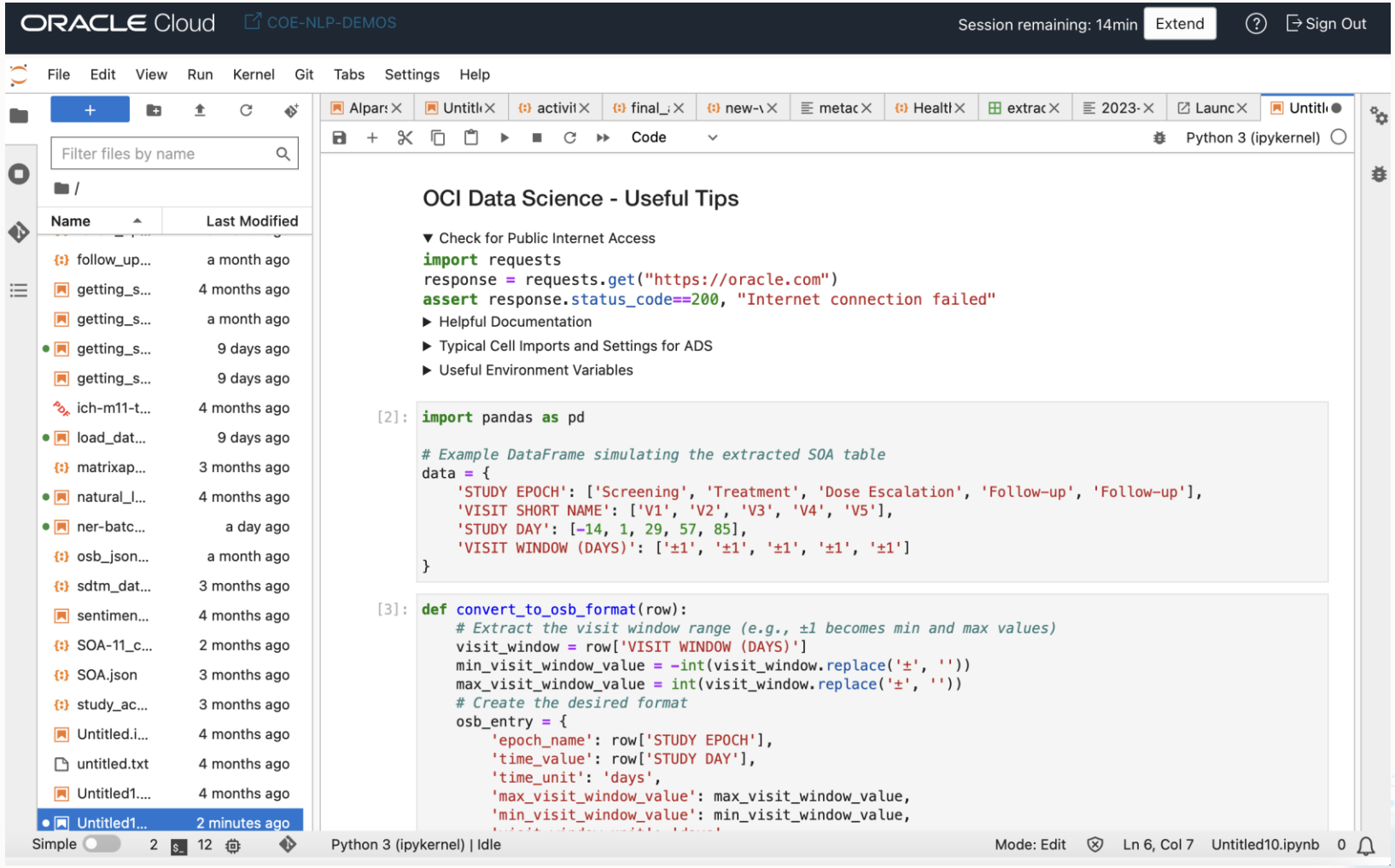
Table extraction



OCI Data Science

Example of scripts

Output: OSB specific JSON format



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

(available from November)

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

Demonstration

EDC Study Build Automation

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

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

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