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A simplified low-code tool to execute logics against clinical data

Presented by Haiping Yu, Director, Technical Operation Lead, Data Management,
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30Jul2022

Meet the Speaker

Haiping Yu

Title: Director, Technical Operation Lead

Organization: dMed Biopharmaceutical Co., Ltd.

15+ years of experience in the new drug research industry and focuses on software development and data standard implementation in this field. Joining dMed in 2017, he and his team developed a clinical metadata repository (MDR) and many other tools to automate clinical data workflows. Prior to joining dMed, he worked at Pfizer China R&D.
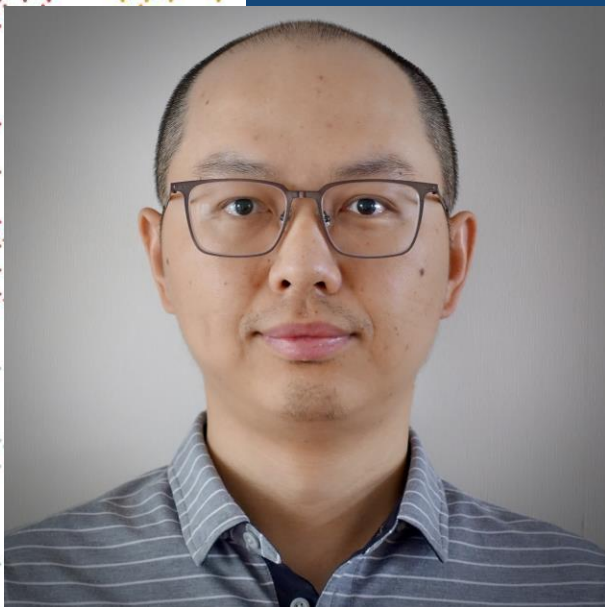
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- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

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Agenda

What, Who and Why

Disclaimer and Disclosures

- *Led to closer collaboration , developers and domain experts across all functions and disciplines , enabling closer collaboration*
- *Build from your design with a back-end data schema*
- *Along with authoring and advanced admin options*

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What is *Low-Code Application Platform (LCAP)* ?

- *LCAP is a software*

- *LCAP is a rapid application development (RAD) technique*

- *LCAP is characterized by its use of model-driven or visual development paradigms supported by expression languages and possibly scripting*
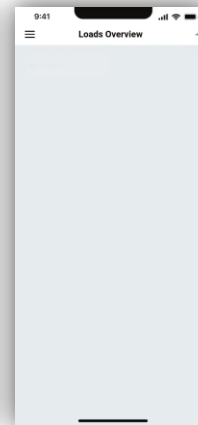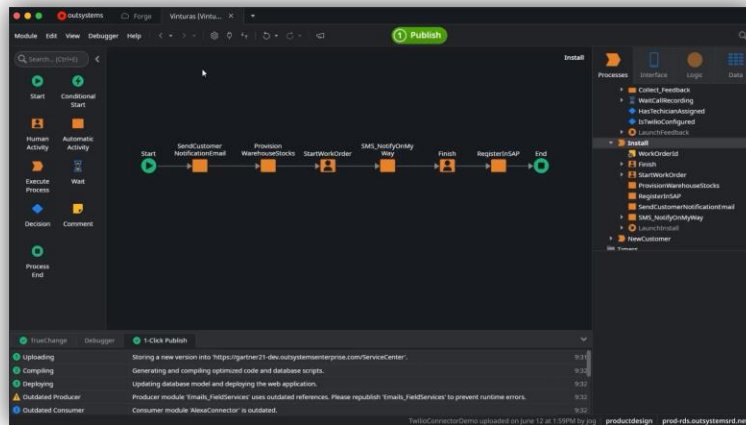
LCAP History

- *DOS*
  - *Dbase/Foxbase*
- *Windows*
  - *VB、PB、Delphi*
- *Web*
  - *Dreamweaver*
- *Cloud*
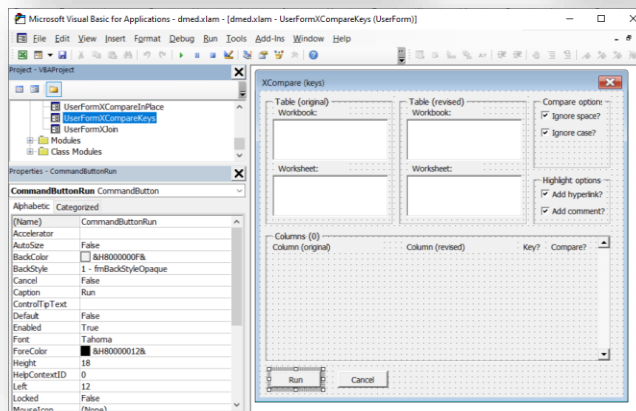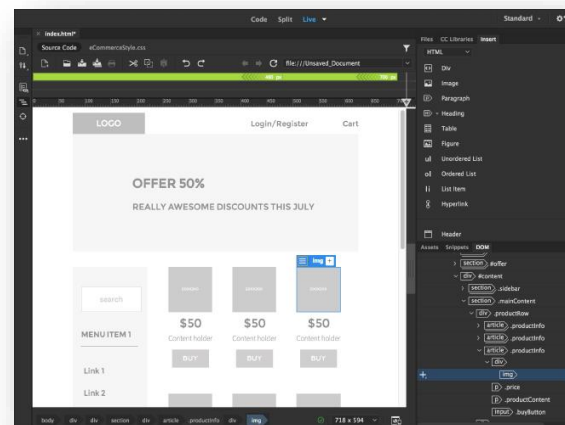
Who use LCAP?

- *Professional Developers*
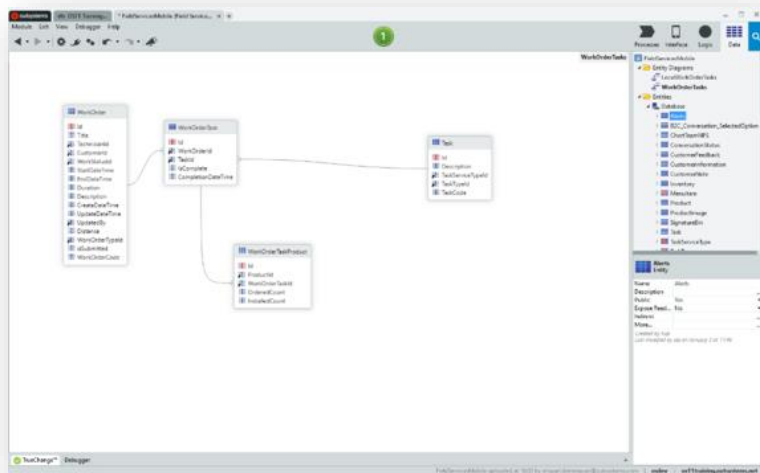- *Citizen Developers*
- *Domain Expert*

Why LCAP become popular?

- *Changing workforce*
- *A growth need for digitalizing*
- *More developers are hired outside the core technology companies, and traditional industries are struggling to hire professional developer*
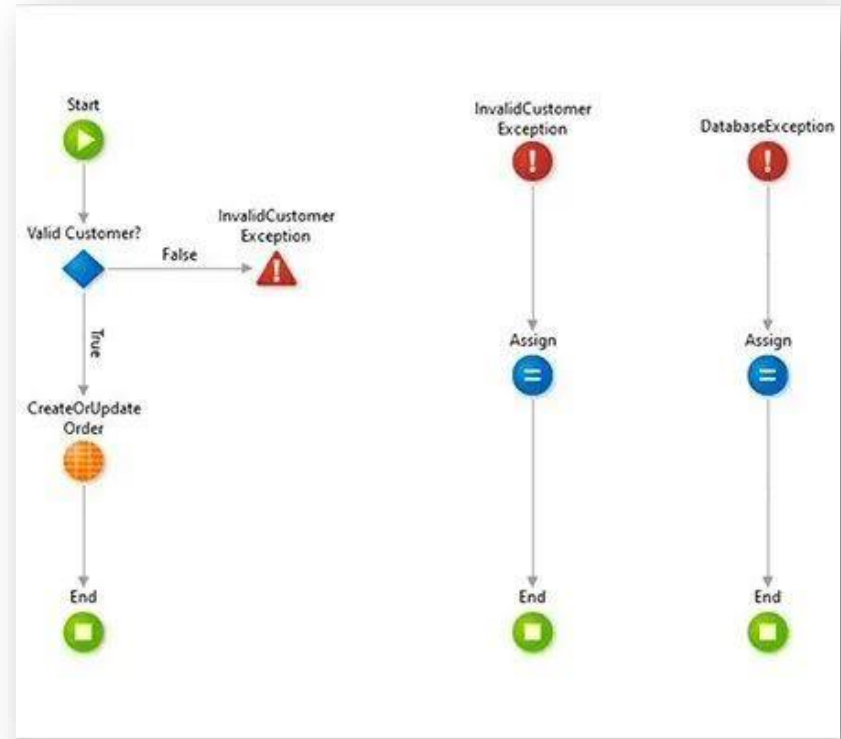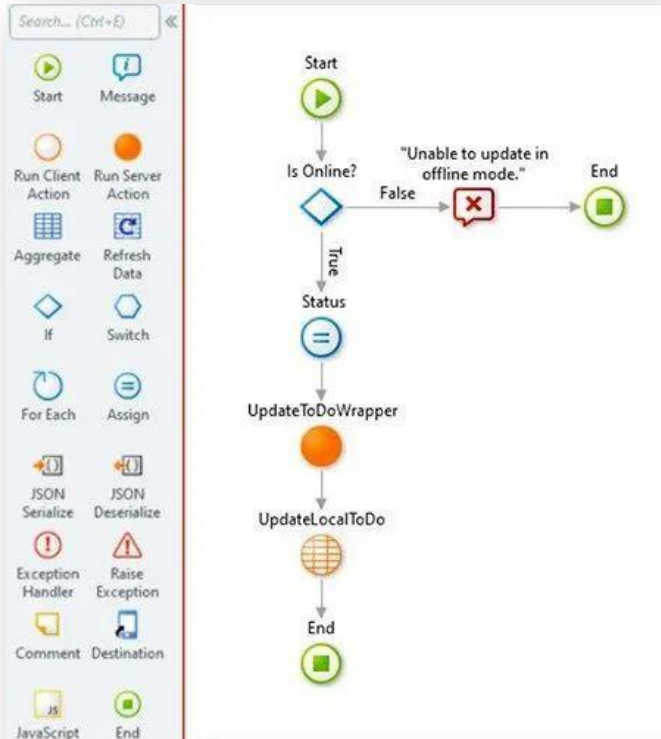
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LCAP Features

LCAP Features – Model-driven & Form-driven

LCAP Features – Visual tool

LCAP Features – Expression Language

LCAP Features – Software Engineering

- Testing and debugging
- Versioning

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LCAP Features – Open

- Interoperability
- Align with industry standards

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LCAP Features – Scripting

LCAP in Clinical World

Low-Code in Clinical World

- *Electronic Data Capture (EDC) Systems*
    - *System vendor and developers create and maintain that platform*
    - *Data Manager manage the requirements*
    - *Database Builder "draw" the electronic Case Report Form (eCRF) and "program " edit check procedures through the visual Designer and code Editor*
    - *Site users enters the subject data through the end user UI*

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EDC – *"draw" the eCRF*

A Simplified Low-Code Tool

The need in data validation

- Another common need is to ensure the cleanliness and submission-readiness of clinical data,

- data managers and programmers work together to specify, program, validate and execute edit check logics and conformance rules against the collected clinical data,

- organizations including vendors, CROs and sponsors all had their own tools and best practices.

- look for open and holistic solutions.

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Data Model

- CDISC ODM-XML schema
  - MedataDataVersion
  - ClinicalData
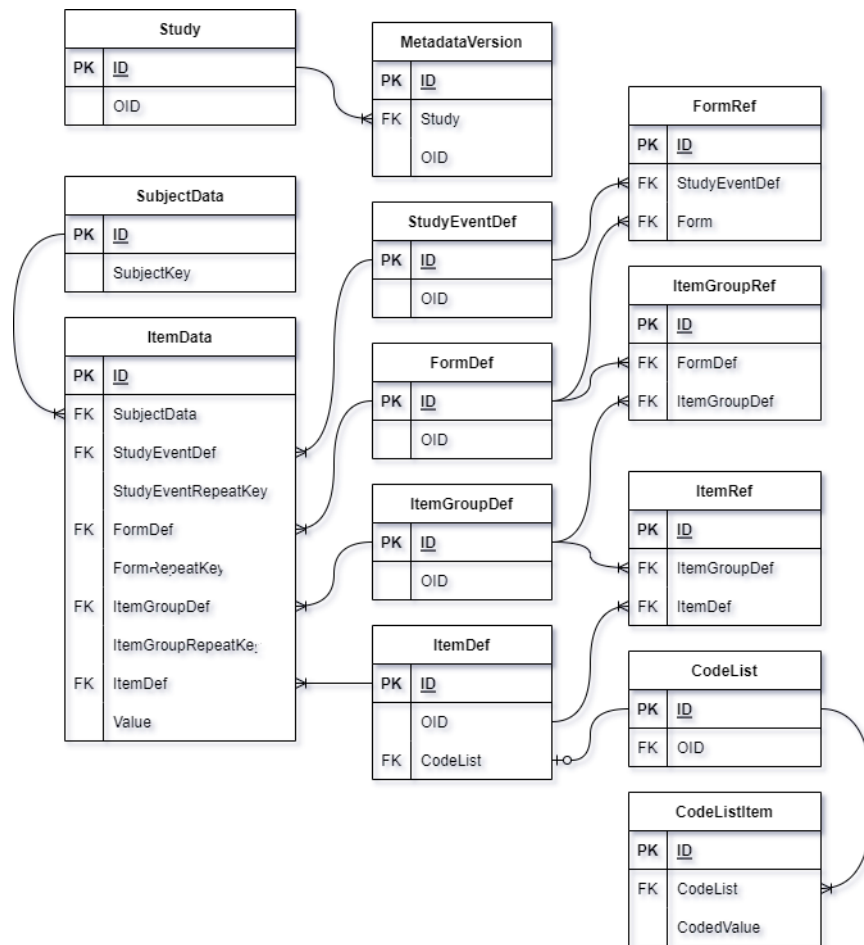
Data Exchange

- Metadata
  - ODM-XML (EDC/CDASH)
  - Define-XML(SDTM)
  - CDISC Library JSON
- ClinicalData
  - ODM-XML (EDC/CDASH)
  - Dataset-XML/JSON (SDTM)
- Edit Check Logics and Conformance Rules
  - ?

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CDISC Open Rules Engine (CORE)

- *Registered with the CDISC Open-Source Alliance (COSA)*

- *Publish the machine readable and executable CDISC Conformance Rules through the CDISC Library*

- *Execute the Conformance Rules against ClinicalData via the Engine*
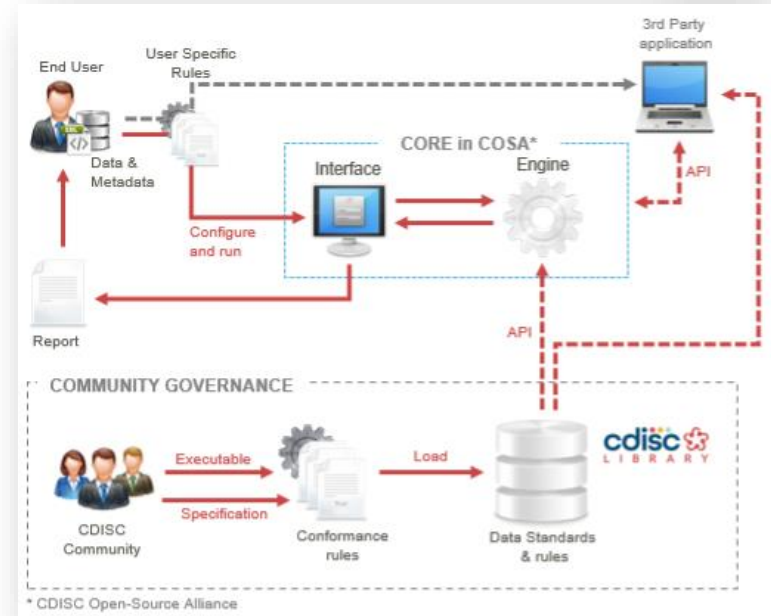
Design
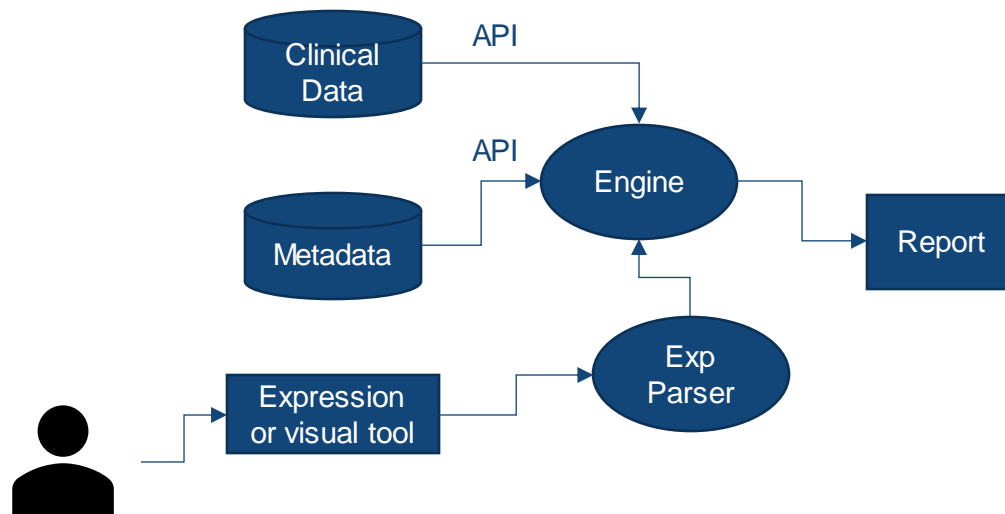
Execute

```
[ ]:  import magic as Magic
      import studty as Study

      magic = Magic()
      study = Study("StudyA")

      clinicaldata = study.read_clinicaldata()
      metadata = study.read_metadata("V1.0")

      exp = '''>SCR>DM>DM>AGE NOT BETWEEN 18 AND 65'''
      result = magic.execute(clinicaldata, metadata, exp)
```

●●●

		ISSUE#	SUBJ	ITEM	VALUE	ERRMSG
0		1	1003	>SCR>DM>DM>AGE	16	年龄 (16) 超出范围 (18-65) 。
1		2	1007	>SCR>DM>DM>AGE	66	年龄 (66) 超出范围 (18-65) 。

Execute

```
import magic as Magic
import studty as Study

magic = Magic()
study = Study("StudyA")

clinicaldata = study.read_clinicaldata()
metadata = study.read_metadata("V1.0")

exp = '''>EG>EG>EGPERF IS EQUAL TO '是' AND (>EG>EG>EGCLSIG IS NOT IN ('异常无临床意义','异常有临床意义') AND >EG>EG>EGDESC IS EMPTY)'''
result2 = magic.execute(clinicaldata, metadata, exp)
```
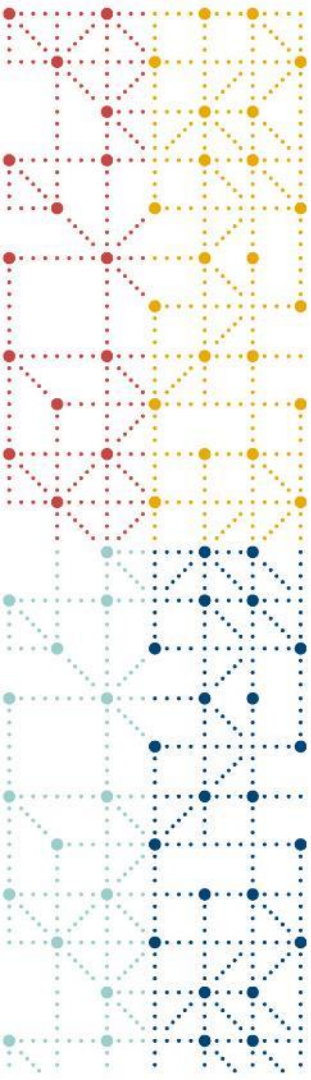
```
● ● ●

|    |  ISSUE# |  SUBJ | ITEM                | VALUE             |
|---:|---------:|------:|:--------------------|:------------------|
|  0 |        1 |  1011 | V1>EG>EG>EGPERF     | 是                |
|  1 |        1 |  1011 | V1>EG>EG>EGCLSIG    | 异常无临床意义    |
|  2 |        1 |  1011 | V1>EG>EG>EGDESC     |                   |
|  3 |        2 |  1022 | V2>EG>EG>EGPERF     | 是                |
|  4 |        2 |  1022 | V2>EG>EG>EGCLSIG    | 异常有临床意义    |
|  5 |        2 |  1022 | V2>EG>EG>EGDESC     |                   |
```

Thank You!

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