

Single Day Event

Automation Construction & Consideration In Whole Delivery Flow
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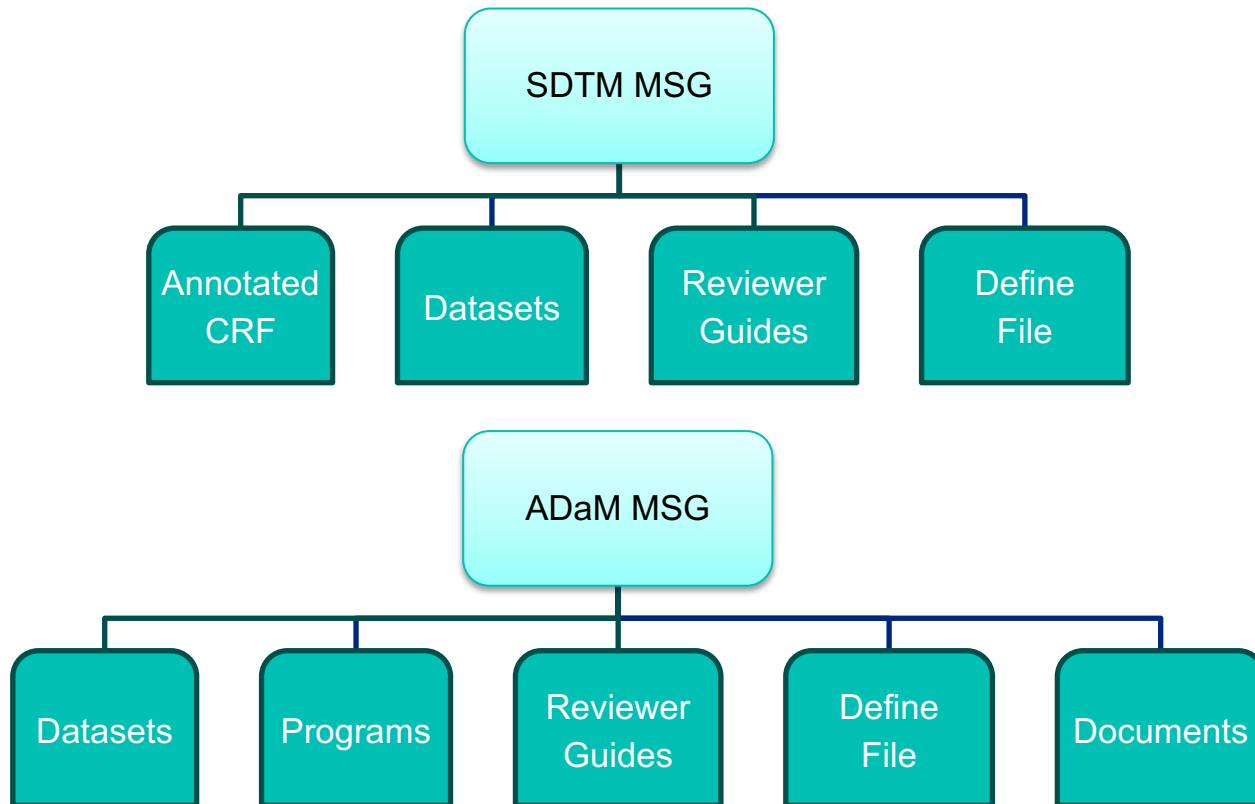


Agenda

- Work Scope
- Preparation Before Automation
- Automation Procedure in aCRF & TLF
- Discussion



Metadata Submission Guideline





Scope

01

Data Collection & STD

- EDC template library for different type study
- Standardize data from various sources into the SDTM-friendly format to ensure consistency.

02

CRF Automation

- **Rule Formulation:** Develop a set of rules and algorithms to automatically annotate CRFs.
- **Automated Data Extraction:** Automatically extract data from CRFs to reduce manual intervention.

03

SDTM/ADaM Automation

- **Automated Data Transformation:** Create automated tools to generate SDTM and ADaM datasets in compliance with standards.
- **Data Quality Control:** Implement data quality control rules to ensure the quality and accuracy of generated datasets.

04

Report Automation

- **Template Design:** Design standardized templates for statistical analysis reports, including TLFs.
- **Automated Report Generation:** Develop automated tools to generate

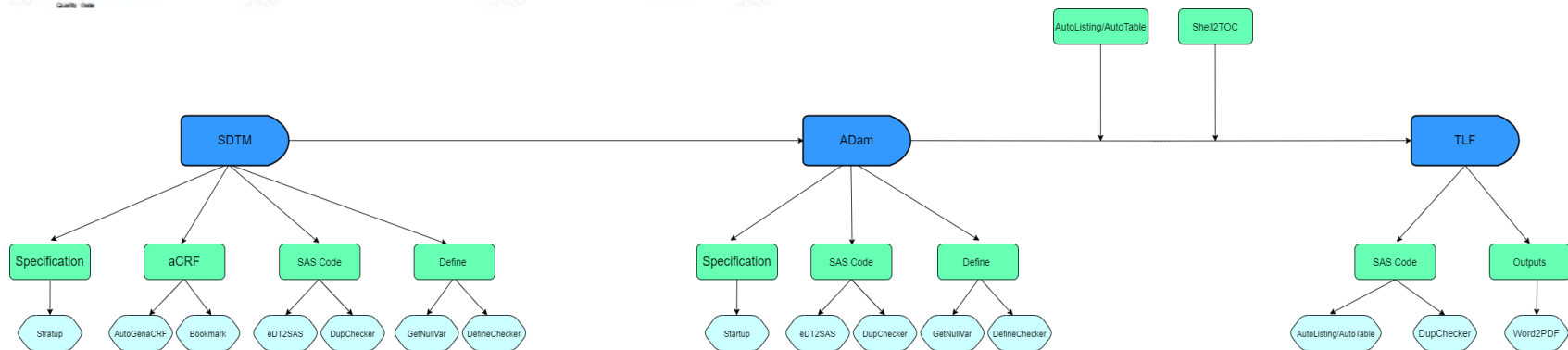
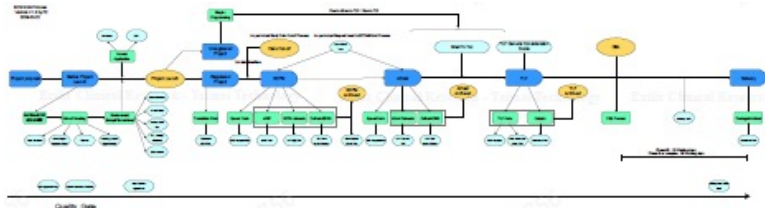
05

Define Automation

- Define File Auto-Generation



Tool & Macro





Cooperation

**Unified Up & Downstream make
Work-flow more fluent.**



Upstream

CRF style/EDC library/...

Midstream

aCRF/SDTM/ADaM/...

Downstream

TLF/SAR/...



Data Collection

Stable & Flexible & Standard

eCollect
Electronic Data Capture
System
Version 5

eCRF设计

数据迁移

参数配置

对接设置

数据采集 ePRO患者记录 CRF构建 实验室管理 报表 数据导出 研究设置

太美医疗系统演示专用 > 圣方统计培训项目

草案概况 方案CRF版本 中心数据库版本

环境 数据库版本1 研究中心

中心编号	研究中心	eCRF版本	数据库版本1
------	------	--------	--------



CRF Automation



CRF



Data
structure
file



Base
info
Excel



Contain:

Name
Location
STD Name
Annotated Text.....
Dash Border
BookMark



aCRF



Extraction Step

Demographics

Year of Birth

Age Years

Sex
☐ Male
☐ Female

FormOID	FormName	SASDatasetName	ItemGroupRepeat	ItemGroupActive	SASFieldName	ItemName	DisplayMode	DataFormat	CodeListOID
DM	Demographics	DM	N	Y	BRTHYY	Year of Birth	PartialDateTime	{yyyy}	
DM	Demographics	DM	N	Y	AGE	Age	Number	2	
DM	Demographics	DM	N	Y	SEX	Sex	RadioButton	2	D24=[1 Male,2 Female,]



Mapping Step

Step 1: Demographics → Domain: DM

dm mapping lib

Step 2: Text: Year of Birth

BRTHDTC CT: NA

Coord: (X,Y) Dash Border: N

Step 3:

Year of Birth **BRTHDTC**

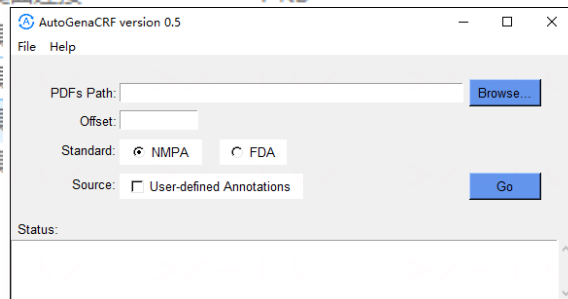
FORM	FormOID	ItemName	FIELDROID	FIELD_SEQUENCE	PAGE	X1	X2	Y1	Y2	DataFormat	DisplayMode	CodeListOID	ANNOTATION
人口统计学	DM	Demographics		0	16								DM = Demographics
人口统计学	DM	Year of Birth	BRTHDAT	1	16	482.55	500.55	674.78	688.768	{yyyy}-{MM}-{dd}	DateTime		BRTHDTC
人口统计学	DM	Age	AGE	2	16	482.55	500.55	650.86	664.848	2	Number		AGE AGEU
人口统计学	DM	Sex	SEX	3	16	482.55	500.55	626.94	640.928	1	RadioButton	D74=[1 Male,2 Female,]	SEX



aCRF Example

		2023/3/29 11:10	远程桌面连接
		2023/3/29 11:10	远程桌
	AutoGenaCRF.rdp	2023/3/29 11:10	远程桌
	Bookmark.rdp	2023/3/29 11:10	远程桌
		2023/3/29 11:10	远程桌

1 KB



Demographics **DM (Demographics)**

Year of Birth **BRTHDTC**

Age **AGE**

AGEU Years

Sex

☐ Male

☐ Female

SEX



aCRF Example

- Domains
 - Subject
 - Visit
 - Unscheduled Forms
 - Informed Consent
 - Inclusion / Exclusion Criteria
 - Demographics
 - Medical History
 - Prior Radiotherapy
 - Prior Systemic Treatments
 - Prior CAR-T Therapy
 - Prior Cancer-Related Surgery
 - Visits
 - Screening
 - Screen Fail
 - Cycle 1 Day 1
 - Cycle 1 Day 8
 - Cycle 1 Day 15
 - Cycle 2 Day 1
 - Cycle 2 Day 8
 - Cycle 2 Day 15
 - Cycle 3 and beyond
 - Unscheduled
 - End of Treatment
 - Survival Follow-Up
 - End of Study
 - Running Record

TR (肿瘤/病灶测量)

TU (肿瘤/病灶标识)

RECIST V1.1 肿瘤评估-目标病灶

TUORRES = 靶病灶 when TUTESTCD
= TUMIDENT and TUTEST = 肿瘤鉴别

受试者是否进行了RECIST ☐ 是

NOT SUBMITTED

V1.1 目标病灶肿瘤评估?

If this box was checked, no record will be submitted

TRSTAT = 未查

病灶直径总和 (自动计算)

mm

TRORRESU

TRORRES when TRTESTCD = SUMDIAM and TRTEST = Sum of Diameter

病灶编号

OT1

OT2

OT3

OT4

OT5

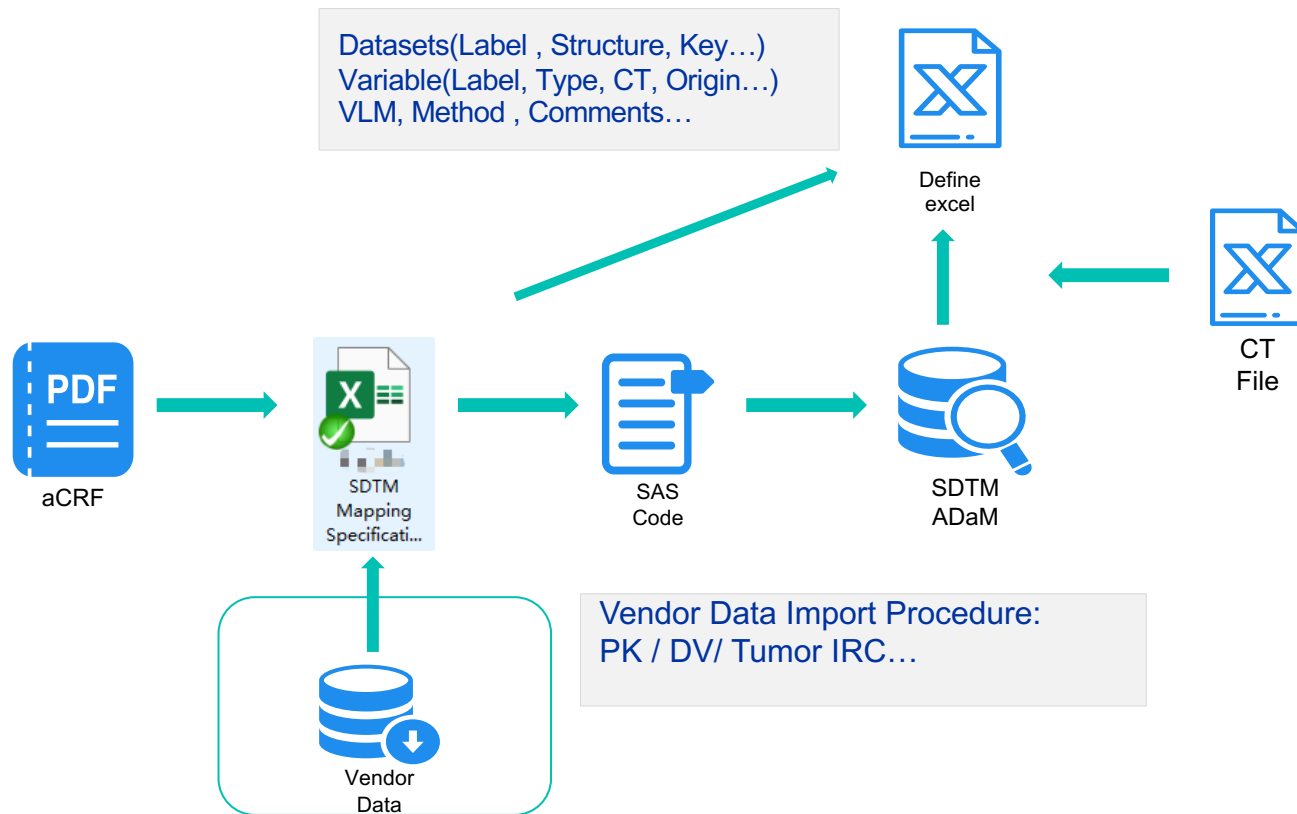
TULNKID

TRLNKID

RELREC when TRLNKID = TULNKID



SDTM/Define Automation





Listing Automation

Shell includes 3 sections for display

方案编号: XXXXX

统计分析计划-表格模板

列表 16.2.1.1 受试者试验完成情况 - 所有随机受试者

中心号	受试者编号	签署知情同意书日期	受试者状态	完成/提前退出日期	提前退出原因
XXXX	XXXX	XXXX-XX-XX	提前退出	XXXX-XX-XX	XXXXXX
	XXXX	XXXX-XX-XX	完成试验	XXXX-XX-XX	XXXXXX
	XXXX	XXXX-XX-XX	完成试验	XXXX-XX-XX	XXXXXX
	XXXX	XXXX-XX-XX	完成试验	XXXX-XX-XX	XXXXXX

PGM=xxxx.sas Date of TLF Generation= YYYY-MM-DD HH:MM:SS Date of Data Extraction= YYYY-MM-DD

Programming note:
按照入组序列、受试者编号顺序排序

Title Section

Content Section

Footnote Section

Not Display



T&F Extraction

Extracting Title & Footnote Information

ORDER	SECTION	RTFNAME	TITLE1	FWOTE1
70	Listing	l_16_2_1_1	列表16.2.1.1 受试者试验完成情况 - 所有随机的受试者	
71	Listing	l_16_2_1_2	列表16.2.1.2 筛选失败 - 所有筛选失败受试者	
72	Listing	l_16_2_1_3	列表16.2.1.3 提前退出研究 - 所有提前退出研究受试者	注: @[super 1]研究持续时间 = (退出日期 - 签署知情同意日期) + 1。
73	Listing	l_16_2_2_1	列表16.2.2.1 方案偏离 - 所有随机的受试者	
74	Listing	l_16_2_3_1	列表16.2.3.1 分析数据集 - 所有随机受试者	
75	Listing	l_16_2_4_1	列表16.2.4.1 人口学信息 - 全分析集	
76	Listing	l_16_2_4_2	列表16.2.4.2 研究疾病史 - 全分析集	注: MedDRA版本&med.
77	Listing	l_16_2_4_3	列表16.2.4.3 既往史 - 全分析集	注: MedDRA版本&med.
78	Listing	l_16_2_4_4	列表16.2.4.4 现病史 - 全分析集	注: MedDRA版本&med.
79	Listing	l_16_2_4_5	列表16.2.4.5 手术史 - 全分析集	注: MedDRA版本&med.
80	Listing	l_16_2_4_6	列表16.2.4.6 过敏史 - 全分析集	注: MedDRA版本&med.
81	Listing	l_16_2_4_7	列表16.2.4.7 既往用药 - 全分析集	注: WHODrug版本为&who. 版
82	Listing	l_16_2_4_8	列表16.2.4.8 合并用药 - 全分析集	注: WHODrug版本为&who. 版
83	Listing	l_16_2_4_9	列表16.2.4.9 非药物治疗 - 全分析集	注: MedDRA版本&med.

Storing info

Listing Codes Calling Macros
Inserting these to Outputs



Variables Mapping

列表 16.2.1.1 受试者试验完成情况 - 所有随机受试者

ADSL ITTFL

中心号	受试者编号	签署知情同意书日期	受试者状态	完成/提前退出日期	提前退出原因
XXX	XXXX	XXXX-XX-XX	提前退出	XXXX-XX-XX	XXXXX
	XXXX	XXXX-XX-XX	完成试验	XXXX-XX-XX	XXXXX
	XXXX	XXXX-XX-XX	完成试验	XXXX-XX-XX	XXXXX
	XXXX	XXXX-XX-XX	完成试验	XXXX-XX-XX	XXXXX

PGM=xxxx.sas

Date of TLF Generation= YYYY-MM-DD HH:MM:SS

Date of Data Extraction= YYYY-MM-DD

Programming note:

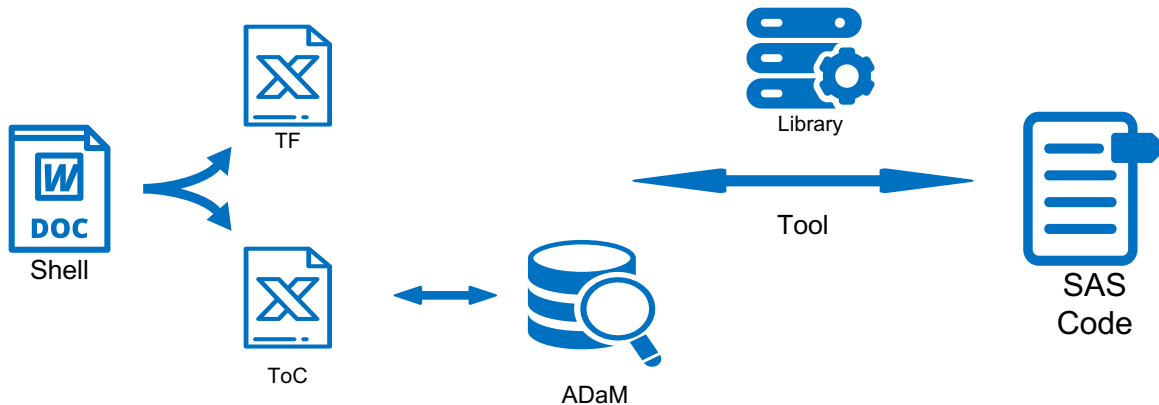
按照入组序列、受试者编号顺序排序

Mapping and Select ADaM Variables
basing these headers

TFL Number	Code Name	Input Datasets	Population Flag	Column Variable	Column Label	Source Variable	ID Variable	Order Variable
列表16.2.1.1	l_ds.sas	adan.adsl	ITTFL='Y'	COL1	中心号	SITEID		ARM RANUM
列表16.2.1.1				COL2	受试者编号	SUBJID		
列表16.2.1.1				COL3	签署知情同意书日期	IRCDTC		
列表16.2.1.1				COL4	受试者状态	COMPLFL		
列表16.2.1.1				COL5	完成/提前退出日期	EOSDT		
列表16.2.1.1				COL6	提前退出原因	DCSREAS/DCSREASP		



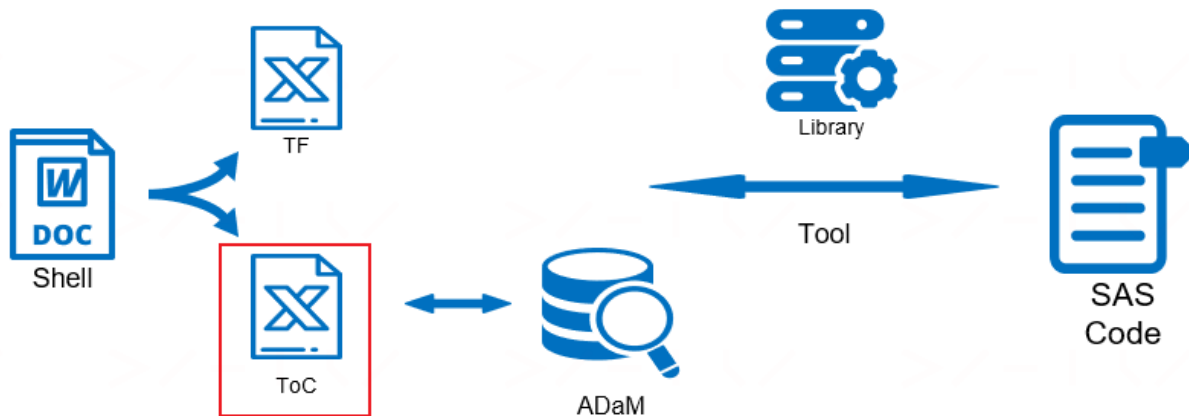
Listing Automation



All ready, Then Auto-generate Listing Codes and Outputs

Tables Automation

Same Procedure as Listing Automation , More Steps in Toc



Extracting Shell Structure & Format Info & Treatment Group Info



Tables Shell

表 1.2 性别及年龄分组

	周期内 N=XX	周期前 N=XX	总计 N=XX
年龄 (年), n (%)			
n	XX	XX	XX
<2	XX (XX.X)	XX (XX.X)	XX (XX.X)
3-17	XX (XX.X)	XX (XX.X)	XX (XX.X)
18-64	XX (XX.X)	XX (XX.X)	XX (XX.X)
65-85	XX (XX.X)	XX (XX.X)	XX (XX.X)
>85	XX (XX.X)	XX (XX.X)	XX (XX.X)
未指明	XX (XX.X)	XX (XX.X)	XX (XX.X)
省份			
n	XX	XX	XX
性别	XX	XX	XX
性别, n (%)	XX	XX	XX
男性	XX (XX.X)	XX (XX.X)	XX (XX.X)
女性	XX (XX.X)	XX (XX.X)	XX (XX.X)
未指明	XX (XX.X)	XX (XX.X)	XX (XX.X)
Age			
n (n miss)	XX (XX)	XX (XX)	XX (XX)
Mean (SD)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Median (Q1; Q3)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Min; Max	XX (XX.X)	XX (XX.X)	XX (XX.X)

Shell Mapping

Mapping With TLF library

ADSL Baseline Realated

ADSL.AGEGRP

表1.2 性别及年龄分组

年龄 (年), n (%)

n	周期内N=XX	周期前N=XX	总计N=XX
<2	XX (XX.X)	XX (XX.X)	XX (XX.X)
3-17	XX (XX.X)	XX (XX.X)	XX (XX.X)
18-64	XX (XX.X)	XX (XX.X)	XX (XX.X)
65-85	XX (XX.X)	XX (XX.X)	XX (XX.X)
>85	XX (XX.X)	XX (XX.X)	XX (XX.X)
未指明	XX (XX.X)	XX (XX.X)	XX (XX.X)

TRTPN: 1 / 2 / 99



Shell Extraction

A	B	C	D	E	F	G	H	I	J
Title	表1.2 性别及年龄分组								
Display Text	年龄（年）， n (%)		周期内N=XX	周期前N=XX	总计N=XX	Groups			
Format	n		XX	XX	XX	%gm_cat(	1		
	<2		XX (XX.X)	XX (XX.X)	XX (XX.X)				
	3-17		XX (XX.X)	XX (XX.X)	XX (XX.X)				
	18-64		XX (XX.X)	XX (XX.X)	XX (XX.X)				
	65-85		XX (XX.X)	XX (XX.X)	XX (XX.X)				
	>85		XX (XX.X)	XX (XX.X)	XX (XX.X)				
	未指明		XX (XX.X)	XX (XX.X)	XX (XX.X)				
省份		Category : N & Percentage			%gm_cat(	1			
n		XX	XX	XX					
性别		XX	XX	XX	%gm_cat(	1			
性别, n (%)		XX	XX	XX	%gm_cat(	1			
男性		XX (XX.X)	XX (XX.X)	XX (XX.X)					
女性		XX (XX.X)	XX (XX.X)	XX (XX.X)					
未指明		XX (XX.X)	XX (XX.X)	XX (XX.X)					
Age					%gm_stat	1			
n (n miss)		XX (XX)	XX (XX)	XX (XX)					
Mean (SD)		XX (XX.X)	XX (XX.X)	XX (XX.X)					
Median (Q1;Q3)		XX (XX.X)	XX (XX.X)	XX (XX.X)					
Min; Max		XX (XX.X)	XX (XX.X)	XX (XX.X)					
Display Text	Age, n (n miss)		XX (XX)	XX (XX)	XX (XX)	%gm_stat	1		
	Mean (SD)		XX (XX.X)	XX (XX.X)	XX (XX.X)				
	Median (Q1;Q3)		XX (XX.X)	XX (XX.X)	XX (XX.X)				
	Min; Max		XX (XX.X)	XX (XX.X)	XX (XX.X)				
性别, n (%)					%gm_cat(	1			
n		XX	XX	XX					
男性		XX (XX.X)	XX (XX.X)	XX (XX.X)					
女性		XX (XX.X)	XX (XX.X)	XX (XX.X)					
未指明		XX (XX.X)	XX (XX.X)	XX (XX.X)					
Footnotes	程序名称: xxx.sas		数据提取日期: YYYY-MM-DD HH: MM				XXX Page of XXX		
Programming note: 1. 年龄分组与性别分组固定, 可直接设置。 2. Table 1.2 中Age变量来源于Age字段。 年龄单位换算: Age(year)=Age(天)/365.25; Age(year)=Age(周)/ 52.18; Age(year)=Age(月)/ 12 3. 性别来源于Gender字段。 4. 按报告编号去重后计数									
返回目录									



Discussion

01

Quality Control & Validation

- **QC:** Implement automated quality control steps to check the accuracy and completeness.
- **Validation Process:** Ensure that the automation process complies with regulations and industry standards.

02

Workflow Management

- **Workflow Monitoring:** Use workflow management tools to coordinate and monitor the automation process.
- **Exception Handling:** Establish an exception handling mechanism to address errors and issues within the automation process.

03

Training and Support

- **Team Training:** Train team members to ensure proficiency in using automation tools.
- **Technical Support:** Provide technical support to address issues during usage.

04

Continuous Improvement

- Update automation tools based on new regulations, standards, and requirements.

Discussion or Question



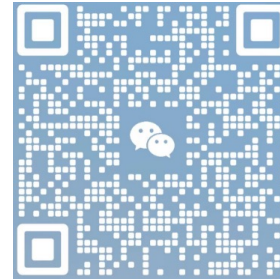
**The Global Healthcare
Data Science Community**

Contact Channels

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🌐 phuse.global

Social Media

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