

CDISC Therapeutic Area Data Standards Overview

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Nov 4, 2016



dMed -- a China based CRO

Serves both Local and Global Clients

Customized Services



Strategic Consultation



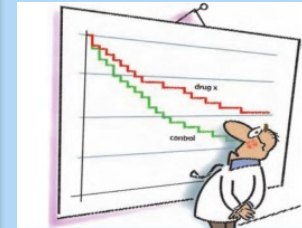
Clinical Operations



Data Management and Biostatistics



Medical Writing



Safety and Risk Management



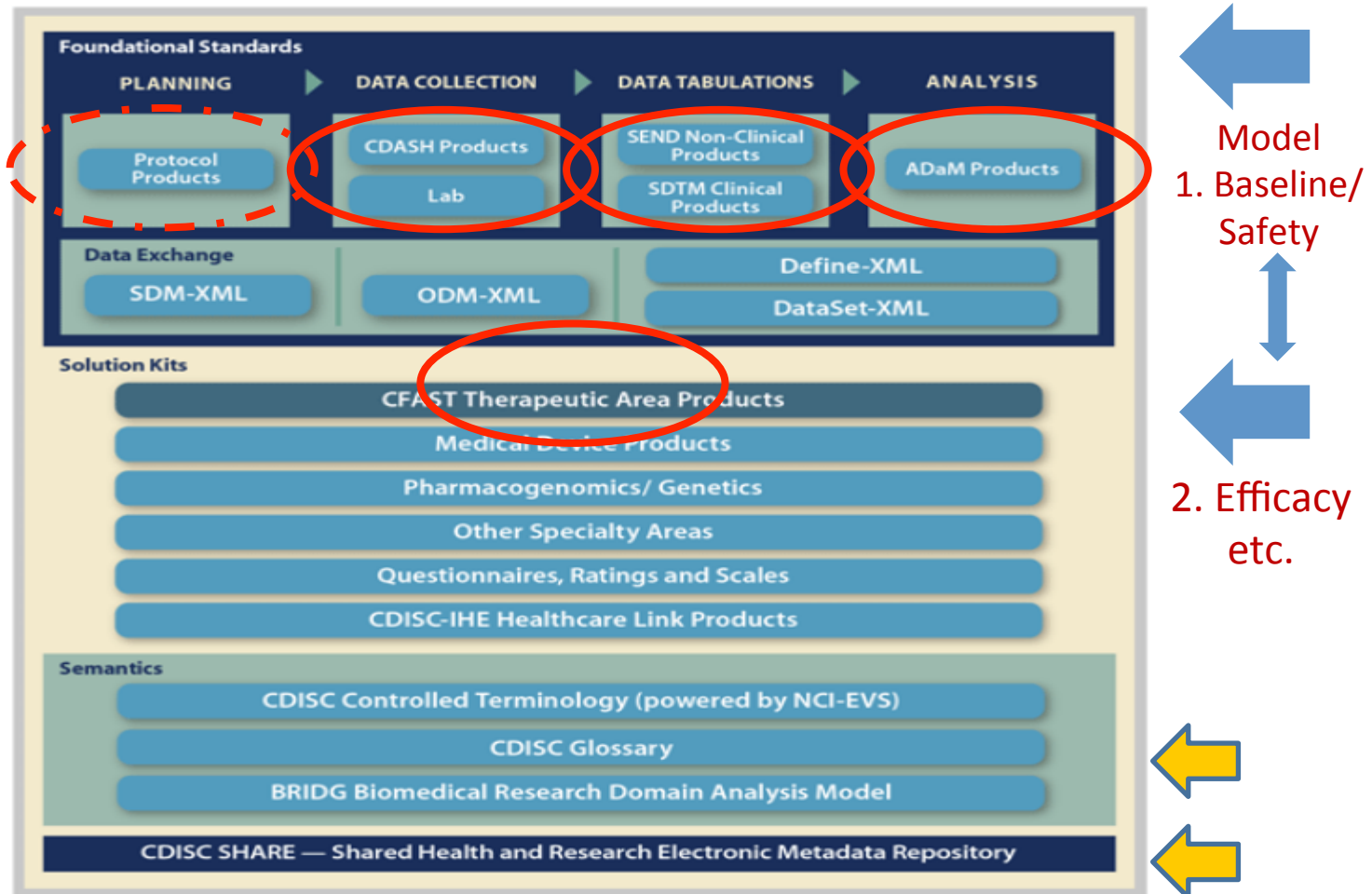
Regulatory Operations



QA, Audit, and Inspection readiness



CDISC Standard – Global Standard for Medical Research (from Protocol to Submission)



CDISC website www.cdisc.org

- CDISC TA Standards治疗领域 (TA) 标准
 - Background/Objectives/Methodology
背景/目标/方法
- Example 1-Diabetes糖尿病TAUG (CDASH/SDTM)
- Example 2-Dyslipidemia血脂异常TAUG (ADaM)
- Example 3-TCB CPT (Protocol)
- Outlook展望
- Q&A

- 结核病 (TB) - Duke, Gates Foundation, TB Alliance联盟
- 心血管 (CVD) – ACC, FDA
- 阿尔茨海默氏病 (AD)– CAMD, Critical Path Inst.
- 多囊肾病 (PKD) – Tufts Univ大学, PKD Foundation基金会
- 疼痛 – ACTION Alliance联盟

----- 2012 -----

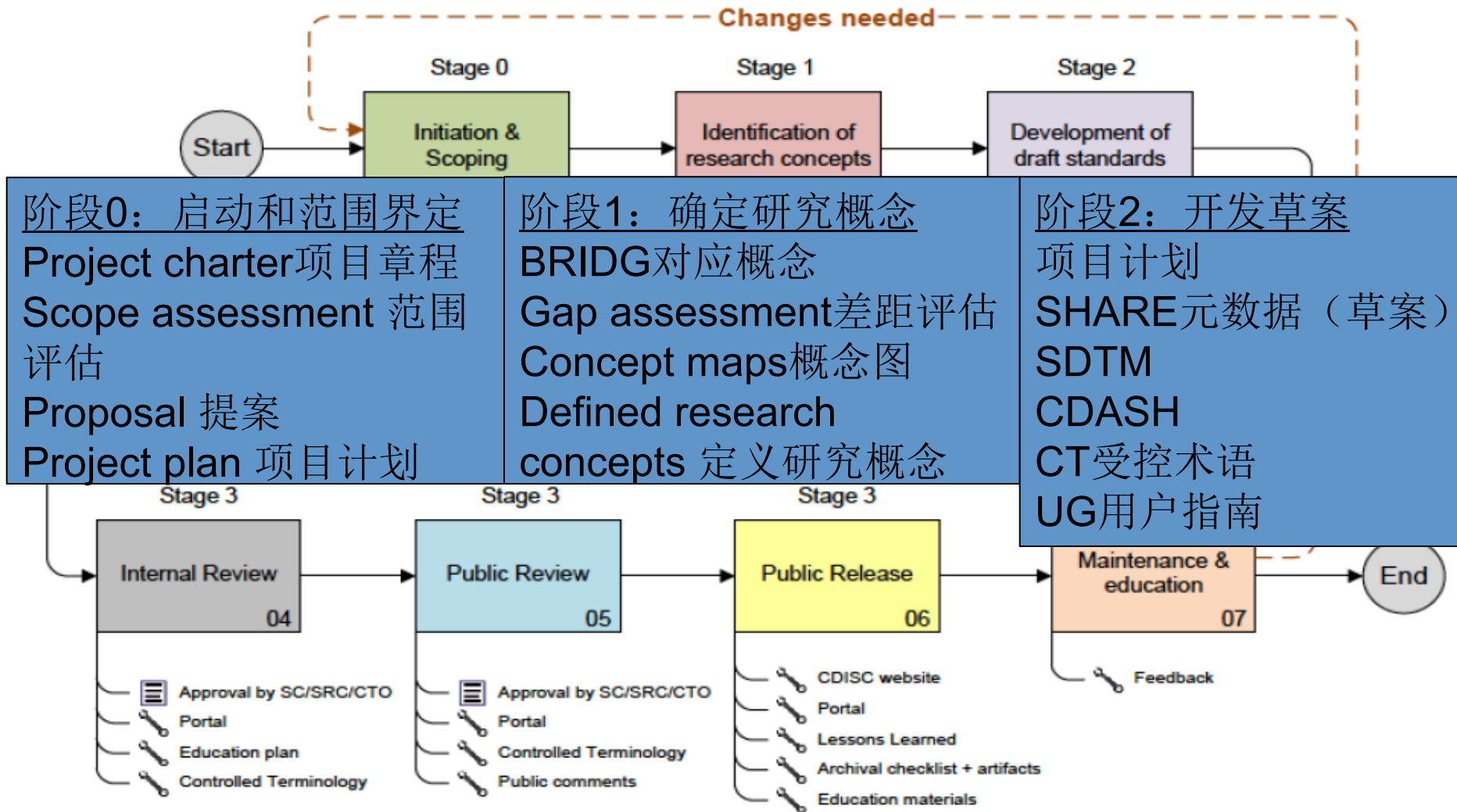


Therapeutic Area Standards (TAS) Initiative

~60 TAs by 2017

- Identify a core set of clinical concepts and endpoints for targeted therapeutic Areas
确定目标治疗领域的核心临床概念和指标
- Translate them into CDISC standards to
将其转换成CDISC标准
 - improve semantic understanding,
 - support data sharing, and
 - Facilitate global regulatory submission
- Used in efficacy evaluations 可用于疗效评估等

TA Standard Dev. Process 流程 (~12 months)



Published/Progress 发布和开发中 (> 30 TAs)



治疗领域	发布年份	CDASH	SDTM	ADaM
Tuberculosis (结核病) v1	2012		X	
Pain (疼痛) v1	2012		X	
Parkinson's Disease (帕金森氏病) v1	2012		X	
Virology (病毒学) v1	2012		X	
Polycystic Kidney Disease (多囊肾病) v1	2013		X	
Asthma (哮喘) v1	2013		X	
Alzheimer's Disease (阿尔茨海默氏病) v2	2013		X	
Multiple Sclerosis (多发性硬化症) v1	2014		X	
*Diabetes (糖尿病) v1	2014	X	X	v2 X
Cardiovascular (心血管) v1	2014		X	
QT studies (QT研究) v1	2014		X	X
Influenza (流感) v1	2014	v2?	X	v2?
*Hep C (慢性丙型肝炎) v1	2014	X	X	v2?
Schizophrenia (精神分裂症) v1	2015		X	X
*TAUG-Dyslipidemia (血脂异常)v1	2015	X	X	X

*SHARE metadata

Published/Progress 发布和开发中 (> 30 TAs) - 续



治疗领域	发布年份	CDASH	SDTM	ADaM
Traumatic Brain Injury 创伤性脑损伤 v1	2015	X	X	
Virology (病毒学) v2	2015		X	
Diabetes (糖尿病) ADaM v1	2015			X
*COPD (慢性肺阻) v1	2016	X	X	X
Tuberculosis (结核病) v2	2016		X	
Breast Cancer 乳腺癌) v1	2016	X	X	X
Kidney Transplant v1	2016		X	X
Tuberculosis (结核病) v2	2016		X	
Breast Cancer 乳腺癌)v1	2016	X	X	X
Malaria v1– 征求意见	2016	X	X	
Ebola v1– 征求意见	2016	X	X	X?
>10 under development				

*SHARE metadata

Example 1: TA-Diabetes UG

用户指南 (170pp)



Therapeutic Area Data Standards User Guide for Diabetes

Version 1.0 (Provisional)

Notes to Readers

- This is version 1.0 of the Therapeutic Area Data Standards User Guide for Diabetes. It makes use of domains and assumptions which are not final as of its publication, and is therefore a provisional, rather than final, release.
- This document is intended to be used in conjunction with the SDTM v1.4 and SDTMIG v3.2, and with the CDASH Standard v1.1.
- The TAUG-Diabetes v1.0 includes a user guide, a set of proposed SDTM variables, a set of draft SDTMIG assumptions, four draft SDTMIG domains, five sets of CDASH metadata tables with example CRFs, and six workbooks of somewhat simplified, prototype SHARE metadata displays.



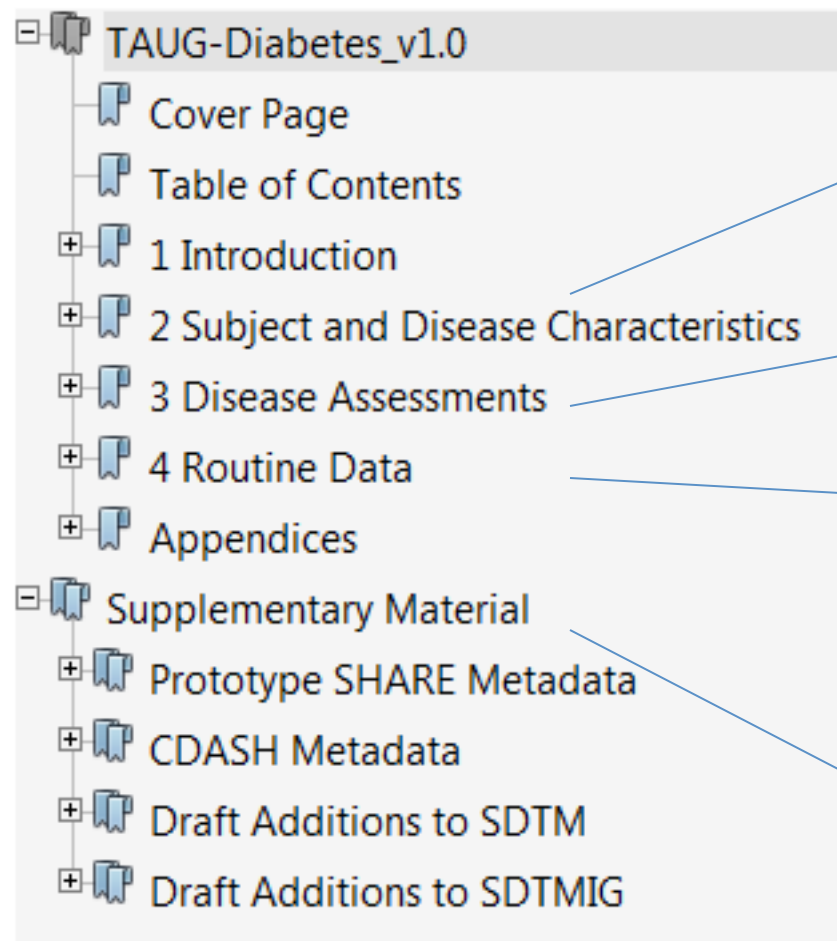
ADaM Supplement to the TAUG-Diabetes Version 1.0 (Provisional)

Notes to Readers

- This is Version 1.0 of the CDISC ADaM Supplement to the TAUG-Diabetes. It makes use of domains and assumptions which are not final as of its publication, and is therefore a provisional, rather than final, release.
- This supplement is intended to be incorporated into the next version of the TAUG-Diabetes as Section 5, Analysis Data.
- This document is based on ADaM v2.1 and ADaMIG v1.0.

Date	Version	Summary of Changes
2015-12-18	1.0	Provisional Release
2015-07-17	1.0 Draft	Draft for Public Review

TAUG-Diabetes v1 – ToC目录



TAUG-Diabetes_v1.0

- Cover Page
- Table of Contents
- + 1 Introduction
- + 2 Subject and Disease Characteristics
- + 3 Disease Assessments
- + 4 Routine Data
- + Appendices
- + Supplementary Material
 - + Prototype SHARE Metadata
 - + CDASH Metadata
 - + Draft Additions to SDTM
 - + Draft Additions to SDTMIG

• 2受试者和疾病特征

• 3疾病评估

• 4常规数据

• 5统计分析 (v2)

• SHARE等 metadata

- 1.1 Purpose 目的
- 1.2 Organization of this Document 文档组织
- 1.3 Concept Maps 概念图
- 1.4 Controlled Terminology 受控术语
- 1.5 Relationships to Other Standards 和其它标准关系
- 1.6 Known Issues 已知问题

Concept Classification概念图分类

- Based on BRIDG model (class)

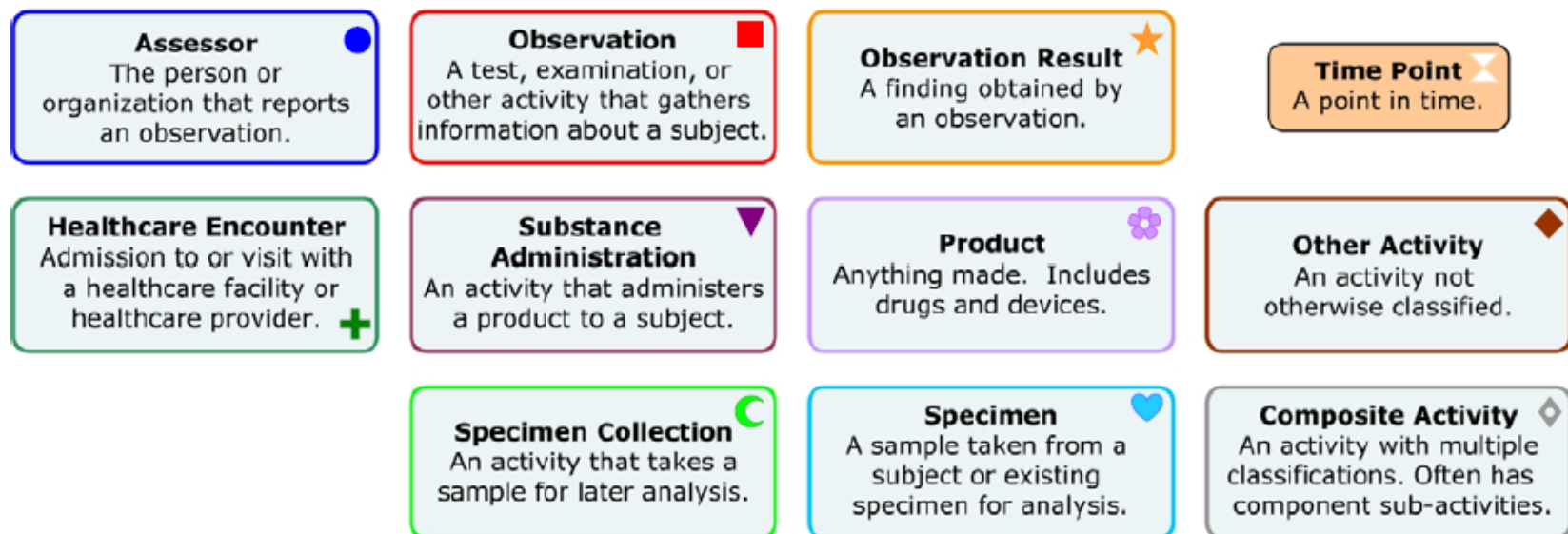


Figure 2: Coding Key for Concept Classification

2 Subject and Disease Characteristics

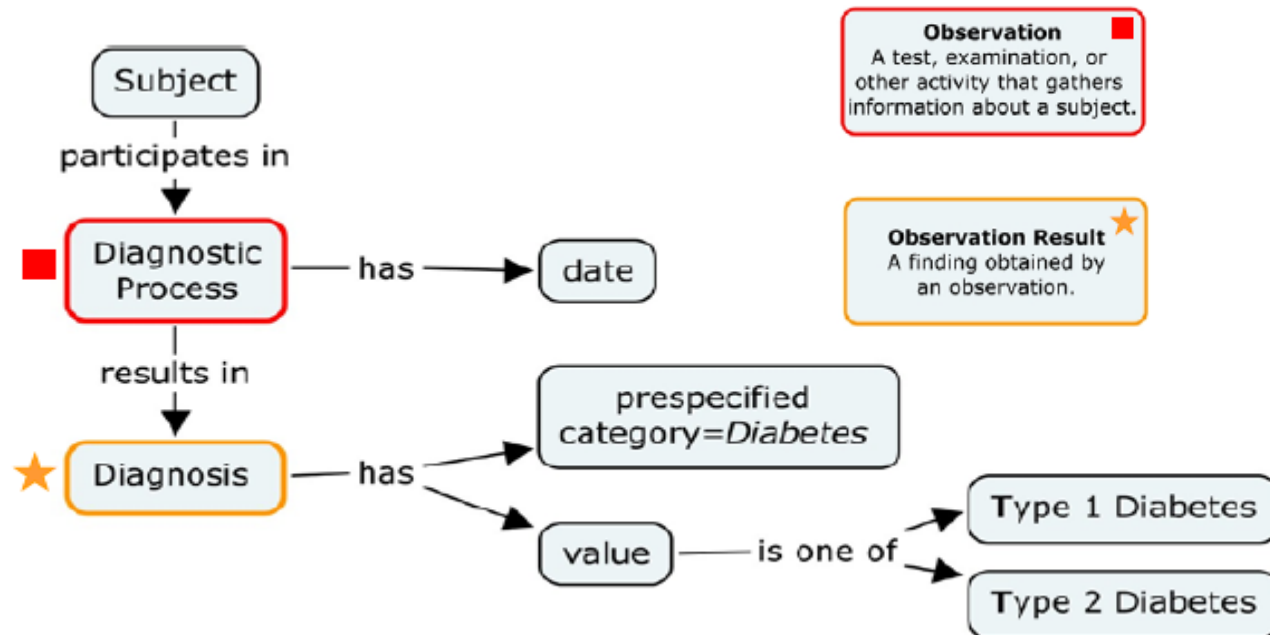
受试者和疾病特征



- 2.1 糖尿病病史 - MH (CDASH/SDTM, 下同)
- 2.2 糖尿病并发症 - MH
- 2.3 初次治疗Treatment-Naïveté - CM

Medical History – Concept Map -> CRF Design

糖尿病病史 -- 概念图 → CRF设计



Concept Map 1: Diagnosis of Diabetes

Diabetes	(pre-specified)
Date of Diagnosis of Diabetes	----- (DD-MMM-YYYY)
Type of Diabetes	Type 1 Diabetes Type 2 Diabetes
Medical History Category	DIABETES (pre-specified)

Medical History – CDASH/SDTM Examples

Example CRF 1: Diabetes History

Diabetes	(pre-specified)	MHPRESP= Y MHOCCUR= Y	
Date of Diagnosis of Diabetes	---- (DD-MMM-YYYY)	MHSTDTC MHSTDAT	QVAL in SUPPMH where QNAM = "MHDXDTC" and QLABEL = "Date of diagnosis"
Type of Diabetes	Type 1 Diabetes Type 2 Diabetes	MHTERM	
Medical History Category	DIABETES (pre-specified)	MHCAT	

mh.xpt

Row	STUDYID	DOMAIN	USUBJID	MHSEQ	MHTERM	MHCAT	MHPRESP	MHOCCUR	MHDTTC	MHSTDTC
1	XYZ	MH	XYZ-001-001	1	TYPE 1 DIABETES	DIABETES	Y	Y	2010-09-26	2010-03-25
2	XYZ	MH	XYZ-001-002	1	TYPE 2 DIABETES	DIABETES	Y	Y	2010-10-26	2010-04-25

suppmh.xpt

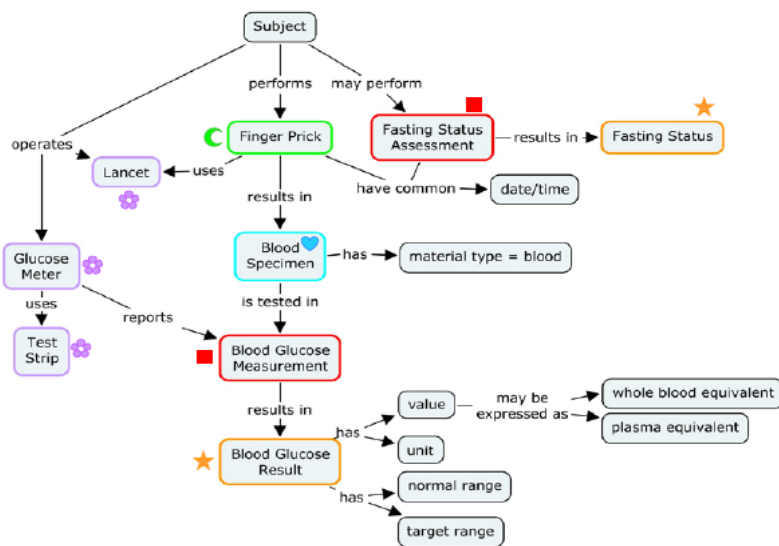
Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL
1	XYZ	MH	XYZ-001-001	MHSEQ	1	MHDXDTC	Date of Diagnosis	2010-03-25
2	XYZ	MH	XYZ-001-002	MHSEQ	1	MHDXDTC	Date of Diagnosis	2010-04-25

- 3.1 Lab 实验室检测 - LB (CDASH/SDTM, 下同)
- 3.2 Glucose 血糖测量 - LB, AG*
- 3.3 Hypo 低血糖 - CE, FA, CM, ML*
- 3.4 CV 心血管事件/结局 (参见心血管TA标准 TAUG-CV)

*draft domains

3.2 Glucose Measurement 血糖测量

- 3.2.1 血糖自测 (如右)
- 3.2.2 糖耐受测试



Concept Map 4: Self-Monitoring Glucose Measurement



Example CRF 3: Self-Monitored Blood Glucose

SMBG Collection	No Yes (If yes complete)	LBPERF		
Date of Measurement	--- (DD-MMM-YYYY)	LBDTC	LBDAT	LBDD LBMO LBYS
Pre-Morning Meal Measurement	--- (24 hour clock)	LBTPT	LBDTC LBTIM	--- Glucose Result Not Done LBSTAT LBORRES/LBORRESU when LBTEST = Glucose
Post-Morning Meal Measurement	--- (24 hour clock)	LBTPT	LBDTC LBTIM	--- Glucose Result Not Done LBSTAT mmol/L LBORRES/LBORRESU mg/dL LBORRES/LBORRESU
Pre-Midday Meal Measurement	--- (24 hour clock)	LBTPT	LBDTC LBTIM	--- Glucose Result Not Done LBSTAT mmol/L LBORRES/LBORRESU mg/dL LBORRES/LBORRESU
Post-Midday Meal Measurement	--- (24 hour clock)	LBTPT	LBDTC LBTIM	--- Glucose Result Not Done LBSTAT mmol/L LBORRES/LBORRESU mg/dL LBORRES/LBORRESU
Pre-Evening Meal Measurement	--- (24 hour clock)	LBTPT	LBDTC LBTIM	--- Glucose Result Not Done LBSTAT mmol/L LBORRES/LBORRESU mg/dL LBORRES/LBORRESU
Post-Evening Meal Measurement	--- (24 hour clock)	LBTPT	LBDTC LBTIM	--- Glucose Result Not Done LBSTAT mmol/L LBORRES/LBORRESU mg/dL LBORRES/LBORRESU
Bedtime Measurement	--- (24 hour clock)	LBTPT	LBDTC LBTIM	--- Glucose Result Not Done LBSTAT mmol/L LBORRES/LBORRESU mg/dL LBORRES/LBORRESU
Next Day Date of Measurement	--- (DD-MMM-YYYY)	LBTPT	LBDTC LBDAT	LBDD LBMO LBYS
Overnight Measurement	--- (24 hour clock)	LBTPT	LBDTC LBTIM	--- Glucose Result Not Done LBSTAT mmol/L LBORRES/LBORRESU mg/dL LBORRES/LBORRESU
Next Day Pre-Morning Meal Measurement	--- (24 hour clock)	LBTPT	LBDTC LBTIM	--- Glucose Result Not Done LBSTAT mmol/L LBORRES/LBORRESU mg/dL LBORRES/LBORRESU
Specimen Type		LBSPEC		Specimen Type
Device		SPDEVID		Device Identifier

CRF annotated to show mapping. SDTM variables in Red. If CDASH variable differs from SDTM the CDASH variable is in Blue.

4 Routine Data 常规数据



- 4.1 既往和伴随用药 (CM) – 胰岛素
- 4.2 生命体征 (VS)

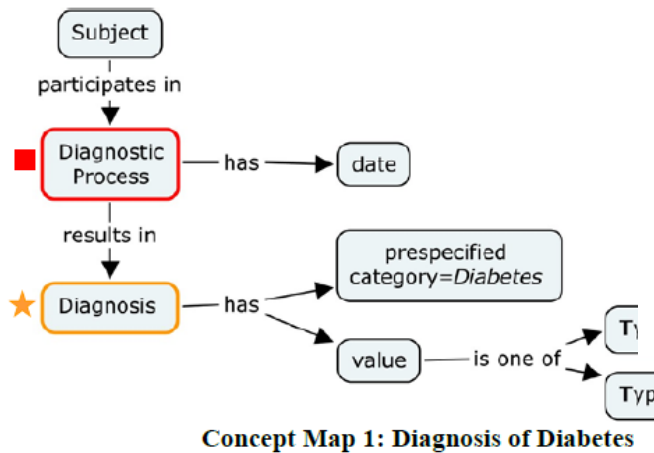
- Appendix A: Project Proposal
- [Appendix B: CFAST Diabetes Team](#)
- Appendix C: Glossary and Abbreviations
- Appendix D: Metadata
- Appendix E: References

Appendix B: CFAST Diabetes Team

Name	Institution/Organization
Rachael Zirkle, Team Leader	Eli Lilly and Company
Maria Alba	Johnson & Johnson
Caryl J. Antalis	Eli Lilly and Company
Melissa Cook	Accenture
Dan Crawford	Accenture
Debbie Cummings	Takeda
Rene Dahlheimer	CDISC
Rhonda Facile	CDISC
Stephen Faulkner	Pfizer
Scott Getzin	Eli Lilly and Company
Lorna Griffin	Merck
Jody Hawes	Pfizer
Brooke Hinkson	Sanofi
Jennie G. Jacobson	Eli Lilly and Company
Gloria Jones	Johnson & Johnson
Dawn Kaminski	Accenture
Lakshmi Mallela	Johnson & Johnson
Jim Malone	Eli Lilly and Company
Sarah McLaughlin	Biogen Idec
Elizabeth Mendel	Novartis
Erin Muhlbradt	NCI EVS
Birgitte Ronn	Novo Nordisk
Benjamin Shim	Eli Lilly and Company
Lorraine Spencer	Takeda
Petra Struecker	Roche
Madavi Vemuri	Johnson & Johnson
Gary Walker	Quintiles
Michael Ward	Eli Lilly and Company
Darcy Wold	CDISC consultant
Diane Wold	GSK
Fred Wood	Accenture
Bernice Yost	CDISC
Shuyu Zhang	Eli Lilly and Company
Boris Brodsky	FDA
Ron Fitzmartin	FDA

- **Prototype SHARE metadata**
- CDASH metadata and CRF
- Draft additions to SDTM
- Draft additions to SDTMIG

Concept Map概念图->CDASH->SDTM



Question Text	Prompt	CDASH Variable Name	CDASH Core	SDTM Variable Name	SDTM Core	Case Report Form completion instructions	Mapping Instructions	Implementation Instructions
Date of Diagnosis of Diabetes	DD-MMM-YYYY	MHSTDAT	HR	MHSTDTC	Perm	Enter the date of diagnosis of diabetes.	Map directly to SDTM. Also maps to QVAL in	Full Date Optional, Year expected.

mh.xpt

Row	STUDYID	DOMAIN	USUBJID	MHSEQ	MHTERM	MHCAT	MHPRESP	MHOCCUR	MHDTCT	MHSTDTC
1	XYZ	MH	XYZ-001-001	1	TYPE 1 DIABETES	DIABETES	Y	Y	2010-09-26	2010-03-25
2	XYZ	MH	XYZ-001-002	1	TYPE 2 DIABETES	DIABETES	Y	Y	2010-10-26	2010-04-25

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Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL
1	XYZ	MH	XYZ-001-001	MHSEQ	1	MHDXDTC	Date of Diagnosis	2010-03-25
2	XYZ	MH	XYZ-001-002	MHSEQ	1	MHDXDTC	Date of Diagnosis	2010-04-25

Not specified	N/A	MHOCCUR	R/C	MHOCCUR	Perm		Map directly to SDTM	specified, this value is "Y".
Not specified	N/A	MHCAT	R/C	MHCAT	Perm	Pre-specified = DIABETES	Map directly to SDTM	When MHTERM is pre-specified, this value is "Y".

Diabetes	(pre-specified)	MHPRESP= Y MHOCCUR= Y	
Date of Diagnosis of Diabetes	---- (DD-MMM-YYYY)	MHSTDTC	MHSTDAT
Type of Diabetes	Type 1 Diabetes Type 2 Diabetes	MHTERM	QVAL in SUPPMH where QNAM = "MHDXDTC" and QLABEL = "Date of diagnosis"
Medical History Category	DIABETES (pre-specified)	MHCAT	

CRF annotated to show mapping SDTM variables are in **Red**. If CDASH variable differs from SDTM the CDASH variable is in **Blue**.

Example 2: TA-Dyslipidemia

血脂异常 用户指南 (38pp)



Therapeutic Area Data Standards User Guide for Dyslipidemia Version 1.0 (Provisional)

Prepared by
The CFAST Dyslipidemia Team



Notes to Readers

- This is the provisional version 1.0 of the Therapeutic Area Data Standards User Guide for Dyslipidemia.
- This document is based on CDASH v1.1, SDTM v1.4 and SDTMIG v3.2, and ADaM v2.1 and ADaMIG v1.0.
- The TAUG-Dyslipidemia v1.0 package contains this user guide, a set of CDASH metadata tables, and a prototype SHARE metadata display.

Revision History

Date	Version	Summary of Changes
2015-06-02	1.0 Provisional	Provisional release.
2015-03-13	1.0 Draft	Draft for Public Review

5. Statistical Analysis 统计分析



- **5.1 Statistical Endpoints 统计分析指标**

- • Percent change from baseline
- • Change from baseline
- • Proportion of subjects achieving a pre-defined cutoff level by a pre-defined time

- **5.2 Subject Level Analysis Dataset 基线数据**

- ADSL and Baseline variables

- **5.3 Efficacy Analysis Datasets 疗效分析数据**

- ADEFF: CHG and %CHG in LDL-C etc
- ADRESP: responder%

→ table shells, dataset metadata, analysis result metadata, etc

E1: Analysis of Percent Change From Baseline in LDL-C (mg/dL) at Week 24
(Full Analysis Set Population)

Example
Analysis Dataset for Primary Efficacy (ADEFF)

Variable	Label	Type	Length / Display Format	Controlled Terms or Format	Source / Derivation / Comment	Drug A (N=xxx)	Placebo (N=xxx)
STUDYID	Study Identifier	text	\$20		Predecessor: ADSL.STUDYID	x.x	x.x
USUBJID	Unique Subject Identifier	Text	\$20		Predecessor: ADSL.USUBID	x.x	x.x
SEX	Sex	Text	\$2	M/F	Predecessor: ADSL.SEX	(x.x, x.x)	(x.x, x.x)
FASFL	Full Analysis Set Population	Text	\$1	Y / N	Predecessor: ADSL.FASFL	aus Placebo	
AVISIT	Analysis Visit	Text	4.0	Screening, Run-In, Baseline, Week 4, Week 8, Week 24	Derived: Derived based on windowing algorithm described in SAP, Section 8.2	x.x	
ADY	Analysis Relative Day	Integer	4.0		Derived: When ADY >= TRTSDY then	x.x	

Analysis Results Metadata for ANCOVA Example

Metadata Field	Metadata
DISPLAY IDENTIFIER	E1
DISPLAY NAME	Analysis of Percent Change From Baseline in LDL-C (mg/dL) at Week 24 (Full Analysis Set Population)
RESULT IDENTIFIER	Treatment difference results (LS Mean, confidence interval, p-value)
PARAM	LDL Cholesterol (mg/dL)
PARAMCD	LDL
ANALYSIS VARIABLE	PCHG
REASON	Primary efficacy analysis as pre-specified in protocol
DATASET	ADEFF
SELECTION CRITERIA	FASFL="Y" and PARAMCD="LDL" and AVISITN=24
DOCUMENTATION	See SAP Section XX for details. Program: t-ldl-pchg.sas LS Mean, SE, and 95% CI for within-treatment percent change from baseline and p-Value for effects based on an ANCOVA with terms for treatment and baseline LDL-C value
PROGRAMMING STATEMENTS	proc mixed data=adeff; where FASFL="Y" and PARAMCD="LDL" and AVISITN=24; class trt01p; model pchg = trt01p base/ddfm=satterth; lsmeans trt01p /cl pdiff; ods output lsmeans = lpchg; ods output diffs=diff wkN ; ods output tests3 = pvalue; run;

Example 3: TA->Protocol TransCelerate BioPharma CPT

• Common Protocol Template (CPT)

4. Objectives and Endpoints

Objectives	Endpoints
Primary	
- To evaluate the efficacy of x mg of <Compound> administered <frequency> in individuals with Type 1 or Type 2 DM	- The change [percentage] in HbA1c from Baseline to Week X - The percent age of patients with HbA1c (%) $\leq x\%$ at Week X
Secondary	
Tertiary/Exploratory	

+ Objectives and Endpoints

- Available Content

PT_Library_Diabetes_20150611.docx

- Objectives and Endpoints

- Primary Objectives

[frequency] in individuals with Type 1 or Type 2 DM...

[comparator] in individuals with Type 1 or Type 2 DM...

- Primary Endpoints

- Hemoglobin A1c [HbA1c] (%)

Change [absolute] in HbA1c from Baseline to Week X

Change [percentage] in HbA1c from Baseline to Week X

Percentage of patients with HbA1c (%) $\leq x\%$ at Week X

+ Key Secondary Objectives

- Key Secondary Endpoints

+ Glycemia

+ Hypoglycemia

+ Body Weight (kg)

+ Insulin Dose

+ Delay in Diagnosis of Type 1 DM

+ Delay in Diagnosis of Type 2 DM

+ Exploratory Objectives

- Exploratory Endpoints

+ Glucose AUC

Outlook展望1: CFAST Pipeline/ 规划项目



Program Overview – September 2016



Therapeutic Area	Charter Approved	Check of Concepts Completed	Posted for Internal Review	Posted for Public Review	Projected Publication
Kidney Transplant v1	Jan	Mar	Apr	Jun	Q3 2016
Rheumatoid Arthritis v1	Jun 15	Oct 15	Jan	May	Q3 2016
CV Imaging v1	May 15	Jul 15	Dec 15	May	Q3 2016
Major Depressive Disorder v1**	Dec 15	Feb	May	Jul	Q3 2016
Diabetic Kidney Disease v1	May 15	Aug 15	Jan	Jul	Q4 2016
Ebola v1*	Sep 15	Mar	Mar	Sep	Q4 2016
Malaria v1*	Oct 15	Jul	Jul	Sep	Q4 2016
Prostate Cancer v1	Nov 15	Mar	Jul	Oct	Q4 2016
Vaccines v1*	Q4 14	Oct 15	Sep		Q1 2017
Nutritional Standards v1*	Mar 15	Sep			Q4 2016
Coronary Heart Disease – TCM v1*	Apr	Sep			Q4 2016
Acupuncture – TCM v1*	Apr	Oct			Q1 2017
Colorectal Cancer v1	May	Sep			Q1 2017
Duchenne Muscular Dystrophy	Aug	Nov			Q3 2017

Key| ■ Stage completed | ■ Stage ongoing | All months reflect when stage is, or is projected to be, completed

*Project duration dependent on volunteer resourcing

**General Anxiety Disorder and Bipolar Disorder pending resource availability

US FDA TA Standards Roadmap



Standardize **efficacy** data elements in 57 therapeutic areas in the next 7 years

- FDA intends to require submission using these standards by 2017
- PDUFA V approved by US Congress
- PDUFA V Key Performance Goals; section XII E. 'Clinical Terminology Standards'

Priority Disease/Domain Areas for Data Standardization

Tier 1

Acne	Pain*	Schizophrenia
Alzheimer's Disease*	Parkinson's Disease*	Solid organ transplantation
Anti-diabetic agents*	Prevention of pregnancy	Treatment of Hepatitis C*
Crohn's Disease	Psoriasis	Treatment of postmenopausal osteoporosis
Infections of skin and/or subcutaneous tissue	QT Studies	Tuberculosis*
Oncology: time to efficacy event other than overall survival*	Rheumatoid arthritis	Urinary tract infections

Tier 2

Addiction	Gastroesophageal reflux disease	Pneumonia
Anticonvulsants	Influenza	Prevention of HIV
Asthma	Irritable bowel syndrome	Treatment of HIV
Bipolar Disorder	Lipid-altering drug groups	Treatment of overactive bladder
Clostridium difficile colitis	Major depressive disorder	Treatment of vasomotor symptoms due to menopause
Diabetic nephropathy	Objective tumor response*	Ulcerative colitis

Tier 3

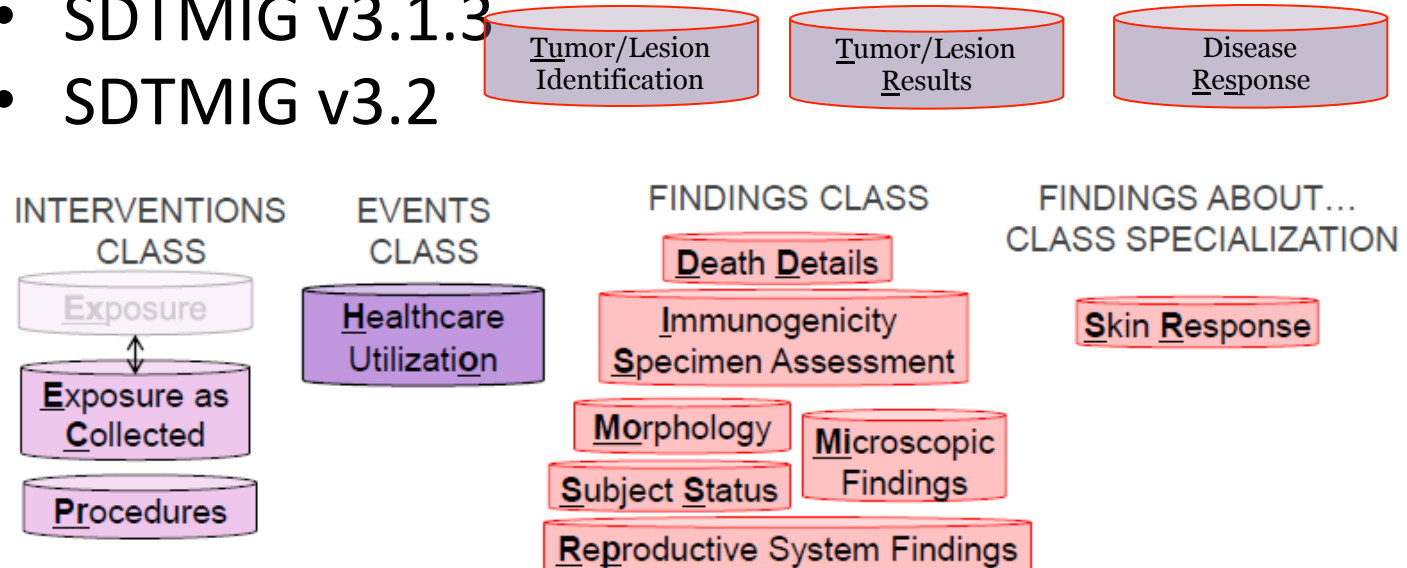
Actinic keratoses	Decompensated CHF	Tinea pedis
Aerosolized antimicrobials for cystic fibrosis	Diagnostic radiopharmaceuticals	Tramatic brain injury
Atrial fibrillation	General Anxiety Disorder	Treatment of cough
Attention Deficit Hyperactivity Disorder	Helicobacter pylori ulcer disease	Treatment of erectile dysfunction
Bacterial vaginosis	Infectious diseases of the abdomen	Treatment of hepatitis B
Chemotherapy-induced	MRI contrast agents	

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm269946.htm>

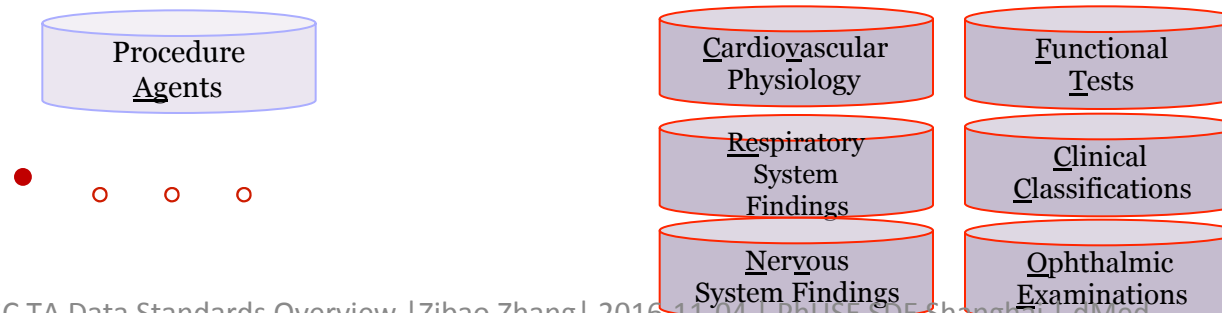
Outlook展望2: TA Standards → SDTMIG/CDASH New Domains新域



- SDTMIG v3.1.3
- SDTMIG v3.2



- SDTMIG v3.3 (batch#1/#2 draft domains)



Outlook展望₃: TA Standards数据标准 → Protocol/ SAP/ADaM Standardization?

- Study Design and Analysis设计和分析
 - Study Design试验设计 -> OK?
 - Data Collection Endpoints数据采集指标 -> OK
 - Statistical Endpoints 统计分析指标 -> OK
 - Common Analysis Methods 推荐分析方法 -> OK?
 - Table shells -> OK?
- TA Analysis Datasets 数据分析集 -> OK?

Outlook展望4: Research Concept

研究概念准确定义 →

CDISC SHARE



CDISC Prototype SHARE Metadata: Hba1c and Glucose

Key to Layout

Concept: Semi-quantitative concentration of glucose

At the top of the sheet are the concept name and the SDTM domain to which it is assigned. For tests, the TEST and TESTCD are also held here.

Domain: LB
TEST: Glucose
TESTCD: GLUC

BRIDG-based concept variable	value(s)	Attribute	SDTM variable
GLUCURSQ_O DefinedObservation.methodCode.CD.code	C50322,	specified method	METHOD
GLUCURSQ_O DefinedObservation.methodCode.CD.displayName.value	Test Strip		
GLUCURSQ_O DefinedObservation.dateRange.IVL<TS>.low.value	datetime		
GLUCURSQ_O DefinedObservation.studyDayRange.IVL<INT>.low.value	integer	Study Day of Test	
GLUCURSQ_O DefinedObservation.negationIndicator.BL.value	TRUE, FALSE (SDTM NOT DONE, null)	Negation Indicator	LBSTAT
GLUCURSQ_O DefinedObservation.negationReason.DSET<SC>.item.value	free text	Negation Reason	LBND
GLUCURSQ_O DefinedClinicalResult.value.CD.originalText.value	free text	Coded Result	LBES, LBSC
GLUCURSQ_O DefinedClinicalResult.value.CD.code	from sponsor code system		
GLUCURSQ_O DefinedClinicalResult.value.CD.displayName.value	from sponsor code system		
GLUCURSQ_O DefinedClinicalResult.baselineIndicator.BL.value	TRUE, FALSE (SDTM Y, null)	Baseline Indicator	LBBLFL
GLUCURSQ_R PerformedClinicalResult.comment.ST.value	free text	Comment	COVAL

Possible associated concepts

At the bottom of the sheet are other research concepts to which the research concept may or must be connected.	The first column shows the BRIDG-based data items. The names in this column are comprised of a short name for the concept, and the names of a BRIDG class, a BRIDG class attribute, and the (possibly multi-layered) name of a component of a complex datatype.	The second column shows either code values associated with the data item or a description of the data format (e.g., ISO8601 datetime or free text or integer).	The third column describes an "attribute" of the test. There may be several BRIDG-based data items for a single attribute.	The fourth column shows the where the attribute is stored in SDTM. The mapping from data item to SDTM variable is not necessarily 1:1. Some data items are not stored in SDTM, and some are transformed.
Collection of the specimen on which the test was performed		Specimen collection		LBDTC, LBDY
Laboratory which performed the test		Laboratory		LBNAM

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New Therapeutic Area Standards

User Guide for Chronic Hepatitis C Now Available for Public Comment Due 28 January 2015

The CDISC Therapeutic Area Data Standards User Guide for Chronic Hepatitis C Virus Infection (TAUG-CHCV) Version 1.0 Draft is now available public comment. The TAUG-CHCV describes the data endpoints for clinical studies focusing on phase 1 to 3 clinical trials of drugs to treat adults with Chronic HCV infection (CHC), covering genotypes 1-6 in the out-patient setting.

Please access the **document package** and provide comments through the **CDISC Public Comment Tracker tool**. You will need to **login** or **register** for a CDISC portal account to use the tool. **Help** is also available on the Public Comment Tracker page.

Instructions on using the Public Comment Tool

Alzheimer's | Asthma | Cardiovascular | **Diabetes** | **Influenza** | Multiple Sclerosis | Pain | Parkinson's Disease | Polycystic Kidney Disease | QT Studies | Tuberculosis | Virology

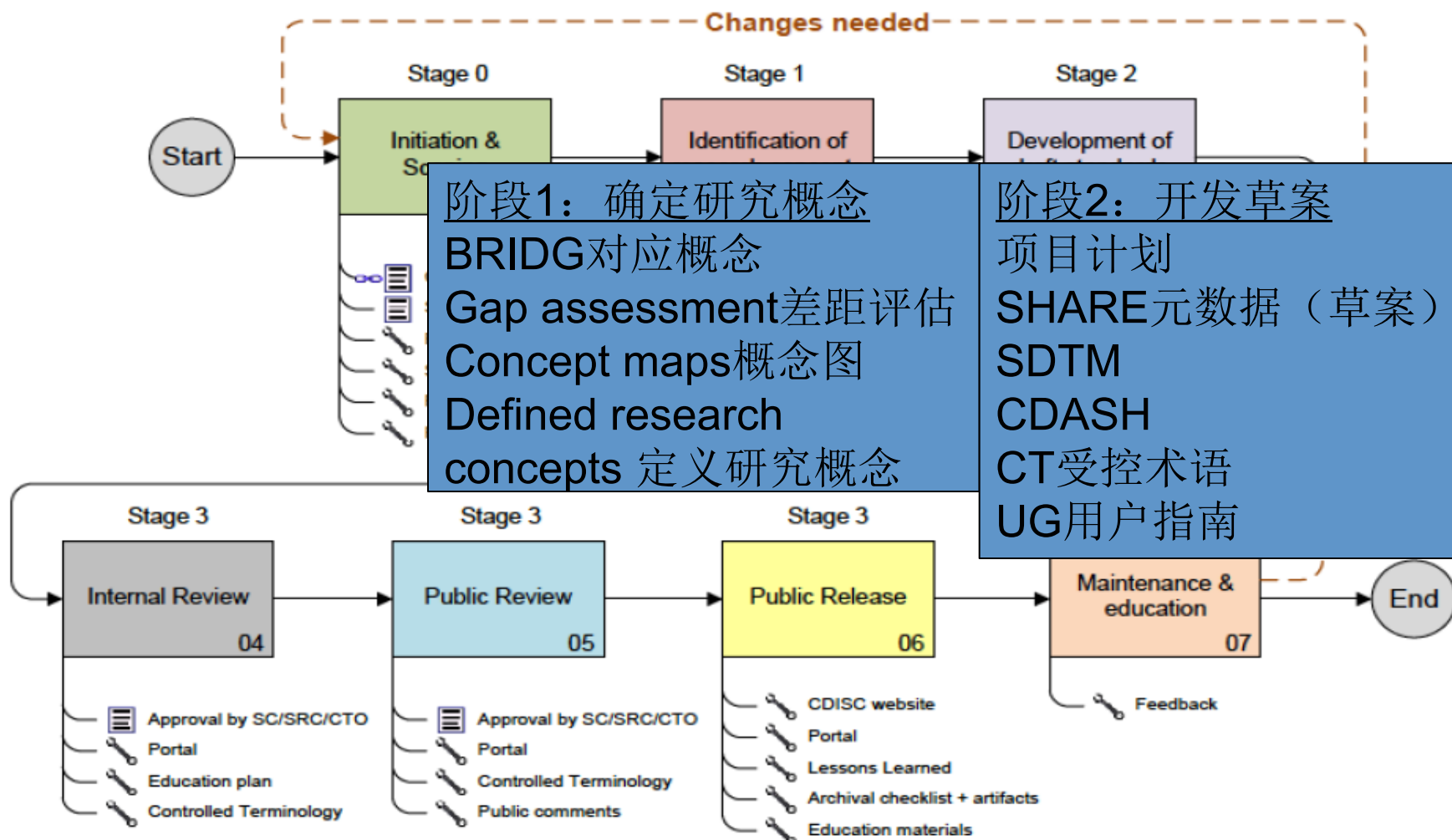
--Public Review--

Hepatitis C TAUG Comments due 28 January 2015
CDISC in RDF Reference Comments Due 20 February 2015
Terminology Package 21 Comments Due by 23 January 2015

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Summary总结



Questions?



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