

Advancing SDTM annotation through automation

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DISCLOSURE

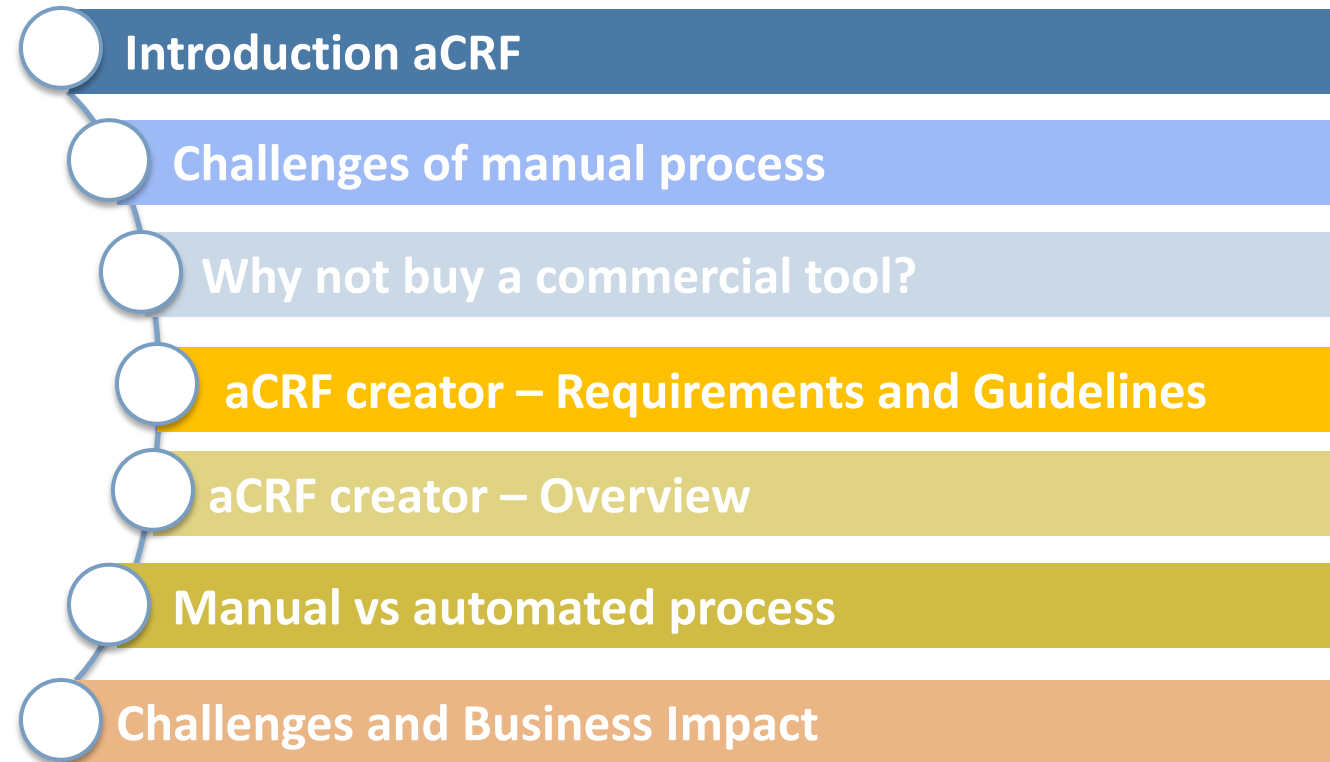
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Anja Kreis is an employee AbbVie and may own AbbVie stock.

Wolfgang Rohnert is an employee AbbVie and may own AbbVie stock.

Gerald Leahy works for AbbVie as a contractor and may own AbbVie stock.

AGENDA



Annotated Case Report Forms (aCRF)

Annotated Case Report Forms (aCRF) - Key CDISC submission deliverable.

Importance of the aCRF for regulatory agencies.
Support FDA reviewer to find the origin of data variables.

Importance of the aCRF for study teams

- SDTM annotation performed per study at least two times:
 - beginning of study for study team
 - end of study for SDTM submission package
- Use by Data Management/Data Science
- Use for creating ADaM datasets

VS = Vital Signs

Folder: UNIQUE
Form: Vital Signs
Generated On: 31 MAY 2018 17:01:34

Body position **VSPOS** Sitting ☒

1. - Systolic blood pressure Fixed Unit: mm Hg

VSORRES when VSTESTCD=SYSBP

2. - Diastolic blood pressure Fixed Unit: mm Hg

VSORRES when VSTESTCD=DIABP

Blood pressure units beats/min ☐
breaths/min ☐
mmHg ☒

VSORRESU when VSTESTCD=SYSBP or DIASP

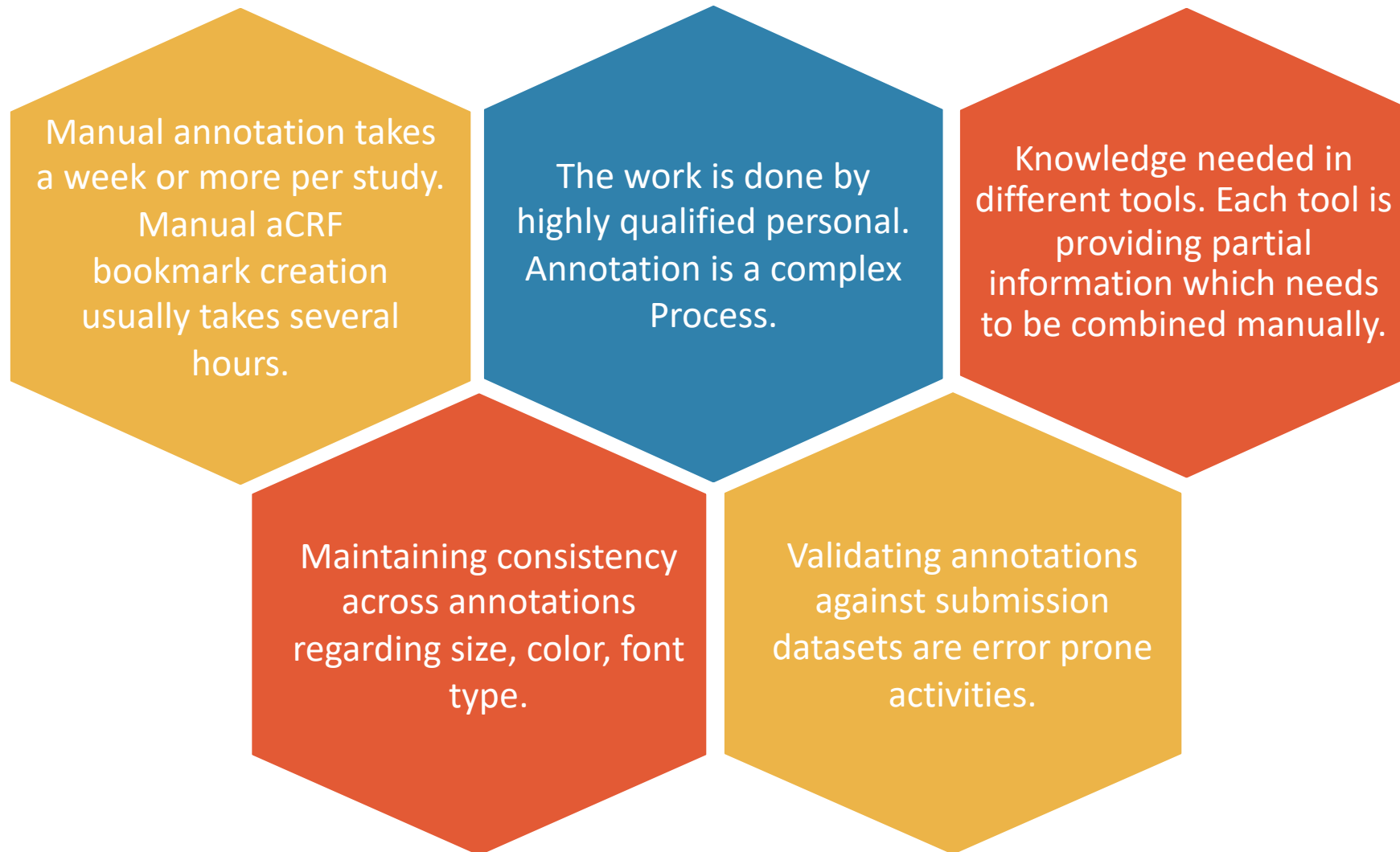
3. - Pulse Fixed Unit: beats/min

VSORRES when VSTESTCD=PULSE

Pulse units beats/min ☒
breaths/min ☐
mmHg ☐

VSORRESU when VSTESTCD=PULSE

Challenges of manual process



Why not buy a commercial tool?

Tools on the market

- Use blank Case Report Form (CRF) document from Electronic Data Capture (EDC) system
- Often require pre-annotation of the form
- Cannot be linked to in-house systems
- Cannot handle complex pages
- Entail updates of created annotation

aCRF Creator

- Automated creation of SDTM annotated CRF
- CRF creation based on EDC system metadata instead of using blank CRF from EDC system
- Use of Metadata stored and maintained in Metadata Repository, no pre-annotation is needed
- Annotation based on study specific metadata from Clinical Data Repository (CDR)
- Complete annotation process is automated

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aCRF creator – Regulatory Requirements

- Regulatory Requirement documents
 - Technical Conformance Guide



- FDA's portable document PDF Specifications

aCRF creator – CDISC Guidelines

- **Metadata Submission Guidelines v1.0 – CDISC SDS Metadata Team**

aCRF should be bookmarked by form and by visit.

aCRF should not have database annotations on it.

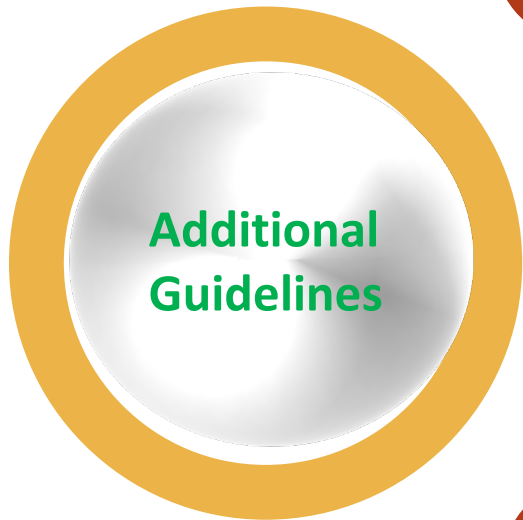
aCRF must contain all final unique CRF pages/modules. It should not contain blank pages.

Domain should have its annotation with 2-letter domain code and domain name.

If more than one domain exists on a page, each domain , and all of its variables should be color-coded.

All text in the annotation that represent variable and domain names should be capitalized.

aCRF creator – Additional Guidelines



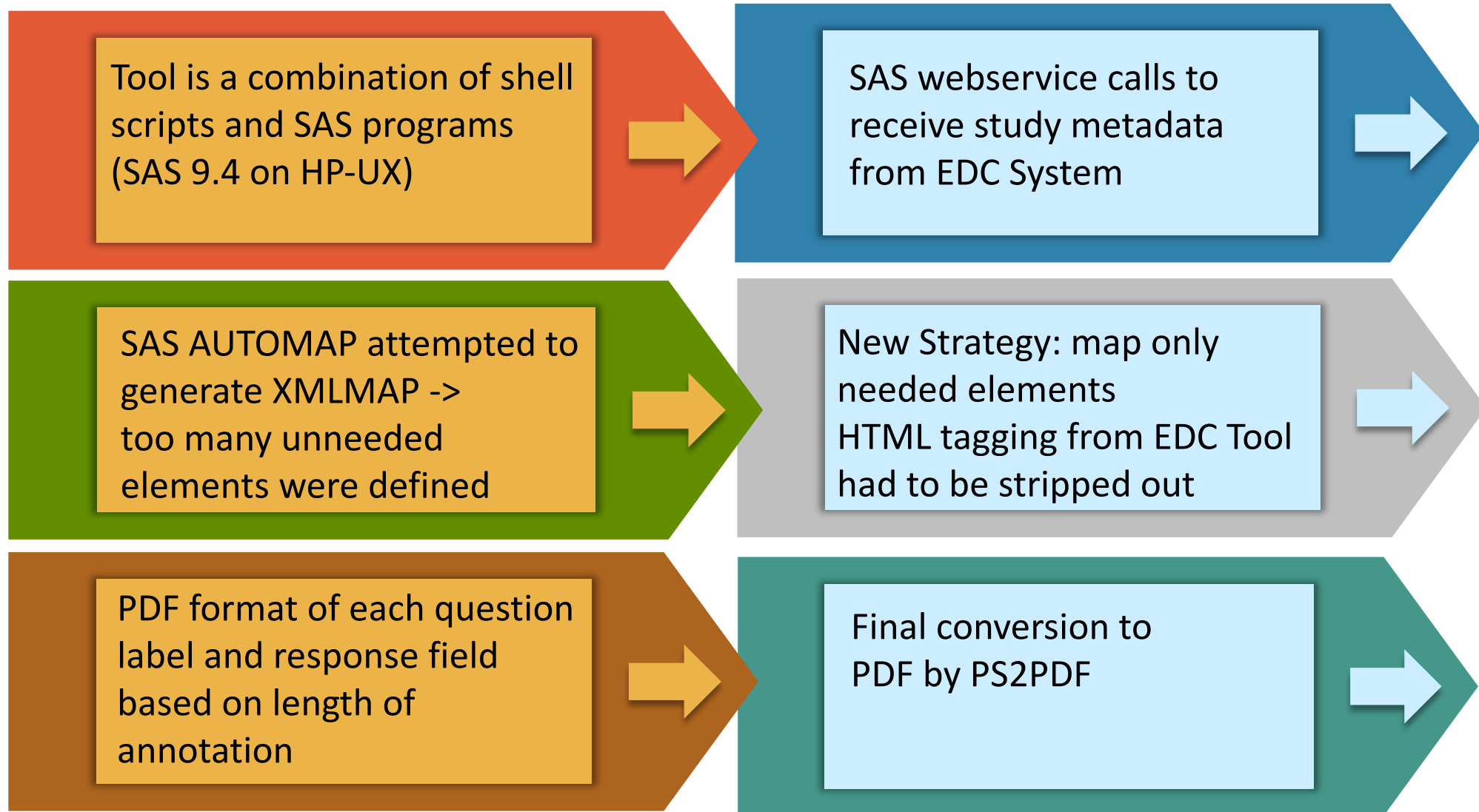
Appearance recommendations (font, color)

Domains [Domain Short Name] =
[Domain Long Name]

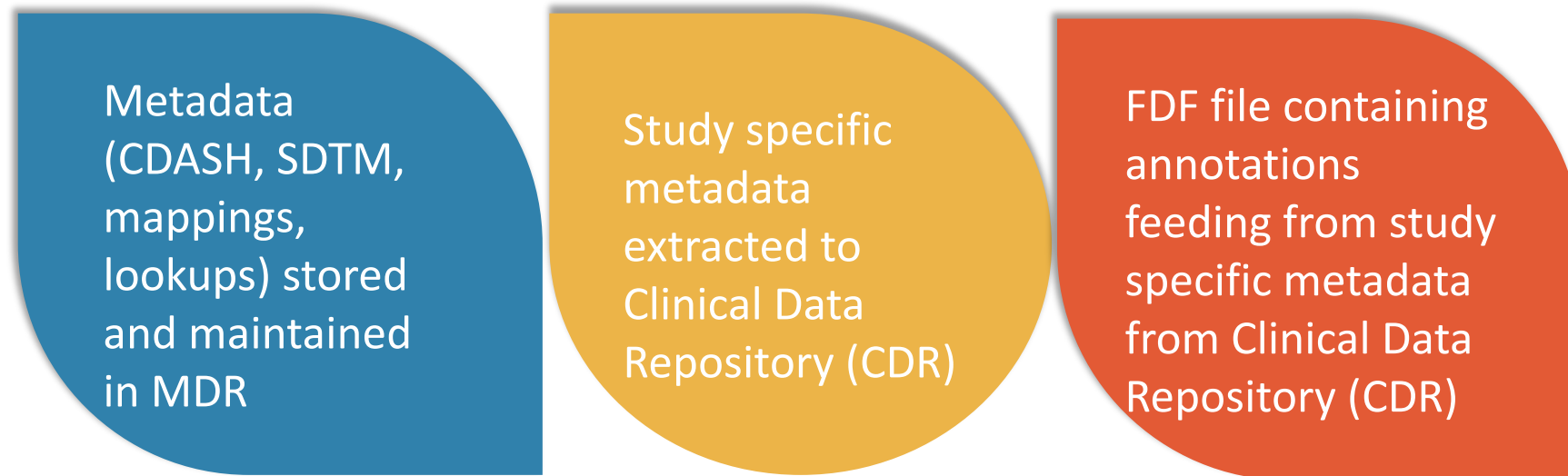
Supplemental Qualifiers SUPPXX.QVAL
when QNAM = VARNAME

Test Codes e.g. VSORRES when VSTESTCD=
“WEIGHT”, VSORRESU when VSTESTCD=“WEIGHT”

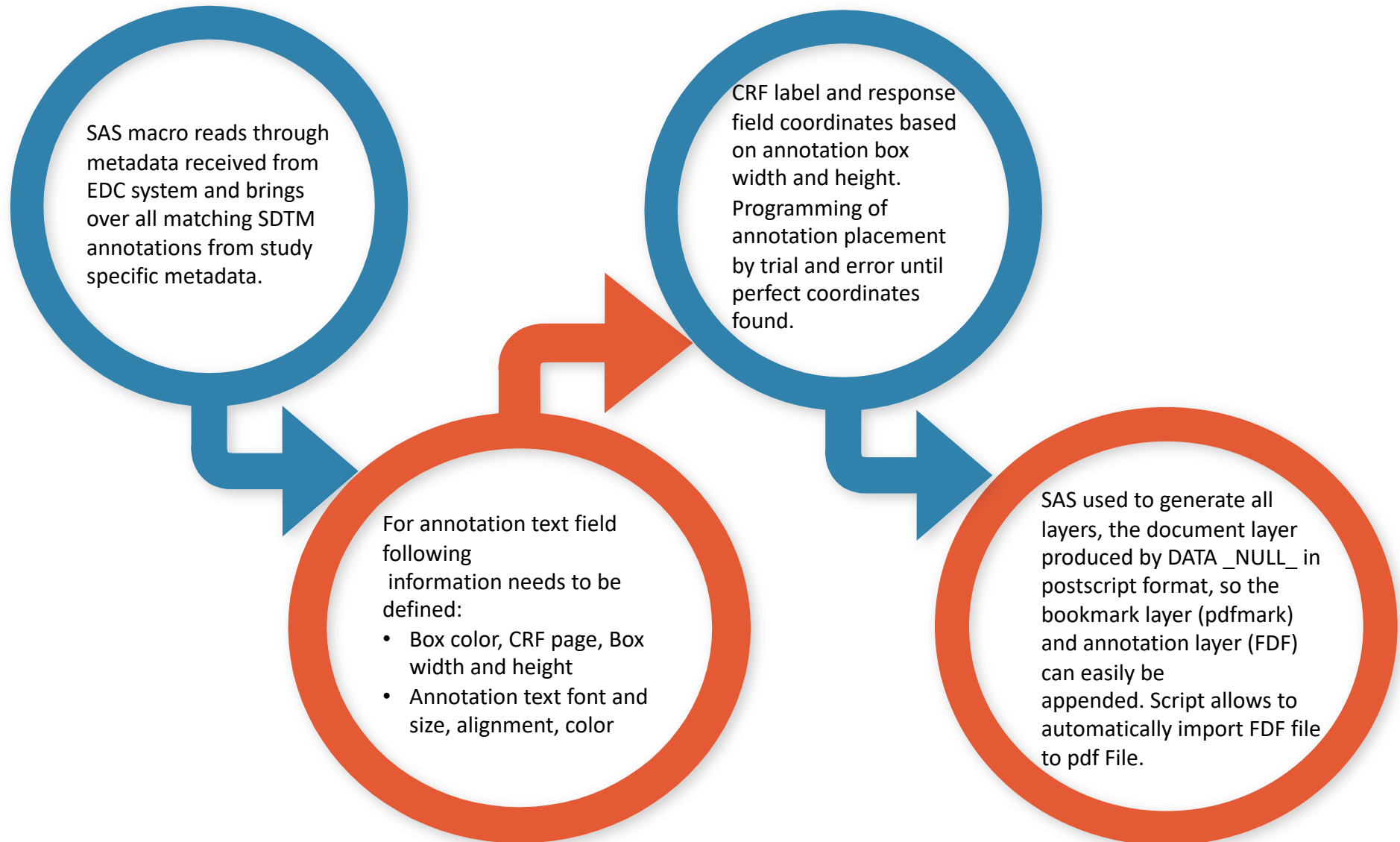
aCRF Creator Overview – CRF creation



aCRF Creator Overview – Access Metadata

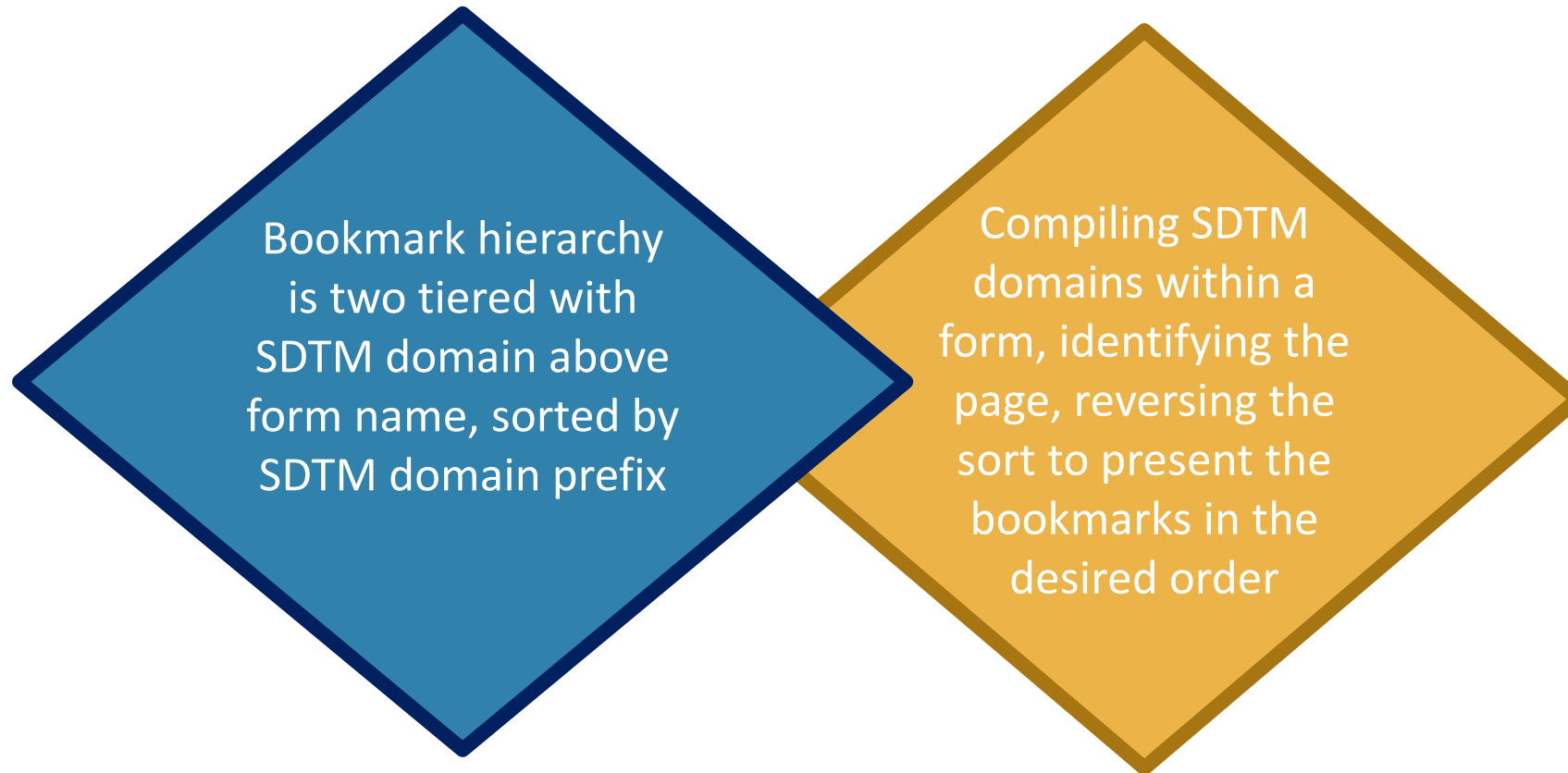


aCRF Creator Overview – Creation of Annotation

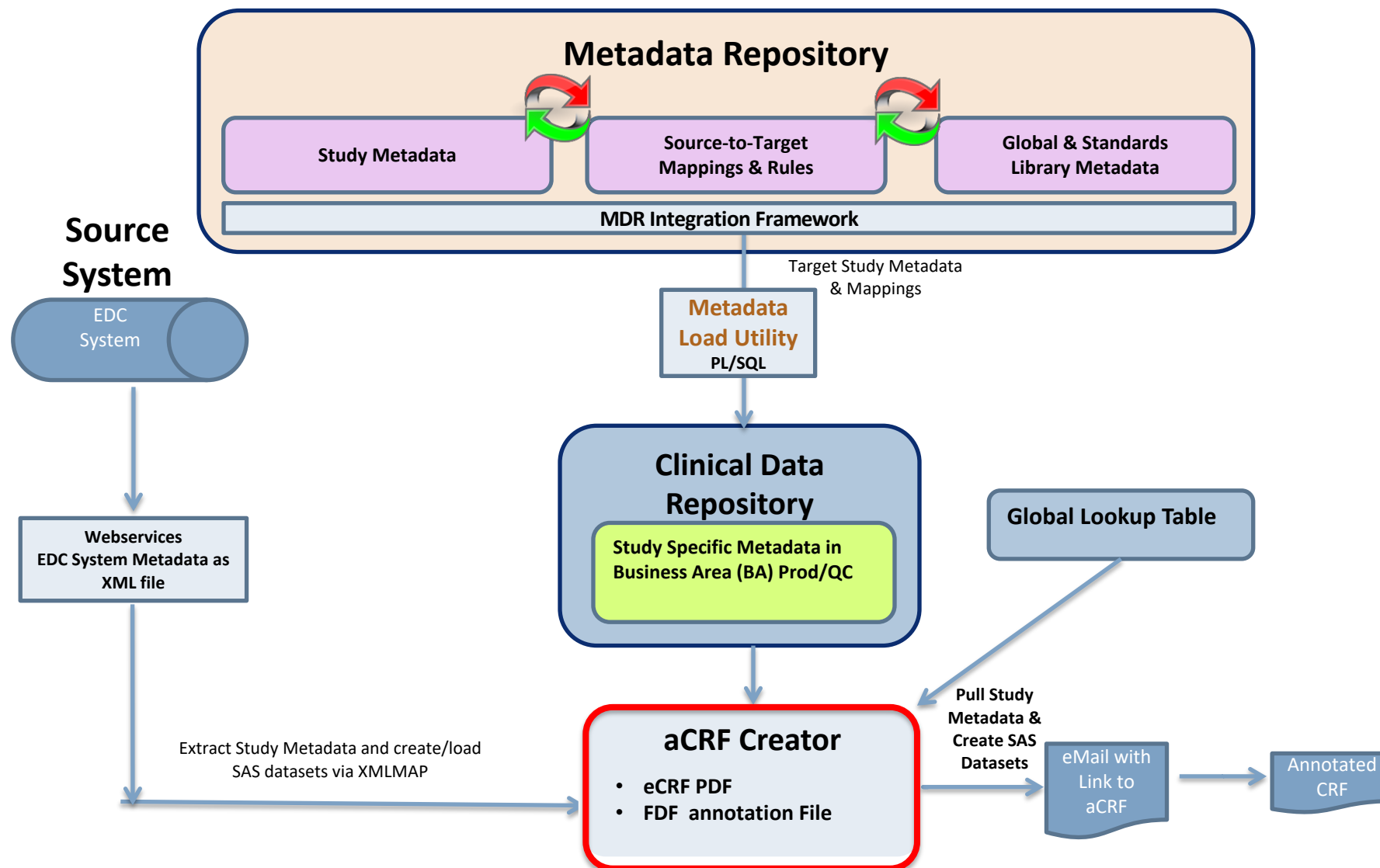


aCRF Creator - Bookmarking

- Tool creates automated bookmarking of domains

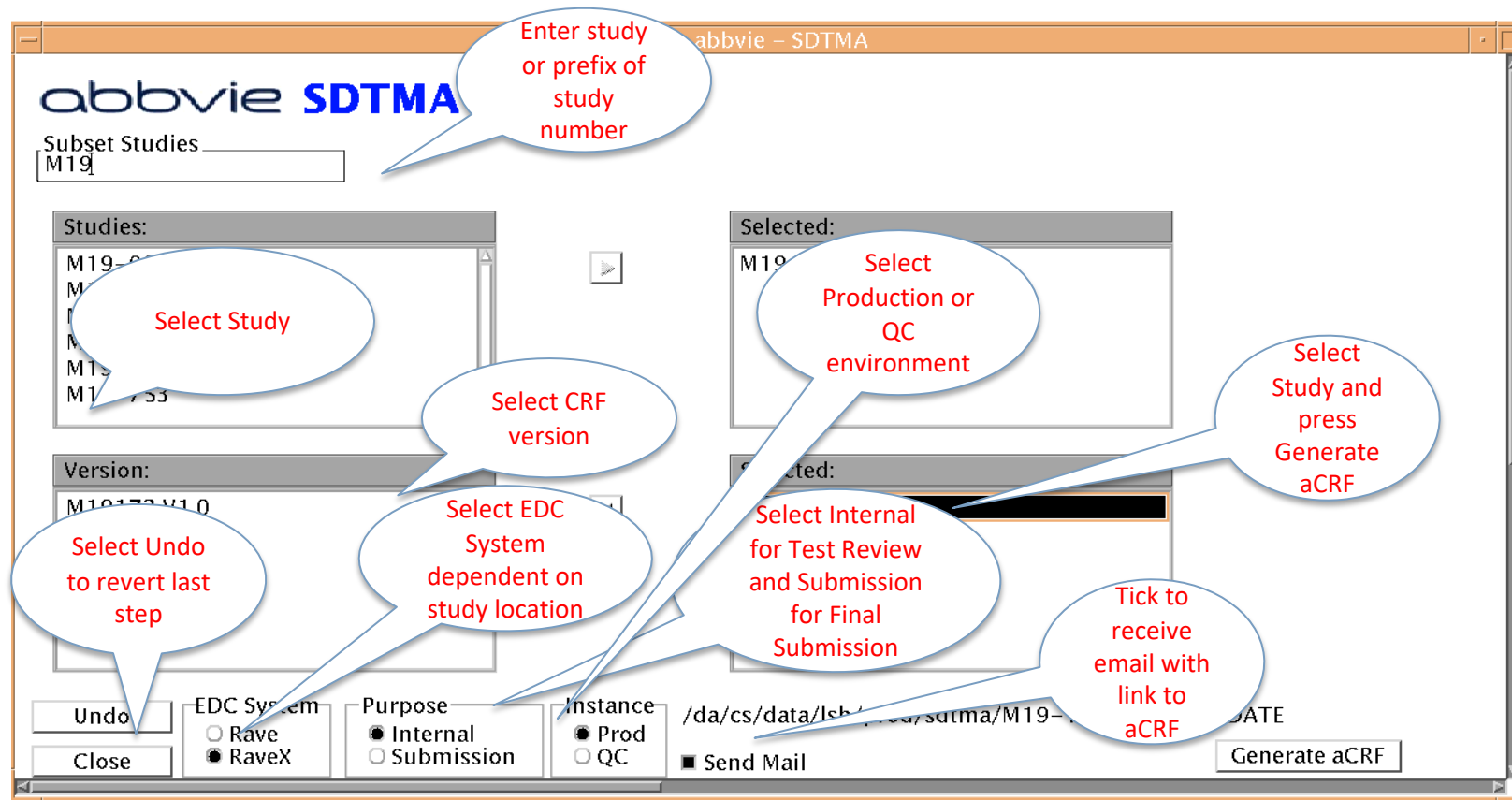


aCRF Creator – System Architecture Diagram



aCRF Creator - UI overview

- General overview of user interface



aCRF Creator Output

Domains

Adverse Events (AE)

Associated Persons Medical History (APMH)

Associated Persons Protocol Deviations (APDV)

Clinical Classification (CC)

Concomitant Medications (CM)

Death Details (DD)

Demographics (DM)

Disposition (DS)

Informed Consent

Study Completion - Screen Failure

Study Drug Completion CYP

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VS=Vital Signs

Form: Vital Signs
Folder: UNIQUE
Generated on: 27JAN2020 08:23

Question	Response
1. Systolic blood pressure Fixed Unit: mm Hg	VSORRES when VSTESTCD=SYSEP [_____]
2. Diastolic blood pressure Fixed Unit: mm Hg	VSORRES when VSTESTCD=DIABP [_____]
Blood pressure units	VSORRESU when VSTESTCD=SYSEP or DIABP [] beats/min [] breaths/min [X] mmHg
3. Body position	VSPCB ☐ Sitting ☐ Supine
4. Pulse Fixed Unit: beats/min	VSORRES when VSTESTCD=PULSE [_____]
Pulse units	VSORRESU when VSTESTCD=PULSE [X] beats/min [] breaths/min [] mmHg
5. Respiratory rate Fixed Unit: breaths/min	VSORRES when VSTESTCD=RESP [_____]
Respiratory rate units	VSORRESU when VSTESTCD=RESP [] beats/min [X] breaths/min [] mmHg
6. Temperature	VSORRES/VSORRESU when VSTESTCD=TEMP [] C [] F

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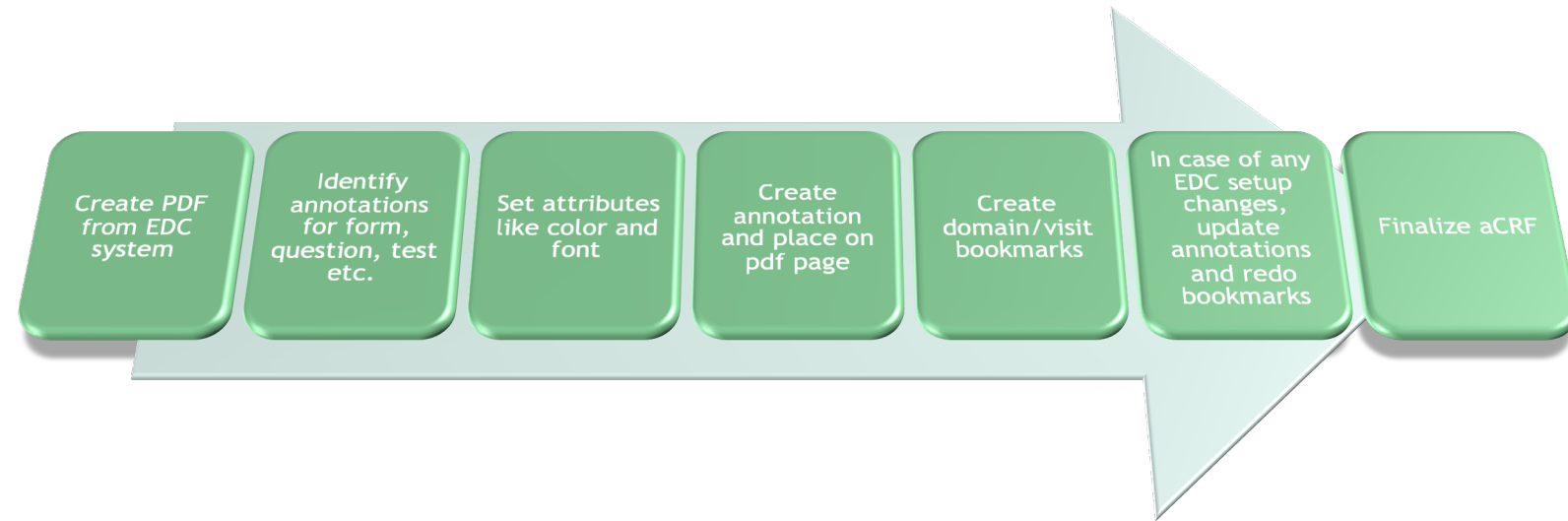
DM=Demographics
DD=Death Details

Form: Death
Folder: UNIQUE
Generated on: 27JAN2020 08:23

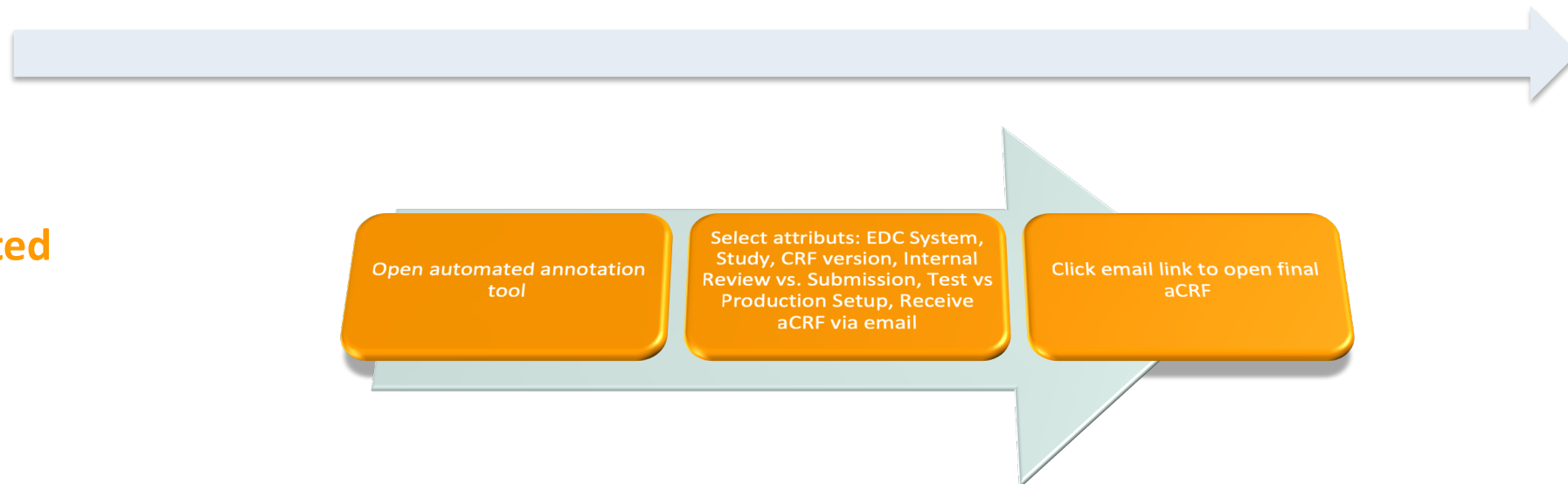
Question	Response
1. Date of death	DDORRES when DDTESTCD=DTHPL [_____]
Category	DDCAT ☐ AUTOPSY REPORT ☐ DEATH CERTIFICATE ☐ OTHER SOURCE
2. Was an autopsy report obtained?	DDORRES when DDTESTCD=AUTOPRT ☐ No ☐ Yes
2a. Primary cause of death the autopsy report	DDORRES when DDTESTCD=PRCDTH [_____]
2b. Secondary cause of death on the autopsy report	DDORRES when DDTESTCD=SECDTH [_____]

Process manual vs automated SDTM annotation

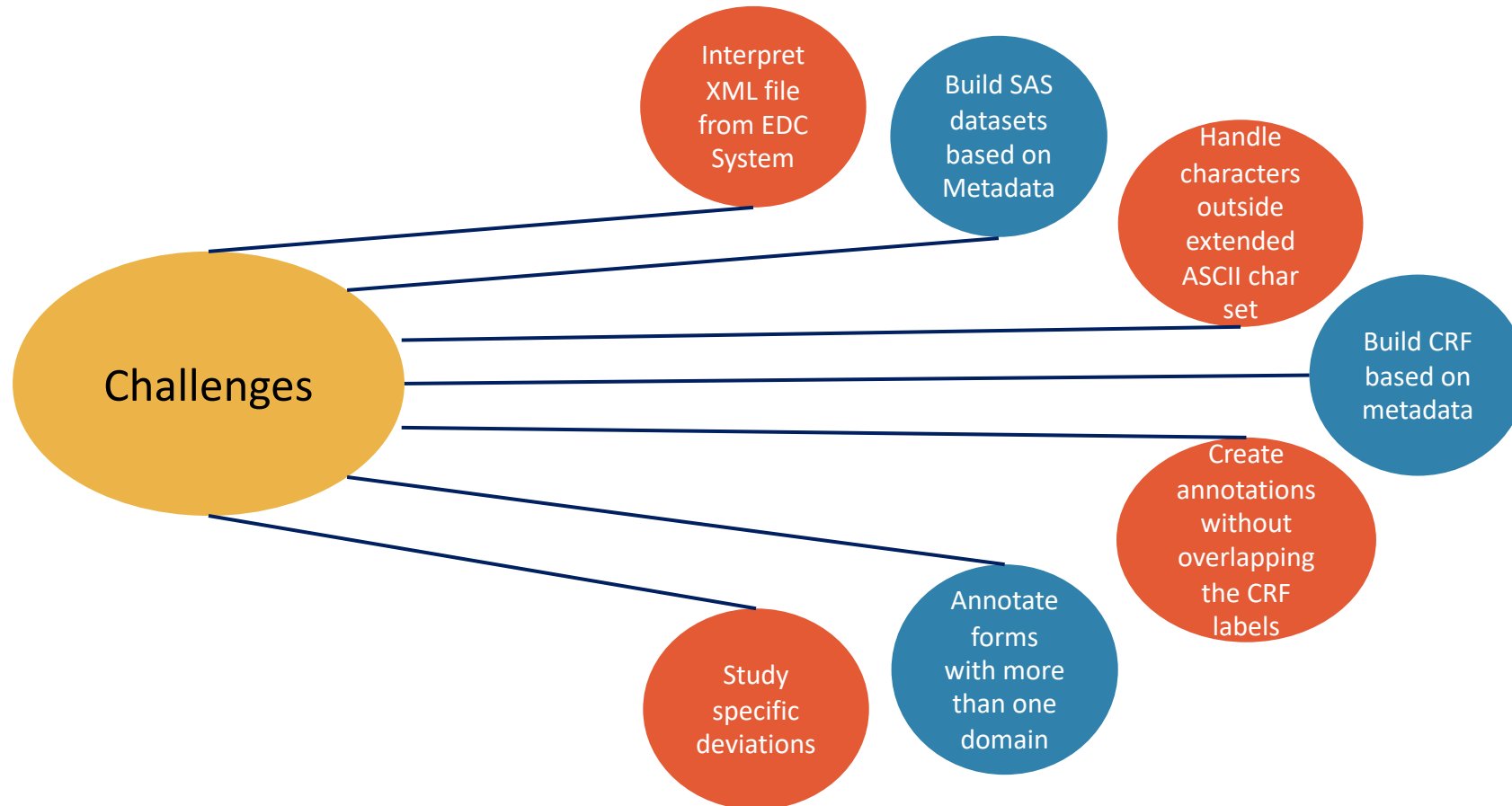
Manual Process



Automated Process



aCRF creator – Challenges



aCRF creator – Business Impact



Gain in efficiency – annotation done in several minutes



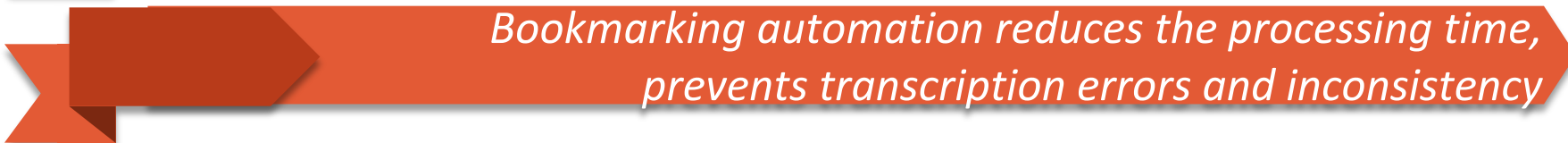
Users can create annotated CRFs ad hoc without waiting time



More user-friendly way to provide higher quality feedback



Better use of highly qualified personnel



*Bookmarking automation reduces the processing time,
prevents transcription errors and inconsistency*



Better quality annotated CRFs

Thank you!

Questions?

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