

# CDISC eSubmission

## You can count on us.

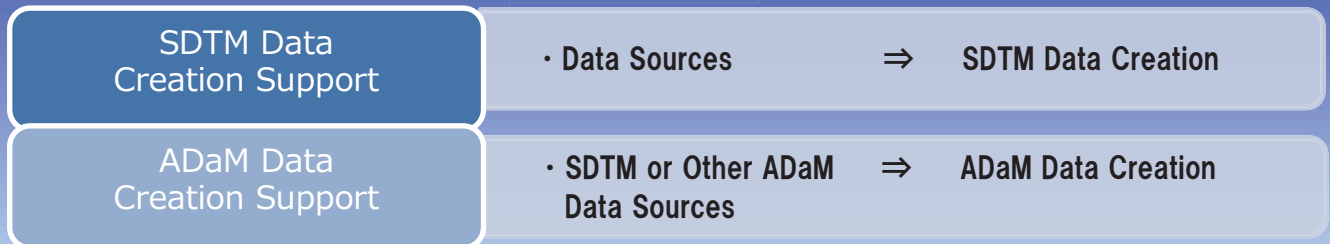
### Services

- CDISC Implementation Consulting Services
- CDISC Data Creation Services

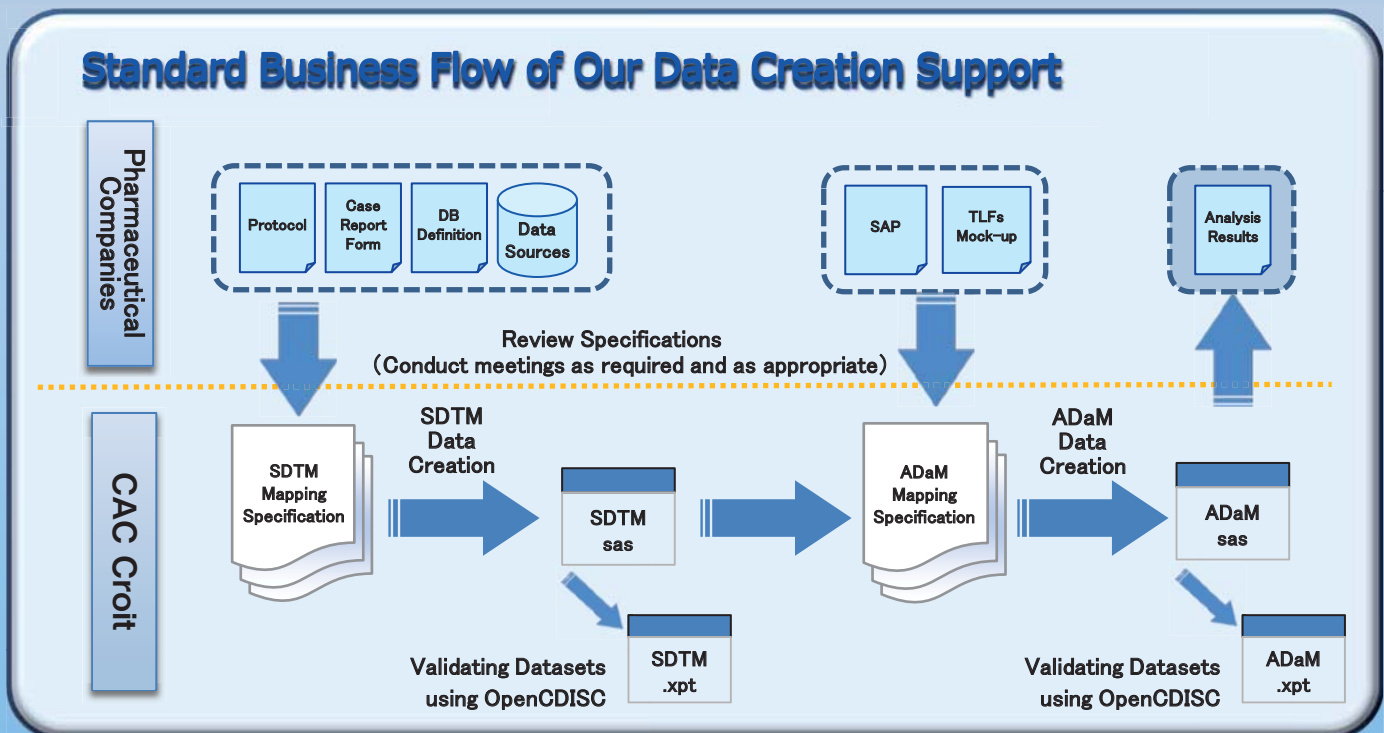
#### 【CDISC Implementation Consulting Services】

Croit's extensive experience and know-how can help you overcome your problems.  
 (Example) · CDISC training  
 · Analyze your current status and identify issues in migrating to the CDISC standard  
 · Support you in defining a procedure that complies with the CDISC standard

#### 【CDISC Data Creation Services】



### Standard Business Flow of Our Data Creation Support



## Past Experience

- SDTM Data Creation Support
- ADaM Data Creation Support

### 【SDTM】

Performed trials with more than 100 studies focusing on SDTM data creation from clinical data.

- Number of Studies: About 110
- Major Phases : Phase I ~ III, post-marketing surveillance trials
- Therapeutic Area : Cardiovascular, Gastrointestinal, Ophthalmology, Dermatology, Endocrine (Urology), etc.
- Target Versions : SDTM v1.3 SDTM Implementation Guide 3.1.3  
SDTM v1.4 SDTM Implementation Guide 3.2

### 【ADaM】

Created data for ADaM-based analysis as part of the statistical analysis process.

- Number of studies : About 20
- Major Phases : Phase I ~ III
- Therapeutic Area : Cancer, Neuropsychiatry, Gastrointestinal, Dermatology, etc.
- Target Versions : ADaM v2.1 ADaM Implementation Guide v1.0

## Support Example

- CDISC Implementation Support Service

### Client Request

- Identifying the issues in migrating the business processes to the CDISC standard.

### Solutions

1. Analyze CDASH data and generate reports complying with the CDISC standard (SDTM, ADaM, Reporting).
2. Confirm how consistent existing process analysis charts are with those of the CDISC process.
3. Generate a Traceability Record to enable data lineage from the reports back to the CDASH data.
4. Review the adequacy of the CDISC process and list up issues and items to be considered.

