



Smart aCRF – Automated CRF Annotation

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Agenda

- CRF Annotation
- Traditional Annotation process
- Challenges of the Traditional process
- Smart aCRF Tool
- Manual aCRF Vs Smart aCRF
- Conclusion

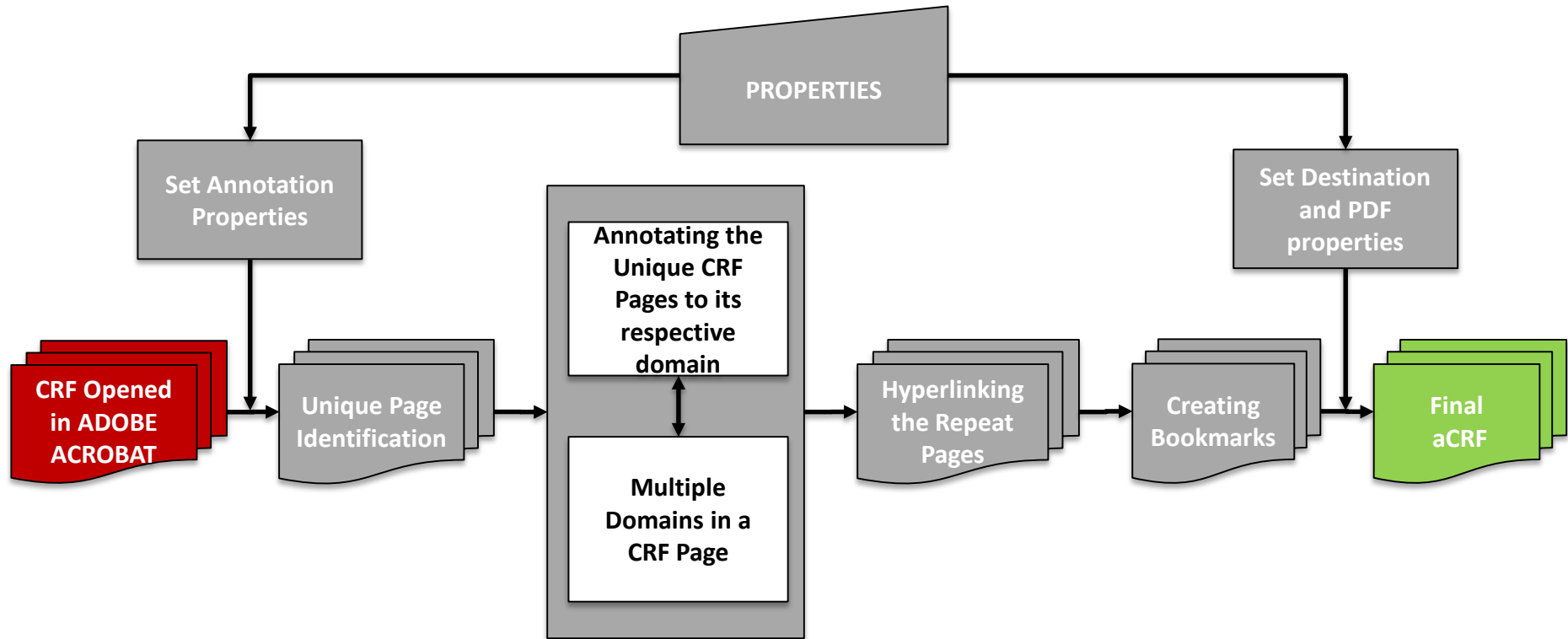


CRF Annotation

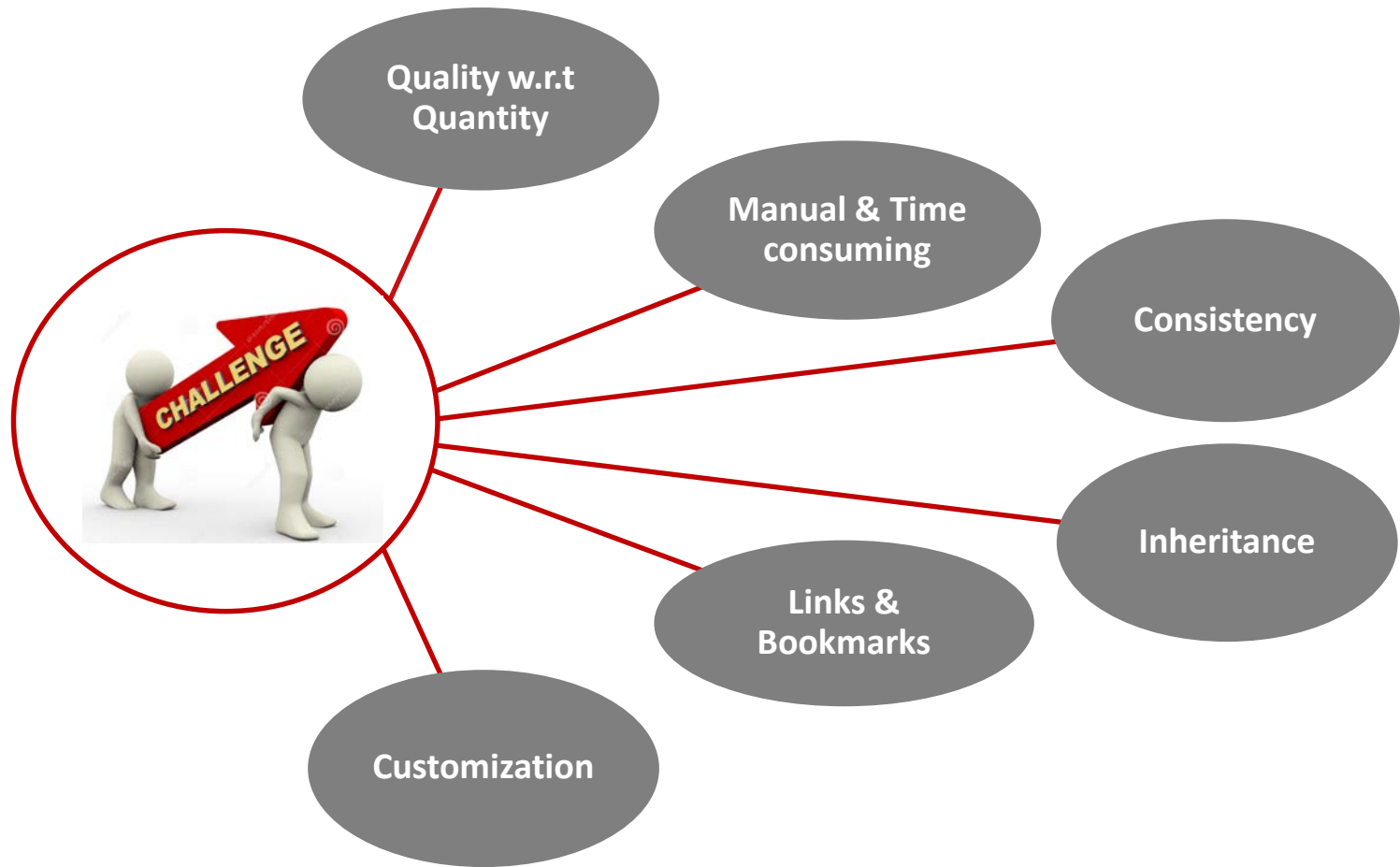
- Key CDISC submission deliverables
- Ensures Traceability
- Portraits Data collection
- Depicts clinical study data that maps to SDTM Domains/NOT SUBMITTED
- Ease the reviewer with a clear recognition of study



Traditional Annotation Process

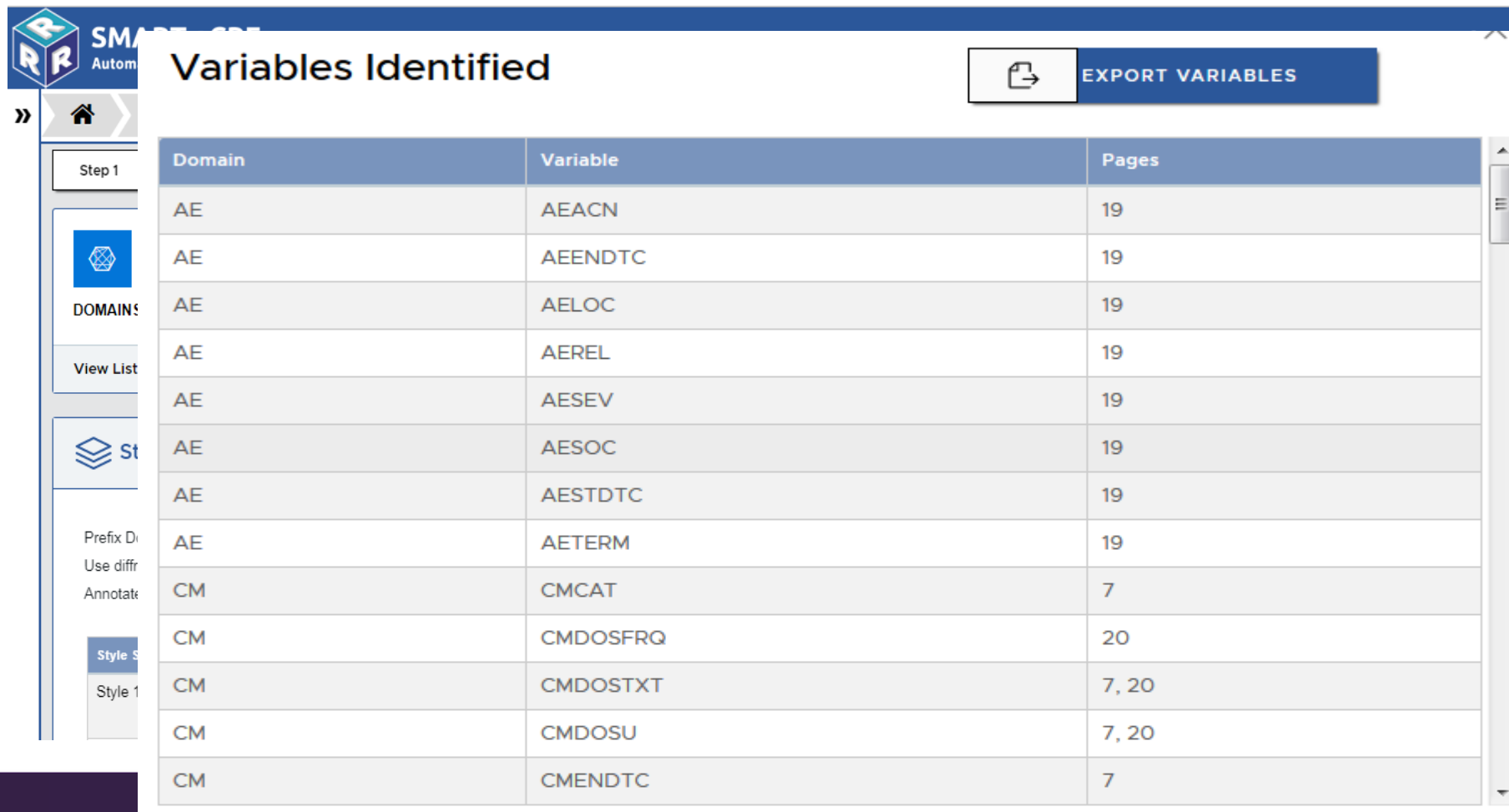


Challenges of the Traditional process



Smart aCRF Tool

- A one stop solution for all the challenges of creating aCRF



The screenshot displays the 'Variables Identified' section of the Smart aCRF Tool. The interface includes a sidebar on the left with navigation options like 'Step 1', 'DOMAINS', 'View List', and 'Style S'. The main area features a table with three columns: 'Domain', 'Variable', and 'Pages'. A blue button labeled 'EXPORT VARIABLES' is located at the top right of the table.

Domain	Variable	Pages
AE	AEACN	19
AE	AEENDTC	19
AE	AELOC	19
AE	AEREL	19
AE	AESEV	19
AE	AESOC	19
AE	AESTDTC	19
AE	AETERM	19
CM	CMCAT	7
CM	CMDOSFRQ	20
CM	CMDOSTXT	7, 20
CM	CMDOSU	7, 20
CM	CMENDTC	7

Smart aCRF Tool

– Key Aspects

**SMART aCRF**
Automated CRF Annotation

sysadmin

CDISC-SAMPLECDISC-STUDY-10232

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TEXTANNOTATION POINTER

DS = Disposition

CDISC	
Study CDISC01	
RANDOMIZATION	
DSTERM/DSDECOD='RANDOMIZED'	

Will the patient be randomized? ☐ Yes Enter Randomization Number

Randomization Date
MM DD YYYY

☐ No Complete Termination

Create Annotation

Keyword

Annotation Type: VARIABLE

Domain Type: STANDARD

Domain: AE

Variable:

Annotation

SAVERESET

Annotation Repository

MATCHEDUNMATCHEDALL DOMAINSFREE TEXT

Search ...

Domain	Variable	Annotation
DS	STUDYID	STUDYID
DS	DOMAIN	DOMAIN
DS	USUBJID	USUBJID



Highlights of aCRF Tool

Annotate the pdf with our propriety tool

Annotation Repository - Growing body of **Keyword–Annotation** pairs

Recommended default Text and Annotation attributes

Attributes saved into the **Annotation Repository** for repeat usage.

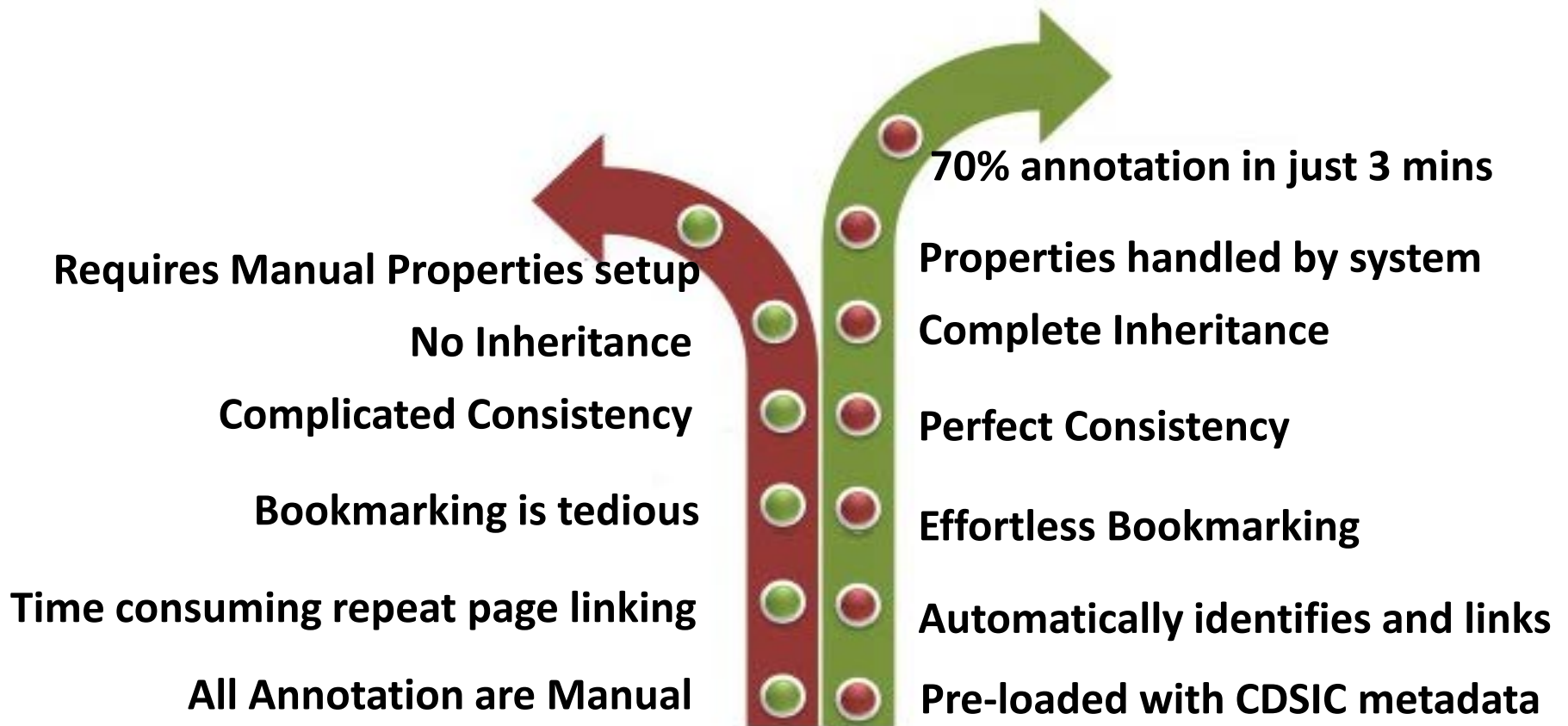
Annotations and Annotation attributes can be created/modified easily

Storage of Annotated CRF's generated for future usage

Facilitates Reverse Engineering using the existing Annotated CRF's



Manual aCRF vs Smart aCRF



Conclusion

- SMART aCRF system integrates the technology and the domain in an effective and efficient manner to overcome the repeated task.
- The resulting annotated BlankCRF.pdf still requires a thorough review by the Analyst but the gain in efficiency is phenomenal.
- What used to take a week or more can now be completed in a day or even hours when the previous trials in the same project have already been annotated.



Information for further communication

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Thank you!
...and now YOUR questions?





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