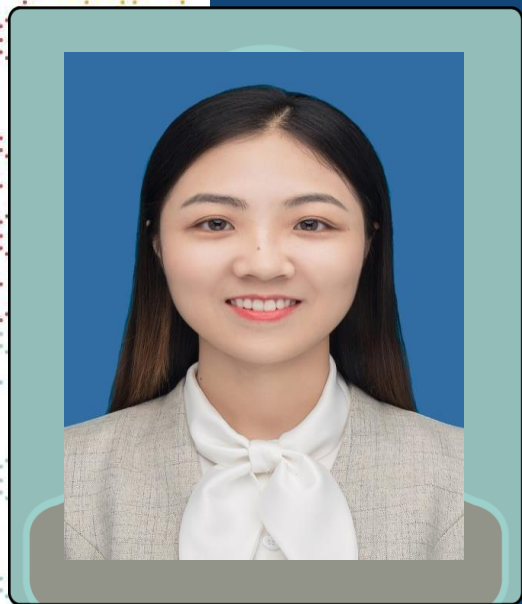cdisc

2022
CHINA
INTERCHANGE
29-30 JULY | VIRTUAL EVENT

Exploration of open-source technology in the metadata driven clinical trial automation process
Presented by Guoyan Zeng, Statistical Program, DO, Novartis

Meet the Speaker

Guoyan Zeng/ Mengyue Han

Title: Statistical Programmer

Organization: Novartis

Guoyan Zeng received her master's degree in statistics last year. She joined Novartis company as a statistical programmer in July 2021, and enjoys exploring the use of open source technologies in daily work.

Mengyue Han. Master of Biostatistics. Statistical programmer of Novartis with 1 year working experience. Passioned about combining innovative tools with daily task to work efficiently and happily.

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.*

- *{Please disclose any financial relationship or conflict of interest relevant to this presentation here OR}*

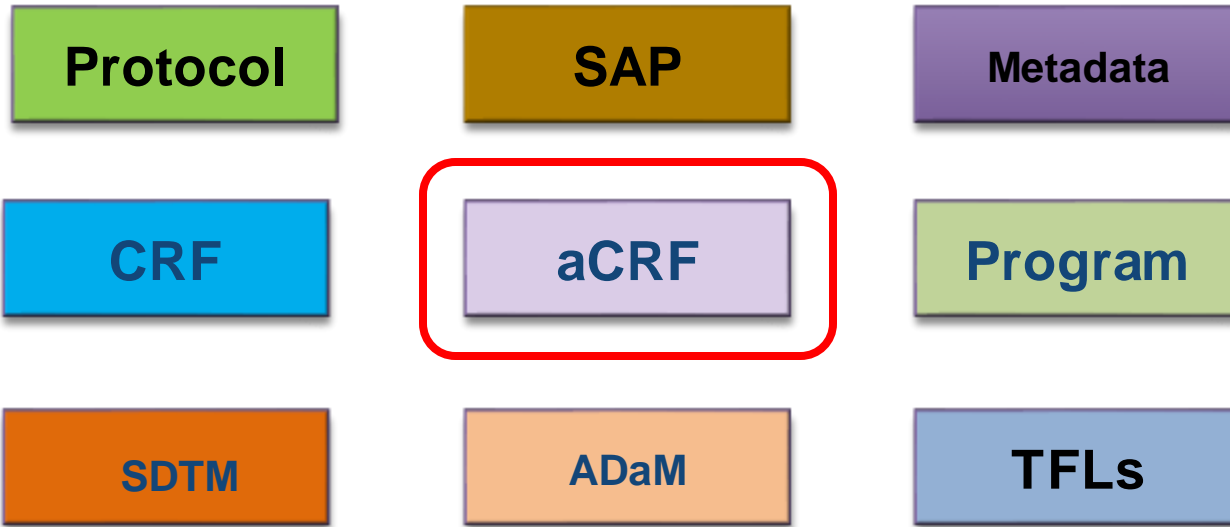- *The author(s) have no real or apparent conflicts of interest to report.*

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Agenda

1. Open-source technology
2. What are the benefits of automating annotated CRFs?
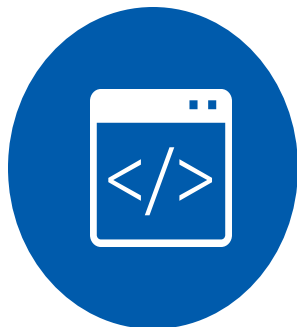3. How to implement aCRF automation?

Open-source technology

JavaScript

R

Python

Open-source technology

Protocol	**SAP**	**Metadata**
CRF	**aCRF**	**Program**
SDTM	**ADaM**	**TFLs**
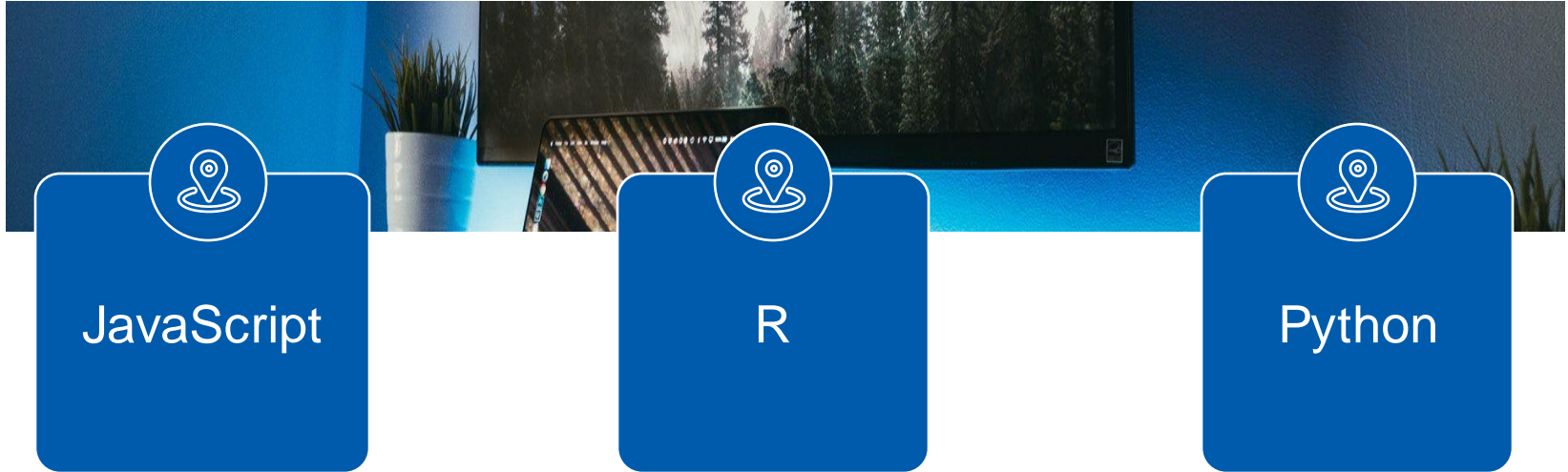
What are the benefits of automating annotated CRFs?

Benefits

Efficient   Friendly   Consistent   Automatic
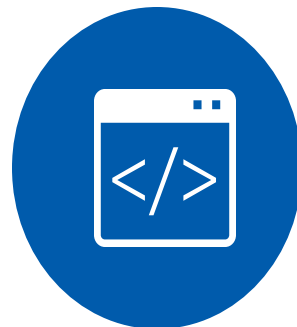
How to implement aCRF automation?

- ➢ Create database from existing annotated CRF
- ➢ Retrieve annotated CRF information
- ➢ Add annotations
- ➢ Create Bookmarks

Workflow

Completed aCRF library

- Global templates
- Similar study
- Others

New blank CRF

Retrieve CRF information

- Template id
- Form name
- Contents
- Comments

Retrieve CRF information

- Template id
- Form name
- Page number
- Contents
- Corresponding coordinate
  (see column X1, Y1, X2, Y2)

Add annotations

Preview

Any change?

Yes

No

Create bookmarks

Publish

Can exactly match with form ?

No → Form differ, using KMP or DFA algorithms

System recommend

User define

Yes

Existing study

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Retrieve annotated CRF information

AE = Adverse Events

Form: Adverse Events_AEGXXX

If during study participation, the subject experiences a Liver/Renal event, please refer to form level help for guidance on recording all related information.
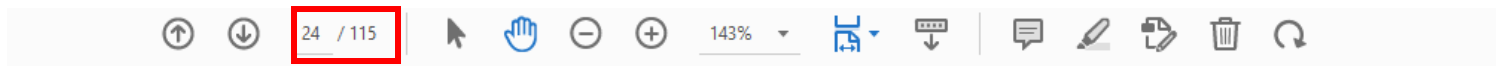
Were any adverse events experienced?

[NOT SUBMITTED]

No ◯
Yes ◯

Adverse Event Category

AECAT

General ◯

FORMNAME	TEMPLATE ID	CONTENT	COMMENT
Adverse Events	AEGXXX	Form: Adverse Events_AEGXXX	AE = Adverse Events
Adverse Events	AEGXXX	Were any adverse events experienced?	[NOT SUBMITTED]
Adverse Events	AEGXXX	Adverse Event Category	AECAT
Adverse Events	AEGXXX	AE Number	AESPID
Adverse Events	AEGXXX	Adverse Event	AETERM
Adverse Events	AEGXXX	Was the adverse event serious?	AESER

No ◯
Yes ◯

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Retrieve blank CRF information

12.0_YYYYYY_yyyymmdd (PROD): UNIQUE

Form: Adverse Events

Generated On: yyyymmdd hh:mm:ss

Were any adverse events experienced? No ◯
                                      Yes ◯

Adverse Event Category   General ◯

PAGE	FormName	CONTENT	X1	Y1	X2	Y2
24	Adverse Events	12.0_YYYYYY_yyyymmdd (PROD): UNIQUE	90	657.796005	278.31601	674.4160004
24	Adverse Events	Were any adverse events experienced?	90	638.796005	287.292023	655.4160004
24	Adverse Events	Adverse Event Category	90	604.684006	207.972015	620.6920013
24	Adverse Events	AE Number	90	585.684006	148.320007	601.6920013
24	Adverse Events	Adverse Event	90	568.684006	160.980011	584.6920013
24	Adverse Events	Was the adverse event serious?	90	550.796005	249.312012	567.4160004

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Add annotations

Form: Adverse Events

Generated On: yyyymmdd hh:mm:ss

Were any adverse events experienced? [NOT SUBMITTED] No ○ Yes ○

Adverse Event Category `AECAT` General ○

AE Number `AESPID`

Adverse Event `AETERM`

Was the adverse event serious? `AESER` No ○ Yes ○

24	Adverse Events	Were any adverse events experienced?	[NOT SUBMITTED]		90	638.796005	287.292023	655.4160004
24	Adverse Events	Adverse Event Category	AECAT		90	604.684006	207.972015	620.6920013
24	Adverse Events	AE Number	AESPID		90	585.684006	148.320007	601.6920013
24	Adverse Events	Adverse Event	AETERM		90	568.684006	160.980011	584.6920013
24	Adverse Events	Was the adverse event serious?	AESER		90	550.796005	249.312012	567.4160004

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Create Bookmarks

- Dual Bookmarking
  - CDISC guidance specifies bookmarks only for **Visit** and **Form**. Follow the examples of dual bookmarking in CDISC's sample aCRF by **linking multiple bookmarks to the same unique form**.
  - Many mistakenly think bookmarks must be in a 1:1 relationship with the form they point to. Create multiple relationships by using both of these hierarchies.
   - By Visit > Visit Name > Form Name
    - By Form > Form Name > Visit Name (if applicable)
  - Note: Bookmarks are *not* needed for **Domains**. Many mistakenly think the opposite, likely because CDISC's sample aCRF has the confusing bookmark label "Domains" to mean "Forms," as seen in the image below. The MSG uses "Domains" to mean simply the topics of pages/forms.
  - Note: Bookmarks are *not* needed for Not Submitted forms.

Link: Formatting Annotated Case Report Forms (aCRFs): Part 2 | Pinnacle 21

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Create Bookmarks
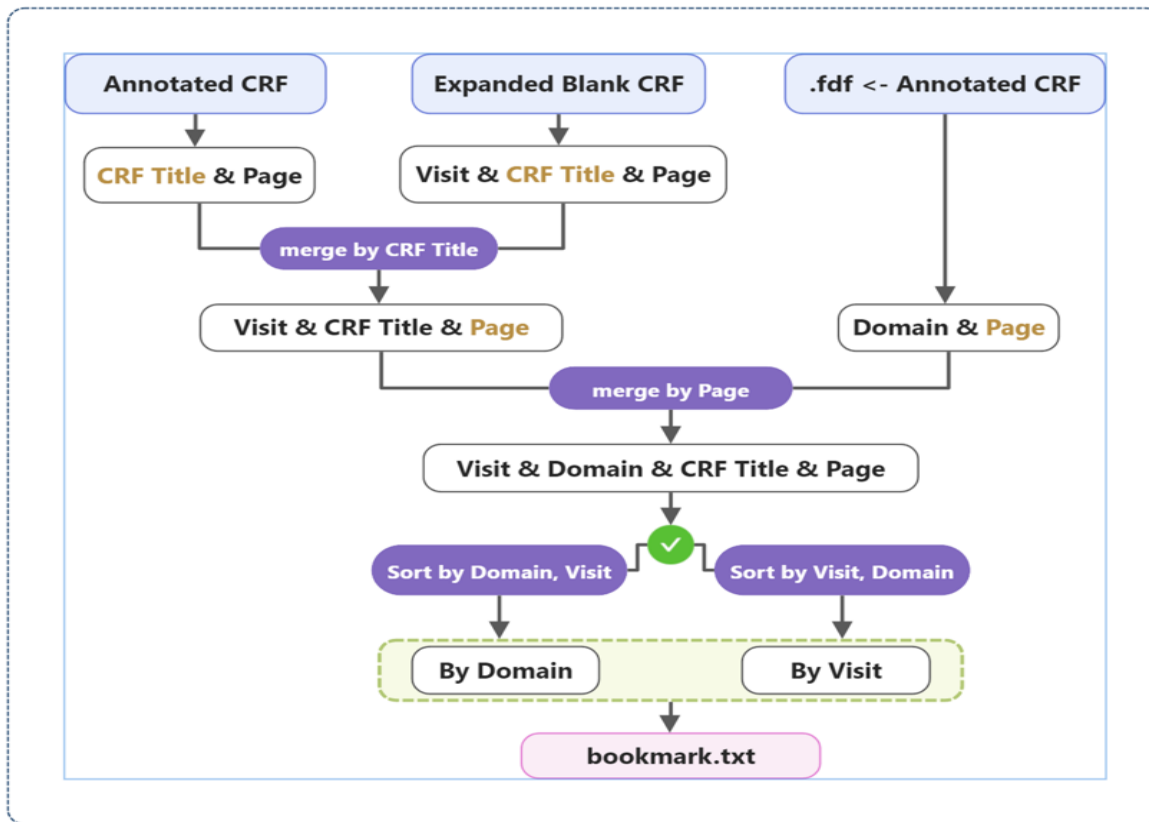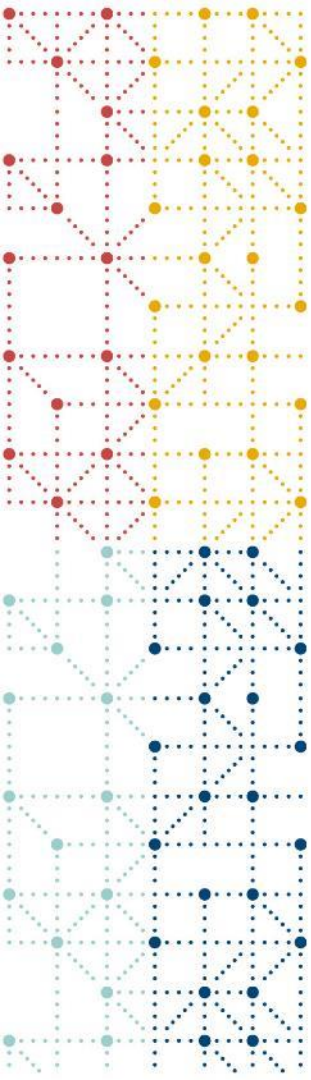
Thank You!

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