Intelligent Study Build

Oracle Clinical One API integration & EvidentIQ ePRO API integration

Srinivas Karri, Global Head, Oracle Centre of Excellence

Nicole Kuisle, Executive Director, Customer Success, EvidentIQ

Sarah Jamal, Senior Solutions Consultant, Oracle

Tomasz Augustik, Product Owner (for Marvin EDC and Integrator), EvidentIQ

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The Objectives
of our demonstration covering **design**, **build** and **execute**

1	2	3
Streamline study design	Identify efficiency gains, lowering operational costs	Reduce time to study start

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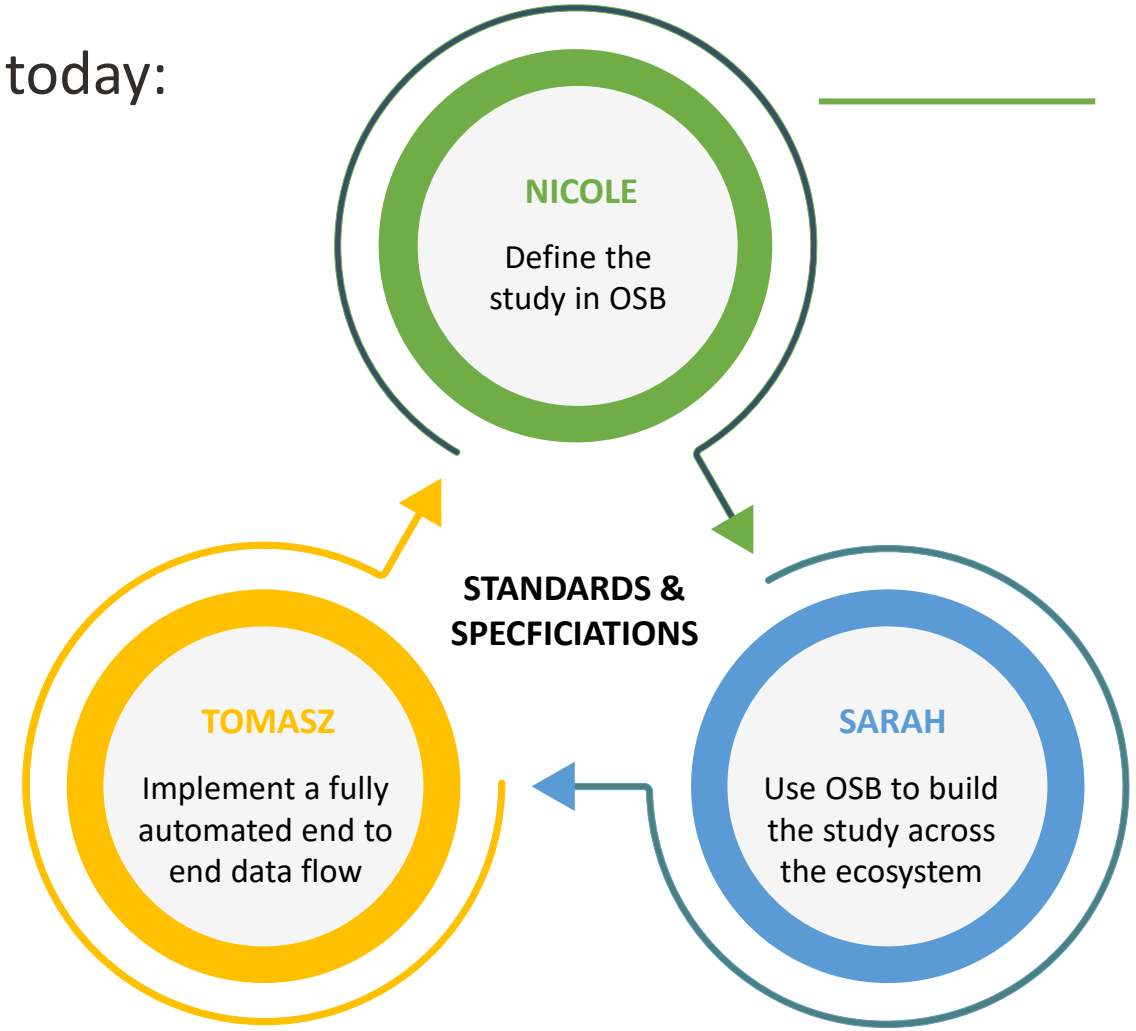
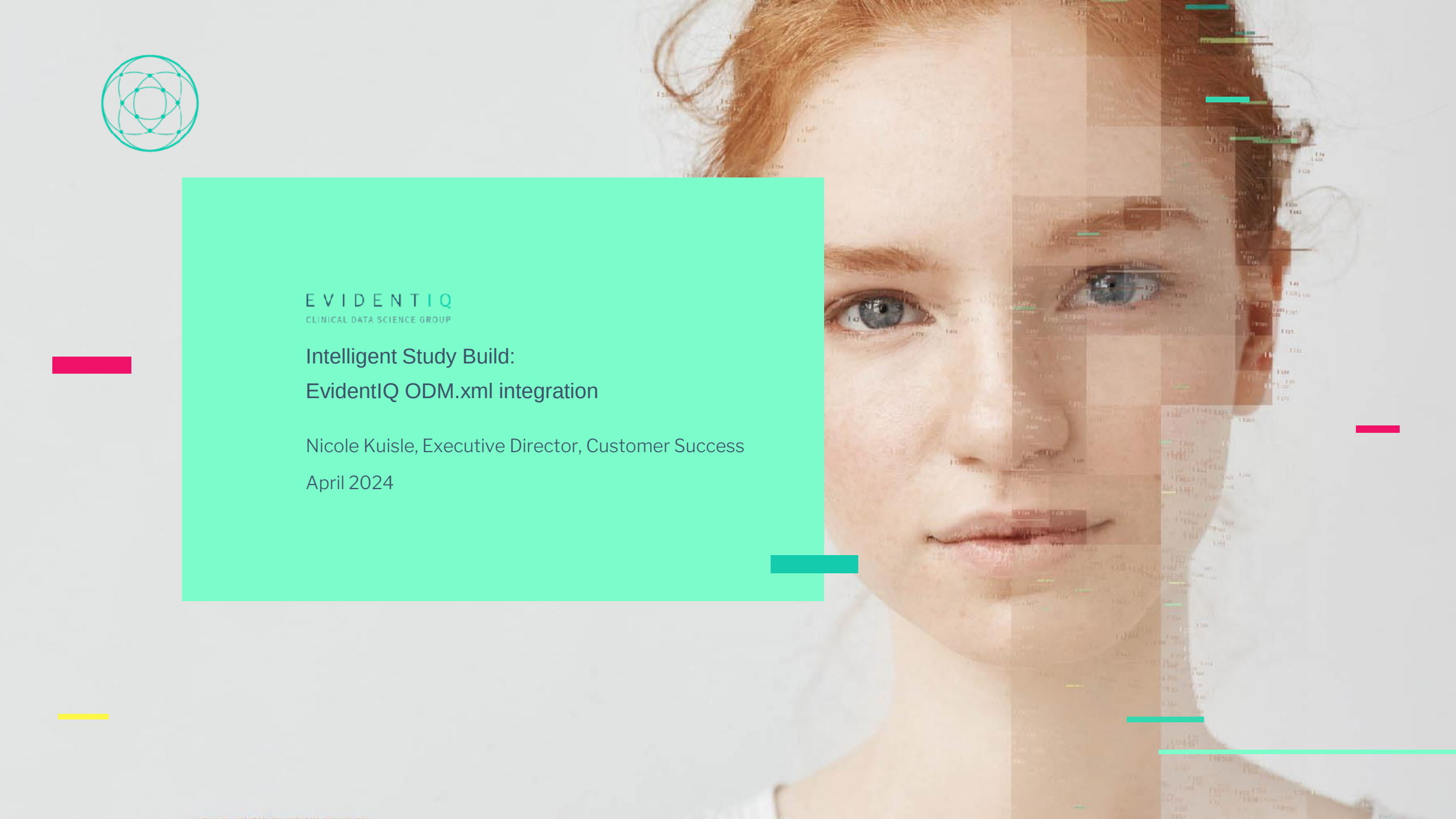
Intelligent Study Build

This is what you will see today:



ORACLE EVIDENTIQ



EVIDENTIQ
CLINICAL DATA SCIENCE GROUP

Intelligent Study Build:
EvidentIQ ODM.xml integration

Nicole Kuisle, Executive Director, Customer Success

April 2024

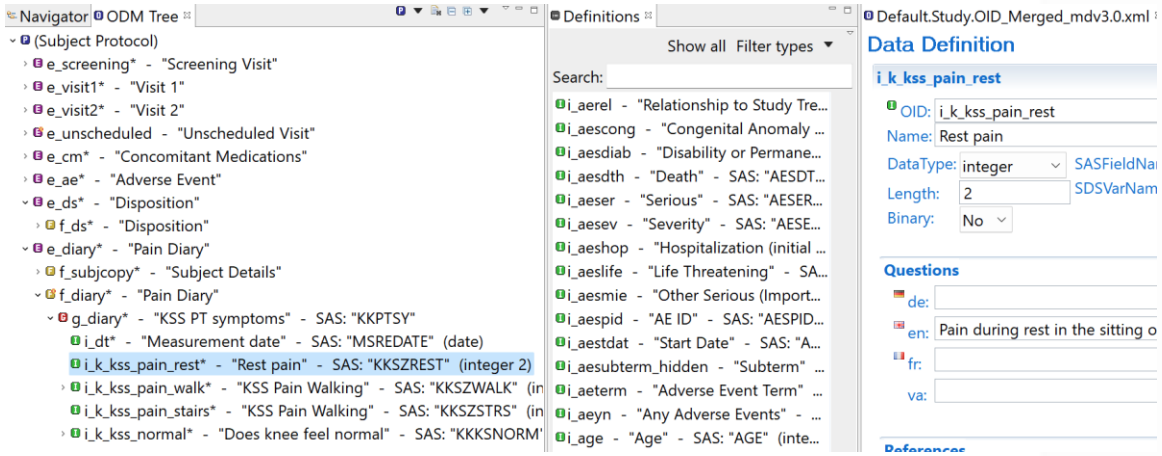
Marvin ePRO is a ODM native tool import files generated by the EvidentIQ Composer

General Approach

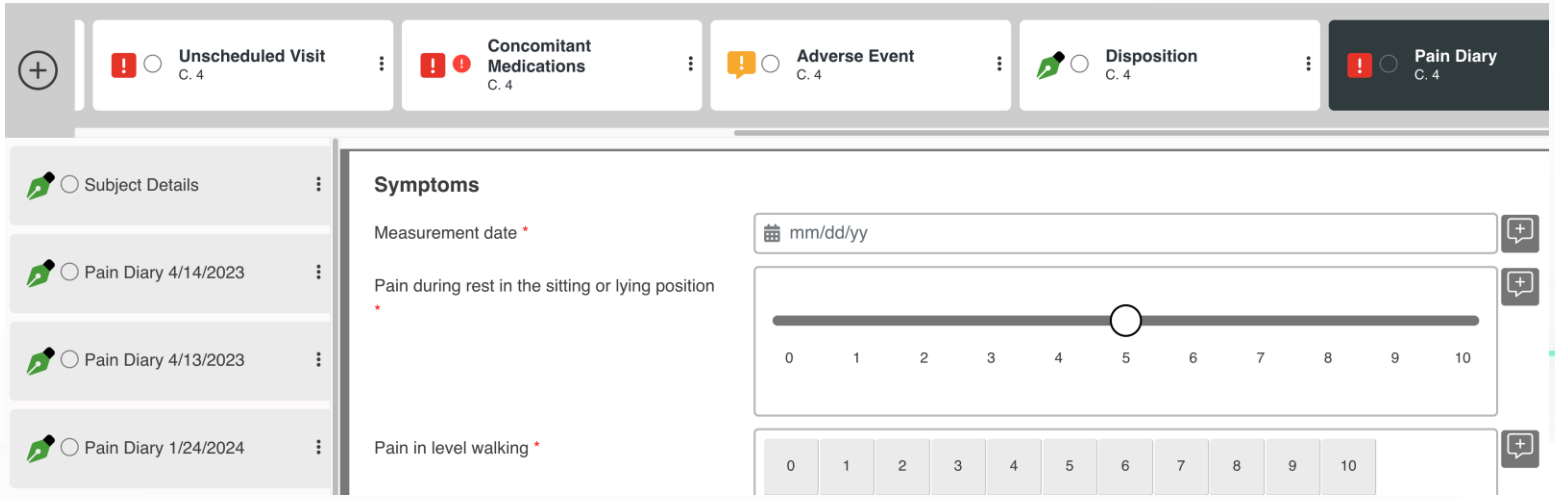
1. Create forms in the Composer which generates an ODM XML file
2. Upload ODM XML into Marvin
3. The eCRF which follows the ODM structure will appear on the screen

→ That's why EvidentIQ opted for the import method using the ODM-XML approach

Composer



Marvin



Demo

ODM XML export from OSB and into Marvin

Challenges for a smooth import from OSB to Marvin

Missing vendor extensions	Marvin is using vendor extensions to circumvent ODM limitations, e.g. display styles items, codelist etc.
OSB sponsor extensions	Marvin cannot process sponsor extensions from the OSB.
Missing conditional dynamics	The ODM XML export contains only the form without any dynamics or data checks.
Form based export	Marvin imports only full Study Definitions and requires the Event.
Lack of checks between systems	Marvin lacks the ability to detect changes made to the eCRF templates, and it doesn't verify if they still adhere to the standard in the OSB.

Prior to uploading to Marvin, the ODM XML requires postprocessing.

We need to integrate software-specific enhancements with our in-house eCRF designer tool.

Intelligent Study Build

Oracle Clinical One API integration

Sarah Jamal, Senior Solutions Consultant, Oracle

Intelligent Study Build

Setup

1. The Power of OpenStudyBuilder
2. Collaborating with consistency

Automated build

3. Introducing the Oracle Apex Tool
4. The Magic of Synchronization
5. Revealing the Clinical One Study Design
6. Validation Rules and Custom Rules

Testing

7. User Acceptance Testing

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Capability @ Play

Form design, visit structure and rules

Scene 1:

The Power of OpenStudyBuilder

1. Study design flexibility
2. Less manual effort
3. Reduced regulatory risk

What you'll see

OpenStudyBuilder's (OSB) capabilities, detailing the creation of visits, forms and form items, and the relevancy of OSB's extensions for defining complex validation rules

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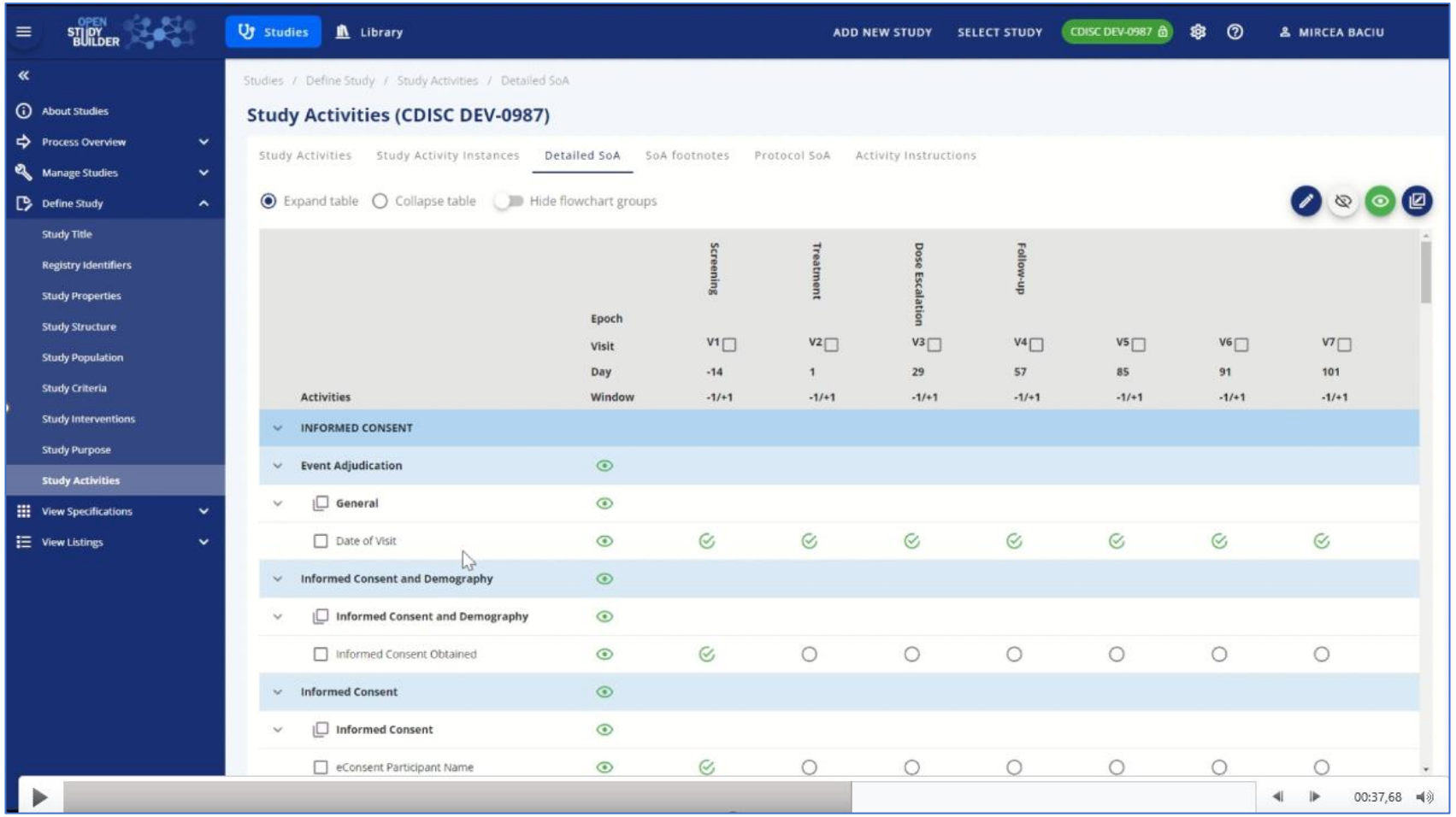
Live Video


OPEN STUDY BUILDER
Studies
Library
ADD NEW STUDY
SELECT STUDY
CDISC DEV-0987
MIRCEA BACIU
About Studies
Process Overview
Manage Studies
Define Study
Study Title
Registry Identifiers
Study Properties
Study Structure
Study Population
Study Criteria
Study Interventions
Study Purpose
Study Activities
View Specifications
View Listings
Studies / Define Study / Study Activities / Detailed SoA
Study Activities (CDISC DEV-0987)
Study Activities
Study Activity Instances
Detailed SoA
SoA footnotes
Protocol SoA
Activity Instructions
Expand table
Collapse table
Hide flowchart groups
Screening
Treatment
Dose Escalation
Follow-up
Epoch
Visit
Day
Window
Activities
V1
V2
V3
V4
V5
V6
V7
-14
1
29
57
85
91
101
-1/+1
INFORMED CONSENT
Event Adjudication
General
Date of Visit
Informed Consent and Demography
Informed Consent and Demography
Informed Consent Obtained
Informed Consent
Informed Consent
eConsent Participant Name
00:37,68

Capability @ Play	Scene 2:	What you'll see

Common data foundation

Collaborating with consistency

1. Consistent metadata
2. Single data structure
3. Direct mapping between vendors

We go deeper into the collaboration with EvidentIQ, ensuring consistency with a common data structure for eConsent and eCOA forms

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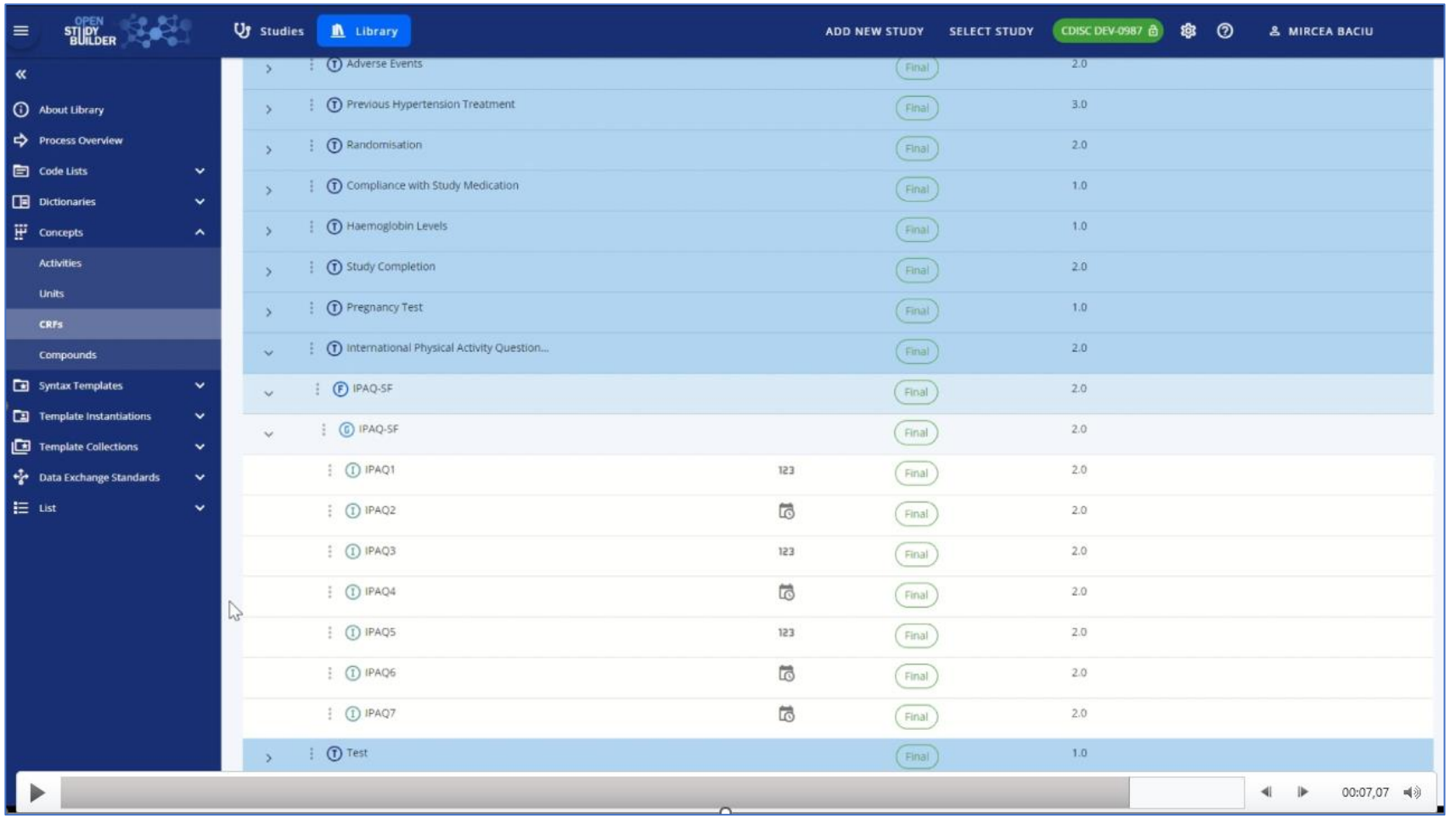
Live Video


OPEN STUDY BUILDER
Studies
Library
ADD NEW STUDY
SELECT STUDY
CDISC DEV-0987
MIRCEA BACIU
About Library
Process Overview
Code Lists
Dictionaries
Concepts
Activities
Units
CRFs
Compounds
Syntax Templates
Template Instantiations
Template Collections
Data Exchange Standards
List
Adverse Events
Previous Hypertension Treatment
Randomisation
Compliance with Study Medication
Haemoglobin Levels
Study Completion
Pregnancy Test
International Physical Activity Question...
IPAQ-SF
IPAQ-SF
IPAQ1
IPAQ2
IPAQ3
IPAQ4
IPAQ5
IPAQ6
IPAQ7
Test
Final
2.0
3.0
1.0
00:07,07

Capability @ Play	Scene 3:	What you'll see

API integration and automated workflows

Introducing the Apex Tool

1. Fast data transfer
2. Seamless integration
3. Reduced human error

Oracle Apex bridges OSB and Oracle Clinical One, emphasizing the efficiency of automating data transfer

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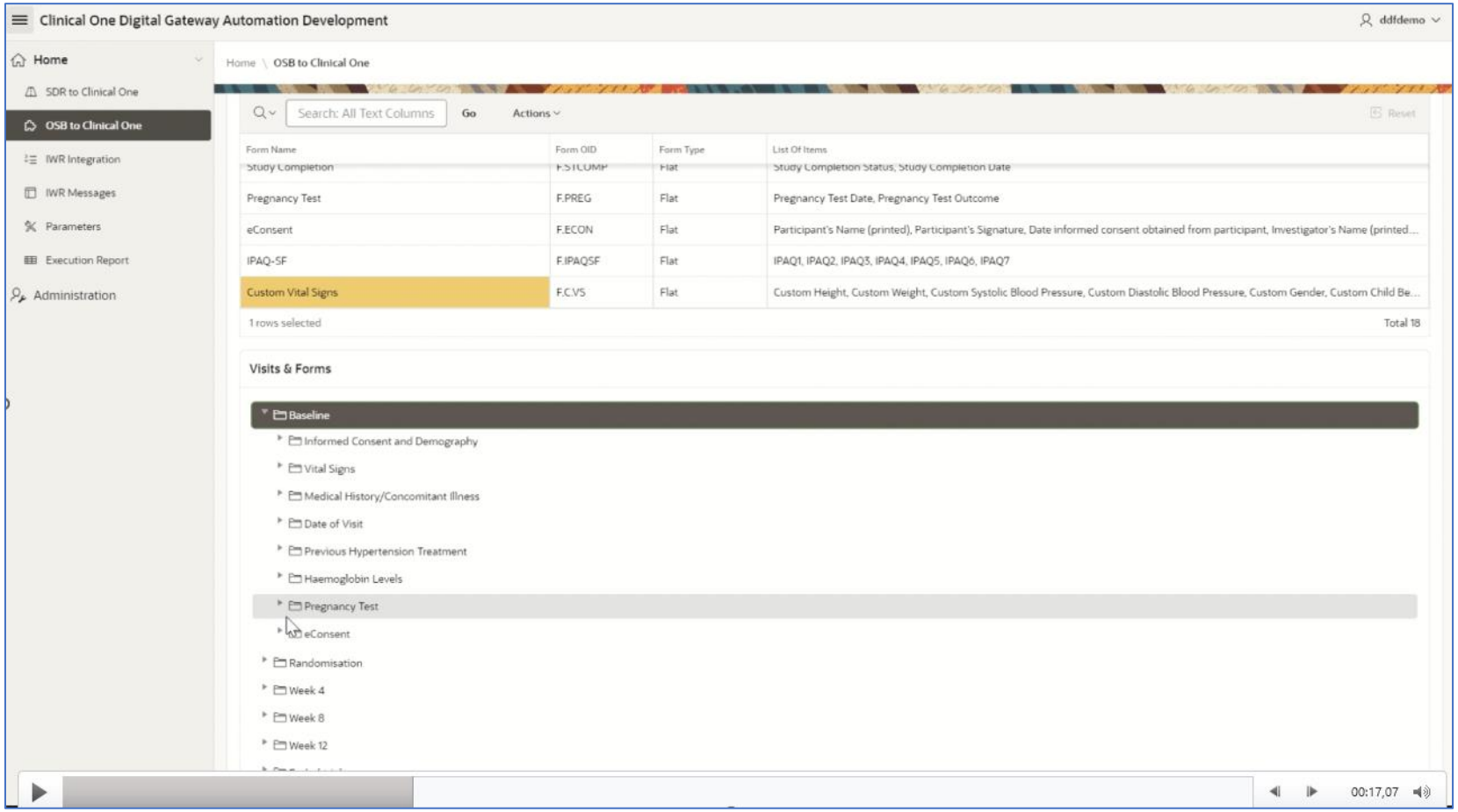
Live Video


Clinical One Digital Gateway Automation Development
ddfdemo
Home
SDR to Clinical One
OSB to Clinical One
IWR Integration
IWR Messages
Parameters
Execution Report
Administration
Home \ OSB to Clinical One
Search: All Text Columns
Go
Actions
Reset
Form Name
Form OID
Form Type
List Of Items
Study Completion
F.STCOMP
Flat
Study Completion Status, Study Completion Date
Pregnancy Test
F.PREG
Flat
Pregnancy Test Date, Pregnancy Test Outcome
eConsent
F.ECON
Flat
Participant's Name (printed), Participant's Signature, Date informed consent obtained from participant, Investigator's Name (printed...
IPAQ-SF
F.IPAQSF
Flat
IPAQ1, IPAQ2, IPAQ3, IPAQ4, IPAQ5, IPAQ6, IPAQ7
Custom Vital Signs
F.C.VS
Flat
Custom Height, Custom Weight, Custom Systolic Blood Pressure, Custom Diastolic Blood Pressure, Custom Gender, Custom Child Be...
1 rows selected
Total 18
Visits & Forms
Baseline
Informed Consent and Demography
Vital Signs
Medical History/Concomitant Illness
Date of Visit
Previous Hypertension Treatment
Haemoglobin Levels
Pregnancy Test
eConsent
Randomisation
Week 4
Week 8
Week 12
00:17,07

Capability @ Play	Scene 4:	What you'll see

Data synchronization and automation tools

The Magic of Synchronization

1. Easy data sync
2. Reduced risk
3. Shortened study setup

The synchronization process is initiated in Oracle Apex, transferring the OSB study design into Oracle Clinical One and realizing the efficiency gains of automating data transfer

Oracle Global Centre of Excellence

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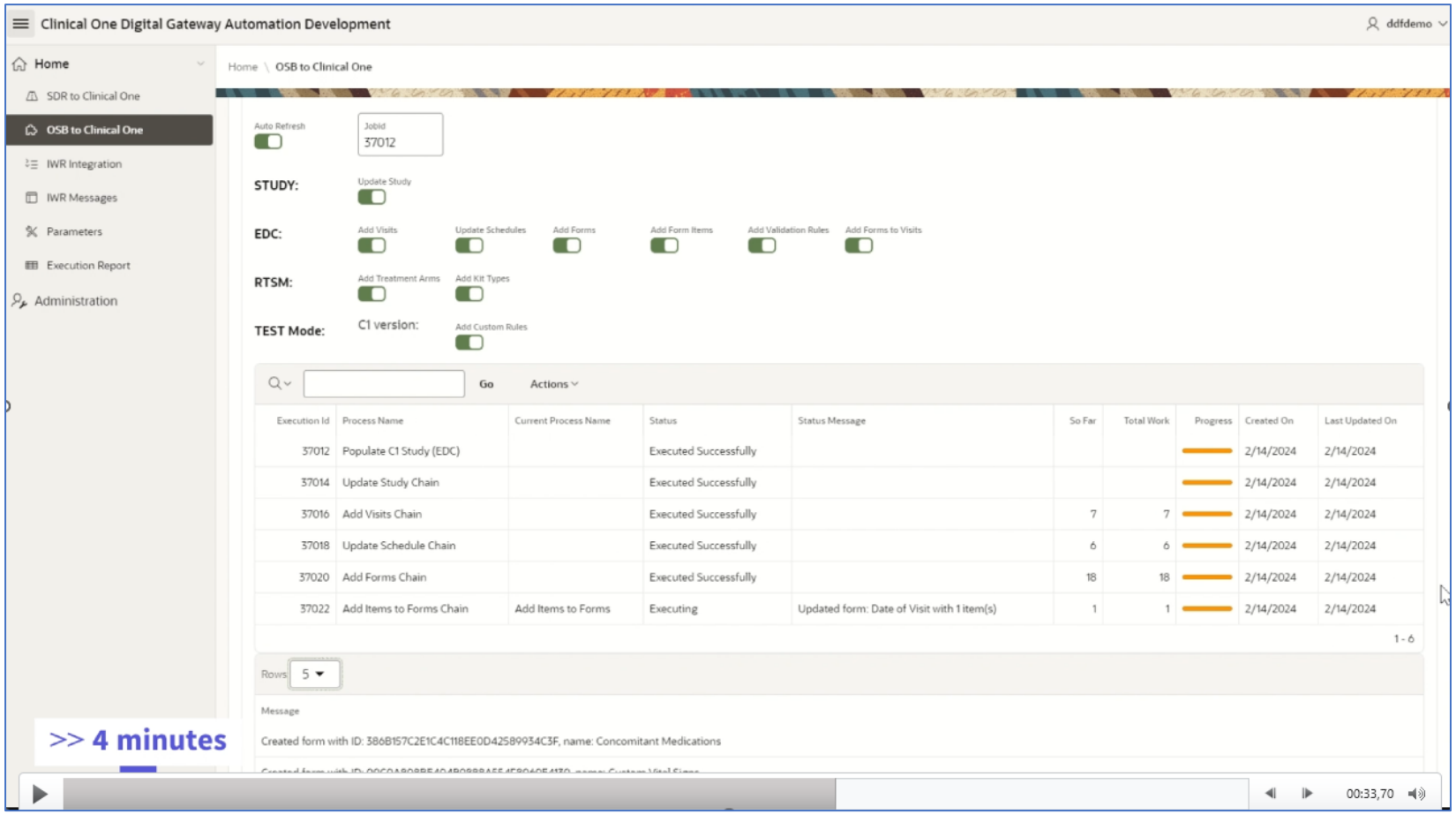
Live Video


Clinical One Digital Gateway Automation Development
ddfdemo
Home
SDR to Clinical One
OSB to Clinical One
IWR Integration
IWR Messages
Parameters
Execution Report
Administration
Home \ OSB to Clinical One
Auto Refresh
JobId
37012
STUDY:
Update Study
EDC:
Add Visits
Update Schedules
Add Forms
Add Form Items
Add Validation Rules
Add Forms to Visits
RTSM:
Add Treatment Arms
Add Kit Types
TEST Mode:
C1 version:
Add Custom Rules
Go
Actions
Execution Id
Process Name
Current Process Name
Status
Status Message
So Far
Total Work
Progress
Created On
Last Updated On
37012 Populate C1 Study (EDC) Executed Successfully 2/14/2024 2/14/2024
37014 Update Study Chain Executed Successfully 2/14/2024 2/14/2024
37016 Add Visits Chain Executed Successfully 7 7 2/14/2024 2/14/2024
37018 Update Schedule Chain Executed Successfully 6 6 2/14/2024 2/14/2024
37020 Add Forms Chain Executed Successfully 18 18 2/14/2024 2/14/2024
37022 Add Items to Forms Chain Add Items to Forms Executing Updated form: Date of Visit with 1 item(s) 1 1 2/14/2024 2/14/2024
1 - 6
Rows 5
Message
Created form with ID: 386B157C2E1C4C118EE0D42589934C3F, name: Concomitant Medications
>> 4 minutes
00:33,70

Capability @ Play	Scene 5:	What you'll see

Data mapping and validation technologies

Revealing the Clinical One Study Design

1. Precise data import
2. Trustful automation
3. Metadata integrity

The populated Oracle Clinical One study design, is compared against the initial OSB design

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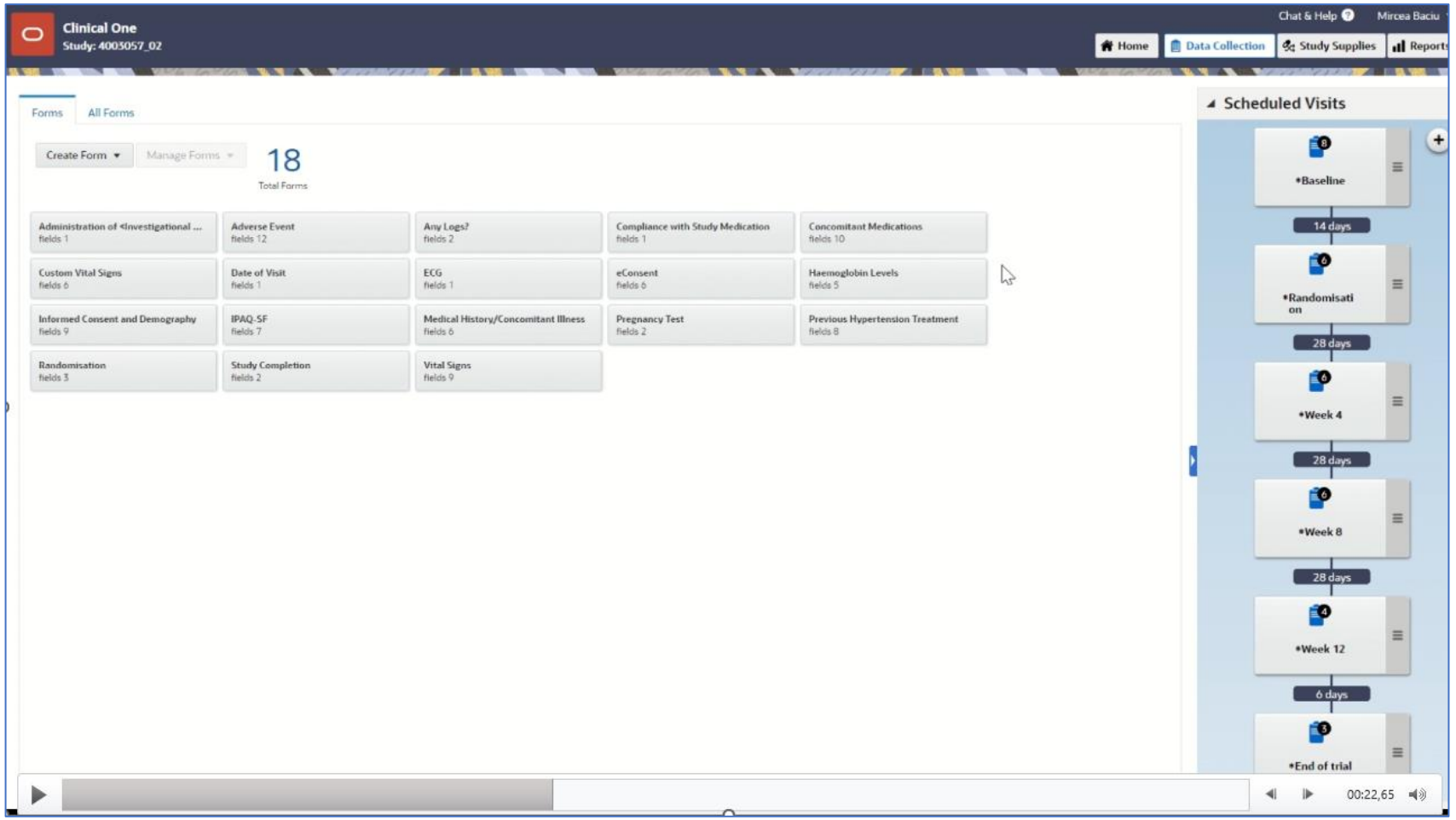
Live Video


Clinical One
Study: 4003057_02
Chat & Help
Mircea Baciu
Home
Data Collection
Study Supplies
Reports
Forms
All Forms
Create Form
Manage Forms
18
Total Forms
Administration of <Investigational ...
fields 1
Adverse Event
fields 12
Any Logs?
fields 2
Compliance with Study Medication
fields 1
Concomitant Medications
fields 10
Custom Vital Signs
fields 6
Date of Visit
fields 1
ECG
fields 1
eConsent
fields 6
Haemoglobin Levels
fields 5
Informed Consent and Demography
fields 9
IPAQ-SF
fields 7
Medical History/Concomitant Illness
fields 6
Pregnancy Test
fields 2
Previous Hypertension Treatment
fields 8
Randomisation
fields 3
Study Completion
fields 2
Vital Signs
fields 9
Scheduled Visits
*Baseline
14 days
*Randomisation
28 days
*Week 4
28 days
*Week 8
28 days
*Week 12
6 days
*End of trial
00:22,65

Capability @ Play	Scene 6:	What you'll see

Rule-based validations

Validation Rules and Custom Rules

1. High study customization
2. Increased data quality
3. Streamlined testing

The integration of validation rules in Clinical One's study design, using specific forms as examples, and looking at custom rules in testing

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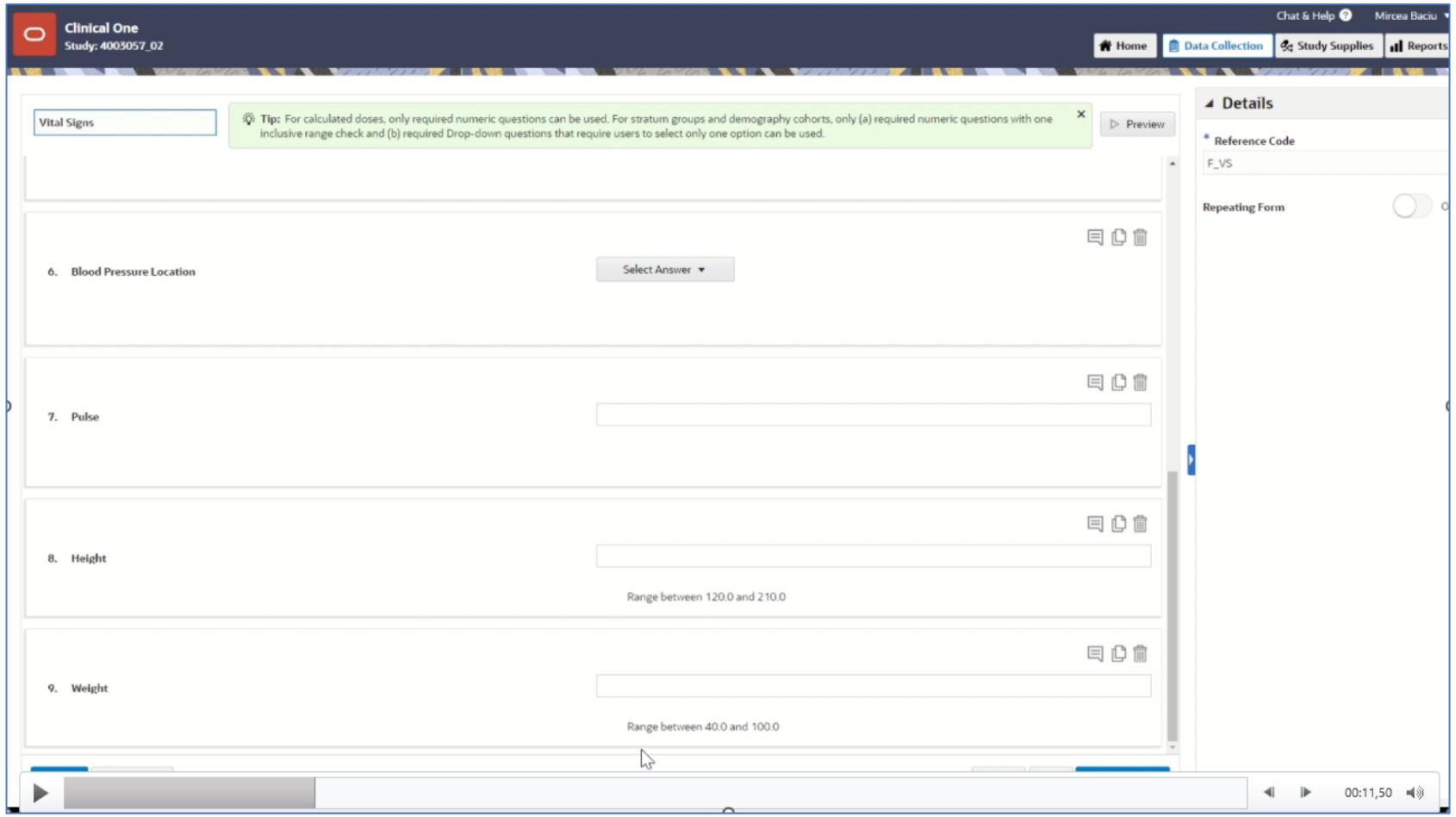
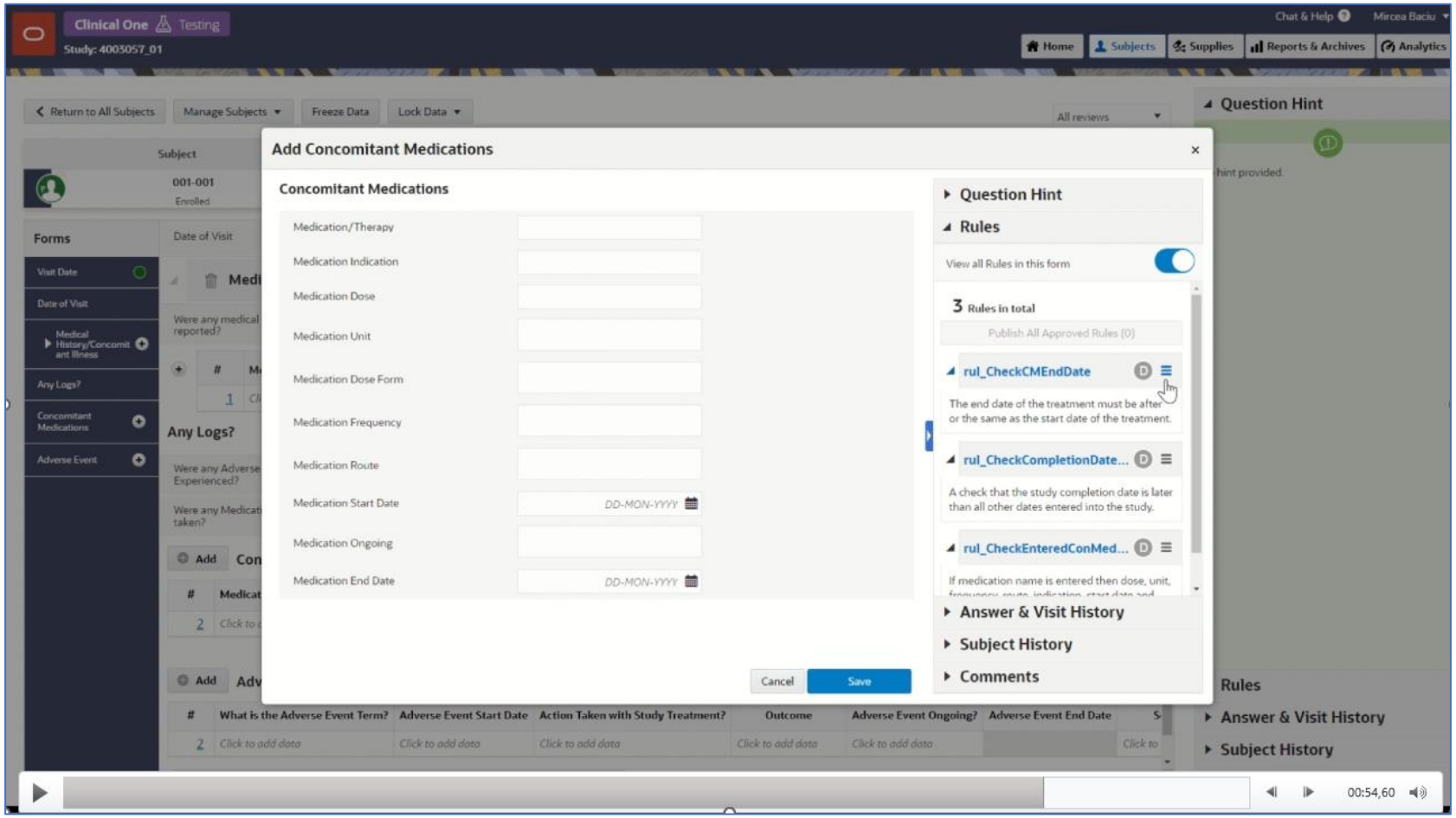
Live Video


Clinical One
Study: 4003057_02
Chat & Help
Mircea Baciu
Home
Data Collection
Study Supplies
Reports
Vital Signs
Tip: For calculated doses, only required numeric questions can be used. For stratum groups and demography cohorts, only (a) required numeric questions with one inclusive range check and (b) required Drop-down questions that require users to select only one option can be used.
Preview
Details
Reference Code
F_VS
Repeating Form
6. Blood Pressure Location
Select Answer
7. Pulse
8. Height
Range between 120.0 and 210.0
9. Weight
Range between 40.0 and 100.0
00:11,50

Live Video


Clinical One
Testing
Study: 4003057_01
Chat & Help
Mircea Baciu
Home
Subjects
Supplies
Reports & Archives
Analytics
Return to All Subjects
Manage Subjects
Freeze Data
Lock Data
All reviews
Question Hint
Subject
001-001
Enrolled
Forms
Visit Date
Date of Visit
Medical History/Concomitant Illness
Any Logs?
Concomitant Medications
Adverse Event
Add Concomitant Medications
Concomitant Medications
Medication/Therapy
Medication Indication
Medication Dose
Medication Unit
Medication Dose Form
Medication Frequency
Medication Route
Medication Start Date
DD-MON-YYYY
Medication Ongoing
Medication End Date
DD-MON-YYYY
Cancel
Save
Question Hint
Rules
View all Rules in this form
3 Rules in total
Publish All Approved Rules (0)
rul_CheckCMEndDate
The end date of the treatment must be after or the same as the start date of the treatment.
rul_CheckCompletionDate...
A check that the study completion date is later than all other dates entered into the study.
rul_CheckEnteredConMed...
If medication name is entered then dose, unit,
Answer & Visit History
Subject History
Comments
Any Logs?
Add
What is the Adverse Event Term?
Adverse Event Start Date
Action Taken with Study Treatment?
Outcome
Adverse Event Ongoing?
Adverse Event End Date
Click to add data
Rules
Answer & Visit History
Subject History
00:54,60

Capability @ Play	Scene 7:	What you'll see

Testing mode and UAT workflow

User Acceptance Testing

1. Confirmation of protocol requirements
2. Validation of rules
3. Streamlined UAT

Validating the study design in the Testing mode. The validation is done by creating sites, subjects and adding data

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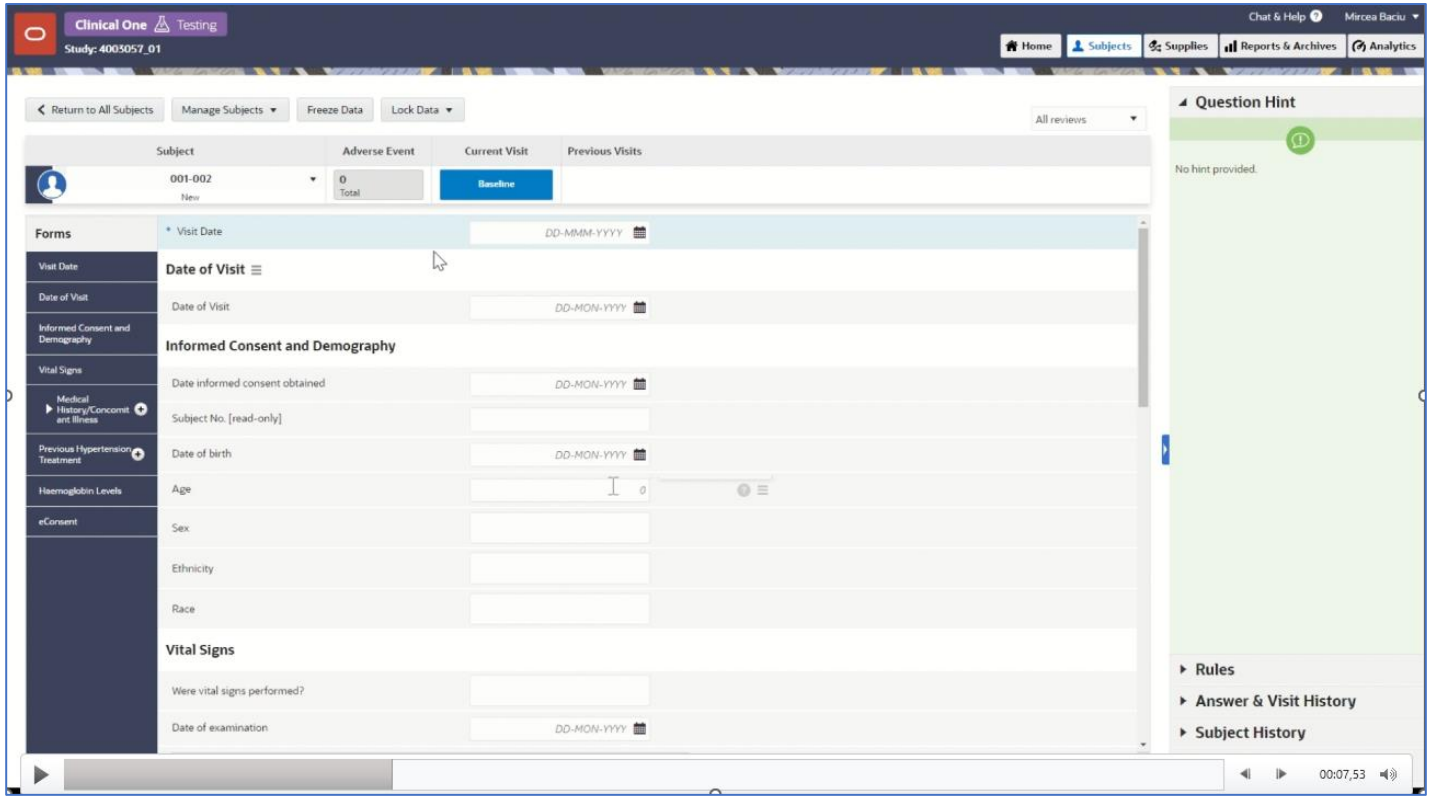
Clinical One
Testing
Study: 4003057_01
Chat & Help
Mircea Baciu
Home
Subjects
Supplies
Reports & Archives
Analytics
Return to All Subjects
Manage Subjects
Freeze Data
Lock Data
All reviews
Subject
Adverse Event
Current Visit
Previous Visits
001-002
New
0
Total
Baseline
Forms
Visit Date
Date of Visit
Informed Consent and Demography
Vital Signs
Medical History/Concomitant Illness
Previous Hypertension Treatment
Haemoglobin Levels
eConsent
* Visit Date
DD-MMM-YYYY
Date of Visit
Date of Visit
DD-MON-YYYY
Informed Consent and Demography
Date informed consent obtained
Subject No. [read-only]
Date of birth
Age
Sex
Ethnicity
Race
Vital Signs
Were vital signs performed?
Date of examination
Question Hint
No hint provided.
Rules
Answer & Visit History
Subject History
00:07,53

EVIDENTIQ
CLINICAL DATA SCIENCE GROUP

Intelligent Study Build:
EvidentIQ ePRO API integration

Tomasz Augustik, Product Owner
(for Marvin EDC and Integrator)

April 2024

Demo

Oracle ClinicalOne and Marvin ePRO

The demo will contain the following steps:

1. Open the ePRO system and create a new subject user
2. Switch into subject view and enter data into the ePRO
3. Go to ClinicalOne EDC and open patient file to demonstrate successful transfer of the data

Intelligent Study Build

Closing Comments

Srinivas Karri, Global Head, Oracle Centre of Excellence

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TAKEAWAYS

1. OpenStudyBuilder maintains **metadata standards** across studies and systems

2. Automated study build **accelerates** study start and ensures **scalability**

3. Consistent data structure facilitates **collaboration**, enabling Sponsors to use **best-of-breed** for a competitive edge

Want to work with us to build & automate your study in OSB and Clinical One?

Just SCAN the QR-code and provide basic contact info and we will be in touch.