

CDISC Implementation in China

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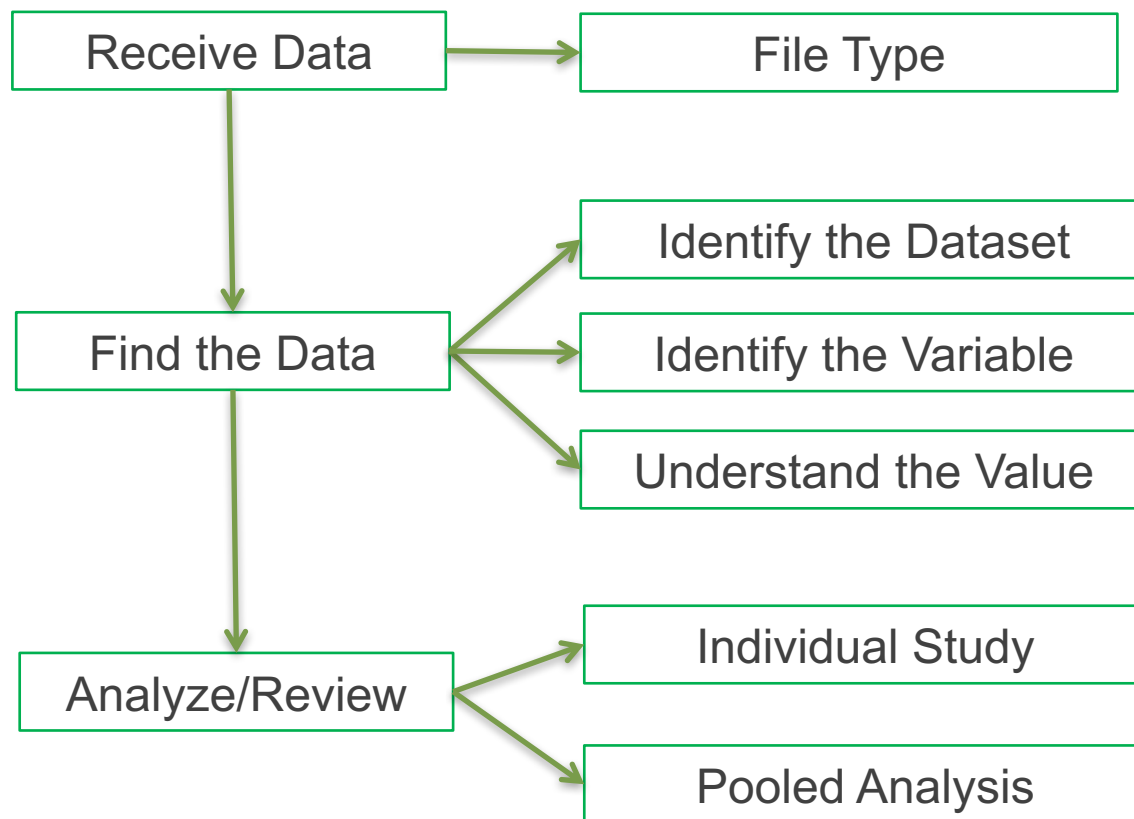
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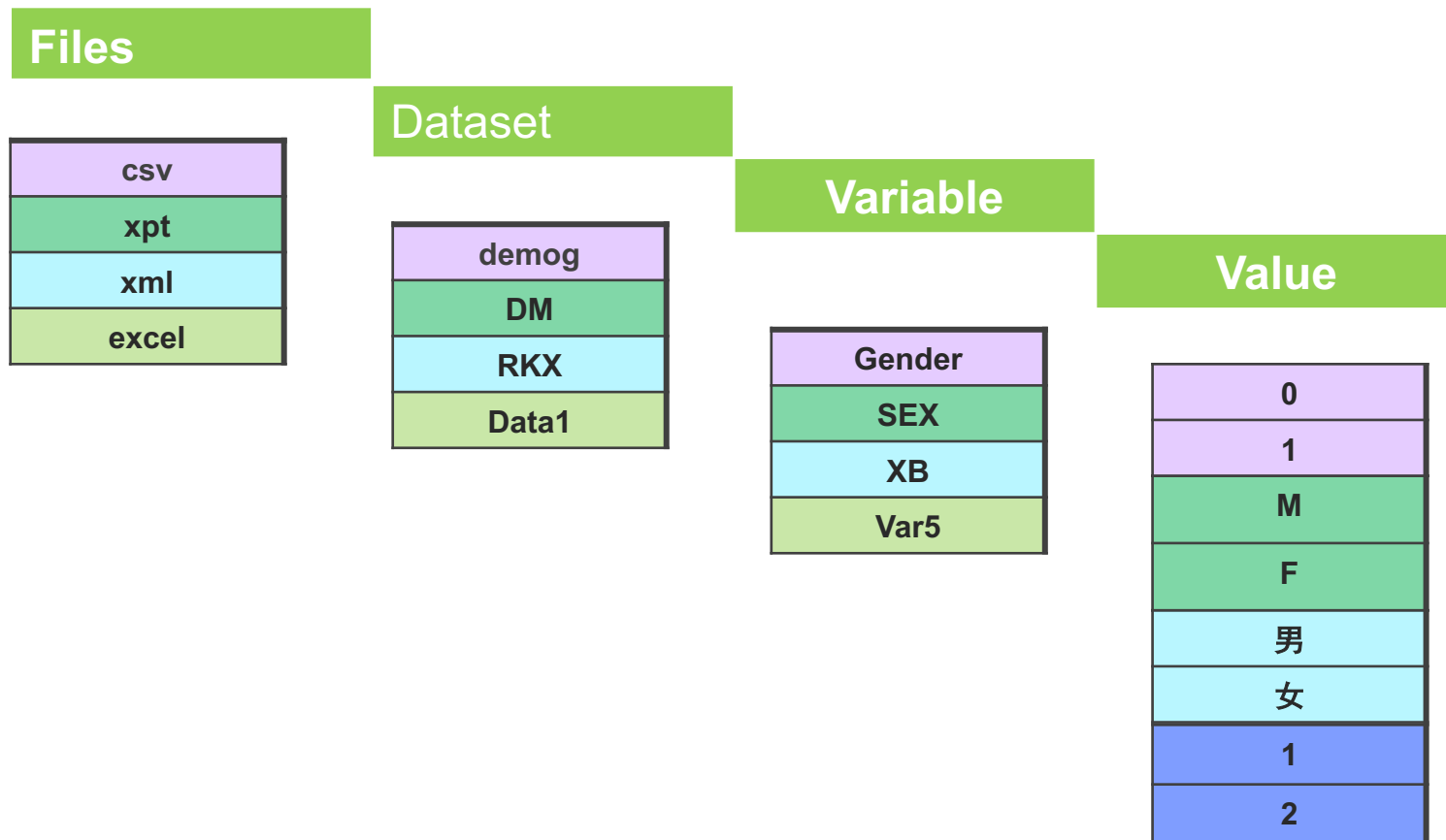
- ▶ Current status
- ▶ Challenges
- ▶ Solutions

The process to review data



Data without Standardization

► Demographics?



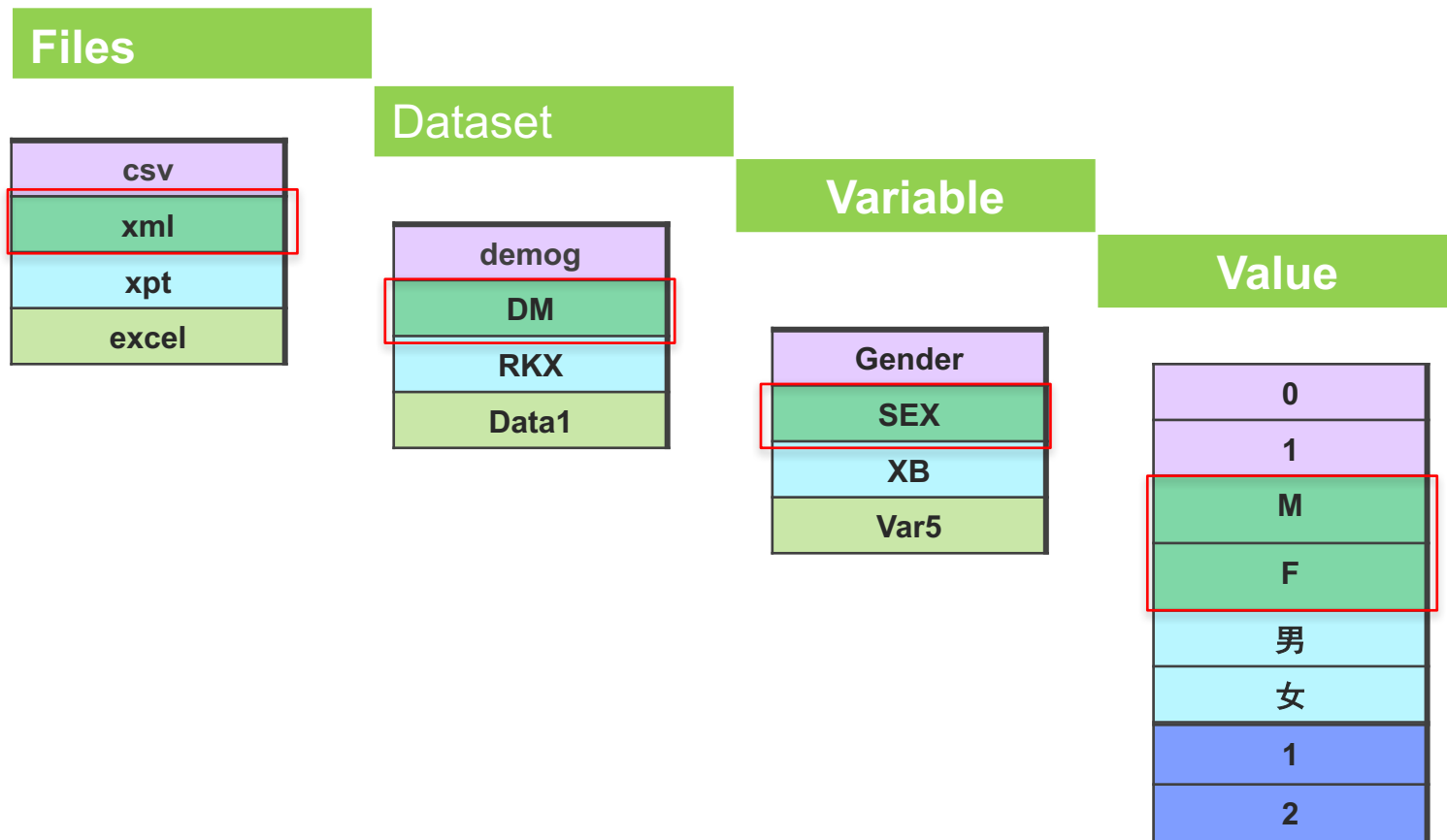
More Data, More Headaches?

- Where is data needed?
- What dose it mean?!
- The data was coded in different way, pool them?!



Data Standardization

► Demographics



Standardized vs Non-standardized

- Dataset level
 - Name
 - Description
 - Structure
 - Allowed Variables
- Variable level
 - Name
 - Label
 - Type
 - Format
- Value level
 - Controlled Terminology

Predictable
vs
Unpredictable

Data Submission Status

▶ FDA

- 2016 Dec

▶ PMDA

- 2016 - March 31, 2020

▶ EMA

- requested for use by the European Innovative Medicines Initiative (IMI)

▶ CFDA

- Suggest to adopt

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- ▶ Current status
- ▶ Challenges
- ▶ Solutions

Challenges - Technically

- ▶ Language issue;
- ▶ Conformance Validation;
- ▶ Traditional Chinese Medicine

TOC

- ▶ Current status
- ▶ Challenges
- ▶ Solutions

Solutions - Policy

- ▶ **Regulatory need to be more aggressive:**
 - ▶ Japan is a good example
- ▶ Statistical review become routine practice, there will be immediate needs

It is coming!

Solutions - Language

► Language:

- Standardized Parts - Automatically
 - Metadata: Dataset attributes, Variable attributes
 - CT: Values
- Non-Standardized Parts
 - Free text of Chinese Chars in xxTRT/xxTERM: fine
 - Free text of Chinese Chars in [Other specify]: SUPPxx?
 - Chinese Chars in xxORRES: fine?
 - Chinese Chars in xxTEST: leave it as it is or translate?
- PMDA:
 - Japanese dataset and alphanumeric dataset

Solutions – Conformance Validation

▶ FDA:

- Validation Rules (FDA)
- Validation Tools (JumpStart) – Pinnacle(OpenCDISC)

▶ PMDA

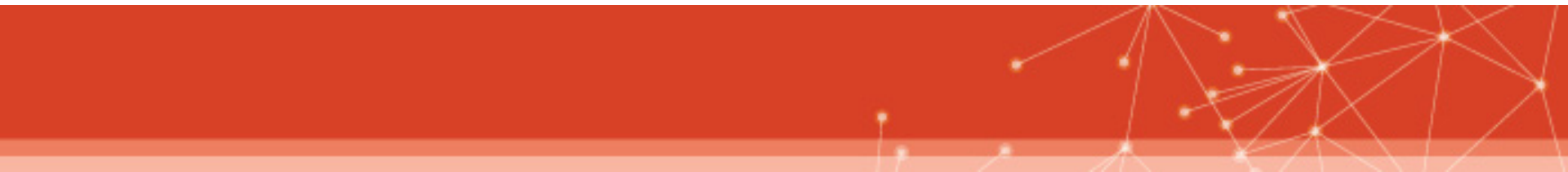
- Validation Rules (FDA)
- Validation Tools: Pinnacle(OpenCDISC)

▶ CFDA?

- Validation Rules (CFDA): less strict than CDISC Validation rules
- Validation Tools: local vendors? (Open and Free)

Solutions – TCM

- ▶ CDISC is leading to develop CDISC TA standards:
 - Angina Pectoris – TCM: 心绞痛-中医
 - Symptoms, Signs; Tongue and Pulse:
 - WB (whole body)?
 - FA?
 - A new domain?
- x QS: not validated tools



**Statistical review has already
become regular, will it still be long
time from standardized data
submission?**

Ask



Thank You 谢谢!



Strength *through collaboration.*

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