

Single Day Event

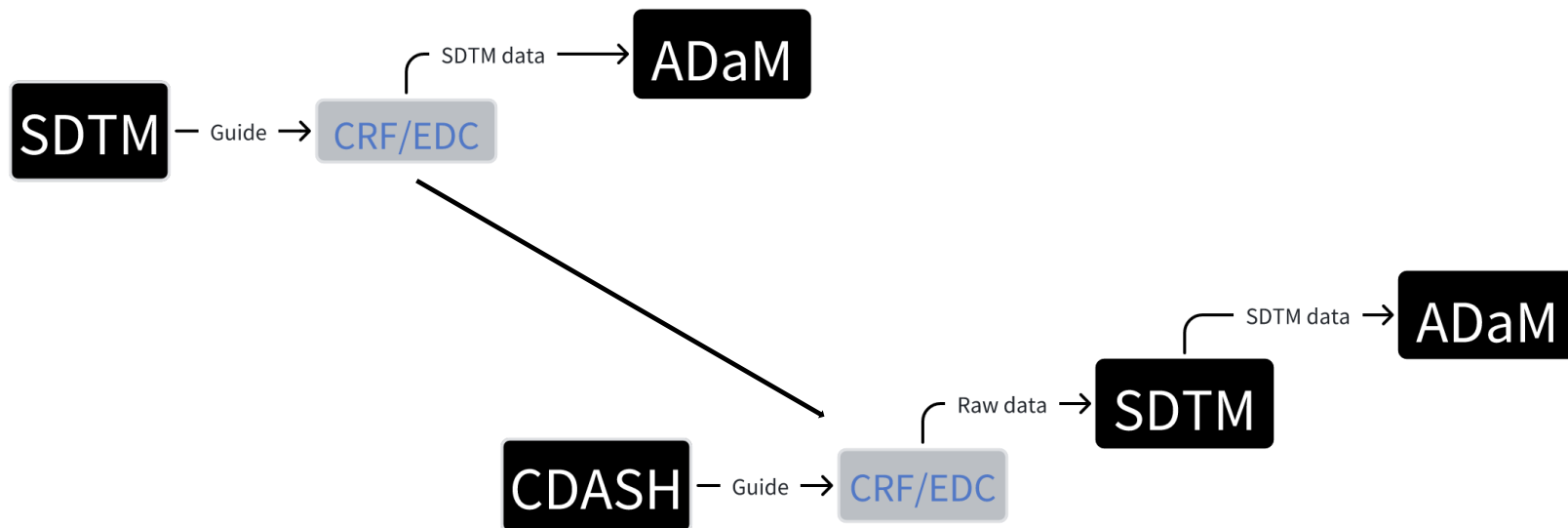
A thin layer on top of CDASH and SDTM
to promote the automation of SDTM

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Why do we need CDASH?

Since SDTM is submitted as raw data,
Why don't we **directly** follow the SDTM standard when designing the CRF?





Different purposes between CDASH and SDTM

CDASH and **SDTM** are each optimized for different purposes

CDASH:

User-friendly

Human-readable formats

Patient-centered

Collecting data according to the schedule

SDTM:

Data review

Standard data structure

Data reuse

Organize datasets by domain



Differences between CDASH and SDTM

Case 1: Missing Data

NOT SUBMITTED

Were any adverse events experienced?

Yes

No

1

Case 2: Data standardization

CDASH:	SUBJECT	AETERM	AESTDAT
	XXX001	LEUKOPENIA	10Oct2023
↓			
SDTM:	USUBJID	AETERM	AESTDTC
	XXX001	LEUKOPENIA	2023-10-10



Differences between CDASH and SDTM

Case 3: Data Organization

CDASH – Data on each CRF is driven by what is captured together

SDTM – Data needs to be placed in the target domain

DM = Demographics

RP = Reproductive System Findings

V2.1 1Feb21 2127 DEV: ALL FORMS

Project Name: Standard Library

Form: Demographics

Generated On: 09 Feb 2021 16:42:44

BRTHDTC

Year of birth

AGE

Age

Fixed Unit: Years

Sex

SEX = M

Male

SEX = F

Female

RPTST = Childbearing Potential

RPTSTCD = CHILDPOT

RPORRES = Y

Yes

RPORRES = N

No

Is subject of child-bearing potential?

SUBJECT

XXX001

BRTHDAT

01Jan2000

AGE

23

SEX

Male

CHILDPOT

Yes

USUBJID

XXX001

DOMAIN

DM

BRTHDTC

2020-01-01

AGE

23

AGEU

YEARS

SEX

M

USUBJID

XXX001

DOMAIN

RP

RPTST

CHILDPOT

RPTSTCD

Childbearing
Potential

RPORRES

Y



Differences between CDASH and SDTM

Case 3: Data Orientation

CDASH – Findings data may have to be horizontal for each test

SDTM – Findings data must be in a vertical structure

Lab results

LBTEST=Hemoglobin	LBORRES where LBTESTCD=HGB	LBORRESU	9
Hemoglobin			
LBTEST=Hematocrit	LBORRES where LBTESTCD=HCT	LBORRESU	10
Hematocrit			
LBTEST=Erythrocytes	LBORRES where LBTESTCD=RBC	LBORRESU	11
Red Blood Cell Count			

SUBJECT	HGB	HCT	RBC
XXX001	143	43	4.68

USUBJID	DOMAIN	LBTEST	LBTESTCD	LBORRES	LBORRESU
XXX001	LB	Hemoglobin	HGB	143	g/L
XXX001	LB	Hematocrit	HCT	43	%
XXX001	LB	Erythrocytes	RBC	4.68	10^12/L



A more complex example

DM = Demographics

DS = Disposition

DSCAT = PROTOCOL MILESTONE

V2.1 1Feb21 2127 DEV: ALL FORMS

Project Name: Standard Library

Form: Informed Consent

Generated On: 09 Feb 2021 16:42:44

RFICDTC **DSSTDTC where DSDECOD = INFORMED CONSENT OBTAINED**

Date informed consent signed _____ ①

DSTERM = INFORMED CONSENT FOR STUDY ENROLLMENT OBTAINED

Protocol version _____

SUPPDS.QVAL where QNAM = DSPROTVS

Original ☐ ②

Amendment 1 ☐

Amendment 2 ☐

Amendment 3 ☐

Amendment 4 ☐

Amendment 5 ☐

USUBJID	RFICDTC
XXX001	2020-01-01

DSTERM = INFORMED CONSENT FOR OPTIONAL TISSUE SAMPLES OBTAINED if Yes

Did the subject consent to optional biopsy? Yes ☐ ③ No ☐

DSDECOD = INFORMED CONSENT OBTAINED if Yes

DSSTDTC ★ _____ ④

Date of subject consent to Optional Tissue samples _____

DSTERM = INFORMED CONSENT FOR OPTIONAL BLOOD BIOMARKERS OBTAINED if Yes

Did the subject consent to optional blood collection? Yes ☐ ⑤ No ☐

DSDECOD = INFORMED CONSENT OBTAINED if Yes

DSSTDTC ★ _____ ⑥

Date of subject consent to Optional Blood Biomarkers _____

DSDECOD = INFORMED CONSENT OBTAINED if Yes

Did the subject consent to storage and future research with biomarker and biological samples? (Optional) Yes ☐ ⑦ No ☐

DSTERM = INFORMED CONSENT FOR STORAGE AND FUTURE RESEARCH WITH BIOMARKER AND BIOLOGICAL SAMPLES OBTAINED if Yes

USUBJID	DOMAIN	DSTERM	DSDECOD	DSSTDTC	DSPROTVS
XXX001	DS	xxx (Omit)	XXX (Omit)	2020-01-01	Original
XXX001	DS	xxx (Omit)	XXX (Omit)	2020-02-01	
XXX001	DS	xxx (Omit)	XXX (Omit)	2020-03-01	
XXX001	DS	xxx (Omit)	XXX (Omit)		



Build a Form model

Form x

Field 1

Field 2

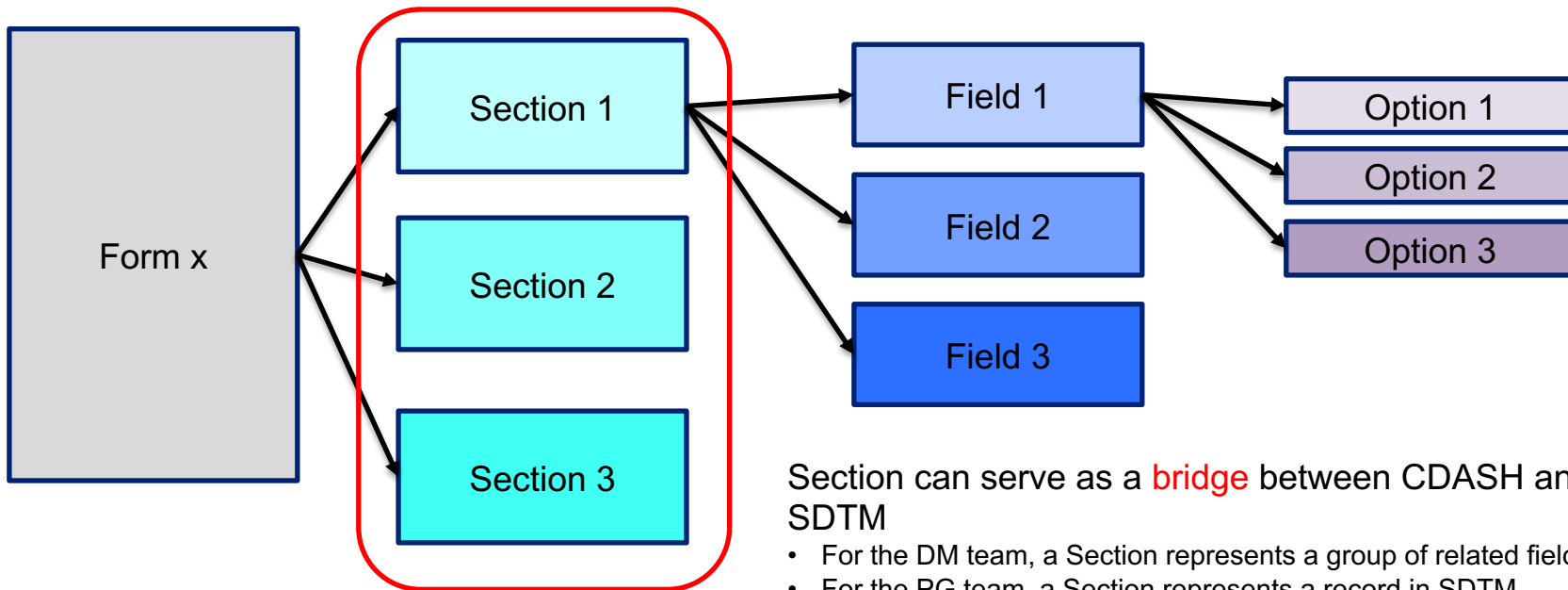
Field 3

Option 1
Option 2
Option 3

Field 4



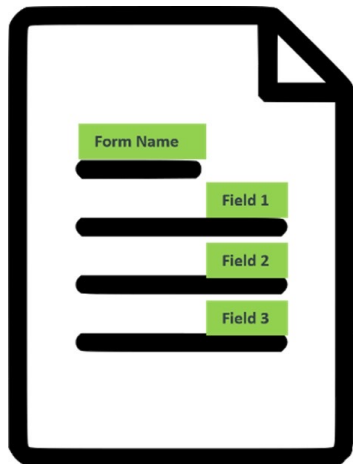
Expand the Form model



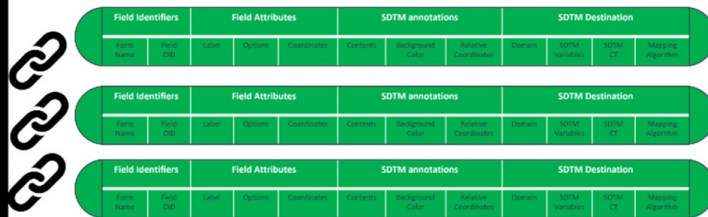


CRF-driven Coding-free SDTM Transformation

Field Identifiers		Field Attributes			SDTM annotations			SDTM Destination			
Form Name	Field OID	Label	Options	Coordinates	Contents	Background Color	Relative Coordinates	Domain	SDTM Variables	SDTM CT	Mapping Algorithm

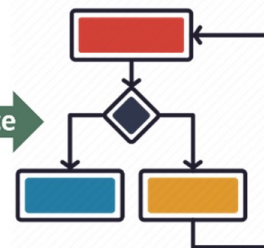


CRF



CRF Field Digital Capsules

Translate



SAS Code



How many capsules should be taken at a time?

Interoperable UI

Section information

CRF Field Digital Capsules
With **Record** Information

SAS Code



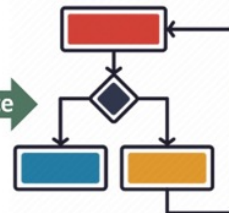
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          "Record": "record 1"
        }
      ],
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        {
          "option": "option 1",
          "Annotations": [
            {
              "text": "Annotation 1",
              "Record": "record 1"
            }
          ]
        }
      ]
    }
  ]
}
```

Rcd1

Rcd2

Field Identifiers			Field Attributes		SDTM annotations				SDTM Destination			
Field ID	Field Label	Field Type	Display Name	Default Value	SDTM Element	SDTM Data Type	SDTM Domain	SDTM Code	SDTM Element	SDTM Data Type	SDTM Domain	SDTM Code
Rcd1												
Rcd2												

Translate



Data Standard Team
HIGH-INTERACTION
Easy Customize

Programmer Team
LOW-CODE
Easy Review

AI ASSISTANCE



2. Record Section Information

3. Preview the structure of SDTM



Thank You!



**The Global Healthcare
Data Science Community**

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