



2023

CHINA

INTERCHANGE

BEIJING | 25-26 AUGUST



**New CDISC Data Submission Standards  
Implementation with Intelligent Assistance**

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# Meet the Speaker

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**Organization:** SANOFI/Biostatistics & Programming

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## Agenda

1. What are the New *Data Submission Standards*?
2. How to *implement* these standards?
3. What are the benefits of implementing *intelligent assistance*?
4. What's *next*?
5. Reference



What are the new  
**Data**  
**Submission**  
**Standards?**



# DATA SUBMISSION STANDARDS

## SDTM-MSG

*Study Data Tabulation Model  
Metadata Submission Guidelines*

**v2.0**

**(30MAR2021)**

**v1.0**

**(31DEC2011)**

## ADaM-MSG

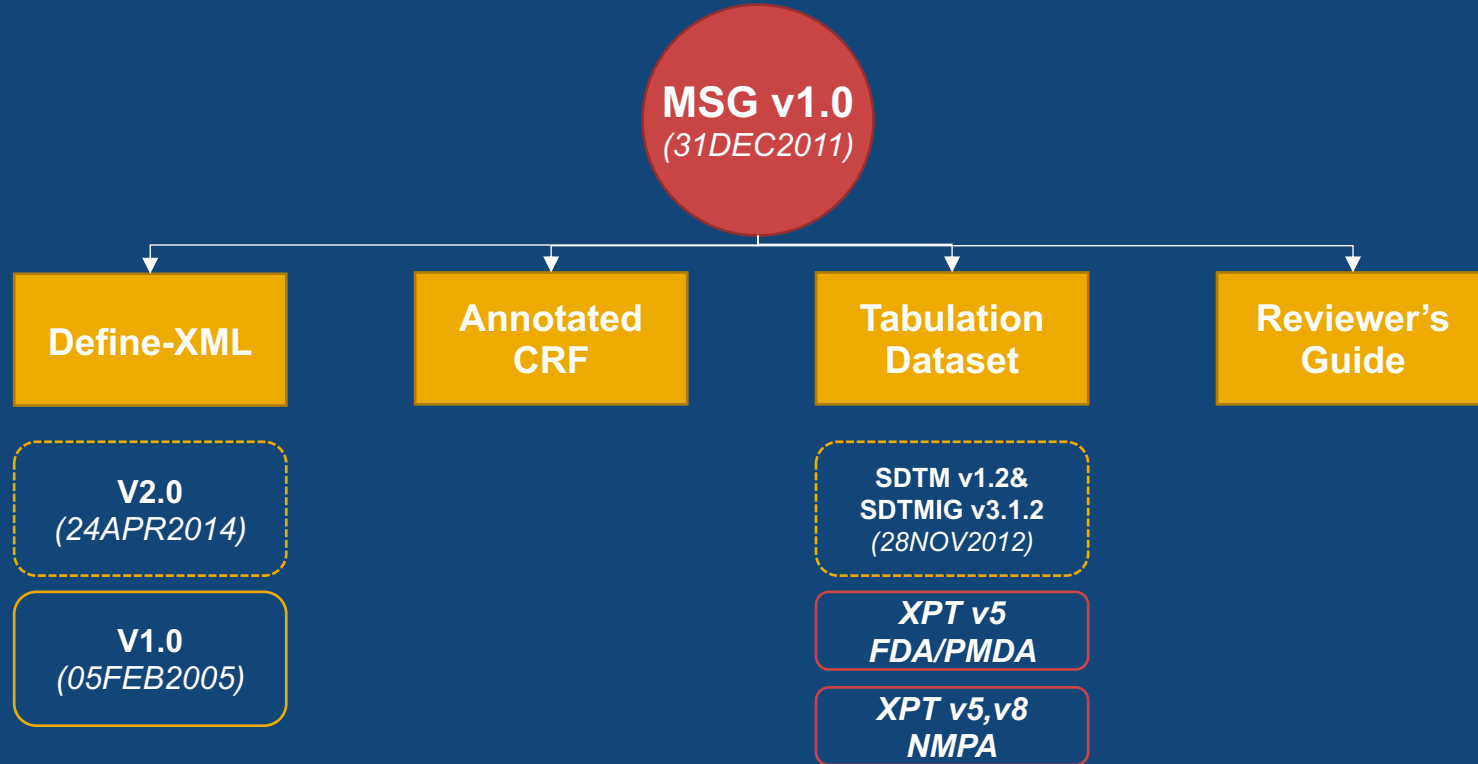
*Analysis data Model  
Metadata Submission Guidelines*

**v1.0**

**(18MAR2023)**

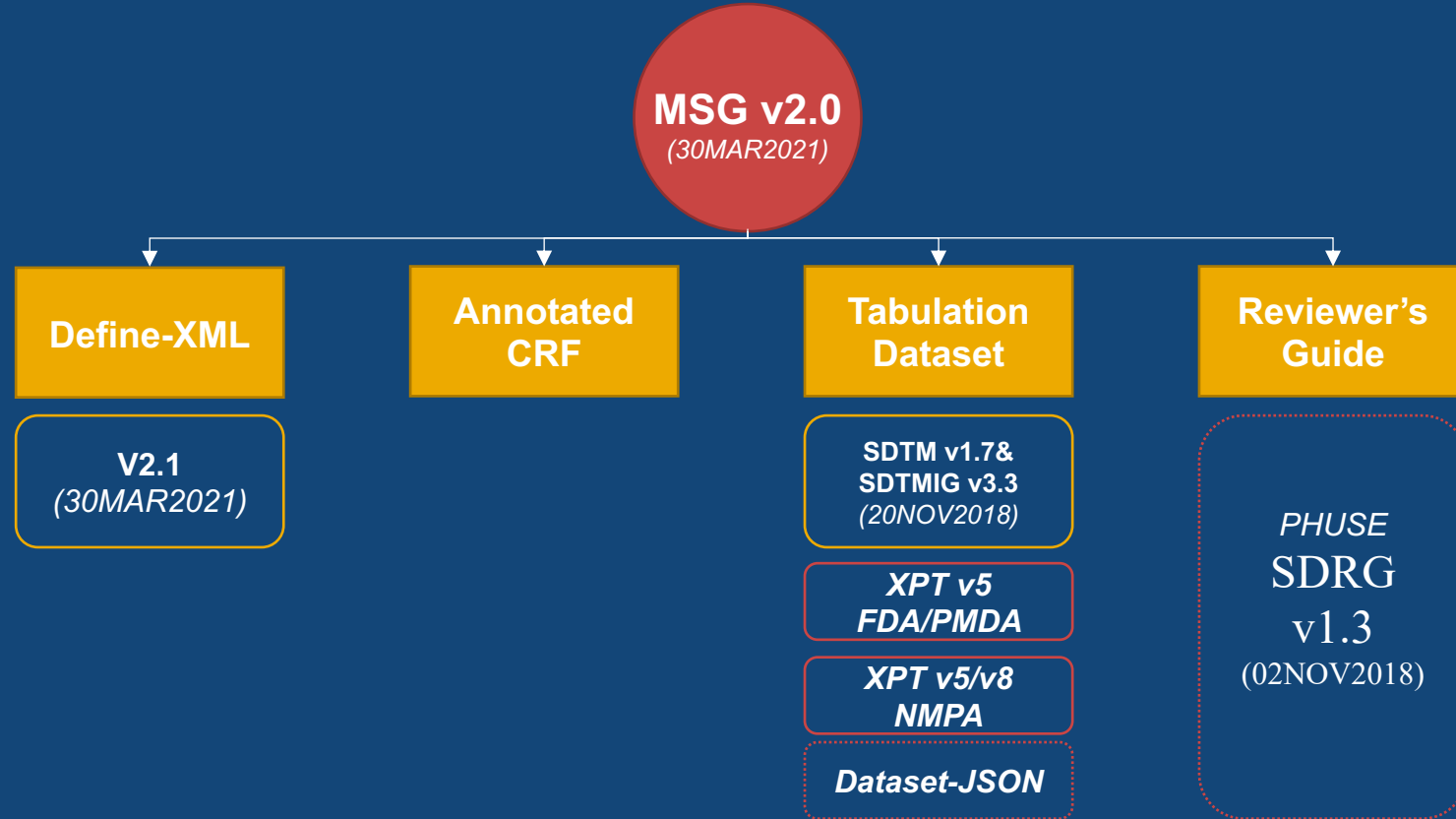
# SDTM-MSG

(Study Data Tabulation Model Metadata Submission Guidelines)



# SDTM-MSG

(Study Data Tabulation Model Metadata Submission Guidelines)





# ADaM-MSG

(Analysis data Model Metadata Submission Guidelines)

**MSG v1.0**  
(18MAR2023)

**Define-XML**

**V2.1**  
(30MAR2021)

**ARM v1.0**  
(27JAN2015)

**Tabulation  
Dataset**

**ADaMv2.1&  
ADaMIGv1.1**  
(12FEB2016)

**XPT v5  
FDA/PMDA**

**XPT v5,v8  
NMPA**

**Dataset-JSON**

**Reviewer's  
Guide**

**PHUSE  
ADRG  
V1.2**  
(18JUL2018)

**Programs**

*ADaM  
TFL*

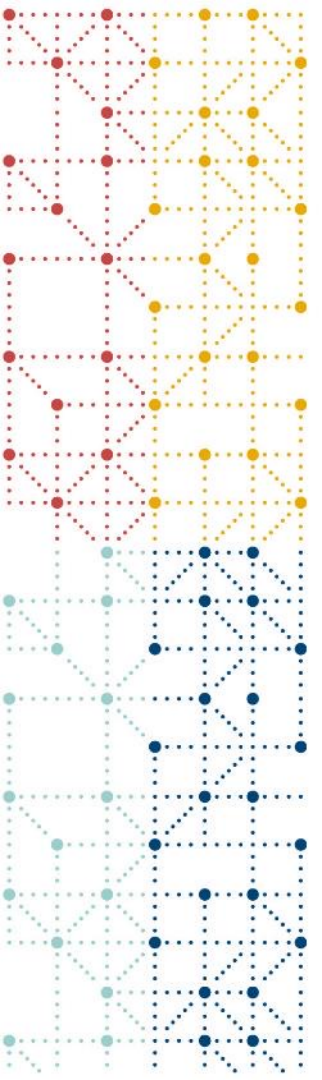
**TXT ASCII  
FDA**

**TXT/SAS ASCII  
PMDA**

**TXT/SAS  
euc-cn/UTF-8  
NMPA**

**Supplement  
Document**

**PDF  
FDA/EMA/PM  
DA /NMPA**



How to  
**Implement**  
these standards?

## INTELLIGENCE(Calibration)

*Check and correct the issues*

## INTELLIGENCE(Generation)

*Create files/code with customized requirement*

## INTELLIGENCE(Monitor)

*Validate input information in real time*

## STRUCTION/METADATA

*Modify/Decorate metadata manually*

## AUTOMATION

*Build automatic product environment*

## STANDARDIZATION

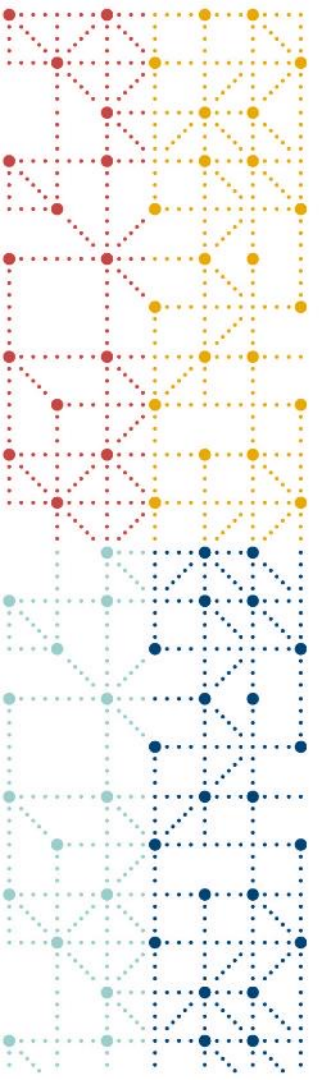
*Establish standard model/framework*

MULTI REGION

MIX PROGRAMMING

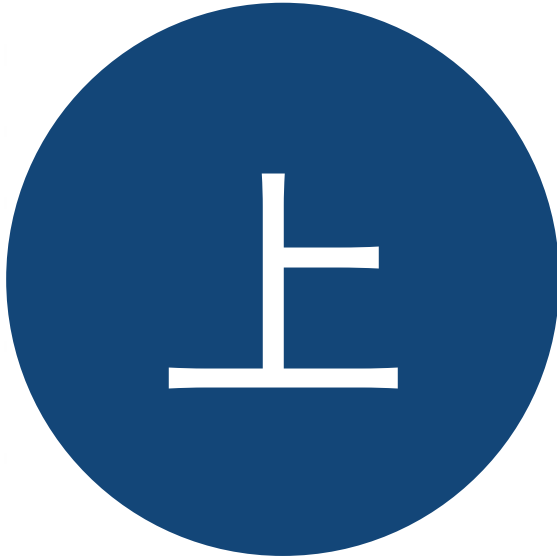
MULTI LAUNGUAGE

KNOWLEDGE REPOSITORY



What are the benefits of implementing  
**Intelligence Assistance?**

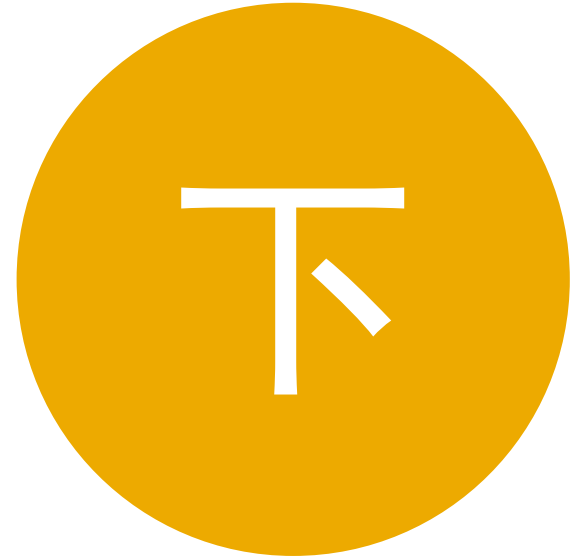
# PREVENT HINTING CORRECT



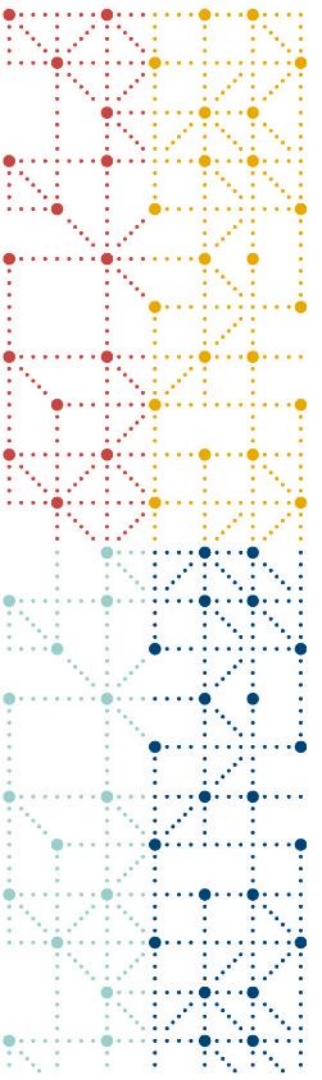
*Prevent potential problems and avoid duplication of effort.*



*Hinting at possible problems and improving the quality of results.*



*Correct existing problems to meet minimum requirement.*



What's  
**Next?**

# LOW-CODE HIGH-INTERACTION AI ASSISTANCE

## NETWORK FRIENDLY DATA/FILE

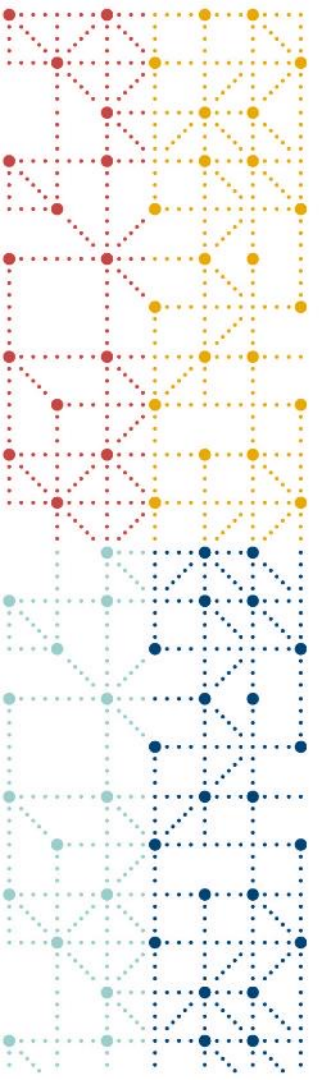
Storage  
Exchange  
Visualization  
(*DATASET-JSON/XML*)

## FORMATING TLF

Easy Review  
Customized Result  
Diversify Exhibition  
Faster Approval

## ASSISTANT APPROVAL/TRIAL DESIGN

Data Issue  
Indicator Abnormal  
Potential Risk Prevention  
Cross Check  
(*STUDY/PHASE/TA*)



# Reference





**FDA** <https://www.fda.gov/>

<STUDY DATA TECHNICAL CONFORMANCE GUIDE May 2023>

**NMPA** <https://www.nmpa.gov.cn/>

<药物临床试验数据递交指导原则（试行）>

**PMDA** <https://www.pmda.go.jp/english/>

<STUDY DATA TECHNICAL CONFORMANCE GUIDE >

**CDISC** <https://www.cdisc.org/>

<Study Data Tabulation Model Metadata Submission Guidelines (SDTM-MSG): Human Clinical Trials Version 2.0 (Final)>

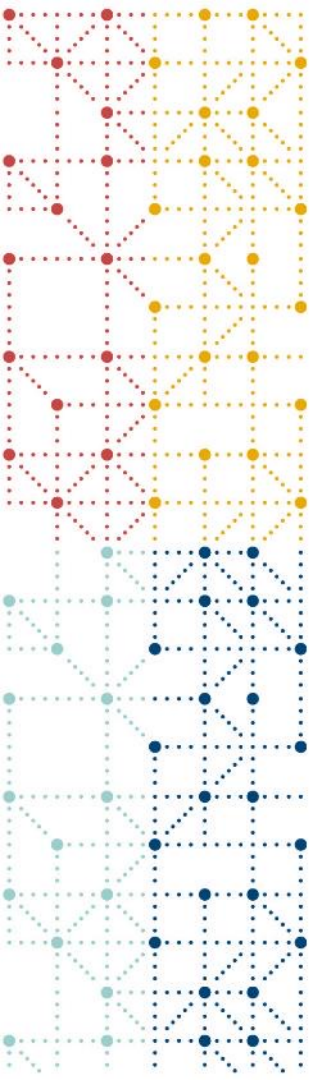
<Study Data Tabulation Model Metadata Submission Guidelines (SDTM-MSG)>

<Analysis Data Model Metadata Submission Guidelines (ADaM MSG): Human Clinical Trials Version 1.0 (Final)>

<Analysis Results Metadata Specification Version 1.0 for Define-XML Version 2>

<STUDY DATA TECHNICAL CONFORMANCE GUIDE Version 2.1>

<CDISC Define-XML Specification Version 2.0>



**Thank You!**

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