



2023

KOREA

INTERCHANGE

SEOUL | 11-14 DECEMBER



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



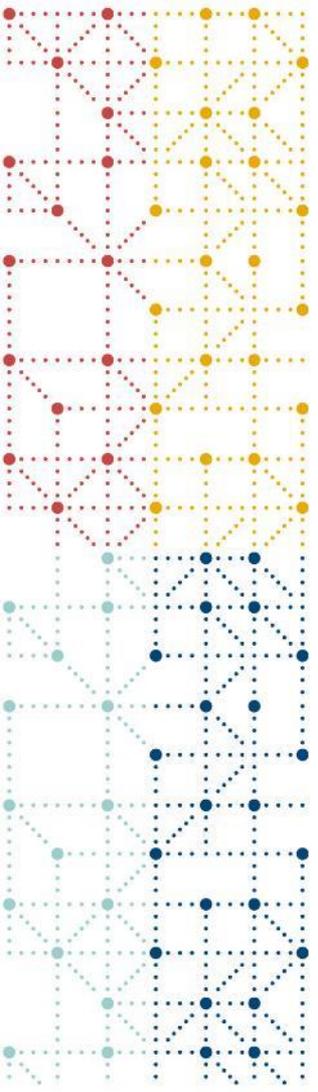
Meet the Speaker

Dong-hoon, Cho

Title: Chairman(Chairman of the BOD)

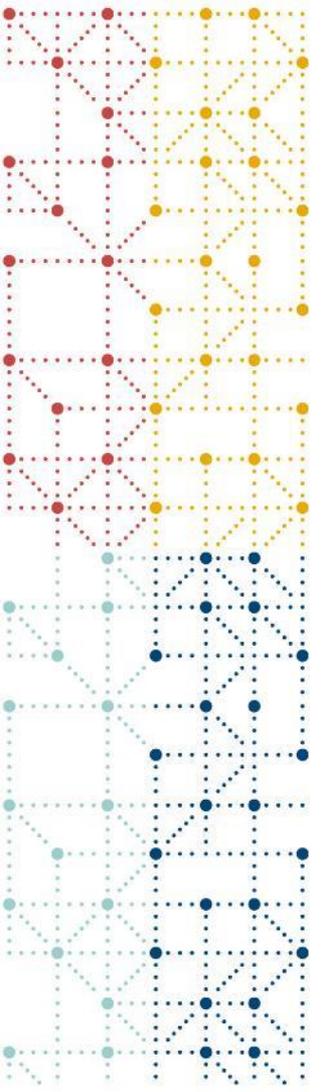
Organization: Clupea Inc.

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

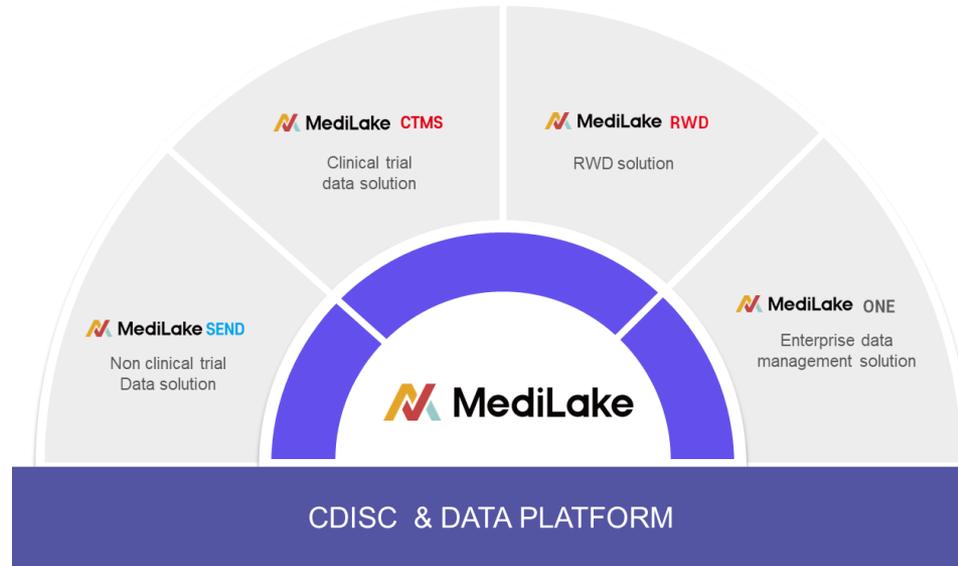
1. Introduce & Challenges And Opportunities In Clinical Data Management
2. Accelerating cdisc & data management



Introduce & Challenges And Opportunities In Clinical Data Management

CLUPEA

Data business full-line up for pharmaceutical & bio industry



CLUPEA

business field & R&D

Certified

- FDA, EMA Certification
- GAMP5, US FDA 21 CFR Part 11, EU Annex 11
- CDISC Platinum Member



client

CLINICAL



NON-CLINICAL



Global client

CRO Syncorp Health 社



Big data & RWD

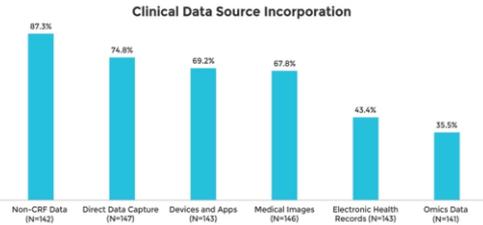
- RWD (Gil hospital)
- SaMD for RWD
- Non-clinical data platform
- Rehabilitation Exercise Service for Bigdata




Clinical data issue

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

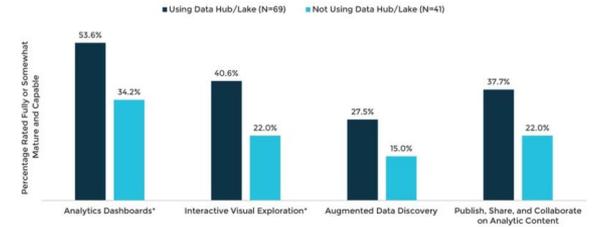
Clinical Data Source Incorporation



Data management activity labor intensiveness



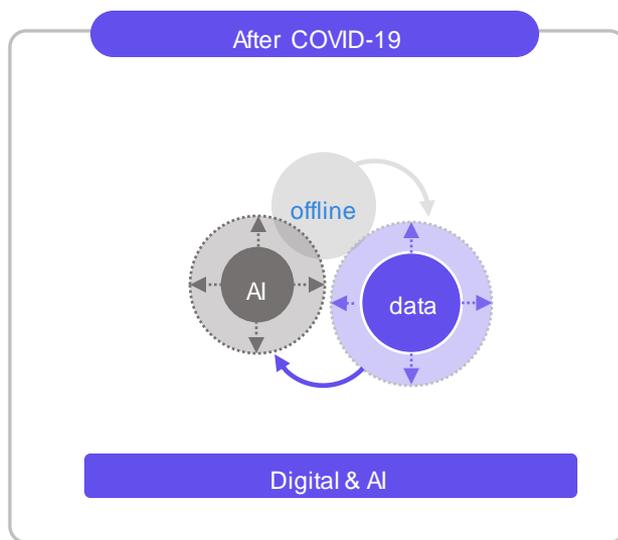
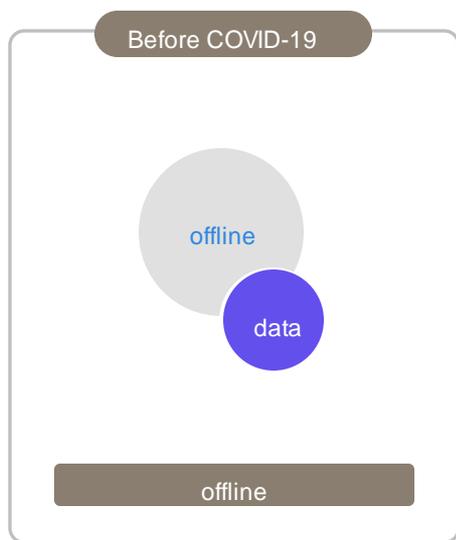
Respondent Analytics Critical Capabilities Maturity by Use of Data Hub/Lake



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

Clinical data issue

Challenges And Opportunities In Clinical Data Management



CRO M&A after CRO

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

(글로벌 상위 CRO 시장점유율('18년 & '20년))

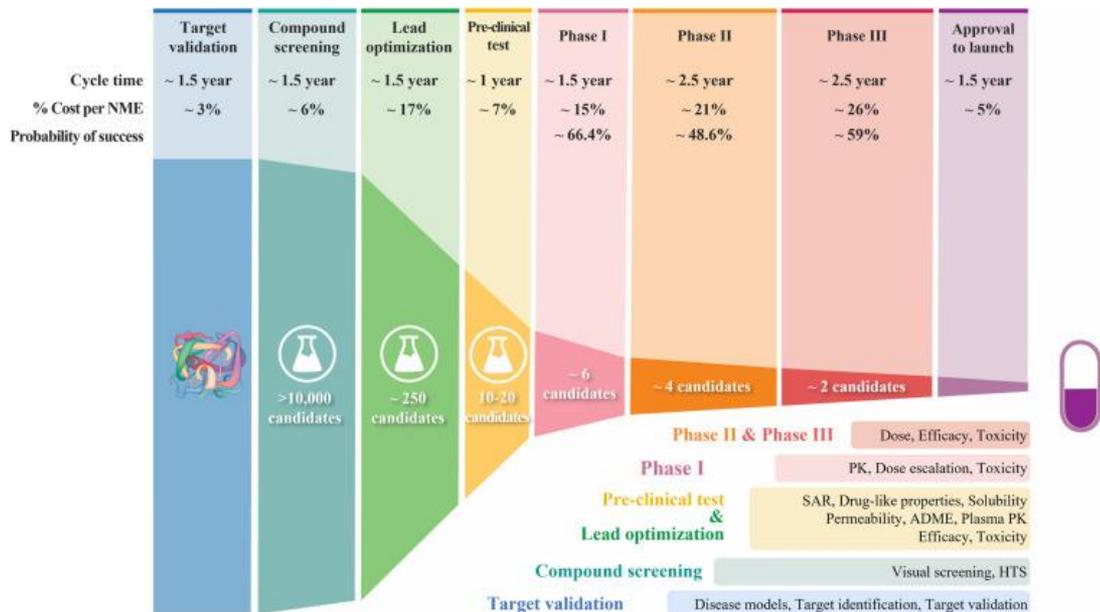
| 순위 | 2018년 | | 2020년 | | 2021년 동향 |
|----|-------------------|-------|-------------------|-------|--------------------------|
| | 기업명 | 점유율 | 기업명 | 점유율 | |
| 1 | IQVIA | 11.9% | IQVIA | 11.9% | |
| 2 | Covance(LabCorp) | 9.4% | Covance(LabCorp) | 10.0% | |
| 3 | Icon PLC | 5.7% | PPD | 9.5% | Thermo가 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 파라셀 인수('21. 7월) |
| 9 | Wuxi Apttec | 1.7% | Wuxi Apttec | 3.3% | |
| 10 | Medpace | 1.2% | Medpace | 1.8% | |
| - | Others | 48.2% | Others | 31.3% | |

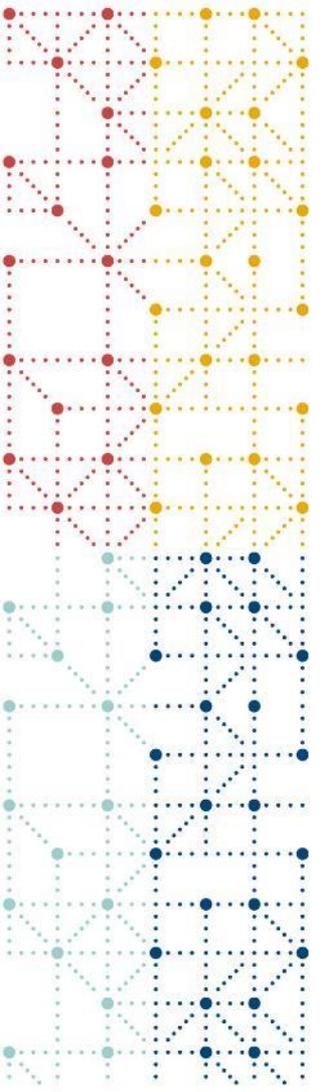
주: 원 보고서 자료에 2020년 Parexel 점유율 추가
 ※ 출처 : Frost & Sullivan 보고서를 바탕으로 재구성

Data & AI is important & essential

Clinical data issue

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

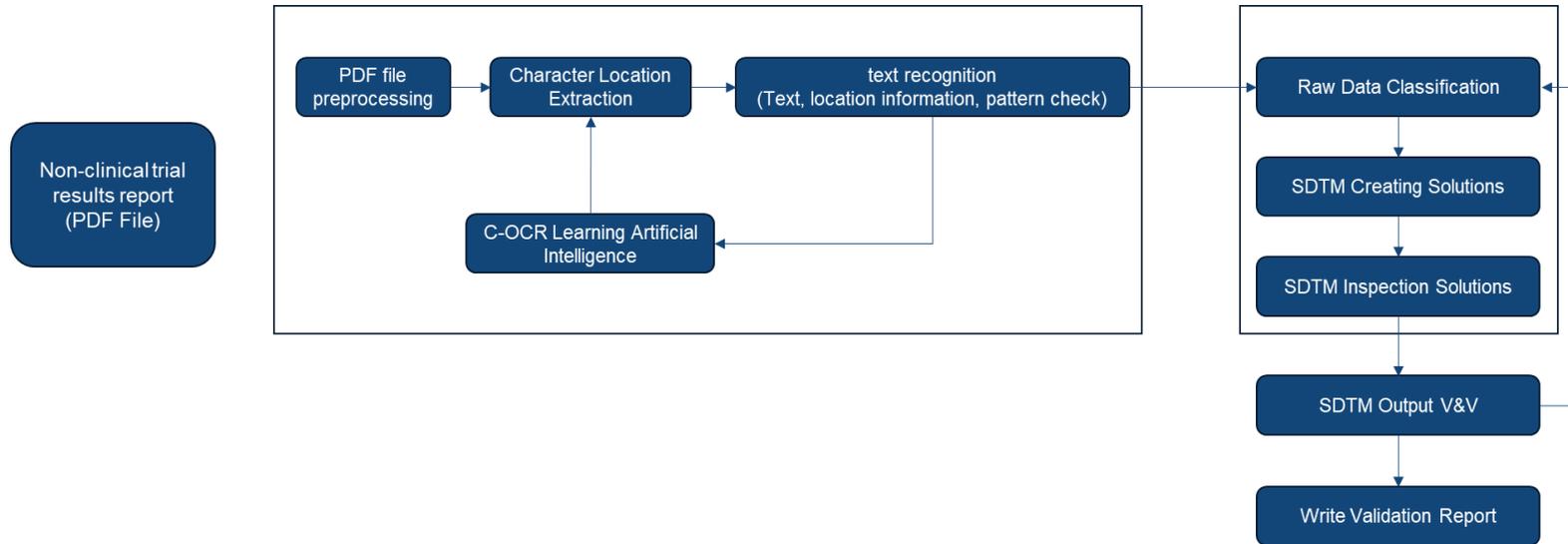




Accelerating cdisc & data management - SEND

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

Appendix 2: Individual body weights 1

| Group | Sex | Animal ID | Days (g) 5 | | |
|-----------------|-----|--------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|--------|----------------------------------------------------------------------------------------|
| | | | 0 | 8 | 15 3 |
| Female | | G1-1 2 | 170.17 | 211.29 | 218.80 |
| | | G1-2 | 166.60 | 205.21 | 207.29 4 |
| | | G1-3 | 164.71 | 193.95 | 187.83 |
| | | G1-4 | 157.75 | 189.43 | 183.08 |
| | | G1-5 | 157.57 | 192.90 | 205.26 |
| G1 (Vehicle) | | G1-6 | 152.05 | 184.39 | 184.61 |
| | | G1-1 | 250.71 | 324.84 | 333.57 |
| | | G1-2 | 241.07 | 308.08 | 325.15 |

| STUDYID | Domain | USUBJID | BWNOMLBL | VISITDY | BWORRES | BWORRESU |
|---------|--------|---------|----------|---------|---------|----------|
| | BW | -G1-001 | DAY 0 | | 250.71 | g |
| | BW | -G1-001 | DAY 8 | | 324.84 | g |
| | BW | -G1-001 | DAY 15 | | 333.57 | g |
| | BW | -G1-002 | DAY 0 | | 241.07 | g |
| | BW | -G1-002 | DAY 8 | | 308.08 | g |
| | BW | -G1-002 | DAY 15 | | 325.15 | g |
| | BW | -G1-003 | DAY 0 | | 240.43 | g |
| | BW | -G1-003 | DAY 8 | | 299.12 | g |
| | BW | -G1-003 | DAY 15 | | 308.73 | g |
| | BW | -G1-004 | DAY 0 | | 235.20 | g |
| | BW | -G1-004 | DAY 8 | | 299.70 | g |
| | BW | -G1-004 | DAY 15 | | 308.77 | g |
| | BW | -G1-005 | DAY 0 | | 232.17 | g |
| | BW | -G1-005 | DAY 8 | | 285.53 | g |
| | BW | -G1-005 | DAY 15 | | 298.80 | g |

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

Appendix 7 Individual serum chemistry

| Group | Sex | Result | AST | ALT | TP | CREA | T-BIL | GLU | TG | ALP | CHOL | ALB | GGT | CA | PHOS | LDL | HDL | BUN | GLOB |
|--------------|--------|--------|-------|------|-------|-------|--------|--------|--------|--------|-------|------|-------|-------|-------|-------|-------|-------|------|
| | | UI | UI | g/dL | mg/dL | mg/dL | mg/dL | mg/dL | mg/dL | UI | mg/dL | g/dL | UI | mg/dL | UI | mg/dL | mg/dL | mg/dL | g/dL |
| Female | G1-1 | 124.00 | 37.00 | 7.50 | 0.74 | 0.12 | 136.00 | 39.00 | 205.00 | 89.00 | 4.30 | 0.00 | 13.90 | 14.30 | 9.00 | 35.00 | 21.00 | 2.70 | |
| | G1-2 | 127.00 | 31.00 | 6.90 | 0.56 | 0.10 | 82.00 | 50.00 | 166.00 | 97.00 | 4.30 | 1.00 | 12.40 | 10.50 | 9.00 | 47.00 | 17.00 | 2.60 | |
| | G1-3 | 127.00 | 30.00 | 7.90 | 0.63 | 0.12 | 97.00 | 49.00 | 287.00 | 128.00 | 4.80 | 0.00 | 13.50 | 11.70 | 14.00 | 61.00 | 17.00 | 3.10 | |
| | G1-4 | 108.00 | 23.00 | 6.50 | 0.63 | 0.10 | 105.00 | 28.00 | 148.00 | 78.00 | 4.30 | 0.00 | 11.20 | 10.70 | 9.00 | 42.00 | 15.00 | 2.20 | |
| | G1-5 | 134.00 | 38.00 | 7.50 | 0.67 | 0.13 | 126.00 | 47.00 | 244.00 | 110.00 | 4.60 | 1.00 | 13.20 | 10.70 | 12.00 | 47.00 | 19.00 | 2.90 | |
| G1 (Vehicle) | G1-6 | 150.00 | 49.00 | 8.10 | 0.78 | 0.14 | 117.00 | 40.00 | 132.00 | 88.00 | 4.90 | 0.00 | 14.20 | 12.60 | 10.00 | 40.00 | 21.00 | 3.20 | |
| | G1-1 | 110.00 | 44.00 | 7.10 | 0.64 | 0.13 | 82.00 | 52.00 | 286.00 | 89.00 | 4.30 | 0.00 | 12.80 | 13.30 | 11.00 | 28.00 | 17.00 | 2.80 | |
| G1-2 | 133.00 | 35.00 | 5.50 | 0.43 | 0.08 | 89.00 | 46.00 | 193.00 | | 42.00 | 3.50 | 0.00 | 9.70 | 10.00 | 9.00 | 20.00 | 18.00 | 2.00 | |

| STUDYID | Domain | USUBJID | LBIDTC | LBCAT | LBTESTCD | LBORRES | LBORRESU |
|---------|--------|---------|------------|---------|----------------------------|---------|----------|
| LB | | -G1-001 | 2019-10-01 | AST | Aspartate Aminotransferase | 169.00 | IU/L |
| LB | | -G1-001 | 2019-10-01 | ALT | Alanine Aminotransferase | 44.00 | IU/L |
| LB | | -G1-001 | 2019-10-01 | PROT | Protein | 7.10 | g/dL |
| LB | | -G1-001 | 2019-10-01 | CREAT | Creatinine | 0.64 | mg/dL |
| LB | | -G1-001 | 2019-10-01 | BILU | Bilirubin | 0.13 | mg/dL |
| LB | | -G1-001 | 2019-10-01 | GLUCOSE | Glucose | 82.00 | mg/dL |
| LB | | -G1-001 | 2019-10-01 | TRIG | Triglycerides | 52.00 | mg/dL |
| LB | | -G1-001 | 2019-10-01 | ALP | Alkaline Phosphatase | 286.00 | IU/L |
| LB | | -G1-001 | 2019-10-01 | CHOL | Cholesterol | 89.00 | mg/dL |
| LB | | -G1-001 | 2019-10-01 | ALB | Albumin | 4.30 | g/dL |
| LB | | -G1-001 | 2019-10-01 | GGT | Gamma Glutamyl Transferase | 0.00 | IU/L |
| LB | | -G1-001 | 2019-10-01 | CA | Calcium | 12.80 | mg/dL |
| LB | | -G1-001 | 2019-10-01 | PHOS | Phosphate | 13.30 | IU/L |
| LB | | -G1-001 | 2019-10-01 | LDL | LDL Cholesterol | 11.00 | mg/dL |
| LB | | -G1-001 | 2019-10-01 | HDL | HDL Cholesterol | 28.00 | mg/dL |
| LB | | -G1-001 | 2019-10-01 | UREAN | Urea Nitrogen | 17.00 | mg/dL |
| LB | | -G1-001 | 2019-10-01 | ALBLOB | Albumin/Globulin | 2.80 | g/dL |

Accelerating Non- Clinical data & SEND

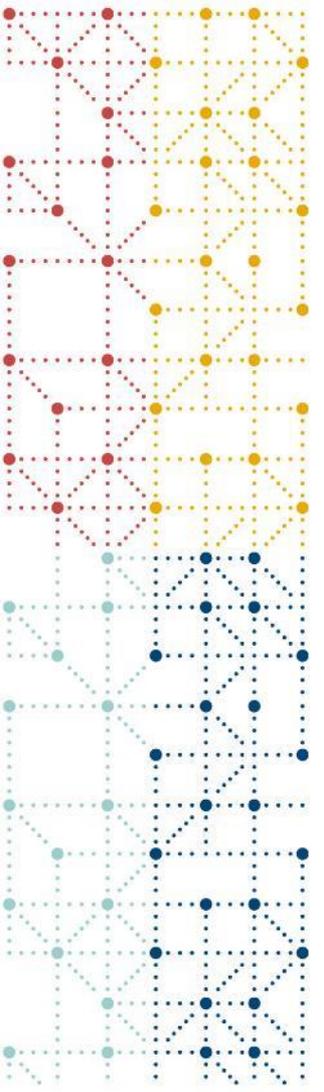
CDISC SEND OM Domain Extraction case

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

Appendix 4. Individual absolute organ weights

| Group | Sex | Result | Brain (g) | | Thymus (g) | Heart (g) | Long (g) | Liver (g) | Kidney (g) | | Spleen (g) | Ovary-(g)-Testis (g) | | Epididymis (g) | | Uterus (g) |
|-------|-----------|--------|-----------|--------|------------|-----------|----------|-----------|------------|--------|------------|----------------------|--------|----------------|----|------------|
| | | | Rt | Lt | Rt | Lt | Rt | Lt | Rt | Lt | Rt | Lt | Rt | Lt | Rt | Lt |
| G1-1 | | 1.7645 | 0.5601 | 0.7736 | 1.1503 | 6.2023 | 0.8487 | | | 0.4819 | 0.0751 | 0.0791 | - | - | - | 0.3072 |
| G1-2 | | 1.8215 | 0.5796 | 0.8378 | 1.0120 | 5.7436 | 0.7887 | | | 0.4157 | 0.0453 | 0.0439 | - | - | - | 0.3096 |
| G1-3 | | 1.8421 | 0.5719 | 0.7502 | 1.0150 | 5.6655 | 0.6878 | | | 0.6849 | 0.4225 | 0.0474 | 0.0522 | - | - | 0.3851 |
| G1-4 | Female | 1.7555 | 0.4057 | 0.7709 | 0.9553 | 5.6515 | 0.7665 | 0.7606 | 0.3259 | 0.0616 | 0.0441 | - | - | - | - | 0.3354 |
| G1-5 | | 1.9719 | 0.4057 | 1.7453 | 0.9408 | 5.7486 | 0.7239 | 0.7424 | 0.4298 | 0.0458 | 0.0400 | - | - | - | - | 0.2668 |
| G1-6 | | 1.7383 | 0.3570 | 0.7188 | 0.9516 | 5.3348 | 0.6883 | 0.6732 | 0.4702 | 0.0628 | 0.0624 | - | - | - | - | 0.2540 |
| G11 | (Vehicle) | | | | | | | | | | | | | | | 0.4375 |

| STUDYID | Domain | USUBJID | OMDTC | OMSPEC | OMLAT | OMORRES | OMORRESU |
|---------|--------|---------|------------|------------|-------|---------|----------|
| | OM | -G1-001 | 2019-10-01 | BRAIN | | 2.0452 | g |
| | OM | -G1-001 | 2019-10-01 | THYMUS | | 0.7527 | g |
| | OM | -G1-001 | 2019-10-01 | HEART | | 1.1426 | g |
| | OM | -G1-001 | 2019-10-01 | LUNG | | 1.4941 | g |
| | OM | -G1-001 | 2019-10-01 | LIVER | | 9.0214 | g |
| | OM | -G1-001 | 2019-10-01 | KIDNEY | RIGHT | 1.2739 | g |
| | OM | -G1-001 | 2019-10-01 | KIDNEY | LEFT | 1.2894 | g |
| | OM | -G1-001 | 2019-10-01 | SPLEEN | | 0.6069 | g |
| | OM | -G1-001 | 2019-10-01 | OVARY | RIGHT | 1.8285 | g |
| | OM | -G1-001 | 2019-10-01 | TESTIS | LEFT | 1.7704 | g |
| | OM | -G1-001 | 2019-10-01 | EPIDIDYMIS | RIGHT | 0.5164 | g |
| | OM | -G1-001 | 2019-10-01 | EPIDIDYMIS | LEFT | 0.4375 | g |



Accelerating cdisc & data management - SDTM

SDTM Work Process

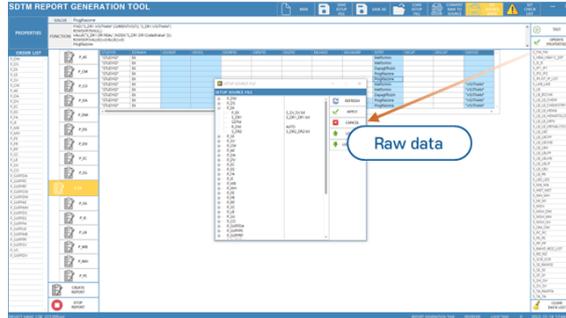


Accelerating Clinical data & SDTM

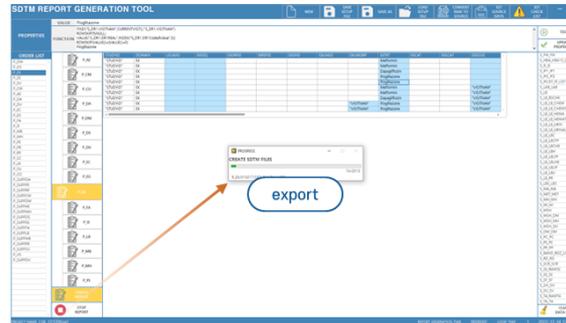
SDTM creation process based on raw data specification and setup

SDTM Generation Solution

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



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



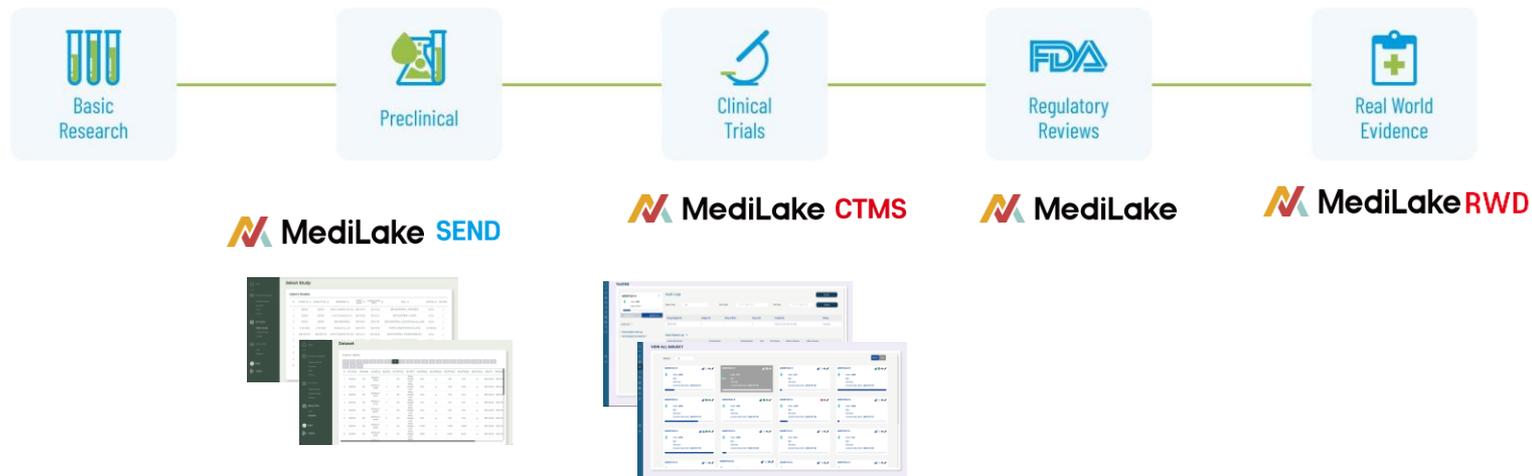
VALIDATION

- SDTM Dataset Verification with Pinnacle 21
- Define xml Generation

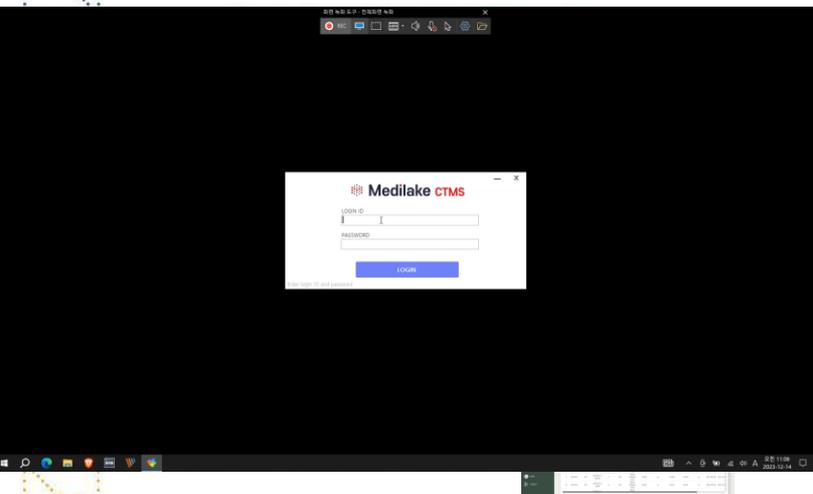


Accelerating end-to-end your clinical trial

Drug Development Process



Accelerating end-to-end your clinical trial



 **MediLake CTMS**



 **MediLake**

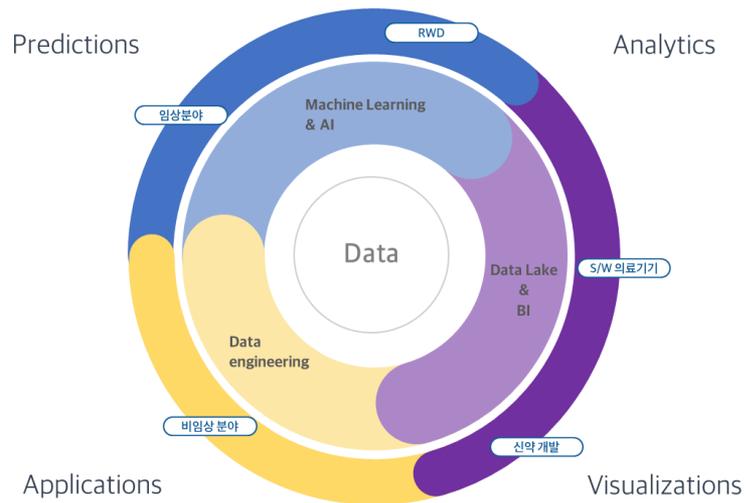


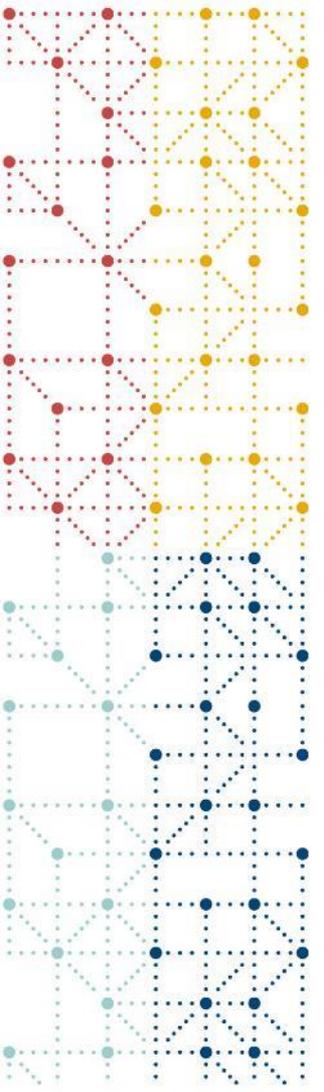
 **MediLake RWD**



Our vision

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





Thank you!

cdisc

Clear data. Clear impact.