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2023
CHINA
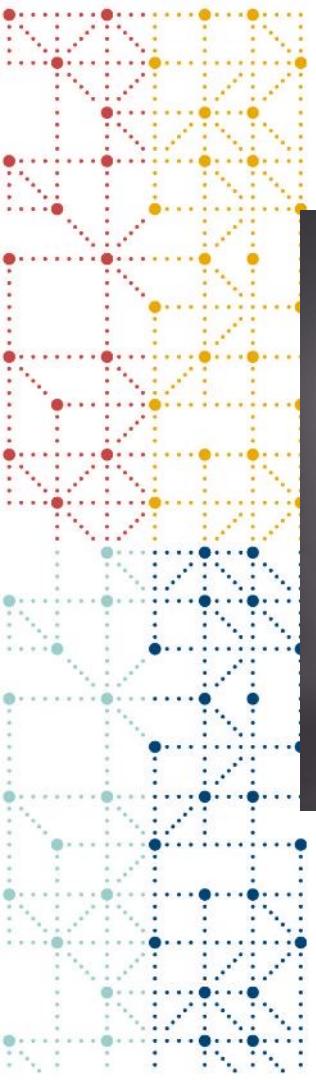## INTERCHANGE
BEIJING | 25-26 AUGUST

试验设计域的符合性验证规则

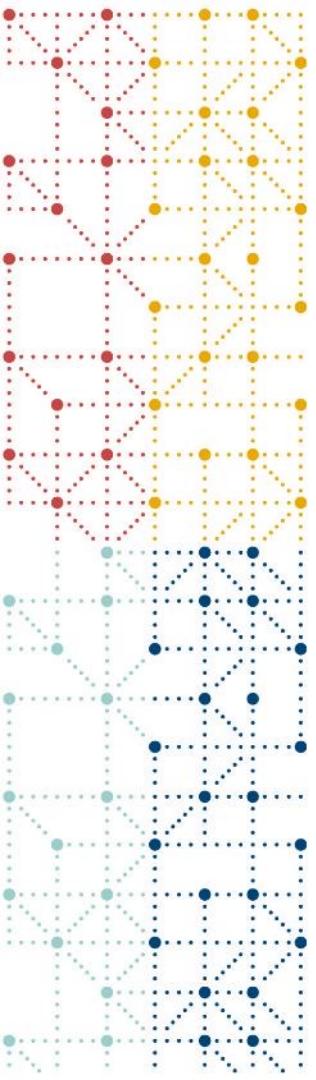Presented by
吴超珺，统计编程部副总监，凯诺医药

Meet the Speaker

吴超珺

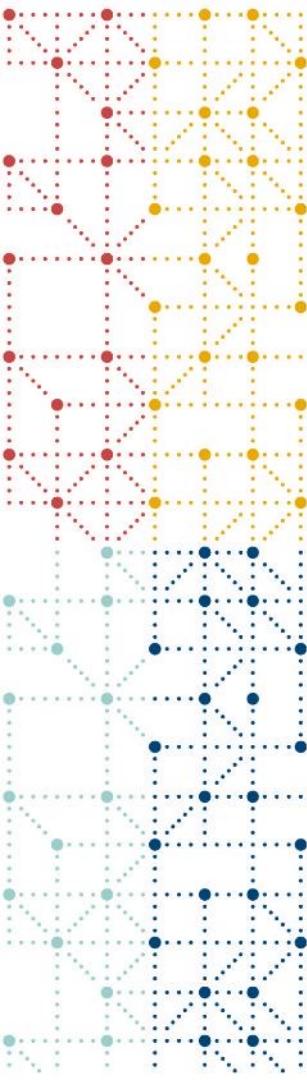Title: 统计编程部副总监

Organization: 凯诺医药

从事统计编程工作十余年，曾任职于泰格医药、太美医疗，在肿瘤、血液病、糖尿病、高血压等治疗领域均有丰富的编程经验。

2019年7月加入凯诺医药，目前主要负责项目管理与执行、团队管理等工作。

Agenda

1. CDISC试验设计域的符合性验证规则
2. FDA与PMDA的试验设计域的符合性验证规则
3. 案例分析

CDISC试验设计域的符合性验证规则

SDTM and SDTMIG Conformance Rules v2.0

- **发布日期**：2021.11.29
- **对应文档的版本**：包括SDTM到2.0版本和SDTMIG到3.4版本的所有规则
- **指南**：《SDTM and SDTMIG Conformance Rules Guide v2.0》
- **创建与维护**：CDISC - Submission Data Standards (SDS) SDTM Conformance Rules Subteam
- **作用**：描述了符合CDISC标准必须满足的标准

下载地址：**https://www.cdisc.org/standards/foundational/sdtmig/sdtm-and-sdtmig-conformance-rules-v2-0**

SDTM and SDTMIG Conformance Rules v2.0

Rule ID	SDTMIG Version	Rule Version	Class	Domain	Variable	Condition	Rule	Document	Section	Item	Cited Guidance	Release Notes
CG0153	3.2	1	SPC, TDM	DM, TA	ARMCD		ARMCD value length <= 20	IG v3.2	4.1.2.1		ARMCD is limited to 20 characters and does not have special character restrictions.	
CG0153	3.3	1	SPC, TDM	DM, TA	ARMCD		ARMCD value length <= 20	IG v3.3	4.2.1		ARMCD is limited to 20 characters and does not have special character restrictions.	
CG0153	3.4	1	SPC, TDM	DM, TA	ARMCD		ARMCD value length <= 20	IG v3.4	4.2.1		ARMCD is limited to 20 characters and does not have the character restrictions that apply to --TESTCD	Updated cited guidance to match full sentence from IG
CG0154	3.2	1	SPC, TDM	SE, TA, TE	ETCD	ELEMENT present in dataset and ETCD present in dataset	ELEMENT and ETCD have a one-to-one relationship	IG v3.2	5|7.2	Specification	ETCD (the companion to ELEMENT) is limited to 8 characters and does not have special character restrictions.	
CG0154	3.3	1	SPC, TDM	SE, TA, TE	ETCD	ELEMENT present in dataset and ETCD present in dataset	ELEMENT and ETCD have a one-to-one relationship	IG v3.3	5.2|7.2	Specification	ETCD (the companion to ELEMENT) is limited to 8 characters and does not have special character restrictions.	
CG0154	3.4	1	SPC, TDM	SE, TA, TE	ETCD	ELEMENT present in dataset and ETCD present in dataset	ELEMENT and ETCD have a one-to-one relationship	IG v3.4	5.3|7.2.1|7.2.2	Specification	ETCD (the companion to ELEMENT) is limited to 8 characters and does not have special character restrictions.	Section change in SDTMIG v3.4

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SDTM and SDTMIG Conformance Rules v2.0

| 列名	作用	描述
Rule ID	用于唯一标识规则的标识符	
SDTMIG Version	IG 的版本	例如，版本3.2标识来自SDTM v1.4、SDTMIG v3.2和SDTMIG- ap v1.0的所有规则
Rule Version	规则的版本	值为1: 该规则与最初发布的SDTMIG v3.2规则集基本没有变化，或者是在此版本中确定的新规则；值为2: 在规则的v1中发布的规则已经更新 (例如，影响实现的更改）
Class	分类	可选值：**TDM SPC FND EVT INT REL AP ALL**
Domain	域	多个用逗号隔开；涉及全部域则用ALL
Variable	变量	如果涉及多个domain的变量，则用破折号代替域缩写，如--STDY；涉及全部变量则用ALL
Condition	条件	如果规则仅在一组条件情况中应用，则在此列中定义条件
Rule	规则	要应用的符合性规则的简单和明确的陈述，每条规则只陈述了一条原则
Document	文件	关联的文档，如：IG v3.2, AP v1.0
Section	章节	对应的章节，如：4.1.2.1
Item	条目	Section对应需要说明的子项，如：Assumption 1
Cited Guidance	引用的文本	
Release Notes	发布说明	自由文本，记录了与规则相关的注意事项，如更新的细节、版本的变化等

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试验设计域相关 - 以TA域为例

TA – Specification for Trial Arms Dataset

ta.xpt, Trial Arms — Trial Design, Version 3.2. One record per planned Element per Arm

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	TA	Identifier	Two-character abbreviation for the domain.	Req
ARMCD	Planned Arm Code	Char	*	Topic	ARMCD is limited to 20 characters and does not have special character restrictions. The maximum length of ARMCD is longer than that for other "short" variables to accommodate the kind of values that are likely to be needed for crossover trials. For example, if ARMCD values for a seven-period crossover were constructed using two-character abbreviations for each treatment and separating hyphens, the length of ARMCD values would be 20.	Req
ARM	Description of Planned Arm	Char	*	Synonym Qualifier	Name given to an Arm or treatment group.	Req
TAETORD	Planned Order of Element within Arm	Num		Timing	Number that gives the order of the Element within the Arm.	Req
ETCD	Element Code	Char	*	Record Qualifier	ETCD (the companion to ELEMENT) is limited to 8 characters and does not have special character restrictions. These values should be	Req
					short for ease of use in programming, but it is not expected that ETCD will need to serve as a variable name.	
ELEMENT	Description of Element	Char	*	Synonym Qualifier	The name of the Element. The same Element may occur more than once within an Arm.	Perm
TABRANCH	Branch	Char		Rule	Condition subject met, at a "branch" in the trial design at the end of this Element, to be included in this Arm; (e.g., randomization to DRUG X).	Exp
TATRANS	Transition Rule	Char		Rule	If the trial design allows a subject to transition to an Element other than the next Element in sequence, then the conditions for transitioning to those other Elements, and the alternative Element sequences, are specified in this rule (e.g., Responders go to washout).	Exp
EPOCH	Epoch	Char	(EPOCH)	Timing	Name of the Trial Epoch with which this Element of the Arm is associated.	Req

试验设计域相关 - 以**TA**域为例

- **ARM** – 值不能等于：'Screen Failure', 'Not Assigned', 'Unplanned Treatment', 'Not Treated' 。

- **ARMCD** – 值的长度不能超过20；是一个有效的计划分组编码。

- **ELEMENT** – 与ETCD一一对应；如果有超过一个ARM / EPOCH，那么 ELEMENT的值不能指向任何一个特定的ARM / EPOCH （TESTRL should be expressed without referring to Arm/Epoch）。

- **ETCD** – 值的长度不能超过8；当ETCD不等于 'UNPLAN'时，TA.ETCD的值 在TE.ETCD中均可找到。

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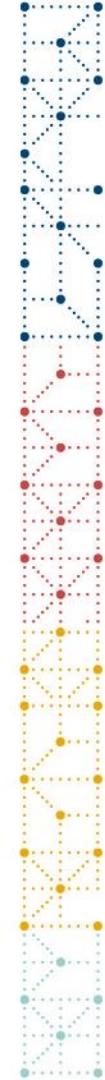
试验设计域相关 - 以TA域为例

- **TAETORD** – 必须是整数；同一计划分组下的TAETORD必须是唯一值。
- **TATRANS**

✓If element does not end with a decision that could lead to a shortened path within the Arm then TATRANS = null；

✓If trial design allows for a subject to transition to an element other than the next element in sequence then TATRANS ^= null 。

- **EPOCH** – 不同的试验时期，对应的EPOCH的值必须不同。
- **TABRANCH** –如果试验设计有分支，那么TABRANCH不为空。

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试验设计域相关 - 以TE域为例

## TE – Specification for Trial Elements Dataset

te.xpt, Trial Elements — Trial Design, Version 3.2 One record per planned Element

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	TE	Identifier	Two-character abbreviation for the domain.	Req
ETCD	Element Code	Char	*	Topic	ETCD (the companion to ELEMENT) is limited to 8 characters and does not have special character restrictions. These values should be short for ease of use in programming, but it is not expected that ETCD will need to serve as a variable name.	Req
ELEMENT	Description of Element	Char	*	Synonym Qualifier	The name of the Element.	Req
TESTRL	Rule for Start of Element	Char		Rule	Expresses rule for beginning Element.	Req
TEENRL	Rule for End of Element	Char		Rule	Expresses rule for ending Element. Either TEENRL or TEDUR must be present for each Element.	Perm
TEDUR	Planned Duration of Element	Char	ISO 8601	Timing	Planned Duration of Element in ISO 8601 format. Used when the rule for ending the Element is applied after a fixed duration.	Perm

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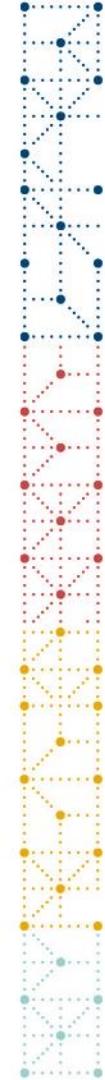
试验设计域相关 - 以TE域为例

- **TEENRL** – TEENRL的值不应指向任何特定的ARM。

- **TEDUR** – TEDUR与TEENRL至少一个不为空。

- **ELEMENT、TESTRL、TEENRL和TEDUR**的组合对于每个**ETCD**都是独一无二的，即，具有不同的开始和结束规则的元素是不同的元素，并且必需具有不同的ELEMENT 和ETCD 值。

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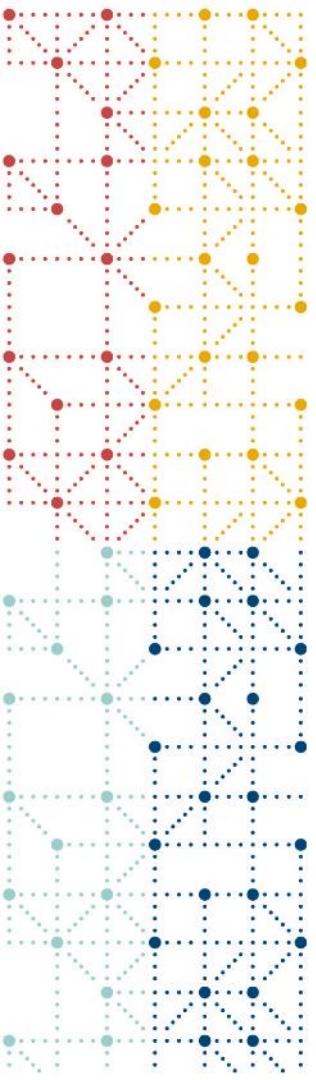
FDA与PMDA的试验设计域的符合性验证规则

FDA Business and Validator Rules

- **FDA Business Rules v1.5：**

✓分类：Clinical and Nonclinical (36条，包括弃用的10条) / Clinical Only (21条，包括弃用的4条) / Nonclinical Only (29条，包括弃用的2条)

Version 1.5 finalized June 2019	
FDA Business Rule ID	**FDA Business Rule**
Clinical and Nonclinical	
FDAB008	All treatment exposure date/time should be between first and last study treatment date/time.
FDAB009	All paired variables should have a one-to-one relationship. Examples include short name and name of test; parameter name and parameter code or number; variable name and variable label, etc.
FDAB011	**All trial design data should be submitted as specified in the FDA Study Data Technical Conformance Guide (TCG).**
FDAB012	Deprecated in v1.5.
FDAB013	Deprecated in v1.5.

FDA Validator Rules v1.6

FDA Validator Rule ID	Publisher	Publisher ID	FDA Validator Rule Message	FDA Validator Rule Description	Domains	SDTMIG 3.1.2	SDTMIG 3.1.3	SDTMIG 3.2	SDTMIG 3.3
SD0011	CDISC	CG0127	ARM is not 'Screen Failure', when ARMCD equals 'SCRNFAIL', or vice versa	Description of Arm (ARM) must equal 'Screen Failure', when Arm Code (ARMCD) is 'SCRNFAIL', and vice versa.	DM, TA	X	X	X	
SD0053	CDISC	CG0129	ARM is not 'Not Assigned', when ARMCD equals 'NOTASSGN', or vice versa	Description of Arm (ARM) must equal 'Not Assigned', when Arm Code (ARMCD) is 'NOTASSGN', and vice versa.	DM, TA	X	X	X	
SD0067	CDISC	CG0414, 123	Invalid ETCD	Element Code (ETCD) values should match entries in the Trial Elements (TE) dataset, except for unplanned Element (ETCD = 'UNPLAN').	SE, TA	X	X	X	X
SD1004	CDISC	CG0153, 27	Invalid value for ARMCD	The value of Planned Arm Code (ARMCD) should be no more than 20 characters in length.	DM, TA, TV	X	X	X	X
SD1009	CDISC	CG0246, 24	Invalid value for ETCD	The value of Element Code (ETCD) should be no more than 8 characters in length.	SE, TA, TE	X	X	X	X

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PMDA study data validation rules v4.0 (2023-02-28)

RULE ID	MESSAGE	DESCRIPTION	DOMAINS	PMDA Severity	3.1.2	3.1.3	3.2	3.3	PMDA NOTES
SD0011	ARM is not 'Screen Failure', when ARMCD equals 'SCRNFAIL', or vice versa	Description of Arm (ARM) must equal 'Screen Failure', when Arm Code (ARMCD) is 'SCRNFAIL', and vice versa.	DM, TA	Error	X	X	X		
SD0053	ARM is not 'Not Assigned', when ARMCD equals 'NOTASSGN', or vice versa	Description of Arm (ARM) must equal 'Not Assigned', when Arm Code (ARMCD) is 'NOTASSGN', and vice versa.	DM, TA	Error	X	X	X		
SD0067	Invalid ETCD	Element Code (ETCD) values should match entries in the Trial Elements (TE) dataset, except for unplanned Element (ETCD = 'UNPLAN').	SE, TA	Error	X	X	X	X	
SD1004	Invalid value for ARMCD	The value of Planned Arm Code (ARMCD) should be no more than 20 characters in length.	DM, TA, TV	Error	X	X	X	X	
SD1009	Invalid value for ETCD	The value of Element Code (ETCD) should be no more than 8 characters in length.	SE, TA, TE	Error	X	X	X	X	

下载地址：**https://www.pmda.go.jp/english/review-services/reviews/0002.html**

CDISC、FDA与PMDA 验证规则比较

- **Rule ID / Publisher ID**

举例说明	CDISC	FDA		PMDA
		Business Rules	**Validator Rules**	**PMDA**
Rule ID	CG0001	FDAB009	SD0011 / CT0021 / SE2201(只与SEND相关)	SD0019 / CT0021
Publisher			FDA/CDISC/空值 (空值大部分与SEND相关)	
Publisher ID			244(SEND) / CG0257(SDTM) / eCTD 1734 /TCG 3.3.5 / FDAB009	

以TA域的验证规则为例 – 相同项

CDISC	FDA	PMDA
ARMCD value length <= 20	Invalid value for ARMCD (The value of Planned Arm Code (ARMCD) should be no more than 20 characters in length.)	Invalid value for ARMCD (The value of Planned Arm Code (ARMCD) should be no more than 20 characters in length.)
ARM not in ('Screen Failure', 'Not Assigned', 'Unplanned Treatment', 'Not Treated') ARMCD is a valid planned arm code.	Unexpected value for ARMCD variable (Records for subjects who failed a screening or were not assigned to study treatment (ARMCD is 'SCRNFAIL' or 'NOTASSGN') should not be included in the Trial Arms (TA) or Trial Visits (TV) datasets.)	Unexpected value for ARMCD variable (Records for subjects who failed a screening or were not assigned to study treatment (ARMCD is 'SCRNFAIL' or 'NOTASSGN') should not be included in the Trial Arms (TA) or Trial Visits (TV) datasets.)
ETCD value length <= 8	Invalid value for ETCD (The value of Element Code (ETCD) should be no more than 8 characters in length.)	*Invalid value for ETCD (The value of Element Code (ETCD) should be no more than 8 characters in length.) - TE*
ELEMENT and ETCD have a one-to-one relationship	Non-unique value for ELEMENT within ETCD (Description of Element (ELEMENT) must have a unique value for a given value of Element Code (ETCD) within the domain.)	Non-unique value for ELEMENT within ETCD (Description of Element (ELEMENT) must have a unique value for a given value of Element Code (ETCD) within the domain.)
TAETORD is unique within an ARM	Non-unique value for TAETORD within ARMCD (Order of Element within Arm (TAETORD) must have a unique value for a given value of Planned Arm Code (ARMCD) within the domain.)	Non-unique value for TAETORD within ARMCD (Order of Element within Arm (TAETORD) must have a unique value for a given value of Planned Arm Code (ARMCD) within the domain.)
TAETORD is an integer	Invalid value for TAETORD (Planned Order of Element within Arm (TAETORD) variable value must be an integer.)	Invalid value for TAETORD (Planned Order of Element within Arm (TAETORD) variable value must be an integer.)
ETCD = TE.ETCD (ETCD ^= 'UNPLAN')	ETCD value not present in TA (Element Code (ETCD) values defined in Trial Elements (TE) should be assigned for at least one Arm Code (ARMCD) in Trial Arms (Trial Arms).) ETCD value not present in SE (Element Code (ETCD) values defined in Trial Elements (TE) should be assigned to at least one subject (USUBJID) in Subject Elements (SE).) Invalid ETCD/ELEMENT (The combination of Element Code (ETCD) and Description of Element (ELEMENT) values should match entries in the Trial Elements (TE) dataset, except for unplanned Element (ETCD = 'UNPLAN').) Invalid ETCD (Element Code (ETCD) values should match entries in the Trial Elements (TE) dataset, except for unplanned Element (ETCD = 'UNPLAN').)	*ETCD value not present in TA (Element Code (ETCD) values defined in Trial Elements (TE) should be assigned for at least one Arm Code (ARMCD) in Trial Arms (Trial Arms).)- TE* *ETCD value not present in SE (Element Code (ETCD) values defined in Trial Elements (TE) should be assigned to at least one subject (USUBJID) in Subject Elements (SE).) - TE* Invalid ETCD/ELEMENT (The combination of Element Code (ETCD) and Description of Element (ELEMENT) values should match entries in the Trial Elements (TE) dataset, except for unplanned Element (ETCD = 'UNPLAN').) Invalid ETCD (Element Code (ETCD) values should match entries in the Trial Elements (TE) dataset, except for unplanned Element (ETCD = 'UNPLAN').)
ARMCD in TA.ARMCD (ARMCD not in ('SCRNFAIL', 'NOTASSGN')) (for ig3.2-DM domain)	ARMCD value not present in DM (Arm Code (ARMCD) values defined in Trial Arms (TA) should be assigned to at least one subject (USUBJID) in Demographics (DM).)	ARMCD value not present in DM (Arm Code (ARMCD) values defined in Trial Arms (TA) should be assigned to at least one subject (USUBJID) in Demographics (DM).)
ACTARMCD = ARMCD (ACTARMCD in ('SCRNFAIL', 'NOTASSGN')) (for ig3.2-DM domain)	ARM is not 'Screen Failure', when ARMCD equals 'SCRNFAIL', or vice versa (Description of Arm (ARM) must equal 'Screen Failure', when Arm Code (ARMCD) is 'SCRNFAIL', and vice versa.)	ARM is not 'Screen Failure', when ARMCD equals 'SCRNFAIL', or vice versa (Description of Arm (ARM) must equal 'Screen Failure', when Arm Code (ARMCD) is 'SCRNFAIL', and vice versa.)
ARMCD = ACTARMCD (ARMCD in ('SCRNFAIL', 'NOTASSGN')) (for ig3.2-DM domain)	ARM is not 'Not Assigned', when ARMCD equals 'NOTASSGN', or vice versa (Description of Arm (ARM) must equal 'Not Assigned', when Arm Code (ARMCD) is 'NOTASSGN', and vice versa.)	ARM is not 'Not Assigned', when ARMCD equals 'NOTASSGN', or vice versa (Description of Arm (ARM) must equal 'Not Assigned', when Arm Code (ARMCD) is 'NOTASSGN', and vice versa.)

CDISC部分验证规则与FDA/PMDA一致，可能描述不同。
FDA与PMDA的重合度较高

以TA域的验证规则为例 – 不同项

CDISC	FDA	PMDA
TATRANS = null (Element does not end with a decision that could lead to a shortened path within the Arm)		
Each value of EPOCH is not associated with more than one conceptual trial period (values of EPOCH must be different for different epochs)		
TABRANCH ^= null (Trial design branches)		
TATRANS ^= null (Trial Design allows for a Subject to transition to an Element other than the next Element in sequence)		
ELEMENT value does not refer to any specific ARM (ELEMENT is associated with > 1 ARM) (TESTRL should be expressed without referring to Arm)		
ELEMENT value does not refer to any specific EPOCH (ELEMENT is associated with > 1 EPOCH) (TESTRL should be expressed without referring to Epoch)		
	Non-unique value for ETCD within ELEMENT (Element Code (ETCD) must have a unique value for a given value of Description of Element (ELEMENT) within the domain.)	**Non-unique value for ETCD within ELEMENT** (Element Code (ETCD) must have a unique value for a given value of Description of Element (ELEMENT) within the domain.)
	Inconsistent value for ARM (A value for Description of Planned Arm (ARM) must have a unique value for Planned Arm Code (ARMCD) with the domain.)	**Inconsistent value for ARM** (A value for Description of Planned Arm (ARM) must have a unique value for Planned Arm Code (ARMCD) with the domain.)
	Inconsistent value for ARMCD (A value for Planned Arm Code (ARMCD) must have a unique value for Description of Planned Arm (ARM) with the domain.)	**Inconsistent value for ARMCD** (A value for Planned Arm Code (ARMCD) must have a unique value for Description of Planned Arm (ARM) with the domain.)
	Missing TA dataset (Trial Arms (TA) dataset should be included in every submission.)	**Missing TA dataset** (Trial Arms (TA) dataset should be included in every submission.)
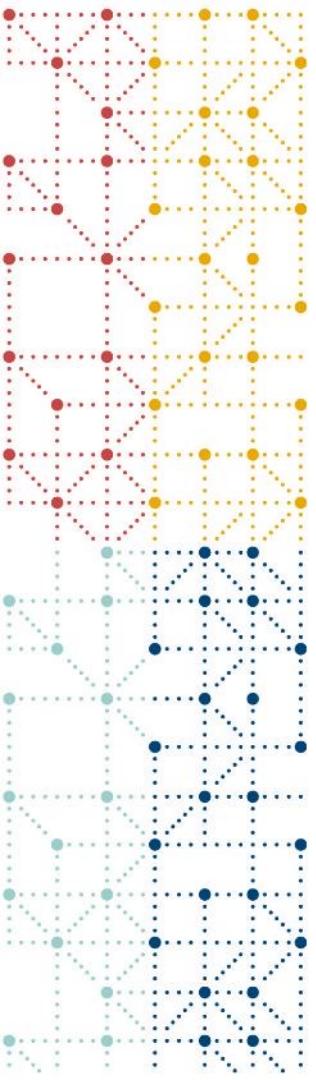
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案例分析

以TS数据集为例

STUDYID	DOMAIN	TSSEQ	TSGRPID	TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
XYZ	TS	1		TITLE	试验标题	一项口服加巴喷丁对比安慰剂联合苯妥英治疗神经纤维瘤病所致癫痫患者的24周研究				
XYZ	TS	1		TPHASE	试验分期分类	Phase II Trial		C15601	CDISC	2020-11-06
XYZ	TS	1		SPONSOR	临床研究申办者	XXX公司		1234567	DUNS	
XYZ	TS	1		STYPE	研究类型	干预治疗		C98388	CDISC	2020-11-06
XYZ	TS	1		TRT	试验药物或治疗	加巴喷丁		6CW7F3G59X	UNII	
XYZ	TS	1		TINDTP	试验适应症类型	治疗		C49656	CDISC	2020-11-06
XYZ	TS	1		INTMODEL	干预模型	平行设计		C82639	CDISC	2020-11-06
XYZ	TS	1		INTTYPE	干预类型	药物治疗		C1909	CDISC	2020-11-06
XYZ	TS	1		PCLAS	试验药物的药理学分类	抗癫痫药		N0000175753	MED-RT	
XYZ	TS	1		OBJPRIM	试验主要目的	3个月癫痫发作频率较基线降低				
XYZ	TS	1		OBJSEC	试验次要目的	3个月癫痫发作频率较基线降低百分比				
XYZ	TS	2		OBJSEC	试验次要目的	3个月强直阵挛性发作频率较基线降低				

STUDYID	DOMAIN	TSSEQ	TSGRPID	TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
XYZ	TS	1		TTYPE	试验类型	有效性研究		C49666	CDISC	2020-11-06
XYZ	TS	2		TTYPE	试验类型	安全性研究		C49667	CDISC	2020-11-06
XYZ	TS	1		OUTMSPRI	主要结果测量	发作频率				
XYZ	TS	1		OUTMSSEC	次要结果测量	发作频率				
XYZ	TS	2		OUTMSSEC	次要结果测量	发作持续时间				
XYZ	TS	1		SEXPOP	参与者的性别	两者均有			CDISC	2020-11-06
XYZ	TS	1		HLTSUBJI	健康受试者指标	N			CDISC	2020-11-06
XYZ	TS	1		TDIGRP	诊断群	神经纤维瘤病综合征(紊乱)患者		19133005	SNOMED	
XYZ	TS	1		AGEMAX	计划受试者的最大年龄	P70Y			ISO 8601	
XYZ	TS	1		AGEMIN	计划受试者的最小年龄	P0Y				
XYZ	TS	1		PLANSUB	计划的受试者人数	300				
XYZ	TS	1		ADDON	加在已存在的疗法之上	Y		C49488	CDISC	2020-11-06
XYZ	TS	1		CURTRT	当前的疗法	苯妥英		6158TKW0C5	UNII	
XYZ	TS	1		TCNTRL	对照类型	PLACEBO		C49648	CDISC	2020-11-06
XYZ	TS	1		TBLIND	试验设盲概要	双盲		C15228	CDISC	2020-11-06
XYZ	TS	1		RANDOM	试验是随机化的	Y		C49488	CDISC	2020-11-06

若无最小年龄限制，则填写P0Y

若为Y，则需列CURTRT

STUDYID	DOMAIN	TSSEQ	TSGRPID	TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
XYZ	TS	1		INDIC	试验适应症	强直阵挛性癫痫(紊乱)				
XYZ	TS	1	DateDesc1	DCUTDTC	数据截止日期	2011-04-01				
XYZ	TS	1	DateDesc1	DCUTDESC	数据截止描述	数据库锁定				
XYZ	TS	1		NARMS	计划组数	3				
XYZ	TS	1		STOPRULE	研究终止条例	NONE				
XYZ	TS	1		LENGTH	计划的试验长度	P3M			ISO 8601	
XYZ	TS	1		REGID	注册编号	NCT123456789		NCT123456789	ClinicalTrials.GOV	
XYZ	TS	2		REGID	注册编号	XXYYZZ456				
XYZ	TS	1		ADAPT	适应性设计	N				2020-11-06
XYZ	TS	1		SSTDTC	研究开始日期	2009-03-11			ISO 8601	
XYZ	TS	1		SENDTC	研究结束日期	2011-04-01			ISO 8601	
XYZ	TS	1		ACTSUB	实际受试者数量	304				
XYZ	TS	1		FCNTRY	计划研究中心国家	United States of America		USA	ISO 3166	

若方案中未规定研究终止条例，则填NONE

锁库后，与数据截止日期一致

cdisc

Thank You!

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