



CDISC on your C:\DISK

PhUSE

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Ferring Pharmaceuticals

MEDICINE ON THE



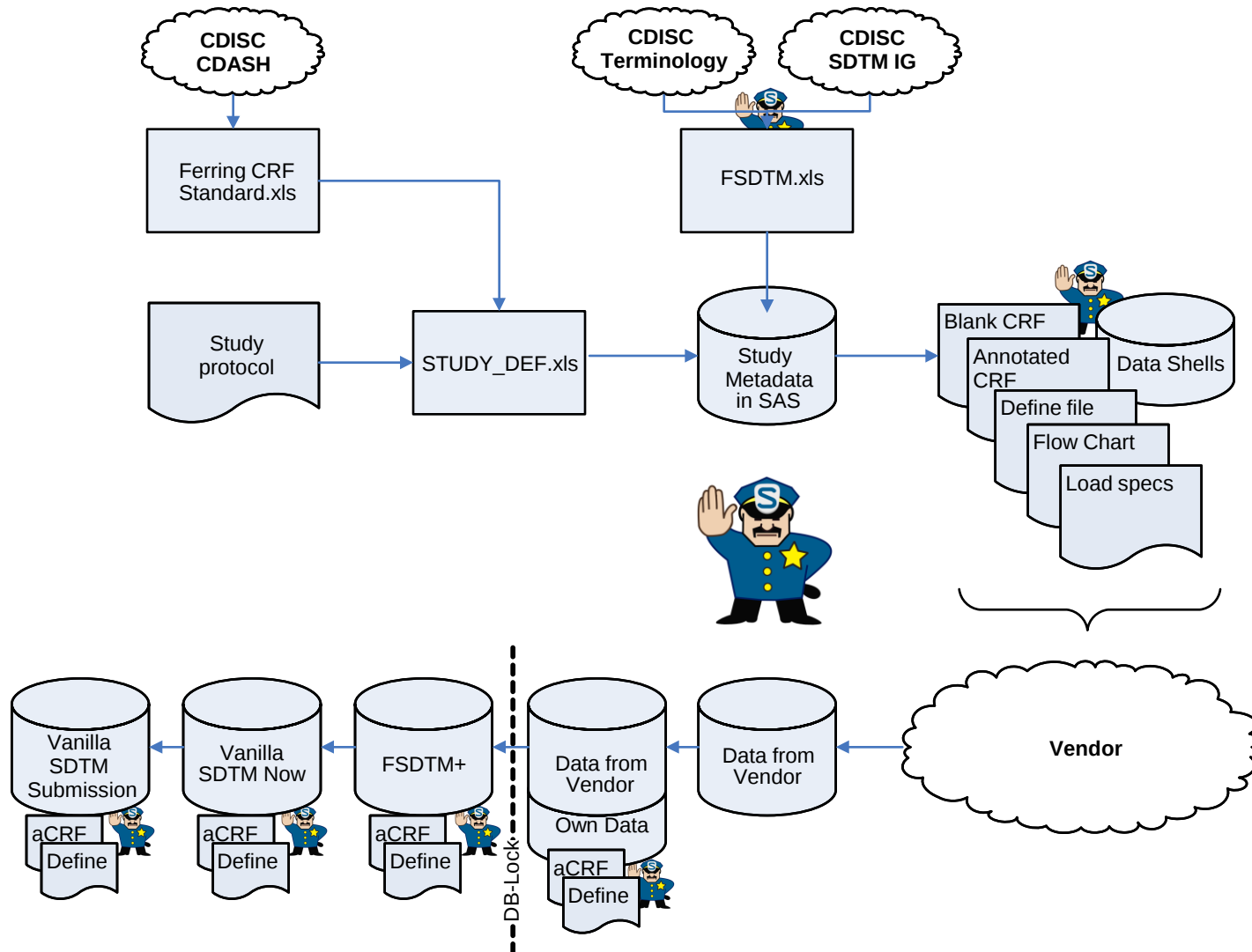
FERRING

PHARMACEUTICALS

MEDICINE ON THE BODY'S OWN TERMS



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CDISC ODM

Study Events

└─ Forms

└─ Item Groups

└─ Items

Define once

Reference as you please

CDISC ODM at Ferring

CDISC ODM:

Item: HEIGHT having a unit attribute set to "cm"

Ferring ODM:

Item: VSTESTCD set to "HEIGHT"

Item: VSORRES set to whatever sites enter

Item: VSORRESU set to "cm"

...and we don't do XML....yet

Blank CRF

PhUSE Status (Screening)

Height		Centimeter
Temperature		☐ Degree Celsius ☐ Degree Fahrenheit
Are you also hungry	☐ No ☐ Yes	
Do you also love PhUSE	☐ Yes ☐ Yes ☐ Yes ☐ Yes	
Scandinavian PhUSE Happiness Score		

Annotated CRF

PhUSE Status (Screening)

DOMAIN: VS

Pre-defined columns for this Item Group: VSCAT=[PHUSE], VSSCAT=[GENERAL]

Measurement =VSTESTCD	Result =VSORRES	Unit =VSORRESU
Height=[HEIGHT]	integer(8)	Centimeter=[cm]
Temperature=[TEMP]	float(8)	☐ Degree Celsius=[C] ☐ Degree Fahrenheit=[F]
Are you also hungry=[HUNGRY]	☐ No=[N] ☐ Yes=[Y]	
Do you also love PhUSE=[PHLOVE]	☐ Yes=[Y] ☐ Yes=[Y] ☐ Yes=[Y] ☐ Yes=[Y]	
Scandinavian PhUSE Happiness Score=[PHUSESCR]	text(200) Derived	

Define file - Domains

Data Sets

Domain	Description	Class	Structure	Purpose	Keys	Location
IE	Inclusion/Exclusion Exceptions	Findings	One record per Inclusion/Exclusion criteria per subject	Tabulation	STUDYID, USUBJID, SUBJID, SCREENNO, IECAT, IESPID, IETESTCD	IE_sas7bdat
VS	Vital Signs	Findings	One record per vital sign measurement per time point per visit per subject	Tabulation	STUDYID, USUBJID, SUBJID, SCREENNO, VISITNUM, VSTESTCD, VSCAT, VSSCAT	VS_sas7bdat

Define file - Variables

Vital Signs (VS)

Variable	Label	Type	Length	Controlled Terms or Format	ITOrigins	Role	Comments
STUDYID	Study Identifier	text	20	PhUSE	Assigned		
DOMAIN	Domain Abbreviation	text	2	VS	Assigned		
USUBJID	Unique Subject Identifier	text	30		Derived		See Computational Method: USUBJID
SUBJID	Subject Identifier for the Study	text	20		Derived		See Computational Method: SUBJID
SCREENNO	Screening Number	text	20		Derived		See Computational Method: SCREENNO
VISIT	Visit Name	text	50		Derived		See Computational Method: DECODE(VISITNUM)
VISITNUM	Visit Number	float	8	XVISITNUM	Assigned		Screening - PhUSE Status
VSTESTCD	Vital Signs Test Short Name	text	8		Assigned		Screening - PhUSE Status
VSTEST	Vital Signs Test Name	text	40		Derived		See Computational Method: DECODE(VSTESTCD)
VSCAT	Category for Vital Signs	text	100	XVSCAT	Assigned		Screening - PhUSE Status
VSSCAT	Subcategory for Vital Signs	text	100	XVSSCAT	Assigned		Screening - PhUSE Status
VSORRES	Result or Finding in Original Units	text	200		CRF		Screening - PhUSE Status See Computational Method: PHUSESCORE
VSORRESU	Original Units	text	15	UNIT	CRF		Screening - PhUSE Status

Define file - Computations

Computational Algorithms

Reference Name	Computation Method
DECODE	Decode of variable
PHUSESCORE	No matter what set the score to "Simply Excellent"
SCREENNO	From Registration page screening number
SUBJID	From Randomisation page subject ID
USUBJID	Study ID concatenated with subject number or screening number

Define file – Value Level Metadata

Value Level Metadata

Source Variable	Value	Label	Type	Controlled Terms or Format	Origin	Role	Comments
IETESTCD	INCL01	Have you paid your 2010 PhUSE fee	text	NY	CRF		Screening - Inclusion Criteria
	INCL02	Have you registered in the reception	text	NY	CRF		Screening - Inclusion Criteria
	INCL03	Have you taken the elevator to the 19th floor	text	NY	CRF		Screening - Inclusion Criteria
	INCL04	Can you spell CDISC	text	NY	CRF		Screening - Inclusion Criteria
VSTESTCD	HEIGHT	Height	integer		CRF		Screening - PhUSE Status
	TEMP	Temperature	float		CRF		Screening - PhUSE Status
	HUNGRY	Are you also hungry	text	NY	CRF		Screening - PhUSE Status
	PHLOVE	Do you also love PhUSE	text	NY	CRF		Screening - PhUSE Status
	PHUSESCR	Scandinavian PhUSE Happiness Score	text		CRF		See Computational Method: PHUSESCORE

Hurdles

- Learn CDISC SDTM + Tool
- Backlog in setup
- Versioning / amendments
- User friendliness vs. flexibility
- System Validation
- Working methods into SOPs

Future

- FSDTM -> FSDTM+ -> SDTMNow -> SDTM@Submission
- More police:
 - Between study police
 - Police on specifications before they are sent out
 - Police on data returned
 - Check against standards
- HTML+SAS7bdat -> XML, PDF, XPT
- SDTM Trial Metadata + Protocol Metadata
- Standard CRFs in Tool and align more with CDASH

Future

- Integrate more with vendors (e.g. ODM XML)
- Data validation plan partly build into tool
- Early and realistic test data for testing and stat. prog.
- Better metadata entry interface
- More DTC functions
- BUGS
- Better metadata change control

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