General Introduction of Data Management
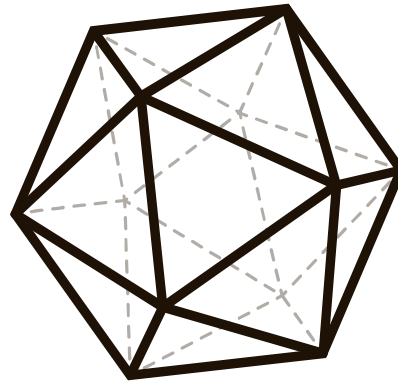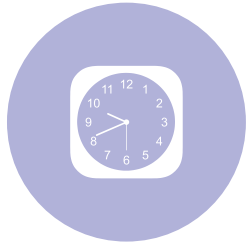
CONTENTS

What's Data Management

Definition of Data Management

Working Process

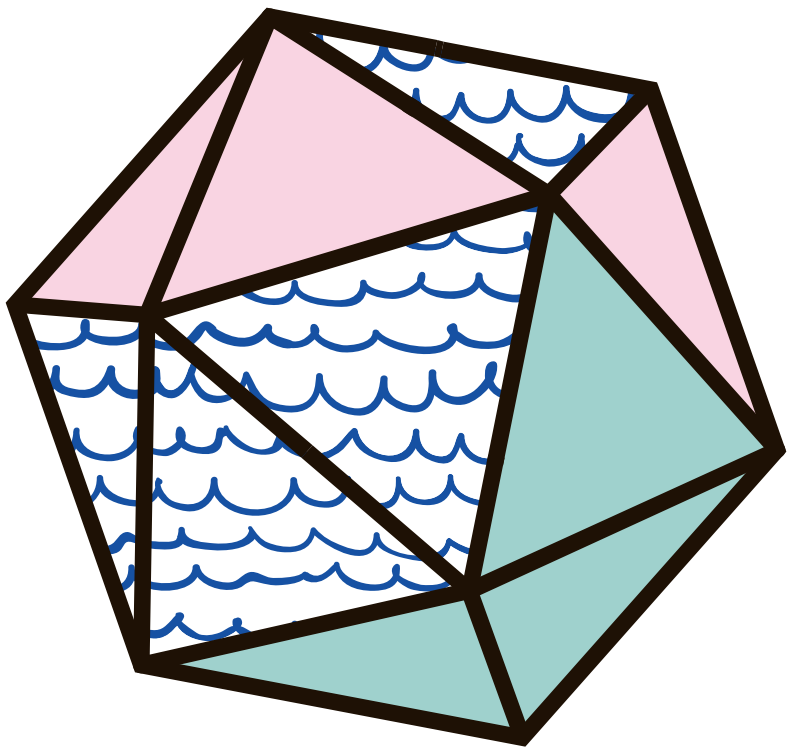*Regular DM Tasks*
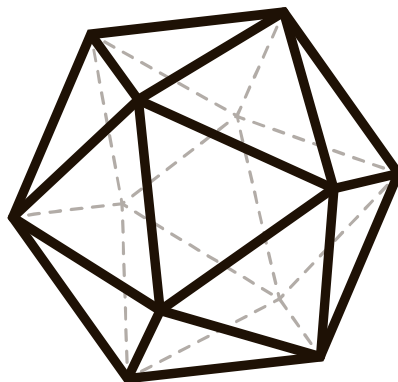
Tools/Standards

EDC/e-Dairy/e-PRO

CDISC

Challenges

Industry and Role Changes

/01

What's Data Management

好的DM是临床试验的连接器和润滑剂。

What's Data Management?

Objective

Ensure the authenticity, accuracy and integrity of data.

Data Collection

- *Collect Data via paper of electronic methods*
- *Source Data is not included*

Data Clean
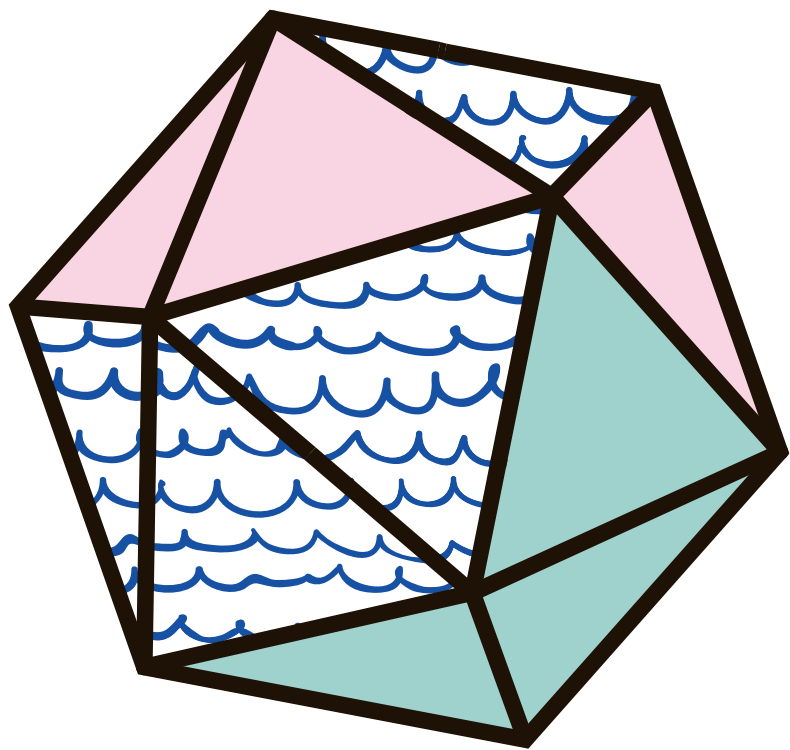
- *Ensure data logicality through electronic and manual check*

Data Submission

- *CRF and Data Submission*
- *Data Management Report*

/02 **Working Process**

没有执行力，就没有竞争力。

Working Process

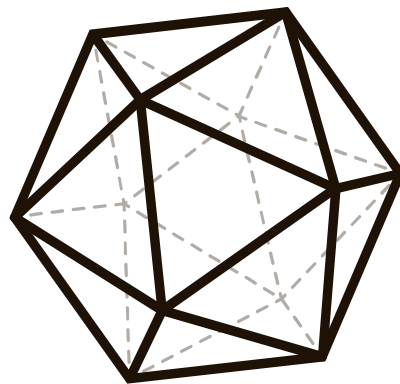| SOP NO#	SOP Name
SOP-DM-01	Project Management within DM
SOP-DM-02	CRF or eCRF Setup Specification Design
SOP-DM-03	CRF Printing
SOP-DM-04	Database Setup
SOP-DM-06	Data Management Plan
SOP-DM-07	Data Validation Plan
SOP-DM-08	User Acceptance Testing
SOP-DM-09	DM Document Processing
SOP-DM-10	Data Entry in Clinical Data Management System
SOP-DM-11	Data Review and Discrepancy Management
SOP-DM-12	Query Generation and Resolution
SOP-DM-13	Medical Coding
SOP-DM-14	SAE Reconciliation
SOP-DM-15	External Data Handling
SOP-DM-16	Final Database Quality Control
SOP-DM-17	Database Lock and Unlock
SOP-DM-18	DM Trial Master File
SOP-DM-19	Local Lab Data Handling
SOP-DM-20	Data Extraction from DM System
SOP-DM-21	Protocol Deviation Handling
SOP-DM-22	(Blind) Data Review Meeting
SOP-DM-23	Data Transfer
SOP-DM-24	Data Management Report
SOP-DM-25	DM Final Deliverables
SOP-DM-26	DB Programming Quality Control

✓ *There are so many tasks and seems trivial*

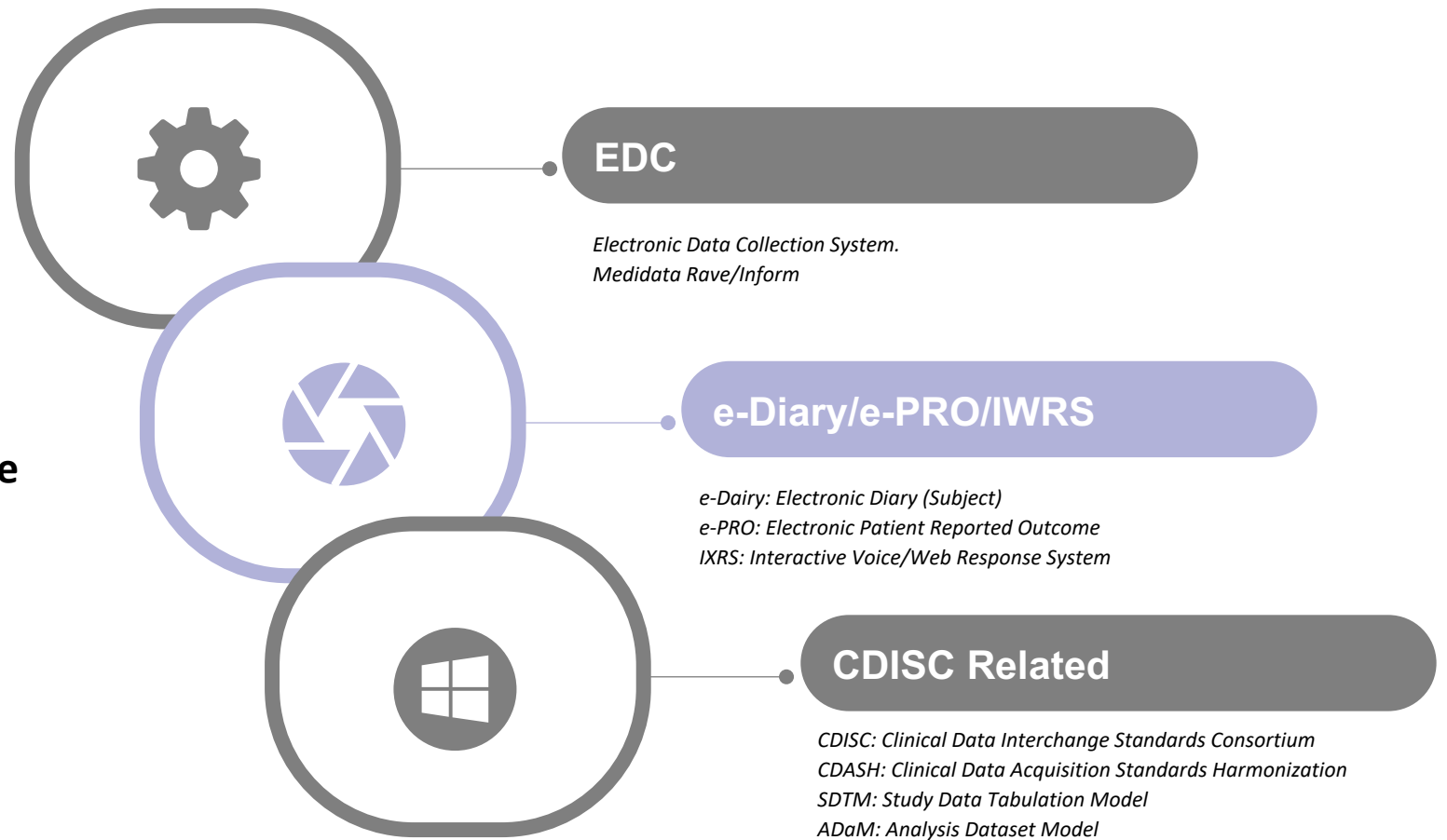✓ *The whole process takes 3-5 years to complete*
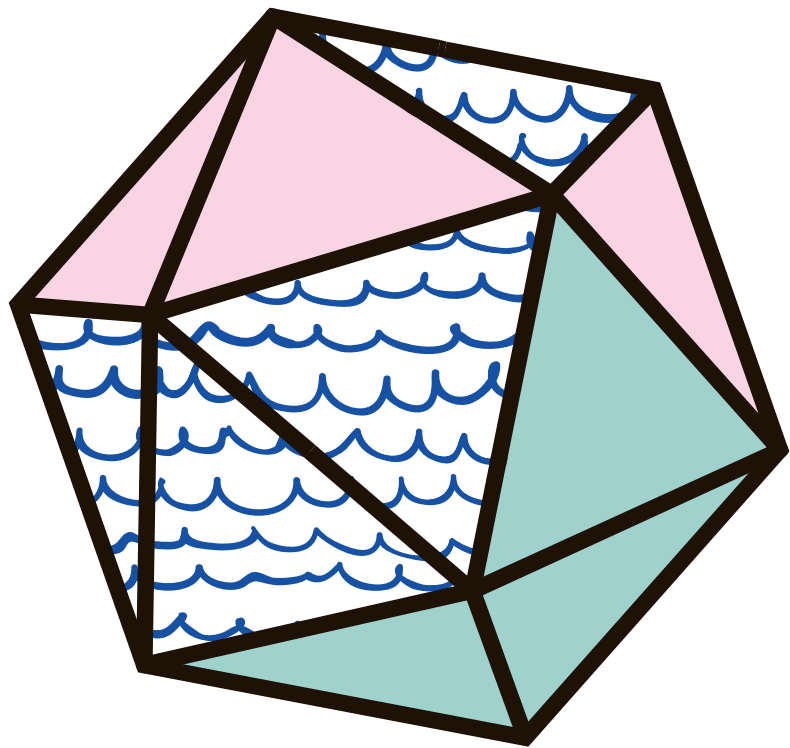
✓ *Details are important*
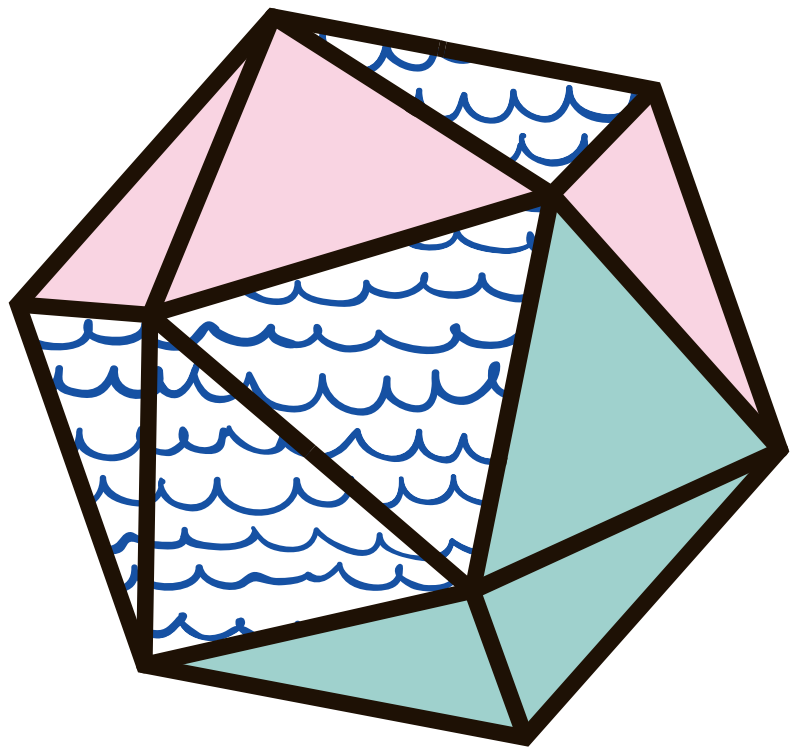
/03 Tools and Standards

结果不好，就是不好。

Tools and Standards

All the works of data management are serviced for final statistical analysis.

EDC

Electronic Data Collection System.
Medidata Rave/Inform

e-Diary/e-PRO/IWRS

e-Dairy: Electronic Diary (Subject)
e-PRO: Electronic Patient Reported Outcome
IXRS: Interactive Voice/Web Response System

CDISC Related

CDISC: Clinical Data Interchange Standards Consortium
CDASH: Clinical Data Acquisition Standards Harmonization
SDTM: Study Data Tabulation Model
ADaM: Analysis Dataset Model

/04 Challenges

即便被淘汰，也要努力做到最后一个。

Challenges

Quality Management System

Reasonable quality management system and assessment standards

New Technology

AI/Big Data Analysis/Other new technology improves the efficiency of data management

Service Improvement

We can only survive by continuous improved service.

IDEASSTORM

ThAnKs!