2023
KOREA
INTERCHANGE
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The Need for CDISC-Based Total Medical Data Platforms and the Current and Future of Drug Development Platforms

Dong-Hoon, Cho
Chairman(Chairman of the BOD)
CLUPEA

Meet the Speaker

Dong-hoon, Cho

Title: Chairman(Chairman of the BOD)
Organization: Clupea Inc.

Dong-Hoon Cho is a member of K3C and is chairman of BOD, Clupea. In particular, he is interested in designing and developing CDISC-based big data and automated processing of non-clinical and clinical trials. And he is working on ways to reduce time and cost by analyzing all the processes of non-clinical and clinical trials. We are working with many public institutions to expand the CDISC base in Korea, and we analyze their work environment and establish plans. We are also making active efforts to translate CDISC into Korean.
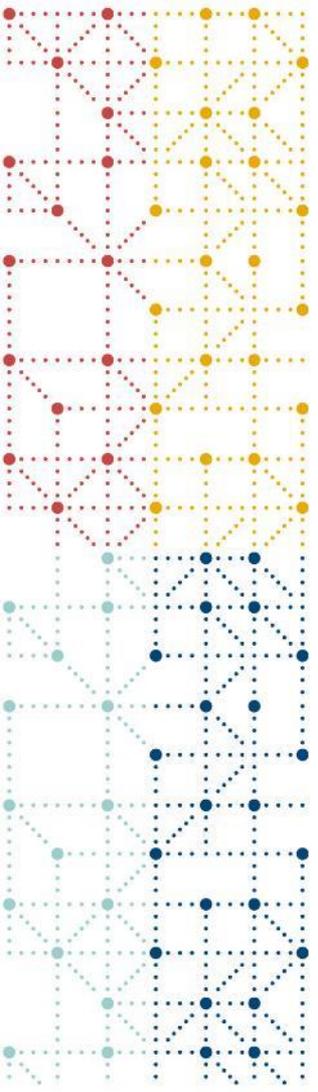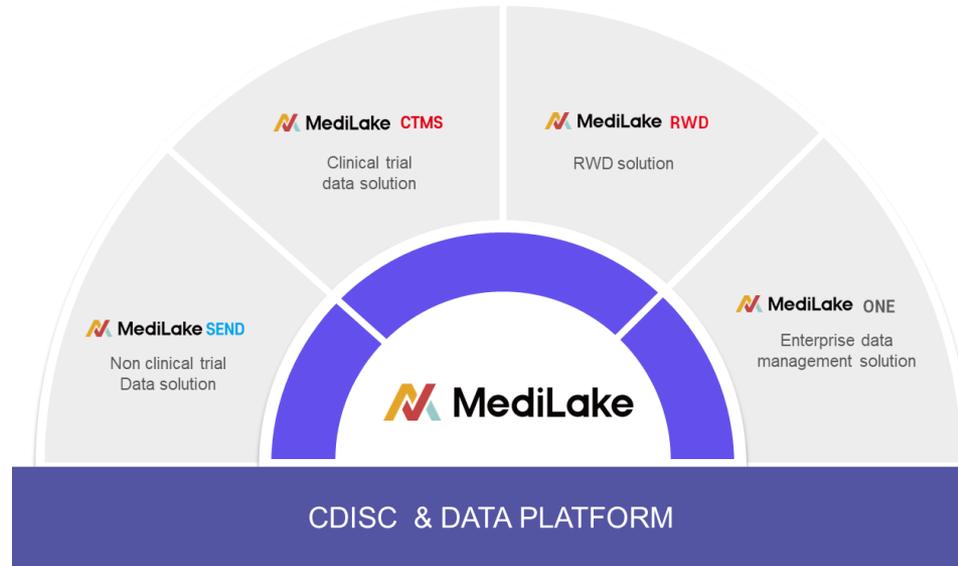
Agenda

1. Introduce & Challenges And Opportunities In Clinical Data Management

2. Accelerating cdisc & data management
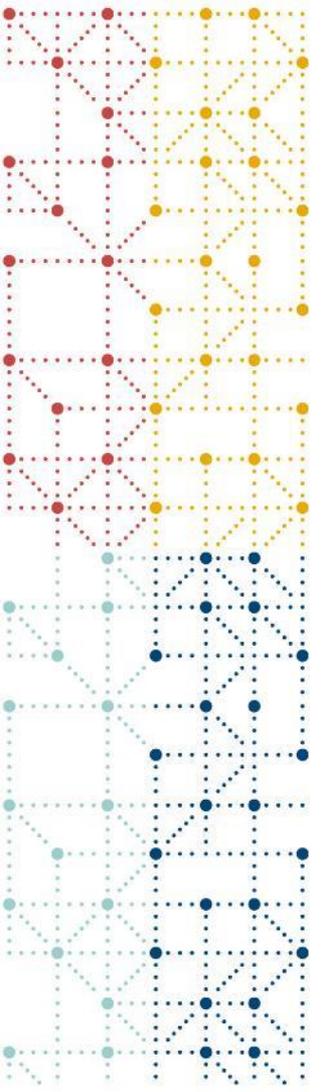
Introduce & Challenges And Opportunities In Clinical Data Management

CLUPEA

Data business full-line up for pharmaceutical & bio industry

CLUPEA

business field & R&D

Clinical data issue

high-pressured, fast-paced clinical development environment a huge challenge exists with the cleanliness, completeness and quality of clinical trial data
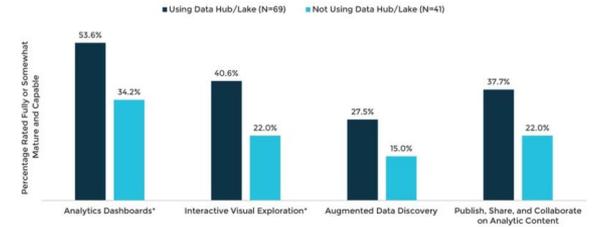

Clinical Data Source Incorporation
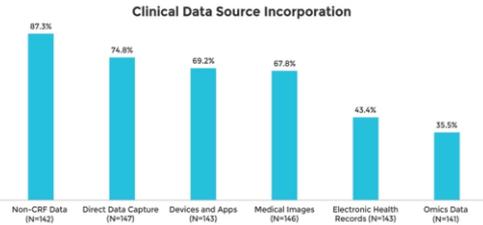
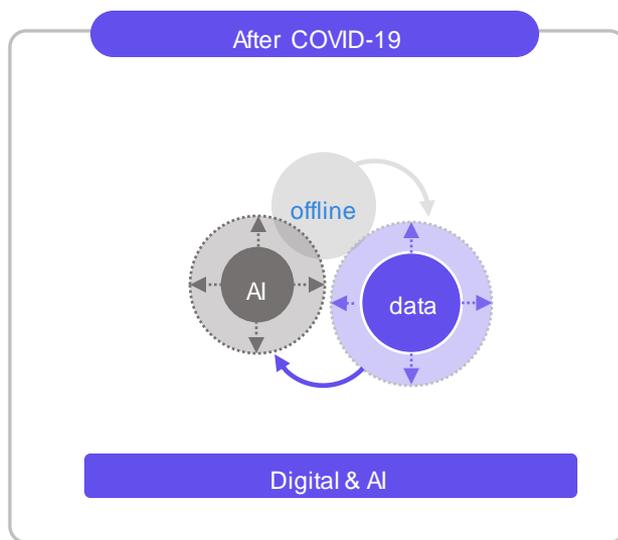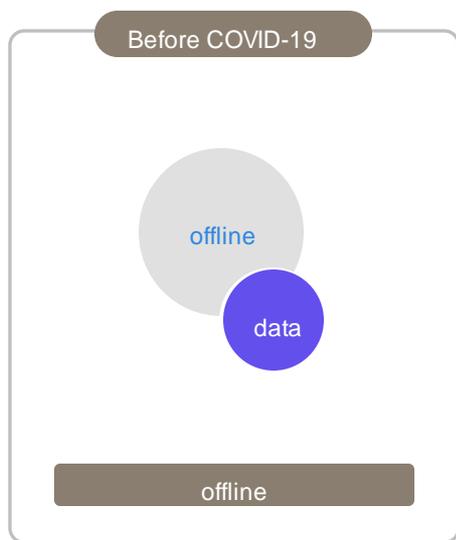Data management activity labor intensiveness

Respondent Analytics Critical Capabilities Maturity by Use of Data Hub/Lake

※Challenges And Opportunities In Clinical Data Management, ORACLE, 2018 Tufts CSDD, 2021

Clinical data issue

Challenges And Opportunities In Clinical Data Management

Before COVID-19

offline

data

offline

After COVID-19

offline

AI

data

Digital & AI

CRO M&A after CRO

Top CROs empower digital data technology with M&A or partnerships

〈글로벌 상위 CRO 시장점유율('18년 & '20년)〉

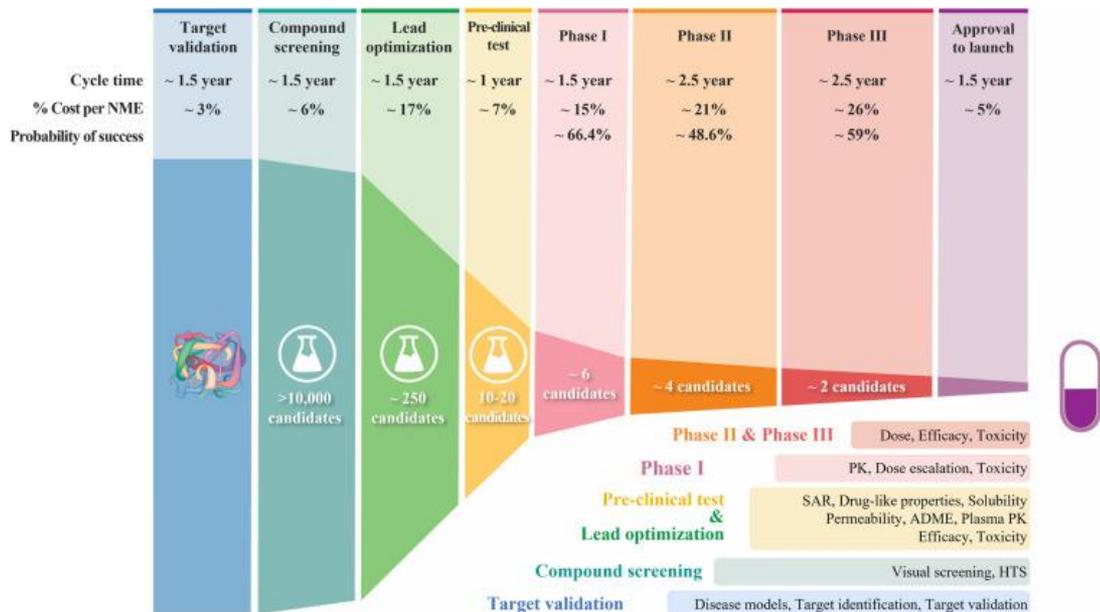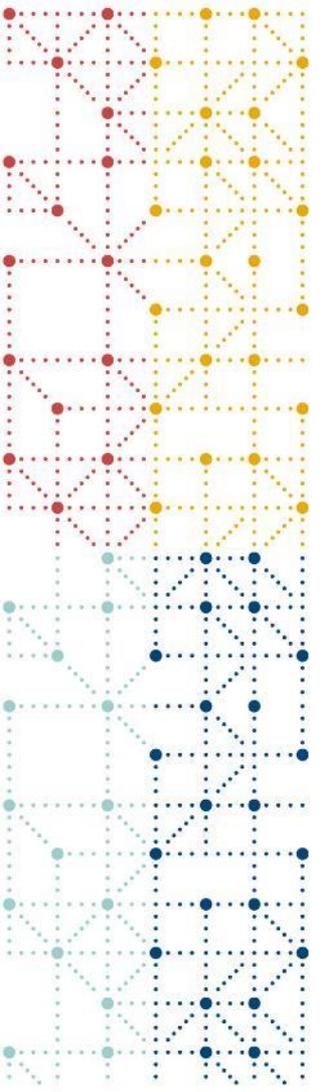| 순위	2018년		2020년		2021년 동향
	기업명	점유율	기업명	점유율	
1	IQVIA	11.9%	IQVIA	11.9%	
2	Covance(LabCorp)	9.4%	Covance(LabCorp)	10.0%	
3	Icon PLC	5.7%	PPD	9.5%	Thermo가 PPD 인수('21. 4월)
4	Syneos health	5.7%	Syneos health	8.9%	
5	PRA Health	5.3%	PRA Health	6.6%	PRA, ICON에 인수('21. 2월)
6	Paraxel	4.2%	Charles River Lab	6.0%	
7	PPD	4.1%	ICON PLC	5.7%	ICON이 PRA 인수('21. 2월)
8	Charles River Lab	2.6%	Parexel*	5.0%	골드만삭스가 파랙셀 인수('21. 7월)
9	Wuxi Apptec	1.7%	Wuxi Apptec	3.3%	
10	Medpace	1.2%	Medpace	1.8%	
-	Others	48.2%	Others	31.3%	

주: 원 보고서 자료에 2020년 Parexel 점유율 추가
※ 출처 : Frost & Sullivan 보고서를 바탕으로 재구성

Data & AI is important & essential

cdisc

Clinical data issue

## Data & AI reduce cost of new drug research by 69%

	Target validation	Compound screening	Lead optimization	Pre-clinical test	Phase I	Phase II	Phase III	Approval to launch
Cycle time	~ 1.5 year	~ 1.5 year	~ 1.5 year	~ 1 year	~ 1.5 year	~ 2.5 year	~ 2.5 year	~ 1.5 year
% Cost per NME	~ 3%	~ 6%	~ 17%	~ 7%	~ 15%	~ 21%	~ 26%	~ 5%
Probability of success					~ 66.4%	~ 48.6%	~ 59%	

>10,000 candidates — ~ 250 candidates — 10-20 candidates — ~ 6 candidates — ~ 4 candidates — ~ 2 candidates

Phase II & Phase III — Dose, Efficacy, Toxicity
Phase I — PK, Dose escalation, Toxicity
Pre-clinical test & Lead optimization — SAR, Drug-like properties, Solubility Permeability, ADME, Plasma PK, Efficacy, Toxicity
Compound screening — Visual screening, HTS
Target validation — Disease models, Target identification, Target validation

technologies	NLP	Data management	mobile
	RWD	Cloud	Data standard

Accelerating cdisc & data management - SEND

Accelerating Non- Clinical data & SEND

Accelerating Non- Clinical data & SEND Process, using AI & Data engineering
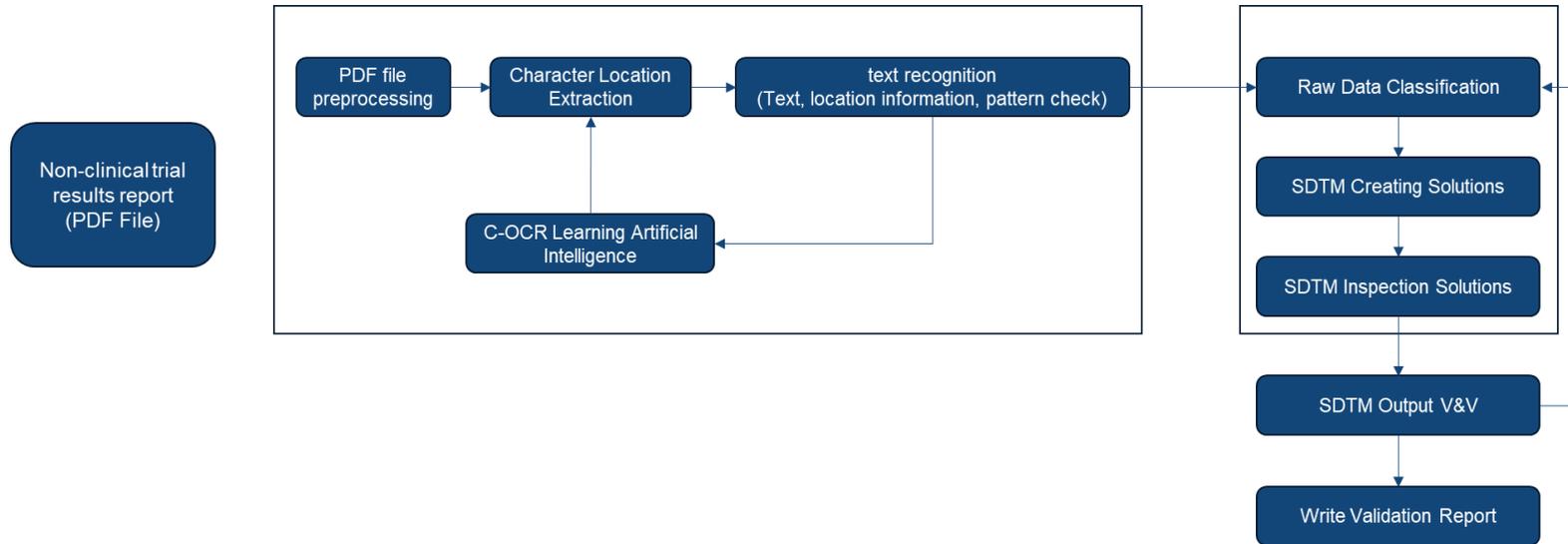
Accelerating Non- Clinical data & SEND

CDISC SEND BW Domain Extraction case

→ case of location and content-based extraction from body weight raw data in the result report

Accelerating Non- Clinical data & SEND

CDISC SEND LB Domain Extraction case

→ case of location and content-based extraction from serum chemistry raw data in the result report
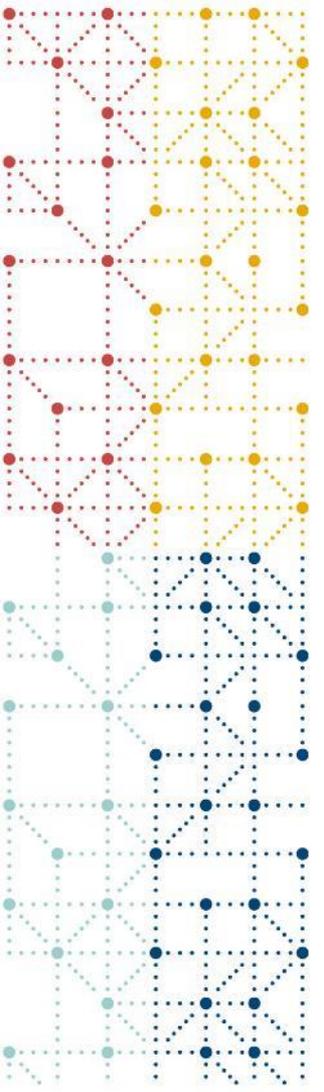
Accelerating Non- Clinical data & SEND

CDISC SEND OM Domain Extraction case

→ case of location and content-based extraction from organ weights raw data in the result report

Accelerating cdisc & data management - SDTM

SDTM Work Process

Refining clinical trial data → SDTM specification generation → Creating SDTM Datasets → SDTM Validation → Forwarding SDTM

Accelerating Clinical data & SDTM

- Setting Raw data path, SDTM version using preference "SDTM Generation Solution"
  - ➤ Add SDTM Format

Accelerating Clinical data & SDTM

Check SDTM variable and output function settings and error tests for their contents

SDTM Generation Solution

➤ Setting SDTM Variables and Output Functions

➤ Modification and testing within SDTM variables and output functions Solution
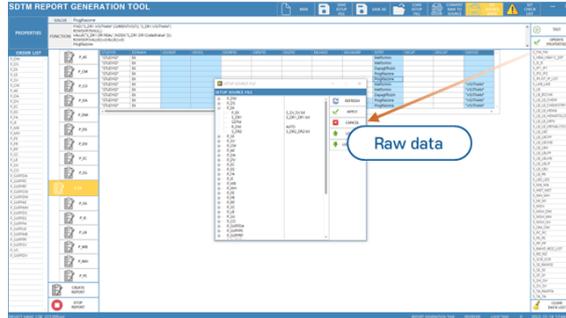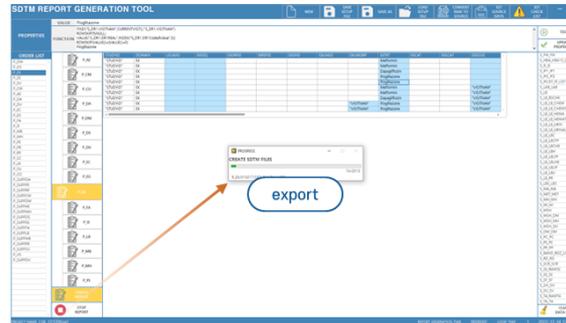
Accelerating Clinical data & SDTM

SDTM creation process based on raw data specification and setup

SDTM Generation Solution

➤ Specify the raw data associated with SDTM DOMAIN that you want to output

Raw data

➤ Select the SDTM DOMAIN you want to output from the list and output via the CREATE REPORT button
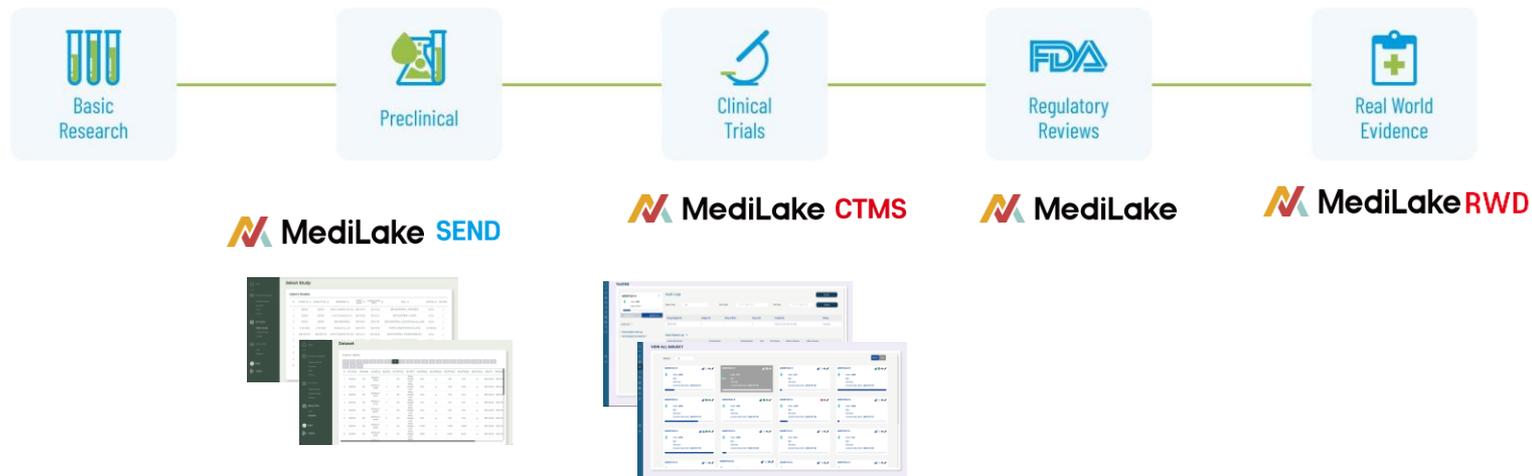
export

VALIDATION

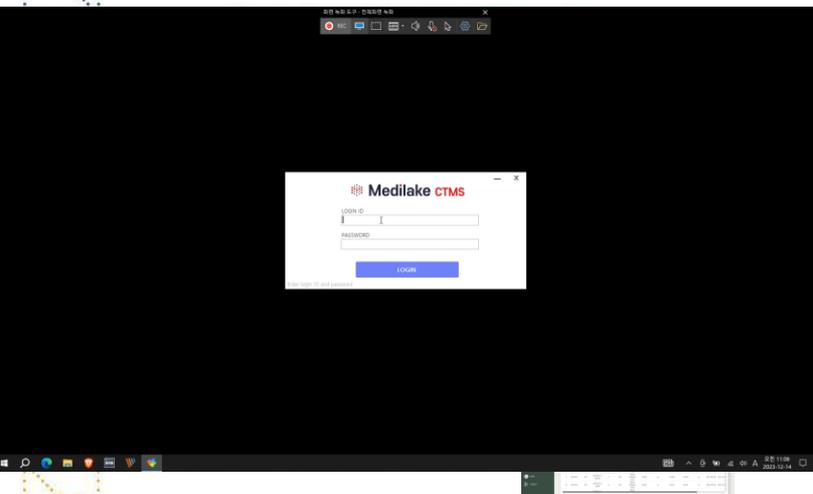➤ SDTM Dataset Verification with Pinnacle 21

➤ Define xml Generation

Accelerating end-to-end your clinical trial

Drug Development Process

Basic Research — Preclinical — Clinical Trials — Regulatory Reviews — Real World Evidence

MediLake SEND · MediLake CTMS · MediLake · MediLake RWD

Accelerating end-to-end your clinical trial

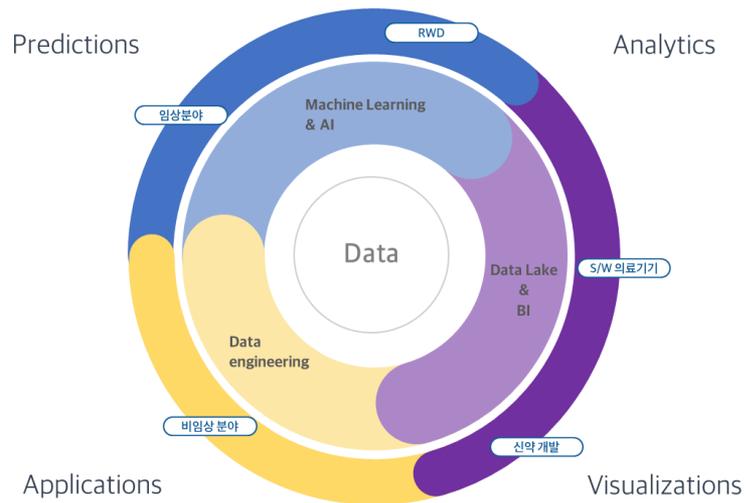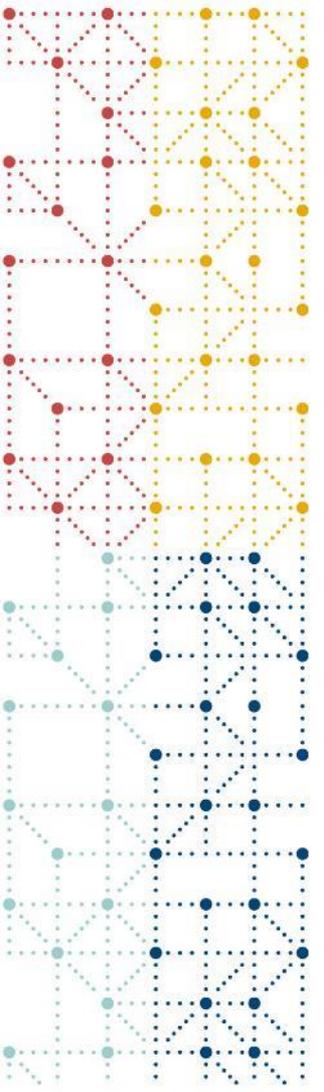# Our vision

An open, unified,
and intelligent
Bio-pharma Data ecosystem

Thank you!

cdisc

Clear data. Clear impact.