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

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dMed Biopharmaceutical Co., Ltd.

30Jul2022

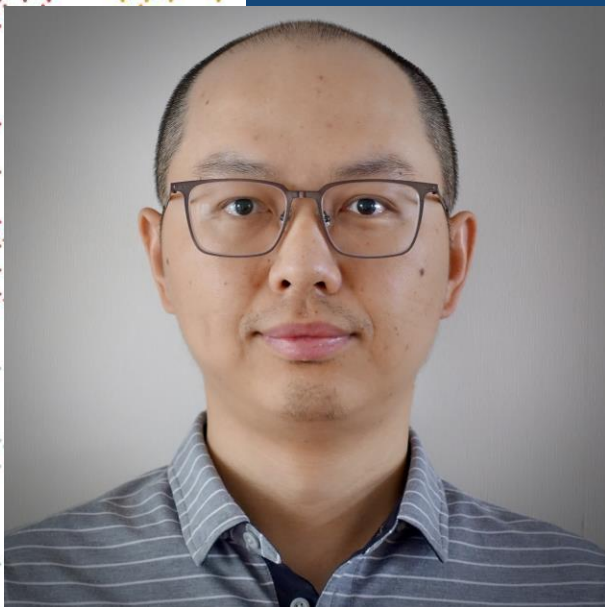
# Meet the Speaker

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.





# Disclaimer and Disclosures

- *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.*



## Agenda

1. What, Who and Why
2. LCAP Features
3. LCAP in Clinical World
4. A Simplified Low-Code Tool



# What, Who and Why

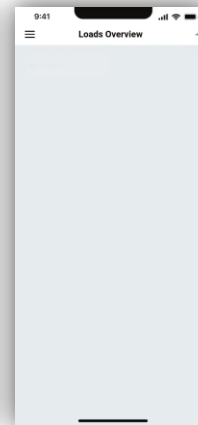
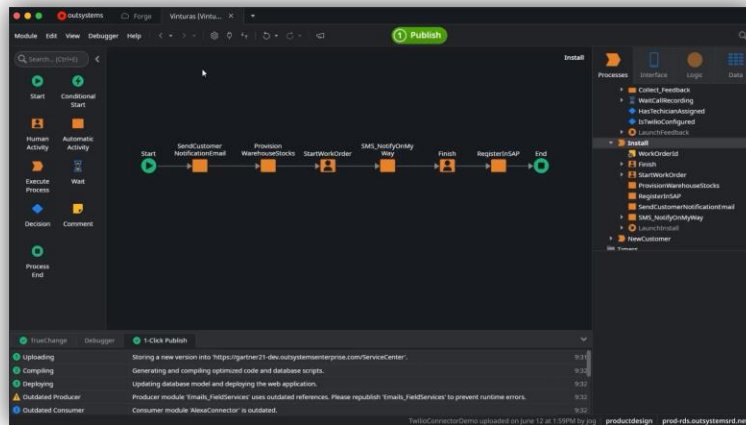


# Disclaimer and Disclosures

- *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*

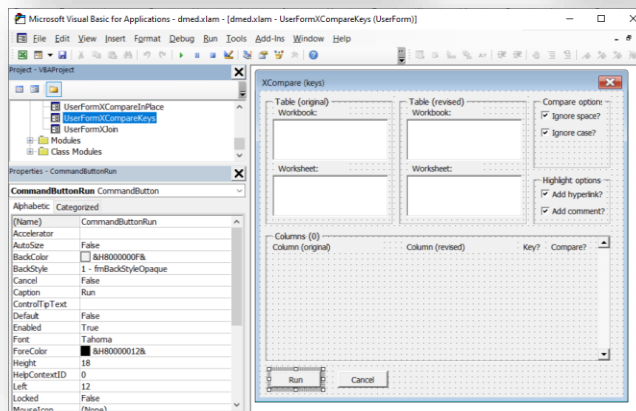
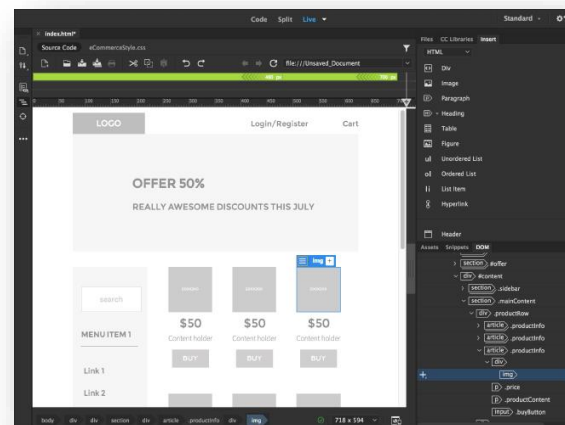
# What is *Low-Code Application Platform (LCAP)* ?

- *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*

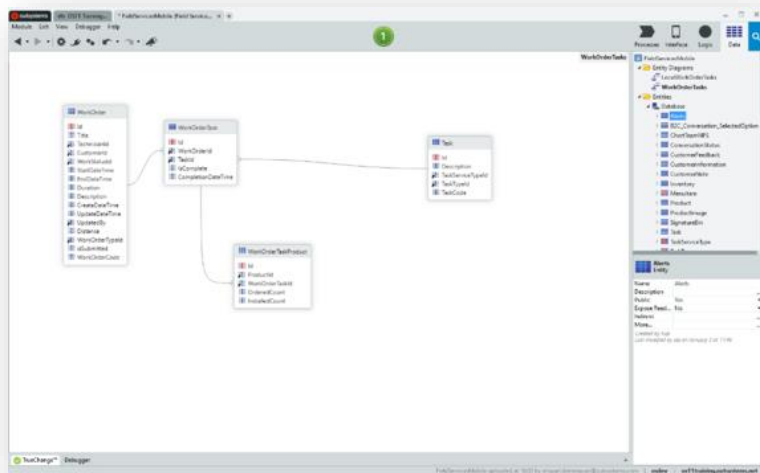
# Why LCAP become popular?

- *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*



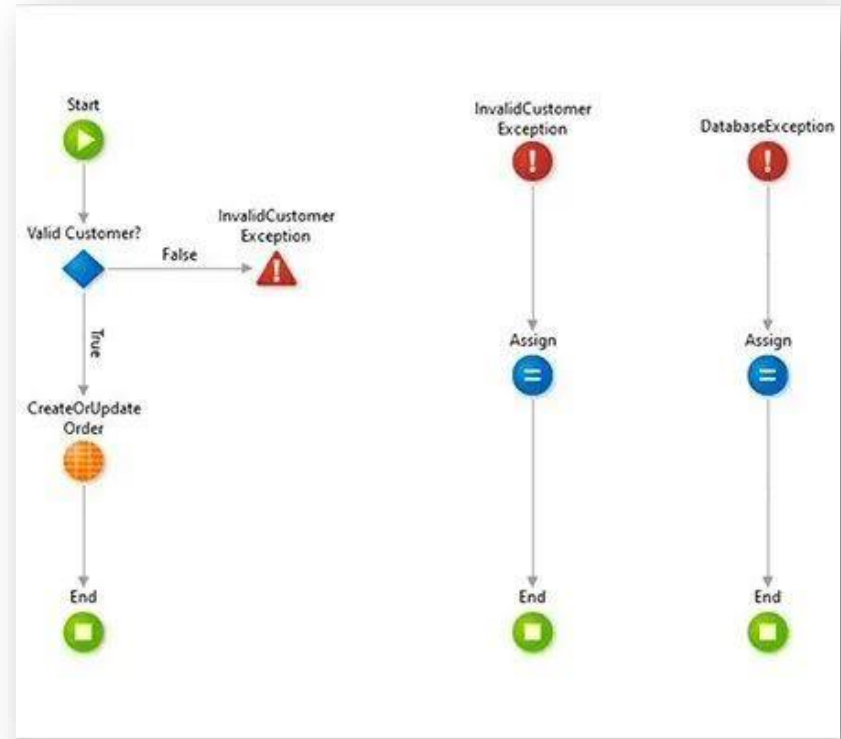
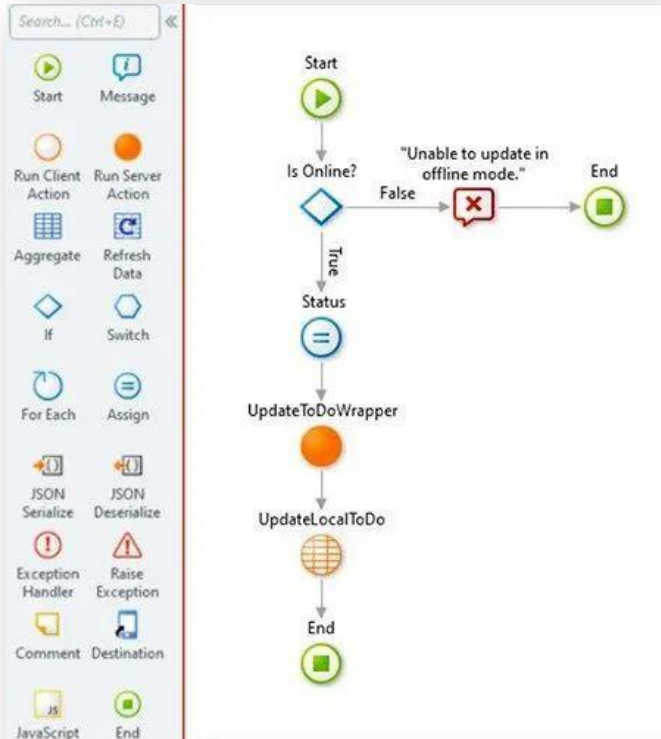
# LCAP Features

# LCAP Features – Model-driven & Form-driven



The screenshot shows a form-driven development interface. The main area is titled '正在编辑表单: 订单' (Editing Form: Order). It includes a '表单设计' (Form Design) section with a 'A 名称' field and a 'A 描述' field. A configuration panel for 'A 文本' (Text) is visible on the right, with options for '字段名称' (Field Name), '单行' (Single Line), '多行' (Multiple Lines), '验证' (Validation), and '字段属性' (Field Properties).

# LCAP Features – Visual tool



# LCAP Features – Expression Language

测验成绩单


得分1      得分2



请输入内容      请输入内容

总分

请输入内容 

通过公式计算  
SUM ( 得分1, 得分2 )

=  `Right(Input.Text,Len(Input.Text)-Find("|",Substitute(Input.Text," ","|",Len(Input.Text)-Len(Substitute(Input.Text," ","")))))`

 Format text     Remove formatting

Input:

Label:



# LCAP Features – Software Engineering

- Testing and debugging
- Versioning



# LCAP Features – Open

- Interoperability
- Align with industry standards



# LCAP Features – Scripting

The screenshot displays the OutSystems Studio interface for a project named 'OutTracker'. The main workspace shows a flowchart for the 'DeleteOnClick' event. The flow starts with an 'AllExceptions' node, followed by a 'Set error' node, and then an 'End' node. A 'Set error' node is also shown on the left, connected to another 'End' node. The right-hand panel shows the 'Elements' list with 'DeleteOnClick' selected. Below the list, the configuration for the 'Expense deleted' message is shown, with the following settings:

Property	Value
Label	Expense deleted
Message	"Expense deleted"
Type	Success

At the bottom of the interface, there is a status bar indicating 'My App uploaded at 16:08' and the URL 'productdesign ns.outsystemscloud.com'.



# 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*

# EDC – “draw” the eCRF

Filter

▼ Draft V1.1

▼ [DM001] Demography

- ▼ [DM001\_1]
  - [DM001\_1|BRTHDAT] Birth Date: [edit] [delete]
  - [DM001\_1|AGE] Age: [edit] [delete]
  - [DM001\_1|AGEU] Age Unit: [edit] [delete]
  - [DM001\_1|SEX] Sex: [edit] [delete]
  - [DM001\_1|ETHNIC] Ethnicity: [edit] [delete]
  - [DM001\_1|CRACE] Collected Race: [edit] [delete]
  - [DM001\_1|RACEOTH] If other Race, please specify: [edit] [delete]

FormName	Demography
TranslatedText_ENUS	Demography
TranslatedText_ZHCN	人口统计学
Repeating	No
dmed.CompletionGuideline	
dmed.DesignGuideline	

### Edit Item

Label

DescriptionText  English  Chinese

TranslatedTextENUS Birth Date

TranslatedTextZHCN 出生日期

• OID DM001\_1|BRTHDAT

• Name BRTHDAT

• Mandatory No

• Datatype date

### Form : Demography

Birth Date:

Age:

Age Unit:  Years

Sex:  Male  Female

Collected Race:  Asian  Black  White  Other

If other Race, please specify:



# A Simplified Low-Code Tool

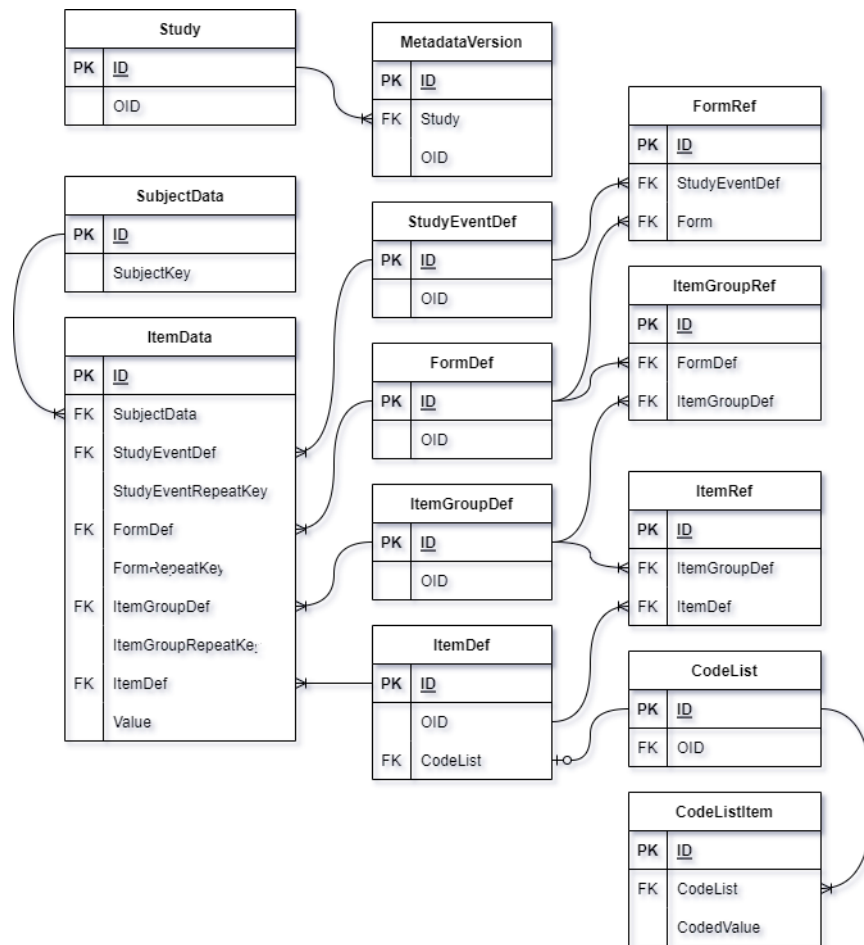


# The need in data validation

- 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.

# Data Model

- CDISC ODM-XML schema
  - MetadataVersion
  - ClinicalData





# Data Exchange

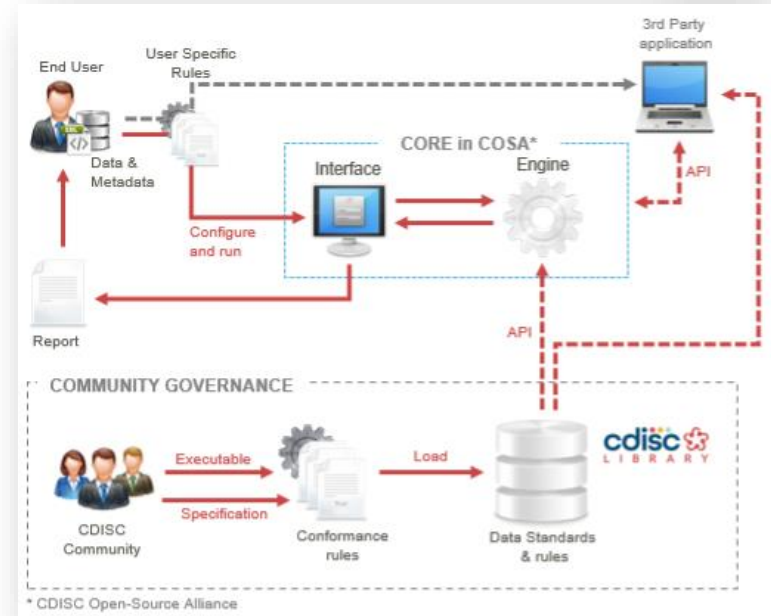
- Metadata
  - ODM-XML (EDC/CDASH)
  - Define-XML(SDTM)
  - CDISC Library JSON
- ClinicalData
  - ODM-XML (EDC/CDASH)
  - Dataset-XML/JSON(SDTM)
- Edit Check Logics and Conformance Rules
  - ?



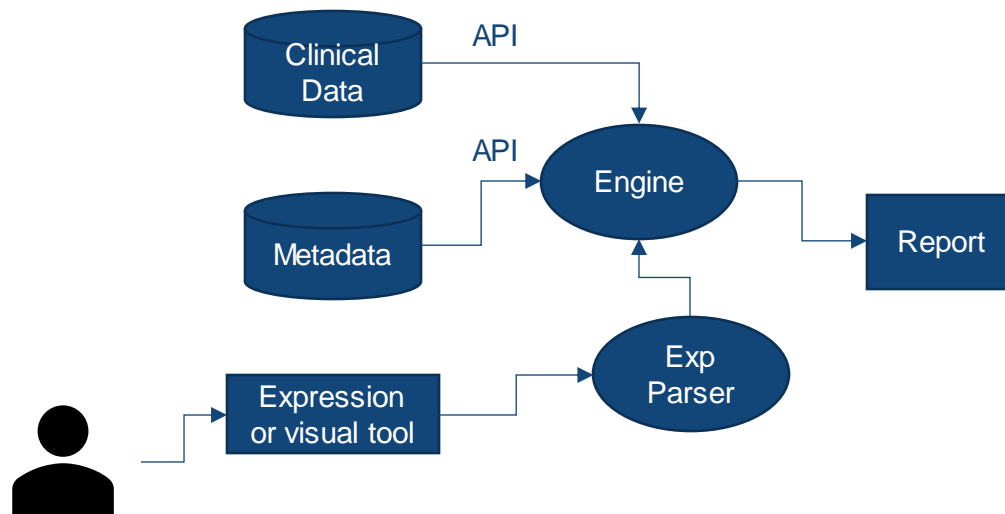


# CDISC Open Rules Engine (CORE)

- *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 study 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	年齡 (16) 超出范围 (18-65)。
1	2	1007	>SCR>DM>DM>AGE	66	年齡 (66) 超出范围 (18-65)。



# Execute

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

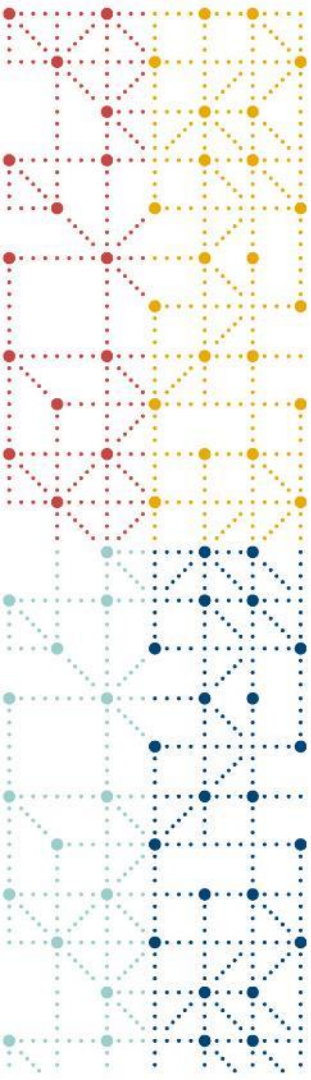
magic = Magic()
study = Study("StudyA")

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!**

**cdisc**