Key Challenges and Solutions in SEND Implementation

이민행 / 팀장 / 데이터관리팀 / 코아스템켐온㈜

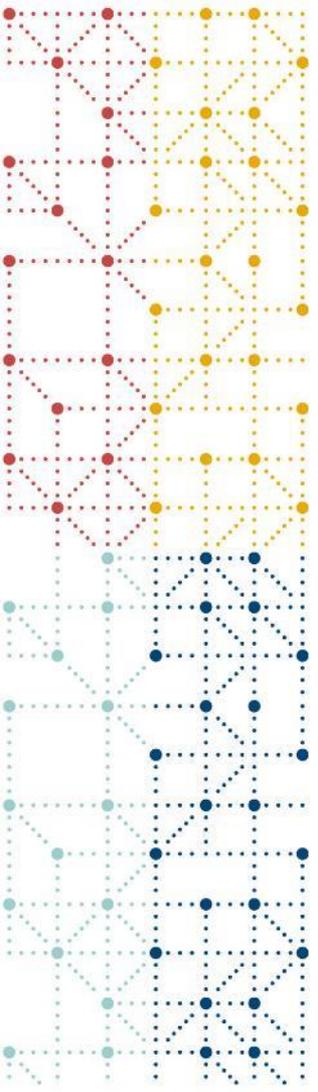# Meet the Speakers

이민행

Title: Key Challenges and Solutions in SEND Implementation
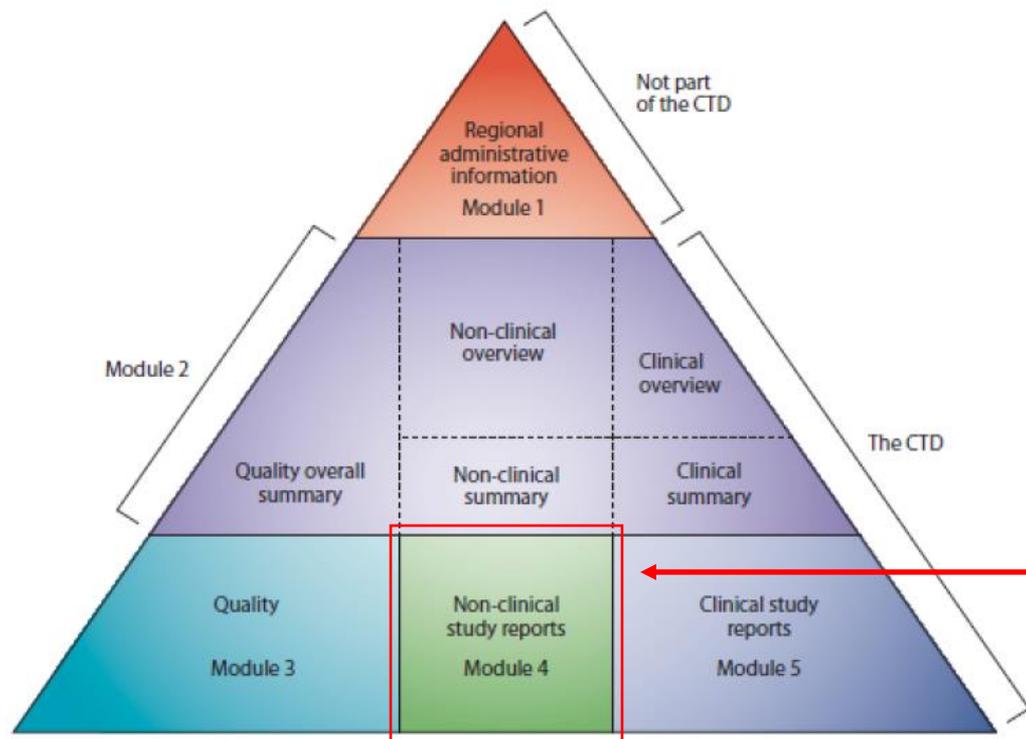
Organization: 코아스템켐온㈜
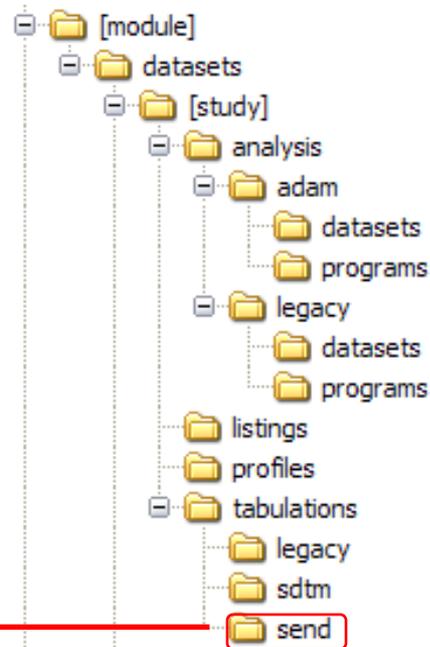
데이터관리팀 팀장 / 수석연구원

Agenda

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

FDA Data Standards Catalog v10.2

Full description of column headings in Instr.& Column Descriptions tab. Rows with data models are in bold with blue fill. Dependant properties (i.e., IG, technical document) for each model are listed beneath. Sorting may obscure these de

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**		**CBER**	**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		CBER	07-14-2020		03-15-2023
Nonclinical study datasets	SEND	XPT	CDISC	SENDIGv3.1.1		CDER, CBER	02-15-2022		03-15-2023
Nonclinical study datasets	SEND	XPT	CDISC	SENDIG-Genetoxv1.0		CDER, CBER	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(l) 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 "Da

[9] The simplified TS.xpt is a specific implementation of the CDISC SDTM standard being utilized by FDA (CDER and CBER) to establish the study start date or indicate that the study is exempted for evaluation by the Study Data Technical Rejection Criteria (TRC). For spe

[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 accor

[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 Phamacology

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

SEND 변환 현황

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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, Codelist, 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 by 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 RFSTDTC 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	
HOUSETYP	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

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

⏱ 소요기간 (In-house)

- 단회 독성시험 : 1일

- DRF 독성시험 : 2일

- 반복 + 회복군 + TK 시험 : 3일

- 안전성약리시험 : 1일

- 생식발생독성시험 : 5일

사례 연구

2. A + B CRO 에서 각 시험별 진행

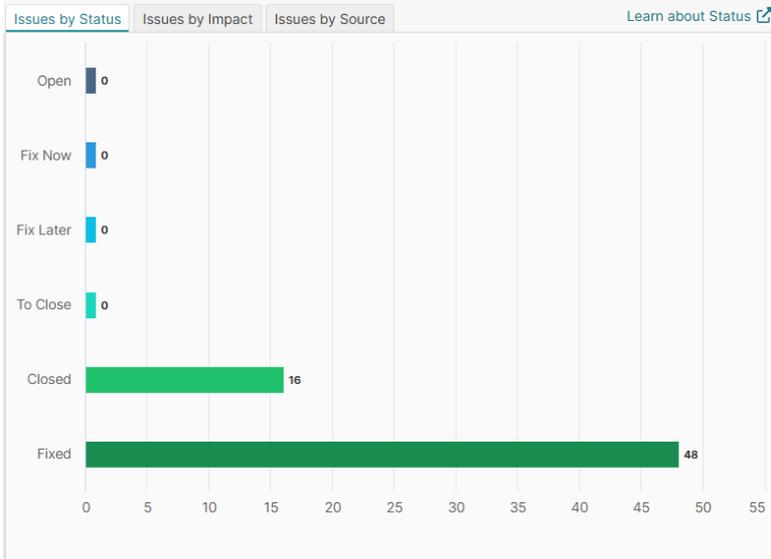- 데이터 입력 시간 소요

- 최종보고서 및 data QC 시간 소요

- 용어 정리
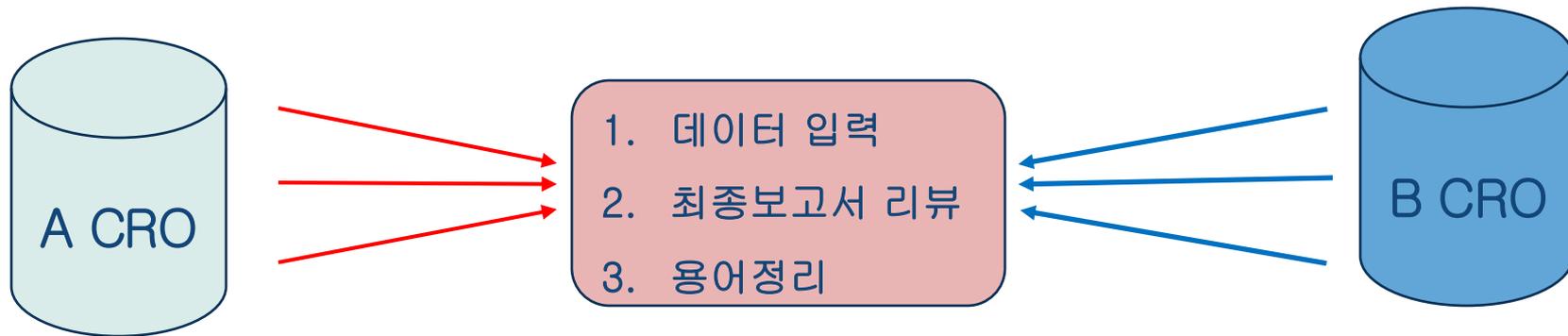
A CRO

1. 데이터 입력
2. 최종보고서 리뷰
3. 용어정리

B CRO
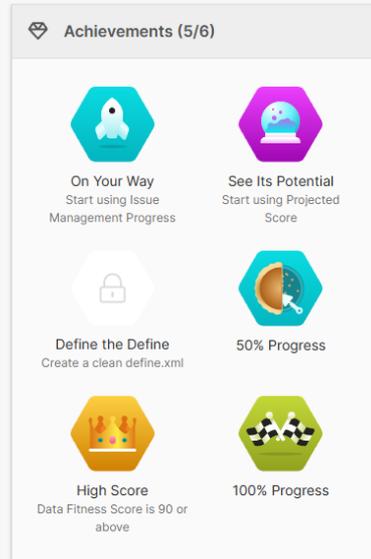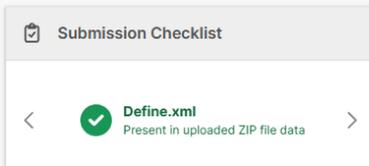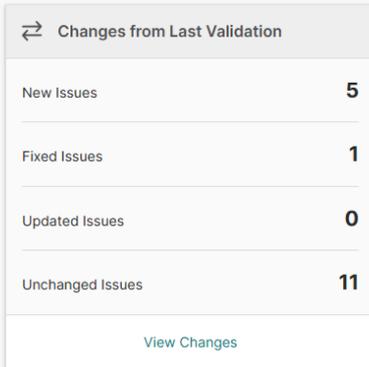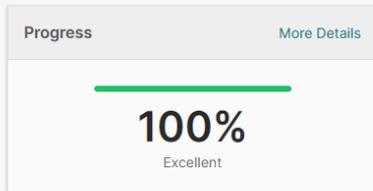
사례 연구

사례 연구

Study Data Reviewer's Guide

Nonclinical

Study Title
<Study ID>

Sponsor Name

Sponsor Address

Confidentiality Statement.

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Confidential – FOIA Exemptions Apply in U.S.   2

사례 연구

사례 연구

사례 연구

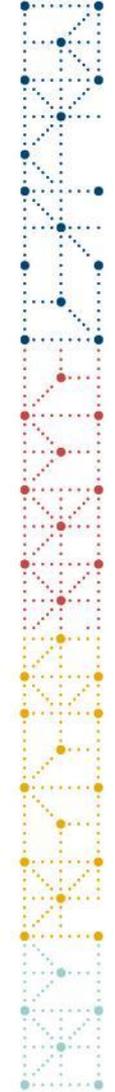Multi-Study Line Graph

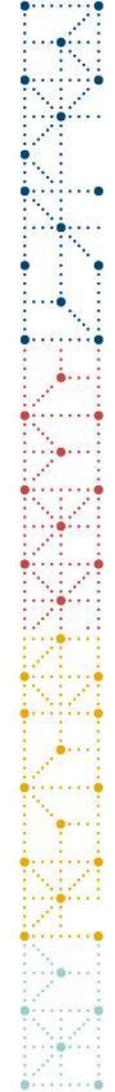24DR0133 / DOG

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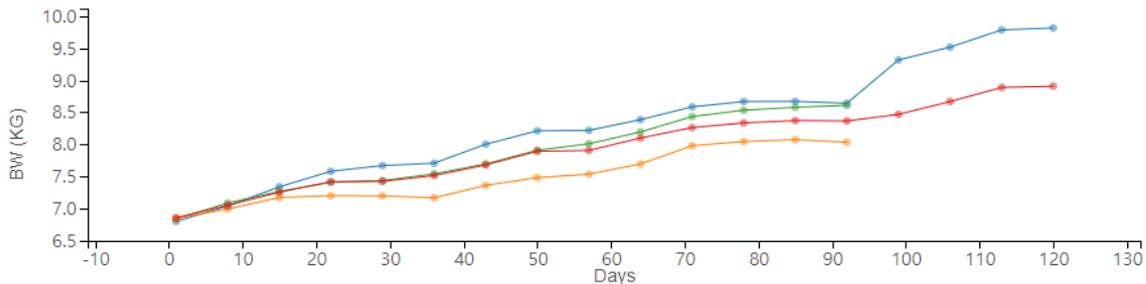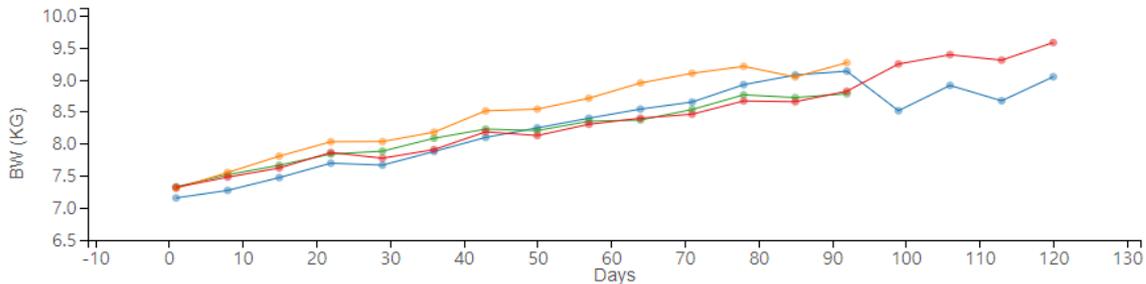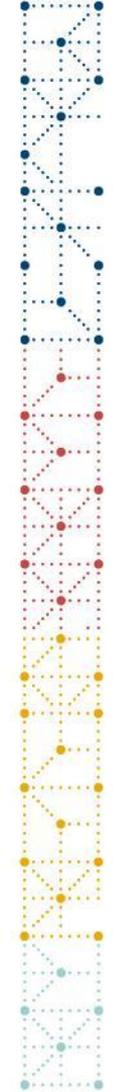
솔루션 제안

1. 교육 및 훈련

2. 프로세스 최적화

3. 최종보고서의 정확성

4. 전문가 협업

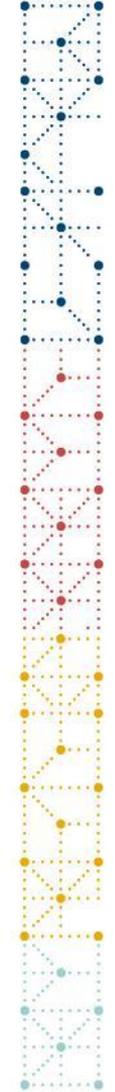5. 한글판 가이드라인 구축

솔루션 제안

1. 교육 및 훈련

- CDISC 표준에 대한 교육을 통해 이해도 향상

- 연구자 및 데이터 관리자 대상 정기 교육

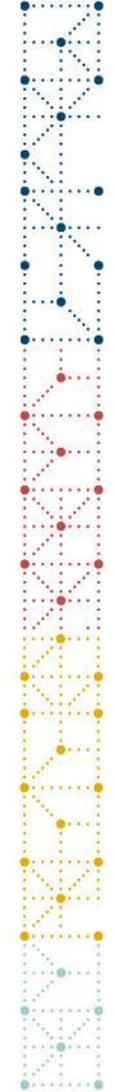- 규제 요구사항 이해

- 내부 전문성 구축

솔루션 제안

2. 프로세스 최적화

– 비임상 Data 입력시간 최소화

– Excel file (raw data) 제공

– 최종 file 관리

– 데이터 수집 자동화

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3. 최종보고서의 정확성

- Table & Appendix

- 물질 정보

- 동물 정보 (입수 및 투여개시 주령, 공급처 등)
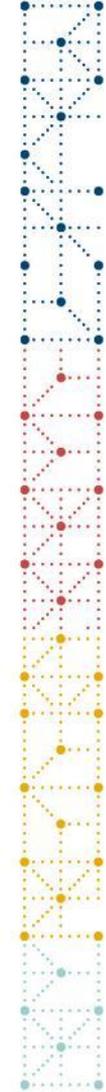
- 시험방법 (시험지침 등)

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.

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✓ 031-329-9912