



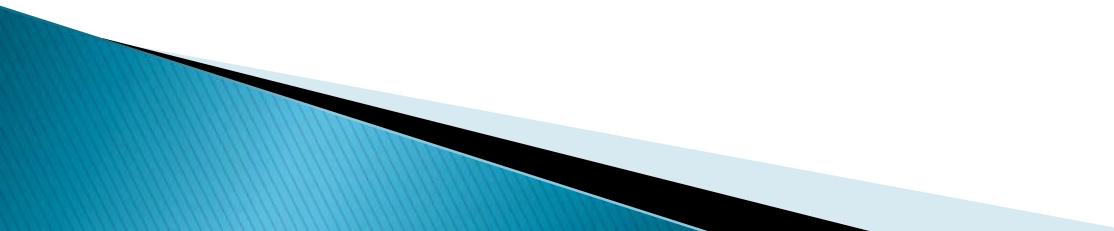
Strategy to Start to Implement CDISC Standards

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- ▶ Status of CDISC in Data Submission
 - ▶ Difficult to implement?
 - ▶ How to get started to implement CDISC?
- 



Section 1: Status of CDISC in Data Submission

Status of CDISC in Data Submission

- ▶ FDA:
 - 2016Dec

- ▶ PMDA:
 - 2016–2020

- ▶ CFDA: (27Jul2016)
 - ▶ ...为了提高临床试验数据质量以及统计分析的质量和效率，方便数据的交流与汇总分析，在新药上市注册申请时，建议采用CDISC标准递交原始数据库和分析数据库。
 - ▶ ...to improve the quality of clinical trial data and the quality and efficiency of statistical analysis, and facilitate the data interchange and integrated analyses, in NDA, it is **suggested** to adopt **CDISC** standards in submission of raw and analysis database.”

Where we are?

▶ 2013

- June: Steering Committee, China CDE Specific Work on Clinical Data Standardization 指导组
- August: 5 Working Groups, China CDE Specific Work on Clinical Data Standardization 工作组

▶ 2014 – 2016

- CDASH, SDTM, ADaM, CT, ODM document Translation
- Quarterly Seminar on CDISC
- Public Training

▶ 2016 Objectives:

- Complete draft proposal for data submission in China
 - Including conformance Guide

Section 2: Difficult to implement?

What's your reaction if saying to require to submit data following CDISC Standards?

Scared?



- lack of knowledge and
- Lack of experience

CDASH example (CRF)

访视 1

访视日期: _ _ / _ _ / _ _ _ _ (DD/MMM/YYYY)

知情同意

知情同意签署日期: _ _ / _ _ / _ _ _ _ (DD/MMM/YYYY)

人口统计学

出生日期: _ _ / _ _ / _ _ _ _ (DD/MMM/YYYY)

性别:

☐ M 男

☐ F 女

种族:

☐ 1 白人

☐ 2 黑人/非洲裔美国人

☐ 3 亚洲人

☐ 4 夏威夷原住民或其它太平洋岛人

☐ 5 美洲印第安人或阿拉斯加原住民

☐ 99 其它, 请说明: _____

aCRF example

方案编号: CDE01 STUDYID

VISIT

访视 1

VISITNUM

SVSTDTC

DMDTC

访视日期: _ _ / _ _ / _ _ _ _ (DD/MMM/YYYY)

知情同意

RFICDTC

知情同意签署日期: _ _ / _ _ / _ _ _ _ (DD/MMM/YYYY)

人口统计学

BRTHDTC

出生日期: _ _ / _ _ / _ _ _ _ (DD/MMM/YYYY)

性别: SEX

☐ M 男

☐ F 女

种族: RACE

☐ 1 白人

☐ 2 黑人/非洲裔美国人

☐ 3 亚洲人

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☐ 99 其它, 请说明: _____

SDTM example (DM)

STUDYID	DOMAIN	USUBJID	SUBJID	RFICDTC	BRTHTDTC	AGE	AGEU	SEX	RACE
CDE01	DM	CDE01-701-1015	1015	2013-12-26	1951-04-03	63	岁	女	白人
CDE01	DM	CDE01-701-1023	1023	2012-07-22	1948-10-26	64	岁	男	白人
CDE01	DM	CDE01-701-1033	1033	2014-03-10	1940-08-06	74	岁	男	白人
CDE01	DM	CDE01-701-1047	1047	2013-01-22	1928-04-03	85	岁	女	白人
CDE01	DM	CDE01-701-1097	1097	2013-12-23	1946-01-20	68	岁	男	白人
CDE01	DM	CDE01-701-1111	1111	2012-08-25	1931-11-02	81	岁	女	白人
CDE01	DM	CDE01-701-1115	1115	2012-11-23	1929-02-24	84	岁	男	白人
CDE01	DM	CDE01-701-1118	1118	2014-02-27	1962-09-02	52	岁	男	白人
CDE01	DM	CDE01-701-1130	1130	2014-02-09	1930-05-20	84	岁	男	白人

ADaM example (ADSL)

USUBJID	TRT01P	TRT01A	AGE	AGEU	RACE	RACEN	SEX	SAFFL	ITTFL
CDE01-701-1015	安慰剂	安慰剂	63	岁	白人	1	女	Y	Y
CDE01-701-1023	安慰剂	安慰剂	64	岁	白人	1	男	Y	Y
CDE01-701-1033	CDE_001	CDE_001	74	岁	白人	1	男	Y	Y
CDE01-701-1047	安慰剂	安慰剂	85	岁	白人	1	女	Y	Y
CDE01-701-1097	CDE_001	CDE_001	68	岁	白人	1	男	Y	Y
CDE01-701-1111	CDE_001	CDE_001	81	岁	白人	1	女	Y	Y
CDE01-701-1115	CDE_001	CDE_001	84	岁	白人	1	男	Y	Y
CDE01-701-1118	安慰剂	安慰剂	52	岁	白人	1	男	Y	Y
CDE01-701-1130	安慰剂	安慰剂	84	岁	白人	1	男	Y	Y

Standardized vs Non-standardized

- Dataset level
 - Name
 - Description
 - Structure
 - Allowed Variables
- Variable level
 - Name
 - Label
 - Type
 - Format
- Value level
 - Controlled Terminology

Predictable
vs
Unpredictable

CDISC

So 'easy

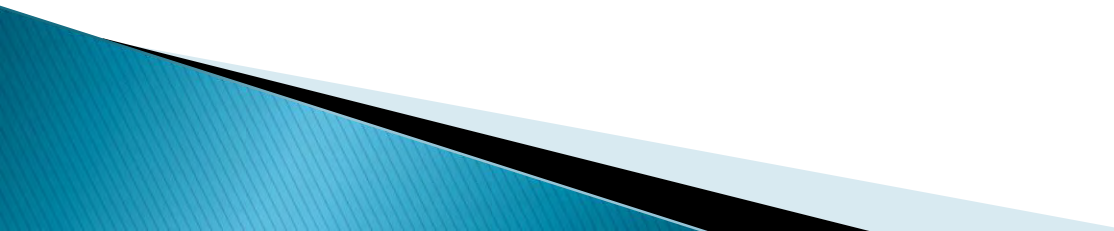




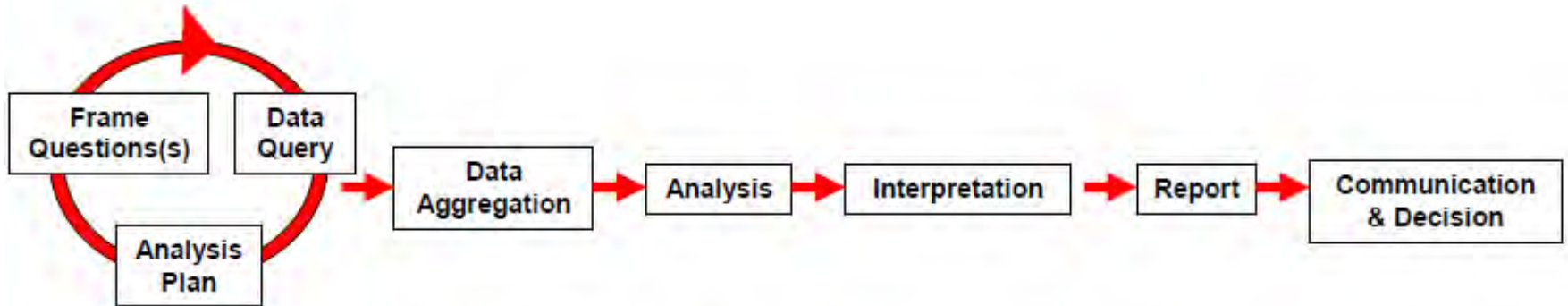
Section 3: How to get started to implement CDISC?

Company level - Why

► Do you need standards?

- Do you want high quality data?
 - Do you want to save time?
 - Do you have limited resources?
 - Do you have limited time to complete our clinical program?
 - Do you ever go to back and look at old data for knowledge extraction?
 - Do you intend or have you acquired another company?
 - Do you use partners?
- 

Time to spend on?



Present Time Emphasis- 'Doing'



Source: Theresa Mullen, PhD, FDA CDER Associate Director

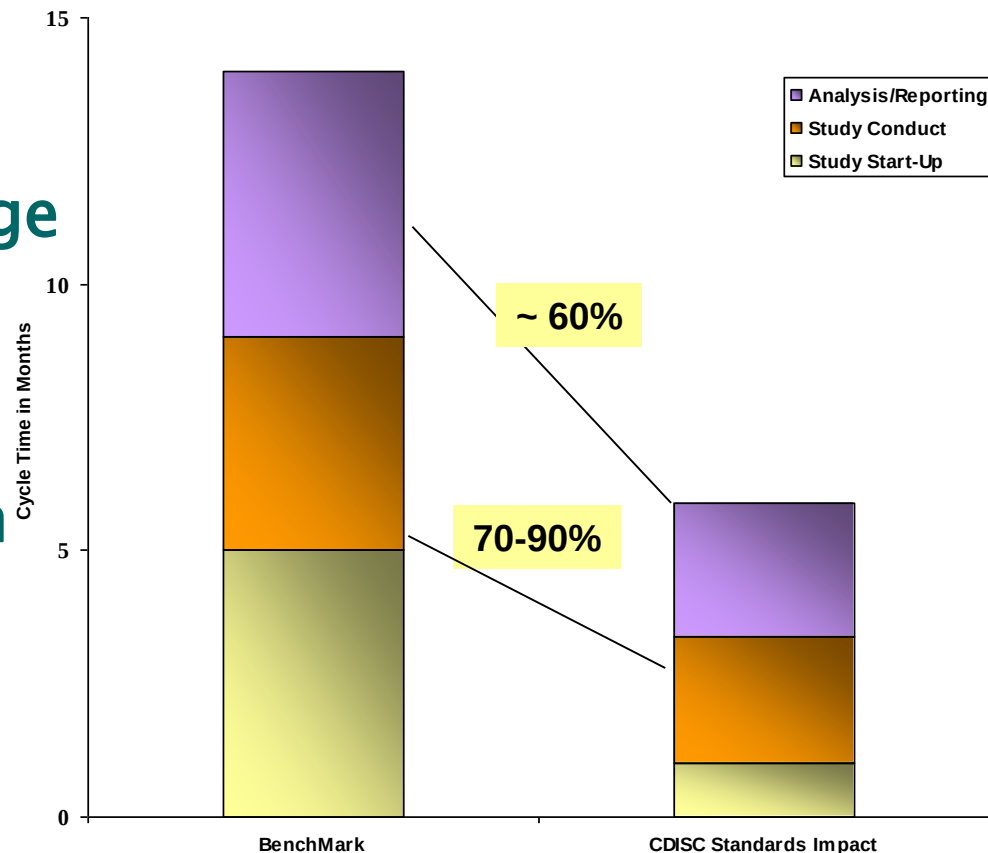
Company level – When?

- ▶ When to start?
 - Now or wait?
 - The earlier, the earlier benefited from it

Implement CDISC standards from beginning

- 70-90% start-up stage

- 60% of the non-subject participation time



- + Better data quality and accuracy
- + Improve communication among project teams
- + Enable data integration, re-usability

Company level – When?

- ▶ When to start?
 - Now or wait?
 - The earlier, the earlier benefited from it

Company level – How

- ▶ Investment
 - ▶ Staff
 - Hire Experienced Staff
 - Train new Staff
 - ▶ Process
 - Template
 - tools
 - ▶ Pilot
- 

Staff level – Why

- Do you want to communicate more smoothly?
- Do you want to work more efficiently?
- Do you want to be more professional?

Staff level – How

▶ How?

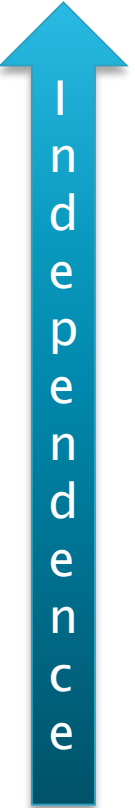
- Attend CDISC Public training
- Do exercise
- Communicate and exchange: do not be shame to ask silly questions
- Love thinking
- Last but most important: Get a mentor

▶ Levels: Study, imitate, think, innovate, master

Another way - Turn to external experts?

- ▶ Get the process, templates and tools ready
- ▶ Leverage knowledge and experience

Step	Staff	External Partner
3	Do	Consult
2	Do	Supervise
1	Observe	Do



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Any Questions?

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