CDISC Library Construction Practice: Key Processes, Experience Discussions and Case Analyses
CDISC库构建实践：关键流程、经验讨论与案例剖析

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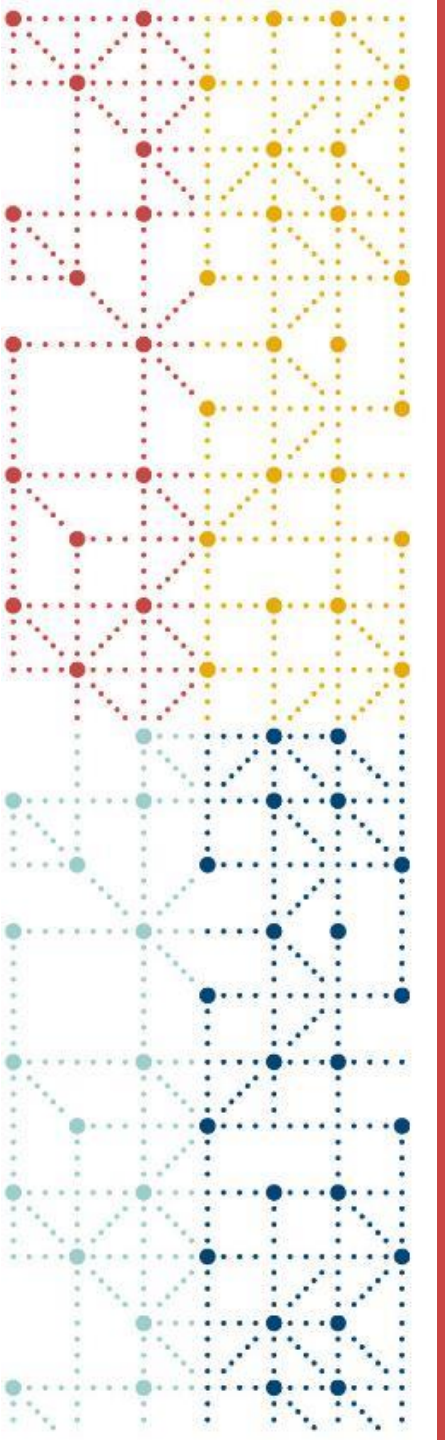
- *The views and opinions expressed in this presentation are those of the author(s), and do not necessarily reflect the official policy or position of CDISC.*
- *The views and opinions expressed in this presentation are those of the author(s), and do not necessarily reflect the official policy or position of Caidya.*

John Wang, Senior Director Statistical Programming

- 20 years experience in international pharmaceutical company or CRO
- Extensive statistical analysis experience in all phases of clinical trials. Familiar with regulatory agencies' data submission requirements.
- Familiar with different kinds of statistical analysis programming languages and data management system tools in clinical research
- Chairman and SDTM group team lead of CDISC China. Expert in CDISC fundamental data standards. Authorized CDISC SDTM Instructor since Jan 2016
- Many presentations on conferences DIA, PharmaSUG, PhUSE, CDISC Interchange, C3C seminars.
- MPH degree from Fudan University



Caidya Practices

1. What is CDISC Library
2. Who/How use CDISC Library

Platform

- CDISC Library on Microsoft Azure
- Refined RESTful API
- Advanced Analytical Capabilities
- Azure Cognitive Search Functionality
- API Management Developer Portal

Content

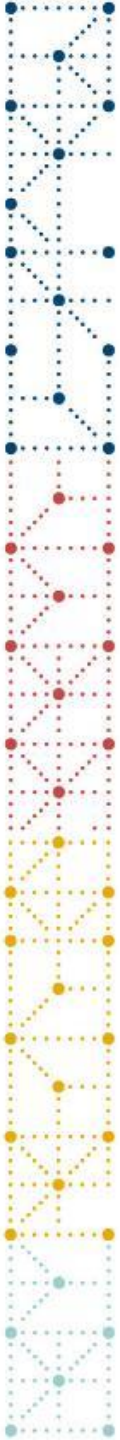
- Authoritative Source for Machine-Readable Normative CDISC Standards & Terminology Metadata
- Version Traceability
- Model-Based Standards Metadata
- Traceability of Standards Lineage Identification
- Future Novel Metadata & Functionality
- Continuous Loading of New Content
- Available Media Types (JSON, XML, CSV, Excel)

Innovation

- Agile Development Methodology
- Exploration of Advanced Technology Solutions
- Dynamically-Driven API Data Standards Browser
- Future Media Types (ODM-XML, Define-XML, etc.)
- CDISC 360 Implementation Requirements
- CDISC Library Community Roundtable (User Feedback & Support)

Snapshot

- 85+ Versioned Standards
- 1+ Million Resources (100k+ Controlled Terms, 1.2k CDASH Fields, 2k+ SDTM Variables, 740 ADaM Variables)
- 6+ Million Relationships
- 1.5k CDASH-to-SDTM Mapping Statements
- 35 Regulatory Support Statements



https://www.cdisc.org/cdisc-library

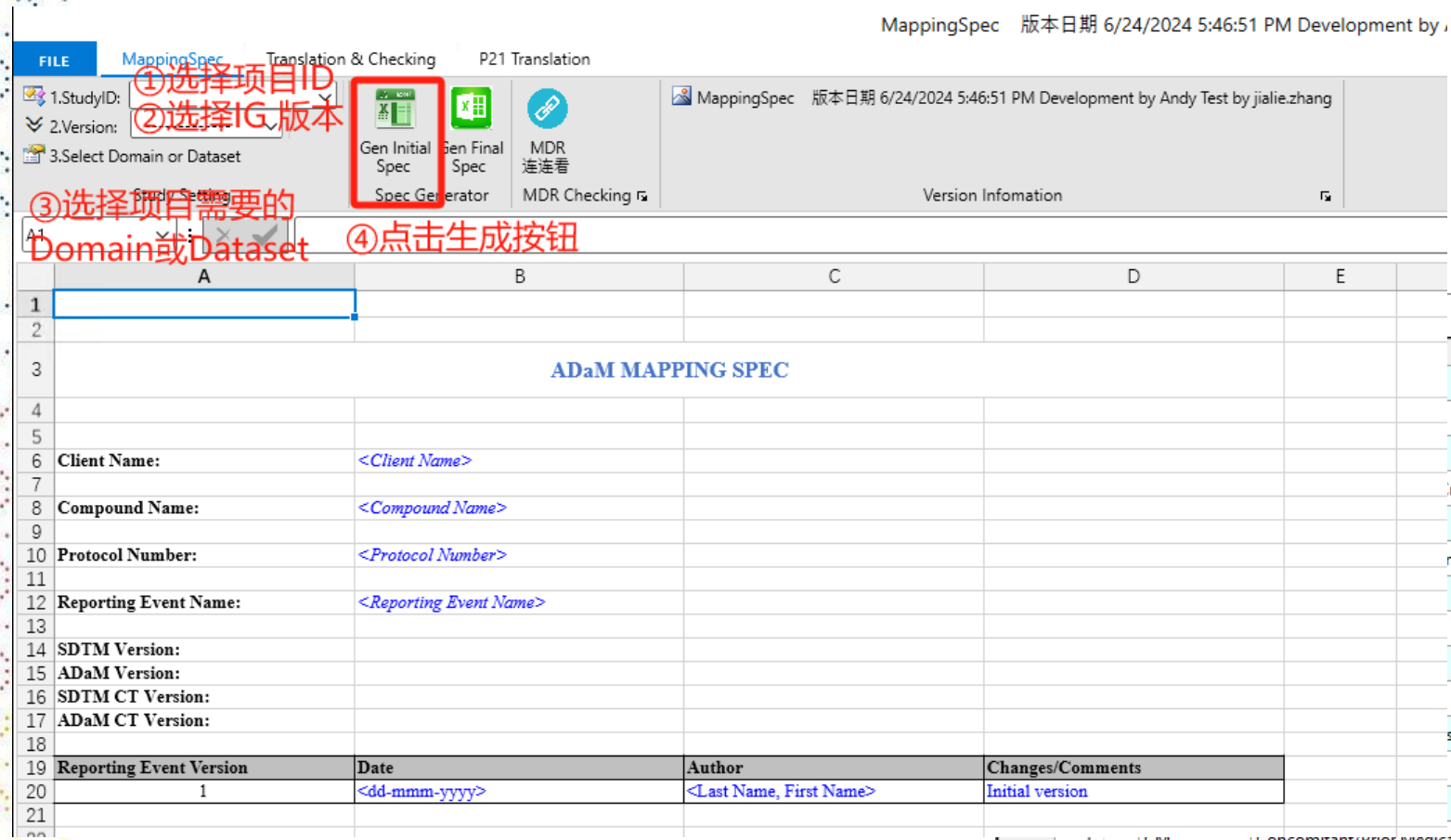
CDASH/CDASHIG	• CDASH Model v1.0, v1.1, v1.2, v1.3 • CDASHIG v2.0, v2.1, v2.2, v2.3 • CDASH v1.1/CDASHUG v1.0
SDTM	• SDTM v1.2, v1.3, v1.4, v1.5, v1.6, v1.7, v1.8, v2.0
SDTMIG	• SDTMIG v3.1.2, v3.1.3, v3.2, v3.3, v3.4 • SDTMIG-AP v1.0 • SDTMIG-MD v1.0, v1.1 • SDTMIG-PGx v1.0
SENDIG	• SENDIG v3.0, v3.1, 3.1.1 • SENDIG-DART v1.1 • SENDIG-AR v1.0
ADaMIG	• ADaMIG v1.0, v1.1, v1.2, v1.3 • ADaM ADAE v1.0 • ADaM BDS for TTE v1.0 • ADaM OCCDS v1.0, v1.1 • ADaMIG NCA v1.0 • ADaMIG MD v1.0 • ADaM popPK v1.0

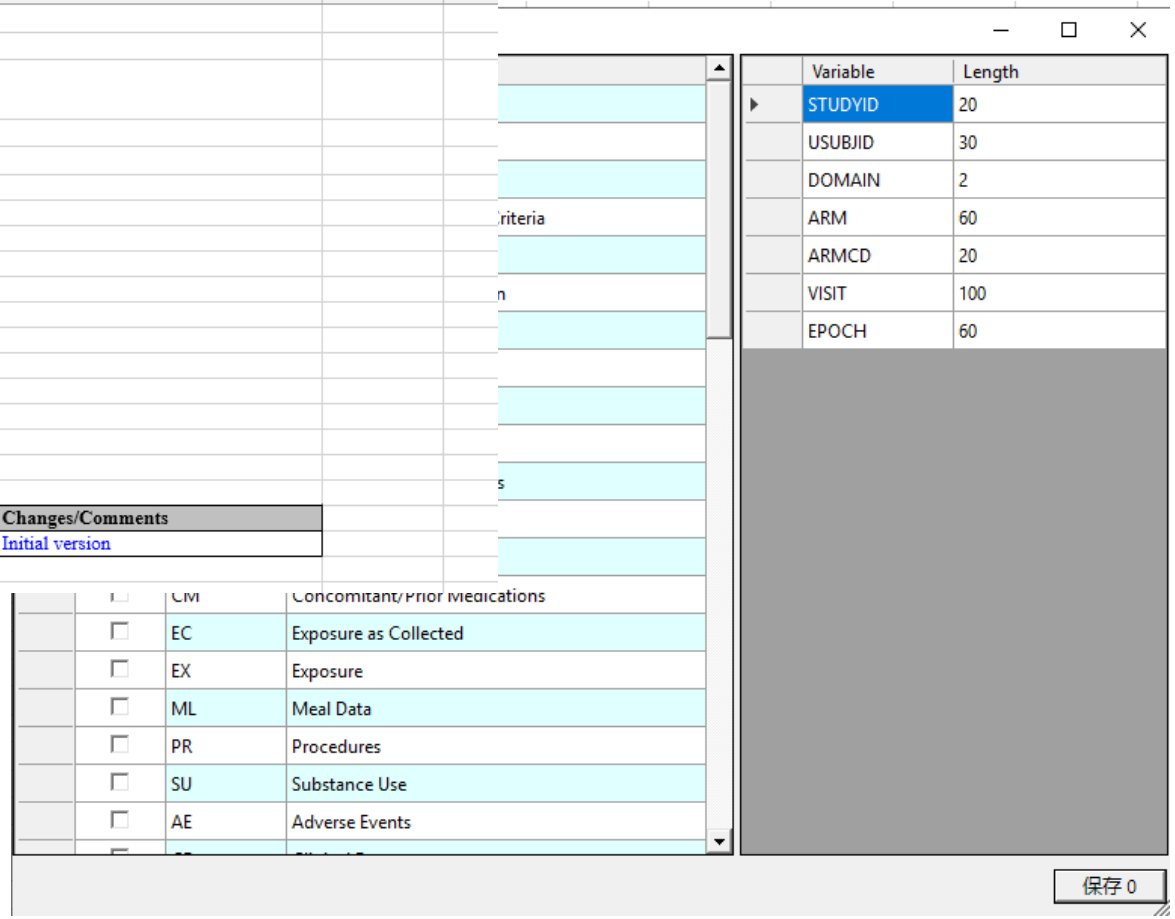
Caidya Practices

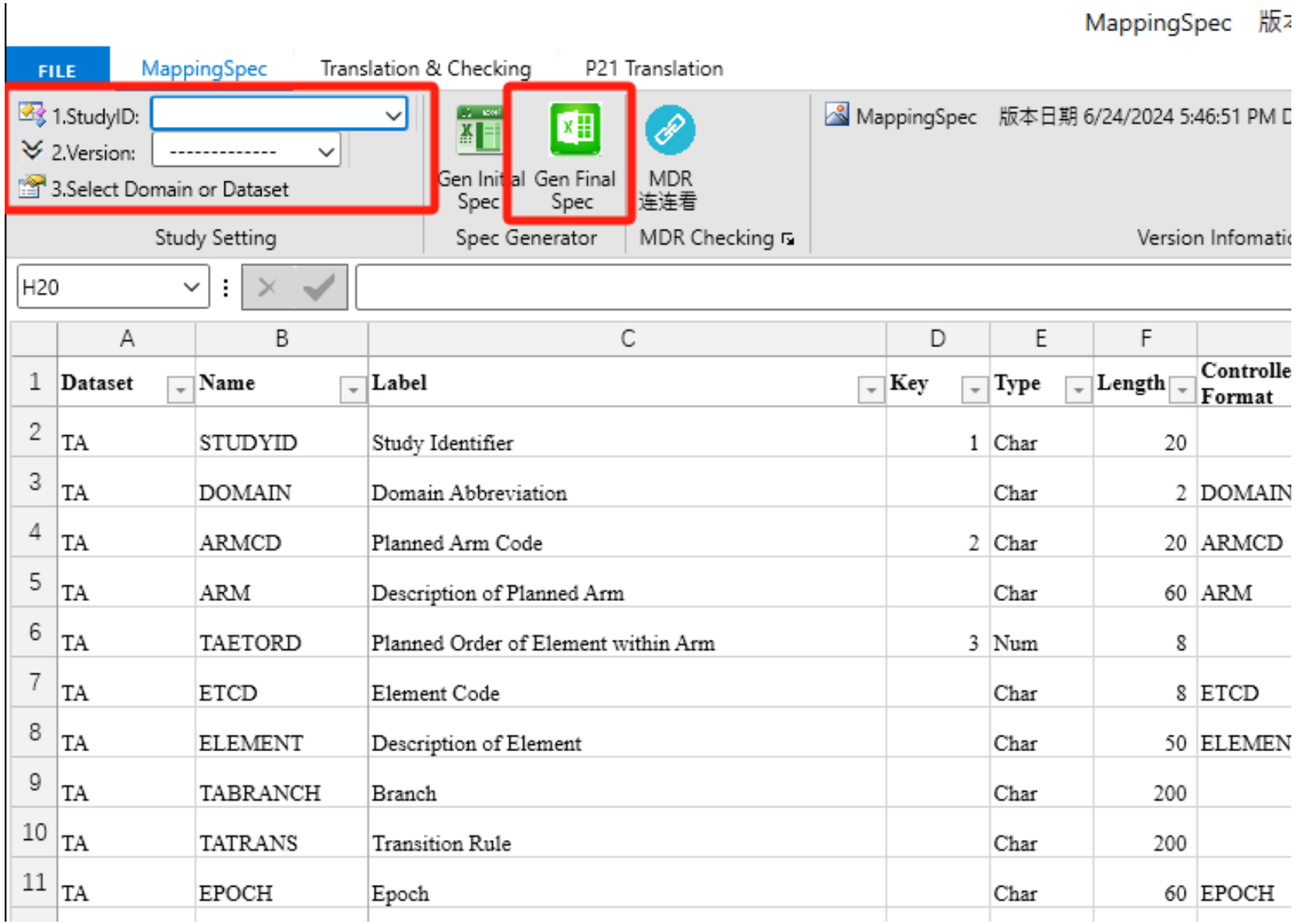
- DM - MDR
  - CDASH Library
  - Setup EDC specs and edit checks, push to each study EDC

Caidya Practices

- Programming – Mapping Specs
  - SDTM & ADaM Library
  - Setup mapping specs
  - Check if all variables are mapped to SDTM


MappingSpec 版本日期 6/24/2024 5:46:51 PM Development by
FILE
MappingSpec
Translation & Checking
P21 Translation
①选择项目ID
②选择IG版本
1.StudyID:
2.Version:
3.Select Domain or Dataset
Gen Initial Spec
Gen Final Spec
Spec Generator
MDR 连连看
MDR Checking
MappingSpec 版本日期 6/24/2024 5:46:51 PM Development by Andy Test by jialie.zhang
Version Infomation
③选择项目需要的Domain或Dataset
④点击生成按钮
ADaM MAPPING SPEC
Client Name: <Client Name>
Compound Name: <Compound Name>
Protocol Number: <Protocol Number>
Reporting Event Name: <Reporting Event Name>
SDTM Version:
ADaM Version:
SDTM CT Version:
ADaM CT Version:
Reporting Event Version
Date
Author
Changes/Comments
1
<dd-mmm-yyyy>
<Last Name, First Name>
Initial version


EC Exposure as Collected
EX Exposure
ML Meal Data
PR Procedures
SU Substance Use
AE Adverse Events
Variable
Length
STUDYID 20
USUBJID 30
DOMAIN 2
ARM 60
ARMCD 20
VISIT 100
EPOCH 60
保存 0



	A	B	C	D	E	F	
1	**Dataset**	**Name**	**Label**	**Key**	**Type**	**Length**	**Controlle Format**
2	TA	STUDYID	Study Identifier	1	Char	20	
3	TA	DOMAIN	Domain Abbreviation		Char	2	DOMAIN
4	TA	ARMCD	Planned Arm Code	2	Char	20	ARMCD
5	TA	ARM	Description of Planned Arm		Char	60	ARM
6	TA	TAETORD	Planned Order of Element within Arm	3	Num	8	
7	TA	ETCD	Element Code		Char	8	ETCD
8	TA	ELEMENT	Description of Element		Char	50	ELEMEN
9	TA	TABRANCH	Branch		Char	200	
10	TA	TATRANS	Transition Rule		Char	200	
11	TA	EPOCH	Epoch		Char	60	EPOCH

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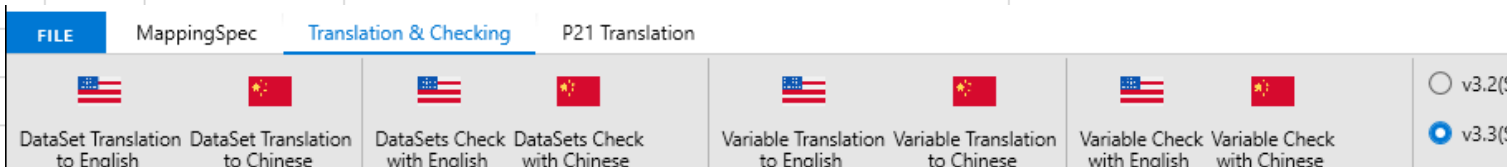
	A	B	C	D	E	F	G	H
1	**Dataset**	**Name**	**Label**	**Key**	**Type**	**Length**	**Controlled Terms or Format**	**Source/Derivation**
2	TA	STUDYID	研究标识符	1	Char	20		"TRACE"
3	TA	DOMAIN	域名缩写		Char	2	DOMAIN_TA	"TA"
4	TA	ARMCD	计划分组编码	2	Char			
5	TA	ARM	计划分组描述		Char			
6	TA	TAETORD	组内元素计划顺序	3	Num			
7	TA	ETCD	元素编码		Char			
8	TA	ELEMENT	元素描述		Char			
9	TA	TABRANCH	分叉条件		Char			
10	TA	TATRANS	过渡规则		Char			
11	TA	EPOCH	时期		Char			



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	A	B	C	D	E	F	G	
1	**Dataset**	**Name**	**Label**	**Key**	**Type**	**Length**	**Controlled Terms or Format**	**Source/Derivatio**
2	TA	STUDYID	Study Identifier	1	Char	20		"TRACE"
3	TA	DOMAIN	Domain Abbreviation		Char	2	DOMAIN_TA	"TA"
4	TA	ARMCD	Planned Arm Code	2	Char	20	ARMCD	see "TA_Data" sh
5	TA	ARM	Description of Planned Arm		Char	60	ARM	see "TA_Data" sh
6	TA	TAETORD	Planned Order of Element within Arm	3	Num	8		see "TA_Data" sh
7	TA	ETCD	Element Code		Char	8	ETCD	see "TA_Data" sh
8	TA	ELEMENT	Description of Element		Char	50	ELEMENT	see "TA_Data" sh
9	TA	TABRANCH	Branch		Char	200		see "TA_Data" sh
10	TA	TATRANS	Transition Rule		Char	200		see "TA_Data" sh
11	TA	EPOCH	Epoch		Char	60	EPOCH	see "TA_Data" sh

Challenges

- Different Versions
- Derivations, not good enough for AI to generate code.
  - Need continuous polish.
  - CT Chinese, core, not all terms like English version.