



Key Challenges and Solutions in SEND Implementation

이민행 / 팀장 / 데이터관리팀 / 코아시스템컴온(주)



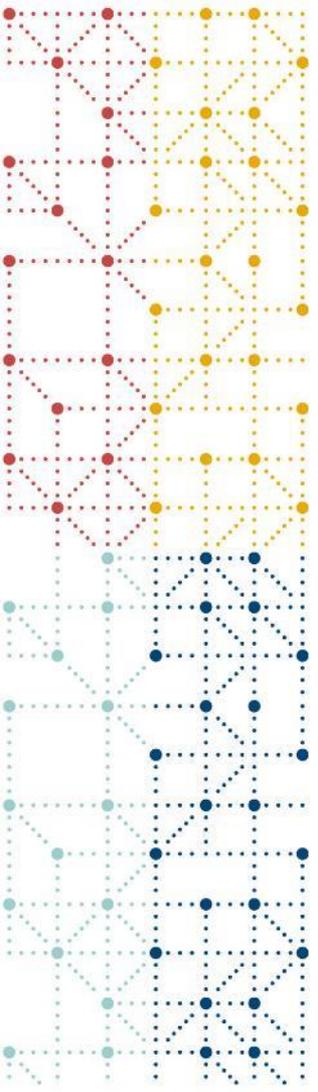
Meet the Speakers

이민행

Title: Key Challenges and Solutions in SEND Implementation

Organization: 코아시스템켐온(주)

데이터관리팀 팀장 / 수석연구원



Agenda

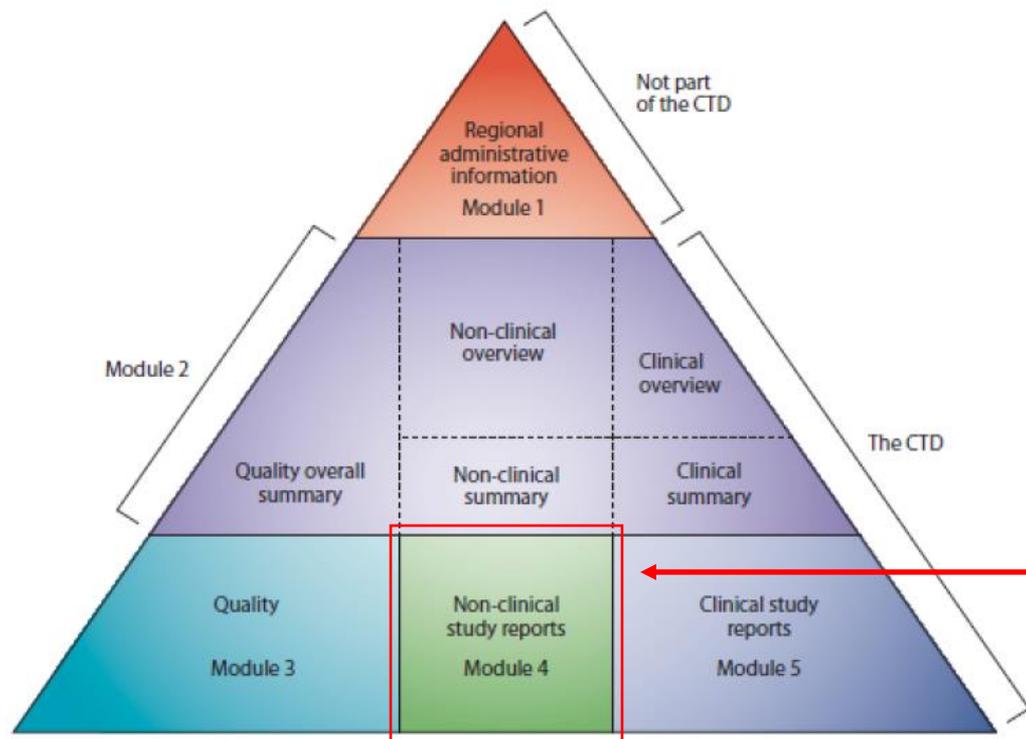
1. CDISC 필요성
2. SEND 필요성
3. SEND 변환 시험의 종류 및 일정
4. SEND 변환 현황
5. 사례 연구
6. 솔루션 제안

CDISC 필요성

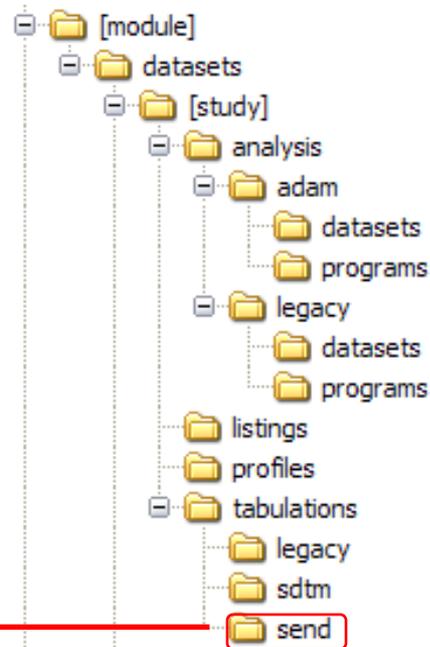
데이터의 일관성을 높이고 다양한 시스템 간의 상호 운용성을 개선

- 데이터 통합 및 공유 : 각 기관별 비임상 데이터를 통합하고 공유
- 규제 준수 : 규제 기관의 요구 사항에 부합하는 데이터 제공
- 효율성 증대 : 데이터 전송 및 관리의 효율성을 높여 시간 단축
- 품질 보장 : 일관된 데이터 형식으로 오류 감소 및 데이터 품질 향상

SEND 필요성



The CTD triangle. The Common Technical Document is organized into five modules. Module 1 is region specific and modules 2, 3, 4 and 5 are intended to be common for all regions.



SEND 변환 시험의 종류 및 일정

Final Guidance – 2014년 12월 17일

NDA 신청 – 2016년 12월 17일 이후 개시되는 시험

IND 신청 – 2017년 12월 17일 이후 개시되는 시험

- FDA는 임상시험 및 비임상시험 모두 전자 데이터 제출을 필요로 하고 있음

SEND 변환 시험의 종류 및 일정

- 단회투여 독성시험
- 반복투여 독성시험 (TK 시험)
- 발암성 시험
- 안전성 약리시험 (호흡기계, Telemetry)
- 생식발생독성시험 (SEG II)
- 유전독성 (소핵시험, Comet) – 2025. 03. 15 시험 시작

SEND 변환 시험의 종류 및 일정

Use	Standard	Exchange Format	SDO	Property	Related Properties	FDA Center(s)	Date Support Begins	Date Support Ends	Date Requirement Begins [10] [11]
Nonclinical study datasets	SEND	XPT	CDISC	SENDIGv3.0		CDER	06-13-2011	03/15/2019 [1] [12] 03/15/2020 [2] [12]	12/17/2016 [1] 12/17/2017 [2]
Nonclinical study datasets	SEND	XPT	CDISC	SDTMv1.5		CDER	08-21-2017		03/15/2019 [1] 03/15/2020 [2]
Nonclinical study datasets	SEND	XPT	CDISC	SDTMv1.5		CDER	03-15-2021		03-15-2023
Nonclinical study datasets	SEND	XPT	CDISC	SENDIGv3.1		CDER	08-21-2017		03/15/2019 [1] 03/15/2020 [2]
Nonclinical study datasets	SEND	XPT	CDISC	SENDIGv3.1		CDER	07-14-2020		03-15-2023
Nonclinical study datasets	SEND	XPT	CDISC	SENDIGv3.1.1		CDER, CDER	02-15-2022		03-15-2023
Nonclinical study datasets	SEND	XPT	CDISC	SENDIG-Genetox1.0		CDER, CDER	12/13/2023 [12]		03-15-2025
Nonclinical study datasets	SEND	XPT	CDISC	SDTMv1.6		CDER	03-05-2021		03/15/2023 [1] 03/15/2024 [2]
Nonclinical study datasets	SEND	XPT	CDISC	SENDIG-DARTv1.1		CDER	03-05-2021		03/15/2023 [1] 03/15/2024 [2]

- [1] For NDAs, ANDAs, and certain BLAs. See section II.A of the [Providing Regulatory Submissions In Electronic Format — Standardized Study Data](#) guidance document
- [2] For certain INDs. See section II.A of the [Providing Regulatory Submissions In Electronic Format - Standardized Study Data](#)
- [3] [Providing Regulatory Submissions in Electronic Format - Content of Labeling](#)
- [4] The requirements of the electronic labeling rule can be found in § 314.50(f) for NDAs, § 314.94(d) for ANDAs, § 601.14(b) for BLAs, and § 314.81(b) for annual reports to marketing applications. The effective date of the rule was June 8, 2004
- [5] For NDAs, ANDAs, and BLAs. See section B of the [Providing Regulatory Submissions in Electronic Format - Certain Human Pharmaceutical Product Applications and Related Submission Using the eCTD Specifications](#) guidance document
- [6] For Commercial INDs and Master Files. See section B of the [Providing Regulatory Submissions in Electronic Format - Certain Human Pharmaceutical Product Applications and Related Submission Using the eCTD Specifications](#) guidance document
- [7] The pill image is optional, but it is highly recommended to address numerous potential patient safety issues. Also see Federal Register Volume 76, Number 99, and Federal Register Volume 79, Number 182 as background
- [8] "Ongoing" - Prior to the posting of an FDA Data Standards Catalog in 2011, FDA supported a number of data standards and there was no specific date when support began for some of these standards. As a result, the support status of "Ongoing" was entered for "D:
- [9] The simplified TS.xpt is a specific implementation of the CDISC SDTM standard being utilized by FDA (CDER and CDER) to establish the study start date or indicate that the study is exempted for evaluation by the Study Data Technical Rejection Criteria (TRC). For sp
- [10] Please see the Study Data Technical Conformance Guide for clarification regarding when electronic standardized study data are required as part of a submission to address a public health emergency declared by the Secretary of Health and Human Services in acco
- [11] Please see the Study Data Technical Conformance Guide for clarification regarding when electronic standardized study data are required for particular types of studies, such as pilot studies and failed studies submitted to ANDAs
- [12] **if a study started before** the support ends date, the study can continue to use this specified version of the standard. If a study starts after the support ends date, the study can NO longer use this specified version of the standard. Sponsors cannot use

SEND 변환 시험의 종류 및 일정

2016 2017 2018 2019 2020 2021 2022 2023 2024 2025

Sing-dose Toxicology, Repeat-dose
Toxicology, Carcinogenicity

CDER: SENDIG v3.0

- NDA/ANDA/BLA : 17-DEC-2016
- IND : 17-DEC-2017

Sing-dose Toxicology, Repeat-dose Toxicology, Carcinogenicity
Cardiovascular, Respiratory Safety Pharmacology

CDER: SENDIG v3.1

- NDA/ANDA/BLA : 15-MAR-2019
- IND : 15-MAR-2020

CDER/CBER: SENDIG v3.1.1

- IND/NDA/ANDA/BLA : 15-MAR-2023

Embryo-Fetal Development (EFD)

CDER: SENDIG DART v1.1

- NDA/ANDA/BLA : 15-MAR-2023
- IND : 15-MAR-2024

Micronucleus, Comet Assay (In vivo)

CDER/CBER: GT. V1.0

- IND/NDA/ANDA/BLA : 15-MAR-2025

SEND 변환 현황



Standard for Exchange of Nonclinical Data Implementation Guide: Nonclinical Studies Version 3.1

Prepared by the
CDISC Standard for Exchange of Nonclinical Data Team

Notes to Readers

- This is the implementation guide for nonclinical studies based upon Version 1.5 of the CDISC Study Data Tabulation Model (SDTM).
- This Implementation Guide is Version 3.1 of the CDISC Standard for Exchange of Nonclinical Data

Revision History

Date	Version
2016-06-27	3.1
2015-07-17	3.1 Draft B
2014-10-29	3.1 Draft
2011-04-30	3.0

Note: Please see [Appendix F](#) for Representations and Warranties, Limitations of Liability, and Disclaimers.



Standard for Exchange of Nonclinical Data Implementation Guide: Developmental and Reproductive Toxicology

Version 1.2 (Final)

Prepared by the CDISC SEND Reproductive Toxicology Subteam

Notes to Readers

- This is the implementation guide for nonclinical developmental and reproductive toxicology study data and is based upon Version 1.6 of the CDISC Study Data Tabulation Model (SDTM).
- This document should be used in conjunction with Version 3.1.1 of the CDISC Standard for Exchange of Nonclinical Data (SEND) and domain models. This document includes proposed enhancements for developmental and reproductive toxicology (DART) data submission. The information here will remain as a separate document and will not be integrated into a later version of the SEND Implementation Guide (SENDIG).

Revision History

Date	Version	Summary of Changes
2023-06-28	1.2 Final	Inclusion of juvenile animal studies
2017-12-11	1.1 Final	Reflects changes based on SDTM v1.6
2016-08-01	1.0 Provisional	

See [Appendix H](#) for Representations and Warranties, Limitations of Liability, and Disclaimers.



SEND 변환 현황

Centrus Control Console

Seed Data Protocol Services Data Adapters Published Terminology Terms Translations Licenses Roles SDTM Viewer Credentials Service Controller Help

Data Systems
 Services
 Published Terminology
 Terms
 Translations
 Flat File to SEND 3.1
 Provantis
 Provantis to DART 1.1
 Provantis to SEND 3.1
 Provantis-NEW
 Roles

CT Version for Mapping: <None>
 CT Version for Comparison: <None>

Target Terms - SEND 3.1

- SEND 3.1
 - SEND Terminology 2024-03-29
 - SEND Terminology 2023-12-15
 - SEND Terminology 2023-09-29
 - SEND Terminology 2023-06-30
 - SEND Terminology 2023-03-31
 - SEND Terminology 2022-12-16
 - SEND Terminology 2022-09-30
 - SEND Terminology 2022-06-24
 - SEND Terminology 2022-03-25
 - SEND Terminology 2021-12-17
 - SEND Terminology 2021-09-24
 - SEND Terminology 2021-03-26
 - SEND Terminology 2020-12-18
 - SEND Terminology 2020-09-25
 - SEND Terminology 2020-06-26
 - SEND Terminology 2020-03-27
 - SEND Terminology 2019-12-20
 - SEND Terminology 2019-09-27
 - SEND Terminology 2019-06-28
 - SEND Terminology 2019-03-29
 - SEND Terminology 2018-12-21

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
C158118		Yes	Age Estimation Method Response	AGESMETH	Age Estimation Method Response	Terminology related to the method by which the age of an individual is determined through estimation.	CDISC SEND Age Estimation Method Response Terminology
C158324	C158118		Age Estimation Method Response	ANIMAL RECORDS		Information obtained from medical records, acquisition records, or other official documentation associated with the animal.	Animal Record Information
C158323	C158118		Age Estimation Method Response	DENTAL EXAM		A systematic evaluation of the mouth, face, and neck, which may include tooth counting, cleaning and visual assessment.	Dental Examination
C20989	C158118		Age Estimation Method Response	PHYSICAL EXAMINATION	Physical Exam	A systemic evaluation of the body and its functions using visual inspection, palpation, percussion and auscultation.	Physical Examination
C128940	C158118		Age Estimation Method Response	RADIOGRAPHY	Radiographic Exam	A radiographic procedure using the emission of penetrating energy waves to form an image of the structure.	Radiographic Examination
C17998	C158118		Age Estimation Method Response	UNKNOWN	U; UNK; Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown
C66781		No	Age Unit	AGEU	Age Unit	Those units of time that are routinely used to express the age of a subject.	CDISC SDTM Age Unit Terminology
C25301	C66781		Age Unit	DAYS		A unit of measurement of time equal to 24 hours.	Day
C25529	C66781		Age Unit	HOURS	h; Hours; hr	A unit of measurement of time equal to 60 minutes.	Hour
C29846	C66781		Age Unit	MONTHS	Month	One of the 12 divisions of a year as determined by a calendar. It corresponds to the unit of time of approximately to one cycle of the moon's phases, about 30 days or 4 weeks. (NCI)	Month
C29844	C66781		Age Unit	WEEKS	Week	Any period of seven consecutive days. (NCI)	Week
C29848	C66781		Age Unit	YEARS	Year	The period of time that it takes for Earth to make a complete revolution around the sun, approximately 365 days; a specific one year period. (NCI)	Year

SEND 변환 현황

Centrus Control Console

Seed Data Protocol Services Data Adapters Published Terminology Terms Translations Licenses Roles SDTM Viewer Credentials Service Controller Help

CT Version for Mapping: SEND Terminology 2024-03-29 CT Version for Comparison: <None>

Target Terms - SEND 3.1

CT Code	Target Terms	Source Terms
C81328	Body Weight	Bodyweight
C124477	Gravid Uterus Adjusted Body Weight	Corrected Bodyweight (rodent)
	Net Body Weight	Corrected Bodyweight (non-rodent)
C90464	Terminal Body Weight	Net BW
		Terminal Bodyweight
		Terminal Bodyweight_S
		Terminal Body Weight(Non-Rodent)_S

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
C81328	C89962		Body Weight Test Code	BW	Body Weight	The weight of a subject. (NCI)	Body Weight
C81328	C89961		Body Weight Test Name	Body Weight	Body Weight	The weight of a subject. (NCI)	Body Weight
C90464	C89962		Body Weight Test Code	TERMBW	Terminal Body Weight	The weight of a subject at a specified end point. (NCI)	Terminal Body Weight
C90464	C89961		Body Weight Test Name	Terminal Body Weight	Terminal Body Weight	The weight of a subject at a specified end point. (NCI)	Terminal Body Weight

USUBJID	BWSE	BWTEST	BWTEST	BWORRE	BWORRES
22-MR-0955-1	1	BW	Body Weight	22.55	g
22-MR-0955-1	4	TERMBW	Terminal Body Weight	22.37	g

SEND 변환 현황

No.	Domain(s)		No.	Domain(s)	
1	BG	Body Weight Gain	19	PM	Palpable Masses
2	BW	Body Weight	20	TF	Tumor Findings
3	CL	Clinical Observation	21	RE	Respiratory Test Results
4	CO	Comments	22	POOLDEF	Pool Definition
5	CV	Cardiovascular Test Results	23	RELREC	Related Records
6	EG	ECG Test Results	24	SUPP	Supplemental Qualifiers (--CL, --MA, --MI, --TF)
7	VS	Vital Signs	25	TA	Trial Arms
8	DM	Demographics	26	TE	Trial Elements
9	DS	Disposition	27	TX	Trial Sets
10	SE	Subject Elements	28	TS	Trial Summary
11	EX	Exposure	29	TP	Trial Repro Paths
12	FW	Food And Water	30	TT	Trial Repro Stages
13	LB	Laboratory Test Results	31	SJ	Subject Repro Stages
14	MA	Macroscopic Findings	32	DP	Developmental Milestones
15	MI	Microscopic Findings	33	PY	Nonclinical Pregnancy Results
16	OM	Organ Measurements	34	IC	Implantation Classification
17	PC	Pharmacokinetics Concentrations	35	FX	Fetal Pathology Findings
18	PP	Pharmacokinetics Parameters	36	FM	Fetal Measurements

SEND 변환 현황

Variable Name	Variable Label	Type	Controlled Terms, Code list, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	BW	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
BWSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
BWTESTCD	Test Short Name	Char	(BWTESTCD)	Topic	Short name of the measurement, test, or examination described in BWTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in BWTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). BWTESTCD cannot contain characters other than letters, numbers, or underscores.	Req
BWTEST	Test Name	Char	(BWTEST)	Synonym Qualifier	Long name for BWTESTCD. The value in BWTEST cannot be longer than 40 characters.	Req
BWORRES	Result or Findings as Collected	Char		Result Qualifier	Result of the measurement or finding as originally received or collected.	Exp
BWORRESU	Unit of the Original Result	Char	(UNIT)	Variable Qualifier	The unit for the original result. The unit of the original result should be mapped to a synonymous unit on the Controlled Terminology list.	Exp
BWSTRESC	Standardized Result in Character Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from BWORRES in a standard format or standard units. BWSTRESC should store all results or findings in character format; if results are numeric, they should also be submitted in numeric format in BWSTRESN.	Exp
BWSTRESN	Standardized Result in Numeric Format	Num		Result Qualifier	Used for numeric results or findings in standard format; contains the numeric form of BWSTRESC. BWSTRESN should store all numeric test results or findings.	Exp
BWSTRESU	Unit of the Standardized Result	Char	(UNIT)	Variable Qualifier	Standardized unit used for BWSTRESC and BWSTRESN.	Exp
BWSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate when a test is not done or result is missing. Should be null if a result exists in BWORRES.	Perm
BWREASND	Reason Not Done	Char		Record Qualifier	Describes why BWSTAT is NOT DONE, such as BROKEN EQUIPMENT or TECHNICIAN OVERSIGHT.	Perm
BWBLFL	Baseline Flag	Char	(NY)	Record Qualifier	A baseline indicator may be used to calculate differences or changes from baseline. Value should be Y or null. The baseline flag is sponsor defined.	Exp
BWFAST	Fasting Status	Char	(NY)	Record Qualifier	Indicator used to identify fasting status. The value should be Y or null.	Perm
BWEXCLFL	Exclusion Flag	Char	(NY)	Record Qualifier	Y if the result should be excluded from all calculations, otherwise null.	Perm
BWREASEX	Reason for Exclusion	Char		Record Qualifier	The reason the result should be excluded from all calculations. Used only when BWEXCLFL is Y.	Perm
BWUSCHFL	Unscheduled Flag	Char	(NY)	Record Qualifier	Indicates whether the timing of a performed test or observation was unscheduled. If a test or observation was performed based upon a schedule defined in the protocol, this flag should be null. Expected values are Y or null.	Perm
VISITDY	Planned Study Day of Collection	Num		Timing	Planned study day of collection. Should be an integer.	Perm
BWDTC	Date/Time Animal Weighed	Char	ISO 8601	Timing	Date/Time of body weight collection in ISO 8601 format.	Exp
BWDY	Study Day Animal Weighed	Num		Timing	Study day of body weight collection, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSIDTC variable in the Demographics (DM) domain.	Perm
BWNOMDY	Nominal Study Day for Tabulations	Num		Timing	Nominal study day used for grouping records for observations that may occur on different days into a single reported study day. Should be an integer.	Exp
BWNOMLBL	Label for Nominal Study Day	Char		Timing	A label for a given value of BWNOMDY as presented in the study report. Examples: "Week 4," "Day 28," "Terminal Sac".	Perm

USUBJID	BWSEQ	BWTESTCD	BWTEST	BWORRES	BWORRESU	BWSTRESC	BWSTRESN	BWSTRESU	BWBLFL	BWFAST	BWDTC	BWDY
22-RR-0144-1	1	BW	Body Weight	198.90	g	198.90	198.9 g		Y		2022-08-09	1
22-RR-0144-1	2	BW	Body Weight	273.28	g	273.28	273.28 g				2022-08-16	8
22-RR-0144-1	3	BW	Body Weight	325.73	g	325.73	325.73 g				2022-08-21	13
22-RR-0144-1	4	TERMBW	Terminal Body Weight	297.26	g	297.26	297.26 g		Y		2022-08-23	15
22-RR-0144-10	1	BW	Body Weight	195.10	g	195.10	195.1 g		Y		2022-08-09	1
22-RR-0144-10	2	BW	Body Weight	263.44	g	263.44	263.44 g				2022-08-16	8
22-RR-0144-10	3	BW	Body Weight	309.98	g	309.98	309.98 g				2022-08-21	13
22-RR-0144-10	4	TERMBW	Terminal Body Weight	287.73	g	287.73	287.73 g		Y		2022-08-23	15

Core

- Req : Requirements
- Exp : Expected
- Perm : Permissible

SEND 변환 현황

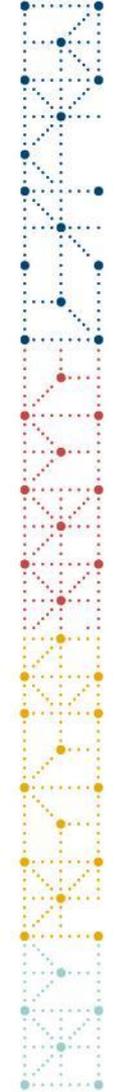
LBTESTCD	LBTEST	LBSCAT	LBORRES	LBORRESU	LBSTRESC	LBSTRESN	LBSTRESU	LBNAM	LBSPEC	LBMETHOD	LBFAST	LBDTC	LBDY
ALB	Albumin	LIVER FUNCTION	3.26	g/dL	3.26	3.26	g/dL	Nonclinical Research Institute, CORESTEMCHEMON Inc.	SERUM	SERUM BIOCHEMISTRY ANALYZER	Y	2022-08-23	15
CL	Chloride	ELECTROLYTES	101.28	mmol/L	101.28	101.28	mmol/L	Nonclinical Research Institute, CORESTEMCHEMON Inc.	SERUM	SERUM BIOCHEMISTRY ANALYZER	Y	2022-08-23	15
CREAT	Creatinine	KIDNEY FUNCTION	0.43	mg/dL	0.43	0.43	mg/dL	Nonclinical Research Institute, CORESTEMCHEMON Inc.	SERUM	SERUM BIOCHEMISTRY ANALYZER	Y	2022-08-23	15
K	Potassium	ELECTROLYTES	4.56	mmol/L	4.56	4.56	mmol/L	Nonclinical Research Institute, CORESTEMCHEMON Inc.	SERUM	SERUM BIOCHEMISTRY ANALYZER	Y	2022-08-23	15
SODIUM	Sodium	ELECTROLYTES	142.28	mmol/L	142.28	142.28	mmol/L	Nonclinical Research Institute, CORESTEMCHEMON Inc.	SERUM	SERUM BIOCHEMISTRY ANALYZER	Y	2022-08-23	15
PROT	Protein	LIVER FUNCTION	5.96	g/dL	5.96	5.96	g/dL	Nonclinical Research Institute, CORESTEMCHEMON Inc.	SERUM	SERUM BIOCHEMISTRY ANALYZER	Y	2022-08-23	15
ALT	Alanine Aminotransferase	LIVER FUNCTION	38.10	IU/L	38.10	38.1	IU/L	Nonclinical Research Institute, CORESTEMCHEMON Inc.	SERUM	SERUM BIOCHEMISTRY ANALYZER	Y	2022-08-23	15
ALP	Alkaline Phosphatase	LIVER FUNCTION	227.50	IU/L	227.50	227.5	IU/L	Nonclinical Research Institute, CORESTEMCHEMON Inc.	SERUM	SERUM BIOCHEMISTRY ANALYZER	Y	2022-08-23	15
AST	Aspartate Aminotransferase	LIVER FUNCTION	116.10	IU/L	116.10	116.1	IU/L	Nonclinical Research Institute, CORESTEMCHEMON Inc.	SERUM	SERUM BIOCHEMISTRY ANALYZER	Y	2022-08-23	15
CA	Calcium	KIDNEY FUNCTION	10.15	mg/dL	10.15	10.15	mg/dL	Nonclinical Research Institute, CORESTEMCHEMON Inc.	SERUM	SERUM BIOCHEMISTRY ANALYZER	Y	2022-08-23	15
GLUC	Glucose		127.40	mg/dL	127.40	127.4	mg/dL	Nonclinical Research Institute, CORESTEMCHEMON Inc.	SERUM	SERUM BIOCHEMISTRY ANALYZER	Y	2022-08-23	15
CK	Creatine Kinase	HEART FUNCTION	472.00	IU/L	472.00	472	IU/L	Nonclinical Research Institute, CORESTEMCHEMON Inc.	SERUM	SERUM BIOCHEMISTRY ANALYZER	Y	2022-08-23	15
BILI	Bilirubin	LIVER FUNCTION	0.134	mg/dL	0.134	0.134	mg/dL	Nonclinical Research Institute, CORESTEMCHEMON Inc.	SERUM	SERUM BIOCHEMISTRY ANALYZER	Y	2022-08-23	15
CHOL	Cholesterol	HEART FUNCTION	88.00	mg/dL	88.00	88	mg/dL	Nonclinical Research Institute, CORESTEMCHEMON Inc.	SERUM	SERUM BIOCHEMISTRY ANALYZER	Y	2022-08-23	15
TRIG	Triglycerides	HEART FUNCTION	35.00	mg/dL	35.00	35	mg/dL	Nonclinical Research Institute, CORESTEMCHEMON Inc.	SERUM	SERUM BIOCHEMISTRY ANALYZER	Y	2022-08-23	15
UREAN	Urea Nitrogen		16.10	mg/dL	16.10	16.1	mg/dL	Nonclinical Research Institute, CORESTEMCHEMON Inc.	SERUM	SERUM BIOCHEMISTRY ANALYZER	Y	2022-08-23	15
PHOS	Phosphate		8.89	mg/dL	8.89	8.89	mg/dL	Nonclinical Research Institute, CORESTEMCHEMON Inc.	SERUM	SERUM BIOCHEMISTRY ANALYZER	Y	2022-08-23	15
ALBGLOB	Albumin/Globulin	LIVER FUNCTION	1.21	RATIO	1.21	1.21	RATIO	Nonclinical Research Institute, CORESTEMCHEMON Inc.	SERUM	SERUM BIOCHEMISTRY ANALYZER	Y	2022-08-23	15

SEND 변환 현황

TSPARMCD	TSPARM	TSVAL	TSVALNF
AGE	Age	6	
AGEU	Age Unit	WEEKS	
SPECIES	Species	RAT	
STRAIN	Strain/Substrain	SPRAGUE-DAWLEY	
SPLRNAM	Test Subject Supplier		
SPLRLOC	Test Subject Supplier Site		
ENVTEMP	Environmental Temperature	20.6-24.7	
ENVTEMPU	Environmental Temperature Units	C	
HUMIDT	Housing Humidity	33.7-55.1	
HUMIDTU	Housing Humidity Units	%	
LIGHT	Light Cycle	12 / 12	
HOUSEGRP	Housing Group	Less than 3 animals / cage	
HOSETYP	Housing Type	Polysulfone cage	
IDMETH	Method of Identification	Tail by permanent marker	
IDMETH	Method of Identification	Ear punch	
DIET	Basal Diet	Standard	
FEEDREG	Feeding Regimen	ad libitum	
WATER	Drinking Water	Tap water	
WTRDLVRY	Water Delivery	Polycarbonate water bottle, ad libitum	
GLPFL	GLP Flag	Y	
GLPTYP	Good Laboratory Practice Type	MFDS	
GLPTYP	Good Laboratory Practice Type	OECD	
GLPTYP	Good Laboratory Practice Type	US FDA	
SDESIGN	Study Design	PARALLEL	
SSTYP	Study Type	REPEAT DOSE TOXICITY	
STCAT	Study Category	TOX	
SEXPOP	Sex of Participants	BOTH	
SPLANSUB	Planned Number of Subjects	208	
SRANDOM	Study Is Randomized	Y	
TRT	Investigational Therapy or Treatment	CX213	
TRTV	Treatment Vehicle	Normal Saline injection	
ROUTE	Route of Administration	INTRAVENOUS	
PDOSFRQ	Planned Dose Frequency	Once a day for 14 days	
DOSDUR	Dosing Duration	P14D	
TRTCAS	Primary Treatment CAS Registry Number	2844332-55-2	
TRTUNII	Primary Treatment Unique Ingredient ID		NA
PCLASS	Pharmacologic Class		NA
STITLE	Study Title		
DOSSTDTC	Start Date/Time of Dose Interval	2023-08-30	
DOSSTDTC	Start Date/Time of Dose Interval	2023-08-31	
DOSENDTC	End Date/Time of Dose Interval	2023-09-12	
DOSENDTC	End Date/Time of Dose Interval	2023-09-13	

SEND 변환 현황

All Domains	Markers	STUDYID	DOMAIN	USUBJID	BWSEQ	BWTESTCD	BWTEST	BWORRES	BWORRESU	BWSTRES	BWSTRESN	BWSTRESU	BWBLFL	BWFAST	BWDTC	BWDY	BWNOMDY	BWNOMLBL
Body Weight Gains	1	22-RR-1193	BW	22-RR-1193-1	1	BW	Body Weight	208.62	g	208.62	208.62	g	Y		2022-12-29	1	1	Day 1
Body Weights	2	22-RR-1193	BW	22-RR-1193-1	2	BW	Body Weight	258.70	g	258.70	258.7	g			2023-01-04	7	7	Day 7
	3	22-RR-1193	BW	22-RR-1193-1	3	BW	Body Weight	317.26	g	317.26	317.26	g			2023-01-11	14	14	Day 14
Clinical Observations	4	22-RR-1193	BW	22-RR-1193-1	4	BW	Body Weight	359.59	g	359.59	359.59	g			2023-01-18	21	21	Day 21
Demographics	5	22-RR-1193	BW	22-RR-1193-1	5	BW	Body Weight	395.20	g	395.20	395.2	g			2023-01-25	28	28	Day 28
Disposition	6	22-RR-1193	BW	22-RR-1193-1	6	TERMBW	Terminal Body Weight	365.24	g	365.24	365.24	g		Y	2023-01-26	29	29	Day 29
Exposure	7	22-RR-1193	BW	22-RR-1193-2	1	BW	Body Weight	190.95	g	190.95	190.95	g	Y		2022-12-29	1	1	Day 1
Food and Water Consumption	8	22-RR-1193	BW	22-RR-1193-2	2	BW	Body Weight	230.49	g	230.49	230.49	g			2023-01-04	7	7	Day 7
Laboratory Test Results	9	22-RR-1193	BW	22-RR-1193-2	3	BW	Body Weight	279.71	g	279.71	279.71	g			2023-01-11	14	14	Day 14
Macroscopic Findings	10	22-RR-1193	BW	22-RR-1193-2	4	BW	Body Weight	316.70	g	316.70	316.7	g			2023-01-18	21	21	Day 21
Organ Measurements	11	22-RR-1193	BW	22-RR-1193-2	5	BW	Body Weight	347.16	g	347.16	347.16	g			2023-01-25	28	28	Day 28
Pharmacokinetics Concentrations	12	22-RR-1193	BW	22-RR-1193-2	6	TERMBW	Terminal Body Weight	317.55	g	317.55	317.55	g		Y	2023-01-26	29	29	Day 29
Pharmacokinetics Parameters	13	22-RR-1193	BW	22-RR-1193-3	1	BW	Body Weight	219.48	g	219.48	219.48	g	Y		2022-12-29	1	1	Day 1
Pool Definition	14	22-RR-1193	BW	22-RR-1193-3	2	BW	Body Weight	272.46	g	272.46	272.46	g			2023-01-04	7	7	Day 7
Related Records	15	22-RR-1193	BW	22-RR-1193-3	3	BW	Body Weight	331.84	g	331.84	331.84	g			2023-01-11	14	14	Day 14
Subject Elements	16	22-RR-1193	BW	22-RR-1193-3	4	BW	Body Weight	383.33	g	383.33	383.33	g			2023-01-18	21	21	Day 21
SUPPCL	17	22-RR-1193	BW	22-RR-1193-3	5	BW	Body Weight	418.86	g	418.86	418.86	g			2023-01-25	28	28	Day 28
SUPPMA	18	22-RR-1193	BW	22-RR-1193-3	6	TERMBW	Terminal Body Weight	386.16	g	386.16	386.16	g		Y	2023-01-26	29	29	Day 29
Trial Arms	19	22-RR-1193	BW	22-RR-1193-4	1	BW	Body Weight	204.93	g	204.93	204.93	g	Y		2022-12-29	1	1	Day 1
Trial Elements	20	22-RR-1193	BW	22-RR-1193-4	2	BW	Body Weight	251.68	g	251.68	251.68	g			2023-01-04	7	7	Day 7
Trial Sets	21	22-RR-1193	BW	22-RR-1193-4	3	BW	Body Weight	303.43	g	303.43	303.43	g			2023-01-11	14	14	Day 14
Trial Summary	22	22-RR-1193	BW	22-RR-1193-4	4	BW	Body Weight	345.67	g	345.67	345.67	g			2023-01-18	21	21	Day 21
	23	22-RR-1193	BW	22-RR-1193-4	5	BW	Body Weight	377.90	g	377.90	377.9	g			2023-01-25	28	28	Day 28
	24	22-RR-1193	BW	22-RR-1193-4	6	TERMBW	Terminal Body Weight	350.68	g	350.68	350.68	g		Y	2023-01-26	29	29	Day 29
	25	22-RR-1193	BW	22-RR-1193-5	1	BW	Body Weight	206.92	g	206.92	206.92	g	Y		2022-12-29	1	1	Day 1
	26	22-RR-1193	BW	22-RR-1193-5	2	BW	Body Weight	251.16	g	251.16	251.16	g			2023-01-04	7	7	Day 7
	27	22-RR-1193	BW	22-RR-1193-5	3	BW	Body Weight	295.72	g	295.72	295.72	g			2023-01-11	14	14	Day 14



사례 연구

1. A CRO 에서 full package 진행

- 데이터 자동화 시스템(Provantis) 사용으로 인한 SEND 변환 시간 단축
- 데이터 검토 과정의 자동화를 통해 인적 오류를 줄이고 효율성 증가
- Data review 전문화

사례 연구



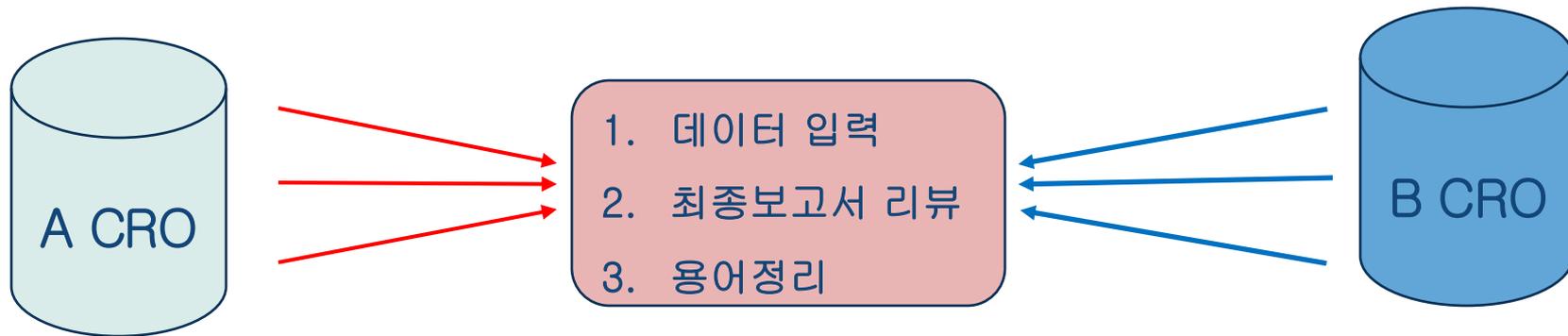
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- DRF 독성시험 : 2일
- 반복 + 회복군 + TK 시험 : 3일
- 안전성약리시험 : 1일
- 생식발생독성시험 : 5일

사례 연구

2. A + B CRO 에서 각 시험별 진행

- 데이터 입력 시간 소요
- 최종보고서 및 data QC 시간 소요
- 용어 정리

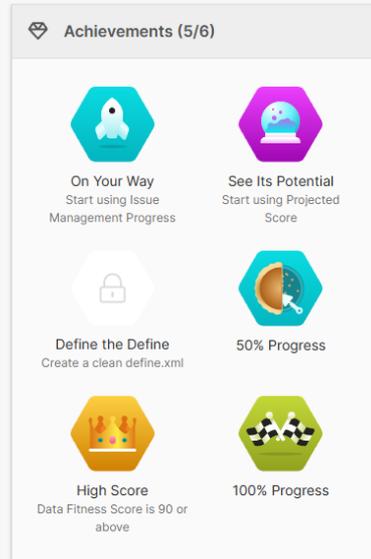
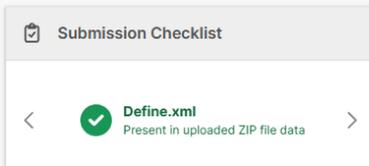
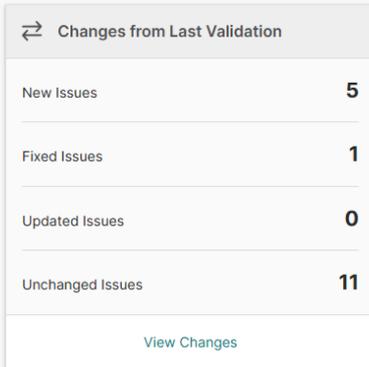
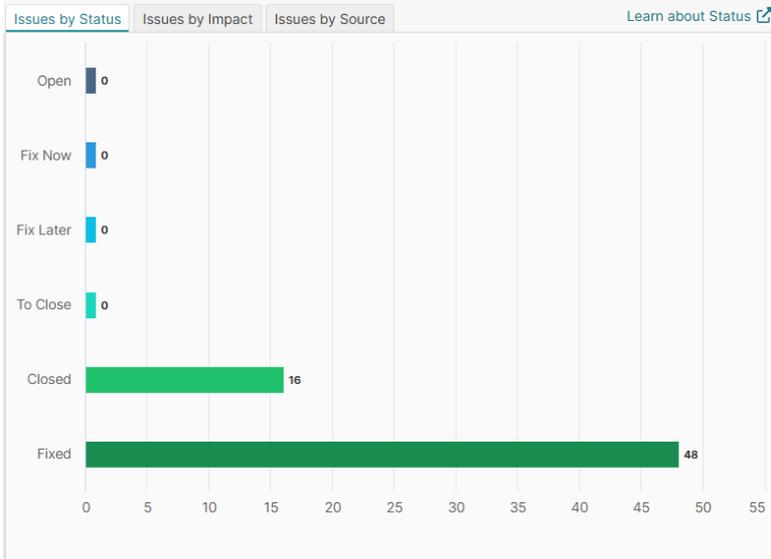
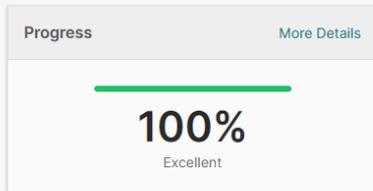


사례 연구

SEND

Package Details 🕒 Last validated on 2024-09-12 2:25 PM

[Export Report](#)



사례 연구

Study Data Reviewer's Guide

Nonclinical

Study Title
<Study ID>

Sponsor Name
Sponsor Address

Confidentiality Statement.

The information provided herein contains Company trade secrets, commercial or financial information that the Company customarily holds close and treats as confidential. The information is being provided under the assurance that the recipient will maintain the confidentiality of the information under the Trade Secrets Act, Procurement Integrity Act, other applicable statutes, regulations, rules, protective orders or otherwise and as such, the information provided herein is exempt from disclosure under Exemption 4 of the Freedom of Information Act ("FOIA").

Confidential – FOIA Exemptions Apply in U.S..



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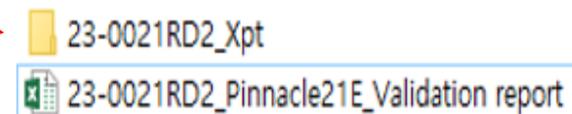
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1. nSDRG Introduction	3.
1.1 Study Title, Number, and Report Version	3.
1.2 Summary of SEND Dataset Creation Process	3.
1.3 SEND Dataset Verification	3.
2. Study Design	3.
2.1 Study Design Summary	3.
2.2 Trial Design Domain Overview	3.
3. Standards, Formats, and Terminologies and their Versions	4.
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3.2 Rationale for Standards Selection	4.
3.3 Nonstandard Terminology	4.
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4.1 Dataset Summary	4.
4.2 Dataset Explanation	5.
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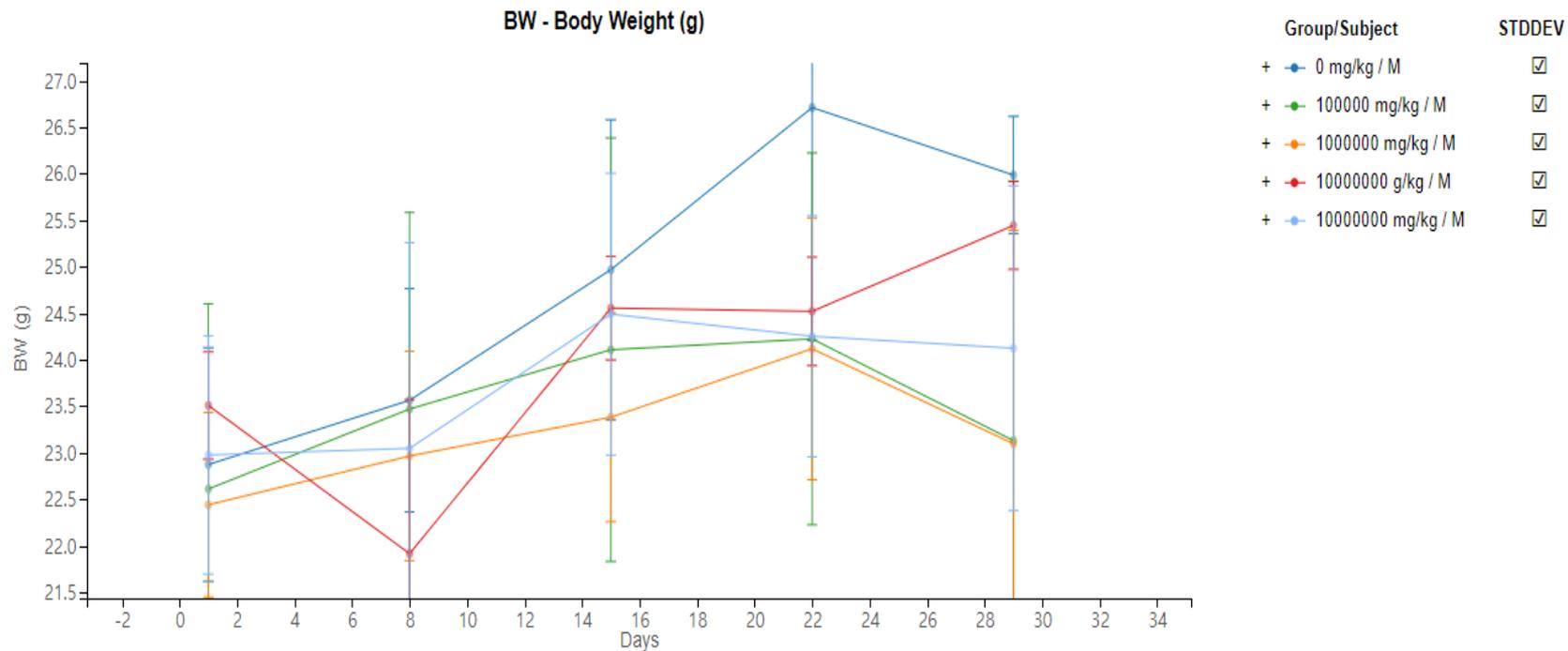
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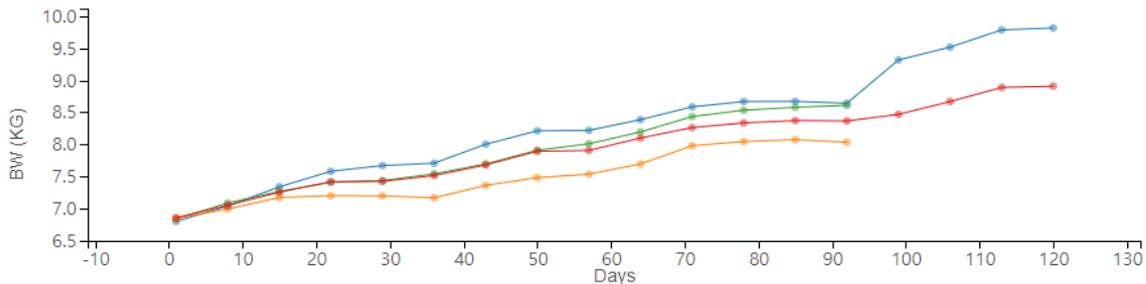


사례 연구

Multi-Study Line Graph

24DR0133 / DOG

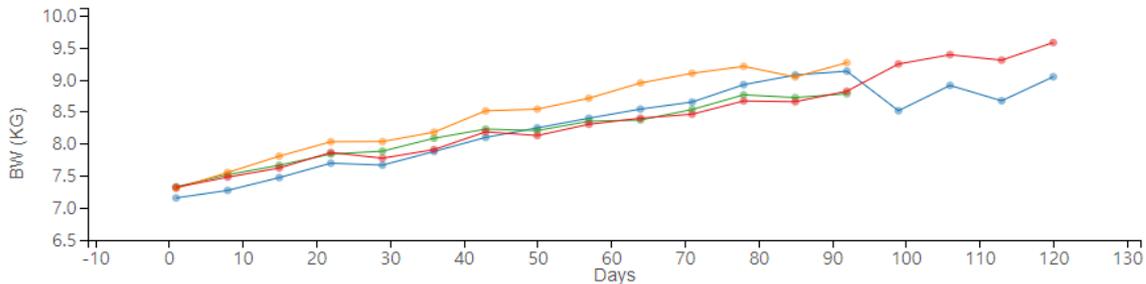
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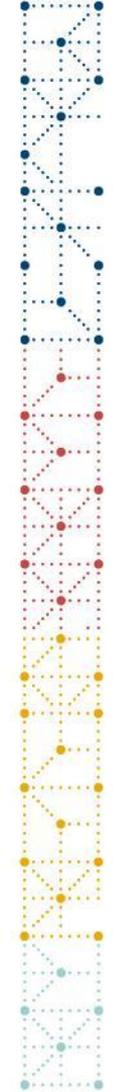


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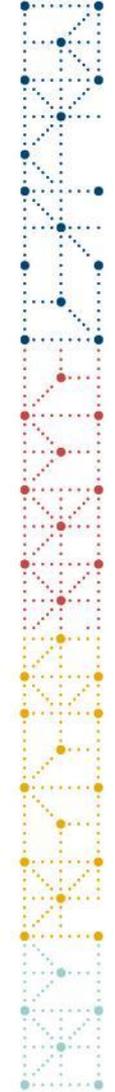
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솔루션 제안

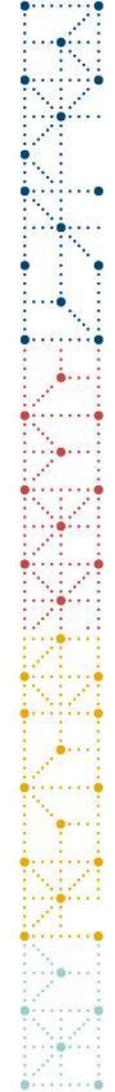
1. 교육 및 훈련
2. 프로세스 최적화
3. 최종보고서의 정확성
4. 전문가 협업
5. 한글판 가이드라인 구축



솔루션 제안

1. 교육 및 훈련

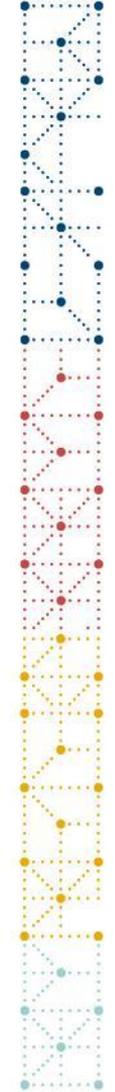
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- 연구자 및 데이터 관리자 대상 정기 교육
- 규제 요구사항 이해
- 내부 전문성 구축



솔루션 제안

2. 프로세스 최적화

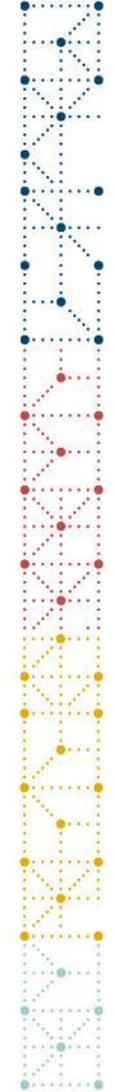
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- Excel file (raw data) 제공
- 최종 file 관리
- 데이터 수집 자동화



솔루션 제안

3. 최종보고서의 정확성

- Table & Appendix
- 물질 정보
- 동물 정보 (입수 및 투여개시 주령, 공급처 등)
- 시험방법 (시험지침 등)



솔루션 제안

4. 전문가 협업

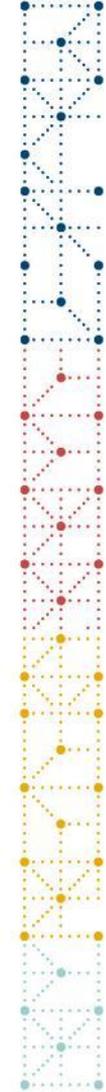
- 경험 공유
- 문제 해결
- 각 분야별 전문가의 협업 팀 구성

(SEND, Data review, 번역, 규제, 문서화 등)

솔루션 제안

5. 한글판 가이드라인 구축

- 국제 표준을 정확히 반영
- 한국 내 규제 요구 사항에 맞는 정보 추가
- SEND 포맷을 보다 쉽게 이해하고 활용할 수 있도록 도움
- 유용하고 실용적인 가이드라인 제공



감사합니다.

✓ lmh4883@cscs.co.kr

✓ 031-329-9912